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
Official Journal L 154 , 05/06/1992 P. 0001 - 0029

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, 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 (7);

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 (8); 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 (9) 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
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 (10), as last amended by Directive 87/21/EEC (11);

(b) cosmetic products defined by Directive 76/768/EEC (12), as last amended by Directive 86/199/EEC (13);

(c) mixtures of substances which, in the form of waste, are covered by Directives 75/442/EEC (14) and 78/319/EEC (15);

(d) foodstuffs;

(e) animal feedingstuffs;

(f) pesticides;

(g) radioactive substances as defined by Directive 80/836/EEC (16);

(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.

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.

(17) OJ No 22, 9. 2. 1965, p. 369.
(18) OJ No L 15, 17. 1. 1987, p. 36.
(19) OJ No L 262, 27. 9. 1976, p. 169.
(20) OJ No L 149, 3. 6. 1986, p. 38.
(21) OJ No L 194, 15. 7. 1975, p. 39.
(22) OJ No L 84, 31. 3. 1978, p. 43.
(23) 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 (24), save where contrary requirements for dangerous preparations are specified in separate Directives.

3. Annex I (25) 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.

(26) See also OJ No L 257, 16. 9. 1983, p. 1. (27) 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,

- when the quantity of the substance placed on the market reaches 100 tonnes per year per manufacturer or when the total quantity placed on the market reaches 500 tonnes per manufacturer; in this case, the competent authority shall require the additional tests/studies laid down in Annex VIII, level 1, to be carried out within a time limit it will determine, unless the notifier can give good reason why a given test/study is not appropriate or an alternative scientific test/study would be preferable,

- when then quantity of a substance placed on the market reaches 1 000 tonnes per year per manufacturer or when the total quantity placed on the market reaches 5 000 tonnes per manufacturer; in this case, the competent authority shall draw up a programme of tests/studies according to Annex VIII, level 2, to be carried out by the notifier within a time limit which the competent authority will determine.

3. When additional testing is carried out either in accordance with the requirements of paragraph 2 or voluntarily, the notifier shall provide the competent authority with the results of the studies carried out.

Article 8
Reduced notification requirements for substances placed on the market in quantities of less than one tonne per annum per manufacturer

1. Without prejudice to Articles 1 (2), 13 (1) and 16 (1), any notifier intending to place a substance on the Community market in quantities of less than one tonne per annum per manufacturer shall be required to submit to the competent authority referred to in Article 16 (1) of the Member State in which the substance is produced, 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. B, together with a full and detailed description of the studies conducted and of the methods used or a bibliographical reference to them if the Member State in which the notification is made so requires,

- all the other information referred to in Article 7 (1).

2. When the quantities to be placed on the market are below 100 kg per year per manufacturer the notifier may, without prejudice to Article 16 (1), restrict the information in the technical dossier of the said notification above to that provided for in Annex VII. C.

3. In the case of a notifier who has submitted a reduced notification dossier in conformity with paragraph 2, he shall, before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, provide the competent authority with the additional information necessary to complete the technical dossier to the level of Annex VII. B.

4. Similarly, when a notifier has submitted a reduced notification dossier in conformity with paragraph 1 he shall, before the quantity of the substance placed on the market reaches 1 tonne per year per manufacturer, or before the total quantity placed on the market reaches 5 tonnes per manufacturer, submit a full notification according to the requirements of Article 7.

5. The substances notified in conformity with paragraphs 1 and 2 must, in so far as the notifier may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled in accordance with the rules laid down in
Articles 22 to 25 and with the criteria imposed in Annex VI. Where it is not yet possible to label them in accordance with the principles set out in Article 23, the label should bear, in addition to the label deriving from the tests already carried out, the warning "Caution - substance not yet fully tested".

Article 9
Substances already notified (10-year rule)

A notifier need not supply the information required under Articles 7 and 8 for the technical dossiers in Annexes VII. A, VII. B, VII. C and VII. D with the exception of items 1 and 2 thereof, if the data were originally submitted at least 10 years previously.

Article 10
Placing of notified substances on the market

1. Substances notified under Article 7 may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 60 days after receipt by the authority of a dossier in conformity with the requirements of this Directive.

If the competent authority considers that the dossier is not in conformity with the Directive and advises the notifier accordingly, as provided for in Article 16 (2), the substance may be placed on the market only 60 days after receipt by the authority of the information necessary to bring the notification into conformity with the Directive.

2. Substances notified under Article 8 (1) or (2) may, in the absence of any indication to the contrary from the competent authority, be placed on the market no sooner than 30 days after receipt by the authority of a dossier in conformity with the requirements of this Directive.

If the competent authority considers that the dossier is not in conformity with the Directive and advises the notifier accordingly, as provided for in Article 16 (3), the substance may be placed on the market only 30 days after receipt by the authority of the information necessary to bring the notification into conformity with the Directive. However, if the notifier has received notice in accordance with Article 16 (3) that the dossier has been accepted, the substance may be placed on the market no sooner than 15 days after receipt of the dossier by the competent authority.

Article 11
Substances manufactured outside the Community

Where, for substances manufactured outside the Community, more than one notification exists for a substance manufactured by the same manufacturer, the cumulative yearly tonnages placed on the Community market shall be determined by the Commission and the national authorities on the basis of the information submitted under Articles 7 (1), 8 (1) and 14. The obligation to carry out supplementary testing in accordance with Article 7 (2) will fall collectively on all notifiers.

Article 12
Polymers

For polymers, the specific provisions concerning the technical dossiers contained in the notifications and referred to in Articles 7 (1) and 8 (1) shall be laid down in Annex VII, in the form of Annex VII. D, in accordance with the procedure referred to in Article 29 (4) (b).

Article 13
Exemptions

1. The following substances shall be exempt from the provisions of Articles 7, 8, 14 and 15:

- substances which appear on the EINECS inventory,

- additives and substances for exclusive use in animal feedingstuffs as covered by Directives 70/524/EEC and 82/471/EEC (28),

- substances used exclusively as additives in foodstuffs, as covered by Directive 89/107/EEC (29), and substances used exclusively as flavourings in foodstuffs and which are covered by Directive 88/388/EEC,

- active ingredients used exclusively in the medicinal products referred to in Article 1 (2) (a). This does not include chemical intermediates,

- substances for exclusive use in other product sectors for which Community notification or approval procedures exist and for which the requirements for data submission are equivalent to those laid down in this Directive. 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 such Community legislation. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

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

- polymers, with the exception of those which contain in combined form 2 % or more of any substance which is not on EINECS,

- substances placed on the market in quantities of less than 10 kg per year per manufacturer, provided the manufacturer/importer satisfies all the conditions imposed by the Member States in which the substance is placed on the market. These conditions shall not exceed the information provided for in Annex VII. C, points 1 and 2,

- substances placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per year, and intended solely for purposes of scientific research and development carried out under controlled conditions.

Any manufacturer or importer making use of this exemption must maintain written records containing the identity of the substance, labelling data, quantities and a list of customers; this information shall be made available upon request to the competent authorities of each Member State where the manufacture, importation or scientific research and development takes place,

- substances placed on the market for the purposes of process-orientated research and development with a limited number of registered customers in quantities which are limited to the purpose of process-orientated research and development. These substances shall qualify for an exemption for a period of one year provided that the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers and the research and development programme to the competent authorities of each Member State where the manufacture, importation or process-orientated research and development takes place and complies with any conditions imposed by these authorities or the Member States on such research and development. The conditions imposed by the Member States may include information not exceeding that provided for in Article 8. After one year, these substances will normally be subject to notification. The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available to the general public at any time either on its own or in a preparation. In addition, if the competent authority considers that there may exist an unacceptable risk for man and the environment, it may extend the restriction referred to above to include any products containing the new substances which were produced during the process-orientated research and development.

The one-year exemption period referred to above may in exceptional circumstances be extended for a further year if the notifier can demonstrate, to the satisfaction of the competent authorities, that such an extension is justified.

3. The substances referred to in paragraph 2 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 22 to 25 and with the criteria imposed in Annex VI.

If it is not possible to label the substances completely, and in accordance with the principles set out in Article 23, because the results of tests provided for in Annex VII. A are not all available, the label should bear, in addition to the label deriving from tests already carried out, the warning "Caution - substance not yet fully tested".

4. Where a substance as referred to in paragraph 2, labelled in accordance with the principles set out in Article 23, is very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the manufacturer or importer of such a substance must transmit to the competent authority any appropriate information as regards Annex VII. A, Sections 2.3, 2.4 and 2.5. Moreover, acute toxicity data shall be given where available.

(30) OJ No L 213, 21. 7. 1982, p. 8.
(31) OJ No L 40, 11. 2. 1989, p. 27.

Article 14
Follow-up information

1. Any notifier of a substance already notified in conformity with Articles 7 (1) or 8 (1) shall be responsible on his own initiative for informing in writing the competent authority to which the initial notification was submitted of:

- changes in the annual or total quantities placed on the Community market by him or, in the case of a substance manufactured outside the Community for which the notifier has been designated as sole representative, by him and/or others,

- 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 of which he may reasonably be expected to have become aware,

- any change in the composition of the substances as given in Annex VII. A, B or C, section 1.3,

- any change in his status (manufacturer or importer).

2. Any importer of a substance produced by a manufacturer established outside the Community who imports the substance within the framework of a notification previously submitted by a sole representative in accordance with Article 2 (1) (d) shall be required to ensure that the sole representative is provided with up-to-date information concerning the quantities of the substance introduced by him on to the Community market.

Article 15
Renotification of the same substance and avoidance of duplicating testing on vertebrate animals

1. In the case of a substance which has already been notified in accordance with Articles 7 (1) or 8 (1), the competent authority may agree that the subsequent notifier of that substance may, for the purposes of sections 3, 4 and 5 of Annex VII. A and B and sections 3 and 4 of Annex VIII. C, refer to the results of the tests/studies forwarded by the first notifier, in so far as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities. The first notifier must give his agreement in writing to the reference to the results of the tests/studies he has forwarded before such reference can be made.

2. Before carrying out testing on vertebrate animals for the purpose of submitting a notification in conformity with Articles 7 (1) or 8 (1), and without prejudice to paragraph 1, prospective notifiers shall enquire of the competent authorities of the Member State within which they intend subsequently to notify; as to:

(a) whether or not the substance they intend to notify has already been notified; and

(b) the name and address of the first notifier.

This enquiry shall be supported by evidence that the prospective notifier has intention to place the substance on the market and of the quantities he intends to place on the market.

In the event that:

(a) the competent authority receiving the enquiry is satisfied that the prospective notifier intends to place the substance on the market in the quantities stated; and

(b) the substance has been notified previously; and

(c) the first notifier has not requested and been granted a temporary exemption from the provisions of this Article,
the competent authority shall provide the prospective notifier with the name and address of the first notifier and shall inform the first notifier of the name and address of the prospective notifier.

The first notifier and the prospective notifier shall take all reasonable steps to reach an agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

3. Notifiers of the same substance who have agreed to share information relating to Annex VII in accordance with paragraphs 1 and 2 shall also take all necessary steps to reach an agreement on the sharing of information derived from testing on vertebrate animals submitted in conformity with Article 7 (2).

4. If, despite the provisions of paragraphs 2 and 3, notifiers and prospective notifiers of the same substance can still not reach an agreement on the sharing of data, Member States may, for notifiers and prospective notifiers located within their territory, introduce national measures obliging notifiers and prospective notifiers to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, including regulations on the temporary exemption referred to in the final indent of Article 7 (1) and the reasonable balance of the interests of the parties concerned.

Article 16
Rights and duties of the authorities

1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Articles 7 to 14 and examining its conformity with the requirements of this Directive.

Moreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authorities may ask for further information, verification and/or confirmatory tests concerning the substances or their transformation products, of which they have been notified or have received information under this Directive; this may also include requesting any of the information referred to in Annex VIII earlier than provided for in Article 7 (2).

Additionally, the competent authorities may:

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

- require the notifier to supply such quantities of the notified substance as it deems necessary for the carrying out of verification tests,

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

In the case of substances notified in accordance with Articles 7 (1) and 8 (1) and (2), the competent authority which received notification shall carry out an assessment of the risks in accordance with the general principles laid down in Article 3 (2). The assessment shall include recommendations on the most appropriate method for testing the substance and, where appropriate, also include recommendations on measures which will enable the risk for man and the environment in connection with the marketing of the substance to be lessened. The assessment shall be updated from time to time in the light of additional information provided under this Article or Articles 7 (2), 8 (3) and 14 (1).

2. In the case of notifications submitted in conformity with Article 7, within a period of 60 days following receipt of the notification, the authority shall inform the notifier in writing as to whether the notification has, or has not, been accepted as being in conformity with this Directive.

If the dossier is accepted, the authority shall at the same time advise the notifier of the official number which has been allocated to the notification. If the dossier is not accepted, the authority shall inform the notifier as to what further information he is required to provide in order to bring the dossier into conformity with this Directive.

3. For notifications submitted in accordance with Article 8, the competent authority shall, within a period of 30 days following receipt of the notification, decide whether the notification is in conformity with this Directive and, where the notification is adjudged not to be in conformity, inform the notifier as to what further information he is required to provide in order to bring the dossier into conformity with the Directive. Where the notification is in conformity with the Directive, the authority shall, within the same period, advise the notifier of the official number which has been allocated to his notification.

4. For substances manufactured outside the Community for which more than one notification has been submitted for the substance produced by one manufacturer, the competent authorities, together with the Commission, shall be responsible for calculating the annual and cumulative tonnages placed upon the Community market. If the tonnage thresholds detailed in Article 7 (2) are attained, the competent authority responsible for receiving the notification(s) shall contact each notifier informing them of the identity of the other notifiers and drawing their attention to their collective responsibility as outlined in Article 11.

5. The procedure laid down in Article 28 shall be followed confirming or amending proposals for classification and labelling.

6. Without prejudice to Article 19 (1), Member States and the Commission shall ensure that any information concerning commercial exploitation or manufacturing is kept secret.

Article 17
Involvement of the Commission in the notification procedure

When a Member State has received the notification dossier referred to in Articles 7 (1) and 8 (1), or information on the supplementary testing carried out in accordance with Articles 7 (2) and 8 (3), or follow-up information submitted in conformity with
Article 14, it shall as soon as possible send the Commission a copy of the dossier or of the further information or a summary thereof.

In the case of the further information referred to in Article 16 (1), the competent authority shall notify the Commission of the tests chosen, the reasons for their choice, the results and, if appropriate, an assessment of the results. In the case of information received in conformity with Article 13 (2), the competent authority shall forward to the Commission such elements as would be of common interest for the Commission and the other competent authorities.

The assessment of the risks referred to in Article 16 (1) or a summary of that assessment shall be forwarded to the Commission as soon as it becomes available.

Article 18
Duties of the Commission

1. On receipt of the dossiers and information referred to in Article 17, the Commission shall forward copies to the Member States. In addition, the Commission may also forward any other relevant information it has collected pursuant to this Directive, as it sees fit.

2. The competent authority of any Member State may consult directly the competent authority which received the original notification, or the Commission, on specific details of the data contained in the dossier required under this Directive or the assessment of the risks provided for in Article 16 (1); it may also suggest that further tests or information be requested or that the assessment of the risks be modified. If the competent authority which received the original notification fails to comply with the suggestions of other authorities regarding further information, confirmation tests or amendments in the study programmes provided for in Annex VIII or the assessment of the risks, it shall give its reasons to the other authorities concerned. Should it not be possible for the authorities concerned to reach agreement and should any one authority feel, on the basis of detailed reasons, that additional information, confirmation tests or amendments in the study programmes or an assessment are nevertheless really necessary to protect man and the environment, it may ask the Commission to take a decision in accordance with the procedure laid down in Article 29 (4) (b).

Article 19
Confidentiality of data

1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Articles 7, 8 and 14 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases.

With respect to the notifications and information submitted in conformity with Articles 7 (1) and (2), 8 (1), (2) and (3), industrial and commercial secrecy shall not apply to:

(a) the trade name of the substance;

(b) the name of the manufacturer and the notifier;

(c) physico-chemical data concerning the substance in connection with section 3 of Annexes VII. A, VII. B and VII. C;

(d) the possible ways of rendering the substance harmless;

(e) the summary results of the toxicological and ecotoxicological tests;

(f) if essential to classification and labelling for the purpose of introducing the substance into Annex I, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous within the meaning of
Article 2 (2);

(g) the recommended methods and precautions referred to in Annex VII, section 2.3, and the emergency measures referred to in Annex VII, sections 2.4 and 2.5;

(h) the information contained in the safety data sheet;

(i) in the case of substances in Annex I, analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

If the notifier, manufacturer or importer should himself later disclose previously confidential information, he shall inform the competent authority accordingly.

2. The authority receiving the notification/ information shall decide on its own responsibility which information is covered by industrial and commercial secrecy in accordance with paragraph 1.

Information accepted as being confidential by the authority receiving the notification dossier from the notifier shall be treated as being confidential by the other competent authorities and the Commission.

3. For substances appearing in the list provided for in Article 21 (1) and which are not classified as dangerous within the meaning of this Directive, the name may be included in the form of its trade name in those cases where the competent authority to which the notification has been submitted so requests. Normally, such substances may be included in the list in the form of their trade name for a maximum of three years. However, if the competent authority to which the dossier was submitted considers that the publication of the chemical name in the IUPAC nomenclature itself could reveal information concerning commercial exploitation or manufacture, the name of the substance may be recorded under its trade name alone for as long as that competent authority sees fit.

Dangerous substances may, at the request of the competent authority receiving the notification, be entered on the list in the form of their trade names alone until such time as they are introduced into Annex I.

4. Confidential information brought to the attention either of the Commission or of a Member State shall be kept secret.

In all cases such information:

- may be brought to the attention only of the authorities whose responsibilities are specified in Article 16 (1),

- may, however, be divulged to persons directly involved in administrative or legal proceedings involving sanctions which are undertaken for the purpose of controlling substances placed on the market and to persons who are to participate or be heard in legislative proceedings.

Article 20
Exchange of the summary dossier

1. The data supplied in accordance with Articles 17 and 18 may be forwarded to the Commission and the Member States in summary form.

In such cases and in the context of Article 18 (2), the competent authorities of a Member State and the Commission shall have access to the notification dossier and the additional information at all times.

2. For the purpose of the exchange of information referred to in Articles 17 and 18 (1), the Commission shall develop a common format. This format shall be adopted by the procedure laid down in Article 29.

Article 21
Lists of existing and new substances

1. The Commission shall keep a list of all substances notified under this Directive. This list shall be compiled in accordance with the provisions of Commission Decision 85/71/EEC (32).

2. The Commission shall allocate an EEC number to each substance contained on the EINECS inventory and on the list referred to in paragraph 1.

(33) OJ No L 30, 2. 2. 1985, p. 33.

Article 22
Packaging

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

(a) it shall 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 adverse attack by the contents, or liable to form dangerous compounds with the contents;

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

(d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

(e) every container of whatever capacity, containing substances sold or made available to the general public and labelled "very toxic", "toxic" or "corrosive", as defined in this Directive, must have a child-resistant fastening and a tactile warning of danger;

(f) every container, of whatever capacity, containing substances sold or made available to the general public and labelled "harmful", "extremely flammable" or "highly flammable" as defined in this Directive must bear a tactile warning of danger.

2. Member States may also prescribe that packaging shall be closed initially with a seal in such a way that when the packaging is opened for the first time the seal is irreparably damaged.

3. The categories of substances for which the packaging must be equipped with the devices mentioned in paragraph 1 (e) and (f) shall be modified in accordance with the procedure provided for in Article 29.

4. The technical specifications relating to the devices referred to in paragraph 1 (e) and (f) shall be modified in accordance with the procedure provided for in Article 29 (4) (a) and are to be found in points A and B of Annex IX to this Directive.

Article 23
Labelling

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

2. Every package shall show clearly and indelibly the following:

(a) the name of the substance under one of the designations given in Annex I. If the substance is not yet listed in Annex I, the name must be given using an internationally recognized designation;

(b) the name and full address including the telephone number of the person established in the Community who is responsible for placing the substance on the market whether it be the manufacturer, the importer or the distributor;

(c) danger symbols, when laid down, and indication of the danger involved in the use of the substance. The design of the danger symbols and the wording of the indications of danger shall comply with those laid down in Annex II (34). The symbol shall be printed in black on an orange-yellow background. The danger symbols and indications of danger to be used for each substance shall be those indicated in Annex I. For dangerous substances not yet appearing in Annex I the danger symbols and indications of danger shall be assigned according to the rules laid down in Annex VI.

When more than one danger symbol is assigned to a substance:

- the obligation to indicate the symbol T makes the symbols X and C optional, unless Annex I provides otherwise,

- the obligation to indicate the symbol C makes the symbol X optional,

- the obligation to indicate the symbol E makes the symbol F and O optional;

(d) standard phrases (R-phrases) indicating the special risks arising from the dangers involved in using the substance. The wording of those R-phrases shall comply with that laid down in Annex III. The R-phrases to be used for each substance shall be as indicated in Annex I. For dangerous substances not yet appearing in Annex I the R-phrases to be used shall be assigned according to the rules laid down in Annex VI;

(e) standard phrases relating to the safe use of the substance (S-phrases). The wording of these S-phrases shall comply with that laid down in Annex IV. The S-phrases to be used for each substance shall be as indicated in Annex I. For dangerous substances not yet appearing in Annex I, the S-phrase to be used shall be assigned according to the rules laid down in Annex VI;

(f) the EEC number, when allocated. The EEC number shall be obtained from the EINECS or from the list referred to in Article 21 (1).

In addition, as regards substances appearing in Annex I, the label shall also include the words "EEC label".

3. In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of R-phrases and S-phrases need not be given where the package does not contain more than 125 ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.

4. Indications such as "non-toxic", "non-harmful" or any other similar indications must not appear on the label or packaging of substances subject to this Directive.

5. Austria may from 1 January 1999 until 31 December 2000 reuire the use of:

- the additional S-phrase “Antidote exists, medical staff contact Poisons Information Centre” regarding counter-measures in the case of accident, not listed in Annex IV.

6. Sweden may from 1 January 1999 until 31 December 2000 require the use of the following additional R-phrases, not listed in Anned III:

- “R-322” for substances which present acute toxic effects not covered by criteria for classification of Annex VI (Swedish category “moderately harmful”), and

- “R-340” for substances classified as carcinogenic, category 3, instead of R-phrases R40.

(35) See the following adaptations to technical progress: OJ No L 257, 16. 9. 1983, p. 1, OJ No L 247, 1. 9. 1986, p. 1.

Article 24
Implementation of labelling requirements

1. Where the particulars required by Article 23 appear on a label, that label shall be firmly affixed to one or more surfaces of the packaging so that these particulars can be read horizontally when the package is set down normally. The dimensions of the label shall be as follows:

Capacity of the package	Dimensions (in millimetres)
- not exceeding 3 litres	at least 52 × 74
- greater than 3 litres but not exceeding 50 litres	at least 74 × 105
- greater than 50 litres but not exceeding 500 litres	at least 105 × 148
- greater than 500 litres	at least 148 × 210

Each symbol shall cover at least one-tenth of the surface area of the label but not be less than 1 cm². The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provisions of the information required by this Directive and if necessary of any supplementary health or safety indications.

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

3. The colour and presentation of the label - or, in the case of paragraph 2, of the package - shall be such that the danger symbol and its background stand out clearly.

4. The information required on the label under Article 23 shall stand out clearly from its background and shall be of such size and spacing as to be easily read.

Specific provisions regarding the presentation and dimensions of this information shall be laid down in Annex VI in accordance with the procedure referred to in Article 29 (4) (b).

5. Member States may make the placing on the market of dangerous substances in their territories subject to the use of the official language or languages in respect of the labelling thereof.

6. For the purpose 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, if the outer package is labelled in accordance with international rules on the transport of dangerous substances and the inner package or packages are labelled in accordance with this Directive;

(b) in the case of a single package:

- if such a package is labelled in accordance with international rules on the transport of dangerous substances and with Article 23 (2) (a), (b), (d), (e) and (f), and

- where appropriate, for particular types of packaging such as mobile gas cylinders, in accordance with the specific requirements referred to in Annex VI.

Where dangerous substances do not leave the territory of a Member State, labelling may be permitted which complies with national rules instead of with international rules on the transport of dangerous substances.

Article 25
Exemptions from labelling and packaging requirements

1. Articles 22, 23 and 24 shall not apply to the provisions governing munitions and explosives placed on the market with a view to producing a practical effect by explosion or a pyrotechnic effect.

Nor shall the abovementioned Articles be applicable to the provisions relating to butane, propane and liquefied petroleum gas until 30 April 1997.

2. In addition, Member States may:

(a) permit the labelling required by Article 23 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 24 (1) and (2);

(b) by way of derogation from Articles 23 and 24, permit the packaging of dangerous substances which are not explosive, very toxic or toxic to be unlabelled or to be labelled in some other way if they contain such small quantities that there is no reason to fear any danger to persons handling such substances or to other persons;

(c) where packages are too small for the labelling provided for in Articles 23 and 24 and there is no reason to fear any danger to persons handling such substances or to other persons, by way of derogation from the above provisions, permit the packaging of explosive, very toxic or toxic substances to be labelled in some other appropriate way.

This derogation does not permit use of symbols, indications of danger, risk (R) phrases or safety (S) phrases different from those laid down in this Directive.

3. If a Member State makes use of the options provided for in paragraph 2, it shall inform the Commission thereof forthwith.

Article 26
Advertisement

Any advertisement for a substance which belongs to one or more of the categories referred to in Article 2 (2) shall be prohibited if no mention is made therein of the category or categories concerned.

Article 27
Safety data sheet

1. To enable professional users in particular to take the necessary measures as regards the protection of the environment and health and safety at the workplace, at, or if appropriate, before the first delivery of a dangerous substance, any manufacturer, importer or distributor shall communicate to the recipient a safety data sheet. This sheet must contain the information necessary for protection of man and the environment.

It may be communicated on paper or electronically. Subsequently, the manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new relevant information on the substance which has become known to him.

2. General rules for the elaboration, distribution, contents and format of the safety data sheet referred to in paragraph 1 will be established in accordance with the procedure laid down in Article 29 (4) (a).

Article 28
Adaptation to technical progress

The amendments necessary for adapting the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 29.

Article 29
Procedure for adaptation to technical progress

1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

4. (a) Except in the cases referred to in subparagraph (b) below, if, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission. This period shall be six weeks in the case referred to in Article 31 (2).

(b) In the case of measures for adaptation to technical progress in Annexes II, VI, VII and VIII, if, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 30
Free movement clause

Member States may not prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive.

Article 31
Safeguard clause

1. Where, in the light of new information, a Member States has justifiable reasons to consider that a substance, which has been accepted as satisfying the requirements of the Directive, nevertheless constitutes a danger for man or the environment, by reason of classification, packaging or labelling which is no longer appropriate, it may temporarily reclassify or, if necessary, prohibit the placing on the market of that substance or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. The Commission shall take a decision in accordance with the procedure referred to in Article 29 (4) (a).

3. If, subsequent to the decision taken in accordance with paragraph 2, the Commission considers that for cases falling under paragraph 1 above, technical adaptations to the Annexes of this Directive are necessary, it shall take a decision on the matter in accordance with the procedure provided for in Article 29.

Article 32
Reports

1. Every three years, Member States shall forward to the Commission a report on the implementation of this Directive in their respective territories. The first report shall be submitted three years after the implementation of this Directive.

2. Every three years, the Commission shall prepare a composite report based on the information referred to in paragraph 1, which shall be forwarded to the Member States.'

Article 33

Member States shall inform the Commision of all laws, regulations and administrative provisions which they adopt in the field covered by this Directive.

Article 34 (Article 3 of Directive 92/32/EEC)

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 October 1993. They shall forthwith inform the Commission thereof.

2. When these measures are adopted by Member States, the shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

3. Member States shall communicate the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 35 (Article 4 of Directive 92/32/EEC)

Articles 24, 25 and 27 shall become Articles 33, 34 and 35.

Annexes II, VI, VII and VIII are hereby amended as follows:

- Annex II shall be amended by the addition of a symbol indicating danger for the environment as in Annex 1 to this Directive,
- Annex VI, Part 1. A shall be replaced by Annex 2 to this Directive,
- Annex VII shall be replaced by Annex 3 to this Directive,
- Annex VIII shall be replaced by Annex 4 to this Directive.

Article 2
The following Directives are hereby amended as follows:
1. Directive 73/173/EEC (36)():
- replace 'Article 6' by 'Article 23' in Article 5 (2) (c),
- replace 'Article 8c' by 'Article 28' in Articles 9 (2) and 10;
2. Directive 77/728/EEC (37)():
- replace 'Article 6' by 'Article 23' in Article 6 (2) (c),
- replace 'Article 8c' by 'Article 28' in Articles 10 (3) and 11;
3. Directive 78/631/EEC:
- replace 'Article 6' by 'Article 23' in Article 6 (2) (g),
- replace 'Article 8c' by 'Article 28' in Article 10 (3) and 11;
4. Directive 88/379/EEC:
- replace the reference to Directive 79/831/EEC by a reference to the present Directive in the second and eighth recitals,
- replace 'carcinogenic, mutagenic and teratogenic effects' by 'carcinogenic and mutagenic effects and effects on reproduction' in Article 3 (3),
- replace 'Article 8 (2) of Directive 67/548/EEC' by 'Article 13 (3) of Directive 67/548/EEC' in Article 3 (5),
- Article 3 (5) (o) shall read as follows:
'(o) Preparations should be regarded as: toxic for reproduction and assigned at least the symbol and the indication of danger "toxic" if they contain a substance producing such effects which is assigned at least one of the R-phrases defined in Annex VI to Directive 67/548/EEC as characterizing substances as toxic for reproduction in category 1, in a concentration equal to or exceeding:
- either the concentrations specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits; ',
- Article 3 (5) (p) shall read as follows:
'(p) Preparations shall be regarded as: having to be treated as toxic for reproduction and assigned at least the symbol and the indication of danger "toxic" if they contain a substance producing such effects which is assigned at least one of the R-phrases defined in Annex VI to Directive 67/548/EEC as characterizing substances as toxic for reproduction in category 2, in a concentration equal to or exceeding:
- either the concentrations specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits; ',
- Article 3 (5) (q) shall read als follows:

'(q) Preparations shall be regarded as: having to be regarded as toxic for reproduction and assigned at least the symbol and the indication of danger "harmful" if they contain a substance producing such effects which is assigned at least one of the R-phrases defined in Annex VI to Directive 67/548/EEC as characterizing substances as dangerous for reproduction in category 3 in a concentration equal to or exceeding:
- either the concentrations specified in Annex I to Directive 67/548/EEC for the substance under consideration, or
- the concentration specified at point 6 of Annex I (Table VI) to this Directive where the substance or substances under consideration do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits; ',
- replace 'Article 15 (1)' by 'Article 22 (1)' in Article 6 (1) (a),
- replace 'Article 21' by 'Article 28' in Article 6 (3),
- replace 'Article 11 (4)' by 'Article 19 (4)' in Article 7 (1) (c) (ii),
- replace 'Article 16 (2) (c)' by 'Article 23 (2) (c)' in Article 7 (1),
- the following paragraph shall be inserted in Article 8:
'3a. The information required on the label under Article 7 shall stand out clearly from the background and shall be of such size and spacing as to be easily read.
Specific provisions regarding the presentation and dimensions of this information shall be laid down in Annex VI to Directive 67/548/EEC in accordance with the procedure referred to in Article 28 (4) (b) of that Directive.',
- replace 'Article 21' by 'Article 28' in Articles 10, 14 (2) and 15,
- replace 'teratogenic effects' by 'effects on reproduction' in the title of Annex I, Part 6,
- replace 'teratogenic substances' by 'substances toxic for reproduction' in Annex I, Table VI.

Article 3
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 October 1993. They shall forthwith inform the Commission therof.
2. When these measures are adopted by Member States, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

Article 4
This Directive is addressed to the Member States.
Done at Luxembourg, 30 April 1992.
For the Council
The President
José da SILVA PENEDA

(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.(7) OJ No C 146, 15. 6. 1990, p. 1.(8) OJ No L 358, 18. 12. 1986, p. 1.(9) OJ No L 15, 17. 1. 1987, p. 29.(10)() Directives 73/173/EEC and 77/728/EEC will cease to apply on 8 June 1991, the date of implementation of Directive 88/379/EEC.

ANNEX I

The following symbol and text shall be added to Annex II to Directive 67/548/EEC:

ANNEX 2
Part I.A of Annex VI to Directive 67/548/EEC shall be replaced by the following:
GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES Part I. A

Save where otherwise provided for in the separate Directives on dangerous preparations, the substances and preparations shall be classified as very toxic, toxic or harmful according to the following criteria:
(a) Where the acute toxicity in animals of the commercial substance or preparation has been determined by a method which permits estimation of the LD50 or LC50, classification as very toxic, toxic or harmful shall be effected using the following parameters as reference values:

Category	LD50 Oral in rat mg/kg bodyweight	LD50 Dermal in rat or rabbit mg/kg bodyweight	LC50 (inhalation) in rat mg/litre/4 hours
Very toxic	& ge; 25	& ge; 50	& ge; 0,25
Toxic	25 to 200	50 to 400	0,25 to 1
Harmful	200 to 2 000	400 to 2 000	1 to 5

(b) Where the acute oral toxicity in animals of the commercial substance or preparation has been determined using the fixed dose procedure, classification as very toxic, toxic or harmful shall be effected on the basis of the discriminating dose. This is the dose level which produces evident toxicity, but no mortality, and is one of four fixed dose levels (5, 50, 500 or 2 000 mg/kg bodyweight). "Evident toxicity" is a term used to describe signs of toxicity following administration of a test substance, which are of a severity such that administration of the next higher fixed dose level would be expected to result in mortality.

As this test method is based on the selection of doses from a series of fixed doses, it is inappropriate to give values for classification. The following parameters are used as reference values:

Category
Discriminating dose
(mg/kg bodyweight)
Very toxic
< 5
Toxic
[5
Harmful
50-500

The 2 000 mg/kg dose level is used primarily to obtain information on signs of toxicity that may occur with substances which are of low acute toxicity and are not classified on the basis of acute toxicity;

(c) If facts show that for the purposes of classification it is inadvisable to use the reference values given in paragraphs (a) and (b) because the substances or preparations produce other effects, the substances and preparations shall be classified according to the magnitude of these effects.'

ANNEX 3
Annex VII to Directive 67/548/EEC shall be replaced by the following:
Annex VII. A INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 7 (1) If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.
The name of the body or bodies responsible for carrying out the studies shall be mentioned.
0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE
For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.
1. IDENTITY OF THE SUBSTANCE
1.1. Name
1.1.1. Names in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including isomers and by-products
1.3.3. Percentage of (significant) main impurities
1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ..... ppm, ... %
1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6. HPLC, GC
1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references
Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allows detection of a substance and its

transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production

2.0.2. Exposure estimates related to production:

- working environment
- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

2.1.1.1. Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to use (where known):

- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketing preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:

- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identity of the recipients of the substance

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in tonnes per year:

- the first calendar year
- the following calendar years

For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:

- the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.3.6. If relevant, information concerning the susceptibility of the substance to explode when presented in the form of a dust

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE
3.0. State of the substance at 20 oC and 101,3 kPA
3.1. Melting-point
3.2. Boiling-point
3.3. Relative density
3.4. Vapour pressure
3.5. Surface tension
3.6. Water solubility
3.8. Partition coefficient n/octanol/water
3.9. Flash-point
3.10. Flammability
3.11. Explosive properties
3.12. Self-ignition temperature
3.13. Oxidizing properties
3.15. Granulometry:
For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, a test should be conducted to determine the particle size distribution of the substance as it will be marketed.
4. TOXICOLOGICAL STUDIES
4.1. Acute toxicity
For tests 4.1.1 to 4.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.
4.1.1. Administered orally
4.1.2. Administered by inhalation
4.1.3. Administered cutaneously
4.1.5. Skin irritation
4.1.6. Eye irritation
4.1.7. Skin sensitization
4.2. Repeated dose
The route of administration should be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications the oral route is usually the preferred one.
4.2.1. Repeated dose toxicity (28 days)
4.3. Other effects
4.3.1. Mutagenicity
The substance shall be examined in two tests. One shall be a bacteriological (reverse mutation) test, with and without metabolic activation. The second shall be a non-bacteriological test to detect chromosome aberrations or damage. In the absence of contra-indications, this test should normally be conducted in vitro, both with and without metabolic activation. In the event of a positive result in either test, further testing according to the strategy described in Annex V should be carried out.
4.3.2. Screening for toxicity related to reproduction (for the record)
4.3.3. Assessment of the toxicokinetic behaviour of a substance to the extent that can be derived from base set data and other relevant information
5. ECOTOXICOLOGICAL STUDIES
5.1. Effects on organisms
5.1.1. Acute toxicity for fish
5.1.2. Acute toxicity for daphnia
5.1.3. Growth-inhibitor test on algae

5.1.6. Bacterial inhibition
In those cases where biodegradation may be affected by the inhibitory effect of a substance on the bacteria, a test for bacterial inhibition should be carried out prior to undertaking the biodegradation.
5.2. Degradation
- biotic
- antibiotic:
If the substance is not readily biodegradable then consideration should be given to the need to carry out the following tests: hydrolysis as a function of pH.
5.3. Absorption/desorption screening test
6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS
6.1. For industry/skilled trades
6.1.1. Possibility of recycling
6.1.2. Possibility of neutralization of unfavourable effects
6.1.3. Possibility of destruction:
- controlled discharge
- incineration
- water purification station
- others
6.2. For the public at large
6.2.1. Possibility of recycling
6.2.2. Possibility of neutralization of unfavourable effects
6.2.3. Possibility of destruction:
- controlled discharge
- incineration
- water purification station
- others
ANNEX VII. B INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (1) AND (3) If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.
The name of the body or bodies responsible for carrying out the studies shall be mentioned.
In addition to the information requested below, Member States may, if they consider it necessary for the risk assessment, require that the notifier provides the following additional information:
- vapour pressure,
- daphnia acute toxicity test.
0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE
For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community
1. IDENTITY OF THE SUBSTANCE
1.1. Name
1.1.1. Names in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including isomers and by-products
1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ..... ppm, ... %
1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6. HPLC, GC
1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references
Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans
2. INFORMATION ON THE SUBSTANCE
2.0. Production
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.
2.0.1. Technological process(es) used in production
2.0.2. Exposure estimate related to production:
- working environment
- environment
2.1. Proposed uses
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.
2.1.1. Types of use: description of the function and the desired effects
2.1.1.1. Technological process(es) related to the use of the substance (where known)
2.1.1.2. Exposure estimate(s) related to the use of the substance (where known):
- working environment
- environment
2.1.1.3. Form under which the substance is marketed: substance, preparation, product
2.1.1.4. Concentration of the substance in marketed preparations and products (where known)
2.1.2. Fields of application with approximate breakdown:
- industries
- farmers and skilled trades
- use by the public at large
2.1.3. Where known and where appropriate, the identity of the recipients of the substance
2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
2.2.1. Overall production and/or imports in tonnes per year:
- first calendar year
- the following calendar years
For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.
2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:
- the first calendar year
- the following calendar years
2.3. Recommended methods and precautions concerning:
2.3.1. Handling
2.3.2. Storage
2.3.3. Transport
2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water
2.4. Emergency measures in the case of accidental spillage
2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
2.6. Packaging
3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE
3.0. State of the substance at 20 oC and 101,3 kPA
3.1. Melting-point
3.2. Boiling-point
3.6. Water solubility
3.8. Partition coefficient n-octanol/water
3.9. Flash-point
3.10. Flammability
4. TOXICOLOGICAL STUDIES
4.1. Acute toxicity
For tests 4.1.1 to 4.1.2 one route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.
4.1.1. Administered orally
4.1.2. Administered by inhalation
4.1.5. Skin irritation
4.1.6. Eye irritation
4.1.7. Skin sensitization
4.3. Other effects
4.3.1. Mutagenicity
The substance should be examined in a bacteriological (reverse mutation) test with and without metabolic activation.
5. ECOTOXICOLOGICAL STUDIES
5.2. Degradation:
biotic
ANNEX VII. C INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (2) If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.
The name of the body or bodies responsible for carrying out the studies shall be mentioned.
0. IDENTITY OF MANUFACTURER AND THE NOTIFIER IF THESE ARE NOT THE SAME; LOCATION OF THE PRODUCTION SITE
For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community
1. IDENTITY OF THE SUBSTANCE
1.1. Name
1.1.1. Names in the IUPAC nomenclature
1.1.2. Other names (usual name, trade name, abbreviation)
1.1.3. CAS number and CAS name (if available)
1.2. Molecular and structural formula
1.3. Composition of the substance
1.3.1. Degree of purity (%)
1.3.2. Nature of impurities, including isomers and by-products
1.3.3. Percentage of (significant) main impurities
1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude:
..... ppm; ..... %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)
1.3.6. HPLC, GC
1.4. Methods of detection and determination
A full description of the methods used or the appropriate bibliographical references
Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans
2. INFORMATION ON THE SUBSTANCE
2.0. Production
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.
2.0.1. Technological process(es) used in production
2.0.2. Exposure estimate related to production:
- working environment
- environment
2.1. Proposed uses
Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.
2.1.1. Types of use: description of the function and the desired effects
2.1.1.1. Technological process(es) related to the use of the substance (where known)
2.1.1.2. Exposure estimate(s) related to the use of the substance (where known):
- working environment
- environment
2.1.1.3. Form under which the substance is marketed:
- substance, preparation, product
2.1.1.4. Concentration of the substance in marketed preparations and products (where known)
2.1.2. Fields of application with approximate breakdown:
- industries
- farmers and skilled trades
- use by the public at large
2.1.3. Where known and where appropriate, the identity of the recipients of the substance
2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
2.2.1. Overall production and/or imports in tonnes per year:
- the first calendar year
- the following calendar years
For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above
2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:
- the first calender year
- the following calendar years
2.3. Recommended methods and precautions concerning:
2.3.1. Handling
2.3.2. Storage
2.3.3. Transport
2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
2.3.5. Other dangers, particularly chemical reaction with water

2.4. Emergency measures in the case of accidental spillage
2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
2.6. Packaging
3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE
3.0. State of the substance at 20 oC and 101,3 kPa
3.9. Flash-point
3.10. Flammability
4. TOXICOLOGICAL STUDIES
4.1. Acute toxicity
One route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.
4.1.1. Administered orally
4.1.2. Administered by inhalation.'
ANNEX VII. D (*) (p.m.)
(*) This Annex will be drawn up in accordance with the provisions of Article 12.

ANNEX 4
Annex VIII to Directive 67/548/EEC shall be replaced by the following:
ANNEX VIII
ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER ARTICLE 7 (2) If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.
The name of the body or bodies responsible for carrying out the studies shall be indicated.
LEVEL 1
Physico-chemical studies
Further studies on physico-chemical properties dependent upon the results of the studies laid down in Annex VII. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.
Toxicological studies
Fertility study (one species, one generation, male and female, most appropriate route of administration).
If there are equivocal findings in the first generation, study of a second generation is required.
Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.
- Teratology study (one species, most appropriate route of administration)
This study is required if teratogenicity has not been examined in the fertility study.
- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII or other relevant information demonstrate the need for further appropriate investigation.
The effects which would indicate the need for such a study could include for example:
(a) serious or irreversible lesions;
(b) a very low or absence of a "no effect" level;
(c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.
- Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V.
When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the purposed use of the substance.

When a test or both tests were positive in the base set, a supplementary study should include the same or different end points in other in vivo test methods.
- Basic toxicokinetic information.

Ecotoxicity studies
- Prolonged toxicity study with Daphnia magna (21 days)
- Test on higher plants
- Test on earthworms
- Further toxicity studies with fish
- Tests for species accumulation; one species, preferably fish
- Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Annex VII
- Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII.

LEVEL 2

Toxicological studies

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:
- Chronic toxicity study
- Carcinogenicity study
- Fertility study (e.g. three-generation study); only if an effect on fertility has been established at level 1
- Developmental toxicity study on peri- and postnatal effects
- Teratology study (species not employed in the respective level 1)
- Additional toxicokinetic studies which cover biotransformation, pharmacokinetics
- Additional tests to investigate organ or system toxicity.

Ecotoxicological studies
- Additional tests for accumulation, degradation, mobility and absorption/desorption
- Further toxicity studies with fish
- Toxicity studies with birds
- Additional toxicity studies with other organisms.'