STATUTORY INSTRUMENTS

1982 No. 1496

HEALTH AND SAFETY

The Notification of New Substances Regulations 1982

Made - - - -	*20th October* 1982
Laid before Parliament	*5th November* 1982
Coming into Operation	*26th November* 1982

ARRANGEMENT OF REGULATIONS

Schedule 4. Categories of substances subject to Regulation 4(3).

Schedule 5. (Which reproduces the requirements of Annex VIII to the Directive). Additional information and tests which may be required for the purposes of Regulation 6(2).

The Secretary of State, being the designated (**a**) Minister for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to the notification and control of substances, in the exercise of the powers conferred on him by the said section 2 and sections 15(1), (2), (3)*(c)*, (5)*(b)* and (6)*(b)* and 82(3)*(a)* of, and paragraphs 1(1)*(b)*, (4) and (5), 2 and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(**c**) and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)*(d)* of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances Regulations 1982 and shall come into operation on 26th November 1982.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"the Directive" means Council Directive No. 67/548/EEC on the classification, packaging and labelling of dangerous substances (**d**) as amended (**e**) in particular for the sixth time by Council Directive No. 79/831/EEC(**f**);

"the Executive" means the Health and Safety Executive;

"importer" means a person who imports a new substance into the United Kingdom (whether or not that substance was consigned from the territory of a member State);

"manufacturer" means a person in a member State who extracts, synthesises or otherwise produces a new substance;

"member State" means a member State of the European Communities;

"new substance" means any substance except a substance which had been supplied (either alone or as the component of a preparation) to a person in a

(**a**) S.I. 1981/1536.
(**b**) 1972 c. 68.
(**c**) 1974 c.37; section 15 was amended by the Employment Protection Act 1975 (c. 71), section 116 and Schedule 15, paragraph 6.
(**d**) OJ No L196, 16.8.67, p. 1 (OJ/SE 1967, p. 234).
(**e**) OJ No L68, 19.3.69, p. 1; OJ No L59, 14.3.70, p. 33 (OJ/SE 1970 p. 147); OJ No L74, 29.3.71, p. 15 (OJ/SE 1971 p. 180); OJ No L167, 25.6.73, p. 1; OJ No L183, 14.7.75, p. 22; OJ No L360, 30.12.76, p. 1; OJ No L88, 7.4.79, p. 1.
(**f**) OJ No L259, 15.10.79, p. 10.

member State at any time in the period from 1st January 1971 to 18th September 1981;

"notifiable substance" means a new substance which has been or is required to be notified under Regulation 4(1);

"preparation" means a mixture or a solution composed of two or more substances;

"substance" means a chemical element or a chemical compound as it occurs in the natural state or as produced by industry, including any additive required for the purpose of supplying the substance;

"supply" means supply (whether as principal or agent for another) to any person in a member State by way of—

(a) sale, offer for sale, lease, hire or hire purchase; or

(b) commercial sample,

and includes importation into the United Kingdom;

"toxic" and "very toxic" have the meanings assigned to them by Part I of Schedule 2 (which reproduces the provisions of Article 2(2) of the Directive) in accordance with the criteria set out in Part II of that Schedule (which reproduces the requirements of Part I of Annex VI to the Directive).

(2) In these Regulations, unless the context otherwise requires, any reference to—

(a) a numbered Regulation or Schedule is a reference to the Regulation of, or Schedule to, these Regulations so numbered;

(b) a numbered paragraph is a reference to the paragraph so numbered in the Regulation or Schedule in which that reference appears.

Application of these Regulations

3.—(1) These Regulations shall apply in relation to all new substances which are supplied except—

(a) any quantity of a substance which is supplied exclusively as, or exclusively for use in, either—

(i) a medicinal product as defined in section 130 of the Medicines Act 1968(**a**), or

(ii) a substance specified in an order made under section 104 or section 105 of the Medicines Act 1968 which is for the time being in force and which directs that specified provisions of that Act shall have effect in relation to that substance as such provisions have effect in relation to medicinal products within the meaning of that Act;

(b) any quantity of a substance which is supplied exclusively as, or exclusively for use in, food within the meaning of section 135(1) of the Food and Drugs Act 1955(**b**) or section 58(1) of the Food and Drugs (Scotland) Act 1956(**c**);

(**a**) 1968 c. 67.
(**b**) 1955 c. 16 (4 & 5 Eliz. 2).
(**c**) 1956 c. 30.

(c) any quantity of a substance which is supplied exclusively as, or exclusively for use in, a feeding stuff within the meaning of section 66(1) of the Agriculture Act 1970(**a**);

(d) a radioactive substance within the meaning of Regulation 2(2) of the Ionising Radiations (Unsealed Radioactive Substances) Regulations 1968(**b**);

(e) any quantity of a substance which is supplied exclusively as, or exclusively for use in, a pesticide—

(i) in any other member State or States in as far as that substance is subject to the provisions of Article 1(4)(b) of the Directive, or

(ii) in the United Kingdom in as far as a manufacturer or importer thereof has, for the time being, been exempted from the requirements of these Regulations by a certificate granted in accordance with Regulation 12;

(f) a substance which has been imported into and which is in transit through the United Kingdom under customs control provided that it does not undergo any treatment or processing; and

(g) a substance which is supplied as the component of a preparation but, in such a case, only if its manufacturer or importer had—

(i) also supplied it alone in a quantity of one tonne or more in any period of twelve months, and

(ii) notified it in accordance with Regulation 4(1) or Article 6(1) of the Directive.

(2) These Regulations shall not apply to Northern Ireland except in as far as they relate to the importation of new substances into the United Kingdom.

Notification of new substances

4.—(1) Subject to paragraphs (2) and (3), a manufacturer or importer shall not supply a new substance in a total quantity of one tonne or more in any period of 12 months unless, at least 45 days before the quantity supplied reaches that amount, he has sent to the Executive a notification including—

(a) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may create for man or the environment and containing the information and the results of the studies referred to in Schedule 1 (which reproduces the requirements of Annex VII to the Directive) together with a detailed and full description of the studies conducted and of the methods used or bibliographical references to them;

(b) a declaration concerning any adverse effects of the substance with respect to the uses envisaged;

(c) a declaration as to whether the substance is dangerous within the meaning of Part I of Schedule 2 (which reproduces the provisions of Article 2(2) of the Directive) and if the substance is dangerous—

(**a**) 1970 c. 40.
(**b**) S.I. 1968/780.

(i) particulars of its classification in accordance with that Part, and

(ii) except in the case of munitions or explosives supplied with a view to producing a practical effect by explosion or a pyrotechnic effect, recommendations for labelling in accordance with Schedule 3 (which reproduces the requirements of Article 16(2) of the Directive); and

(d) proposals for any recommended precautions relating to the safe use of the substance.

(2) Paragraph (1) above shall not apply to a person who imports from another member State a new substance which has been duly notified in accordance with Article 6(1) of the Directive.

(3) Subject to paragraph (4), where a new substance is of a class specified in column 2 of Schedule 4 and its use is limited to the purposes (if any) specified in that column, then the manufacturer or importer of that substance shall either notify that substance in accordance with paragraph (1) or shall—

(a) comply with the conditions (if any) specified in the appropriate entry in column 3 of Schedule 4;

(b) in the case of items 1 and 5 of Schedule 4 comply with any other conditions imposed by the Executive on such supply where—

(i) a notice has been served on him by the Executive specifying those conditions, and

(ii) those conditions are reasonably required for the protection of man or the environment; and

(c) in the case of a substance which is very toxic or toxic send to the Executive the particulars relating to the substance specified in Schedule 1, paragraphs 2.3, 2.4 and 2.5 (recommendations for safe handling and use).

(4) Where it is not reasonably practicable, in relation to a substance to which paragraph (3) applies, for the information (if any) required under that paragraph to be given to the Executive before the substance is supplied, it shall be a sufficient compliance with that paragraph if the manufacturer or importer—

(a) supplies the substance in a container labelled "Caution—substance not yet fully tested";

(b) informs the Executive in writing that he intends to supply the substance in a container so labelled; and

(c) complies with any conditions imposed by the Executive on such supply where—

(i) a notice has been served on him by the Executive specifying those conditions, and

(ii) the conditions are reasonably required for the protection of man or the environment.

Notification to be made of material change of circumstances

5.—(1) The manufacturer or importer of a notifiable substance shall forthwith notify the Executive in writing of—

(a) any material change in the particulars previously notified relating to—

(i) the intended uses for which the substance is supplied, and

(ii) the properties of the substance; and

(b) any other information which is in his possession or which comes to his knowledge which might reasonably be expected to affect the interpretation of any information given by him under Regulation 4(1) or 6(1).

(2) Without prejudice to the generality of paragraph (1), the manufacturer or importer of a notifiable substance shall notify the Executive when the quantity of that substance supplied by him reaches—

(a) 10 tonnes in any period of 12 months or a total of 50 tonnes;

(b) 100 tonnes in any period of 12 months or a total of 500 tonnes; and

(c) 1000 tonnes in any period of 12 months or a total of 5000 tonnes.

Requirement for further testing

6.—(1) Subject to paragraph (3) the Executive may, by notice served on the manufacturer or importer of a notifiable substance, require him to carry out such tests in relation to that substance as are specified in the notice, and the manufacturer or importer of that substance shall cause such tests to be carried out and shall send to the Executive a report of those tests within such time as is specified in the notice or within such further time as the Executive may subsequently allow.

(2) Without prejudice to the generality of paragraph (1), the Executive shall review the need for further tests under that paragraph when it is notified that any of the quantities specified in Regulation 5(2)(*b*) or (*c*) is reached and in making that review, the Executive shall have regard to the provisions of Schedule 5 (which reproduces the requirements of Annex VIII to the Directive).

(3) The Executive shall not serve a notice under paragraph (1) unless either—

(a) the tests are reasonably required for the evaluation of the risks that may be created by the substance for man or the environment having regard to the circumstances of the case and in particular to—

(i) the nature of the risks that may be created by the substance,

(ii) the quantity of the substance which has been or is intended to be supplied,

(iii) the intended uses of the substance,

(iv) any knowledge relating to substances of that type or of by-products or impurities that the substance may reasonably be expected to contain,

(v) the cost of carrying out the tests,

(vi) the time required to carry out the tests, and

(vii) any suggestion for such tests made to the Executive by an authority appointed in accordance with the Directive to receive notifications of new substances in Northern Ireland or a member State other than the United Kingdom; or

(b) it is acting in accordance with—

(i) a direction of the Secretary of State made under Regulation 8, or

(ii) a decision adopted by the Commission of the European Communities in accordance with Articles 10(2) and 21 of the Directive.

Use of the results of studies carried out by other notifiers

7. For the purposes of—

(a) the technical dossier mentioned in Regulation 4(1)(*a*);

(b) further particulars required under Regulation 5; and

(c) a requirement for further testing under Regulation 6,

the Executive may agree that the notifier may refer to the results of studies carried out by one or more previous notifiers, but only if those previous notifiers have given their agreement in writing and copies of those agreements have been sent to the Executive.

Particulars to be sent to the Department of the Environment

8. The Executive shall send to the Department of the Environment particulars of—

(a) any notification relating to a new substance under Regulation 4(1) or information provided under Regulation 4(3);

(b) any further notification relating to that substance made in accordance with Regulation 5; and

(c) any further tests reported pursuant to a notice served under Regulation 6,

and, if directed to do so by the Secretary of State, shall serve a notice, in accordance with Regulation 6, on the manufacturer or importer of the said substance requiring him to carry out such further tests as the Secretary of State may specify.

Particulars to be sent to the Commission of the European Communities and other member States

9.—(1) The Executive shall send to the Commission of the European Communities a summary of—

(a) any notification relating to a new substance under Regulation 4(1);

(b) any further notification relating to that substance made in accordance with Regulation 5; and

(c) any further tests reported pursuant to a notice served under Regulation 6,

and shall comply with any request for further information made by the Commission in accordance with the Directive.

(2) Where the Commission of the European Communities has adopted a decision under Articles 10(2) and 21 of the Directive which requires further tests of the said substance, the Executive shall serve a notice, in accordance with Regulation 6, on the manufacturer or importer of that substance requiring him to carry out those tests.

(3) The Executive shall, on the request of an authority in another member State appointed in accordance with the Directive to receive notifications of new substances, send to that authority information relating to a notification, but nothing in this paragraph shall oblige the Executive to send such information to any such authority where that authority does not apply legislation or administrative procedures for the protection of commercially sensitive information which are at least as strict as those imposed—

(a) by Articles 7(3) and 11(4) of the Directive;

(b) by the requirements of these Regulations and the procedures that are operated under them; and

(c) by or under any other provision of national law which applies to the disclosure of that information in Great Britain.

Disclosure of information notified

10.—(1) Subject to Regulation 9 and the following paragraphs of this Regulation, in as far as any provision of Regulations 4, 5 and 6 is made under section 2 of the European Communities Act 1972(**a**), information notified under that provision shall be treated as relevant information for the purposes of section 28 of the 1974 Act (which imposes restrictions on the disclosure of information) and information disclosed by the Executive to the Department of the Environment pursuant to Regulation 8 shall for the purposes of section 28(5)(*a*) of that Act be deemed to be information disclosed to that Department under sub-section (3)(*a*) of that section.

(2) Where for the purpose of evaluating information notified under Regulation 4, 5 or 6, the Executive or the Department of the Environment discloses that information to some other person, that other person shall not use that information for any purpose except a purpose of the Executive or of the Department, as the case may be, and before disclosing any such information the Executive or the Department, as the case may be, shall inform that other person of his obligations under this paragraph.

(3) Where a person making a notification under Regulation 4, 5 or 6 indicates in it that certain information is commercially sensitive and should not be disclosed to any person other than the Executive or the Department of the Environment, full justification for that indication shall be given and in such a case the Executive or the Department, as the case may be, shall, before disclosing that information to any other person, inform the person making the notification that it intends so to do, except that nothing in this paragraph shall apply to the following information, namely:—

(a) the trade name of the substance;

(b) the physico-chemical data concerning the substance which is referred to in paragraph 3 of Schedule 1;

(**a**) 1972 c. 68.

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

(d) the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests; and

(e) the recommended methods and precautions referred to in paragraph 2.3 of Schedule 1 and the emergency measures referred to in paragraphs 2.4 and 2.5 of that Schedule.

Tests under these Regulations to conform to the principles of good current laboratory practice

11.—(1) Where a manufacturer or importer requires tests to be carried out for the puposes of making a notification under Regulation 4, 5 or 6, he shall take all reasonably practicable steps to ensure that those tests are carried out in accordance with the principles of good current laboratory practice and where such tests are carried out at a laboratory not under his control, he shall inform that laboratory that the tests are required for the purposes of making a notification under these Regulations before those tests are commenced.

(2) A person having control of a laboratory in which tests are carried out for the purposes of these Regulations shall ensure that those tests are carried out in accordance with the principles of good current laboratory practice.

(3) In any proceedings for an offence under paragraph (2), it shall be a defence for any person to prove either—

(a) that he did not know and could not reasonably be expected to have known, at the time that the tests were carried out that they were required for the purposes of these Regulations; or

(b) that he had taken all reasonable precautions and had exercised all due diligence to avoid the commission of that offence.

Certificates of exemption for certain substances supplied for use as pesticides

12. The Minister of Agriculture, Fisheries and Food or the Executive may, by a certificate in writing, exempt any manufacturer or importer of a new substance from all or any of the requirements or prohibitions imposed by these Regulations in relation to the supply of that substance exclusively for use as or in a pesticide if the substance concerned is subject to an approval procedure for pesticides containing notification requirements which are, in the opinion of the Minister or the Executive as the case may be, at least equivalent to the requirements of these Regulations and any such certificate may be granted subject to conditions and to a limit of time and may be revoked by the Minister or the Executive as the case may be by a certificate in writing at any time.

Regulation of unnotified substances

13.—(1) Where a new substance is required to be notified under Regulation 4, the importation into the United Kingdom of that substance (whether or not that importation is made from a member State or from outside the European Communities) is prohibited unless it has been duly notified in accordance with that Regulation.

(2) Where the Executive has reasonable cause to believe that a manufacturer

or importer has in his possession a new substance to which these Regulations apply which he has manufactured or imported, as the case may be, and which has not been duly notified in accordance with Regulation 4 or Article 6(1) of the Directive, it may by notice in writing prohibit—

(a) that manufacturer from supplying or disposing of the substance; or

(b) that importer from supplying, using or disposing of the substance,

until 45 days after it has been duly notified.

Enforcement

14.—(1) In as far as any provision of these Regulations is made under section 2(2) of the European Communities Act 1972, that provision shall be enforced as if it were a health and safety regulation made under section 15 of the 1974 Act and, subject to Regulation 10(1), the provisions of the 1974 Act (including the provisions relating to the approval of codes of practice and the use of approved codes of practice in criminal proceedings) and any health and safety regulations made under it shall apply to that provision as they apply to health and safety regulations except that any contravention of Regulation 13(1) shall not be punishable as a contravention of health and safety regulations but shall be punishable under the Customs and Excise Management Act 1979(**a**).

(2) Notwithstanding the provisions of the Health and Safety (Enforcing Authority) Regulations 1977(**b**), but subject to paragraph (1), the enforcing authority for these Regulations shall be the Executive.

Defence in proceedings for the contravention of certain Regulations

15. It shall be a defence in proceedings against any person for an offence consisting of a contravention of Regulation 4(3)(*b*), 4(4)(*c*) or 6(1) for that person to prove that, at the time the proceedings were commenced—

(a) an improvement notice under section 21 of the 1974 Act relating to the contravention had not been served on him; or

(b) if such notice had been served on him—

(i) the period for compliance had not expired, or

(ii) he had appealed against the notice and that appeal had not been dismissed or withdrawn.

Information supplied to the Executive to be in the English language

16. Where under these Regulations any information is required to be supplied to the Executive, that information shall be in the English language.

Transitional Provision

17. Until 26th May 1983 it shall be a sufficient compliance with Regulation 4(1) if the manufacturer or importer of a new substance—

(**a**) 1979 c. 2.
(**b**) S.I. 1977/746, amended by S.I. 1980/1744.

(a) before supplying the substance informs the Executive of the date on which he intends to supply it; and

(b) notifies it in accordance with that Regulation by 11th April 1983.

Signed by order of the Secretary of State.

David Waddington,
Joint Parliamentary Under Secretary of State,
Department of Employment.

20th October 1982.

Giles Shaw,
Joint Parliamentary Under Secretary of State,
Department of the Environment.

20th October 1982.

SCHEDULE 1 Regulations 4(1) and (3) and 10(3)

(Which reproduces the requirements of Annex VII to the Directive)

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER REFERRED TO IN REGULATION 4(1)(*a*)

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 of 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**
..... N/m (..... °C)

3.6. **Water solubility**
..... mg/litre (..... °C)

3.7. **Fat solubility**
Solvent—oil (to be specified)
..... mg/100g 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 Part I of Schedule 2, paragraph 2(c), (*d*) and (*e*))

3.11. **Explosive properties** (within the meaning of the definition given in Part I of Schedule 2, paragraph 2(*a*))

3.12. **Auto-flammability**
..... °C

3.13. **Oxidizing properties** (within the meaning of the definition given in Part I of Schedule 2, paragraph 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 .....
Species selected (one or more) .....

5.1.2. Acute toxicity for daphnia
LC_{50} ..... (ppm)
Duration of exposure .....

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 .....

Note: (This note does not form part of Annex VII)

1. A reference in this Schedule to a substance being placed on the market or to be marketed shall be treated as a reference to that substance being supplied or to be supplied as the case may be.

2. "IUPAC nomenclature" means the nomenclature of the International Union of Pure and Applied Chemistry details of which are obtainable from the Chemical Nomenclature Abstracts Service, Laboratory of the Government Chemist, Stamford Street, London E.1.

3. "CAS No." means the number assigned by the Chemical Abstracts Service details of which are obtainable from the United Kingdom Chemical Information Service, University of Nottingham, Nottingham.

SCHEDULE 2 Regulations 2(1) and 4(1)

PART I

(Which reproduces the provisions of Article 2(2) of the Directive)

DEFINITIONS OF SUBSTANCES WHICH ARE DANGEROUS

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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) 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;

(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 contacted 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.

PART II

(Which reproduces the requirements of Part I of Annex VI to the Directive)

CRITERIA FOR CLASSIFICATION AS VERY TOXIC, TOXIC OR HARMFUL

Substances shall be classified as "very toxic", "toxic" or "harmful" in accordance with the following criteria:—

(a) classification as very toxic, toxic or harmful shall be effected by determining the acute toxicity of the commercial substance 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 2000	>400 to 2000	>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 produce other effects, the substances shall be classified according to the magnitude of these effects.

SCHEDULE 3 Regulation 4(1)(*c*)(ii)

(Which reproduces the requirements of Article 16(2) of the Directive)

Labelling Data for Substances Which Are Dangerous

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.

Note: (This note does not form part of Article 16(2).)

For the purposes of this Schedule references to Annexes I to IV of the Directive may be treated as references to Schedules 1 to 4 respectively of The Packaging and Labelling of Dangerous Substances Regulations 1978(**a**).

(**a**) S.I. 1978/209, amended by S.I. 1981/792.

SCHEDULE 4 Regulation 4(3)

CATEGORIES OF SUBSTANCES SUBJECT TO REGULATION 4(3)

Column 1 Item	Column 2 Specification of new substance	Column 3 Conditions
1.	A new substance which is supplied solely for the purposes of commercial development to persons who have undertaken that the substance will be handled only by themselves and their employees and in particular will not be made available to members of the public.	(a) The Executive has been supplied with the information specified in the following paragraphs of Schedule 1— (i) paragraph 1 (identity), and (ii) paragraph 2.2 (quantity to be supplied), and a statement in accordance with Regulation 4(1)(*c*) (recommendations for classification and labelling). (b) A statement has been supplied to the Executive that the supplier or the importer of the substance has received an undertaking from all persons who will be supplied with the substance that it will be used only by themselves or their employees. (c) The substance has not been supplied for commercial development for more than 1 year.
2.	A new substance which is a polymer and which contains less than 2% of any monomer which if it was in uncombined form would be a new substance.	None.
3.	A new substance which is supplied in any quantity solely for the purpose of testing to determine its properties in accordance with these Regulations.	None.
4.	A new substance which is supplied in a quantity of less than one tonne in any period of twelve months by any manufacturer or importer for the purposes of research or analysis and intended solely for laboratories.	None.
5.	A new substance which is supplied in a quantity of less than one tonne in any period of twelve months otherwise than in accordance with item 4.	The Executive has been supplied with the information specified in the following paragraphs of Schedule 1— (i) paragraph 1 (identity), and (ii) paragraph 2.2 (quantity to be supplied), and a statement in accordance with Regulation 4(1)(*c*) (recommendations for classification and labelling).
6.	A substance which was notified by a previous manufacturer or importer in accordance with Regulation 4(1) or Article 6(1) of the Directive at least ten years before the date on which the manufacturer or importer intends to supply the substance.	The Executive has been supplied with the information specified in the following paragraphs of Schedule 1— (i) paragraph 1 (identity), (ii) paragraph 2 (information on the substance).

Regulation 6(2) SCHEDULE 5

(Which reproduces the requirements of Annex VIII to the Directive)

ADDITIONAL INFORMATION AND TESTS WHICH MAY BE REQUIRED FOR THE PURPOSES OF REGULATION 6(2)

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 the 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 Schedule 1 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 Daphnia magna (21 days, this 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 of the Directive.

- 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; this 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 of the Directive.

- 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 Schedule 1, 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 1000 tonnes per year or a total of 5000 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 physiochemical 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.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

1. These Regulations implement as respects Great Britain the provisions relating to the notification of substances of the Council Directive 79/831/EEC ("the Directive") amending for the sixth time Council Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances.

2. The Regulations impose a duty on any manufacturer or importer of a new substance to notify to the Health and Safety Executive ("the Executive") the particulars about the substance, including particulars specified in Schedule 1, before he supplies that substance in a quantity of one tonne or more in any period of 12 months. The Regulations also provide for more limited notification requirements where certain new substances are supplied in quantities of less than one tonne or for experimental purposes. A new substance is, with certain specified exceptions, any substance except a substance which had been supplied to any person in a member State of the European Communities between 1 January 1971 and 18 September 1981.

3. The Regulations require the manufacturer or importer of a substance which he has notified to notify the Executive of any subsequent change of circumstances which might affect the particulars previously notified and also when the quantity he has supplied reaches specified amounts. Where additional testing is required to evaluate the risks created by the substance, the Regulations provide that the Executive may require the manufacturer or importer to carry out those tests.

4. Under the Regulations, any tests conducted on a new substance are required to conform to the principles of good current laboratory practice. The Regulations also prohibit the importation of any substance which is required to be, but has not been, duly notified and provide for the Executive to prohibit the supply or disposal of any such substance.

5. The Executive is required under the Regulations to send particulars of substances notified to the Department of the Environment, to the Commission of the European Communities and, subject to certain safeguards, to the competent authority of any other member State if that authority so requests. The Regulations restrict the use that may be made of particulars notified and in particular safeguard commercially sensitive information.

6. The Regulations make provision for enforcement and contain a transitional provision which allows unnotified new substances to be supplied, subject to outline notification only, for six months after the Regulations come into operation.

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