II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/32/EEC

of 30 April 1992

amending for the seventh 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

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 disparity between the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and to the notification of new substances in the Member States may lead to barriers to trade between Member States and create unequal conditions of competition; whereas the disparity between these measures in the Member States has a direct impact on the functioning of the internal market and does not guarantee the same level of protection of public health and the environment;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market shall, inasmuch as they concern health, safety and the protection of man and the environment, take as their basis a high level of protection;

Whereas, in order to protect man and the environment from 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 amend and reinforce the provisions of Council Directive 67/548/EEC (4), as last amended by Directive 90/517/EEC (5);

Whereas any new substance placed on the market should be notified to the competent authorities by means of a notification containing certain information; whereas, in the case of substances placed on the market in quantities of less than one tonne per year per manufacturer, the notification requirements may be reduced; whereas, however, where the quantity of a substance placed on the market exceeds certain limits, provision should be made for additional studies;

Whereas it is necessary to lay down measures to make it possible to introduce a notification procedure under which a notification made in one Member State is then valid for the Community; whereas it may be worthwhile, in the case of substances manufactured outside the Community, for the manufacturer to appoint an exclusive representative in the Community for the purpose of notification;

Whereas, in order to forecast the effects on man and the environment, it is advisible that any new substance that is notified be the subject of an assessment of the risks, and whereas uniform principles for risk assessment should be laid down;

Whereas it is, moreover, important to follow closely the evolution and use of new substances placed on the market and whereas it is therefore necessary to institute a system which allows all new substances to be listed;

Whereas the Commission, pursuant to Article 13 (1) of Directive 67/548/EEC (6), drew up, in accordance with the guidelines laid down in Commission Decision 81/437/EEC,

(1) OJ No C 33, 13. 2. 1990, p. 3.
(2) OJ No C 284, 12. 11. 1990, p. 85 and OJ No C 13, 20. 1. 1992, p. 82.
(3) OJ No C 332, 31. 12. 1990, p. 9.
(4) OJ No 196, 16. 8. 1967, p. 1.
(5) OJ No L 287, 19. 10. 1990, p. 37.
(6) OJ No L 167, 24. 6. 1981, p. 31.

an inventory of substances on the Community market as at 18 September 1981 (EINECS); whereas that inventory was published in the *Official Journal of the European Communities* (1);

Whereas it is appropriate to reduce to a minimum the number of animals used for experimental purposes, in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of the laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (2); whereas all appropriate measures should be taken to avoid the duplication of tests on animals;

Whereas Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (3) specifies the Community principles of good laboratory practice which must be followed for tests on chemicals;

Whereas, in order to promote environmental protection and safety and health at work, it is desirable for safety data on dangerous substances to be available to professional users;

Whereas provisions should be adopted at Community level on the classification and labelling of substances in order to promote the protection of the population and, in particular, of the workers who use them;

Whereas, in order to ensure an adequate level of protection for man and the environment, it is necessary to introduce measures for the packaging and provisional labelling of dangerous substances not appearing in Annex I to Directive 67/548/EEC; whereas, for the same reason, it is necessary to make the indication of safety advice mandatory;

Whereas Article 2 of Directive 67/548/EEC classifies substances and preparations as toxic, harmful, corrosive or irritant by the use of general definitions; whereas experience has shown that it is necessary for this classification to be improved upon; whereas it seems appropriate to provide precise criteria for classification; whereas, in addition, Article 3 of the Directive provides for an assessment of the environmental hazard, making it necessary to enumarate certain characteristics and parameters of assessment and to establish a phased test programme;

Whereas it is desirable to add a new common danger symbol, 'dangerous for the environment', to appear on packaging;

Whereas the confidential nature of certain information covered by individual or commercial secrecy should be guaranteed;

Whereas Member States should be allowed to take safeguard measures, under certain conditions;

Whereas the Commission should be given the powers necessary to adapt all the Annexes to Directive 67/548/EEC to technical progress,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 67/548/EEC is hereby amended as follows:

1. Article 1 to 23 shall be replaced by the following Articles:

'*Article 1*

Objectives and Scope

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

(a) the notification of substances;

(b) the exchange of information on notified substances;

(c) the assessment of the potential risk to man and the environment of notified substances;

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

where such substances are placed on the market in the Member States.

2. This Directive shall not apply to the following preparations in the finished state, intended for the final user:

(a) medicinal products for human or veterinary use, as defined in Directive 65/65/EEC (1), as last amended by Directive 87/21/EEC (2);

(b) cosmetic products defined by Directive 76/768/EEC (3), as last amended by Directive 86/199/EEC (4);

(c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC (5) and 78/319/EEC (6);

(d) foodstuffs;

(e) animal feedingstuffs;

(f) pesticides;

(g) radioactive substances as defined by Directive 80/836/EEC (7);

(h) other substances or preparations for which Community notification or approval procedures exist and for which requirements are equivalent to those laid down in this Directive.

(1) OJ No C 146, 15. 6. 1990, p. 1.
(2) OJ No L 358, 18. 12. 1986, p. 1.
(3) OJ No L 15, 17. 1. 1987, p. 29.

Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 29 (4) (a), shall establish a list of substances and preparations referred to above. This list will be re-examined periodically and as necessary revised in accordance with the said procedure.

In addition, this Directive shall not apply to:

— the carriage of dangerous substances by rail, road, inland waterway, sea or air,

— substances in transit which are under customs supervision, provided they do not undergo any treatment or processing.

(1) OJ No 22, 9. 2. 1965, p. 369.
(2) OJ No L 15, 17. 1. 1987, p. 36.
(3) OJ No L 262, 27. 9. 1976, p. 169.
(4) OJ No L 149, 3. 6. 1986, p. 38.
(5) OJ No L 194, 15. 7. 1975, p. 39.
(6) OJ No L 84, 31. 3. 1978, p. 43.
(7) OJ No L 246, 17. 9. 1980, p. 1.

Article 2

Definitions

1. For the purpose of this Directive:

(a) "substances" means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

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

(c) "polymer" means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer;

(d) "notification" means the documents, with the requisite information, presented to the competent authority of a Member State:

— for substances manufactured within the Community, by the manufacturer who places a substance either on its own or in a preparation on the market,

— for substances manufactured outside the Community, by any person established in the Community who is responsible for placing the substance either on its own or in a preparation on the Community market, or alternatively by the person established within the Community who is, for the purposes of submitting a notification for a given substance placed on the Community market, either on its own or in a preparation, designated by the manfacturer as his sole representative.

The person submitting the notification, as described above, shall be referred to as "the notifier".

(e) "placing on the market" means the making available to third parties. Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive;

(f) "scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development;

(g) "process-orientated research and development" means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance;

(h) "EINECS" means the European Inventory of Existing Commercial Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981.

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

(a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

(b) oxidizing substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

(c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

(d) highly flammable substances and preparations:
- 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 very low flash-point, or
- substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable substances and preparations: liquid substances and preparations having a low flash-point;

(f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

(k) sensitizing substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

(o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment.

Article 3

Testing and assessment of the properties of substances

1. Tests on chemicals carried out within the framework of this Directive shall as a general principle be conducted according to the methods laid down in Annex V. The physico-chemical properties of substances 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 the methods specified in Annex V. C.

However, for some of the substances on the EINECS it is possible that test data exist which have been generated by methods other than those laid down in Annex V. The adequacy of such data for the purposes of classification and labelling and the need to conduct new tests according to Annex V must be decided on a case-by-case basis taking into account among other factors the need to minimize testing on vertebrate animals.

Laboratory tests shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.

2. The real or potential risk to man and the environment shall be assessed on the basis of the principles adopted, by 30 April 1993, in accordance with the procedure laid down in Article 29 (4) (b). These principles shall be regularly reviewed and, where appropriate, revised in accordance with the same procedure.

Article 4

Classification

1. Substances shall be classified on the basis of their intrinsic properties according to the categories laid down in Aricle 2 (2). In the classification of substances, impurities shall be taken into account as far as the concentration(s) of the latter exceed the concentration limits specified in paragraph 4 of this Article and in Article 3 of Directive 88/379/EEC.

2. The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI [1], save where contrary requirements for dangerous preparations are specified in separate Directives.

3. Annex I [2] contains the list of substances classified in accordance with the principles outlined in paragraphs 1 and 2, together with their harmonized classification and labelling. The decision to place a substance in Annex I together with the harmonized

classification and labelling shall be taken in accordance with the procedure laid down in Article 29.

4. The dangerous substances listed in Annex I shall, where appropriate, be characterized by concentration limits or any other parameter enabling an assessment to be made of the health or environmental hazard of preparations containing the said dangerous substances or substances containing other dangerous substances as impurities.

(1) See also OJ No L 257, 16. 9. 1983, p. 1.
(2) See also the following adaptations to technical progress:
— OJ No L 360, 30. 12. 1976, p. 1.
— OJ No L 88, 7. 4. 1979, p. 1.
— OJ No L 351, 7. 12. 1981, p. 5.
— OJ No L 106, 21. 4. 1982, p. 18.
— OJ No L 257, 16. 9. 1983, p. 1.
— OJ No L 247, 1. 9. 1986, p. 1.
— OJ No L 239, 21. 8. 1987, p. 1.
— OJ No L 259, 19. 9. 1988, p. 1.

Article 5

Duties of the Member States

1. Without prejudice to Article 13, Member States shall take all the necessary measures to ensure that substances cannot be placed on the market on their own or in preparations unless they 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 22 to 25 and with the criteria in Annex VI, and in accordance with the results of the tests provided for in Annexes VII and VIII, save in the case of preparations where provisions exist in other Directives.

In addition, Member States shall take all the necessary measures to ensure that the provisions concerning safety data sheets as laid down in Article 27 are observed.

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 29.

Article 6

Obligation to carry out investigations

Manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules laid down in Articles 22 to 25 and the criteria in Annex VI.

Article 7

Full notification

1. Without prejudice to Articles 1 (2), 8 (1), 13 and 16 (1), any notifier of a substance shall be required to submit to the competent authority referred to in Article 16 (1) of the Member State in which the substance is manufactured, or in the case of a manufacturer located outside the Community, the Member State within which the notifier is established, 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 all available relevant data for this purpose. As a minimum, the dossier shall contain the information and results of the studies referred to in Annex VII. A, 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 foreseeable uses,

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

— in the case of dangerous substances only, a proposal for a safety data sheet as provided for in Article 27,

— in the case of a manufacturer located outside the Community, the notifier shall, in accordance with Article 2 (1) (d), second indent, include, if appropriate, a statement from the manufacturer to the effect that, for the purpose of submitting a notification for the substance in question, he is designated as the manufacturer's sole representative,

— if so desired, a statement by the notifier requesting, on reasoned grounds, that the notification be exempted from the provisions of Article 15 (2) for a maximum period which shall not in any case exceed one year following the date of notification.

Besides the information referred to above, the notifier may also provide the authority with a preliminary assessment of the risks, which he has made in accordance with the principles laid down in Article 3 (2).

2. Without prejudice to Article 14, any notifier of a substance already notified shall inform the competent authority:

— when the quantity of the substance placed on the market reaches 10 tonnes per year per manufacturer or when the total quantity placed on the market reaches 50 tonnes per manufacturer; in this case, the competent authority may require some or all of the additional tests/studies laid down in Annex VIII, level 1, to be carried out within a time limit it will determine,