COUNCIL DIRECTIVE

of 18 September 1979

amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(79/831/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 to protect man and the environment against potential risks which could arise from the placing on the market of new substances, it is necessary to lay down appropriate measures and in particular to reinforce the recommendations provided 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 (3), as last amended by Directive 75/409/EEC (4);

Whereas it is necessary for these reasons to amend Directive 67/548/EEC which at the moment by an adequate classification, packaging and labelling of dangerous substances protects the population and principally the workers using them;

Whereas in order to control the effects on man and the environment it is advisable that any new substance placed on the market be subjected to a prior study by the manufacturer or importer and a notification to the competent authorities conveying mandatorily certain information; whereas it is, moreover, important to follow closely the evolution and use of new substances placed on the market, and that in order to do this it is necessary to institute a system which allows all new substances to be listed;

Whereas, moreover, it is necessary, if the Directive is to be properly applied, to draw up an inventory of substances on the Community market by 18 September 1981;

Whereas it is necessary to provide for measures making it possible to introduce a procedure of notification to one Member State which is then valid for the Community; whereas, it is, moreover, necessary to provide that the measures relating to the classification and labelling of substances may be laid down at Community level;

Whereas it is necessary to introduce measures for the packaging and provisional labelling of dangerous substances not yet appearing in Annex I to Directive 67/548/EEC;

Whereas it is necessary to make the indication of safety advice obligatory;

Whereas Article 2 of the abovementioned Directive classifies substances and preparations as toxic, harmful, corrosive or irritant by the use of general definitions; whereas experience has shown that it is necessary to improve this classification; whereas in the absence, at the moment, of specifications necessary for allocation to these classes, it seems appropriate to provide precise criteria for classification; whereas in addition Article 3 of the Directive provides for an evaluation of danger for the environment and it is therefore necessary to enumerate certain characteristics and parameters of assessment, and to establish a phased study programme,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Articles 1 to 8 of Directive 67/548/EEC are hereby replaced by the following Articles:

'*Article 1*

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

(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 183, 14. 7. 1975, p. 22.

(a) the notification of substances, and

(b) the classification, packaging and labelling of substances dangerous to man and the environment,

which are placed on the market in the Member States.

2. This Directive does not apply to the provisions relating to:

(a) medicinal products, narcotics and radioactive substances;

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

(c) foodstuffs or feedingstuffs;

(d) substances in the form of waste which are covered by Council Directive 75/442/EEC of 15 July 1975 relating to waste (1) and Council Directive 78/319/EEC of 20 March 1978 relating to toxic and dangerous waste (2);

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

3. Articles 15, 16 and 17 do not apply to the provisions governing:

(a) containers which contain gases compressed, liquefied or dissolved under pressure, excluding aerosols which comply with the requirements of Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (3);

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

4. Articles 5, 6 and 7, in so far as they are concerned with notification, do not apply:

(a) — until six months after publication of the inventory referred to in Article 13 (1), to substances placed on the market before 18 September 1981;

— six months after publication of the inventory referred to in Article 13 (1), to substances which appear in that inventory;

(b) to pesticides and fertilizers, in as far as they are subject to approval procedures which are at least equivalent or Community notification procedures or procedures which are not yet harmonized;

(c) to substances which are already subject to similar testing and notification requirements under existing Directives.

Article 2

1. For the purpose of this Directive:

(a) "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market;

(b) "preparations" means mixtures or solutions composed of two or more substances;

(c) "environment" means water, air and land and their inter-relationship as well as relationships between them and any living organisms;

(d) "notification" means the documents whereby the manufacturer or any other person established in the Community who places a substance on its own or in a preparation on the market presents the requisite information to the competent authority of a Member State. The person so doing shall hereinafter be referred to as "the notifier";

(e) "placing on the market" means supplying or making available to third parties.

Importation into Community customs territory shall be deemed to be placing on the market for the purposes of this Directive.

2. The following substances and preparations are "dangerous" within the meaning of this Directive:

(a) explosive:

substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene;

(b) oxidizing:

substances and preparations which give rise to highly exothermic reaction when in contact with other substances, particularly flammable substances;

(c) extremely flammable:

liquid substances and preparations having a flash point lower than 0 °C and a boiling point lower than or equal to 35 °C;

(1) OJ No L 194, 15. 7. 1975, p. 39.
(2) OJ No L 84, 31. 3. 1978, p. 43.
(3) OJ No L 147, 9. 6. 1975, p. 40.

(d) highly flammable:

— substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

— solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

— liquid substances and preparations having a flash point below 21 °C, or

— gaseous substances and preparations which are flammable in air at normal pressure, or

— substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable:

liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C;

(f) very toxic:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve extremely serious, acute or chronic health risks and even death;

(g) toxic:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death;

(h) harmful:

substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks;

(i) corrosive:

substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant:

non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation;

(k) dangerous for the environment:

substances and preparations the use of which presents or may present immediate or delayed risks for the environment;

(l) carcinogenic:

substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer in man or increase its incidence;

(m) teratogenic;

(n) mutagenic.

Article 3

1. The physico-chemical properties of the substances and preparations shall be determined according to the methods specified in Annex V (A); their toxicity shall be determined according to the methods specified in Annex V (B) and their ecotoxicity according to those specified in Annex V (C).

2. The real or potential environmental hazard shall be assessed according to the characteristics set out in Annexes VII and VIII, on the basis of any existing internationally recognized parameters.

3. The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate Directives.

Article 4

1. The classification of dangerous substances according to the degree of hazard and to the specific nature of the risks involved shall be based on the categories laid down in Article 2 (2). For categories (a) to (j) the substances shall be classified according to the greatest degree of hazard, in accordance with Article 16 (4).

2. The dangerous substances listed in Annex I shall, where appropriate, be given a rating enabling the health hazard of preparations to be assessed. The ratings shall be determined in accordance with the criteria established by a subsequent Council Directive.

Article 5

1. The Member Sates shall take all the measures necessary to ensure that without prejudice to Article 8 substances cannot be placed on the market on their own or in preparations unless the substances have been:

— notified to the competent authority of one of the Member States in accordance with this Directive,

— packaged and labelled in accordance with Articles 15 to 18 and with the criteria in Annex VI, and in accordance with the results of the tests provided for in Article 6.

2. The measures referred to in the second indent of paragraph 1 shall apply until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

Dangerous substances not yet appearing in Annex I but included in the list referred to in Article 13 (1) or already on the market before 18 September 1981 must, in so far as the manufacturer whether or not established in the Community may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria in Annex VI.

Article 6

1. Without prejudice to Articles 1 (4) and 8 (1), any manufacturer or importer into the Community of a substance within the meaning of this Directive shall be required to submit to the competent authority referred to in Article 7 of the Member State in which the substance is produced or into which it is imported into the Community, at the latest 45 days before the substance is placed on the market, a notification including:

— a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing at least the information and results of the studies referred to in Annex VII, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,

— a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged,

— the proposed classification and labelling of the substance in accordance with this Directive,

— proposals for any recommended precautions relating to the safe use of the substance.

2. However, in the case of a substance which has already been notified, the competent authority may agree that the notifier of that substance may, for the purposes of the technical dossier, refer to the results of the studies carried out by one or more previous notifiers, provided the latter have given their agreement in writing.

3. If a substance is already listed in Annex I, the notifier need not present the declaration concerning its unfavourable effects, the proposed classification and the proposals for any recommended precautions relating to safe use. Furthermore, the notifier need not supply the information required for the technical dossier in Annex VII, with the exception of points 1 and 2 of that Annex, if the substance was originally notified at least 10 years previously.

4. Any notifier of a substance already notified shall be required to inform the competent authority of:

— changes in the annual or total quantities placed on the market by him in accordance with the tonnage range laid down in Annex VII, point 2.2.1,

— new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware,

— new uses for which the substance is placed on the market (within the meaning of Annex VII, point 2.1.2) of which he may reasonably be expected to have become aware,

— any change in the properties resulting from a modification of the substance referred to in Annex VII, point 1.3.

5. The notifier shall also be required to inform the competent authority of the results of the studies carried out in accordance with Annex VIII.

Article 7

1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Article 6 and examining its conformity with the requirements of the Directive, and in particular:

— the notifier's proposed findings on any foreseeable risks which the substance may entail,

— classification and labelling,

— the proposals for any recommended precautions relating to safe use submitted by the notifier.

Moreover, if it can be shown to be necessary for the evaluation of the hazard which may be caused by a substance, the competent authorities may:

— ask for further information and/or verification tests concerning the substances of which they have been notified; this may also include requesting the information referred to in Annex VIII earlier than provided for therein,

— carry out such sampling as is necessary for control purposes,

— take appropriate measures relating to safe use of a substance pending the introduction of Community provisions.

2. The procedure laid down in Article 21 shall be followed in confirming or amending proposals for:

— classification,

— labelling, and

— the recommended precautionary measures provided for in Annex VII, points 2.3, 2.4 and 2.5.

3. Member States and the Commission shall ensure that any information concerning commercial exploitation or manufacturing is kept secret.

Article 8

1. The substances listed below, shall be considered as having been notified within the meaning of this Directive when the following conditions are fulfilled:

— polymerizates, polycondensates and polyadducts except those containing in combined form 2% or more of any monomer unmarketed before 18 September 1981,

— substances for research and analysis purposes, in so far as they are placed on the market for the purpose of determining their properties in accordance with this Directive;

— substances placed on the market for research or analysis purposes in quantities of less than one tonne per year per manufacturer or importer and intended solely for laboratories,

— substances placed on the market in quantities of less than one tonne per year per manufacturer provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of the Member States where the substances are placed on the market and complies with any conditions imposed by those authorities.

However, substances placed on the market at the research and development stage with a limited number of registered customers, in quantities which are limited to the purpose of the research and development but which amount to more than one tonne per year per manufacturer, shall qualify for exemption for a period of one year, provided that the manufacturer announces their identity, labelling data and quantity to the competent authorities of each Member State where the manufacture, research or development takes place and complies with any conditions imposed by those authorities on such research and development; after this period, these substances shall be subject to notification. The manufacturer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled by customers' staff only, under controlled conditions, and will not be made available to the public.

2. The substances referred to in paragraph 1 must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 15 to 18 and with the criteria imposed in Annex VI.

If labelling in accordance with the principles set out in Article 16 is not yet possible, the label should bear the warning: "Caution — substance not yet fully tested".

3. Where a substance as referred to in paragraph 1, labelled in accordance with the principles set out in Article 16, is very toxic or toxic, the manufacturer or importer of such a substance must transmit to the competent authority any appropriate information as regards Annex VII, points 2.3, 2.4 and 2.5.

Article 9

When a Member State has received the notification dossier or additional information referred to in Article 6 it shall forthwith send to the Commission a copy of the dossier or a summary thereof together with any relevant comments; in the case of the further information referred to in Article 7 (1) and the additional information or studies provided for in Annex VIII, the competent authority shall notify the Commission of the tests chosen, the reasons for their choice, and the assessment of their results.

Article 10

1. On receipt of the copy of the notification dossier, the summary thereof or the additional information sent by a Member State, the Commission shall forward:

— the notification dossier or the summary thereof to the other Member States,

— any other relevant information it has collected pursuant to this Directive to all Member States.

2. The competent authority of any Member State may consult direct the competent authority which received the original notification, or the Commission, on specific details of the data