II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 93/18/EEC

of 5 April 1993

adapting for the third time to technical progress Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 (1), and in particular Article 15 thereof,

Whereas Council Directive 92/32/EEC (2) amending Directive 67/548/EEC (3) for the seventh time, replaces the definition 'teratogenic' by 'toxic for reproduction' and introduces this modification into Directive 88/379/EEC;

Whereas Annex VI to Directive 67/548/EEC, as last amended by Commission Directive 92/37/EEC (4), provides for new criteria and new R type phrases for the category of danger 'toxic for reproduction', as well as new criteria for the use of certain R phrases concerning the nature of particular risks attributed to dangerous substances and preparations and in particular phrases R 33 and R 64;

Whereas the provisions set out in Annex I to Directive 88/379/EEC, as amended by Directive 90/492/EEC (5), should therefore be revised and supplemented;

Whereas Annex II to Directive 88/379/EEC contains special labelling provisions applicable to certain preparations; whereas these special labelling provisions apply without distinction to all preparations under consideration whether or not considered dangerous within the meaning of the Directive;

Whereas it is necessary to make special provisions in addition to those relating to labelling in the case of preparations which although they contain at least one substance which is dangerous are not necessarily dangerous within the meaning of Directive 88/379/EEC;

Whereas the special provisions applicable to certain preparations set out in Annex II to Directive 88/379/EEC as amended by Directive 89/178/EEC (6) should therefore be revised and supplemented;

Whereas the amendments to Annex II result in its restructuring featuring in particular a new presentation by chapter in order to maintain the clarity required in all legislation;

Whereas Article 8a of the Treaty established an area without internal barriers in which the free circulation of goods, of persons, of services and capital is assured;

Whereas, according to the scope and effects of the proposed action, the Community measures envisaged by this regulation are not only necessary but also indispendable for the attainment of the stated objectives and that these objectives cannot be achieved by Member States individually, and that furthermore their attainment at Community level is already provided for by Directive 88/379/EEC;

(1) OJ No L 187, 16. 7. 1988, p. 14.
(2) OJ No L 154, 5. 6. 1992, p. 1.
(3) OJ No L 196, 16. 8. 1967, p. 1.
(4) OJ No L 154, 5. 6. 1992, p. 30.
(5) OJ No L 275, 5. 10. 1990, p. 35.
(6) OJ No L 64, 8. 3. 1989, p. 18.

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in Dangerous Substances and Preparations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I and II to Directive 88/379/EEC are replaced by the Annex to this Directive.

Article 2

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 1 July 1994 at the latest and shall forthwith inform the Commission thereof.

2. These provisions shall take effect by 1 July 1994 at the latest.

3. 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 Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 5 April 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX I

CONCENTRATION LIMITS TO BE USED IN APPLYING THE CONVENTIONAL METHOD OF ASSESSING HEALTH HAZARDS IN ACCORDANCE WITH ARTICLE 3 (5)

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. sensitizing 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 sybmol and one or more risk phrases or by categories (category 1, category 2 or category 3) also expressed by 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. *Other than gaseous preparations*

The concentration limits fixed in Table I 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 R 26, R 27, R 28	concentration ≥ 7 %	1 % ≤ concentration < 7 %	0,1 % ≤ concentration < 1 %
T with R 23, R 24, R 25		concentration ≥ 25 %	3 % ≤ concentration < 25 %
X_n with R 20, R 21, R 22			concentration ≥ 25 %

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 R 26, R 27, R 28	concentration ≥ 1 %	0,2 % ≤ concentration < 1 %	0,02 % ≤ concentration < 0,2 %
T with R 23, R 24, R 25		concentration ≥ 5 %	0,5 % ≤ concentration < 5 %
X_n with R 20, R 21, R 22			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. *Other than 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 determine, when appropriate, the classification of the preparation.

TABLE II

Classification of the substance	Classification of the preparation		
	T^+	T	X_n
T^+ with R 39/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 R 39/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. *Other than gaseous preparations*

For substances that produce severe effects after repeated exposure (R 48/route of exposure), the individual concentration limits specified in Table III 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.