COUNCIL DIRECTIVE

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

(88/379/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas rules on dangerous substances have already been laid down in Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (4), as last amended by Directive 79/831/EEC (5);

Whereas rules on certain dangerous preparations having very specific uses have already been laid down:

— in Council Directive 73/173/EEC of 4 June 1973 on the approximation of Member States' laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (solvents) (6), as last amended by Directive 80/781/EEC (7),

— in Council Directive 77/728/EEC of 7 November 1977 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of paints, varnishes, printing inks, adhesives and similar products (8), as last amended by Directive 83/265/EEC (9),

Whereas, despite the abovementioned Community provisions, the rules, if any, applying to certain dangerous preparations in the Member States exhibit considerable differences as regards classification according to the degree of risk; whereas these differences constitute a not insignificant barrier to trade and directly affect the establishment and functioning of the common market;

Whereas it is therefore necessary to remove this barrier by approximating the relevant legislation existing in the Member States and incorporating in it the *'acquis communautaires'*;

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, especially children and the visually handicapped, and also for the environment;

Whereas provisions on the classification, packaging and labelling of the preparations must be laid down at Community level; whereas the provisions concerning the information appearing on the label, the dimensions of the label and the assignment of the various danger symbols, standard phrases concerning risks and safety advice have also to be brought into line with Directive 67/548/EEC;

Whereas some preparations, although they contain constituents which are dangerous to health, are not necessarily dangerous in the form in which they are placed on the market; whereas there are exceptions, however, and whereas the latter must be the subject of special labelling, as appropriate, in accordance with the provisions of Directive 67/548/EEC as amended by Directive 79/831/EEC, or of Annex II to this Directive;

Whereas the assessment of the health hazards of a preparation may, under Article 3, be carried out by a calculation method, by determining the toxicological properties according to well-defined test methods or by a combination of the two; whereas Directive 86/609/EEC stipulates in Article 7 (2) that an experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the

(1) OJ No C 317, 10. 12. 1986, p. 10 and OJ No C 353, 30. 12. 1987, p. 1.
(2) OJ No C 318, 30. 11. 1987, p. 73 and Decision of 13 April 1988 (not yet published in the Official Journal).
(3) OJ No C 189, 28. 7. 1986, p. 1.
(4) OJ No 196, 16. 8. 1967, p. 1.
(5) OJ No L 259, 15. 10. 1979, p. 10.
(6) OJ No L 189, 11. 7. 1973, p. 7.
(7) OJ No L 229, 30. 8. 1980, p. 57.
(8) OJ No L 303, 28. 11. 1977, p. 23.
(9) OJ No L 147, 6. 6. 1983, p. 11.
(10) OJ No L 358, 18. 12. 1986, p. 1.

use of an animal, is reasonably and practically available; whereas this Directive makes use of the results of assessments of toxicological properties only when these are already known and entails no obligation to conduct further experiments on animals;

Whereas the label constitutes a basic tool for users of the 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 intended for professional users, and the second for the bodies appointed by the Member States and whose responsibility it is to give information reserved solely for medical purposes, both curative and preventive;

Whereas dangerous preparations may, although conforming to the provisions of this Directive, nevertheless constitute a danger to health or the environment; whereas it is therefore advisable to provide a procedure to reduce this danger;

Whereas the Commission will, on the basis of information to be supplied by the Member States be obliged to submit a report, within two years of application of this Directive, concerning any inadequacies or loopholes, as compared with the present Directive, in 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) [1], as last amended by Directive 84/291/EEC [2]; whereas on the basis of this report, the Commission will, if appropriate, submit the necessary proposals,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States on the:

— classification,

— packaging, and

— labelling

of preparations dangerous to man and the environment when they are placed on the market in the Member States.

2. This Directive shall apply to preparations which are placed on the market in the Member States and which:

— contain at least one substance classified as dangerous, within the meaning of Article 2, and

— are regarded as dangerous within the meaning of Article 3.

This Directive shall also apply to the preparations listed in Annex II.

3. This Directive shall not apply to:

(a) medicinal or veterinary products as defined by Directive 65/65/EEC [3], as last amended by Directive 87/21/EEC [4];

(b) cosmetic products as defined by Directive 76/768/EEC [5], as last amended by Directive 86/199/EEC [6];

(c) mixtures of substances which, in the form of waste, are covered by Directive 75/442/EEC [7] and Directive 78/319/EEC [8], as last amended by the Act of Accession of Spain and Portugal;

(d) pesticides covered by Directive 78/631/EEC, as last amended by Directive 83/291/EEC;

(e) munitions and explosives placed on the market with a view to obtaining a practical effect by explosion or a pyrotechnic effect.

In addition, this Directive shall not apply to:

(f) foodstuffs in a finished stage intended for the final consumer;

(g) animal feedingstuffs in a finished stage intended for the final consumer;

(h) the carriage of dangerous substances by rail, road, inland waterway, sea or air;

(i) preparations in transit which are under customs supervision provided they do not undergo any treatment or processing.

Article 2

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

1. 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 the alternative criteria referred to below are applied.

2. The requisite physico-chemical properties for the classification of preparations shall be determined by the methods specified in Annex V (A) to Directive 67/548/EEC.

(1) OJ No L 206, 29. 7. 1978, p. 13.
(2) OJ No L 144, 30. 5. 1984, p. 1.
(3) OJ No 22, 9. 2. 1965, p. 369/65.
(4) OJ No L 15, 17. 1. 1987, p. 36.
(5) OJ No L 262, 27. 9. 1976, p. 169.
(6) OJ No L 149, 3. 6. 1986, p. 38.
(7) OJ No L 194, 25. 7. 1975, p. 39.
(8) OJ No L 84, 31. 3. 1978, p. 43.

Preparations shall be regarded as explosive, oxidizing, extremely flammable, highly flammable or flammable when the results of the tests carried out by the methods mentioned above comply with the definitions in Article 2 of Directive 67/548/EEC and the specific evaluation criteria detailed in those methods.

By way of derogation from the preceding:

(a) the determination of the explosive, oxidizing, 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 dangers of this kind;

(b) the preparations placed on the market in the form of aerosols are subject to the flammability criteria specified in paragraphs 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC [1], as last amended by the Act of Accession of Spain and Portugal.

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

(a) by the conventional method described below 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 an appropriate classification and label in accordance with the criteria in Annex VI to that Directive.

Any one or more of the toxicological properties of the preparation which are not assessed by the method set out in (b) hereof 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 (b) shall be used for classifying the preparation except in the case of carcinogenic, mutagenic and teratogenic effects.

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,

— 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 classified in accordance with method 3 (b) above a new health hazard assessment either by method 3 (a) or (b) shall be performed whenever:

— changes of composition of the initial concentration as a weight/weight 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 %	± 15 %
> 2,5 ≤ 10 %	± 10 %
> 10 ≤ 25 %	± 6 %
> 25 ≤ 50 %	± 5 %
> 50 ≤ 100 %	± 2,5 %

— 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.

5. In accordance with Article 3 (3) (a), the health hazards shall be assessed by the conventional method described below, using individual concentration limits.

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 below, these concentration limits must be used.

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 below, the concentration limits shall be assigned in accordance with the specifications in Annex I to this Directive.

When a preparation contains at least one substance which, in accordance with Article 8 (2) of Directive 67/548/EEC, bears the warning 'Caution — substance not yet fully tested', the label of the preparation must bear the warning 'Caution — this preparation contains a substance not yet fully tested' if the substance is present in a concentration equal to or in excess of 1 %.

[1] OJ No L 147, 9. 6. 1975, p. 40.

However, this substance must be treated on the same basis as the other substances present in the preparation when applying the method of evaluation by calculation, if the labelling gave at least an indication of the health hazard.

In that case,

(a) The following preparations shall be regarded as very toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic in individual concentrations exceeding:

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

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

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each very toxic substance in the preparation by the limit specified for that substance is 1 or more, i.e.

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

where:

P_{T+} = is the percentage by weight of each very toxic substance in the preparation,

L_{T+} = is the limit specified for each very toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

— the concentration specified at point 2 of Annex I (Table II) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(b) The following preparations shall be regarded as toxic:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or in individual concentrations exceeding:

— either the concentrations specified in Annex I to Directive 67/548/EEC for the substance or substances under consideration, or

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

(ii) owing to their acute lethal effects, preparations containing more than one substance classified or regarded as very toxic or toxic in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the toxic limit specified for that substance is 1 or more, i.e.

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

where:

P_{T+} is the percentage by weight of each very toxic substance in the preparation,

P_T is the percentage by weight of each toxic substance in the preparation,

L_T is the limit specified for each very toxic or toxic substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

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

(iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

— the concentration specified at point 3 of Annex I (Table III) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(c) The following preparations shall be regarded as harmful:

(i) owing to their acute lethal effects, preparations containing one or more substances classified or regarded as very toxic, toxic or harmful in individual concentrations exceeding:

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

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

(ii) owing to their acute lethal effects, preparations containing more than one of the substances classified or regarded as very toxic or toxic or harmful in individual concentrations not exceeding the limits specified either in Annex I to Directive 67/548/EEC or at point 1 of Annex I (Table I) to this Directive if the sum of the quotients obtained by dividing the percentage by weight of each substance in the preparation by the harmful limit specified for that substance is 1 or more, i.e.

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

where:

P_{T+} is the percentage by weight of each very toxic substance in the preparation,

P_T is the percentage by weight of each toxic substance in the preparation,

P_{Xn} is the percentage by weight of each harmful substance in the preparation,

L_{Xn} is the limit specified for each very toxic, toxic or harmful substance expressed as a percentage;

(iii) owing to their non-lethal irreversible effects after one exposure, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

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

(iv) owing to their long-term effects, preparations containing one or more dangerous substances that produce such effects in individual concentrations exceeding:

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

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

(v) owing to their sensitizing effects by inhalation, preparations containing at least one dangerous substance to which is assigned phrase R 42 that produces such effects in individual concentrations exceeding:

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

— the concentration specified at point 5 of Annex I (Table V) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

(d) The following preparations shall be regarded as very corrosive (1):

(i) preparations containing one or more substances classified or regarded as corrosive to which is assigned phrase R 35 in individual concentrations exceeding:

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

— the concentration specified at point 4 of Annex I (Table IV) to this Directive where the substance

(1) Within the meaning of this Directive 'very corrosive substance' means a substance to which is assigned the symbol C and the phrase denoting a risk R 35.