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Proposal for a

COUNCIL DIRECTIVE

the sixth modification of the Council Directive of 27 June 1967 on the approximation of the laws of Member States relating to the classification, packaging and labelling of dangerous substances

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(sybmitted by the Commission to the Council)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

During the past few years, the large scale changes in the chemical industry have led to a rapid increase in both the number and quantity of synthetic chemical compounds which has in turn given rise to more and more serious problems with respect to their control.

Chemical compounds now have a place in most human activities and each year the list lengthens. There is a risk that among these compounds there may be substances which could have harmful effects directly or indirectly for man and the environment.

At the moment on a Community basis this is regulated by the Council Directive of 27 June 1967 (67/548/CEE) on dangerous substances which lays down conditions for their classification and the way in which they are offered for sale as well as by Council Directives on solvants (73/173/CEE, detergents (73/404/CEE) and methods of measurement of the biodegradibility of anionic surfactants (73/405/CEE).
Other directives on certain preparations are in course of adoption.

Today scientific circles, public opinion and the authorities of Member States are confronted increasingly by problems caused by toxic, harmful or polluting substances. Polychlorbiphenyls (PCB), polychlorterpheryls (PCT), vinyl chloride monomer (VCM), mercury compounds, and certain organohalogen compounds are the most current examples.

A directive on the limitation of the placing on the market and use of the first three substances was approved by the Council on 30 June 1967. This directive is not limited to these three pollutants it includes the possibility of extension of its field of application to any chemical substance which may prove to be dangerous.

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In view of the growing concern of public authorities there is now increased interest in the different ways of evaluating the effects of chemical products before these offer a real danger so that this danger can be avoided as much as possible.

It seems more and more necessary at the moment not to continue placing on the market chemical compounds potentially dangerous for man and the environment without having available a minimum of knowledge about the risks which are produced. By the nature and importance of the solutions and their impact on trade and the free circulation of goods this problem could only be solved on a Community basis notably because of the fundamental objectives of the European Economic Community and in particular because of the measures arising from the existence of the directive of 27 June 1967.

In effect by the European Community Action Programme for the Environment of 22 November 1973 the Council has charged the Commission to examine the possibilities of harmonizing and reinforcing the control which the public authorities should exercise on certain new synthetic substances and products before they are placed on the market.

This examination has shown not only the necessity of setting up a system of control but equally of establishing this with a view to preventing pollution, in accordance with the first principle of the Environmental Policy Programme previously mentioned, and to undertake this in a systematic way, that is to say by a generalised control.

In June 1975 the French Government in accordance with the information agreement on environment of 5 March 1973, notified to the Commission a draft law on the control of chemical products dispersed in the environment. The Commission invited the French authorities to postpone the application of the measures envisaged in order that it could prepare proposals for Community measures to be presented to the Council. The preparatory work was carried

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out with the help of the group of national experts "Elimination of technical barriers to trade: dangerous substances". Three plenary meetings and one restricted meeting were held to examine the draft modification of the directive of 27 June 1967.

In parallel with this work of modification of the directive of 1967 to include the criteria "dangerous for the environment" the Committee for Adaptation to Technical Progress unanimously voted a modification of Annexes I, III and IV of this directive respectively to the list of dangerous substances indications of risk and safety advice.

The present proposal of modification of the directive of 27 June 1967 envisages the reinforcement of measures relating to the classification, packaging and labelling of substances which had as its objective the p protection of users and workers.

In order to supervise the effects on man and the environment, it is proposed that any placing on the market of a new substance would imply the carrying out of a prior study by the manufacturer and notification to the competent authorities when the substance was first placed on the market in a Member State. To follow closely the evolution of substances placed on the market and their use, a system should be set up which provides for the listing of all new substances which are placed on the market. A body should be set up.

In this way, the competent authority of a Member State will be in a position to evaluate the consequences which would result from the marketing of the substance and could if necessary intervene immediately in modifying the classification proposal either by limiting or forbidding the marketing of the substance.

This limitation or prohibition would take place when the competent authority judged it to be necessary and indispensible for the protection of man and the environment.

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The present proposal of directive has as its objective the laying down of Community measures in the field of chemical products in view of their danger for man and the environment and is a natural sequel to directives elaborated in the field of dangerous substances and preparations.

In order to facilitate the reading of the directive a new numbering of the articles is proposed.

II COMMENTS ON THE ARTICLES

It is proposed to replace Articles 1 to 11 of the Council Directive of 27 June 1967 by a new text.

COMMENTARIES ON THE MAIN MODIFICATIONS ENVISAGED

Article 1

The field of application of this article has been enlarged to include the notification of new substances. The new sub-paragraph 2a states that substances used as foodstuff or animal feedingstuffs are submitted to other Community measures with respect to their labelling.

Article 2

In Article 2 (c) (d) and (e) the definitions of new substances and notification are given. In paragraph 2 (i) a new classification 'dangerous for the environment ' is created to take account of the new objectives of the directive.

Article 3

The new paragraphs 2 and 3 of this article specify the method of determining the classification envisaged by the directive and refers to technical annexes VI, VII and VIII.

Article 5

This article fixes the general conditions to which new substances must be submitted to be placed on the market.

Article 6

This article sets out the general principle according to which the notifier must carry out a prior study with the aim of assessing the effects on man and the environment of the new substance. It obliges him to communicate a certain number of indispensable results from the examination of the new substance. Paragraph 3 in particular envisages a continuity of information.

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Article 7

This article envisages the nomination of competent authorities in fixing the framework of their responsibilities with regard to the marketing of a new substance.

Article 8

This article lists the sectors excluded from the notification procedure. This exclusion is necessary either to cover the needs for research or for other Community measures. Articles 9, 10 and 11 set up the Community notification procedure.

Article 14

The principal modification of this article is at sub-paragraph 2c which makes the use of safety advice obligatory. It should also be noted that the new paragraph 5 envisages that the indications enumerated at paragraph 2 must, where necessary, be accompanied by appropriate inscriptions decided by application of Article 7 in the framework of the requirements relating to conditions of use.

Article 15

To paragraph 1 a new more complete format is proposed according to the capacity of the package.

Article 21

Paragraph 1 enlarges the scope of the safeguard clause in the case where a Member State deems that the information notified accroding to Article 6 are clearly false.

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Annex VI

Characteristics for assessment of danger for the environment which is offered by substances.

Annex VII

Characteristics forming part of the technical dossier envisaged in Article 6.

Annex VIII

Determination of the applicability of the categories toxic, harmful, corrosive and irritant.

III. CONSULTATION OF INTERESTED PARTIES

The proposal of directive was written in consultation with a Working Group of experts competent in the field of public health, of the environment and of health and safety at work and with which representatives of the consumers and the appropriate industrial sector were associated.

IV. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

In application of Article 100, paragraph 2 of the Treaty, taking into account the fact that the application of this directive will require modifications to the legal provisions of Member States, the opinion of the European Parliament and the Economic and Social Committee is necessary.

PROPOSAL FOR A COUNCIL DIRECTIVE

the sixth modification of the Council Directive of 27.6.1967 on the approximation of the laws of Member States relating to the classification, packing and labelling of dangerous substances

THE COUNCIL OF THE EUROPEAN COMMUNITIES

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

Having regard to the proposal of the Commission

Having regard to the Opinion of the European Parliament

Having regard to the Opinion of the Economic and Social Committee,

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 controls envisaged in Council Directive 67/548/CEE of 27 June 1967 on the approximation of the legislative, regulatory and administrative measures relating to the classification, packing and labelling of dangerous substances (1) modified most recently by Directive 75/409/CEE (2),

Whereas it is necessary for these reasons to modify the Directive 67/548/CEE which at the moment by a classification, packing 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 is subjected to a prior study by the manufacturer and a notification to the competent authorities conveying mandatorily certain information; and 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 it is necessary to envisage measures allowing the Commission to introduce the procedure of notification to all the Member States; and whereas it is, moreover, necessary to envisage that the measures relating to the classification, packing and labelling and the conditions of use of new substances may be laid down at the Community level by Directives of the Commission or Council as appropriate;

(1) OJ No 196, 16.8.1967, p.1
(2) OJ No L183, 14.7.1975, p.22

Whereas the competent authority of a Member State must be in a position to appraise the consequences resulting from the placing on the market of a new substance and may, where necessary, intervene in limiting or in prohibiting the placing on the market of the aforementioned substance when it judges this to be necessary for the protection of man and the environment;

Whereas it is necessary to make it obligatory that safety advice accompanies the packing of dangerous substances;

Whereas Article 2 of the above directive classes substances and preparations as toxic, harmful or corrosive by the use of general definitions; whereas in the absence, at the moment, of specifications allowing their allocation to these classes, it seems appropriate to envisage precise criteria for classification; whereas in addition Article 3 of the directive envisages an evaluation of danger for the environment and that arising from this it is necessary to enumerate certain characteristics and parameters of assessment;

Whereas for the better understanding of the directive a new presentation and a different numbering of the articles have been necessary,

HAS ADOPTED THIS DIRECTIVE

HAS ADOPTED THIS DIRECTIVE

Article 1

1. Articles 1 to 11 of the Council Directive of 27 June 1967 relating to the approximation of legislative, regulatory and administrative measures concerning the classification, packaging and labelling of dangerous substances (67/548/EEC) modified in the last instance by Directive 75/409/EEC are replaced by the following articles :

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"Article 1

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

   - notification of new substances
   - classification
   - packaging, and
   - labelling

   of substances dangerous for man and the environment which are placed on the market in the Member States of the Community.

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) munitions and objects containing explosive matter in the form of igniters or motor fuels;
   d) additives to foodstuffs or to animal feedingstuffs, as to [illegible] which are labelled according to the provisions of the Council Directives of

3. The classification, packaging and labelling provisions of this directive do not apply to dangerous substances exported to third countries.

4. Articles 13 to 15 of this Directive do not apply to containers for gases which are compressed, liquefied or dissolved under pressure.

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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;

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

c) 'new substances'
substances which have not previously been placed on the market either as a substance or mixture before 1st January 1979 [illegible] Article 13 with the exception of those made available to research laboratories.

d) environment
Water, air, earth, biological forms; the relation between them and with man.

e) notification
An informative declaration to the competent authority by the manufacturer or any other person placing a new substance on the market, hereafter called the notifier.

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

c) easily 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;

d) flammable
liquid substances and preparations having a flash point between 21°C and 55°C;

e) toxic
substances and preparations which, if they are inhaled or taken internally or if they penetrate the skin, may involve serious, acute or chronic health risks and even death;

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f) harmful
substances and preparations which, if they are inhaled or taken internally or if they penetrate the skin, may involve limited health risks;

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

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

i) dangerous for the environment
substances, the use of which presents or could present immediate or prolonged risks for the environment.

Article 3

1. The flash point of the flammable liquid substances and preparations mentioned in Article 2 paragraph 2 (c) and (d) shall be determined according to the methods and with the apparatus laid down in Annex V.

2. The environmental or potential environmental hazard shall be determined in accordance with the characteristics set out in Annex VII taking into account the parameters of appreciation contained in Annex VI.

3. The determination of the categories toxic, harmful, corrosive and irritant mentioned in Article 2, paragraph 2, e), f), g) and h) as is carried out according to the criteria in Annex VIII.

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Article 4

The classification of dangerous substances according to the degree of hazard and specific nature of risks shall be based on the categories laid down in Article 2 (2). For categories (a) to (h) the substances shall be classified according to the greatest degree of hazard.

Article 5

1. Member States shall take all the necessary measures to ensure that the new substances referred to in Article 2 are not placed on the market unless they have been :

   - notified to the competent authority in accordance with this directive;
   - packaged in accordance with the principles of Art. 13;
   - labelled in accordance with the principles of Art. 14;

2. These measures of prohibition are valid until the substance is listed into Annex I. From the time the substance is listed in Annex I it must be :

   - packaged according to Art. 13;
   - labelled according to Art. 14;
   - and used under the conditions which, when necessary, have been laid down in respect of it in Annex I.

Article 6

1. The notifier is required to carry out a study prior to marketing a new substance to enable its effects on man and the environment to be assessed and to submit to the competent authority envisaged in Art. 7, at the latest on the date of marketing, a notification with an acknowledgement of receipt including:

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- a technical dossier containing all the information necessary to evaluate forseeable direct or indirect risks which the new substance might entail for man and the environment in respect of the various uses envisaged and which contains at least comments relating to the characteristics listed in Annex VII which hear an asterisk.
- a declaration concerning the unfavourable effects of the substance;
- the classification and labelling of the substance in accordance with this directive;
- proposals for any measures relating to the conditions of use which are intended to limit the unfavourable effects.

2. The notifier may at the same time send a copy of the dossier to the Commission.

3. The notifier is further required to inform the competent authority of any significant change in or addition to the information previously notified in particular in relation to :

- new uses for which he markets the substance (see Annex VII, para 2.1)
- annual increases in the quantities which he markets (see Annex VII, para 2.2)
- toxic or ecotoxic characteristics not previously notified.

Article 7

1. Member States shall appoint a competent authority (or authorities) who shall be responsible for :
- receiving the notification and examining its conformity with the prescriptions of the directive;
- examining the forseeable risks that these new substances might give rise to;
- examining the classification and labelling proposal;
- examining the proposals of measures relating to the conditions of use;

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Moreover, if the authorities see fit they may :

- ask for further information and/or verification tests;
- carry out such sampling as is necessary for control purposes;
- take appropriate measures relating to conditions of use while awaiting Community dispositions.

2. According to the procedure laid down in Article 19 other proposals for :

- classification
- labelling
- dispositions relating to conditions of use.

3. Member States and the Commission shall ensure that any information concerning marketing or manufacturing shall be kept secret.

Article 3

Substances in as much as they are placed on the market in the following ways shall be excluded from the notification procedure :

a) for research, development or analysis;
b) as substance or in mixtures for :
   - special pharmaceutical products
   - components of materials or objects intended to come into contact with foodstuffs
   - components of pesticides subjected to type approval
   - cosmetic products.

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Article 9

A Member State which has received the notification dossier or additional information envisaged in Article 6 shall with the agreement of the notifier send a copy of it immediately to the Commission together with any relevant comments.

Article 10

On receipt of the copy of the notification dossier or some other complementary information from a Member State, the Commission shall transmit :

- the elements of the notification to the other Member States;
- any relevant information which it has gathered to all Member States.

This transmission shall be deemed to constitute a notification to the competent authorities of other Member States within the meaning of Article 6.

Article 11

1. The Commission shall keep at the disposal of the Member States a catalogue of all substances notified under this Directive.

2. The Member States may be called upon to give the Commission any information necessary to up-date this catalogue notably in respect of quantities placed on the market.

Article 12

Annex I of this Directive contains the list of substances classified under the provisions of Article 4 and where appropriate dispositions relating to conditions of use.

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Article 13

Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the strength and impermeability of their packaging satisfies the following requirements, any packaging meeting these requirements being regarded as adequate :

1. The packagings must be so arranged and fastened as to preclude any loss of the contents; this requirement does not apply where special safety devices are prescribed;

2. The materials constituting the packaging and fastenings must not be liable to attack by the contents, or liable to form harmful or dangerous compounds with the contents;

3. The packagings 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 normal handling.

Article 14

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 must 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,
- a reference to the special risks arising from such dangers;

a) the name of the substance must be one of the terms listed in Annex I to this Directive;

b) the indication of origin must include the name and address of the manufacturer, the distributor or the importer;

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c) the following symbols and indications of danger are to be used :

- explosive	: an exploding bomb (E)
- oxidising	: a flame over a circle (O)
- very flammable	: a flame (F)
- toxic	: a death's head and crossbones
- harmful	: a St. Andrew's Cross (Xn)
- corrosive	: the symbol showing the damaging effect of any acid (C)
- irritant	: a St. Andrew's Cross (Xi)

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

d) The nature of the special risks involved in using the substances must be indicated by one or more of the standard phrases which, in conformity with the references contained in the list in Annex I, are set out in Annex III to this Directive.

e) The packaging shall be accompanied by safety advice relating to the use of the substances where it is materially impossible for these to be given on the label or package itself. The wording of such precautions shall, in conformity with the references contained in the list in Annex I, be based on Annex IV to this Directive.

3. For packages of harmful, irritant, highly flammable, flammable and oxidising substances, indication need not be given of special risks and safety advice where the package contains no more than 125 ml.

4. When more than one danger symbol is assigned to a preparation :

- the obligation to indicate the symbol T makes, in general, the symbols X and C optional;
- 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.

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5. The indications mentioned in paragraph 2 must, where necessary, be accompanied by appropriate indications required in application of Article 7 with respect to measures relating to conditions of use.

Article 15

1. When the particulars required by Article 14 appear on a label, the latter must be placed on one or more faces of the package so that it can be read horizontally when the package is put down normally. The dimensions of the label must be as follows :

Package content		Dimension
- less than or equal to 0.5 litres	: if possible, at least	52 x 74 mm
- greater than 0.5 litres, and not exceeding 1 litre	: at least	74 x 105 mm
- greater than 1 litre, and not exceeding 10 litres	: at least	105 x 148 mm
- greater than 10 litres, and not exceeding 50 litres	: at least	148 x 210 mm
- greater than 50 litres	: at least	210 x 296 mm

Each symbol must cover at least one-tenth of the surface of the label and be at least 1 cm^2. The entire area of the label must adhere to the package immediately containing the substance.

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

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

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

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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, where 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, where such a package is labelled in accordance with international rules on the transport of dangerous substances and with Article 14 (2) (a), (b) and (d).

In the case of dangerous substances, which do not leave the sovereign 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 16

Member States may :

a) permit the labelling required by Article 14 to be applied in some other appropriate manner on packages which are either too small or otherwise unsuitable to allow labelling in accordance with Article 15.

b) by way of derogation from Articles 14 and 15, permit the packaging of dangerous substances which are neither explosive nor toxic to be unlabelled, or to be labelled in some other way if they contain such small quantities that there is no danger to workers or others.

Article 17

The amendments necessary to adapt the Annexes to technical progress shall be adapted in accordance with the procedure laid down in Article 19

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Article 18

1. A Committee shall be established for the adaptation to technical progress of Directives for removing technical barriers to trade in the sector of dangerous substances and preparations, hereinafter called 'Committee', which shall consist of representatives of the Member States under the Chairmanship of a representative of the Commission.

2. The Committee shall establish its internal regulations.

Article 19

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

2. The representative from the Commission shall submit a draft of the measures to be taken to the Committee. The Committee shall express its Opinion on this draft within a period specified by the Chairman in the light of the urgency of the matter in question. A majority of 41 votes shall suffice for a Decision, the votes of the Member States being weighted as laid down in Article 148 subparagraph 2 of the Treaty. The Chairman shall not vote.

3. a) The Commission shall adapt the measures envisaged when they are in accordance with the Opinion of the Committee.

   b) When the measures have not been agreed on by the Committee, or in the absence of an Opinion, the Commission shall submit to the Council without delay a proposal on the measures to be taken. The Council shall give judgement by the qualified majority.

   c) If, after the matter has been before the Council for a period of three months, there has been no decision by the Council, the proposed measures shall be adopted by the Commission.

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Article 20

Member States shall not prohibit, restrict or impede on the grounds of notification, classification, packaging or labelling as defined in this Directive, the placing on the market of dangerous substances which satisfy the requirements of this Directive and the Annex thereto.

Article 21

1. Where a Member State has detailed grounds for establishing that a dangerous substance, although satisfying the requirements of this Directive, constitutes a hazard to health or safety, it may provisionally prohibit the sale of that substance or subject it to special conditions ruling in its territory. It may similarly take such measures where it is obvious that the information notified according to Article 6 is falsely false.

   It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.

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

3. Where the Commission is of the opinion that technical adaptations to this Directive are necessary, such adaptations shall be adopted by either the Commission or the Council under the procedure laid down in Article 19. In this event, the Member State having adopted safeguard measures may maintain them until such adaptations enter into force.

Article 22

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

Annexes VI, VII and VIII, which appear in the annex to this directive, are added to the directive mentioned in the first paragraph of this article.

Article 2

Member States shall adopt the measures needed in order to comply with this Directive and shall apply them by 1st January 1979 at the latest. They will inform the Commission and the other Member States immediately of such measures.

Article 3

This Directive is addressed to the Member States.

ANNEX VI

Parameters for evaluating the environmental risk of certain substances

The environmental risk of a substance is evaluated on the basis of the following primary concepts and their possible correlation.

A. Quantities

B. Potential toxicity for various targets

C. Exposure of various targets

As regards these concepts the following parameters should particularly be taken into account :

A.1 Tonnages forecast by the manufacturer, expressed in tonnes/year

A.2 Production broken down according to type of utilization and expressed as a percentage of the total production.

B.1 Acute toxicity to man determined by experiments on mammals depending on the intended use of the substance. They may be administered in these tests orally, percutaneously or by inhalation.

B.2 Chronic and miscellaneous toxicity

The following parameters should be taken into consideration as appropriate :

- sub-chronic toxicity (repeated daily doses on rats for 90 days),
- chronic toxicity (studies on rats (1 year) and possibly on dogs (3 years)),
- carcinogenesis
- mutagenesis over three generations,
- teratogenesis

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B.3 Toxic effects on other living creatures

Depending on the anticipated uses of the substance and on the potential receiving media, an analysis should be made of the toxicological effects on other forms of life such as bacteria, algae, fish and birds.

C.1 Anticipated uses

- Initial media : the specific purpose of the substance should be considered with a view to identifying primary targets liable to exposure;

- type of distribution : this involves an assessment of dispersal risks. As a guide, the following distinctions might be borne in mind :

  - substances whose use is confined to closed systems;

  - substances used only by approved users or specialists; substances whose use is confined to a limited number of industrial establishments;

  - substances used only by professional specialists working in industry, craft trades and agriculture;

  - substances retailed to the general public.

C.2 Dispersal : In this case the transport of a substance from its initial medium should be assessed as far as possible with the aim of identifying the receiving media. Account should be taken of the physical, chemical and biochemical properties of the substance.

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C.3 Stability in the presence of natural agents

This involves assessing the stability of a substance under abiotic and biotic conditions in various environments.

The physico-chemical properties of the substance should be taken into account, for example, stability as a function of pH, thermo-stability, redoc potential, and the possibilities of biodegradation in the receiving medium. Where studies have been carried out on models, consideration should be given to the half-life figures; where this is not possible, a rough assessment of this period should be made on the basis of the data available.

C.4 Accumulation within receiving media and the creatures living therein

The aim here is to assess as far as possible whether the substance is likely to build up in a given target in the receiving medium. This may either take the form of geoaccumulation or bioaccumulation.

Where studies (e.g., accumulation in fish) have been carried out on models, consideration should be given to relative preferential accumulation figures; when this cannot be done, the possible extent of any accumulation phenomena should be considered in the light of the relevant physico-chemical properties, e.g., the partition coefficients of H_2O/organic solvents.

C.5 Possibilities of disposal

At issue here is whether the substance, once it has become waste material, can be disposed of by suitable treatment bearing in mind the behaviour of the substance in a purification or incineration plant.

ANNEX VII

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER REFERRED TO IN ARTICLE 6 OF THIS DIRECTIVE

Thi Annex is intended as a guide. Consequently, some of the information requested may at time be superfluous or alternatively require amplification.

The obligatory information which the manufacturer must provide is marked by an asterisk; if it is not possible to give an answer, the reasons must be stated.

* I. IDENTITY OF THE SUBSTANCE

* I.1. Chemical name

* I.1.1. Name in the IUPAC nomenclature

* I.1.2. Other names

* I.2. Empirical and structural formula

* I.3. Composition of the chemical product

* I.3.1. Degree of purity (%)

* I.3.2. Nature of impurities, including isomers and secondary products

* I.3.3. Percentage of main impurities

* I.4. Methods of detection and determination

A full descrpition of the methods used or the appropriate bibliographical references.

* 2. DATA ON UTILIZATION

* 2.1. Proposed uses

* 2.1.1. Type of use

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

- the desired effects .....

* 2.1.2. Type of distribution

Indicate destination of substance :

- Closed system ..... ☐
- Processing industries ..... ☐
- Farmers and skilled trades ..... ☐
- The substance is retailed to the public ..... ☐

* 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:

- First 12 months ..... t/year
- Thereafter ..... t/year

* 2.2.2. Breakdown of production and/or imports according to points 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 .....

* 2.4. Emergency measures in case of accidental spillage

3. PHYSICO-CHEMICALS PROPERTIES OF THE SUBSTANCE

(State whether this is the pure or the commercial substance and give the reference of the internationally recognized methods or a description of the methods used).

* 3.1. Melting point

..... °C

* 3.2. Boiling point

..... °C at ..... Pa

* 3.3. Relative density

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

* 3.4. Vapour pressure

..... Pa at ..... °C

..... Pa at ..... °C

* 3.5. Surface tension

..... N/m (..... °C)

* 3.6. Water-solubility

..... mg/l (..... °C)

* 3.7. Fat-solubility

Solvent = [fish oil - corn oil]

..... mg/100 gr. solvent (..... °C)

* 3.8. Partition coefficient

Water/non-miscible solvent (please specify):

Water/lipid (please specify):

* 3.9. Flash point

..... °C ☐ open-air situation ☐ enclosed situation

* 3.10. Explodability (within the meaning of Directive 67/548/EEC)

3.11. Redox potential

3.12. Stability related pH

3.13. Other properties (e.g. chelating tendancy)

4 - TOXICOLOGICAL STUDIES

(State whether the tests were carried out with the pure or the commercial substances)

* 4.1. Acute toxicity

* 4.1.1. Absorbed orally

LD_{50} (rat) ..... (mg/kg)

Symptoms observed in the organs affected (including allergic reactions) .....
.....

* 4.1.2. Absorbed through the skin

LD_{50} (rat) ..... (mg/kg)

Symptoms observed in the organs affected (including allergic reactions) .....
.....

* 4.1.3. Absorbed by inhalation

LC_{50} (rat) ..... (ppm) (..... h)

Symptoms observed in the organs affected. (including allergic reactions) .....
.....

* 4.1.4. Irritant/corrosive effects

(Within the meaning of this Directive, Annex VIII Points 2 & 3)

4.2. Delayed toxicity

* 4.2.1. Subacute toxicity (90 days)

Symptoms observed according to the concentrations used:
.....

4.2.2. Chronic toxicity (substance and its metaholites)

Symptoms observed during tests lasting more than 90 days:
.....

* 4.2.2.1 Substances retailed to the public as forseen on point 2.1.2 4th dash.

4.2.2.2 Other substances

4.3. Other effects

4.3.1. Mutagenic effects

* 4.3.1.1 Screening test

4.3.1.2 Whole study

4.3.2 Carcinogenic effects

4.3.3 Effects on reproduction, including teratogenicity

4.4. Special studies specific to the substance

For example : biochemical kinetic studies, neurophysiological toxicity studies

* 5. ECOTOXICOLOGICAL STUDIES

(State whether the tests were carried out with the pure or the commercial substance).

5.1. Effects on typical species

* 5.1.1. Effects on fish: at least two species including rainbow trout

LC_{50} ..... mg/l; duration of test: ..... h

5.1.2. Specific effects of the substance on other typical species in relation with its dispersion in the environment.
For example: birds, bacteria

* 6. BIOTIC AND ABIOTIC DEGRADABILITY AND PERSISTANCE

Evaluate the half-life of the substance:

$T\frac{1}{2} \geq$ 1 year ☐

3 months $\leq T\frac{1}{2} \leq$ 1 year ☐

1 month $\leq T\frac{1}{2} \leq$ 3 months ☒

1 week $\leq T\frac{1}{2} \leq$ 1 month ☐

$T\frac{1}{2} \leq$ 1 week ☐

Specify the data on which this evaluation is based (stability to heat photochemical stability, biodegradability etc).

* 7. POSSIBILITIES OF RENDERING THE SUBSTANCE HARMLESS

* 7.1. For industry/craft trades

* 7.1.1. Recovery possibilities:

* 7.1.2. Neutralization possibilities:

* 7.1.3. Destruction possibilities:

- Controlled discharge
- Incineration
- Water purification station
- Others

* 7.2. For the public at large

* 7.2.1. Recovery possibilities:

* 7.2.2. Destruction possibilities:

- Controlled discharge
- Incineration
- Water purification station
- Others

8. SPECIAL STUDIES

8.1. Degradation products and metabolites

8.2. Biotic accumulation

8.3. Abiotic accumulation

ANNEX VIII

DETERMINATION OF CLASSIFICATION IN THE CATEGORIES, TOXIC, HARMFUL, CORROSIVE AND IRRITANT

(See Art. 3, para 3)

1. Substances and preparations shall be classified by establishing the actual acute toxicity of the commercial product, expressed in LD_{50} values, determined in animals. For this purpose the following LC_{50} values shall be taken as reference values:

Absorbed orally: (LD_{50} oral in rat)

up to 25 mg/kg body weight: "highly toxic",

over 25 mg/kg but not more than 200 mg/kg body weight: "Toxic"

over 200 mg/kg but not more than 2,000 mg/kg body weight: "harmful".

Absorbed through the skin: (LD_{50} cutaneous in rat or rabbit)

up to 50 mg/kg body weight: "highly toxic",

over 50 mg/kg but not more than 400 mg/kg body weight: "toxic"

over 400 mg/kg but not more than 2,000 mg/kg body weight: "harmful".

Absorbed by inhalation (LC_{50} inhalation in rat)

For gaseous and volatile products or products which contain volatile components:

up to 0.5 mg/l air: "highly toxic"

over 0.5 mg/l air but not more than 2 mg/l air: "toxic",

over 2 mg/l air but not more than 20 mg/l air: "harmful".

For mixtures of components with varying vapour pressures, for preparations as are not unequivocally gaseous and for fumigants and aerosols, it must be checked whether the commercial preparation contains volatile components which could be released into the environment in actively toxic quantities:

If the rat does not die within 14 days of being exposed for 1 hour to a saturated air-vapour mixture (not acute respiratory toxicity), the classification shall be aligned on the LD_{50} values found. Should death occur, the LC_{50} value will have to be ascertained.

2. Substances and preparations shall be classified as:
"corrosive" if, in tests on rabbits, the commercial product destroys the tissue (necrosis) within 30 minutes of being in uninterrupted contact with the skin for a period of 7 days in a quantity of 0.5 ml or 0.5 g;

3. Substances and preparations shall be classified as:
"irritant" if, in tests on rabbits, they cause inflammation within 30 minutes of being in uninterrupted contact with the skin for a period of 3 days in a quantity of 0.5 ml or 0.5 g.

4. If there are indications of the existence of toxic effects, apart from acute effects (e.g. carcinogenic effects, etc.), substances and preparations may also be classified as highly toxic, toxic or harmful depending on the importance of these effects.