COUNCIL DIRECTIVE

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)

(78/631/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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 (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas there are in the Member States regulations governing dangerous substances and preparations; whereas these regulations differ, especially as regards labelling to indicate risk and classification according to the degree of danger; whereas these differences constitute a barrier to trade and directly affect the establishment and functioning of the common market;

Whereas it is therefore important to eliminate these barriers and it is necessary, in order to attain this objective, to approximate the relevant legislation existing in the Member States;

Whereas rules for dangerous substances have already been laid down in Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (3), as last amended by Directive 76/907/EEC (4), which covers the active substances in pesticides; whereas it is necessary to introduce parallel rules for dangerous preparations composed of two or more substances;

Whereas many dangerous substances and preparations are used in plant and wood protection and pest control; whereas more use is made of preparations than of substances as such in this sector; whereas most of these preparations contain substances which are toxic to varying degrees, so that toxicological classification, together with prescriptions regarding labelling (danger symbols, indications of risk and safety advice) and rules concerning packaging are necessary in order to preclude the risk of damage, particularly to public health, as a result of the marketing of pesticides;

Whereas this Directive applies to the classification, packaging and labelling of pesticides; whereas it will in addition be necessary to include in later Directives special provisions concerning the authorization, distribution and use of these pesticides, which will themselves contain further requirements as to labelling and possibly first aid information for doctors;

Whereas the principal objective of this Directive must be to improve the protection of the public and in particular of persons handling pesticides;

Whereas this Directive can also contribute, through its requirements as to the indication of risk, to the protection of the consumer;

Whereas dangerous preparations used as pesticides may, although conforming to the provisions of this Directive, nevertheless constitute a danger to public health or safety; whereas it is therefore advisable to provide for a procedure intended to reduce this danger,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply, without prejudice to other relevant Community provisions, to the approximation of the laws of Member States relating to:

— the classification according to danger,

— the packaging, and

— the labelling to indicate risk,

of dangerous preparations (pesticides), hereinafter referred to as 'pesticides', in the form in which they are supplied to the user and intended for use as pesticides.

(1) OJ No C 30, 7. 2. 1977, p. 35.
(2) OJ No C 114, 11. 5. 1977, p. 20.
(3) OJ No 196, 16. 8. 1967, p. 1.
(4) OJ No L 360, 30. 12. 1976, p. 1.

2. This Directive shall not apply to:

(a) medicines, narcotics and radioactive preparations;

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

(c) pesticides for export to third countries;

(d) pesticides in transit subject to customs control, provided that they undergo no processing or transformation.

3. The definitions laid down in Article 2 of Directive 67/548/EEC shall apply for the purposes of this Directive.

Article 2

For the purposes of this Directive 'pesticides' shall mean preparations designed:

1. to destroy organisms harmful to plants or to plant products or to protect plants and plant products from such organisms; or

2. to improve or regulate plant production, with the exception of fertilizers and soil conditioners; or

3. to preserve plant products, including wood preservatives, in so far as there are no other Community provisions specifically relating to preservatives, except those products which are applied to surfaces and do not contain preserving substances which penetrate into the plant product; or

4. to destroy undesired plants; or

5. to destroy parts of plants or to prevent undesired growth; or

6. to render harmless or to destroy, or to give protection against, harmful organisms which do not attack plants, and undesired organisms.

Article 3

1. Pesticides shall be classified by means of the determination of the acute oral or percutaneous toxicity of the preparation, expressed in LD_{50} values determined in the rat, or respiratory toxicity expressed in LC_{50} values determined in the rat.

(a) The following shall serve as reference values for oral LD_{50} in the rat:

(1) for solids (except bait preparations and pesticides in tablet form):

5mg/kg of body weight or less: 'very toxic',

more than 5 but not more than 50 mg/kg of body weight: 'toxic',

more than 50 but not more than 500 mg/kg of body weight: 'harmful';

(2) for liquids (including bait preparations and pesticides in tablet form):

25 mg/kg of body weight or less: 'very toxic',

more than 25 but not more than 200 mg/kg of body weight: 'toxic',

more than 200 but not more than 2 000 mg/kg of body weight: 'harmful'.

(b) For pesticides in the form of gas or liquefied gas, and for fumigants and aerosols, the following reference LC_{50} values, determined by means of a four-hour inhalation test on rats, shall be applicable:

0·5 mg/litre of air or less: 'very toxic',

more than 0·5 but not more than 2 mg/litre of air: 'toxic',

more than 2 but not more than 20 mg/litre of air: 'harmful'.

For pesticides in powder form in which the diameter of the particles does not exceed 50 microns the values must be determined by inhalation test. However, where such pesticides are already marketed or are in the process of being authorized at the date on which this Directive is adopted, they may be classified in accordance with the provisions laid down for the liquid pesticides referred to in point (a).

(c) For pesticides which can be absorbed through the skin, and where the percutaneous LD_{50} value is such that it would place the pesticides in a more restrictive class than the oral LD_{50} value or the inhalation LC_{50} value would indicate, the following reference values, determined by the percutaneous test on rats and/or, where a Member State so requires, on rabbits, shall be applicable:

(1) for solids (except bait preparations and pesticides in tablet form):

10 mg/kg of body weight or less: 'very toxic',

more than 10 but not more than 100 mg/kg of body weight: 'toxic',

more than 100 but not more than 1 000 mg/kg of body weight: 'harmful';

(2) for liquids (including bait preparations and pesticides in tablet form):

50 mg/kg of body weight or less: 'very toxic',

more than 50 but not more than 400 mg/kg of body weight: 'toxic',

more than 400 but not more than 4 000 mg/kg of body weight: 'harmful'.

The prescribed tests shall be carried out in accordance with internationally recognized methods or with the method, if any, provided for in Directive 67/548/EEC.

2. By way of derogation from paragraph 1, a pesticide containing one active substance may be classified by means of a calculation carried out in accordance with Annexes I and III if:

(a) on the basis of its ingredients, its classification as 'very toxic', 'toxic' or 'harmful' is obvious; or

(b) it is shown that the composition of a pesticide closely resembles that of another pesticide which has already been classified and the toxicological data relating to the latter are sufficiently well established.

In such cases there must be valid grounds for assuming that the classification resulting from a calculation would not vary substantially from those obtainable by biological testing in accordance with paragraph 1.

3. For the classification of pesticides which contain more than one active substance and are intended solely for marketing within their territories, Member States may allow the use of the method of calculation set out in Annex II with the restrictions specified in paragraph 2.

4. If facts appear which leave the correctness of the classification open to doubt, the competent authorities may require that the calculation be replaced by toxicological tests as laid down in paragraph 1.

5. Additional toxicological data may be taken into account for the purpose of classifying a pesticide where,

(a) there are facts which suggest that in normal use a pesticide involves a risk to human health; or

(b) it is shown that, as regards a particular pesticide, the rat is not the most suitable animal for testing and that another species is, for example, clearly more sensitive or displays reactions closer to those of man; or

(c) the LD_{50} values of the pesticide, determined orally or by the percutaneous test should not be used as the main basis of classification (in certain instances, for example, aerosols, other special preparations, powders and fumigants).

Conversely, where it can be shown that a pesticide is less toxic or harmful than its ingredients seem to indicate, this fact will also be taken into account when it is classified.

Article 4

The Member States shall take all necessary measures to ensure that pesticides cannot be placed on the market unless they comply with this Directive.

Article 5

1. The Member States shall take all necessary measures to ensure that pesticides cannot be placed on the market unless their packaging satisfies the following requirements:

(a) the packaging must be so designed and constructed that its contents cannot escape; this requirement shall not apply where special safety devices are prescribed;

(b) the materials constituting the packaging and fastenings must not be susceptible to attack by the contents, or liable to form harmful or dangerous compounds with the contents;

(c) packaging and fastenings must be strong and solid throughout so as to ensure that they will not come apart and will safely withstand normal handling;

(d) containers with fastening devices must be so designed that the container can be repeatedly refastened so that the contents cannot escape.

2. The Member States may also prescribe that:

— packages must initially be closed with a seal in such a way that when the package is opened for the first time the seal is irreparably damaged;

— containers with a capacity not exceeding three litres which contain pesticides intended for domestic use must have childproof fastenings.

Article 6

1. Member States shall take all necessary measures to ensure that pesticides cannot be placed on the market unless the labelling on their packaging satisfies the following requirements.

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

(a) trade name or designation of the preparation;

(b) — in the case of pesticides not subject to authorization, the name and address of the manufacturer or any other person placing the preparation on the market,

— in the case of pesticides subject to authorization, the name and address of the holder of the authorization and the registered number of the preparation and, if different, the name and address of the person placing the preparation on the market;

(c) the name and amount of each active substance expressed:

— for pesticides which are solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C): as a percentage by weight,

— for other liquids: as a percentage by weight and in grams per litre at 20 °C,

— for gases: as a percentage by volume;

(d) the name of each very toxic, toxic, harmful or corrosive substance contained in the preparation, excluding active substances, in concentrations of more than 0·2 % in the case of very toxic and toxic substances, 5 % in the case of harmful substances and 5 % in the case of corrosive substances.

In the case of solvents, account should be taken of the concentration limits laid down in Article 5 (2) of 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 substances (solvents) (1).

The name must be as given in the nomenclature of the list contained in Annex I to Directive 67/548/EEC;

(e) the net quantity of the preparation given in legal units of measurement;

(f) the batch number;

(g) the symbols and indications of the dangers of the preparation as specified in Article 6 (2) (c) of Directive 67/548/EEC and in Annex V thereto;

(h) an indication of the special risks, within the meaning of this Directive, deriving from these dangers;

(i) for very toxic, toxic or harmful pesticides, the indication that the packaging must not be re-used except in the case of containers which are specifically designed for re-use, recharging or refilling by the manufacturer or distributer.

3. In the case of pesticides which are subject to authorization, the indications of special risks shall be specified by the competent authority, and in all other cases by the manufacturer or other person placing the preparation on the market. These indications must be compulsorily selected from among those contained in Annex IV to this Directive and may be supplemented if necessary by indications contained in Annex III to Directive 67/548/EEC.

4. Safety advice concerning the use of the pesticide must appear on the label or the packaging or, when this is not physically possible, on another label firmly affixed to the packaging itself. In the case of pesticides which are subject to authorization, this safety advice shall be selected by the competent authority, and in all other cases by the manufacturer or other person placing the preparation on the market. Safety advice must comply with the indications given in Annex IV to Directive 67/548/EEC and in Annex V to this Directive.

5. Subject to Community rules on the authorization of pesticides, the competent authorities may prescribe additional particulars concerning special risks and safety advice for pesticides which are subject to authorization.

6. In no case may the label or the packaging of pesticides to which this Directive applies bear such indications as 'non-toxic', 'harmless' or other similar indications.

Article 7

1. Where the particulars required by Article 6 appear on a label, that label must be firmly affixed to one or more surfaces of the packaging so that particulars can be read horizontally when the package is set down normally. The dimensions of the label must be as follows:

(1) OJ No L 189, 11. 7. 1973, p. 7.

Capacity of the packaging:

— less than or equal to three litres:
if possible at least 52 × 74 mm,

— greater than three litres but not exceeding 50 litres:
at least 74 × 105 mm,

— greater than 50 litres but not exceeding 500 litres:
at least 105 × 148 mm,

— greater than 500 litres:
at least 148 × 210 mm.

Each symbol must cover at least one tenth of the surface area of the label but not be less than 1 cm^2 in area. The entire surface of the label must adhere to the immediate packaging of the preparation.

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

3. The colour and presentation of the label — or, in the case referred to in paragraph 2, of the packaging — must be such that the danger symbol and its orange-yellow background stand out clearly.

4. Member States may make the placing of pesticides on the market in their territories subject to the use of the national or official language or languages in the labelling thereof.

5. For the purpose of this Directive, labelling requirements shall be deemed to be satisfied when the outer transportation packaging bears a symbol which complies with the international regulations on the transport of dangerous substances and with Article 6 (2) (a) to (f), (h), (i) and (4).

Article 8

1. Member States may:

(a) permit the labelling required by Article 6 to be applied in some other appropriate manner on packaging which is either too small or otherwise unsuitable for labelling in accordance with Article 7 (1) and (2);

(b) by way of derogation from Articles 6 and 7, permit the packaging of pesticides other than those classified as very toxic or toxic to be labelled in some other way if such packaging contains small quantities presenting no danger to persons handling the pesticide or otherwise concerned.

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

Article 9

Member States may not prohibit, restrict or impede, on grounds of classification, packaging or labelling within the meaning of this Directive, the placing on the market of pesticides which satisfy the requirements of this Directive.

Article 10

1. Where a Member State establishes on the basis of detailed evidence that a pesticide, although satisfying the requirements of this Directive, constitutes a danger to health or safety, it may, provisionally, prohibit or impose special conditions on the placing on the market of that pesticide within its territory. It shall immediately inform the other Member States and the Commission of such action and state the reasons for its decision.

2. The Commission shall consult the Member States concerned within six weeks, express its opinion without delay and take the appropriate measures.

3. If the Commission is of the opinion that technical amendments to the Directive are required, such amendments shall be adopted either by the Commission or by the Council in accordance with the procedure laid down in Article 8c of Directive 67/548/EEC. In this event, the Member State which has adopted safeguard measures may maintain them until such amendments enter into force.

Article 11

1. The following shall be drawn up in accordance with the procedure laid down in Article 8c of Directive 67/548/EEC:

— a list of active substances with indications of their conventional LD_{50} and LC_{50} values (Annex III),

— an up-to-date list of active substances for the classification of pesticides containing more than one active substance in accordance with the method of calculation laid down in Annex II.

2. The amendments necessary to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the same procedure.

Article 12

1. The Member States shall bring into force on 1 January 1981 the laws, regulations and administrative provisions necessary for them to comply with this Directive and shall forthwith inform the Commission thereof.