II

*(Acts whose publication is not obligatory)*

# COUNCIL

## COUNCIL DIRECTIVE

**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)**

(73/173/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

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

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Having regard to the Opinion of the Economic and Social Committee;

Whereas dangerous substances and preparations are subject to rules in the Member States; whereas there are considerable differences between these national rules particularly as regards labelling but equally as regards classification according to the degree of risk; whereas these differences constitute a barrier to trade and directly affect the establishment and functioning of the common market;

Whereas rules relating to dangerous substances have already been laid down in Council Directive (1) of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as last amended by the Directive of 21 May 1973 (2); whereas it is necessary to approximate laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations;

Whereas in view of the extent of this field and the many detailed measures which will be required for the approximation of all the provisions relating to dangerous preparations, it is advisable to deal first with the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations such as solvents;

Whereas the main feature of these preparations is the risk of toxicity and harmfulness of their ingredients;

Whereas preparations containing one or more of these dangerous substances are frequently used for industrial, farming, craft and domestic purposes either as solvents as such or as dilutants, cleaning products, degreasing agents or similar products;

Whereas the many different uses of solvents in other preparations require moreover that account be taken in other Directives of the material dangers deriving from the circumstances of use such as prolonged or occasional exposure, the quantity of the dangerous preparations and the dimensions of their packages and from all other possible factors concerning dangerous substances which may aggravate or reduce these risks; whereas such Directives should relate to pesticides, glues, printing inks, paints and varnishes;

Whereas in view of the particular features and conditions of use of preparations consisting exclusively of solvents, account must likewise be taken, quite apart from any other factor, of known data concerning risks of intoxication arising out of prolonged exposure;

(1) OJ No 196, 16. 8. 1967, p. 1.
(2) OJ No L 167, 25. 6. 1973, p. 1.

Whereas technical progress necessitates rapid adaptation of the technical prescriptions laid down in this Directive; whereas, in order to facilitate the implementation of measures required to that end, close cooperation should be established between the Member States and the Commission within the Committee for the adaptation to technical progress of directives for removing technical barriers to trade in the sector of dangerous substances and preparations, established by the Directive of 27 June 1967;

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. This Directive shall concern:

— the classification

— the packaging

— the labelling

of dangerous preparations consisting exclusively of solvents intended for use as such. Substances intended for use as solvents and containing impurities listed in the Annex hereto in quantities exceeding the limits prescribed in Article 2 (5) shall also be considered as dangerous preparations.

2. This Directive shall apply to preparations which are placed on the market in the Member States and which contain one or more of the substances listed in the Annex hereto.

3. This Directive shall not apply to:

(a) medicines, narcotics, radioactive substances and fuels;

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

(c) munitions or objects which contain these preparations in the form of igniters or fuels;

(d) dangerous preparations exported to third countries;

(e) preparations in transit subject to customs control provided they are not altered in any way.

4. The definitions specified in Article 2 of the Directive of 27 June 1967, shall apply to this Directive.

*Article 2*

1. Toxic and harmful substances as defined in the Directive of 27 June 1967 and used as solvents, shall be divided into classes and sub-classes in accordance with the Annex hereto.

Toxic substances are under class I, harmful substances under class II. Each sub-class is given a classification index $I_1$ and an exemption index $I_2$, as in the table below:

| Class of substance | Classification index $I_1$ | Exemption index $I_2$ | Concentration limit to qualify for exemption E % |
|---|---|---|---|
| Toxic I/a | 500 | 500 | 0·2 |
| I/b | 100 | 100 | 1 |
| I/c | 25 | 25 | 4 |
| Harmful II/a | 5 | 20 | 5 |
| II/b | 2 | 8 | 12·5 |
| II/c | 1 | 4 | 25 |
| II/d | 0·5 | 2 | 50 |

2. Preparations containing one or more of the substances listed in the Annex hereto shall be considered toxic if the sum of the products obtained by multiplying the weight percentage of each toxic or harmful substance in a preparation by its respective $I_1$ index exceeds 500, that is:

$$\Sigma [P \times I_1] > 500;$$

where

P is the weight percentage of each substance in the preparation

$I_1$ is the index corresponding to the class of the substance.

3. Preparations containing one or more substances listed in the Annex hereto shall be considered harmful if:

(a) the sum of the products specified in paragraph 2 is less than or equal to 500, that is

$$\Sigma [P \times I_1] \leq 500;$$

and

(b) the sum of the products obtained by multiplying the weight percentage of each toxic or harmful

substance in a preparation by its respective $I_2$ index exceeds 100, that is:

$$\Sigma [P \times I_2] > 100$$

where

P is the weight percentage of each substance in the preparation,

$I_1$ and $I_2$ are the indices corresponding to the class of the substance.

4. Preparations containing one or more of the substances listed in the Annex hereto shall not be considered as toxic or harmful if the sum of the products obtained by multiplying the weight percentage of each toxic or harmful substance in a preparation by its respective $I_2$ index is less than or equal to 100; that is:

$$\Sigma [P \times I_2] \leq 100$$

where

P is the weight percentage of each substance in the preparation,

$I_2$ is the index corresponding to the class of the substance.

5. No account shall be taken of substances in preparations covered by this Directive whether existing as impurities or as additives, the individual concentration of which is less than 0·2 % by weight if falling within class I and 1 % by weight if falling within class II.

*Article 3*

Member States shall take all necessary measures to ensure that dangerous preparations (solvents) cannot be placed on the market unless they comply with the provisions of this Directive and the Annex thereto.

*Article 4*

Member States shall take all necessary measures to ensure that dangerous preparations (solvents) cannot be placed on the market unless their packages fulfil the following conditions:

(a) packages must be made up and closed in such a way as to preclude any loss of the contents save for prescribed safety devices;

(b) the materials constituting the packages and closures must not be liable to attack by the contents or liable to form harmful or dangerous compounds with the contents;

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

Packages meeting these requirements shall be considered as satisfactory.

*Article 5*

1. Member States shall take all necessary measures to ensure that dangerous preparations (solvents) cannot be placed on the market unless the labelling relating to the package fulfils the following conditions.

2. All packages must show clearly and indelibly the following:

(a) the name(s) of the toxic ingredient(s) of the dangerous preparation;

the name of the harmful ingredients present in a concentration which,

— in the case of substances falling within class II/a, exceeds 3 % by weight

— in the case of substances falling within class II/b, exceeds 6 % by weight

— in the case of substances falling within class II/c, exceeds 10 % by weight

— in the case of toluene and xylene, exceeds 5 % by weight

— in the case of substances falling within class II/d, exceeds 20 % by weight

The name must be shown under one of the terms listed in Annex I to the Directive of 27 June 1967.

(b) the name and address of the manufacturer or any other person placing the preparation on the market;

(c) symbols and indications of the dangers attendant to the toxic, harmful or highly flammable preparation, in accordance with Article 6 (2) (c) of the Directive of 27 June 1967 and in connection with Annex V thereto;

(d) a notice of the special risks deriving from these dangers. In the case of non-toxic preparations these risks need not be shown, if the contents of the package do not exceed 100 ml.

3. The notice of the special risks shall be supplied by the manufacturer or any other person putting that preparation on the market according to the importance of the main risks.

This notice should conform with the indications given in Annex III to the Directive of 27 June 1967.

No more than 4 phrases need be shown. Health risks must be given priority over risks concerning explosion or fire.

4. The package shall be accompanied by safety advice on how to avoid the main dangers attendant to the preparation. These warnings shall be selected by the manufacturer or any other person putting that preparation on the market from among the phrases given in the list contained in Annex I to the Directive of 27 June 1967 and Annex IV thereto.

5. Provisions of Article 2 (5) of this Directive shall apply by analogy to labelling.

*Article 6*

1. Where the particulars required by Article 5 appear on a label, that label must be placed on one or more surfaces of the package so that it can be read horizontally when the package is set down normally. The dimensions of the label must be as follows:

| *Package contents* | | *Dimensions* |
|---|---|---|
| — less than or equal to 3 l | if possible | 52 × 74 mm |
| — greater than 3 l and not exceeding 50 l | at least | 74 × 105 mm |
| — greater than 50 l and not exceeding 500 l | at least | 105 × 148 mm |
| — greater than 500 l | at least | 148 × 210 mm |

Each symbol must cover at least one tenth of the surface area of the label. The entire surface of the label must adhere to the package immediately containing the substance.

2. A label shall not be required where the particulars are clearly shown on the package itself as specified in paragraph 1.

3. Member States may make the placing on the market of dangerous preparations in their territories subject to the use of the national language or languages in respect of the labelling thereof.

4. For the purposes 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:

where the outer package is labelled in accordance with regulations on the transport of dangerous materials and where the inner package or packages are labelled in accordance with this Directive;

(b) in the case of a single package, where such a package is satisfactorily labelled in accordance with rules on the transport of dangerous materials and with Article 5 (2) (a), (b) and (d) and (3) of this Directive.

*Article 7*

1. Member States may:

(a) permit the labelling required by Article 5 to be applied in some other appropriate manner on packages too small to allow labelling in accordance with Article 6 (1) and (2);

(b) by way of derogation from Articles 5 and 6, permit the packages of preparations other than toxic preparations to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no danger to workers or others.

2. Member States availing themselves of facilities provided for in paragraph 1 shall immediately inform the Commission thereof.

*Article 8*

Member States shall not prohibit, restrict or impede on the grounds of classification, packaging or labelling as defined in this Directive, the placing on the market of dangerous preparations which satisfy the requirements of this Directive and the Annex thereto.

*Article 9*

1. Where a Member State establishes that a dangerous preparation, although satisfying the requirements of this Directive, presents a health or safety risk necessitating a classification or labelling other than those provided for by this Directive, it may, for a period not exceeding six months, prohibit

the distribution, sale or use of that preparation in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall, within six weeks, consult with the Member States concerned, express its opinion without delay and take the appropriate steps. Where it deems an amendment referred to in Article 10 to be necessary the period provided for in paragraph 1 shall be extended until the procedure laid down in Article 8c of the Directive of 27 June 1967 has been completed.

*Article 10*

The amendments required for adapting the Annex to technical progress shall be adopted in accordance with the procedure laid down in Article 8c of the Directive of 27 June 1967.

*Article 11*

1. The Member States shall introduce the provisions necessary to comply with this Directive within eighteen months from its communication and shall inform the Commission immediately thereof.

However, for a period of three years from the notification of this Directive and by way of derogation from the provisions of this Article, Denmark, Ireland and the United Kingdom may allow the marketing on their territory of dangerous preparations (solvents) the packaging and labelling of which are in accordance with the conditions in force in their territory at the time of Accession.

2. The Member States shall ensure that the internal legal provisions to be adopted in the field covered by this Directive are sent to the Commission.

*Article 12*

This Directive is addressed to the Member States.

Done at Luxembourg, 4 June 1973.

*For the Council*

*The President*

R. VAN ELSLANDE