APPENDIX 1

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COUNCIL DIRECTIVE

of 18 September 1979

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

(79/831/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas to protect man and the environment against potential risks which could arise from the placing on the market of new substances, it is necessary to lay down appropriate measures and in particular to reinforce the recommendations provided in Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (3), as last amended by Directive 75/409/EEC (4);

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

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

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

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

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

'*Article 1*

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

(1) OJ No C 30, 7. 2. 1977, p. 35.
(2) OJ No C 114, 11. 5. 1977, p. 20.
(3) OJ No 196, 16. 8. 1967, p. 1.
(4) OJ No L 183, 14. 7. 1975, p. 22.

(a) the notification of substances, and

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

which are placed on the market in the Member States.

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

(a) medicinal products, narcotics and radioactive substances;

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

(c) foodstuffs or feedingstuffs;

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

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

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

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

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

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

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

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

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

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

Article 2

1. For the purpose of this Directive:

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

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

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

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

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

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

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

(a) explosive:

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

(b) oxidizing:

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

(c) extremely flammable:

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

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

(d) highly flammable:
- substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
- solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
- liquid substances and preparations having a flash point below 21 °C, or
- gaseous substances and preparations which are flammable in air at normal pressure, or
- substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities;

(e) flammable:
liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C;

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

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

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

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

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

(k) dangerous for the environment:
substances and preparations the use of which presents or may present immediate or delayed risks for the environment;

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

(m) teratogenic;

(n) mutagenic.

Article 3

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

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

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

Article 4

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

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

Article 5

1. The Member Sates shall take all the measures necessary to ensure that without prejudice to Article 8 substances cannot be placed on the market on their own or in preparations unless the substances have been:
- notified to the competent authority of one of the Member States in accordance with this Directive,
- packaged and labelled in accordance with Articles 15 to 18 and with the criteria in Annex VI, and in accordance with the results of the tests provided for in Article 6.

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

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

Article 6

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 7

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

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

— classification and labelling,

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

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

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

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

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

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

— classification,

— labelling, and

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

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

Article 8

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

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

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

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

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

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

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

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

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

Article 9

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

Article 10

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

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

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

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

contained in the dossier required under this Directive; it may also suggest that further tests or information be requested. If the competent authority which received the original notification fails to comply with the suggestions of other authorities regarding further information or amendments in the study programmes provided for in Annex VIII, 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 or amendments in the study programmes 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 21.

Article 11

1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Article 6 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.

Industrial and commercial secrecy shall not apply to:

— the trade name of the substance,

— physico-chemical data concerning the substance in connection with Annex VII, point 3,

— the possible ways of rendering the substance harmless,

— the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests,

— the recommended methods and precautions referred to in Annex VII, point 2.3 and the emergency measures referred to in Annex VII, points 2.4 and 2.5.

If the notifier himself subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

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

3. The name of a substance appearing in the list provided for in Article 13 (2) may be included in encoded form where the competent authority to which the notification has been submitted so requests because of the confidentiality problems to which publication of the name of the substance would give rise, provided that the substance is not classified as dangerous.

A substance may be included in the list in encoded form for no longer than three years.

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 7 (1),

— may, however, when administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, be divulged to persons directly involved in such proceedings.

This Article and Article 12 shall not oblige a Member State whose legislation or administrative practices impose stricter limits for the protection of industrial and commercial secrecy than those laid down in these Articles to supply information, where the State concerned does not take steps to comply with these stricter limits.

Article 12

The data supplied in accordance with Articles 9 and 10 (1) may be forwarded to the Commission and the Member States in summary form.

In such cases and in the context of Article 10 (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.

Article 13

1. The Commission shall, on the basis in particular of information provided by the Member States, draw up an inventory of substances on the Community market by 18 September 1981.

In so doing it shall have regard to Articles 1 (4) and 8.

The inventory shall give the chemical name under an internationally recognized chemical

nomenclature (preferably IUPAC), the CAS number and the common name or ISO abbreviation, if any.

2. The Commission shall keep a list of all substances notified under this Directive.

3. The information and the form in which it is recorded in the list and the inventory, together with the criteria covering the provision to the Commission by the Member States of information relating to the inventory, shall be determined in accordance with the procedure laid down in Article 21.

Article 14

Annex I contains the list of substances classified in accordance with Article 4 and any recommendations relating to safe use.

Article 15

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 harmful or 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 repeatedly refastened without the contents escaping.

2. The Member States may also prescribe that:

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

— containers with a capacity not exceeding three litres which contain dangerous substances intended for domestic use shall have child-resistant fastenings,

— containers with a capacity not exceeding one litre which contain very toxic, toxic or corrosive liquids intended for domestic use shall carry a tactile warning of danger.

3. Any technical specifications which may be necessary with regard to the devices referred to in paragraph 2 shall be adopted by the procedure in Article 21 and shall be given in Annex IX, in particular:

— in Annex IX (A) relating to child-resistant fastenings,

— in Annex IX (B) relating to tactile warnings of danger.

Article 16

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:

— the name of the substance,

— the origin of the substance,

— the danger symbol, when laid down, and indication of danger involved in the use of the substance,

— standard phrases indicating the special risks arising from such dangers,

— standard phrases indicating the safety advice relating to the use of the substance.

(a) The name of the substance shall be one of the terms listed in Annex I; if this is not the case the name must be given in accordance with internationally recognized nomenclature.

(b) The indication of origin shall include the name and address of the manufacturer, the distributor or the importer.

(c) The following symbols and indications of danger are to be used:
— explosive:
an exploding bomb (E)
— oxidizing:
a flame over a circle (O)
— extremely flammable:
a flame (F)
— highly flammable:
a flame (F)

— very toxic:
a skull and cross-bones (T)

— toxic:
a skull and cross-bones (T)

— harmful:
a St Andrew's cross (Xn)

— corrosive:
the symbol showing the damaging effect of an acid (C)

— irritant:
a St Andrew's cross (Xi)

The symbols must conform to those in Annex II; they shall be printed in black on an orange-yellow background.

(d) The special risks involved in using the substances shall be indicated by one or more of the standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex III. In the case of a substance not listed in Annex I, the reference to the special risks attributed to the dangerous substances shall comply with appropriate indications given in Annex III.

The phrases "extremely flammable" or "highly flammable" need not be indicated where they repeat the wording of an indication of danger used in accordance with (c) above.

(e) The safety advice relating to the use of the substances shall be indicated by standard phrases which, in accordance with the references contained in the list in Annex I, are set out in Annex IV.

The packaging shall be accompanied by the safety advice required by the above paragraph where it is materially impossible for this to be given on the label or package itself.

In the case of a substance not listed in Annex I, the safety advice relating to the dangerous substances shall comply with appropriate indications given in Annex IV.

(f) 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.

3. In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of special risks and safety advice 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. 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 includes provision to the contrary,

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

— the obligation to indicate the symbol E makes the symbols F and O optional.

Article 17

1. Where the particulars required by Article 16 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 three litres:	if possible at least 52 × 74
— greater than three 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 cm^2. The entire surface of the label shall adhere to the package immediately containing the substance.

These dimensions are intended solely for provision 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 from it.

4. 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.

5. 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 16 (2) (a), (b), (d) and (e).

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 18

1. Member States may:

(a) permit the labelling required by Article 16 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable for labelling in accordance with Article 17 (1) and (2);

(b) by way of derogation from Articles 16 and 17 permit the packaging of dangerous substances which are neither explosive, very toxic nor 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 other persons.

2. If a Member State makes use of the options provided for in paragraph 1, it shall forthwith inform the Commission thereof.

Article 19

The amendments necessary for adapting the Annexes, other than Annex VI, Part I and Annexes VII and VIII, to technical progress, shall be adopted in accordance with the procedure laid down in Article 21.

Article 20

1. A Committee (hereinafter called "the Committee") is hereby set up to adapt to technical progress the Directives concerning the elimination of technical barriers to trade in dangerous substances and preparations. It shall consist of representatives of the Member States, with a Commission representative as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 21

1. Where reference is made to the procedure laid down in this Article, the matter shall be referred to the Committee by its chairman, either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit a draft of the measures to be adopted to the Committee. The Committee shall give its view of the draft within a time limit set by the chairman having regard to the urgency of the matter. Decisions shall be taken by a majority of 41 votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures if they are in accordance with the opinion of the Committee;

(b) If the proposed measures are not in accordance with the opinion of the Committee, or if no opinion has been stated, the Commission shall without delay submit a proposal to the Council concerning the measures to be adopted. The Council shall act by a qualified majority;

(c) If the Council has not acted within three months of the proposal being submitted to it, the proposed measures shall be adopted by the Commission.

Article 22

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

Article 23

1. Where a Member State has detailed evidence that a substance, although satisfying the requirements of this Directive, constitutes a hazard for man or the environment by reason of its classification packaging or labelling, it may provisionally prohibit the sale 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 consult the Member States concerned within six weeks, then give its view without delay and take the appropriate measures.

3. If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted, either by the Commission or by the Council, in accordance with the procedure laid down in Article 21; in such case, the Member State which has adopted safeguard measures may maintain them until the adaptations enter into force.'

Article 2

Articles 9, 10 and 11 of Directive 67/548/EEC hereby become Articles 24, 25 and 26.

Article 3

Annex V to Directive 67/548/EEC is hereby replaced by Annexes V to IX to this Directive.

Article 4

The following amendments shall be made to the Directives listed below:

(a) Directive 73/173/EEC:

— replace 'Article 6' by 'Article 16' in Article 5 (2) (c),

— replace 'Article 8c' by 'Article 21' in Articles 9 (2) and 10;

(b) Directive 77/728/EEC:

— replace 'Article 6' by 'Article 16' in Article 6 (2) (c),

— replace 'Article 8c' by 'Article 21' in Articles 10 (3) and 11;

(c) Directive 78/631/EEC:

— replace 'Article 6' by 'Article 16' in Article 6 (2) (g),

— replace 'Article 8c' by 'Article 21' in Articles 10 (3) and 11.

Article 5

1. No later than 18 September 1981 the Member States shall implement the laws, regulations and administrative provisions necessary to comply with Articles 1 to 4, Article 5 (1) and Articles 6 to 14 of Directive 67/548/EEC as amended by this Directive and shall inform the Commission thereof. No later than 18 September 1983 they shall implement the laws, regulations and administrative provisions necessary to comply with Article 5 (2) of Directive 67/548/EEC as amended by this Directive and shall inform the Commission thereof.

2. No later than 18 September 1981 the Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with Articles 15 to 23 of Directive 67/548/EEC as amended by this Directive, which shall enter into force on 18 September 1981.

3. During the transitional period, when this Directive is not yet in force in certain Member States, the forwarding of the notification dossier and any other information collected by the Commission as provided for in Article 10 (1) of Directive 67/548/EEC as amended by this Directive shall be effective in the case of only those Member States in which the provisions of Articles 5 to 8 of Directive 67/548/EEC as amended by this Directive, relating to notification, are being applied.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 18 September 1979.

For the Council

The President

M. O'KENNEDY

ANNEX V

A. **METHODS FOR THE DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES: for the record**

B. **METHODS FOR THE DETERMINATION OF TOXICITY: for the record**

C. **METHODS FOR THE DETERMINATION OF ECOTOXICITY: for the record**

ANNEX VI

GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES

Part I

A. Save where otherwise provided 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) classification as very toxic, toxic or harmful shall be effected by determining the acute toxicity of the commercial substance or preparation in animals, expressed in LD_{50} or LC_{50} values with the following parameters being taken as reference values:

Category	LD_{50} absorbed orally in rat mg/kg	LD_{50} percutaneous absorption in rat or rabbit mg/kg	LC_{50} absorbed by inhalation in rat mg/litre/four hours
Very toxic	≤ 25	≤ 50	≤ 0·5
Toxic	25 to 200	50 to 400	0·5 to 2
Harmful	200 to 2 000	400 to 2 000	2 to 20

(b) if facts show that for the purposes of classification it is inadvisable to use the LD_{50} or LC_{50} values as a principal basis because the substances or preparations produce other effects, the substances or preparations shall be classified according to the magnitude of these effects.

Part II

B. — Corrosion criteria: for the record
— Irritation criteria: for the record

C. If the facts show the existence of effects other than the acute effects indicated by experiments with animals, e.g. carcinogenic, mutagenic, allergenic, sub-acute or chronic effects, the substances or preparations shall be classified according to the magnitude of these effects.

D. Guide for the labelling of dangerous substances and criteria for the choice of phrases allocated to dangerous substances indicating the special risks (R phrases) and the safety advice (S phrases): for the record.

ANNEX VII

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ('BASE SET') REFERRED TO IN ARTICLE 6 (1)

When giving notification the manufacturer or any other person placing a substance on the market shall provide the information set out below.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance to be marketed. The composition of the sample shall be indicated.

In addition, the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

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 (if available)

1.2. Empirical 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)

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

2. INFORMATION ON THE SUBSTANCE

2.1. Proposed uses

2.1.1. Types of use

Describe: the function of the substance .....

the desired effects .....

2.1.2. Fields or application with approximate breakdown

(a) closed system

— industries .....

— farmers and skilled trades .....

— use by the public at large .....

(b) open system

— industries .....

— farmers and skilled trades .....

— use by the public at large .....

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 order of tonnes per year 1; 10; 50; 100; 500; 1 000 and 5 000

— first 12 months .....tonnes/year

— thereafter .....tonnes/year

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

— first 12 months .....

— thereafter .....

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)

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.1. Melting point

.....°C

3.2. Boiling point

..... °C ..... Pa

3.3. Relative density

..... (D_4^{20})

3.4. Vapour pressure

..... Pa at ..... °C

..... Pa at ..... °C

3.5. Surface tension

..... M/m (..... °C)

3.6. **Water solubility**

..... mg/litre (..... °C)

3.7. **Fat solubility**

Solvent — oil (to be specified)

..... *mg/100 g solvent* (..... °C)

3.8. **Partition coefficient**

n-octanol/water

3.9. **Flash point**

..... °C ☐ open cup ☐ closed cup

3.10. **Flammability (within the meaning of the definition given in Article 2 (2) (c), (d) and (e))**

3.11. **Explosive properties (within the meaning of the definition given in Article 2 (2) (a))**

3.12. **Auto-flammability**

..... °C

3.13. **Oxidizing properties (within the meaning of the definition given in Article 2 (2) (b))**

4. TOXICOLOGICAL STUDIES

4.1. *Acute toxicity*

4.1.1. Administered orally

LD_{50}..... mg/kg

Effects observed, including in the organs .....

4.1.2. Administered by inhalation

LC_{50}..... (ppm) Duration of exposure .....hours

Effects observed, including in the organs .....

4.1.3. Administered cutaneously (percutaneous absorption)

LD_{50}..... mg/kg

Effects observed, including in the organs .....

4.1.4. Substances other than gases shall be administered via two routes at least, one of which should be the oral route. The other route will depend on the intended use and on the physical properties of the substance.

Gases and volatile liquids should be administered by inhalation (a minimum period of administration of four hours).

In all cases, observation of the animals should be carried out for at least 14 days.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

The experiments in 4.1.1, 4.1.2 and 4.1.3 shall be carried out on both male and female subjects.

4.1.5. Skin irritation

The substance should be applied to the shaved skin of an animal, preferably an albino rabbit.

Duration of exposure ..... hours

4.1.6. Eye irritation

The rabbit is the preferred animal.

Duration of exposure ..... hours

4.1.7. Skin sensitization

To be determined by a recognized method using a guinea-pig.

4.2. Sub-acute toxicity

4.2.1. Sub-acute toxicity (28 days)

Effects observed on the animal and organs according to the concentrations used, including clinical and laboratory investigations .....

Dose for which no toxic effect is observed .....

4.2.2. A period of daily administration (five to seven days per week) for at least four weeks should be chosen. The route of administration should be the most appropriate having regard to the intended use, the acute toxicity and the physical and chemical properties of the substance.

Unless there are contra-indications, the rat is the preferred species for oral and inhalation experiments.

4.3. Other effects

4.3.1. Mutagenicity (including carcinogenic pre-screening test)

4.3.2. The substance should be examined during a series of two tests, one of which should be bacteriological, with and without metabolic activation, and one non-bacteriological.

5. ECOTOXICOLOGICAL STUDIES

5.1. Effects on organisms

5.1.1. Acute toxicity for fish

LC_{50}..... (ppm) Duration of exposure determined in accordance with Annex V (C)

Species selected (one or more) .....

5.1.2. Acute toxicity for daphnia

LC_{50}..... (ppm) Duration of exposure determined in accordance with Annex V (C)

5.2. Degradation

— biotic

— abiotic

The BOD and the BOD/COD ratio should be determined as a minimum

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. For industry/skilled trades

6.1.1. Possibility of recovery .....

6.1.2. Possibility of neutralization .....

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 recovery .....

6.2.2. Possibility of neutralization .....

6.2.3. Possibility of destruction:

— controlled discharge .....

— incineration .....

— water purification station .....

— others .....

ANNEX VIII

ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER ARTICLE 6 (5)

Any person who has notified a substance to a competent authority in accordance with the requirements of Article 6 of this Directive shall provide at the request of the authority further information and carry out additional tests as provided for in this Annex.

If it is not technically possible or if it does not appear necessary to give information, the reasons shall be stated.

Tests shall be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The bodies carrying out the tests shall comply with the principles of good current laboratory practice.

When complete studies and the results obtained are submitted, it shall be stated that the tests were conducted using the substance marketed. The composition of the sample shall be indicated.

In addition the description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the technical dossier, together with the name of the body or bodies responsible for carrying out the studies.

LEVEL 1

Taking into account:

— current knowledge of the substance,

— known and planned uses,

— the results of the tests carried out in the context of the base set,

the competent authority may require the following additional studies where the quantity of a substance placed on the market by a notifier reaches a level of 10 tonnes per year or a total of 50 tonnes and if the conditions specified after each of the tests are fulfilled in the case of that substance.

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.

It is also possible in this study to obtain evidence on teratogenicity.

If there are indications of teratogenicity, full evaluation of teratogenic potential may require a study in a second species.

— Teratology study (one species, most appropriate route of administration)

This study is required if teratogenicity has not been examined or evaluated in the preceding fertility study.

— Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration)

If the results of the sub-acute study in Annex VII or other relevant information demonstrate the need for further investigation, this may take the form of a more detailed examination of certain effects, or more prolonged exposure, e.g. 90 days or longer (even up to two years).

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 (including screening for carcinogenesis)

A. If results of the mutagenesis tests are negative, a test to verify mutagenesis and a test to verify carcinogenesis screening are obligatory.

If the results of the mutagenesis verification test are also negative, further mutagenesis tests are not necessary at this level; if the results are positive, further mutagenesis tests are to be carried out (see B).

If the results of the carcinogenesis screening verification test are also negative, further carcinogenesis screening verification tests are not necessary at this level; if the results are positive further carcinogenesis screening verification tests are to be carried out (see B).

B. If the results of the mutagenesis tests are positive (a single positive test means positive), at least two verification tests are necessary at this level. Both mutagenesis tests and carcinogenesis screening tests should be considered here. A positive result of a carcinogenesis screening test should lead to a carcinogenesis study at this level.

Ecotoxicology studies

— An algal test: one species, growth inhibition test.

— Prolonged toxicity study with Daphina magna (21 days, thus study should also include determination of the 'no-effect level' for reproduction and the 'no-effect level' for lethality).

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods laid down in Annex V (C) for acute toxicity tests with Daphnia.

— Test on a higher plant.

— Test on an earthworm.

— Prolonged toxicity study with fish (e.g. Oryzias, Jordanella, etc.; at least a period of 14 days; thus study should also include determination of the 'threshold level').

The conditions under which this test is carried out shall be determined in accordance with the procedure described in Article 21 in the light of the methods adopted under Annex V (C) for acute toxicity tests with fish.

— Tests for species accumulation; one species, preferably fish (e.g. Poecilla reticulata).

— Prolonged biodegradation study, if sufficient (bio)degradation has not been proved by the studies laid down in Annex VII, another test (dynamic) shall be chosen with lower concentrations and with a different inoculum (e.g. flow-through system).

In any case, the notifier shall inform the competent authority if the quantity of a substance placed on the market reaches a level of 100 tonnes per year or a total of 500 tonnes.

On receipt of such notification and if the requisite conditions are fulfilled, the competent authority, within a time limit it will determine, shall require the above tests to be carried out unless in any particular case an alternative scientific study would be preferable.

LEVEL 2

If the quantity of a substance placed on the market by a notifier reaches 1 000 tonnes per year or a total of 5 000 tonnes, the notifier shall inform the competent authority. The latter shall then draw up a programme of tests to be carried out by the notifier in order to enable the competent authority to evaluate the risks of the substance for man and the environment.

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,

— teratology study (non-rodent species) study to verify teratology study at level 1 and experiment additional to the level 1 study, if effects on embryos/foetuses have been established,

— acute and sub-acute toxicity study on second species: only if results of level 1 studies indicate a need for this. Also results of biotransformation studies and studies on pharmacokinetics may lead to such studies,

— additional toxicokinetic studies.

Ecotoxicology

— Additional tests for accumulation, degradation and mobility.

The purpose of this study should be to determine any accumulation in the food chain.

For further bioaccumulation studies special attention should be paid to the solubility of the substance in water and to its n-octanol/water partition coefficient.

The results of the level 1 accumulation study and the physiocochemical properties may lead to a large-scale flow-through test.

— Prolonged toxicity study with fish (including reproduction).

— Additional toxicity study (acute and sub-acute) with birds (e.g. quails): if accumulation factor is greater than 100.

— Additional toxicity study with other organisms (if this proves necessary).

— Absorption — desorption study where the substance is not particularly degradable.

ANNEX IX

A. PROVISIONS RELATING TO CHILD-RESISTANT FASTENINGS: for the record

B. PROVISIONS RELATING TO TACTILE WARNINGS OF DANGER: for the record

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