COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(presented by the Commission)

Explanatory Memorandum

1. INTRODUCTION

In June 1988 the Council adopted Directive 88/379/EEC[1] on the approximation of the Member States' laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations. After adopting this Directive and bearing in mind the points of view expressed in the Council's declarations, the Commission adopted the following directives to complete Community legislation in this area:

- Commission Directive 89/178/EEC[2] of 22 February 1989 adapting Annex II to Directive 88/379/EEC to technical progress;

- Commission Directive 90/35/EEC[3] of 19 December 1989, which defines, pursuant to Article 6 of Directive 88/379/EEC, the categories of preparations for which packaging must be fitted with child-resistant fastenings and/or bear a tactile danger warning;

- Commission Directive 90/492/EEC[4] of 5 September 1990 adapting for a second time Council Directive 88/379/EEC to technical progress and setting the concentration limits, expressed in percent volume, to use when determining health effects when the conventional method for gaseous preparations is applied;

- Commission Directive 91/442/EEC[5] of 23 July 1991 concerning the preparations whose packaging must be fitted with child-resistant fastenings;

- Commission Directive 91/155/EEC[6] of 5 March 1991 that sets down detailed instructions for the specific information system for dangerous preparations in implementation of Article 10 of Directive 88/379/EEC; and

- Commission Directive 93/18/EEC[7] of 5 April 1993 adapting the annexes to Directive 88/379/EEC to technical progress for the third time.

Moreover, in April 1992 the Council adopted Directive 92/32/EEC[8] modifying for the seventh time Council Directive 67/548/EEC[9] concerning the approximation of the Member States' legislation, regulations and administrative provisions related to the classification, packaging and labelling of dangerous substances. Besides this, in April 1993 the

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1 OJ N° L187 of 16.7.1988, p14
2 OJ N° L64 of 8.3.1989, p18
3 OJ No. L 19 of 24.01.1990, p. 14.
4 OJ No. L 275 of 5.10.1990, p. 35.
5 OJ No. L 238 of 27.8.1991, p. 25.
6 OJ No. L 76 of 22.3.1991, p. 35.
7 OJ No. L 104 of 29.4.1993, p. 46.
8 OJ No. L 154 of 5.6.1992, p. 1.
9 OJ No. L 196 of 16.8.1967, p. 1.

Commission adopted Directive 93/21/EEC[10] adapting Directive 67/548/EEC to technical progress for the eighteenth time.

These last two directives have had considerable impact on Directive 88/379/EEC, especially as regards the introduction of a new category of hazards for environmentally dangerous substances, which is backed up by the development of classification criteria for environmental hazards and standard risk and safety advice phrases for substance labelling. As a result of these two directives the provisions of Directive 88/379/EEC concerning the classification and labelling of dangerous preparations have been broadened to include environmental effects.

Besides the directives cited, other directives concerning special preparations need to be taken into account.

Directive 78/631/EEC[11] was introduced to harmonise the rules of classification, packaging and labelling of pesticides between the Member States. In accordance with the provisions of this Directive the classification and labelling of pesticides is based on acute toxicity and physico-chemical hazards.

When Directive 88/379/EEC on classification, packaging and labelling of dangerous preparations was adopted the inclusion of pesticides into the scope of this Directive was proposed. The proposal was rejected by the Member States recognising the fact that the general classification and labelling system was not suitable as such to pesticides taking into account their special uses.

Directive 91/414/EEC[12] harmonises the legislation of the Member States concerning the placing on the market of plant protection products (PPP's). The authorisation of a PPP is a pre-marketing condition and is designed to ensure a high level of protection of human and animal health and the environment. The authorisation should also ensure that protection of animal and human health and the environment should take priority over the objective of improving plant production.

The applicant for a PPP is obliged to submit to the competent authority a detailed documentation for hazard assessment and assessment carried out in the context of authorisation of the PPP. The competent authority will ensure as part of the authorisation process that classification and labelling fulfils the requirements of a high level of protection. Directive 91/414/EEC refers to Directive 78/631/EEC for classification, packaging and labelling rules. When a PPP is authorised in one Member State the authorisation has to be recognised under comparable conditions by other Member States.

Although no serious hurdles have been encountered in implementing Directive 88/379/EEC since its adoption, experience gained since then, as well as the above-mentioned development

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10 OJ No. L 110 of 4.5.1993, p.1.

11 OJ No. L.206 of 29.7.1978, p.13.

12 OJ No. L 230 of 19.8.1991, p. 1.

concerning the Directive and parent (related) directives, indicates that it would be worthwhile to revamp the existing text, bearing in mind all the directives to which it has given rise, and to correct some drawbacks that have come to light since the directive went into effect in 1991.

1.1. Proposal for the classification and labelling of Plant Protection Products included in the scope of the Directive on classification, packaging and labelling of preparations

The new harmonised authorisation process laid down in Directive 91/414/EEC has brought to light the need for updating the legislation on classification, packaging and labelling of pesticides. The Member States have considered that the approach of Directive 78/631/EEC is outdated.

As a result of the discussions with the experts of Member States it is proposed that the classification of PPP's should be based on the Directive on classification, packaging and labelling of preparations, but the labelling of PPP's should take into consideration both classification and assessment carried out in the context of authorisation of PPP's. This means that the classification criteria established in Annex VI of Directive 67/548/EEC will not be affected by secondary rules derived from risk assessment. The final label should in principle include all the information derived from the implementation of the criteria of Annex VI of Directive 67/548/EEC and the proposed Directive. Nevertheless it would be acceptable in well justified cases to modify some information on the label however without reducing the essential information and affecting the level of protection.

The adoption of principles of classification for PPP's in the proposed Directive improves the level of protection by covering all properties dangerous to health (not only acute toxicity) and by extending the classification to properties dangerous for the environment.

Some Member States that have applied a national authorisation system for PPP's have already experience in the selection and modification of R- and S-phrases for the label of PPP's on the basis of classification and assessment based on use.

This proposal introduces only the general principle for labelling of PPP's on the basis of both classification together with assessment carried out in the context of authorisation. Detailed rules for the application of the principle for labelling of Plant Protection Products need to be developed in accordance with Committee procedure of the present Directive. As Directive 78/631/EEC will be repealed as a consequence, the reference in Directive 91/414/EEC should be replaced with a reference to the proposed Directive.

The requirements on packaging of the proposed Directive will apply to PPP's without prejudice to the special requirements on the packages of PPP's of Directive 91/414/EEC.

The proposed Directive will improve the availability of obtaining detailed information on PPP's in the form of Safety Data Sheet (SDS) as it introduces an obligation to compile SDS's for PPP's.

1.2. Proposal to include classification criteria for preparations " dangerous for the environment"

One of the main purposes of modifying this Directive was to include criteria to classify and label preparations as dangerous to the environment.
This task was based on the existing criteria of Annex VI to Dir.67/548/EEC for classifying substances as dangerous for the environment as well as on the results of a study carried out by the Northern European countries. (Nordic Council of Ministers)

Several existing models were tested for the classification of preparations as dangerous to the aquatic environment.
A conventional method of calculation was established which essentially followed the same philosophy as that adopted ealier for the development of a conventional method for health effects. This method uses concentration limits for substances as fixed individually in Annex I to Dir. 67/548/EEC or, if not in Annex I, in a specific Annex to the revised Directive.
In contrast to the classification of preparations for health effects, tests are only allowed in the case of the determination of toxicity to aquatic organisms and under stringent conditions.

To take into account important points such as the real effect on the environment caused by the dangerous substances contained in the preparation, or the correct interpretation of the information provided to the users, the experts proposed to use new risk phrases and also an additional safety advice which would better reflect the information needed for preparations dangerous to the environment.

The criteria for the classification for the hazards to the environment of preparationcontaining ozone depleting substances has also be dealt with in the Annex to the proposal of revision.

1.3. Additional proposals

Aside from the need to introduce environmental hazard criteria and to include PPP's in the scope of the Directive, there was also a need to take account of the opinions of the Member States which were consulted about the revision project. The following important points came out of this consultation.

- including plant protection products and biocides within the scope of this Directive, which garnered strong support from some Member States was made, in order to set up a harmonized classification scheme for all of these preparations.

- extending some of the provisions in Directive 88/379/EEC - notably those concerning packaging, labelling and the submission of a safety data sheet - to include explosives and some preparations that are not classified as dangerous under the terms of the directive but can nevertheless present certain dangers for users.

- setting maximum concentrations to be taken into consideration in implementing the directives based on the various danger categories of substances as defined in Directive 93/21/EEC.

- revising the provisions related to the obligation to perform physico-chemical tests under Good Laboratory Practices (GLP) to avoid repeating tests for preparations whose compositions vary but slightly.

- revising the maximum tolerances for variations in the concentrations of a preparation's ingredients for repeated toxicology trials.

- introducing a procedure for requesting confidentiality that would apply only to harmful substances that are classified by their acute lethal effects.

- harmonizing the directive's terminology with the definitions laid down in Directive 92/32/EEC.

- adapting the annexes to the directive to technical progress.

1.4 Proposals relating to the derogations for Austria, Finland and Sweden within the Treaties of Accession

By this proposal the Commission responds to the important commitments given to the new Member States in the Treaties of the Accession.

Firstly, by introducing provisions relating to classification, packaging and labelling of pesticides and at the same time repealing Directive 78/631/EEC (see under point 1.1). Secondly, by extending some provisions of the Directive to preparations not classified as dangerous.

2. JUSTIFICATION OF THE NEED FOR MODIFICATIONS

2.1. from a legislative standpoint

In an attempt to simplify Community legislation in the area of classification, packaging and labelling of preparations the present proposal on one hand brings together into one instrument the principal act and all its derivated legislation while at the same time makes amendements on matters of substance for reasons of developments on technical aspects.

2.2. from the standpoint of Community harmonization

The provisions related to the classification, labelling and packaging of preparations that are marketed in the European Union must absolutely be implemented in a harmonised way.

Straying from this principle would be highly detrimental to the free circulation of the preparations in the Community market and thus impede its smooth functioning.

2.3. from a safety-health-environment standpoint

The Community basis for taking measures related to human and environmental health, safety and protection is a high level of protection. It thus follows that all provisions in line with these concerns, such as the adoption of classification criteria for environmentally dangerous preparations, should be taken into consideration.

2.4. from an economic standpoint

Applying uniform classification criteria to the greatest possible number of different types of preparations released on the EU market by the chemical sector's extremely diverse array of firms should have positive consequences for Europe's economy.

2.5. from an editorial standpoint

Centralizing all of the provisions relating to dangerous preparations within a single piece of legislation is advisable for obvious practical reasons. It should enable users to grasp more readily the scope of this legislation and would make the text more accessible and easier to understand.

3. COST-BENEFIT ANALYSIS OF THE DRAFT DIRECTIVE

3.1. Additional costs

3.1.1. Impact:

The draft directive can have effects in two areas relating to the preparations marketed in the European Union, namely,

1. the updating of product information that must be provided and

2. the compiling of information for newly classified products and certain unclassified products.

It is vital to take account of the fact that updating information about products marketed in the European Union is a constant process that is not dependent solely on the new directive. Health risk information is constantly being modified due to adaptations to technical progress that may be made in the substances classified as dangerous (Annex I to Directive 67/548/EEC) that may go into the products. As a result, the persons or entities responsible for releasing products on the market must keep abreast of developments in European legislation in this area as well as the related costs. However, it is clear that adding environmental hazard evaluation criteria to the draft directive will entail classifying and labelling many products.

In the case of already labelled products, updating the information will simply be a normal operation linked to the above-mentioned process.

For newly classified products and certain unclassified products, on the other hand, providing such information will be an additional cost to be taken into consideration.

The Commission took an important criterion into account in drawing up the principles for assessing environmental hazards, namely, making certain that the number of environmentally dangerous products classified would not exceed the number of products classified as dangerous to human health. This safeguard should lead to a fair balance as regards product classification and should not lead to overlabelling.

3.1.2. Costs

There are several different types of costs, to wit:

- legal costs (knowledge of legislation: 'know-how'),
- technical costs (knowledge of the products and applicability of the legislation according to product type),

  the sum of the two should allow product classification and the development of a labelling scheme and safety data sheets (SDS).

The costs may be deemed moderate for large companies that already have in-house labelling and safety data-sheet systems for their products, sometimes even for completely safe preparations. In the case of SMEs that have their own product safety managers, the 'know-how' and production of safety data sheets may be covered in-house, but printing the labels and safety data sheets and providing the right packaging will entail additional costs.

The cost for adaptation of the other enterprises could be more substantial, that is to say, they will have to find the know-how as well as the other services.

3.2. Benefits

The obligation to implement the directive's provisions may be beneficial on a number of scores, for example,

- when the manufacturer considers changing his product's composition to reduce the risks for human health and the environment;
- by preventing the market being flooded with products that are considered dangerous;
- by improving the use of information systems and training in their use;

- by providing users with better information through the labelling of dangerous products and safety data sheets.

The advantages are not material only; they can also be measured in the following relative terms:

- reduced risks of accidents, thereby lowering costs for society (social security, illness and accidents);

- making users more aware of the choices they must make.

- it is worthwhile pointing out that one advantage is the elimination of redundant costs bound to existing divergent regulatory constraints and their impact on the circulation of these products

4. CONSULTATIONS REQUIRED FOR THE DRAFT REVISION

The draft revision required numerous meetings of national experts. Meetings of specialized experts were necessary for some particularly technical matters, such as safety data sheets, environmental danger criteria and pesticides.

Both the Member States and other bodies provided a wealth of information and contributed efficaciously to the drafting. Eager to cooperate, the new Member States participated actively with the Commission in the development of the draft revision, especially when it came to setting the classification criteria for environmental hazards.

The following bodies were consulted:

- the Member States' competent authorities

- industry, via chemical trade federations (CEFIC, Eurométaux, etc.).

Some special consumers' associations, such as associations of the visually impaired, were also invited to take part in the revision process.

5. ANALYSIS OF THE CHANGES WITH REGARD TO DIRECTIVE 88/379/EEC

It must stressed that the proposal for revision was guided by the same philosophy as that which had inspired Directive 88/379/EEC, which means that the principles that were adopted previously have not been challenged.

The draft revision comprises twenty-five articles. It contains a table of repealed Directives taking transposition deadlines into account and also an Annex with a table of correlation between the Directive 88/379/EEC and the new proposal.

The main changes made in the parent directive are outlined below.

Changes in Directive 88/379/EEC

Article 1

Paragraph 1

The scope is broadened to include certain preparations that may present a danger for users, even if these preparations are not classified as dangerous according to the definitions laid down in this Directive.

Paragraph 3

These preparations are governed only by the provisions of Articles 9 and 10 the corresponding annexes thereto and the provisions of Article 16.

The article recognizes that a certain number of preparations that are not considered dangerous as defined by this Directive may nevertheless present a danger for man because of their specific properties and the user's risks of exposure to them. Consequently, safety data sheets must be provided for such preparations in compliance with Article 16.

Paragraph 4

The exemptions granted to pesticides have been dropped, meaning that these products are included in the scope of the new directive. However, only some of the provisions, rather than the entire directive, apply to these preparations. The grounds therefor are given in the corresponding articles.

Inclusion of Plant protection products

Without prejudice to the provisions laid down in Directive 91/414/EEC,the classification, packaging and labelling of plant protection products are covered by the new Directive (see § 1.1.).

Explosives

The Member States wanted explosive preparations to be covered by safety data sheets. We must also point out that ammunition, which was previously included under Directive 88/379/EEC, is not covered by the new directive, since ammunition is considered articles, not preparations.

Article 3

Paragraph 1

The determination of a preparation's dangerousness has been broadened to allow for environmental hazards.

Paragraph 2

To make certain that the person/entity responsible for releasing products on the market takes all of the dangerous substances in a preparation into account, a list of the statuses of these substances has been included in the text.

Paragraph 3

This text replaces the text of Article 3(6) of Directive 88/379/EEC and sets the concentration limits to take into consideration for dangerous substances based on the different danger categories as defined in Directive 93/21/EEC.

Article 5

This article replaces Article 3(2) of Directive 88/379/EEC and concerns the determination of physico-chemical properties.

Paragraph 1, 2nd hyphen

The assays need not be repeated when the preparation's composition is modified only slightly.

Examples of the types of justification that must be provided include:

- proving one is outside the limits of explosiveness

- proving that a change in the composition produces no change in the flash point, etc.

Paragraph 1, 3rd hyphen

The text was updated in line with the new provisions of the Aerosol Directive (Directive 94/1/EC).[13]

Paragraphs 2

Reference is made to some exemptions to testing covered in Annex I to the project

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13 OJ No. L 23 of 28.1.1994, p. 28.

Paragraphs 3

Reference is made to the methods of calculation described in Annex I to the present Directive for certain special preparations such as gaseous mixtures. This addition is in conformity with Annex VI to Directive 67/548/EEC (labelling guide).

Paragraph 4

The principle of classification laid down in this Directive applies to plant protection products. Thus, the physico-chemical dangers presented by these products are assessed by the methods given in Annex V to Directive 67/548/EEC (see the preambles to Annex III to Directive 91/414/EEC). However, Directive 91/414/EEC stipulates that Good Laboratory Practices (GLP) must be followed when assaying such products. This requirement has been dropped in this Directive (see 1 hyphen 2). That is why this paragraph was redrafted accordingly.

Remark:

If methods other than those given in Annex V to Directive 67/548/EEC are used, this raises no problems, since the preamble to Annex V authorizes such a situation under the same conditions as Directive 91/414/EEC.

Article 6

This article replaces Article 3(3) and (4) of Directive 88/379/EEC. As Article 3(5) of this directive describes the conventional method, it has been transferred to Part A of Annex II to the draft.

Paragraphs 1 and 2

The principles for the determination of properties affecting health are laid down in these paragraphs

Paragraph 3

As the same principles apply to both industrial preparations and plant protection products and that good laboratory principles must be used in both cases (see Directive 91/414/EEC) a specific reference to applying GLP to toxicity testing and protecting laboratory animals has been included, should assessment of hazards of toxicity be based on such testing.

Remark:

This also implies that carcinogenicity-mutagenicity-toxic for reproduction (CMR) tests are not permitted for plant protection products. However, there is no demand for CMR tests for these preparations (see Annex III to Directive 91/414/EEC).

Paragraph 4

The tolerances on the variations in the concentrations of a preparation's constituents have been revised for repeated toxicity trials. However, this provision does not apply to the products covered by Directive 91/414/EEC.

Article 7

Paragraphs 1 and 2

The principles for the determination of properties of danger to the environment are laid down in these paragraphs

These articles and the corresponding annexes are the most important new developments in the draft Directive. The aim is to include provisions relating to the assessement of the danger of preparations for the environment.

The article basically adheres to the same philosophy as that underlying the assessment of effects on health, that is, one may either use a conventional method based on the concentration limits on the substances of which the preparation is composed or, under conditions specified in Annex III C, conduct tests on living organisms.

Remark

Pending development of criteria for the terrestrial environment in Annex VI to Directive 67/548/EEC, in the case of Plant Protection Products, the provisions of Directive 91/414/EEC must be taken into account, since this Directive refers to dangerous properties for the terrestrial environment.

Article 8

This article replaces Article 5 of Directive 88/379/EEC and contains the following modifications:

Paragraph 3

Two new indents have been added to specify the type of documentation that the person/entity responsible for placing the products on the market must keep to prove the Directive has been complied with fully.

Paragraph 4

This paragraph allows information exchanges between the Member States' national authorities. The aim of this provision is to facilitate the management of and verification of compliance with this Directive.

Article 9

This article replaces Article 6 of the directive. It was updated in conformity with similar provisions in Directive 92/32/EEC and refers to Annex IV to this directive, which sets forth the instructions applicable to the packaging of certain preparations that are offered or sold to the public at large such as defined in Directives 90/35/EEC and 91/442/EEC.

Article 10

This article replaces Article 7 of Directive 88/379/EEC and contains the following changes:

Paragraph 1.1

It is stipulated that minimum labelling requirements apply to the preparations referred to in Article 1(3) of this Directive.

Paragraph 1.2.

This paragraph adresses the principle for labelling plant protection products on the basis of the competent authorities' conclusions using both the results of the classification scheme that complies with this proposed Directive and the results of the assessment deriving from the authorisation procedure such as provided for in Directive 91/414/EEC. Detailed rules for labelling of plant protection products will be developed in accordance with the Committee procedure of the present Directive.

Paragraph 2.3: chemical names

The provisions of Article 7 of Directive 88/379/EEC have been kept in this proposal. However, the following change have been made; the names of substances which must be clearly specified on the label are indicated by reference to their danger categories and not by reference to specific R phrases.

Paragraph 2.3.4

This paragraph describes the names of the substances that do not necessarily have to be specified by danger category.

Paragraph 2.3.5: confidentiality

This paragraph has been changed slightly to define the only substances for which confidentiality may be requested and to refer to Article 11, which defines the procedures for making this request.

Paragraphs 2.5 and 2.6: R and S phrases

Provisions relating to the R and S phrases for preparations that are dangerous for the environment have been added. The number of phrases to be printed has been changed and raised to six in both cases.

Paragraph 3

Introduction of a feasibility clause allowing certain preparations classified as dangerous for the environment and covered by Annex V to this Directive to be labelled differently. These particulars will also be included in the said Annex V.

Paragraph 4

Changes concerning 125-ml packages: The R phrase and safety advice (S phrase) will have to be printed on the labels of preparations classified X_i that have been assigned phrase R41 ('Risk of serious damage to eyes.').

Article 11

This article has been added to Directive 88/379/EEC. It concerns the procedures governing the request for confidentiality for a dangerous substance entering into a preparation's composition that has been classified 'harmful' on the basis of its acute lethal effects. This article also refers to Annex VI of this Directive for more ample technical information.

Article 12

This article has also been added to Directive 88/379/EEC. It lays down an information exchange procedure for the Member States' authorities and then between the latter and the Commission as regards requests for confidentiality.

Article 13

This is basically the same as Article 8 of Directive 88/379/EEC brought in line with the text of Directive 92/32/EEC. However, the minimum label size specifications have been moved to Annex VI to Directive 67/548/EEC (labelling guide).

Article 14

Paragraph 3

This article is a modified version of Article 9 of Directive 88/379/EEC. It has also been brought in line with the corresponding article of Directive 92/32/EEC.

It states that certain preparations - notably explosives and specific preparations defined in Annex VII to this Directive - may derogate from the labelling provisions.

Article 15

This article solves the following problem:

A customer must always have the possibility of refusing to buy a product if the information given on the label shows that the product is dangerous, especially in the case of mail-order purchases. It thus seems useless to mention the danger or dangers in product advertisements in all cases, unless the recipient is bound to the purchase agreement without having had a chance to read the label.

Article 16

This article is completely new. It provides that the person/entity responsible for placing on the market a dangerous preparation for industrial use must provide a safety data sheet with the first delivery.

This provision also applies to preparations that are not classified as dangerous by virtue of Articles 5, 6 and 7 of the directive but contain at least one dangerous substance in a concentration greater than or equal to 1% w/w or 0.2% v/v. However, in this case, the data sheet shall be provided only if requested by the recipient.

Articles 17, 18, 19, 20 and 21

These articles have been brought into line with the corresponding articles of Directive 92/32/EEC.

Article 22

Standard article used in the context of a recast of a Directive.

Articles 23 to 25

These articles are relating to the entry into force of the Directive with an exact date. However, it is foreseen that 5 years between the date of adoption and the date of entry into force is needed for practical reasons to allow enough time for the industry to adapt to the new legislation.

Annexes

Annex I concerns the assessment of the preparation's physico-chemical properties pursuant to Article 5.

Annex II, A & B concerns the assessment of preparations' effects on health. Part B corresponds to Annex I of Directive 88/379/EEC.

Annex III, A, B & C concerns the assessment of dangers for the environment

Annex III, D & E concerns the labelling criteria for preparations dangerous for the environment

Annex IV concerns safety closure devices and tactile warnings (taken from Directive 91/442/EEC)

Annex V concerns particular labelling provisions for some special preparations. This annex corresponds to Annex II to Directive 88/379/EEC.

Annex VI, A & B concerns the procedures for requesting confidentiality for an ingredient that is classified as a harmful substance solely on the basis of its acute lethal effects.

Annex VII concerns specific preparations covered by Article 14 of this Directive.

Annex VIII A repealed Directives
B deadline for transposition

Annex IX Correlation, table

6. LEGAL BASE

The proposed revision is aiming at the realisation of the Internal Market by ensuring free circulation of goods and high level of protection of human health and the environment. As a consequence it is based on Article 100 A paragraph 3 of the Treaty.

7. CONSULTATION OF THE EUROPEAN PARLIAMENT AND ECONOMIC AND SOCIAL COMMITTEE

In accordance with Article 100A of the Treaty, the co-decision procedure applies. The Economic and Social Committee must also be consulted.

Proposal for an European Parliament and Council Directive concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100 A thereof,

Having regard to the proposal of the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2]

Acting in accordance with the procedure laid down in Article 189 b of the Treaty[3]

(1) Whereas Council Directive 88/379/EEC, of 7 June 1988, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[4] has been amended on several occasions; whereas on the occasion of further amendments, the said Directive should, for reasons of clarity be recast;

(2) Whereas, in spite of Community provisions, the rules applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification, packaging and labelling; whereas these differences constitute a barrier to trade, create unequal competition conditions and directly affect the functioning of the internal market; whereas it is therefore necessary to remove this barrier to trade by approximating the relevant legislation existing in the Member States;

(3) Whereas measures for the approximation of the provisions of the Member States affecting the establishment and functioning of the internal market must, in so far as they concern health, safety and protection of man and the environment, adopt a high level of protection as a basis; whereas this Directive must, at the same time, ensure protection for the general public, and, in particular, of persons who come into contact with dangerous preparations in the course of their work or in the pursuit of a hobby, of consumers, and also for the environment;

(4) Whereas containers containing certain categories of dangerous preparations offered or sold to the general public must be fitted with child-resistant fastenings and/or carry a tactile warning of danger; whereas certain preparations not falling within these categories of danger may nevertheless, due to their composition, present a danger for children; whereas the packaging of such preparations should therefore be equipped with child resistant fastening;

(5) Whereas it is necessary to provide concentration limits in the case of preparations marketed in gaseous form; whereas concentration limits expressed as a volume/volume percentage are therefore inserted into Annex II;

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4 OJ n° L 187 of 16.7.1988 p. 14 -Directive as last amended by Commission Directive 93/18/EEC (OJ n° L104 of 29.4.1993, p.46)

(6) Whereas Annex V to this Directive contains special labelling provisions applicable to certain preparations; whereas to ensure an adequate level of protection for man and the environment, special labelling provisions must also be introduced for certain preparations which although not dangerous within the meaning of Article 1.3, may present a danger to the user;

(7) Whereas in April 1992 the Council adopted Directive 92/32/EEC amending for the seventh time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[5] [6]; whereas in April 1993 the Commission adopted Directive 93/21/EEC adapting to technical progress for the eighteenth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[7]; whereas new criteria developed for classifying and labelling substances dangerous for the environment were introduced by these Directives with the appropriate symbols, indication of danger, risk phrases and safety advices for labelling requirement; whereas provisions should be adopted at Community level on the classification and labelling of preparations to take account of their effects on the environment and whereas it is, therefore, necessary to introduce a method for assessing the hazards of a preparation to the environment either by a calculation method, or by determining the ecotoxicological properties by test methods under certain conditions;

(8) Whereas the number of animals used for experiments should be reduced to a minimum, in accordance with the provisions 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[8]; whereas Article 7(2) of the above-mentioned Directive stipulates that an experiment shall not be performed if another scientifically satisfactory method of obtaining the results sought, not entailing the use of an animal, is reasonably and practically available; whereas, therefore, this Directive makes use of the results of assessments of toxicological and ecotoxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

(9) Whereas classification, packaging and labelling of plant protection products covered by Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)[9] require to be revised taking into account technical and scientific developments as well as regulatory developments following implementation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[10] ;

(10) Whereas Council Directive 91/414/EEC and Council Directive .../../EC[11] on biocides, in contrast to chemical preparations covered by the present Directive, provides for an authorization procedure for each product on the basis of a dossier presented by the applicant and an assessment carried out by the competent authority in each Member State, and furthermore that this authorization procedure includes a control relating specifically to the classification, packaging and labelling of each product before it is placed on the market; whereas it is appropriate, as part of a clear and transparent information process to classify plant protection

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[5] OJ n° L 196 of 16.8.1967, p.1. Directive as last amended by Commission Directive 94/69/EC (OJ n°L 381 of 31.12.1994, p.1)

[6] OJ n° L 154 of 5.6.1992, p.1

[7] OJ n° L 110 of 4.5.1993, p.20

[8] OJ n° L 358 of 18.12.1986, p.1

[9] OJ n° L 206 of 29.7.1978 , p.13. Directive as last amended by Council Directive 92/32/EEC (cf 5)

[10] OJ n° L 230 of 19.8.1991, p.1. Directive as last amended by Commission Directive 94/79/EC (OJ n°L 354 of 31.12.1994, p.16)

[11] OJ n° L

products according to the provisions of this Directive, to label them by taking into account both the classification and labelling rules of the present Directive and the results of the evaluation carried out in the framework of Council Directive 91/414/EEC and to ensure that the labelling satifies the high level of protection sought by both this Directive and Directive 91/414/EEC; whereas also a safety data sheet has to be established in accordance with this Directive but subject to the authorization procedure of the Directive on plant protection products;

(11) Whereas although munitions are not covered by this Directive, explosives marketed to produce an explosive or pyrotechnic effect may through their chemical composition present dangers to health; whereas it is, therefore, necessary as part of a transparent information process to classify them and assign to them a safety data sheet in accordance with the provisions of this Directive and also to label them in accordance with the international rules used for the transport of such preparations;

(12) Whereas in order to take account of certain preparations which, although they are not considered dangerous under this Directive may nevertheless present a danger for users, it is necessary to extend certain provisions of this Directive to those preparations;

(13) Whereas the label constitutes a basic tool for users of the dangerous preparations by giving them the initial essential concise information; whereas it nevertheless needs to be supplemented by a two-fold system of more detailed information, one, the safety data sheet, intended for professional users as defined by Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC[12] and the other the bodies appointed by the Member States and whose responsibility is to give information reserved solely for medical purposes, both curative and preventive;

(14) Whereas the confidentiality for certain substances contained in the preparations should be guaranteed and whereas it is, therefore, necessary to institute a system which allows the manufacturer to request confidentiality for such substances;

(15) Whereas the provisions of this Directive are without prejudice to the commitment entered into by the Community and its Member States, in accordance with the goals set under Agenda 21, Chapter 19, at the UNCED conference of June 1992 in Rio de Janeiro, to strive for the future harmonization of systems for the classification of dangerous substances and preparations;

(16) Whereas the Commission should be given the powers necessary to adapt all the Annexes to this Directive to technical progress;

(17) Whereas the adoption of this Directive should not affect the obligations of the Member States concerning the deadlines for transposition into national law and for application of the Directives indicated in Annex VIII;

HAVE ADOPTED THIS DIRECTIVE:

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[12] OJ n° L 76 of 22.3.1991, p.35
Directive last amended by Commission Directive 93/112/EEC (OJ No L314, 16.12.1993, p.38)

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Article 1

Objectives and scope

1. This Directive aims at the approximation of the laws, regulations and administrative provisions of the Member States concerning:

   - the classification, packaging and labelling of dangerous preparations,
   - specific provisions for certain preparations which may present hazards, whether or not they are classified as dangerous within the meaning of this Directive, when such preparations are placed on the market.

2. This Directive shall apply to preparations which:
   - contain at least one dangerous substance within the meaning of Article 2
   and
   - are considered dangerous within the meaning of Articles 5, 6 or 7.

3. The specific provisions set out:
   - in Article 9 and defined in Annex IV,
   - in Article 10 and defined in Annex V, and
   - in Article 16
   of this Directive shall also apply to preparations which are not considered dangerous within the meaning of Articles 5, 6 or 7 but may nevertheless present a hazard to the user.

4. Without prejudice to the provisions of Directive 91/414/EEC concerning the placing of plant protection products on the market, the articles on classification, packaging, labelling and safety data sheets of this Directive shall apply to plant protection products.

5 This Directive shall not apply to the following preparations in the finished state, intended for the final user:

   (a) medicinal products for human or veterinary use, as defined in Council Directive 65/65/EEC[13];
   (b) cosmetic products as defined in Council Directive 76/768/EEC[14];
   (c) mixtures of substances which, in the form of waste, are covered by Council Directives 75/442/EEC[15] and 78/319/EEC [16];
   (d) foodstuffs,
   (e) animal feedingstuffs,
   (f) preparations containing radioactive substances as defined by Directive 80/836/Euratom[17],
   (g) medical devices covered by Directives 90/385/EEC[18], and 93/42/EEC[19], which are intended to be implanted, invasive or used in direct contact with the body.

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[13] OJ No L 22, 09.02.1965, p. 369/65.
Directive last amended by Directive 93/39/EEC (OJ No L214, 24.08.1993, p 22)
[14] OJ No L262, 27.09.1976, p.169.
Directive last amended by Directive 93/47/EEC (OJ No L203, 13.08.1993, p.24)
[15] OJ No L194, 25.07.1975, p.39.
[16] OJ No L84, 31.03.1978, p.43.
[17] OJ No L46, 17.09.1980, p.1.
[18] OJ No L189, 20.7.1990, p.17.
[19] OJ No L169,12.7.1993, p.1.

In addition, this Directive shall not apply to:
- the carriage of dangerous preparations by rail, road, inland waterway, sea or air,
- preparations in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Article 2

Definitions

The definitions appearing in Article 2 of Directive 67/548/EEC, with the exception of the definition in paragraph 1 (d) thereof, shall apply to this Directive.

Article 3

General principles for the determination of dangerous properties of preparations

1. The evaluation of the hazards of a preparation shall be based on the determination of :
   - physico-chemical properties,
   - properties affecting health
   - environmental properties

   These different properties shall be determined in accordance with the provisions laid down in Articles 5, 6 and 7 of this Directive.
   Where laboratory tests are conducted, they must be carried out on the preparation as placed on the market.

2. Where the determination of dangerous properties is carried out in accordance with Articles 5, 6 and 7 of this Directive, all dangerous substances within the meaning of Article 2 of Directive 67/548/EEC and in particular those which :

   - are listed in Annex I to Directive 67/548/EEC
   - are listed in ELINCS (*) in accordance with Article 21 of Directive 67/548/EEC,
   - are labelled provisionally by the person responsible for placing on the market in accordance with Article 6 of Directive 67/548/EEC
   - are classified and labelled in accordance with Article 7 of Directive 67/548/EEC and are not yet included in ELINCS (*)
   - are covered by Article 8 of Directive 67/548/EEC
   - are labelled in accordance with Article 13(2) of Directive 67/548/EEC

   must be taken into consideration in accordance with the provisions laid down in the method used.

3. For preparations covered by this Directive, dangerous substances such as defined in paragraph 2 above which are classified dangerous on the basis of their health effects and environmental effects, whether they are present as impurities or additives, shall be taken into consideration when their concentrations are equal to or greater than those defined in the following table unless lower values are given in Annex I to Directive 67/548/EEC.

Category of danger of the substance	Concentration to take into consideration for	
	gaseous preparations % vol/vol	other preparations % w/w
Very Toxic T^+ R26, R27, R28, R39	≥ 0,02	≥ 0,1
Toxic T R23, R24, R25, R39, R48	≥ 0,02	≥ 0,1
Carcinogenic Carc. Cat. 1 or 2 R45, R49	≥ 0,02	≥ 0,1
Mutagenic Muta. Cat. 1 or 2 R46	≥ 0,02	≥ 0,1
Toxic for reproduction Cat. 1 or 2 R60 Fertility or R61 Development	≥ 0,02	≥ 0,1
Harmful Xn R20, R21, R22 R40, R48	≥ 0,2	≥ 1
Harmful Xn R65	-	≥ 1
Corrosive C, R35, R34	≥ 0,02	≥ 1
Irritant Xi R41, R36, R37, R38	≥ 0,2	≥ 1
Sensitizing R42, R43	≥ 0,2 (R42)	≥ 1
Carcinogenic Carc. Cat. 3 R40	≥ 0,2	≥ 1
Mutagenic Muta. Cat.3 R40	≥ 0,2	≥ 1
Toxic for reproduction Cat. 3 R62 Fertility or R63 Development	≥ 0,2	≥ 1
Dangerous for environment aquatic N, R50, R51, R53		≥ 0.1
Dangerous for environment ozone N, R59	≥ 0.1	≥ 0.1
Dangerous for environment aquatic R52, R53		≥ 1
Dangerous for environment ozone R59	≥ 0.1	≥ 0.1
Dangerous for environment other R54, R55, R56, R57, R58		≥ 0.1

Article 4

General principles of classification and labelling

1. The classification of dangerous preparations according to the degree and the specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in Article 2.

2. The general principles of the classification and labelling of preparations shall be applied according to the criteria in Annex VI to Directive 67/548/EEC save where alternative criteria referred to in Articles 5, 6 or 7 of this Directive are applied.

Article 5

Evaluation of the hazards deriving from physico-chemical properties

1. The hazards of a preparation deriving from its physico-chemical properties shall be assessed by determining, by means of the methods specified in part A of Annex V to Directive 67/548/EEC, the physico-chemical properties of the preparation necessary for appropriate classification and labelling in accordance with the criteria of Annex VI to that Directive.

   By way of derogation from the preceding:

   the determination of the explosive, oxidising, extremely flammable, highly flammable, or flammable properties is not necessary provided, however, that:
   - none of the constituents possesses such properties and that on the basis of the information available to the manufacturer the preparation is unlikely to present hazards of this kind;
   - in the event of a change in the composition of a preparation of known composition, scientific evidence indicates that a reassessment of the hazards will not lead to a change in classification
   - preparations placed on the market in the form of aerosols satisfy the provisions of Article 9a of Directive 75/324/EEC [20] as last amended by Directive 94/1/EC [21]

2. For certain cases for which the methods of Part A of Annex V to Directive 67/548/EEC are not appropriate, alternative calculation methods referred to in Annex I part B to this Directive.
3. Some exemptions to the application of the methods of Part A of Annex V to Directive 67/548/EEC are referred to part A to Annex I to this Directive.

4. The hazards deriving from the physico-chemical properties of a preparation covered by Directive 91/414/EEC shall be assessed by determining the physico-chemical properties of the preparation necessary for appropriate classification in accordance with criteria of Annex VI to Directive 67/548/EEC. These physico-chemical properties will be determined by means of the methods laid down in part A of Annex V to Directive 67 / 548 / EEC unless other internationally recognized methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

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[20] OJ No L 147, 09.06.1975, p. 40.
[21] OJ No L 23, 28.01.1994, p. 28.

Article 6

Evaluation of health hazards

1. The health hazards of a preparation shall be assessed by one or more of the following procedures:

   (a) by the conventional method described in Annex II parts A and B to this Directive using concentration limits;

   (b) by determining, by means of the methods specified in point B of Annex V to Directive 67/548/EEC the toxicological properties of the preparation necessary for appropriate classification and labelling in accordance with the criteria in Annex VI to that Directive.

2. The health hazards of a preparation covered by Directive 91/414/EEC shall be assessed by one or more of the following procedures :

   (a) by the conventional method described in Annex II parts A and B to this Directive using concentration limits;

   (b) by determining the health effect properties of the preparation necessary for appropriate classification in accordance with criteria of Annex VI to Directive 67/548/EEC. These health effect properties will be determined by means of the methods laid down in part B of Annex V to Directive 67/548/EEC unless other internationally recognized methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

3. When a toxicological property is established by method 1(b) or 2(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC [(22)] and with the provisions of Directive 86/609/EEC.

   Any of the toxicological properties of the preparation which are not assessed by the method set out in 1(b) or 2(b) above shall be assessed in accordance with the conventional method.

   Where a toxicological property has been established by both the methods above, the result of method 1(b) or 2(b) shall be used for classifying the preparation except in the case of carcinogenic, mutagenic effects and toxic effects for reproduction for which only the conventional method described in Annex II applies.

   Furthermore, where it can be demonstrated that :

   - toxicological effects on man differ from those suggested by a toxicological determination or a conventional assessment, then the preparation shall be classified according to its effects on man,

   - owing to effects such as potentiation a conventional assessment would underestimate the toxicological hazard, these effects shall be taken into account in classifying the preparation,

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[(22)] OJ No L 15, 17.01.1987, p. 29.

- owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, these effects shall be taken into account in classifying the preparation.

4. For preparations of a known composition with the exception of those covered by Directive 91/414/EEC, classified in accordance with method 1(b) above a new evaluation of health hazard either by method 1(a) or 1(b) shall be performed whenever :

   - changes of composition of the initial concentration, as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table :

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

   - changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions of this Directive, are introduced by the manufacturer.

   This will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

5. In accordance with paragraph 1.a) and 2.a), the health effects of a preparation shall be assessed by the conventional method described in Parts A and B of Annex II to this Directive, using individual concentration limits.

   a) Where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of Annex II to this Directive, these concentration limits must be used.

   b) Where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of Annex II to this Directive, the concentration limits shall be assigned in accordance with the specifications in Part B of Annex II to this Directive.

Article 7

Evaluation of environmental hazards

1. The hazards of a preparation for the environment shall be assessed by one or more of the following procedures :

   (a) by a conventional method described in Parts A and B of Annex III to this Directive using concentration limits,

   (b) by determining, by means of the methods specified in Part C of Annex V to Directive 67/548/EEC, the hazards of a preparation for the environment necessary for appropriate classification and labelling in accordance with the criteria defined in Annex VI to that Directive. The conditions of application of the test methods specified above shall be as described in Annex III Part C to this Directive.

2. The environmental hazards of a preparation covered by Directive 91/414/EEC shall be assessed by one or more of the following procedures :

   (a) by a conventional method described in Parts A and B of Annex III to the present Directive using concentration limits

   (b) by determining the environmental effects of the preparation necessary for appropriate classification in accordance with criteria of Annex VI to Directive 67/548/EEC. These ecotoxicological properties will be determined by means of the methods laid down in part C of Annex V to Directive 67/548/EEC unless other internationally recognized methods are acceptable in accordance with the provisions of Annexes II and III to Directive 91/414/EEC.

3. When an ecotoxicological property is established by method 1.(b) or 2.(b) to obtain new data, the test shall be conducted in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.

   Where the environmental hazards have been assessed by both the procedures mentioned above, the results of the methods referred to in 1.(b) or 2.(b) shall be used for classifying the preparation.

4 For preparations of a known composition with the exception of those covered by Directive 91/414/EEC classified in accordance with method 1.(b) above a new evaluation of environmental hazard either by method 1.(a) or 1.(b) shall be performed whenever :

   - changes of composition of the initial concentration as a weight/weight or volume/volume percentage, of one or more of the dangerous constituents are introduced by the manufacturer, in accordance with the following table :

Initial concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤ 2,5 %	± 30 %
> 2,5 ≤ 10 %	± 20 %
> 10 ≤ 25 %	± 10 %
> 25 ≤ 100 %	± 5 %

- changes of composition involving the substitution or addition of one or more constituents, which may or may not be dangerous within the meaning of the definitions of this Directive, are introduced by the manufacturer.

This will apply unless there is valid scientific justification for considering that a re-evaluation of the hazard will not result in a change of classification.

5. In accordance with paragraphs 1.(a) and 2.(a) above, the environmental hazards of a preparation shall be assessed by the conventional method described in Parts A and B of Annex III to this Directive, using individual concentration limits.

a) Where the dangerous substances listed in Annex I to Directive 67/548/EEC are assigned concentration limits necessary for the application of the method of assessment described in Part A of Annex III to this Directive, these concentration limits must be used.

b) Where the dangerous substances do not appear in Annex I to Directive 67/548/EEC or appear there without the concentration limits necessary for the application of the method of evaluation described in Part A of Annex III to this Directive, the concentration limits shall be assigned in accordance with the specifications in Part B of Annex III to this Directive.

Article 8

Obligations and duties of the Member States

1. Member States shall take all necessary measures to ensure that the preparations covered by this Directive cannot be placed on the market unless they comply therewith.

2. If there is any doubt with regard to the compliance referred to in paragraph 1, the authorities of the Member States may request information on the composition of the preparation and any other pertinent information from any person responsible for placing on the market.

3. Without prejudice to Article 8.2, the Member States shall take all necessary measures to ensure that those responsible for placing the preparation on the market hold at the disposal of the authorities of the Member States :

- the data used for the classification and labelling of the preparation,
- any pertinent information relating to packaging requirements according to Article 9, paragraph 1 (3), including the test certificate issued in accordance with Part A of Annex IX to Directive 67/548/EEC,
- the data used for establishing the safety data sheet, in accordance with Article 16 of this Directive.

4. The Member States shall inform the Commission of the name and full address of the national authorities responsible for communicating and exchanging information relating to the management of this Directive.

   The Commission shall publish the list in the Official Journal.

Article 9

Packaging

Member States shall take all necessary measures to ensure that :

1.1. preparations within the meaning of Article 1.2. and those defined in Annex IV pursuant to Article 1.3 cannot be placed on the market unless their packaging satisfies the following requirements :

- it shall be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;
- the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;
- packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

1.2. containers which contain preparations within the meaning of Article 1.2. and those defined in Annex IV pursuant to Article 1.3. offered or sold to the general public do not have :

- either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers,
- or a presentation and/or a designation used for human and animal foodstuffs, or medicinal or cosmetic products.

1.3. containers which contain certain preparations offered or sold to the general public and defined in Annex IV to this Directive:

- are fitted with child-resistant fastenings

and/or

- carry a tactile warning of danger.

The devices must conform to the technical specifications given in Parts A and B of Annex IX to Directive 67/548/EEC.

Article 10

Labelling

1.1. Member States shall take all necessary measures to ensure that :

a) preparations within the meaning of Article 1.2 cannot be placed on the market unless the labelling on their packaging satisfies all the requirements of this Article and the specific provisions of Part A of Annex V to this Directive.

b) preparations within the meaning of Article 1.3 as defined in Parts B and C of Annex V cannot be placed on the market unless the labelling on their packaging satisfies the requirements of paragraphs 2.1 and 2.2 hereunder and the specific provisions of Parts B and C of Annex V to this Directive.

1.2. Member States, through the authorities designated in Article 9(1) of Directive 91/414/EEC, shall take all necessary measures to ensure that the preparations covered by the above-mentioned Directive are labelled on the basis first of the classification criteria in this Directive and second the assessment conclusions in accordance with the provisions of the above-mentioned Directive, without reducing the level of protection

2. The following information shall be clearly and indelibly marked on any package:

2.1. the trade name or designation of the preparation;

2.2. the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;

2.3. the chemical name(s)

The chemical name of the substance or substances present in the preparation in accordance with the following detailed rules:

2.3.1. for preparations classified T+, T, Xn in accordance with Article 6, only the substances T+, T, Xn present in concentrations equal to or greater than the lowest limit (limit Xn) for each of them laid down in Annex I to Directive 67/548/EEC or, failing that, Annex II B of this Directive have to be taken into consideration

2.3.2. for preparations classified C in accordance with Article 6, only the substances C present in concentration equal to or greater than the lowest limit (limit Xi) laid down in Annex I of Directive 67/548/EEC or, failing that, Annex II B of this Directive have to be taken into consideration

2.3.3. for preparations classified as sensitising in accordance with Article 6, only the sensitising substances present in concentrations equal to or greater than their respective limits laid down in Annex I to Directive 67/548/EEC or, failing that, Annex II B of this Directive have to be taken into consideration

As a general rule a maximum of four chemical names shall suffice to identify the substances primarily responsible for the major health hazards which have given rise to the

classification and the choice of the corresponding phrases referring to the risk involved. In some cases, more than four chemical names may be necessary.

The name of the substances which have given rise to the classification of the preparation in one or more of the following danger categories :

- carcinogen category 1, 2 or 3
- mutagen category 1, 2 or 3
- toxic for reproduction category 1, 2 or 3
- very toxic, toxic or harmful due to non-lethal effects after a single exposure
- toxic or harmful due to severe effects after repeated or prolonged exposure
- sensitizing

shall be mentioned on the label.

The chemical name shall be one of the designations listed in Annex I to Directive 67/548/EEC or an internationally recognised designation if it is not yet listed therein.

2.3.4. As a consequence of the above provisions the name of the substance(s) which led to the classification of the preparation in the following danger categories:

- explosive
- oxidising
- extremely flammable
- highly flammable
- flammable
- irritant
- dangerous for the environment

need not be mentioned on the label unless the substance(s) has (have) already been mentioned pursuant to 2.3.1. or 2.3.2.

2.3.5. Where the disclosure on the label of the chemical identity of a harmful or harmful in combination with one of the properties mentioned in 2.3.4 presenting acute lethal effects alone will put at risk the confidential nature of his property, the person responsible for placing the preparation on the market may request the application of the procedure of Article 11 with a view to using an alternative name.

2.4. the danger symbol(s) and indication(s) of danger

The danger symbols, where specified in this Directive, and indications of the dangers involved in the use of the preparation, shall be in accordance with the wording of Annex II and the provisions of Annex VI to Directive 67/548/EEC and shall be applied in accordance with the evaluation of the hazards in accordance with Annexes I, II and III to this Directive.

Where more than one danger symbol has to be assigned to a preparation :

- the obligation to apply the symbol T shall make the symbols C and X optional unless otherwise specified in Annex I to Directive 67/548/EEC
- the obligation to apply the symbol C shall make the symbol X optional
- the obligation to apply the symbol E shall make the symbols F and O optional
- if the symbol X_n and the indication of danger "harmful" are assigned, the symbol X_i and indication of danger "irritant" are optional.

The symbol(s) shall be printed in black on an orange- yellow background.

2.5. the risk phrases (R phrases)

The indications concerning special risks (R phrases) shall conform to the wording in Annex III and the provisions of Annex VI to Directive 67/548/EEC and shall be assigned, in accordance with the results of the hazards evaluation in accordance with Annex I, II, and III to this Directive.

The indications concerning special risks (R phrases) for preparations classified as dangerous for the environment shall conform to the wording of Annex III D óf this Directive and shall be assigned in accordance with the results of the hazards evaluation in accordance with Annex III A, B and C to this Directive.

As a general rule a maximum of six R phrases shall suffice to describe the risks; for this purpose the combined phrases listed in Annex III to Directive 67/548/EEC shall be regarded as single phrases. However, if the preparation falls within more than one danger category, these standard phrases must cover all the principal hazards associated with the preparation. In some cases more than six R phrases may be necessary.

The standard phrases "extremely flammable" or "highly flammable" need not be indicated where they describe an indication of danger used in accordance with paragraph 2.4.

2.6. the safety advice (S phrases)

The indications giving safety advice (S phrases) shall conform to the wording in Annex IV and the provisions of Annex VI to Directive 67/548/EEC and shall be assigned in accordance with the results of the hazards evaluation in accordance with Annexes I, II and III to this Directive.

The indications giving safety advice six (S phrases) for preparations classified as hazardous to the environment shall conform to the wording of Annex III E of the present Directive and shall be assigned in accordance with the results of the hazards evaluation in accordance with Annex III A, B and C to this Directive.

As a general rule, a maximum of six S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV to Directive 67/548/EEC shall be regarded as single phrases. However, in some cases more than six S phrases may be necessary.

Where it is physically impossible to include the advice on the label or package itself, the package shall be accompanied by safety advice on the use of the preparation.

2.7. the nominal quantity (nominal mass or nominal volume) of the contents in the case of preparations sold to the general public.

3. By way of derogation to 2.4, 2.5 and 2.6, exemptions to certain provisions on labelling in the articles mentioned or specific provisions on labelling replacing those may be indicated in Annex V A and B for certain preparations classified as dangerous within the meaning of Article 7 and defined in Annex V to this Directive.

4. If the contents of the package do not exceed 125 ml :

   - in the case of irritant, highly flammable and oxidising preparations with the exception of those assigned the phrase R41, there is no need to indicate the special risks (R phrases) or the safety advice (S phrases);

   - in the case of flammable preparations there is no need to indicate the safety advice (S phrases).

5. Information such as "non-toxic", "non-harmful" or any other statement indicating that the preparation is not dangerous must not appear on the packaging or labelling of the preparations subject to this Directive.

Article 11

Confidentiality of the identity of a chemical name : procedures and details

1. Where the person responsible for placing a dangerous preparation within the meaning of Article 1.2. on the market avails himself of the provisions of Article 10 paragraph 2.3.5. he shall make a request for confidentiality to the competent authority of one of the Member States in which the preparation is to be placed on the market.

2. This request must provide the information required in the form in Part A of Annex VI to this Directive, without prejudice to further information requested by the competent authority from the person responsible for placing the preparation on the market if it appears necessary to evaluate the validity of the request.

   It shall include a proposal of alternative generic name, using a generic name that identifies the most important chemical groups in accordance with the lexicon presented in Annex VI Part B to this Directive.

3. Member States shall designate to the Commission, at the latest by the date of entry into force of this Directive, the authority or authorities responsible for receiving requests for confidentiality and examining their conformity with this Directive.

4. The authority of the Member State receiving a request for confidentiality shall verify its admissibility and inform the applicant of its decision within a maximum of (45) days.

   If the request is rejected or further information is required, the competent authority shall give its reasons therefor.

   Confidential information brought to the knowledge of the authorities of the Member States or of the Commission shall be dealt with in accordance with Article 19 (4) of Directive 67/548/EEC.

5. Anyone other than the person responsible for placing the preparation on the market, who modifies only the designation or commercial name of a preparation the labelling of which contains one or more alternative designations protecting the chemical identity or identities, shall inform on the one hand the authorities of the Member States where this preparation, together with its new designation or commercial name, is placed on the market for the first time and on the other hand the Commission.

This information shall include :

- the old designation or commercial name,
- the new designation or commercial name,
- the alternative designation(s) employed.

The alternative designations shall not be modified.

Article 12

Exchange of information concerning requests for confidentiality between the Commission and the Member States.

1. In the event of a favourable decision, the responsible authority shall forward a copy of its decision and the request to the Commission as soon as possible.

2. The Commission shall forward this decision and the request file as soon as possible to the responsible authorities of the other Member States.

3. Where one or more authorities referred to in paragraph 2, enters an objection it shall inform the Commission thereof within one month. The Commission shall consult the Member States as soon as possible and shall take an appropriate decision in accordance with Article 21.

4. At the latest by the date of entry into force of this Directive, each Member State shall communicate to the Commission the list of commercial names of preparations in respect of which it has been informed under Directive 88/379/EEC of the use of an alternative name for a harmful substance.

5. The Commission shall communicate each of the lists to the other Member states.

Article 13

Implementation of the labelling requirements

1. Where the particulars required by Article 10 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that the said particulars can be read horizontally when the package is set down normally. The dimensions of the label are laid down in Annex VI to Directive 67/548/EEC and are intended solely for provision of the information required by this Directive and if necessary of any supplementary health or safety information.

2. A label is not required when the particulars are clearly shown on the package itself, as specified in paragraph 1.

3. The colour and presentation of the label - or, in the case of paragraph 2, of the package - shall be such that the danger symbol and its background stand out clearly from it.
4. The information required on the label under Article 10 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

   Specific provisions regarding the presentation and format of this information shall be laid down in Annex VI to Directive 67/548/EEC.

5. Member States may make the placing on the market of preparations covered by this Directive in their territories subject to the use of the official language or languages in respect of the labelling thereof.

6. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied:

   (a) in the case of an outer package containing one or more inner packages, if the outer package is labelled in accordance with international rules on the transport of dangerous preparations and the inner package or packages are labelled in accordance with this Directive;

   (b) in the case of a single package :

   - if such a package is labelled in accordance with international rules on the transport of dangerous preparations and with Article 10 (2) 2.1, 2.2, 2,3, 2.5, and 2.6, or ;

   - where appropriate, for particular types of packaging such as mobile gas cylinders, in accordance with the specific requirements referred to in Annex VI to Directive 67/548/EEC.

   Where dangerous preparations do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous preparations.

Article 14

Exemptions from the labelling and packaging requirements

1. Articles 9, 10 and 13 shall not apply to the provisions relating to explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. For certain dangerous preparations within the meaning of Articles 5, 6 or 7 defined in Annex VII which, in the form in which they are placed on the market, do not present any physico-chemical risk, or risk to health or to the environment, Articles 9, 10 and 13 shall not apply.

3. Member States may :

   (a) permit the labelling required by Article 10 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 13 (1) and (2);

   (b) by way of derogation from Articles 10 and 13, permit the packaging of dangerous preparations which are not explosive, very toxic or toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such preparations or to other persons;

   (c) where packages are too small for the labelling provided for in Articles 10 and 13 and there is no reason to fear any danger to persons handling such preparations or to other persons, by way of derogation from the above provisions, permit the packaging of explosive, very toxic or toxic preparations to be labelled in some other appropriate way.

   This derogation does not permit use of symbols, indications of danger, risk (R) phrases or safety (S) phrases different from those laid down in this directive.

4. If a Member State makes use of the options provided for in paragraph 3, it shall inform the Commission thereof forthwith.

Article 15

Advertisements

Any advertisement for a preparation within the meaning of this Directive communicated exclusively by correspondence or catalogue which imposes an obligation on the buyer shall be prohibited if no mention is made therein of the type or types of hazard indicated on the label.

Article 16

Safety data sheet

Member States shall take all the necessary measures to ensure that :

1. the person responsible for placing on the market a preparation within the meaning of Article 1.2. must provide, at the latest on first delivery, a safety data sheet.

2. The person responsible for placing on the marked a preparation provides on request a safety data sheet for preparations not classified as dangerous within the meaning of Articles 5, 6 and 7 but containing in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least :

   - one substance posing health hazards or
   - one substance for which there are Community exposure limits at the workplace.

3. By way of derogation from paragraphs 1 and 2, the applicant for authorization of a plant protection product must provide to the authorities designated in Article 9(1) of Directive 91/414/EEC a safety data sheet attached to the application for authorization of the plant protection product.

4. Safety data sheets must comply with the provisions of Directive 91/155/EEC[23] as last amended by Directive 93/112/EEC[24].

5. This safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.

6. The necessary amendments required to adapt to technical progress Directive 91/155/EEC as last amended by Directive 93/112/EEC shall be adopted in accordance with the procedure laid down in Article 21 of this Directive.

7. The safety data sheet may be communicated on paper or electronically provided that the addressee has the necessary means of receiving it.

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(23) O.J. No L76, 22.03.1991, p35.
(24) O.J. No L314, 16.12.1993, p38.

Article 17

Rights of Member states regarding safety of workers

This Directive shall not affect the right of Member States to specify, in due compliance with the Treaty, the requirements they deem necessary to ensure that workers are protected when using the dangerous preparations in question, provided this does not mean that the classification, packaging, and labelling of dangerous preparations are modified in a way not provided for in this Directive.

Article 18

Bodies responsible for receiving information relating to health

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, of preparations placed on the market and considered dangerous on the basis of their health effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies shall have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out the tasks for which they are responsible .

Article 19

Free movement clause

Member States may not prohibit, restrict or impede the placing on the market of preparations which comply with the requirements of this Directive.

Article 20

Safeguard clause

1. Where a Member State has detailed evidence that a preparation, although satisfying the requirements of this Directive, constitutes a hazard for man or the environment on grounds relating to the provisions of this Directive, it may provisionally prohibit the placing on the market of that preparation or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member Sates of such action and give reasons for its decision.

2. In the case referred to in paragraph 1, the Commission shall consult the Member States as soon as possible.

3. The Commission shall take a decision in accordance with the procedure laid down to in Article 21 of this Directive.

Article 21

Procedure for adaptation to technical progress

Amendments required to adapt to technical progress the Annexes to this Directive shall be adopted in accordance with the procedure laid down in Article 29 of Directive 67/548/EEC.

Article 22

The Directives listed in Annex VIII, part A are hereby repealed, without prejudice to the obligation of the Member states concerning the deadlines for transposition into national law and for application of the Directives indicated in Annex VIII, part B.
References to the repealed Directives shall be constitued as reference to this Directive and should be read in accordance with the correlation table set out in Annex IX.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by .... 2003 at the latest. They shall immediately inform the Commission thereof.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

Article 24

This Directive shall enter into force on the third day following its publication in the Official Journal of the European Communities.

Article 25

This Directive is addressed to the Member States.

ANNEX I

Methods for the evaluation of physico-chemical properties of preparations in accordance with Article 5

PART A **Exemption to test methods of Annex V - Part A to Directive 67/548/EEC**

See 2.2.5. of Annex VI to Directive 67/548/EEC

PART B. **Alternative calculation methods**

B1. Non-gaseous preparations

Method for the determination of oxidising properties of preparations containing organic peroxides.

see point 2.2.2.1. of Annex VI to 67/548/EEC

B2. Gaseous preparations

1. Method for the determination of oxidising properties

   See 9.1.1.2.of Annex VI to 67/548/EEC

2. Method for the determination of flammability properties

   See 9.1.1.1.of Annex VI to 67/548/EEC

ANNEX II

Methods for the evaluation of health hazards of preparations in accordance with Article 6

PART A: METHOD OF EVALUATION

Introduction

This conventional method is a calculation method which is applicable to all preparations and which takes into consideration all the health hazards of substances contained in the preparation. For that purpose the dangerous health effects have been subdivided into:

1. acute lethal effects:
2. non-lethal irreversible effects after a single exposure;
3. severe effects after repeated or prolonged exposure;
4. corrosive effects, irritant effects;
5. sensitising effects;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The classification of the substance is expressed either by a symbol and one or more risk phrases or by categories (category 1, category 2 or category 3) also assigned risk phrases when substances are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of the substance.

Where they are not given in Annex I to Directive 67/548/EEC, the concentration limits to be taken into account for the application of the conventional method are those set out in Part B of this Annex.

Conventional method for the evaluation of health hazards

1. The following preparations shall be classified as very toxic:

1.1. owing to their acute lethal effects and assigned the risk phrases R26, R27 or R28.

1.1.1. preparations containing one or more substances classified as very toxic in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 1 in Part B of this Annex (Table I and I a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

1.1.2. preparations containing more than one substance classified as very toxic in individual concentrations not exceeding the limits specified under 1.1.1 a) or b) if:

$$\sum\left(\frac{P_{T+}}{L_{T+}}\right)\geq 1$$

where: P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,
L_{T+} is the very toxic limit specified for each very toxic substance, expressed as a percentage by weight or by volume

1.2. owing to their non-lethal irreversible effects after a single exposure, and assigned the risk phrase R39 / route of exposure.

preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than :

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 2 in Part B of this Annex (Table II and II a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2. The following preparations shall be classified as toxic:

2.1. owing to their acute lethal effects, and assigned the risk phrases R23, R24 or R25

2.1.1. preparations containing one or more substances classified as very toxic or toxic in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 1 in Part B of this Annex (Table I and I a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.1.2. preparations containing more than one substance classified as very toxic or toxic in individual concentrations not exceeding the limits specified under 2.1.1.a) or b) if:

$$\sum\left(\frac{P_{T+}}{L_T}+\frac{P_T}{L_T}\right)\geq 1$$

where: P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,
P_T is the percentage by weight or by volume of each toxic substance in the preparation,
L_T is the respective toxic limit specified for each very toxic or toxic substance, expressed as a percentage by weight or by volume

2.2. owing to their non-lethal irreversible effects after a single exposure, and assigned the risk phrases R39 / route of exposure

preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 2 in Part B of this Annex (Table II and II a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

2.3. owing to their long-term effects and assigned the risk phrases R38 / route of exposure

preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 3 in Part B of this Annex (Table III and III a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3. The following preparations shall be classified as harmful:

3.1. owing to their acute lethal effects and assigned the risk phrases R20, R21 or R22

3.1.1. preparations containing one or more substances classified as very toxic, toxic or harmful in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 1 in Part B of this Annex (Table I and I a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.1.2. preparations containing more than one substance classified as very toxic, toxic or harmful in individual concentrations not exceeding the limits specified under 3.1.1.a) or b) if:

$$\sum\left(\frac{P_{T+}}{L_{Xn}}+\frac{P_T}{L_{Xn}}+\frac{P_{Xn}}{L_{Xn}}\right)\geq 1$$

where: P_{T+} is the percentage by weight or by volume of each very toxic substance in the preparation,
P_T is the percentage by weight or by volume of each toxic substance in the preparation,
P_{Xn} is the percentage by weight or by volume of each harmful substance in the preparation,
L_{Xn} is the respective harmful limit specified for each very toxic, toxic or harmful substance, expressed as percentage by weight or by volume

3.2. owing to their acute effects to the lungs if swallowed and assigned the risk phrases R65

3.2.1. preparations containing one or more substances classified as harmful and assigned the risk phrase R65 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 1 in Part B of this Annex (Table I) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.2.2. preparations containing more than one substance classified as harmful and assigned the risk phrase R65 in individual concentrations not exceeding the limits specified under 3.2.1.a) or b) if:

$$\sum\left(\frac{P_{Xn,R65}}{L_{Xn,R65}}\right)\geq 1$$

where: $P_{Xn,R65}$ is the percentage by weight of each harmful substance to which is assigned the risk phrase R65 in the preparation,
$L_{Xn,R65}$ is the respective harmful limit specified for each harmful substance to which is assigned the risk phrase R65, expressed as percentage by weight.

3.3. owing to their non-lethal irreversible effects after a single exposure, and assigned the risk phrases R40 / route of exposure

preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 2 in Part B of this Annex (Table II and II a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

3.4. owing to their long-term effects, and assigned the risk phrases R48 / route of exposure

preparations containing at least one dangerous substance that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 3 in Part B of this Annex (Table III and III a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4. The following preparations shall be classified as corrosive:

4.1. and assigned the risk phrase **R35,**

4.1.1. preparations containing one or more substances classified as corrosive and to which is assigned phrase R35 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.1.2. preparations containing more than one substance classified as corrosive and to which is assigned phrase R35 in individual concentrations not exceeding the limits specified under 4.1.1.a) or b) if:

$$\sum\left(\frac{P_{C,R35}}{L_{C,R35}}\right)\geq 1$$

where: $P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance which is assigned phrase R35 in the preparation,

$L_{C,R35}$ is the corrosive limit R35 specified for each corrosive substance to which is assigned phrase R35, expressed as a percentage by weight or by volume

4.2. and assigned the risk phrase **R34,**

4.2.1. preparations containing one or more substances classified as corrosive and to which is assigned phrase R35 or R34 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

4.2.2. preparations containing more than one of the substances classified as corrosive and to which is assigned phrase R35 or R34 in individual concentrations not exceeding the limits specified under 4.2.1.a) or b) if:

$$\sum\left(\frac{P_{C,R35}}{L_{C,R34}}+\frac{P_{C,R34}}{L_{C,R34}}\right)\geq 1$$

where: $P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$L_{C,R34}$ is the respective corrosive limit R34 specified for each corrosive substance to which is assigned phrase R35 or R34, expressed as a percentage by weight or by volume

5. The following preparations shall be classified as irritants:

5.1 liable to cause serious eye damage and assigned the risk phrase **R41,**

5.1.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R41 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.1.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41 in individual concentrations not exceeding the limits specified under 5.1.1.a) or b) or classified as corrosive and to which is assigned phrase R35 or R34 if:

$$\sum\left(\frac{P_{C,R35}}{L_{Xi,R41}}+\frac{P_{C,R34}}{L_{Xi,R41}}+\frac{P_{Xi,R41}}{L_{Xi,R41}}\right)\geq 1$$

where: $P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,R41}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,

$L_{Xi,R41}$ is the respective irritant limit R41 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, expressed as percentage by weight or by volume

5.2. irritant to eyes and assigned the risk phrase **R36,**

5.2.1. preparations containing one or more substances classified as corrosive and to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R41 or R36 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.2.2. preparations containing more than one of the substances classified as irritant and to which is assigned phrase R41 or R36 in individual concentrations not exceeding the limits specified under 5.2.1 a) or b) or classified as corrosive and to which is assigned phrase R35 or R34 if:

$$\sum\left(\frac{P_{C,R35}}{L_{Xi,R36}}+\frac{P_{C,R34}}{L_{Xi,R36}}+\frac{P_{Xi,R41}}{L_{Xi,R36}}+\frac{P_{Xi,R36}}{L_{Xi,R36}}\right)\geq 1$$

where: $P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,R41}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R41 in the preparation,

$P_{Xi,R36}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R36 in the preparation,

$L_{Xi,R36}$ is the respective irritant limit R36 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R41, or R36 expressed as percentage by weight or by volume

5.3 irritant to skin and assigned the risk phrase **R38,**

5.3.1. preparations containing one or more substances classified as corrosive and to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R38 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.3.2. preparations containing more than one of the substances classified as corrosive and to which is assigned phrase R35 or R34 or as irritant and to which is assigned phrase R38 in individual concentrations not exceeding the limits specified under 5.3.1.a) or b) if:

$$\sum\left(\frac{P_{C,R35}}{L_{Xi,R38}}+\frac{P_{C,R34}}{L_{Xi,R38}}+\frac{P_{Xi,R38}}{L_{Xi,R38}}\right)\geq 1$$

where: $P_{C,R35}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R35 in the preparation,

$P_{C,R34}$ is the percentage by weight or by volume of each corrosive substance to which is assigned phrase R34 in the preparation,

$P_{Xi,R38}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R38 in the preparation,

$L_{Xi,R38}$ is the respective irritant limit R38 specified for each corrosive substance to which is assigned phrase R35 or R34 or irritant substance to which is assigned phrase R38, expressed as percentage by weight or by volume

5.4 irritant to respiratory system and assigned the risk phrase **R37,**

5.4.1. preparations containing one or more substances classified as irritant and to which is assigned phrase R37 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 4 in Part B of this Annex (Table IV and IV a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

5.4.2. preparations containing more than one substance classified as irritant and to which is assigned phrase R37 in individual concentrations not exceeding the limits specified under 5.4.1.a) or b) if:

$$\sum\left(\frac{P_{Xi,R37}}{L_{Xi,R37}}\right)\geq 1$$

where: $P_{Xi,R37}$ is the percentage by weight or by volume of each irritant substance to which is assigned phrase R37 in the preparation,

$L_{Xi,R37}$ is the irritant limit R37 specified for each irritant substance to which is assigned phrase R37, expressed as percentage by weight or by volume

6. The following preparations shall be classified as sensitising :

6.1 by skin contact and assigned the risk phrase **R43,**

preparations containing at least one substance classified as sensitising and to which is assigned phrase R43 that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 5 in Part B of this Annex (Table V and V a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

6.2 by inhalation and assigned the risk phrase **R42,**

preparations containing at least one substance classified as sensitising and to which is assigned phrase R42 that produces such effects in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 5 in Part B of this Annex (Table V and V a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

Remark : if a preparation contains a substance to which is assigned phrases R42/43 the effects are to be considered in accordance with 6.1 - 6.2 above.

7. The following preparations shall be classified as carcinogenic:

7.1. those of category 1 or 2, and assigned phrase R 45 or R 49

preparations containing at least one substance producing such effects, classified as carcinogenic and to which is assigned phrase R45 or R49 which denotes carcinogenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

7.2. those of category 3, and assigned phrase R 40

preparations containing at least one substance producing such effects classified as carcinogenic and to which is assigned phrase R40 which denotes carcinogenic substances in category 3, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

8. The following preparations shall be classified as mutagenic:

8.1. those of category 1 or 2 and assigned phrase R 46,

preparations containing at least one substance producing such effects, classified as mutagenic and to which is assigned phrase R46 which denotes mutagenic substances in category 1 and category 2, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

8.2. those of category 3 and assigned phrase R 40,

preparations containing at least one substance, producing such effects, classified as mutagenic and to which is assigned phrase R40 which denotes mutagenic substances in category 3, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9. The following preparations shall be classified as toxic for reproduction:

9.1. those of category 1 or 2 and assigned R 60 (fertility),

preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R60 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.2. those of category 3 and assigned R 62 (fertility),

preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R62 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.3. those of category 1 or 2 and assigned R 61 (development),

preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R61 which denotes substances toxic for reproduction of category 1 and category 2, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

9.4. those of category 3 and assigned R 63 (development),

preparations containing at least one substance producing such effects, classified as toxic for reproduction and to which is assigned phrase R63 which denotes substances toxic for reproduction of category 3, in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified at point 6 in Part B of this Annex (Table VI and VI a) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

ANNEX II

PART B

CONCENTRATION LIMITS TO BE USED IN APPLYING THE CONVENTIONAL METHOD OF ASSESSING HEALTH HAZARDS IN ACCORDANCE WITH ARTICLE 6

An assessment must be made of all the health hazards that the use of a substance might entail. For that purpose the dangerous health effects have been subdivided into :

1. acute lethal effects;
2. non-lethal irreversible effects after a single exposure;
3. severe effects after repeated or prolonged exposure;
4. corrosive effects, irritant effects;
5. sensitising effects;
6. carcinogenic effects, mutagenic effects, toxic effects for reproduction.

The systematic assessment of all the dangerous health effects is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations (Tables A) where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

The classification of the substance is expressed either by a symbol and one or more risk phrases or by categories (category 1, category 2 or category 3) also assigned risk phrases when substances are shown to be carcinogenic, mutagenic or toxic for reproduction. Therefore it is important to consider, in addition to the symbol, all the phrases denoting specific risks which are assigned to each substance under consideration.

1. Acute lethal effects

1.1. *Non-gaseous preparations*

The concentration limits fixed in Table I, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

TABLE I

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration ≥ 7%	1% ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R23, R24, R25		concentration ≥ 25 %	3 % ≤ concentration < 25 %
X_n with R20, R21, R22			concentration ≥ 25 %
X_n with R65			concentration ≥ 10 %

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria:

- the label shall include one or more of the abovementioned R phrases according to the classification used,
- in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

1.2. *Gaseous preparations*

The concentration limits expressed as a volume/volume percentage in Table 1 A below determine the classification of the gaseous preparations in relation to the individual concentration of the gas(es) present whose classification is also shown.

TABLE I A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R26, R27, R28	concentration ≥ 1 %	0,2% ≤ concentration < 1 %	0,02 % ≤ concentration < 0,2 %
T with R23, R24, R25		concentration ≥ 5 %	0,5% ≤ concentration < 5 %
X_n with R20, R21, R22			concentration ≥ 5 %

The R phrases denoting risk shall be assigned to the preparation in accordance with the following criteria:

– the label shall include one or more of the abovementioned R phrases according to the classification used,

– in general, the R phrases selected should be those applicable to the substance(s) present in the concentration which gives rise to the most severe classification.

2. Non-lethal irreversible effects after a single exposure

2.1. *Non-gaseous preparations*

For substances that produce non-lethal irreversible effects after a single exposure (R 39/route of exposure, R 40/route of exposure), the individual concentration limits specified in Table II, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

TABLE II

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 10 % R 39 (*) obligatory	1 % ≤ concentration < 10 % R 39 (*) obligatory	0,1 % ≤ concentration < 1 % R 40 (*) obligatory
T with R 39/route of exposure		concentration ≥ 10 % R 39 (*) obligatory	1 % ≤ concentration < 10 % R 40 (*) obligatory
X_n with R 40/route of exposure			concentration ≥ 10 % R 40 (*) obligatory

(*) In order to indicate the route of administration/exposure (r of exp) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) shall be used.

2.2. *Gaseous preparations*

For gases that produce non-lethal irreversible effects after a single exposure (R 39/route of exposure, R 40/route of exposure), the individual concentration limits specified in Table II A, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

TABLE II A

Classification of the substance (gas)	Classification of the gaseous preparation		
	T^+	T	X_n
T^+ with R39/route of exposure	concentration ≥ 1 % R 39 (*) obligatory	0,2 % ≤ concentration < 1 % R 39 (*) obligatory	0,02 % ≤ concentration < 0,2 % R 40 (*) obligatory
T with R 39/route of exposure		concentration ≥ 5 % R 39 (*) obligatory	0,5 % ≤ concentration < 5 % R 40 (*) obligatory
X_n with R 40/route of exposure			concentration ≥ 5 % R 40 (*) obligatory

(*) In order to indicate the route of administration/exposure (r of exp) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) shall be used.

3. Severe effects after repeated or prolonged exposure

3.1. *Non-gaseous preparations*

For substances that produce severe effects after repeated exposure (R 48/route of exposure), the individual concentration limits specified in Table III, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

TABLE III

Classification of the substance	Classification of the preparation	
	T	X_n
T with R 48/route of exposure	concentration ≥ 10 % R 48 (*) obligatory	1 % ≤ concentration < 10 % R 48 (*) obligatory
X_n with R 48/route of exposure		concentration ≥ 10 % R 48 (*) obligatory

(*) In order to indicate the route of administration/exposure (r of exp) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) shall be used.

3.2. *Gaseous preparations*

For gases that produce severe effects after repeated or prolonged exposure (R 48/route of exposure), the individual concentration limits specified in Table III A below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

TABLE III A

Classification of the substance (gas)	Classification of the gaseous preparation	
	T	X_n
T with R 48/route of exposure	concentration ≥ 5 % R 48 (*) obligatory	0,5 % ≤ concentration < 5 % R 48 (*) obligatory
X_n with R 48/route of exposure		concentration ≥ 5 % R 48 (*) obligatory

(*) In order to indicate the route of administration/exposure (r of exp) the combined R phrases listed under points 3.2.1, 3.2.2 and 3.2.3 of the labelling guide (Annex VI to Directive 67/548/EEC) shall be used.

4. Corrosive and irritant effects including serious damage to eye

4.1. *Non-gaseous preparations*

For substances that produce corrosive effects (R 34, R 35) or irritant effects (R 36, R 37, R 38, R 41), the individual concentration limits specified in Table IV, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

TABLE IV

Classification of the substance	Classification of the preparation			
	C with R 35	C with R 34	X_i with R 41	X_i with R 36,R 37,R 38
C with R 35	concentration ≥ 10 % R 35 obligatory	5 % ≤ concentration < 10 % R 34 obligatory	(*) 5 %	1 % ≤ concentration < 5 % R 36/38 obligatory
C with R 34		concentration ≥ 10 % R 34 obligatory	(*) 10 %	5 % ≤ concentration < 10 % R 36/38 obligatory
$X_i$with R 41			concentration ≥ 10 % R 41 obligatory	5 % concentration < 10 % R 36 obligatory
$X_i$with R 36, R 37, R 38				concentration ≥ 20 % R 36, R 37, R 38 are obligatory in the light of the concentration present if they apply to the substances under consideration

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R 35 or R 34 must also be considered as being assigned phrase R 41. Consequently, if the preparation contains corrosive substances with R 35 or R 34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R 41) or irritant (R 36).

4.2. *Gaseous preparations*

For gases that produce such effects (R 34, R 35 or R 36, R 37, R 38, R 41), the individual concentration limits specified in Table IV A below, expressed as a volume/volume percentage determine, when appropriate, the classification of the preparation.

TABLE IV A

Classification of the substance (gas)	Classification of the gaseous preparation			
	C with R 35	C with R 34	X_i with R 41	X_i with R 36,R 37,R 38
C with R 35	concentration ≥ 1 % R 35 obligatory	0,2 % ≤ concentration < 1 % R 34 obligatory	0,2 % (*)	0,02 % concentration < 0,2 % R 37 obligatory
C with R 34		concentration ≥ 5 % R 34 obligatory	5 % (*)	0,5 % ≤ concentration < 5 % R 37 obligatory
X_i with R 41			concentration ≥ 5 % R 41 obligatory	0,5 % concentration < 5 % R 36 obligatory
X_i with R 36, R 37, R 38				concentration ≥ 5 % R 36, R 37, R 38 obligatory as appropriate

(*) According to the labelling guide (Annex VI to Directive 67/548/EEC), corrosive substances assigned risk phrases R 35 or R 34 must also be considered as being assigned phrase R 41. Consequently, if the preparation contains corrosive substances with R 35 or R 34 below the concentration limits for a classification of the preparation as corrosive, such substances can contribute to a classification of the preparation as irritant (R 41) or irritant (R 36).

5. Sensitising effects

5.1. *Non-gaseous preparations*

Preparations that produce such effects are classified as sensitising and assigned :
- the symbol X_n and phrase R 42 if this effect can be produced by inhalation,
- the symbol X_i and phrase R 43 if this effect can be produced through contact with the skin,

The individual concentration limits specified in Table V, expressed as a weight/weight percentage, determine, when appropriate, the classification of the preparation.

TABLE V

Classification of the substance	Classification of the preparation	
	sensitising with R 42	sensitising with R 43
sensitising with R 42	concentration ≥ 1 % R 42 obligatory	
sensitising with R 43		concentration ≥ 1 % R 43 obligatory

5.2 *Gaseous preparations*

Gaseous preparations that produce such effects are classified as sensitising and assigned :

- the symbol X_n and phrase R 42 if this effect can be produced by inhalation,

The individual concentration limits specified in Table V A below, expressed as a volume/volume percentage, determine, when appropriate, the classification of the preparation.

TABLE V A

Classification of the substance (gas)	Classification of the gaseous preparation
	sensitising with R 42
sensitising with R 42	concentration ≥ 0,2 % R 42 obligatory

6. Carcinogenic/mutagenic/toxic effects for reproduction

6.1 *Non-gaseous preparations*

For substances which produce such effects, the concentration limits laid down in Table VI, expressed as a weight/weight percentage, shall determine, where appropriate, the classification of the preparation. The following symbol and risk phrases are assigned:

Carcinogenic cat. 1 and 2:	T; R45, R49
Carcinogenic cat. 3:	Xn; R40
Mutagenic cat. 1 and 2:	T; R46
Mutagenic cat. 3:	Xn; R40
Toxic for reproduction fertility cat.1 and 2:	T; R60
Toxic for reproduction development cat.1 and 2:	T; R61
Toxic for reproduction fertility cat.3:	Xn; R62
Toxic for reproduction development cat. 3:	Xn; R63

TABLE VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R 45 or R 49	≥ 0,1 % carcinogenic R 45, R 49 obligatory as appropriate	
carcinogenic substances of category 3 with R 40		≥ 1 % carcinogenic R 40 obligatory
mutagenic substances of category 1 or 2 with R 46	≥ 0,1 % mutagenic R 46 obligatory	
mutagenic substances of category 3 with R 40		≥ 1 % mutagenic R 40 obligatory
substances "toxic for reproduction" of category 1 or 2 with R 60 (fertility)	≥ 0,5 % toxic for reproduction (fertility) R 60 obligatory	—
substances "toxic for reproduction" of category 3 with R 62 (fertility)		≥ 5 % toxic for reproduction (fertility) R 62 obligatory
substances "toxic for reproduction" of category 1 or 2 with R 61 (development)	≥ 0,5 % toxic for reproduction (development) R 61 obligatory	
substances "toxic for reproduction" of category 3 with R 63 (development)		≥ 5 % toxic for reproduction (development) R 63 obligatory

6.2. *Gaseous preparations*

For gases which produce such effects, the concentration limits laid down in Table VI A, expressed as a volume/volume percentage, shall determine, where appropriate, the classification of the preparation. The following symbol and risk phrases are assigned:

Carcinogenic cat. 1 and 2:	T; R45, R49
Carcinogenic cat. 3:	Xn; R40
Mutagenic cat. 1 and 2:	T; R46
Mutagenic cat. 3:	Xn; R40
Toxic for reproduction fertility cat.1 and 2:	T; R60
Toxic for reproduction development cat.1 and 2:	T; R61
Toxic for reproduction fertility cat.3:	Xn; R62
Toxic for reproduction development cat.3 :	Xn; R63

TABLE VI A

Classification of the substance (gas)	Classification of the gaseous preparation	
	Categories 1 and 2	Category 3
carcinogenic substances of category 1 or 2 with R 45 or R 49	≥ 0,1 % carcinogenic R 45, R 49 obligatory as appropriate	
carcinogenic substances of category 3 with R 40		≥ 1 % carcinogenic R 40 obligatory
mutagenic substances of category 1 or 2 with R 46	≥ 0,1 % mutagenic R 46 obligatory	
mutagenic substances of category 3 with R 40		≥ 1 % mutagenic R 40 obligatory
substances "toxic for reproduction" of category 1 or 2 with R 60 (fertility)	≥ 0,2 % toxic for reproduction (fertility) R 60 obligatory	
substances "toxic for reproduction" of category 3 with R 62 (fertility)		≥ 1 % toxic for reproduction (fertility) R 62 obligatory
substances "toxic for reproduction" of category 1 or 2 with R 61 (development)	≥ 0,2 % toxic for reproduction (development) R 61 obligatory	
substances "toxic for reproduction" of category 3 with R 63 (development)		≥ 1 % toxic for reproduction (development) R 63 obligatory

ANNEX III

Methods for the evaluation of the environmental hazards of preparations in accordance to Article 7

INTRODUCTION

The systematic assessment of all the dangerous properties for the environment is expressed by means of concentration limits, expressed as a weight/weight percentage except for gaseous preparations where they are expressed as a volume/volume percentage and in conjunction with the classification of a substance.

PART A : METHODS OF EVALUATION

a) Aquatic environment

I. Conventional method for the evaluation of hazards to the aquatic environment

The conventional method for the evolution of hazards to the aquatic environment takes into account all the hazards that a substance may entail for this medium according to the following specifications.

The following preparations shall be classified as dangerous for the environment

I.1. and assigned the risk phrases **R50 and R53 (R50-53): very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment**

I.1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrases R50-53 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 in individual concentrations not exceeding the limits specified under I.1.1a) or b) if:

$$\sum \left(\frac{P_{N,R50-53}}{L_{N,R50-53}} \right) \geq 1$$

where: $P_{N,R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$L_{N,R50-53}$ is the limit R50-53 for each substance dangerous for the environment to which is assigned the phrases R50-53, expressed as percentage by weight

I.2. and assigned the risk phrases **R51 and R53 (R51-53): toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment**

I.2.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 in individual concentrations not exceeding the limits specified under I.2.1a) or b) if:

$$\sum\left(\frac{P_{N,R50-53}}{L_{N,R51-53}}+\frac{P_{N,R51-53}}{L_{N,R51-53}}\right)\geq 1$$

where: $P_{N,R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N,R51-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

$L_{N,R51-53}$ is the respective limit R51-53 for each substance dangerous for the environment to which is assigned phrases R50-53 or R51-53, expressed as percentage by weight

I.3. and assigned the risk phrases **R52 and R53 (R52-53): harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment**

I.3.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 1) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.3.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrases R51-53 or R50-53 or R52-53 in individual concentrations not exceeding the limits specified under I.3.1a) or b) if:

$$\sum\left(\frac{P_{N,R50-53}}{L_{R52-53}}+\frac{P_{N,R51-53}}{L_{R52-53}}+\frac{P_{R52-53}}{L_{R52-53}}\right)\geq 1$$

where: $P_{N,R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$P_{N,R51-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R51-53 in the preparation,

P_{R52-53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R52-53 in the preparation,

L_{R52-53} is the respective limit R52-53 for each substance dangerous for the environment to which is assigned phrases R50-53 or R51-53 or R52-53, expressed as percentage by weight

I.4. and assigned the risk phrase **R50: very toxic to aquatic organisms**

I.4.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R50 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 2) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.4.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R50 in individual concentrations not exceeding the limits specified under I.4.1a) or b) if:

$$\sum\left(\frac{P_{N,R50}}{L_{N,R50}}\right)\geq 1$$

where: $P_{N,R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50 in the preparation,

$L_{N,R50}$ is the limit R50 for each substance dangerous for the environment to which is assigned phrases R50, expressed as percentage by weight

I.4.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R50 not meeting the criteria under I.4.1 or I.4.2.

and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 if:

$$\sum\left(\frac{P_{N,R50}}{L_{N,R50}}+\frac{P_{N,R50-53}}{L_{N,R50}}\right)\geq 1$$

where: $P_{N,R50}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50 in the preparation,

$P_{N,R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrases R50-53 in the preparation,

$L_{N,R50}$ is the respective limit R50 for each substance dangerous for the environment to which is assigned phrases R50 or R50-53, expressed as percentage by weight

I.5. and assigned the risk phrase **R52: harmful to aquatic organisms**

I.5.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R52 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 3) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.5.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R52 in individual concentrations not exceeding the limits specified under I.5.1a) or b) if:

$$\sum\left(\frac{P_{R52}}{L_{R52}}\right)\geq 1$$

where: P_{R52} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52 in the preparation,

L_{R52} is the limit R52 for each substance dangerous for the environment to which is assigned phrase R52, expressed as percentage by weight

I.6. and assigned the risk phrase **R53: may cause long-term adverse effects in the aquatic environment,**

I.6.1. preparations containing one or more than one substance classified as dangerous to the environment and to which is assigned phrase R53 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or
b) the concentration specified in Part B of this Annex (Table 4) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.6.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase R53 in individual concentrations not exceeding the limits specified under I.6.1a) or b) if:

$$\sum\left(\frac{P_{R53}}{L_{R53}}\right)\geq 1$$

where: P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

L_{R53} is the limit R53 for each substance dangerous for the environment to which is assigned phrase R53, expressed as percentage by weight

I.6.3. preparations containing one or more than one of the substances classified as dangerous for the environment and to which is assigned phrase R53 not meeting the criteria under I.6.2. and containing one or more than one substance classified as dangerous for the environment and to which is assigned phrases R50-53 or R51-53 or R52-53 if:

$$\sum\left(\frac{P_{R53}}{L_{R53}}+\frac{P_{N,R50-53}}{L_{R53}}+\frac{P_{N,R51-53}}{L_{R53}}+\frac{P_{R52-53}}{L_{R53}}\right)\geq 1$$

where: P_{R53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R53 in the preparation,

$P_{N,R50-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R50-53 in the preparation,

$P_{N,R51-53}$ is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R51-53 in the preparation,

P_{R52-53} is the percentage by weight of each substance dangerous for the environment to which is assigned phrase R52-53 in the preparation,

L_{R53} is the respective limit R53 for each substance dangerous for the environment to which is assigned phrase R53 or R50-53 or R51-53 or R52-53, expressed as percentage by weight

b) Non-aquatic environment

b1) Ozone layer

I. Conventional method for the evaluation of preparations dangerous for the ozone layer

The following preparations shall be classified as dangerous for the environment

I.1. and assigned the symbol N, the indication of danger and the risk phrase **R59: Dangerous for the ozone layer**

I.1.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrase (N) R59 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.1.2. preparations containing more than one substance classified as dangerous for the environment and to which is assigned phrase (N)R59 in individual concentrations not exceeding the limits specified under I.1.1a) or b) if:

$$\sum\left(\frac{P_{N,R59}}{L_{N,R59}}\right) \geq 1$$

where: $P_{N,R59}$ is the percentage by weight or by volume of each substance dangerous for the environment to which is assigned phrase (N)R59 in the preparation,

$L_{N,R59}$ is the limit (N)R59 for each substance dangerous for the environment to which is assigned phrase (N)R59, expressed as percentage by weight or by volume

I.2. and assigned the risk phrase **R59: Dangerous for the ozone layer**

I.2.1. preparations containing one or more substances classified as dangerous to the environment and to which is assigned phrase (N) R59 or R59 in individual concentrations equal to or greater than:

a) either the concentration specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

b) the concentration specified in Part B of this Annex (Table 5) where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

I.2.2. preparations containing more than one of the substances classified as dangerous for the environment and to which is assigned phrase (N)R59 or R59 in individual concentrations not exceeding the limits specified under I.2.1a) or b) if:

$$\sum\left(\frac{P_{N,R59}}{L_{R59}}+\frac{P_{R59}}{L_{R59}}\right)\geq 1$$

where: $P_{N,R59}$ is the percentage by weight or by volume of each substance dangerous for the environment to which is assigned phrase (N)R59 in the preparation,

P_{R59} is the percentage by weight or by volume of each substance dangerous for the environment to which is assigned phrase R59 in the preparation,

L_{R59} is the respective limit R59 for each substance dangerous for the environment to which is assigned phrase (N)R59 or R59, expressed as percentage by weight or by volume

b2) Terrestrial environment

I. Evaluation of preparations dangerous for the terrestrial environment

Classification of preparations using the risk phrases below will follow after the detailed criteria for use of the phrases have been incorporated in Annex VI to Directive 67/548/EEC.

R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment.

ANNEX III

PART B: TABLE OF CONCENTRATION LIMITS

I. For the aquatic environment

The concentration limits fixed in the following tables, expressed as a weight/weight percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 1. : Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	Cn ≥25%	2.5% ≤ Cn < 25%	0.25% ≤ Cn < 2.5%
N, R51-53		Cn ≥25 %	2.5% ≤ Cn < 25%
R52-53			Cn ≥ 25%

Table 2. : Acute aquatic toxicity

Classification of the substance	Classification of the preparation N, R50
N, R50	Cn ≥ 25%
N, R50-53	Cn ≥ 25%

Table 3. : Aquatic toxicity

Classification of the substance	Classification of the preparation R52
R52	Cn ≥ 25%

Table 4. : Long-term adverse effects

Classification of the substance	Classification of the preparation R53
R53	Cn ≥ 25%
N, R50-53	Cn ≥ 25%
N, R51-53	Cn ≥ 25%
R52-53	Cn ≥ 25%

II. For the non-aquatic environment

The concentration limits fixed in the following tables, expressed as weight/weight percentage or, for gaseous preparations as a volume/volume percentage, determine the classification of the preparation in relation to the individual concentration of the substance(s) present whose classification is also shown.

Table 5. : Dangerous for the ozone layer

Classification of the substance	Classification of preparation N, R59
Σ N, R59	C ≥ 0.5%

Classification of the substance	Classification of preparation R59
Σ N,,R59 R59	C ≥ 0.5%

ANNEX III

PART C: TEST METHODS FOR THE EVALUATION OF THE HAZARDS FOR THE AQUATIC ENVIRONMENT

Normally, the classification of a preparation is made on the basis of the conventional method. However, for the determination of the acute aquatic toxicity, there may be cases for which it is appropriate to carry out tests on the preparation.

The result of these tests on the preparation may only modify the classification concerning acute aquatic toxicity which would have been obtained by the application of the conventional method

If such tests are chosen by the person responsible for the placing on the market, it must be ensured that the quality criteria of the test methods in Part C of Annex V to Directive 67/548/EEC have been complied with.

Furthermore, the tests shall be carried out on the three species in conformity with the criteria of Annex VI to Directive 67/548/EEC (algae, daphnia and fish), unless the highest hazard classification relating to acute aquatic toxicity has been assigned to the preparation after testing on one of the species.

ANNEX III

PART D: INDICATIONS CONCERNING SPECIAL RISKS (R PHRASES)

Preparations classified as dangerous for the environment within the meaning of Article 7 and in accordance with the provisions of Annex III A, B and C shall be assigned the following risk phrases in accordance with the table below:

Classification and preparation	Risk phrases which must appear on the label
N, R50 - 53	Very toxic to aquatic organisms Contains substances which are dangerous for the aquatic environment
N, R50	Very toxic to aquatic organisms
N, R51 - 53	Toxic to aquatic organisms Contains substances which are dangerous for the aquatic environment
R52 - 53	Harmful to aquatic organisms Contains substances which are dangerous for the aquatic environment
R52	Harmful to aquatic organisms
R53	Contains substances which may be dangerous for the aquatic environment
N, R59, R59	Contains substances which deplete the ozone layer

ANNEX III

PART E: INDICATIONS CONCERNING SAFETY ADVICE (S PHRASES)

Preparations classified as dangerous for the environment within the meaning of Article 7 and in accordance with the provisions of Annex III A, B and C shall be assigned the following safety advice.

"Follow the manufacturer's instructions regarding use and disposal"

The following S phrases must also be taken into consideration

S56 *Dispose this product and its container to a dangerous or special waste collection point*

Applicability:
preparations which are dangerous for the environment

Criteria for use:
recommended for preparations to which the symbol N has been assigned and which are likely to be used by the general public

S57 *Use appropriate containment to avoid environmental contamination*

Applicability:
preparations to which the symbol N has been assigned

Criteria for use:
normally limited to preparations not likely to be used by the general public

S59 *Refer to manufacturer/supplier on information on recovery/recycling*

Applicability:
preparations which are dangerous for the environment

Criteria for use:
- *obligatory* for substances dangerous for the ozone layer
- recommended for preparations to which the symbol N has been assigned and for which recovery/recycling is recommended

S60 *This material and/or its container must be disposed of as hazardous waste*

Applicability:
preparations which are dangerous for the environment

Criteria for use:
recommended for preparations to which the symbol N has been assigned which are not likely to the used by the general public

S61 *Avoid discharge into the environment: consult the special instructions, safety data sheets*

Applicability:
preparations which are dangerous for the environment

Criteria for use:
- normally used for preparations for which the symbol N has been assigned
- recommended for all preparations classified as dangerous for the environment not covered above

ANNEX IV

Special provisions for containers containing preparations offered or sold to the general public.

Part A: containers to be fitted with child-resistant fastenings.

1. Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Article 10 and under the conditions laid down in Article 6 of this Directive, shall be fitted with child-resistant fastenings.

2. Containers of whatever capacity, containing liquid preparations having a cinematic viscosity measured by rotative viscosity in accordance with ISO 3219 (edition of 15 December 1977) of less than 7 x 10^{-6} m^2/sec at 40° C and containing aliphatic and/or aromatic hydrocarbons in a total concentration equal to or greater than 10 % with the exception of preparations placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment, which are offered or sold to the general public shall be fitted with child-resistant fastening.

3. Containers of whatever capacity, having at least one of the substances mentioned below present in a concentration equal to or greater than the maximum individual concentration specified,

N°	Identification of the substance			Concentration limit
	CAS Reg N°	Name	EINECS N°	
1	67-56-1	Methanol	2006596	≥ 3 %
2	75-09-2	Dichloromethane	2008389	≥ 1 %

which are offered or sold to the general public shall be fitted with child-resistant fastenings.

Part B: Containers to be fitted with a tactile warning of danger

Containers of whatever capacity, containing preparations offered or sold to the general public and labelled as very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable in accordance with Article 10 and under the conditions laid down in Articles 5 and 6 of this Directive, shall carry a tactile warning of danger.

ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

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

1. Preparations sold to the general public

1.1. The labels on packages containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S 1, S 2, S 45 or S 46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

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

2. Preparations intended for use by spraying

The package label containing such preparations must compulsorily bear the safety advice S 23 accompanied by safety advice S 38 or S 51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

3. Preparations containing a substance assigned phrase R 33: Danger of cumulative effects

When a preparation contains at least one substance assigned the phrase R 33, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

4. Preparations containing a substance assigned phrase R 64: May cause harm to breastfed babies

When a preparation contains at least one substance assigned phrase R 64, the label of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

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

1. Preparations containing lead

1.1. Paint and varnishes

Labels of packages of paints and varnishes containing lead in quantities exceeding 0.15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

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

In the case of packages the contents of which are less than 12.5 millilitres, the particulars may be as follows.

"Warning. Contains lead".

2. Preparations containing cyanoacrylates

2.1 Adhesives

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

"Cyanoacrylate
Danger
Bonds skin and eyes in seconds
Keep out of the reach of children".

Appropriate advice on safety must accompany the package.

3. Preparations containing isocyanates

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

"Contains isocyanates.
See information supplied by the manufacturer."

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

The package labels of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

"Contains epoxy constituents.
See information supplied by the manufacturer."

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

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

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

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

The packaging of the abovementioned preparations must bear the following inscription printed in clearly legible and indelible characters:

"Warning ! Contains cadmium.
Dangerous fumes are formed during use.
See information supplied by the manufacturer.
Comply with the safety instructions."

7. Preparations available as aerosols

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

8. Preparations containing substances not yet tested completely

Where a preparation contains at least one substance which, in accordance with Article 13.3 of Directive 67/548/EEC, bear the inscription "Warning - substance not yet tested completely", the label of the preparation must bear the inscription "Warning - this preparation contains a substance not yet tested completely" if this substance is present in a concentration ≥ 1 %

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

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

   The label on the packaging of preparations containing at least one substance classified as sensitising and accompanied by a specific note under Annex I to Directive 67/548/EEC must bear the inscription:

   "Contains 'name of sensitising substance'. May produce an allergic reaction in persons already sensitised"

2. Preparations not intended for the general public

   The label on the packaging of the preparations referred to in Article 16.2 must bear the following inscription:

   "Safety data sheet available on request".

ANNEX VI

Request for confidentiality for the chemical identity of a harmful substance presenting only acute lethal effects.

PART A: INFORMATION TO BE COMMUNICATED IN THE REQUEST FOR CONFIDENTIALITY

Introductory notes:

A. Article 10 paragraph 2.3.4. indicates the conditions in which the person responsible for placing a preparation on the market may avail himself of the confidentiality request, namely: -

-the substance whose chemical identity he wishes to protect must be classified only harmful on the basis of its acute lethal effects (X_n, R 20, R 21, R 23) possibly in combination with one or more of the properties referred to in Article 10 paragraph 2.3.4. of this Directive;

-the person responsible for placing the preparation on the market must demonstrate that the disclosure of the chemical identity of a harmful substance on the label of a preparation will put at risk the confidential nature of his property.

B. To avoid multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice if a certain number of preparations have:

– the same dangerous constituents present in the same concentration range;

– the same classification and labelling;

– the same expected uses.

A single alternative denomination must be used to mask the chemical identity of the same substance in the preparations concerned. Furthermore, the request for confidentiality must contain all information indicated in the following request, without forgetting the name or the trade name of each preparation.

C. The alternative designation used on the label must be the same as that given under heading 2 'Composition/information on ingredients' of the Annex to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

This implies that the alternative designation used will contain enough information about the substance to ensure risk-free handling.

Request for confidentiality

In accordance with Article 11, the request for confidentiality must obligatorily contain the following information:

1. Name and full address (including telephone number) of the person established in the Community who is responsible for placing the preparation on the market (manufacturer, importer or distributor).

2. Precise identification of the substance(s) for which confidentiality is proposed and the alternative designation.

CAS N°	EINECS N°	Chemical name according to international nomenclature and classification (Annex I to Council Directive 67/548/EEC or provisional classification)	Alternative designation
(a) (b) (c)			
NB: where substances are classified provisionally, accompanying information (bibliographical references) should be provided as evidence that the provisional classification takes account of all existing pertinent information available on the properties of the substance.			

3. Justification for confidentiality (probability - plausibility)

4. Designation(s) or commercial name(s) of the preparation(s)

5. Is this designation or commercial name the same for all the Community?

   YES NO

   If no, specify the designation(s) or commercial name(s) used in the different Member States

   Austria
   Belgium:
   Denmark:
   Germany:
   Greece:
   Finland:
   France:

Spain:
Sweden:
Ireland:
Italy:
Luxembourg:
Netherlands:
Portugal:
United Kingdom:

6. Composition of the preparation(s) defined in point 2 of the Annex to Directive 91/155/EEC as last modified by Directive 93/112/EEC

7. Classification of the preparation(s) according to Article 6 of this Directive

8. Labelling of the preparation(s) according to Article 10 of this Directive

9. Intended uses for the preparation(s)

10. Safety data sheet(s) conforming to Directive 91/155/EEC as last amended by Directive 93/112/EEC.

PART B: LEXICON-GUIDE FOR ESTABLISHING THE ALTERNATIVE DESIGNATIONS (GENERIC NAMES)

1. Introductory note

The lexicon-guide is based on the procedure for the classification of dangerous substances (division of substances into families) which appears in Annex I to Directive 67/548/EEC.

The families are defined in the following manner :

- inorganic or organic substances whose properties are identified by having a common chemical element as their chief characteristic. The family name is derived from the name of the chemical element. These families are identified as in Annex I by the atomic number of the chemical element (001 to 103)

- organic substances whose properties are identified by having a common functional group as their chief characteristics

The family name is derived from the functional group name.

These families are identified by the conventional number found in Annex I (601 to 650)

Sub-families bringing together substances with a common specific character have been added in certain cases.

2. Establishing the generic name

General principles:

For the purposes of establishing the generic name, the following general approach, involving two successive stages, is adopted:

(i) identification of the functional groups and chemical elements present in the molecule;

(ii) determination of the extent to which account should be taken of the most important functional groups and chemical elements.

The identified functional groups and elements taken into account are the names of the families and sub-families set out in point 3 below in the form of a non-restrictive list.

3. Division of substances into families and sub-families

Family N° Annex I to Directive 67/548/EEC	Families Sub-families
001	Hydrogen compounds Hydrides
002	Helium compounds
003	Lithium compounds
004	Beryllium compounds
005	Boron compounds Boranes Borates
006	Carbon compounds Carbamates Inorganic carbon compounds Salts of hydrogen cyanide Urea and derivatives
007	Nitrogen compounds Quaternary ammonium compounds Acid nitrogen compounds Nitrates Nitrites
008	Oxygen compounds
009	Fluorine compounds Inorganic fluorides
010	Neon compounds
011	Sodium compounds
012	Magnesium compounds Organometallic magnesium derivatives
013	Aluminium compounds Organometallic aluminium derivatives
014	Silicon compounds Silicones Silicates
015	Phosphorus compounds Acid phosphorus compounds Phosphonium compounds Phosphoric esters Phosphates Phosphites Phosphoramides and derivatives
016	Sulphur compounds Acid sulphur compounds Mercaptans Sulphates Sulphites

017	Chlorine compounds Chlorates Perchlorates
018	Argon compounds
019	Potassium compounds
020	Calcium compounds
021	Scandium compounds
022	Titanium compounds
023	Vanadium compounds
024	Chromium compounds Chromium VI compounds
025	Manganese compounds
026	Iron compounds
027	Cobalt compounds
028	Nickel compounds
029	Copper compounds
030	Zinc compounds Organometallic zinc derivatives
031	Gallium compounds
032	Germanium compounds
033	Arsenic compounds
034	Selenium compounds
035	Bromine compounds
036	Krypton compounds
037	Rubidium compounds
038	Strontium compounds
039	Yttrium compounds
040	Zirconium compounds
041	Niobium compounds
042	Molybdenum compounds
043	Technetium compounds
044	Ruthenium compounds
045	Rhodium compounds
046	Palladium compounds
047	Silver compounds
048	Cadmium compounds
049	Indium compounds
050	Tin compounds Organometallic tin derivatives
051	Antimony compounds

052	Tellurium compounds
053	Iodine compounds
054	Xenon compounds
055	Caesium compounds
056	Barium compounds
057	Lanthanum compounds
058	Cerium compounds
059	Praseodymium compound
060	Neodymium compounds
061	Promethium compounds
062	Samarium compounds
063	Europium compounds
064	Gandolinium compounds
065	Terbium compounds
066	Dysprosium compounds
067	Holmium compounds
068	Erbium compounds
069	Thulium compounds
070	Ytterbium compounds
071	Lutetium compounds
072	Hafnium compounds
073	Tantalium compounds
074	Tungsten compounds
075	Rhenium compounds
076	Osmium compounds
077	Iridium compounds
078	Platinum compounds
079	Gold compounds
080	Mercury compounds Organometallic mercury derivatives
081	Thallium compounds
082	Lead compounds Organometallic lead derivatives
083	Bismuth compounds
084	Polonium compounds
085	Astate compounds
086	Radon compounds
087	Francium compounds
088	Radium compounds

089	Actinium compounds
090	Thorium compounds
091	Protactinium compounds
092	Uranium compounds
093	Neptunium compounds
094	Plutonium compounds
095	Americum compounds
096	Curium compounds
097	Berkelium compounds
098	Californium compounds
099	Einsteinium compounds
100	Fermium compounds
101	Mendelevium compounds
102	Nobelium compounds
103	Lawrencium compounds
601	Hydrocarbons Aliphatic hydrocarbons Aromatic hydrocarbons Alicyclic hydrocarbons Polycyclic aromatic hydrocarbons (PAH)
602	Halogenated hydrocarbons (*) Halogenated aliphatic hydrocarbons (*) Halogenated aromatic hydrocarbons (*) Halogenated alicyclic hydrocarbons (*) *(*) specify according to the family corresponding to halogen*
603	Alcohols and derivatives Aliphatic alcohols Aromatic alcohols Alicyclic alcohols Alcanolamines Epoxy derivatives Ethers Glycolethers Glycols and polyols
604	Phenols and derivatives Halogenated phenol derivatives (*) *(*) specify according to the family corresponding to halogen*
605	Aldehydes and derivatives Aliphatic aldehydes Aromatic aldehydes Alicyclic aldehydes Aliphatic acetals Aromatic acetals Alicyclic acetals

606	Ketones and derivatives Aliphatic Ketones Aromatic Ketones (*) Alicyclic Ketones *(*) Quinones included*
607	Organic acids and derivatives Aliphatic acids Halogenated aliphatic acids (*) Aromatics acids Halogenated aromatic acids (*) Alicyclic acids Halogenated alicyclic acids (*) Aliphatic acid anhydrides Halogenated aliphatic acid anhydrides (*) Aromatic acid anhydrides Halogenated aromatic acid anhydrides (*) Alicyclic acid anhydrides Halogenated alicyclic acid anhydrides (*) Salts of aliphatic acid Salts of halogenated aliphatic acid (*) Salts of aromatic acid Salts of halogenated aromatic acid (*) Salts of alicyclic acid Salts of halogenated alicyclic acid (*) Esters of aliphatic acid Esters of halogenated alicyclic acid (*) Esters of aromatic acid Esters of halogenated aromatic acid (*) Esters of alicyclic acid Esters of halogenated alicyclic acid (*) Esters of glycol ether Acrylates Methacrylates Lactones Acyl halogenides *(*) specify according to the family corresponding to halogen*
608	Nitriles and derivatives
609	Nitrated derivatives
610	Chloronitrated derivatives
611	Azoxy and azoic derivatives
612	Aminated derivatives Alphatic amines and derivatives Alicyclic amines and derivates Aromatic amines and derivatives Aniline and derivatives Benzidine and derivatives

613	Heterocyclic bases and derivatives Benzimidazole and derivatives Imidazol and derivatives Pyrethrinoids Quinoline and derivatives Triazine and derivatives Triazole and derivatives
614	Glucosides and alcaloids Alcaloid and derivatives Glucosids and derivatives
615	Cyanates and isocyanates Cyanates Isocyanates
616	Amides and derivatives Acetamide and derivatives Anilides
617	Organic Peroxides
650	Various substances Do not use this family. Instead, use the families or sub-families mentioned above

4. Practical application

After having conducted a search to see if the substance belongs to one or more families or sub-families on the list, the generic name can be established in the following way:

4.1. If the name of a family or sub-family is sufficient to characterise the chemical elements or important functional groups, this name will be chosen as the generic name.

Examples:

1,4 dihydroxybenzen
family 604: phenols and derivatives
generic name: phenol derivatives

- butanol
  family 603: alcohols and derivatives
  sub-family: aliphatic alcohols
  generic name: aliphatic alcohol

- 2-Isopropoxyethanol
  family 603: alcohols and derivatives
  sub-family: glycolethers
  generic name: glycolether

- methacrylate
  family 607: organic acids and derivatives
  sub-family: acrylates
  generic name: acrylate

4.2. If the name of a family or sub-family is not sufficient to characterise the chemical elements of important functional groups, the generic name will be a combination of the corresponding different family or sub-family names:

Examples:

- chlorobenzene
  family 602: halogenated hydrocarbons
  sub-family: halogenated aromatic hydrocarbons
  family 017: chlorine compounds
  generic name: chlorinated aromatic hydrocarbon

- 2,3,6-trichlorophenylacetic acid
  family 607: organic acids
  sub-family: halogenated aromatic acids
  family 017: chlorine compounds
  generic name: chlorinated aromatic acid

- 1-chloro-1-nitropropane
  family 610: chloronitrated derivatives
  family 601: hydrocarbons
  sub-family: aliphatic hydrocarbons
  generic name: chlorinated aliphatic hydrocarbon

- tetrapropyl dithiopyrophosphate
  family 015: phosphorus compounds
  sub-family: phosphoric esters
  family 016: sulphur compounds
  generic name: thiophosphoric ester

N.B. : in the case of certain elements, notably metals, the name of the family or sub-family may be indicated by the words "organic" or "inorganic".

Examples:

- dimercury chloride
  family 080: mercury compounds
  generic name: inorganic mercury compound

- barium acetate
  family 056: barium compounds
  generic name: organic barium compound

- ethyl nitrite
  family 007: nitrogen compounds
  sub-family: nitrites
  generic name: organic nitrite

- sodium hydrosulphite
  family 016: sulphur compounds
  generic name: inorganic sulphur compound

(The examples cited are substances taken from Annex I to Directive 67/548/EEC (19th adaptation) in respect of which requests for confidentiality may be submitted).

ANNEX VII

Preparations covered by Article 14(2)

Examples of preparations classified within the meaning of Article 6:

Alloys
Preparations containing polymers
Preparations containing elastomers

ANNEX VIII

PART A :Repealed Directives in accordance with Artricle 22

- Directive 78/631/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides)

- Directive 88/379/EEC on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations and its following adaptations to technical progress:

  - Directive 89/178/EEC
  - Directive 90/492/EEC
  - Directive 93/18/EEC

- Directive 90/35/EEC defining in accordance with Article 6 of Directrive 88/379/EEC the category of preparations the packaging of which must be fitted with child-resistant fastenings and/ or carry a tactile warning of danger

- Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with child-resistant fastenings

PART B: Deadlines for transposition and for application in accordance with Article 22

Directive	Deadline for transposition	Deadline for application
-78/631/EEC (OJ no L206 of 29/7/1978, p13)	1 January 1981	1 January 1981
-88/379/EEC (OJ no Li87 of 16/7/1988, p 14)	7 June 1991	7 June 1991
-89/178/EEC (OJ no L64 of 8/3/1989; p18)	1 December 1990	1 June 1991
-90/492/EEC (OJ no L275 of 5/10/1990, p35)	1 June 1991	8 June 1991
-93/18/EEC (OJ no L104 of 29/4/1993, p46	1 July 1994	1 July 1994
-90/35/EEC (OJ no L19 of 24/1/1990, p14)	1 August 1992	1 November 1992
-91/442/EEC(OJ no L238 of 27/8/1991, p25)	1 August 1992	1 November 1992

ANNEX IX

Correlation table

This Directive	88/379/EEC
Article 1 1.1 1.2 1.3 1.4 1.5	Article 1 1.1 1.2 1.3
Article 2	Article 2
Article 3	(Art 3.6.)
Article 4	Article 3.1 Article 4
Article 5 5.1 5.1 3rd indt 5.2-5.3 5.4.	Article 3.2. 3.2 3.2 para 3(b)
Article 6 6.1. 6.2 6.3 6.4 6.5	Article 3.3 3.3 para a & b 3.3 para 3 & 4 3.4 3.5 para 1 to 3
Article 7	
Article 8 8.1 8.2 8.3 8.4	Article 5 5.1 5.2 5.3
Article 9 9.1 9.2 9.3	Article 6 6.1 (a) 6.1 (b) 6.2 + 6.3 2nd para
Article 10 10.1.1-1.2 10.2 10.2.3. 10.2.4. 10.2.5.	Article 7 7.1 7.1.(c) 7.1.(d) 7.4
Article 11	
Article 12	
Article 13	Article 8
Article 14	Article 9
Article 15	
Article 16	Article 10
Article 17	Article 11

Article 18	Article 12
Article 19	Article 13
Article 20	Article 14
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FINANCIAL STATEMENT

1. TITLE OF OPERATION

Proposal for a European Parliament and Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

2. BUDGET HEADINGS INVOLVED:

- A 1178: Technical and administrative assistance in support of different activities
- A 2510: Expenditure on meetings of committees whose consultation is compulsory on the procedure for drafting Community legislation
- A 5010: Departmental data processing

3. LEGAL BASIS: Article 100 A of the EU Treaty

4. DESCRIPTION OF OPERATION

4.1. General Objective

The present proposal, by replacing and consolidating existing legislation on dangerous preparations[1] will ensure that the provisions relating to classification, packaging and labelling of dangerous preparations are harmonized.

In addition to replacing and consolidating existing legislation the proposal will also include new provisions:

-updating the existing provisions of the directive to take account of modifications and adaptations to technical progress of the parent directives.
-extending of certain provisions of the directive to phyto pharmaceutical products and explosives, and to preparations which, although not dangerous within the meaning of the directive, can present a hazard to the user
-introducing provisions relating to preparations which are dangerous for the environment

4.2 Duration Unlimited

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[1]Council Directive 88/379/EEC on the class. pack. and lab. of dang. preps. as adapted 3 times to technical progress and implemented through specific implementing directives.

5. CLASSIFICATION OF EXPENDITURE OR REVENUE

5.1 Non - compulsory expenditure

5.2 Non differentiated appropriations

5.3 No revenue is expected

6. TYPE OF EXPENDITURE OR REVENUE

See point 10 "Administrative expenditure"

7. FINANCIAL IMPACT

No financial impact on appropriation for operations

8. FRAUDE PREVENTION MEASURES

None

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1. Specific and quantified objectives; target population

Specific objectives:

The aim of the proposed operation are firstly, to harmonise the rules relating to the classification, labelling and packaging of dangerous preparations placed in the European market so as to avoid creating obstacles to trade and secondly, to guarantee a high level of protection for health and the environment.

The obligation to implement the directive's provisions will be beneficial on a number of scores:

- when the manufacturer considers changing his products composition to reduce the risk for human health and the environment;
- by preventing the market from being flooded with products that are considered dangerous;
- by improving the use of information systems and training in their use;
- by providing users with better information through the labelling of dangerous products and safety data sheet;
- by reducing the risks of accident;
- by making users aware of the choices they must make

In addition, applying uniform classification criteria to the greatest possible number of different types of preparations released on the EU market by the chemical sectors

extremely diverse array of firms should have positive consequences for Europe's economy.

Target population: Chemical industry (producers, importers, distributors) general public (consumers), national authorities.

9.2. Grounds for the operation

9.2.1 Community harmonization

The provisions related to the classification, labelling and packaging of dangerous preparations that are marketed in the European Union absolutely must be implemented in an harmonized fashion. Straying from this principle could lead to distortions in the preparation's labelling or the provision of suitable information for users. This would be highly detrimental to the smooth functioning of the Community market.

9.2.2 Safety-health-environment

The Community basis for taking measures related to human and environmental health, safety and protection is a high level of protection. It thus follows that all provisions in line with these objectives, such as the adoption of classification criteria for environmentally dangerous preparations, should be taken into consideration.

9. 3. Monitoring and evaluation of the operation.

The implementation of this Directive will be monitored by the committee set up under Directive 88/379/EEC.

10. ADMINISTRATIVE EXPENDITURE (SECTION III, PART A OF THE BUDGET)

Actual mobilisation of the necessary administrative resources will depend on the Commission's annual decision on the allocation of resources; taking into account the number of staff and additional amounts authorised by the budget authority.

10.1. Effect on the number of posts

Type of post		Staff to be assigned to managing the operation		Source		Duration
		Permanent posts	Temporary posts	Existing resources in DG or department concerned	Additional resources	
Official	A					
Temporary Staff	B	**1B**		**1**		unlimited
	C					as from 1997
Other resources			**(2 man.Year)**	**2**		1997
Total				**3**		

10.2. Overall financial impact of additional human resources

ECU

	Amounts	Method of calculation
Officials Temporary staff Other resources :		
Total		

The expenses related to human resources required for the completion of this action will be made available upon mobilisation of existing resources and are as follows:

	ECU
Officials (Titles A1, A2, A4, A5)	90.000
Technical assistance (A 1178): establishment of a data base	195.000 (1)
Total	285.000

(1) As from 1999 and onwards provisions must be made for the costs of adapting the data base to any changes (15 % of 195.000 Ecus)

10.3. Increase in other administrative expenditure as result of the operation

ECU

Budget heading	Amounts	Method of calculation
A 5010: Equipment (Computer services "informatique")	100.000	(2)
A 2510: Meetings (Article 21)	105.000	2 plenary meeting (30 experts) 695 x 30 x 2 = 41.700/ year (3) 6 working parties (15 experts) 695 x15 x 6 = 62.550/ year (3)
Total	205.000	

(2) in 1997
(3) yearly as from 1999

IMPACT ON COMPETITIVENESS AND EMPLOYMENT

I. The proposal for a Directive

The proposal for a revision of the Directive relating to the classification, packaging and labelling of dangerous preparations is intended:

- on the one hand, to rework existing legislative texts concerning the classification, packaging and labelling of dangerous preparations, i.e. the base Directive 88/379/EEC and its adaptation to technical progress, as well as derived directives in the interests of user-friendliness, particularly with regard to SMEs and SMIs and
- on the other hand,

- to include provisions on environmentally dangerous preparations,
- to extend certain provisions of the Directive to cover plant protection products, explosives and preparations which, while not dangerous within the meaning of the Directive, may present certain dangers for users,
- to update certain provisions of this Directive so as to take account of the amendments and their adaptation to technical progress,

This proposal must:

- harmonize the rules on the classification, packaging and labelling of dangerous preparations,
- ensure that the internal market functions correctly,
- ensure a high level of protection for health and the environment.

Given its aims and definition, this proposal cannot be carried out by the Member States, but requires action at Community level.

II. The impact on businesses

The measures concerned relate to the whole of the chemicals industry, from large companies down to small and medium-sized enterprises (SMEs).

Under these provisions, the person or entity responsible for placing on the market a preparation covered by the Directive is obliged to use labelling and the safety data sheet to provide information relating to the protection of health and the environment.

The costs arising from these measures will affect different types of company in different ways. In the case of major chemical groups, these measures are already partly in force and the extra costs can readily be absorbed without having any significant effect on the sale price of the product. In the case of SMEs, and especially small businesses, the costs will be more considerable and will be reflected in the price to the consumer.

Costs:

A distinction can be made between different types of costs:
- legal (knowledge of the legislation: "know-how")
- technical (knowledge of products and applications of the legislation according to type of product).

The sum of these two types of cost should enable an appropriate labelling system and a safety data sheet (SDS) to be classified and developed.

Costs will presumably be lower for large businesses which already use SDS labelling systems for their products, even for non-dangerous preparations.

For SMEs with a head of product safety, the "know-how" and safety data sheets can be developed within the enterprise. However, the printing of labels and the SDSs as well as the development of suitable packaging will incur additional costs.

For other businesses, the cost of adjusting may be greater.

III. What must businesses do to comply with the proposal?

First, it must be borne in mind that the process of classifying dangerous substances is constantly changing, entailing frequent amendments to Annex I to Directive 67/548/EEC and, consequently, changes to the preparations which contain these substances. To comply with the draft Directive, therefore, the persons responsible for placing products on the market must, where appropriate, update the labelling of their products and apply the new criteria for classifying environmentally dangerous substances. This new type of classification will supplement the present system of classifying products according to their effects on health and their physical and chemical properties. It should not lead to preparations being classified in too high a category simply on the grounds of the threat they may pose to the environment.

Moreover, these provisions on classifying environmentally dangerous substances should not mean that more information has to be supplied on the safety data sheets, because the data which must appear on these sheets has already been laid down in Directive 91/155/EEC, as last amended by Directive 93/112/EEC.

Businesses will have time to make the necessary adjustments in the time it takes to implement the legislation.

The sectors of industry concerned have been informed and have not objected to a minimum two-year period for implementing the Directive in the Member States.

IV. What are the likely economic effects of the proposal?

IV.1 Effects on competition

Competitiveness will be affected differently from one firm to another. In the longer term, the measures will mean an increase in the sale price of products placed on the market by SMEs. However, the persons responsible for placing products on the market can improve their firm's competitiveness by orienting production towards less dangerous products.

IV.2 Effects on employment

The measures concerned will lead to increased employment, possibly benefiting the persons recruited by firms to handle this work but also the providers of services who are in a position to meet the requirements of this Directive.

V. Consultation

A number of professional and trade associations represented by the Council of the European Federation of the Chemical Industry (CEFIC) have been consulted and have been closely involved in producing the draft Directive. Some particular industries have also been involved - e.g. the European Industrial Gas Association (EIGA), the European Confederation of Associations of Paint and Printing Ink Manufacturers (CEPE) and the International Association of Soap and Detergent Manufacturing Industries (AIS).
Without altering the thinking behind the Directive, the Commission and the Member States have given a positive response to the concern expressed by industry over some measures which might have major financial repercussions:

- Safety data sheets are to be supplied only on request in the case of preparations which are not dangerous within the meaning of the Directive but which contain at least one dangerous substance in a concentration exceeding that laid down in the Directive:
- Physical and chemical data are exempted from laboratory testing under certain conditions and exempted from the compulsory implementation of good laboratory practices;
- Firms will be free to choose the concentration limits deemed acceptable when applying the conventional method of assessing environmentally dangerous properties which do not involve excessive labelling.

In general, the professional and trade associations consider that their concerns have been taken into consideration and that a reasonable balance has been struck.

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