1994 No. 6

HEALTH AND SAFETY

Notification of New Substances Regulations (Northern Ireland) 1994

Made . . . . . *12th January 1994*

Coming into operation . . *28th February 1994*

ARRANGEMENT OF REGULATIONS

PART III

RIGHTS AND DUTIES OF THE COMPETENT AUTHORITY

PART IV

DISCLOSURE OF INFORMATION

PART V

MISCELLANEOUS AND GENERAL

The Department of Economic Development, being a Department designated by the European Communities (Designation) (No. 3) Order 1981(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to measures relating to the notification and control of substances, in exercise of the power conferred on it by the said section 2(2) and being the Department concerned(**c**) in exercise of the powers conferred by

(**a**) S.I. 1981/1536
(**b**) 1972 c. 68
(**c**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)

Articles 17(1), (2), (3), (4) and (5), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (4) and (5), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**a**) and of every other power enabling it in that behalf, after consultation in accordance with Article 46(1) of that Order with the Health and Safety Agency for Northern Ireland and such other bodies as appeared to it to be appropriate, hereby makes the following Regulations:—

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances Regulations (Northern Ireland) 1994 and shall come into operation on 28th February 1994.

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the approved supply list" means the list described in regulation 4(1) of the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993(**b**);

"the competent authority" means—

(*a*) for Northern Ireland, the Department of the Environment and the Department acting jointly; or

(*b*) for Great Britain or another member State, the authority appointed in accordance with Article 16.1 of the Directive, and

unless the contrary intention appears, a reference to "the competent authority" shall be taken as a reference to the competent authority for Northern Ireland;

"controlled conditions" in relation to the use of a substance in "process-orientated research and development" or "scientific research and development" means the use of that substance under conditions which are under the control of the person undertaking that process-orientated research and development or scientific research and development, as the case may be;

"dangerous substance" means a substance which is in one of the categories of danger referred to in Column 1 of Part I of Schedule 1, having characteristic properties described in the corresponding entry in Column 2 of that Schedule and further described in Part II of that Schedule;

"the Department" means the Department of Economic Development;

(**a**) S.I. 1978/1039 (N.I. 9)
(**b**) S.R. 1993 No. 412

"the Directive" means Council Directive No. 67/548/EEC, relating to the classification, packaging and labelling of dangerous substances(**a**) as amended in particular for the seventh time by Council Directive No. 92/32/EEC(**b**);

"EINECS" means the European Inventory of Existing Commercial Chemical Substances(**c**);

"ELINCS" means the European List of Notified Chemical Substances(**d**);

"the Executive" means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974(**e**);

"importer" means a person who imports a new substance into the European Communities' customs territory;

"IUPAC" means the International Union of Pure and Applied Chemistry;

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

"monomer unit" means the reacted form of a monomer in a polymer;

"new substance" means any substance except a substance listed in EINECS;

"notification" means the documents with the requisite information sent to the competent authority in pursuance of regulation 4 or 6—

(*a*) in the case of a new substance manufactured within the European Communities, by the manufacturer who places the substance either alone or in a preparation on the market; or

(*b*) in the case of a new substance manufactured outside the European Communities—

(i) by any person established in the European Communities who is responsible for placing that substance either alone or in a preparation on the market, or

(ii) by the sole representative of its manufacturer;

"placing on the market" in relation to a substance or preparation means supplying that substance or preparation, or making it available to another person within the European Communities and includes importation of the substance;

"polymer" means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and consisting of less than a simple weight majority of molecules of the same molecular weight; such molecules being distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units;

(**a**) O.J. No. L196, 16.8.67, p. 1 (O.J./S.E. 1967 p. 234)
(**b**) O.J. No. L154, 5.6.92, p. 1
(**c**) O.J. No. C146A, 15.6.90, p. 1
(**d**) O.J. No. C130, 10.5.93, p. 1
(**e**) 1974 c. 37

"preparation" means any mixture or solution of two or more substances;

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

"scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions including the determination of intrinsic properties, performance and efficacy as well as scientific investigation relating to product development;

"sole representative", in relation to a substance manufactured outside the European Communities, means a person established in the European Communities who has been appointed by the manufacturer of the substance for the purpose of notifying the substance;

"substance no longer polymer" means—

(*a*) a substance which had been placed on the market before 31st October 1993; and

(*b*) had not been notified under the Notification of New Substances Regulations (Northern Ireland) 1985(**a**) as then in operation by reason that it was reasonably considered by the person placing the substance on the market to be a polymer;

"substance" means a chemical element or compound in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

(2) The Interpretation Act (Northern Ireland) 1954(**b**) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

Application

3.—(1) Subject to paragraphs (2) and (3), these Regulations shall apply in relation to all new substances that are placed on the market either alone or in a preparation.

(2) These Regulations shall not apply in relation to—

(*a*) a new substance which is placed on the market exclusively as, or exclusively for use as an active ingredient in—

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

(**a**) S.R. 1985 No. 63, as amended by S.R. 1986 No. 188 and S.R. 1991 No. 472
(**b**) 1954 c. 33 (N.I.)
(**c**) 1968 c. 67

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

(*b*) a new substance which is placed on the market exclusively as, or exclusively for use in, food within the meaning of Article 2(2) of the Food Safety (Northern Ireland) Order 1991(**a**) including any additives and flavourings;

(*c*) a new substance which is placed on the market exclusively as, or exclusively for use in, an animal feeding stuff within the meaning of the Feeding Stuffs Regulations (Northern Ireland) 1992(**b**) including any additives;

(*d*) a new substance which is placed on the market exclusively as or in, or exclusively for use as an active ingredient in, a plant protection product covered by Council Directive No. 91/414/EEC(**c**) concerning the placing of Plant Protection Products on the market;

(*e*) a radioactive substance within the meaning of regulation 2(1) of the Ionising Radiations Regulations (Northern Ireland) 1985(**d**);

(*f*) a substance in the form of waste which is covered by Council Directive No. 91/156/EEC(**e**) or Council Directive No. 91/689/EEC(**f**);

(*g*) a new substance which is placed on the market exclusively as or in a cosmetic product within the meaning of the Cosmetic Products (Safety) Regulations 1989(**g**);

(*h*) subject to Council Regulation EC 2455/92(**h**) on the export notification and information exchange of dangerous substances, a new substance intended exclusively for export to a country which is not a member State;

(*i*) a new substance which is a substance no longer polymer; or

(*j*) a substance to which the Explosive Acts (Northern Ireland) 1875 to 1970(**i**) or the Explosives (Northern Ireland) Order 1972(**j**) applies.

(3) Regulations 4 and 6 shall not apply to a new substance which has been duly notified by its manufacturer or other person responsible for placing it on the market in accordance with Article 7 or 8 of the Directive in Great Britain or another member State.

(**a**) S.I. 1991/762 (N.I. 7)
(**b**) S.R. 1992 No. 270, as amended by S.R. 1993 No. 349
(**c**) O.J. No. L230, 19.8.91, p. 1
(**d**) S.R. 1985 No. 273
(**e**) O.J. No. L75, 26.3.91, p. 32
(**f**) O.J. No. L377, 31.12.91 p. 20
(**g**) S.I. 1989/2233
(**h**) O.J. No. L251, 29.8.92, p. 13
(**i**) 1875 c. 17; 1924 c. 5 (N.I.) 1970 c. 10 (N.I.)
(**j**) S.I. 1972/730 (N.I. 3)

PART II

NOTIFICATIONS

Full notifications

4. Subject to regulations 6 and 7, a notifier shall not place a new substance on the market in a total quantity of one tonne or more per year unless he has sent to the competent authority a notification including—

(*a*) a technical dossier supplying the information necessary for evaluating the foreseeable risk, whether immediate or delayed, which the substance may create for human health and the environment and containing all available relevant data for this purpose and including at least the information and results of the tests referred to in Part A of Schedule 2 together with a detailed and full description of the studies conducted or bibliographic references to them;

(*b*) a certificate in writing from the body which carried out the tests for the purpose of the technical dossier stating that those tests were carried out in accordance with the principles of good laboratory practice referred to in regulation 14(1);

(*c*) a declaration concerning the unfavourable effects of the substance in terms of the various foreseeable uses of the substance;

(*d*) if the substance is a dangerous substance, proposals for the purposes of the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993 for—

(i) the classification and labelling of the substance for supply, and

(ii) the safety data sheet referred to in regulation 6 of those Regulations;

(*e*) in the case of a substance manufactured outside the European Communities, where appropriate, a statement by the manufacturer that the notifier has been appointed, for the purpose of sending to the competent authority a notification of the substance in question, as his sole representative and that he has informed all the importers of the same substance manufactured by him of the name of the sole representative; and

(*f*) if so desired, a statement that the notifier requests, on reasoned grounds, that the notification be exempted from the provisions of regulation 13 for a period which shall not exceed one year from the date of the notification.

Requirements for further testing for substances notified under regulation 4

5.—(1) Any notifier of a substance already notified under regulation 4 shall inform the competent authority—

(*a*) when the quantity of the substance placed on the market reaches 10 tonnes per year from a single manufacturer or when the total quantity of substance reaches 50 tonnes per manufacturer; the competent authority may then require some or all of the additional tests, studies

or both as appropriate laid down in Schedule 3 at level 1, to be carried out within the time limit that the competent authority shall determine;

(*b*) when the quantity of the substance placed on the market reaches 100 tonnes per year from a single manufacturer or when the total quantity of the substance reaches 500 tonnes per manufacturer; the competent authority shall then require the additional tests, studies or both as appropriate laid down in Schedule 3 at level 1, to be carried out within the time limit that the competent authority shall determine, unless the notifier can give good reason why a given test or study is not appropriate or that an alternative test or study would be preferable;

(*c*) when the quantity of the substance placed on the market reaches 1,000 tonnes per year from a single manufacturer or when the total quantity of the substance reaches 5,000 tonnes per manufacturer; the competent authority shall then draw up a programme of tests, studies or both as appropriate according to Schedule 3 at level 2 to be carried out by the notifier within the time limit determined by the competent authority.

(2) Where additional testing has been carried out, either in accordance with paragraph (1) or voluntarily, the notifier shall forthwith provide the competent authority with the results of those tests together with a certificate in writing from the person who carried out the tests stating that those tests were carried out in accordance with the principles of good laboratory practice referred to in regulation 14(1).

Reduced notification requirements for substances placed on the market in quantities of less than one tonne per year by a single manufacturer

6.—(1) Subject to the following paragraphs and regulation 7, a person responsible for placing a new substance on the market in a total quantity of less than one tonne per year from a single manufacturer shall not place that substance on the market unless he has sent to the competent authority a notification including a summary of—

(*a*) a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may create for human health and the environment and containing all available relevant data for this purpose and including at least the information and results of the tests referred to in Part B of Schedule 2; and

(*b*) all the other information referred to in sub-paragraphs (*b*) to (*f*) of regulation 4.

(2) Subject to paragraph (4), where the quantities to be placed on the market are below 100 kg per year from a single manufacturer, the person responsible for placing the substance on the market may restrict the information in the technical dossier referred to in paragraph (1)(*a*) to that provided for in Part C of Schedule 2, he shall also provide all the other information referred to in paragraph (1)(*b*) and this information shall be notified to the competent authority in summary form.

(3) At the request of the competent authority, the person responsible for placing the substance on the market shall provide it with the full information referred to in paragraph (1) or (2) as appropriate, together with a detailed and full description of the studies conducted or bibliographic references to them.

(4) Subject to paragraph (5) and the conditions set out in this paragraph, the following new substances shall be treated as having been notified under these Regulations—

(*a*) polymers except those containing in combined form 2 per cent or more of a new substance;

(*b*) subject to paragraph (6), substances placed on the market in quantities of less than 10 kg per year per manufacturer;

(*c*) substances placed on the market in quantities of less than 100 kg per year per manufacturer and intended solely for the purposes of scientific research and development on condition that the person placing the substance on the market maintains a record of the identity of the substance, labelling data and a list of customers in member States;

(*d*) substances placed on the market for the purposes of process-orientated research and development with a limited number of customers in quantities that are limited to those purposes, subject to the following conditions—

(i) the substance is duly notified within one year of its first having been placed on the market unless on reasoned grounds provided by the person responsible for placing the substance on the market the competent authority approves an extension for up to a further year,

(ii) the person responsible for placing the substance on the market has notified to the competent authority the following information about the substance, namely, identity, labelling data, and a justification for the quantity placed on the market,

(iii) the person responsible for placing the substance on the market has provided a list of the customers,

(iv) the person responsible for placing the substance on the market has provided an assurance that the substance or a preparation in which it is incorporated will only be handled by or on behalf of a customer listed pursuant to head (iii) in controlled conditions and will not be made available to the general public at any time, and

(v) the person responsible for placing the substance on the market satisfies any condition imposed by the competent authority, which shall be limited to requiring the information provided for in paragraph (1).

(5) In the case of any substance to which paragraph (4) applies and which on the basis of the information available might reasonably be expected to be very toxic, toxic, carcinogenic, toxic for reproduction or mutagenic, the person responsible for placing the substance on the market shall forthwith notify to the competent authority any appropriate information relating to paragraphs 2.3, 2.4 and 2.5 of Part A of Schedule 2, and, where available, any acute toxicity data.

(6) In the case of a substance to which paragraph (4)(*b*) applies, which on the basis of the information available might reasonably be expected to be dangerous for the environment and which is intended to be used outside physical containment, the person responsible for placing the substance on the market shall forthwith notify to the competent authority any appropriate information relating to paragraph 2.3 of Part C of Schedule 2.

(7) Substances to which paragraphs (1), (2) and (4) apply shall be packaged and labelled in accordance with the requirements of the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993 insofar as the notifier may reasonably be expected to be aware of their dangerous properties, and if it is not reasonably practicable to label the substances completely on the basis of tests carried out in accordance with Part A of Schedule 2, the label shall in addition to the label deriving from such tests carry the warning "Caution — substance not yet fully tested".

(8) A notifier who has sent to the competent authority a notification dossier in conformity with paragraph (2), shall before the quantity of the substance reaches 100 kg per year from a single manufacturer or a total quantity of 500 kg per manufacturer, provide the competent authority with the information necessary to complete the dossier to the level of Part B of Schedule 2.

(9) A notifier who has sent to the competent authority a notification dossier in conformity with paragraph (1), shall before the quantity of the substance reaches 1 tonne per year from a single manufacturer or a total quantity of 5 tonnes per manufacturer, send to the competent authority a full notification in conformity with regulation 4.

Notifications relating to polymers

7. Subject to regulation 6(4)(*a*), in relation to polymers the specific provisions relating to the information supplied in a technical dossier contained in a notification sent to the competent authority under regulation 4 or 6(1) or (2) shall be those set out in Part D of Schedule 2.

Placing of notified substances on the market

8.—(1) A substance notified in accordance with regulation 4 may, in the absence of any objection by the competent authority, be placed on the market no sooner than 60 days after receipt of a notification which is in conformity with the requirements of that regulation.

(2) If, within 60 days from receipt of the notification, the competent authority decides the notification is not in conformity with regulation 4, it shall inform the notifier in writing forthwith, and the substance shall only be placed on the market 60 days after receipt by the competent authority of the information necessary to bring the notification into conformity with that regulation.

(3) A substance notified in accordance with regulation 6(1) or (2) may, in the absence of any objection by the competent authority, be placed on the market no sooner than 30 days after receipt of a notification which is in conformity with the requirements of the relevant paragraph of regulation 6.

(4) If, within 30 days from receipt of the notification referred to in paragraph (3), the competent authority decides the notification is not in conformity with the relevant paragraph of regulation 6, it shall inform the notifier in writing forthwith, and the substance shall only be placed on the market 30 days after receipt by the competent authority of the information necessary to bring the notification into conformity with that paragraph.

(5) In the case of a notification made under regulation 6, if the competent authority has informed the notifier in writing that the notification has been accepted as in conformity with that regulation, the substance may be placed on the market no sooner than 15 days after receipt of the summary of the dossier by the competent authority.

(6) If a notification under regulation 4 or 6 has been accepted as conforming to the requirements of these Regulations, the competent authority shall forthwith advise the notifier of the official notification number which has been allocated to the notification.

Requirements for further information

9.—(1) Subject to paragraph (2), in relation to a substance already notified, the competent authority may in writing require further information, verification or confirmation tests concerning the substance or its transformation products within the time limit which it may specify.

(2) The competent authority may only require further information in accordance with paragraph (1) if—

(*a*) it is satisfied that the further information is reasonably required to evaluate the risks created by the substance to human health or the environment; or

(*b*) it is acting in accordance with a decision of the European Commission under Article 18(2) of the Directive.

(3) When further information has been obtained by the notifier in pursuance of paragraph (1), the notifier shall forthwith provide the competent authority with that information in writing.

(4) The information required under paragraph (1) may include requiring the information referred to in Schedule 3 earlier than required under regulation 5.

Follow-up information

10.—(1) The notifier of a substance already notified in accordance with regulation 4 or 6 shall inform the competent authority of—

(*a*) any change in the annual or total quantity of the substance placed on the European Communities' market, by him or in the case of a substance manufactured outside the European Communities for which the notifier has been designated as the sole representative of the manufacturer, by him and other importers whom he represents;

(*b*) new knowledge of which he may be aware of the effects of the substance on human health or the environment or both;

(*c*) new uses for the substance of which he may be aware;

(*d*) any change in the composition of the substance as given in paragraph 1.3 of Part A, B or C of Schedule 2 as appropriate; and

(*e*) any change in his status as manufacturer, importer or sole representative.

(2) Any importer of a new substance manufactured outside the European Communities who imports that substance under a notification made by a sole representative shall ensure that the sole representative is provided with up-to-date information on the quantity of the substance placed on the European Communities' market by that importer.

Notification of substances previously notified

11. In the case of a new substance which had originally been notified at least ten years previously, a subsequent notifier need not provide the information included in Part A, B or C of Schedule 2 with the exception of that specified in paragraphs 1 and 2 of the relevant Part.

Substances manufactured outside the European Communities

12.—(1) Subject to paragraph (2), where for a substance manufactured outside the European Communities—

(*a*) more that one notification exists for the same substance manufactured by the same manufacturer (whether to one or more competent authorities of member States); and

(*b*) the cumulative annual tonnage or the cumulative total tonnage determined by the European Commission and the competent authorities of the member States, on the basis of information notified under Articles 7(1), 8(1) and 14 of the Directive, exceeds for the first time any of the limits specified in regulation 5,

each notifier established in Northern Ireland shall carry out the additional testing required under paragraph (1) of regulation 5 and shall provide the competent authority with the results of those tests in accordance with paragraph (2) of that regulation.

(2) Where the manufacturer has appointed a sole representative, the obligation to comply with paragraph (1) shall not apply to previous notifiers other than the sole representative, and only to the sole representative if he is established in Northern Ireland.

(3) Where in accordance with paragraph (1), the obligation to carry out further testing falls upon one or more notifiers established in Northern Ireland, the competent authority shall inform each such notifier of the identities of other notifiers within the European Communities and draw attention to the collective responsibilities of notifiers under Article 11 of the Directive.

Further notification of the same substance and avoidance of duplication of testing on vertebrate animals

13.—(1) In the case of a substance that has already been notified under regulation 4, 6(1) or 6(2), the competent authority may agree that a subsequent notifier of that substance may, for the purposes of paragraphs 3, 4

and 5 of Part A or B of Schedule 2 or paragraphs 3 and 4 of Part C of Schedule 2, refer to the results of tests, studies or both as appropriate included in the technical dossier sent by the previous notifier if—

(*a*) the subsequent notifier can provide evidence that the substance intended to be notified is the same as the one previously notified, including the degree of purity and the nature of the impurities; and

(*b*) the previous notifier has given his consent in writing that such reference may be made.

(2) Without prejudice to paragraph (1), where a prospective notifier intends to notify a new substance to the competent authority under regulation 4, 6(1) or (2), he shall enquire of the competent authority as to—

(*a*) whether or not the substance that he intends to notify has already been notified to a competent authority of a member State; and

(*b*) the name and address of the previous notifier.

(3) Any enquiry made in accordance with paragraph (2) shall be supported by evidence that the prospective notifier has the intention to place the substance on the market and a statement of the quantities involved.

(4) Where—

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

(*b*) the substance had been notified previously; and

(*c*) the previous notifier had not requested an exemption from the provisions of this regulation in accordance with regulation 4(*f*), to which the competent authority has agreed,

after informing the previous notifier of its intention, the competent authority shall provide the prospective notifier with the name and address of the previous notifier.

(5) Where the competent authority has given the prospective notifier the name and address of the previous notifier in accordance with paragraph (4), those notifiers shall take all reasonable steps to reach an agreement to share information in accordance with paragraph (1) so as to avoid the duplication of testing on vertebrate animals.

(6) Where, notwithstanding the requirements of paragraph (5), the prospective notifier has failed to reach an agreement with the previous notifier, he shall forthwith inform the competent authority in writing and shall not commence testing on vertebrate animals within 30 days of the receipt of that information by the competent authority.

(7) Where, in accordance with paragraph (5), notifiers have agreed to share information to avoid the duplication of testing on vertebrate animals, and additional testing is required under regulation 5, they shall take all reasonable steps to reach agreement to share the information required by that regulation.

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

14.—(1) Where a notifier requires tests to be carried out for the purposes of making a notification under regulation 4, 5 or 6, he shall take all reasonable steps to ensure that those tests are carried out in accordance with the principles of good laboratory practice referred to in Article 1 of Council Directive No. 87/18/EEC(**a**) on the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

(2) Where the tests are carried out at a laboratory not under the control of the notifier, the notifier shall, before the tests are commenced, inform the person having control of that laboratory that the tests are required for the purposes of these Regulations.

(3) A person having control of a laboratory in which tests are carried out for the purposes of these Regulations shall, if it be the case, provide the notifier at his request with a certificate in writing that the tests were conducted in accordance with the principles of good laboratory practice.

(4) The principles of good laboratory practice referred to in paragraph (1) are specified in Annex B of Commission Directive 90/18/EEC(**b**) adapting to technical progress the Annex to Council Directive 88/320/EEC(**c**) on the inspection and verification of Good Laboratory Practice.

Notifications and reports to be in English

15. Notifications and reports required under these Regulations shall be in English.

PART III

RIGHTS AND DUTIES OF THE COMPETENT AUTHORITY

Risk assessments

16.—(1) In the case of a substance notified under regulation 4 or 6(1) or (2), the competent authority shall carry out an assessment of the real and potential risks created by the substance to human health and the environment in accordance with the general principles referred to in Article 3(2) of the Directive and that assessment shall include recommendations—

(*a*) on the most appropriate method for testing the substance; and

(*b*) where appropriate, on measures which will enable the risks to human health and the environment in relation to the placing on the market of the substance to be lessened.

(2) The assessment carried out in accordance with paragraph (1) shall be reviewed in the light of any additional information becoming available to the competent authority, in particular any information provided in accordance with regulation 5, 6(8) or (9), 9 or 10.

(a) O.J. No. L15, 17.1.87, p. 29
(b) O.J. No. L11, 13.1.90, p. 37
(c) O.J. No. L145, 11.6.88, p. 35

Information to be sent by the competent authority to the European Commission

17.—(1) When the competent authority has received a notification under regulation 4 or 6(1), information on additional testing under regulation 5 or 6(8) or (9) or additional information under regulation 9 or 10, it shall forthwith send to the European Commission a copy of that information or, in each case, a summary thereof.

(2) Where the competent authority has required additional tests, studies or both as appropriate in accordance with regulation 5 or further information from the notifier in accordance with regulation 9(1), the competent authority shall notify the European Commission of the tests chosen in pursuance of the regulation concerned, the reasons for the choice, the results and where appropriate an assessment of those results.

(3) In the case of information received in pursuance of regulation 6(4), the competent authority shall send to the European Commission such elements of that information as would, in its opinion, be of common interest to the Commission and other competent authorities.

(4) The competent authority shall send to the European Commission a copy of any risk assessment carried out in pursuance of regulation 16 or a summary thereof as soon as it becomes available.

(5) The competent authority shall—

(*a*) give effect to any decision of the European Commission under Article 18.2 of the Directive addressed to it;

(*b*) in a case where the competent authority has furnished a summary of the dossier or further information in accordance with paragraphs (1) to (4), allow the European Commission or another competent authority access to the full dossier and information; and

(*c*) have regard to suggestions made by other competent authorities for further testing or information made in accordance with Article 18.2 of the Directive.

PART IV

DISCLOSURE OF INFORMATION

Disclosure of information provided under Part II

18.—(1) Subject to paragraphs (2) to (4), insofar as any provision in Part II is made under section 2(2) of the European Communities Act 1972, information notified under that provision shall be treated as relevant information for the purposes of Article 30 of the 1978 Order.

(2) Where a person sending a notification in pursuance of Part II indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and the competent authority shall decide which information shall be kept confidential and shall inform the notifier of the decision.

(3) Nothing in paragraph (2) shall apply to the following information which, where applicable, cannot be kept confidential—

(*a*) the trade name of the substance;

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

(*c*) the physico-chemical data concerning the substance provided in paragraph 3 of Part A, B or C (as appropriate) of Schedule 2;

(*d*) the possible ways of rendering the substances harmless;

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

(*f*) if essential to the classification and labelling for the purpose of introducing the substance into Annex I to the Directive, the degree of purity of the substance and the identity of any impurity or additive which is known to be a dangerous substance;

(*g*) the recommended methods and precautions referred to in paragraph 2.3 and the emergency measures referred to in paragraph 2.4 or 2.5 of Part A, B or C (as appropriate) of Schedule 2;

(*h*) in the case of a substance which is a dangerous substance, the information to be contained in the safety data sheet provided for the purposes of regulation 6 of the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993; and

(*i*) in the case of a substance listed in the approved supply list, analytical methods that make it possible to detect the substance when discharged into the environment and to determine the direct exposure of humans.

(4) If the manufacturer, an importer or the notifier himself subsequently discloses previously confidential information he shall inform the competent authority accordingly and such information shall no longer be treated as being confidential for the purposes of these Regulations.

Treatment of confidential information

19.—(1) Information which the competent authority has agreed shall be kept confidential shall not be disclosed except—

(*a*) with the consent of the notifier;

(*b*) to another competent authority or to the European Commission;

(*c*) to the extent necessary to evaluate the notification and carry out the risk assessment pursuant to regulation 16(2); or

(*d*) for the purpose of legal proceedings.

(2) The competent authority shall inform the other competent authorities and the European Commission of what information it has agreed shall be kept confidential.

(3) Where the competent authority receives information which another competent authority has agreed shall be kept confidental, it shall also treat that information as confidential and shall not disclose it except in accordance with paragraph (1).

Entry of substances in the European List of Notified Chemical Substances

20.—(1) A person who makes a notification under regulation 4 or 6(1) or (2) may at the time of making the notification—

(*a*) in the case of a substance that is not a dangerous substance, request the competent authority to require the European Commission to enter it in ELINCS in the form of its trade name for the maximum of 3 years from the date of the entry; or

(*b*) in the case of a substance which is a dangerous substance, request the competent authority to require the European Commission to enter it in ELINCS in the form of its trade name until such time as that substance has been introduced into Annex I of the Directive;

and in either case the competent authority shall accede to that request.

(2) In a case in which—

(*a*) a request had been made in accordance with sub-paragraph (*a*) of paragraph (1); and

(*b*) the notifier considers that the publication of the chemical name in the IUPAC nomenclature itself could reveal information concerning the commercial exploitation or manufacture of the substance,

the notifier may request the competent authority to require the European Commission to enter it in ELINCS in the form of its trade name for so long as the competent authority sees fit, and in such a case the competent authority shall accede to that request unless it considers that the publication of the chemical name in the IUPAC nomenclature itself could not reveal information concerning the commercial exploitation or manufacture of the substance.

PART V

MISCELLANEOUS AND GENERAL

Enforcement and civil liability

21.—(1) Insofar as any provision of regulations 4 to 20 is made under section 2(2) of the European Communities Act 1972(**a**)—

(*a*) subject to paragraph (2), the provisions of the 1978 Order which relate to the approval of codes of practice and their use in criminal proceedings, enforcement and offences shall apply to that provision as if that provision had been made under Article 17 of that Order; and

(*b*) breach of any duty imposed by any provision of those regulations shall confer a right of action in civil proceedings, if that breach of duty causes damage.

(2) Notwithstanding regulation 4 of the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1993(**b**), the enforcing authority for these Regulations shall be the Department.

(**a**) 1972 c. 68
(**b**) S.R. 1993 No. 147

Prohibition of placing on the market of unnotified substances

22. Where the Department has reasonable cause to believe that a person has or is likely to have in his possession a new substance to which these Regulations apply and which has not been duly notified in accordance with regulation 4 or 6 or Article 7.1 of the Directive it may, by notice in writing prohibit that person from placing that substance on the market or disposing of it until 60 days, or in the case of a substance that is required to be notified under regulation 6 30 days, after in either case it has been duly notified.

Exemption certificates

23.—(1) Subject to paragraph (2) and to any provision imposed by the European Communities in respect of the notification, control and regulation of substances, the Department may, by a certificate in writing, exempt any person or class of persons, substance or class of substances from all or any of the requirements or prohibitions imposed by these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.

(2) The Department shall not grant any such exemption unless, having regard to the circumstances of the case and in particular to—

(*a*) the conditions, if any, that it proposes to attach to the exemption; and

(*b*) any requirements imposed by or under any statutory provision which applies to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption or the protection of the environment will not be prejudiced in consequence of it.

Fees for notifications etc.

24. The fee fixed by Column 2 of Schedule 4 shall be payable in advance by a notifier to the Department in relation to any matter referred to in the corresponding entry in Column 1 of that Schedule.

Revocations, amendments and transitional provisions

25.—(1) The following Regulations are hereby revoked—

(*a*) the Notification of New Substances Regulations (Northern Ireland) 1985(**a**);

(*b*) the Notification of New Substances (Amendment) Regulations (Northern Ireland) 1986(**b**); and

(*c*) the Notification of New Substances (Amendment) Regulations (Northern Ireland) 1991(**c**).

(2) The Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993 shall be amended as follows—

(*a*) in regulation 5(3)—

(**a**) S.R. 1985 No. 63
(**b**) S.R. 1986 No. 188
(**c**) S.R. 1991 No. 472

(i) for "the Notification of New Substances Regulations (Northern Ireland) 1985" there shall be substituted "the Notification of New Substances Regulations (Northern Ireland) 1994 (S.R. 1994 No. 6)", and

(ii) for "regulation 4(1)", there shall be substituted "regulation 4 or 6(1) or (2)"; and

(*b*) in regulation 19(3) at the end (but before the full stop) there shall be added the words "and as if the maximum period of imprisonment on summary conviction specified in subsection (5) thereof were 3 months instead of 6 months"; and

(*c*) regulation 20(1) shall be revoked.

(3) After 28th February 1994, any notification made under the Notification of New Substances Regulations (Northern Ireland) 1985 as in operation immediately before that date shall be treated as a notification made under these Regulations, and the requirements of these Regulations shall apply to any such notification as they apply to a notification made after that date.

(4) Between 28th February 1994 and 31st August 1994, it shall be a sufficient compliance with these Regulations, if a notifier provides such information (if any) about a new substance as was required by the Notification of New Substances Regulations (Northern Ireland) 1985 as in operation immediately before the coming into operation of these Regulations, and other additional information as required under these Regulations by 31st August 1994.

(5) In the case of a new substance which was not required to be notified under the Notification of New Substances Regulations (Northern Ireland) 1985 as for the time being in operation by virtue of a certificate of exemption granted under regulation 12 of those Regulations, it shall be a sufficient compliance with these Regulations if the notifier notifies the substance in accordance with these Regulations before 31st August 1994.

Sealed with the Official Seal of the Department of Economic Development on 12th January 1994.

(L.S.) *Philip B. Strong*
Assistant Secretary

SCHEDULE 1 Regulation 2(1)

Characteristic Properties of Dangerous Substances

PART I

CATEGORIES OF DANGER AND CHARACTERISTIC PROPERTIES

Column 1 *Category of danger*	Column 2 *Property*
Physico-Chemical Properties	
Explosive	Solid, liquid, pasty or gelatinous substances which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which under defined test conditions detonate, quickly deflagrate or upon heating explode when partially confined.
Oxidizing	Substances which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances.
Extremely flammable	Liquid substances having an extremely low flash point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.
Highly flammable	The following substances— (*a*) substances which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, (*b*) solid substances 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, (*c*) liquid substances having a very low flash point, or (*d*) substances which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities.
Flammable	Liquid substances having a low flash point.
Health Effects	
Very toxic	Substances which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.
Toxic	Substances which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.

Column 1 *Category of danger*	Column 2 *Property*
Harmful	Substances which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.
Corrosive	Substances which, on contact with living tissues, may destroy them.
Irritant	Non-corrosive substances which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation.
Sensitizing	Substances which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance, characteristic effects are produced.
Carcinogenic	Substances which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.
Mutagenic	Substances which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.
Toxic for reproduction	Substances which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of non-heritable adverse effects in the progeny or the impairment of male or female reproductive functions or capacity.
Environment	
Dangerous for the environment	Substances which, were they to enter into the environment, would present or may present an immediate or delayed danger for one or more compartments of the environment.

PART II

CRITERIA FOR THE CATEGORIES OF DANGER "VERY TOXIC", "TOXIC" AND "HARMFUL"

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

(*a*) Where the acute toxicity in animals of the commercial substance has been determined by a method which permits estimation of the LD_{50} or LC_{50}, classification as very toxic, toxic or harmful shall be effected using the following parameters as reference values:

Category of danger	LD_{50} *Oral in rat mg/kg body weight*	LD_{50} *Dermal in rat or rabbit mg/kg body weight*	LD_{50} *Inhalation in rat mg/litre/4 hours*	
			gases and vapours	*aerosols and particulars*
Very toxic	≤ 25	≤ 50	≤ 0.5	≤ 0.25
Toxic	> 25 to 200	> 50 to 400	> 0.5 to 2	> 0.25 to 1
Harmful	> 200 to 2,000	> 400 to 2,000	> 2 to 10	> 1 to 5

(*b*) Where the acute oral toxicity in animals of the commercial substance has been determined using the fixed dose procedure, classification as very toxic, toxic or harmful shall be effected on the basis of the discriminating dose. This is the dose level which produces evident toxicity, but no mortality, and is one of four fixed dose levels (5, 50, 500 or 2,000 mg/kg body weight). "Evident toxicity" is a term used to describe signs of toxicity following administration of a test substance, which are of a severity such that administration of the next higher fixed dose level would be expected to result in mortality. As this test method is based on the selection of doses from a series of fixed doses, it is inappropriate to give values for classification. The following parameters are used as reference values:

Category	*Discriminating dose (mg/kg body weight)*
Very toxic	< 5
Toxic	5 to < 50
Harmful	50 to < 500

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

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

SCHEDULE 2 Regulations 4, 6(1) and (2) and 7

(This Schedule sets out the provisions of Annex VII to the Directive)

Information Required in the Technical Dossiers

PART A

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER FOR A FULL NOTIFICATION UNDER REGULATION 4

Tests under this Part shall be according to methods recognised and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the European Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and addresses of the importers who will be bringing the substance into the European Communities.

1. **IDENTITY OF THE SUBSTANCE**

1.1 **Name**

1.1.1 Names in the IUPAC nomenclature

1.1.2 Other names (usual name, trade name, abbreviation)

1.1.3 CAS number and CAS name (if available)

1.2 **Molecular and structural formula**

1.3 **Composition of the substance**

1.3.1 Degree of purity (%)

1.3.2 Nature of impurities, including isomers and by-products

1.3.3 Percentage of (significant) main impurities

1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude:... ppm; ...%

1.3.5 Spectral data (UV, IR, NMR or mass spectrum)

1.3.6 Chromatographic data (HPLC, GC)

1.4 **Methods of detection and determination**

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

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow

detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0 Production

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

2.0.1 Technological process used in production

2.0.2 Exposure estimate related to production:

— working environment,
— environment

2.1 Proposed uses

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

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

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

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

— working environment,
— environment

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

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

2.1.2 Fields of application with approximate breakdown:

— industries,
— farmers and skilled trades,
— use by the public at large

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

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

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

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

— the first calendar year,
— the following calendar years

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

2.2.2 Production and/or imports, broken down in accordance with 2.1.1. and 2.1.2 expressed as a percentage:
— the first calendar year,
— the following calendar years

2.3 **Recommended methods and precautions concerning:**

2.3.1 Handling

2.3.2 Storage

2.3.3 Transport

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

2.3.5 Other dangers, particularly chemical reaction with water

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

2.4 **Emergency measures in the case of accidental spillage**

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

2.6 **Packaging**

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0 **State of the substance at 20°C and 101.3 kPa**

3.1 **Melting point**

3.2 **Boiling point**

3.3 **Relative density**

3.4 **Vapour pressure**

3.5 **Surface tension**

3.6 **Water solubility**

3.8 **Partition coefficient n-octanol/water**

3.9 **Flash point**

3.10 **Flammability**

3.11 **Explosive properties**

3.12 **Self-ignition temperature**

3.13 **Oxidizing properties**

3.15 **Granulometry**

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, a test should be conducted to determine the particle size distribution of the substance as it will be marketed.

4. TOXICOLOGICAL STUDIES

4.1 Acute toxicity

For tests 4.1.1 to 4.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalative route.

4.1.1 Administered orally

4.1.2 Administered by inhalation

4.1.3 Administered cutaneously

4.1.5 Skin irritation

4.1.6 Eye irritation

4.1.7 Skin sensitization

4.2 Repeated dose

The route of administration should be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications the oral route is usually the preferred one.

4.2.1 Repeated dose toxicity (28 days)

4.3 Other effects

4.3.1 Mutagenicity

The substance shall be examined in two tests. One shall be a bacteriological (reverse mutation) test, with and without metabolic activation. The second shall be a non-bacteriological test to detect chromosome aberrations or damage. In the absence of contra-indications, this test should normally be conducted *in vitro*, both with and without metabolic activation. In the event of a positive result in either test, further testing according to the strategy described in Annex V to the Directive should be carried out.

4.3.2 Screening for toxicity related to reproduction

4.3.3. Assessment of the toxicokinetic behaviour of a substance to the extent that can be derived from base set data and other relevant information.

5. ECOTOXICOLOGICAL STUDIES

5.1 Effects on organisms

5.1.1 Acute toxicity for fish

5.1.2 Acute toxicity for daphnia

5.1.3 Growth inhibition test on algae

5.1.6 Bacteriological inhibition

In those cases where biodegradation may be affected by the inhibitory effect of a substance on the bacteria, a test for bacterial inhibition should be carried out prior to undertaking the biodegradation.

5.2 **Degradation**

— biotic,
— abiotic: If the substance is not readily biodegradable then consideration should be given to the need to carry out the following tests: hydrolysis as a function of pH.

5.3 **Absorption/desorption screening test**

6. **POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS**

6.1 **For industry/skilled trades**

6.1.1 Possibility of recycling

6.1.2 Possibility of neutralization of unfavourable effects

6.1.3 Possibility of destruction:

— controlled discharge,
— incineration,
— water purification station,
— others

6.2 **For the public at large**

6.2.1 Possibility of recycling

6.2.2 Possibility of neutralization of unfavourable effects

6.2.3 Possibility of destruction:

— controlled discharge,
— incineration,
— water purification station,
— others.

PART B

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER FOR A NOTIFICATION UNDER REGULATION 6(1)

Tests under this Part shall be according to methods recognised and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

In addition to the information requested below, member States may, if they consider it necessary for the risk assessment, require that the notifier provides the following additional information:

— vapour pressure,
— daphnia acute toxicity test.

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the European Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and addresses of the importers who will be bringing the substance into the European Communities.

1. **IDENTITY OF THE SUBSTANCE**

1.1 **Name**

1.1.1 Names in the IUPAC nomenclature

1.1.2 Other names (usual name, trade name, abbreviation)

1.1.3 CAS number and CAS name (if available)

1.2 **Molecular and structural formula**

1.3 **Composition of the substance**

1.3.1 Degree of purity (%)

1.3.2 Nature of impurities, including isomers and by-products

1.3.3 Percentage of (significant) main impurities

1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm; ...%

1.3.5 Spectral data (UV, IR, NMR or mass spectrum)

1.3.6 Chromatographic data (HPLC, GC)

1.4 **Methods of detection and determination**

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

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. **INFORMATION ON THE SUBSTANCE**

2.0 **Production**

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

2.0.1 Technological process(es) used in production

2.0.2 Exposure estimate related to production:

— working environment,
— environment

2.1 **Proposed uses**

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

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

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

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

— working environment,
— environment

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

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

2.1.2 Fields of application with approximate breakdown:

— industries,
— farmers and skilled trades,
— use by the public at large

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

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

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

— the first calendar year,
— the following calendar years

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

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

— the first calendar year,
— the following calendar years

2.3 **Recommended methods and precautions concerning:**

2.3.1 Handling

2.3.2 Storage

2.3.3 Transport

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

2.3.5 Other dangers, particularly chemical reaction with water

2.4 **Emergency measures in the case of accidental spillage**

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

2.6 **Packaging**

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.0 **State of the substance at 20°C and 101.3 kPa**

3.1 **Melting point**

3.2 **Boiling point**

3.6 **Water solubility**

3.8 **Partition coefficient n-octanol/water**

3.9 **Flash point**

3.10 **Flammability**

4. **TOXICOLOGICAL STUDIES**

4.1 **Acute toxicity**

For tests 4.1.1 to 4.1.2, one route of administration is sufficient. Substances other than gases should be treated by oral administration. Gases should be tested by inhalation.

4.1.1 Administered orally

4.1.2 Administered by inhalation

4.1.5 Skin irritation

4.1.6 Eye irritation

4.1.7 Skin sensitization

4.3 **Other effects**

4.3.1 Mutagenicity

The substance should be examined in a bacteriological (reverse mutation) test with and without metabolic activation.

5. **ECOTOXICOLOGICAL STUDIES**

5.2 **Degradation: biotic.**

PART C

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER FOR A NOTIFICATION UNDER REGULATION 6(2)

Tests under this Part shall be according to methods recognised and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

0. **IDENTITY OF MANUFACTURER AND THE NOTIFIER IF THESE ARE NOT THE SAME: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the European Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and addresses of the importers who will be bringing the substance into the European Communities.

1. **IDENTITY OF THE SUBSTANCE**

1.1 **Name**

1.1.1 Names in the IUPAC nomenclature

1.1.2 Other names (usual name, trade name, abbreviation)

1.1.3 CAS number and CAS name (if available)

1.2 **Molecular and structural formula**

1.3 **Composition of the substance**

1.3.1 Degree of purity (%)

1.3.2 Nature of impurities, including isomers and by-products

1.3.3 Percentage of (significant) main impurities

1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm; ...%

1.3.5 Spectral data (UV, IR, NMR or mass spectrum)

1.3.6 Chromatographic data (HPLC, GC)

1.4 **Methods of detection and determination**

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

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. **INFORMATION ON THE SUBSTANCE**

2.0 **Production**

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

2.0.1 Technological process(es) used in production

2.0.2 Exposure estimate related to production:

— working environment,
— environment

2.1 **Proposed uses**

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

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

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

2.1.1.2 Exposure estimate(s) related to the use of the substance (where known):

— working environment,
— environment

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

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

2.1.2 Fields of application with approximate breakdown:

— industries,
— farmers and skilled trades,
— use by the public at large

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

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

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

— the first calendar year,
— the following calendar years

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

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

— the first calendar year,
— the following calendar years

2.3 **Recommended methods and precautions concerning:**

2.3.1 Handling

2.3.2 Storage

2.3.3 Transport

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

2.3.5 Other dangers, particularly chemical reaction with water

2.4 **Emergency measures in the case of accidental spillage**

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

2.6 **Packaging**

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.0 **State of the substance at 20°C and 101.3 kPa**

3.9 **Flash point**

3.10 **Flammability**

4. **TOXICOLOGICAL STUDIES**

4.1 **Acute toxicity**

One route of administration is sufficient.
Substances other than gases should be tested by oral administration.
Gases should be tested by inhalation.

4.1.1 Administered orally

4.1.2 Administered by inhalation.

PART D

(The provisions set out in this Part were introduced into Annex VII of the Directive by Commission Directive 1993/105/EEC)(a)

INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER FOR A NOTIFICATION UNDER REGULATION 7

Without prejudice to the provisions of Article 3(1) of the Directive tests under this Part shall be according to methods recognised and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

A. For the purpose of this Part

— ''homopolymer'' is a polymer consisting of only one kind of monomer unit.

— ''copolymer'' is a polymer consisting of more than one kind of monomer unit.

— ''polymer for which a reduced test package is acceptable'', ''RTP polymer'', is a polymer that satisfies the criteria laid down in section C.2 of this Part.

— ''family of polymers'' is a group of polymers (either homopolymers or copolymers) with different number-average molecular weights or different compositions resulting from different ratios of monomer units. The difference in the number-average molecular weight or in the composition is determined not by unintentional process-related fluctuations but by deliberate alterations to the process conditions, the process itself remaining the same.

— ''M_n'' is the number-average molecular weight.

— ''MW'' is the molecular weight (of any particular molecule).

(a) O.J.No. L294, 30.11.93, p. 21

B. Family approach

To avoid unnecessary testing, grouping of polymers into families shall be allowed.

The concept consists of testing representative members of a family with:

— M_n variable for homopolymers or

— composition variable with M_n approximately constant for copolymers or

— for $M_n > 1000$, M_n variable with composition approximately constant for copolymers

In certain cases where there are dissimilarities in the effects seen in the representative members, depending on the M_n- or composition-range, additional testing of other representative members shall be required.

C. Information required for the technical dossier referred to in regulation 7

Appropriate available information on the properties of the monomer(s) may be taken into account for the assessment of the properties of the polymer.

C.1 **POLYMERS WITH STANDARD TEST PACKAGE**

C.1.1 **POLYMERS PLACED ON THE EUROPEAN COMMUNITIES' MARKET IN QUANTITIES OF ≥1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF ≥5 TONNES)**

In addition to the information and tests referred to in regulation 4, laid down in Part A of Schedule 2, the following polymer-specific information is required:

1. **IDENTITY OF THE SUBSTANCE**

1.2.1 Number-average molecular weight

1.2.2 Molecular weight distribution (MWD)

1.2.3 Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4 Indication of end groups and identity and frequency of reactive functional groups

1.3.2.1 Identity of non-reacted monomers

1.3.3.1 Percentage of non-reacted monomers.

2. **INFORMATION ON THE SUBSTANCE**

2.1.1.5 Statement, with relevant information, if the polymer has been developed to be environmentally degradable.

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.6.1 Water extractivity

Without prejudice to regulation 16, further tests may be required additionally in certain cases, e.g.:

— Light-stability if the polymer is not specifically light stabilized

— Long-term extractivity (leachate test); depending on the results of this test, appropriate tests on the leachate may be requested on a case by case basis.

C.1.2 **POLYMERS PLACED ON THE EUROPEAN COMMUNITIES' MARKET IN QUANTITIES OF < 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF < 5 TONNES) BUT ≥ 100 KGS PER ANNUM (OR TOTAL QUANTITIES OF ≥ 500 KGS)**

In addition to the information and tests referred to in regulation 6(1), laid down in Part B of Schedule 2, the following polymer-specific information is required:

1.	**IDENTITY OF THE SUBSTANCE**
1.2.1	Number-average molecular weight
1.2.2	Molecular weight distribution (MWD)
1.2.3	Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4	Indication of end groups and identity and frequency of reactive functional groups
1.3.2.1	Identity of non-reacted monomers
1.3.3.1	Percentage of non-reacted monomers.
2.	**INFORMATION ON THE SUBSTANCE**
2.1.1.5	Statement, with relevant information, if the polymer has been developed to be environmentally degradable.
3.	**PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**
3.6.1.	Water extractivity.

C.1.3 **POLYMERS PLACED ON THE EUROPEAN COMMUNITIES' MARKET IN QUANTITIES OF < 100 KGS PER ANNUM (OR TOTAL QUANTITIES OF < 500 KGS)**

In addition to the information and tests referred to in regulation 6(2), laid down in Part C of Schedule 2, the following polymer-specific information is required:

1.	**IDENTITY OF THE SUBSTANCE**
1.2.1	Number-average molecular weight
1.2.2	Molecular weight distribution (MWD)
1.2.3	Identity and concentration of starting monomers and starting substances which will be bound in the polymer
1.2.4	Indication of end groups and identity and frequency of reactive functional groups
1.3.2.1	Identity of non-reacted monomers
1.3.3.1	Percentage of non-reacted monomers.
2.	**INFORMATION ON THE SUBSTANCE**
2.1.1.5	Statement, with relevant information, if the polymer has been developed to be environmentally degradable.

C.2 **POLYMERS FOR WHICH A REDUCED TEST PACKAGE (RTP POLYMERS) IS ACCEPTABLE**

Under certain conditions the base-set test package for polymers can be reduced.

CRITERIA FOR POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE

Substances with a high number-average molecular weight, a low content of low molecular weight species and low solubility/extractivity will be regarded as being non-bioavailable. Consequently the following criteria shall be used to determine the polymers for which a reduced test package is acceptable:

(*a*) for non-readily degradable polymers placed on the European Communities' market in quantities of $\geq$ 1 t/a (or total quantities of $\geq$ 5 t), the following criteria define those polymers for which a reduced test package is acceptable:

I. High number-average molecular weight (M_n). The competent authority shall decide whether or not a polymer satisfies this criterion;

II. Extractivity in water (3.6.1) $<$ 10 mg/l excluding any contribution from additives and impurities;

III. Less than 1% with MW $<$ 1000; the percentage refers only to molecules (components) directly derived from and including monomer(s), excluding other components e.g. additives or impurities.

If all the criteria are fulfilled, the polymer is regarded as a polymer for which a reduced test package is acceptable;

(*b*) in the case of non-readily degradable polymers placed on the European Communities' market in quantities $<$ 1 t/a (or total quantities of $<$ 5 t), it is sufficient that criteria I and II are fulfilled.

If it is not possible to prove the criteria with the assigned tests, the notifier has to demonstrate compliance with the criteria by other means.

Under certain circumstances toxicological and ecotoxicological tests may be required.

C.2.1 **RTP POLYMERS PLACED ON THE EUROPEAN COMMUNITIES' MARKET IN QUANTITIES OF $\geq$ 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF $\geq$ 5 TONNES): FULL LIST OF INFORMATION AND TESTS REQUIRED**

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the European Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and the addresses of the importers who will be bringing the substance into the European Communities.

1. **IDENTITY OF THE SUBSTANCE**

1.1 **Name**

1.1.1 Names in the IUPAC nomenclature

1.1.2 Other names (usual name, trade name, abbreviation)

1.1.3 CAS number and CAS name (if available)

1.2 **Molecular and structural formula**

1.2.1 Number-average molecular weight

1.2.2 Molecular weight distribution (MWD)

1.2.3 Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4 Indication of end groups and identity and frequency of reactive functional groups

1.3 **Composition of the substance**

1.3.1 Degree of purity (%)

1.3.2 Nature of impurities, including by-products

1.3.2.1 Identity of non-reacted monomers

1.3.3 Percentage of (significant) main impurities

1.3.3.1 Percentage of non-reacted monomers

1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm, ...%

1.3.5 Spectral data (UV, IR, NMR or mass spectrum)

1.3.6.1 GPC

1.4 **Methods of detection and determination**

A full description of the methods used or the appropriate bibliograhical references.

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. **INFORMATION ON THE SUBSTANCE**

2.0 **Production**

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

2.0.1 Technological process used in production

2.0.2 Exposure estimates related to production:

— working environment,
— environment

2.1 **Proposed uses**

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

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

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

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

— working environment,
— environment

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

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

2.1.2 Fields of application with approximate breakdown:

— industries,
— farmers and skilled trades,
— use by the public at large

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

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

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

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

— the first calendar year,
— the following calendar years

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

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

— the first calendar year,
— the following calendar years

2.3 **Recommended methods and precautions concerning:**

2.3.1 Handling

2.3.2 Storage

2.3.3 Transport

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

2.3.5 Other dangers, particularly chemical reaction with water

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

2.4 **Emergency measures in the case of accidental spillage**

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

2.6 **Packaging**

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.0 **State of the substance at 20°C and 101.3 kPa**

3.1 **Melting range (e.g. from the thermal stability test)**

3.3 **Relative density**

3.6.1 Water extractivity

3.10 **Flammability**

3.11 **Explosive properties**

3.12 **Auto-flammability**

3.15 **Particle size**

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, a test should be conducted to determine the particle distribution of the substance as it will be marketed.

3.16 **Thermal stability**

3.17 **Extractivity with:**

— water at pH 2 and 9 at 37°C
— cyclohexane

4. **TOXICOLOGICAL STUDIES**

On a case by case basis and without delaying acceptance of the notification the competent authority may on the basis of the presence of reactive groups or structural physical characteristics or knowledge about the properties of low molecular weight components of the polymer or exposure potential require certain tests to be carried out. In particular tests for inhalation toxicity (e.g. 4.1.2, 4.2.1) may be required if exposure by the inhalatory route is considered possible.

5. **ECOTOXICOLOGICAL STUDIES**

On a case by case basis and without delaying acceptance of the notification, the competent authority may on the basis of the presence of reactive groups, structural/physical characteristics or knowledge of the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out.

In particular, the following additional tests may be required:

— Light-stability, if the polymer is not specifically light-stabilized
— Long-term extractivity (leachate test)

Depending on the results of this test, any appropriate test on the leachate may be requested on a case by case basis.

6. **Possibility of rendering the substance harmless**

6.1 **For industry/skilled trades**

6.1.1 Possibility of recycling

6.1.2 Possibility of neutralization of unfavourable effects

6.1.3 Possibility of destruction

— controlled discharge,
— incineration,
— water purification station,
— others

6.2 **For the public at large**

6.2.1 Possibility of recycling

6.2.2 Possibility of neutralization of unfavourable effects

6.2.3 Possibility of destruction:

— controlled discharge,
— incineration,
— water purification station,
— others

C.2.2 **RTP POLYMERS PLACED ON THE EUROPEAN COMMUNITIES' MARKET IN QUANTITIES OF < 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF < 5 TONNES): FULL LIST OF INFORMATION AND TESTS REQUIRED**

0. **IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE**

For substances manufactured outside the European Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and the addresses of the importers who will be bringing the substance into the European Communities.

1. **IDENTITY OF THE SUBSTANCE**

1.1 **Name**

1.1.1 Names in the IUPAC nomenclature

1.1.2 Other names (usual name, trade name, abbreviation)

1.1.3 CAS number and CAS name (if available)

1.2 **Molecular and structural formula**

1.2.1 Number-average molecular weight

1.2.2 Molecular weight distribution (MWD)

1.2.3 Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4 Indication of end groups and identity and frequency of reactive functional groups

1.3 **Composition of the substance**

1.3.1 Degree of purity (%)

1.3.2 Nature of impurities, including by-products

1.3.2.1 Identity of non-reacted monomers

1.3.3 Percentage of (significant) main impurities

1.3.3.1 Percentage of non-reacted monomers

1.3.4 If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ... ppm, ...%

1.3.5 Spectral data (UV, IR, NMR or mass spectrum)

1.3.6.1 GPC

1.4 **Methods of detection and determination**

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

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0 **Production**

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

2.0.1 Technological process used in production

2.0.2 Exposure estimates related to production:

— working environment,
— environment

2.1 **Proposed uses**

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

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

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

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

— working environment,
— environment

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

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

2.1.2 Fields of application with approximate breakdown:

— industries,
— farmers and skilled trades,
— use by the public at large

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

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

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

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

— the first calendar year,
— the following calendar years

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

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

— the first calendar year,
— the following calendar years

2.3 **Recommended methods and precautions concerning:**

2.3.1 Handling

2.3.2 Storage

2.3.3 Transport

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

2.3.5 Other dangers, particularly chemical reaction with water

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

2.4 **Emergency measures in the case of accidental spillage**

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

2.6 **Packaging**

3. **PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE**

3.0 **State of the substance at 20°C and 101.3 kPa**

3.1 **Melting range (e.g. from the thermal stability test)**

3.6.1 Water extractivity

3.10 **Flammability**

(This Schedule sets out the provisions of Annex VIII to the Directive)

Additional Information and Tests required Under Regulation 5

Tests under this Part shall be according to methods recognised and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be indicated.

LEVEL 1

Physico-chemical studies

Further studies on physico-chemical properties dependent upon the results of the studies laid down in Annex VII to the Directive. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.

Toxicological studies

Fertility studies (one species, one generation, male and female, most appropriate route of administration)

If there are equivocal findings in the first generation, study of a second generation is required.

Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.

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

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

— Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII to the Directive or other relevant information demonstrate the need for further appropriate investigation.

The effects which would indicate the need for such a study could include for example:

(*a*) serious or irreversible lesions;

(*b*) a very low or absence of a "no effect" level;

(*c*) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.

— Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V to the Directive

When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the proposed use of the substance.

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

— Basic toxicokinetic information.

Ecotoxicity studies

— Prolonged toxicity study with Daphnia magna (21 days).

— Tests on higher plants.

— Tests on earthworms.

— Further toxicity studies with fish.

— Tests for species accumulation: one species, preferably fish.

— Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Annex VII to the Directive.

— Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII to the Directive.

LEVEL 2

Toxicological studies

This test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

— Chronic toxicity study.

— Carcinogenicity study.

— Fertility study (e.g. three-generation study): only if an effect on fertility has been established at level 1.

— Developmental toxicity study on perinatal and postnatal effects.

— Teratology study (species not employed in the respective level 1).

— Additional toxicokinetic studies which cover biotransformation, pharmokinetics.

— Additional tests to investigate organ or system toxicity.

Ecotoxicological studies

— Additional tests for accumulation, degradation, mobility and absorption/desorption.

— Further toxicity studies with fish.

— Toxicity studies with birds.

— Additional toxicity studies with other organisms.

SCHEDULE 4 Regulation 24

Fees for Notifications etc.

Column 1 *Subject matter*	Column 2 *Fee payable* £
For the evaluation of a notification under regulation 4 (''base set'') (See Note 1)	5,500 (+350 VAT)
For the evaluation of a notification under regulation 5(1)(*a*)	2,000
For the evaluation of a notification under regulation 5(1)(*b*)	4,200
For the evaluation of a notification under regulation 5(1)(*c*)	3,500
For a notification under regulation 6 (see Note 2)—	
(*a*) quantity of the new substance equal to or more than 100 kg (regulation 6(1))	950 (+ 87·50 VAT)
(*b*) quantity of the new substance up to 100 kg (regulation 6(2))	800 (+ 87·50 VAT)
For an application made by a notifier for an exemption relating to him under regulation 23	2,000

		£
Note 1.	Rebate where an adequate draft risk assessment is included	2,000 (and 350 VAT)
Note 2.	Rebate where an adequate draft risk assessment is included	500 (and 87·50 VAT)

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations implement as respects Northern Ireland the provisions of Council Directive 92/32/EEC (O.J. No. L154, 5.6.92, p. 1) (''the Directive'') amending for the 7th time Council Directive 67/548/EEC (O.J. No. L196, 16.8.67, p. 1 (O.J./SE1967, p. 234)) relating to the classification, packaging and labelling of dangerous substances insofar as those provisions relate to the placing on the market of new substances together with the Commission Directive 93/105/EEC (O.J. No. L294, 30.11.93, p. 21) setting out Annex VII D of the Directive (relating to polymers). The Regulations supersede the Notification of New Substances Regulations (Northern Ireland) 1985 which they revoke.

Part I Miscellaneous and general — Regulations 1 to 3

Regulation 2 defines the expressions used in the Regulations, in particular ''new substance'' means a substance which does not appear in the European Inventory of Existing Commercial Chemical Substances (''EINECS'') and the competent authority for Northern Ireland is the Department of the Environment and the Department of Economic Development acting jointly.

With certain specified exceptions the Regulations are applied by regulation 3 to new substances which are placed on the market either alone or in preparations.

Part II Notifications — Regulations 4 to 15

By regulation 4, a person responsible for placing a new substance on the market in a quantity of one tonne or more per year is required to send a notification to the competent authority which shall include the particulars about the substance specified in Part A of Schedule 2. Further testing is required when the quantity of the substance placed on the market reaches 10 tonnes per manufacturer per annum or a total of 50 tonnes (regulation 5).

By regulation 6, reduced notification requirements for new substances placed on the market in quantities of less than one tonne per year are imposed and, with certain specified exceptions, new substances are deemed to have been notified if placed on the market in quantities of less than 10 kg per year. Special notification requirements relate to new substances which are polymers as defined in regulation 2(1) (regulation 7).

By regulation 8, new substances which have been duly notified may be placed on the market no sooner than 60 days after the notification was received by the competent authority, or in cases where the substance is subject to reduced notification requirements under regulation 6, no sooner than 30 days after the receipt of the notification. Where further tests are required to evaluate the risks created by the substance, the competent authority may require the notifier to carry out those tests (regulation 9).

By regulation 10, the notifier of a new substance already notified by him is required to inform the competent authority of any changes to the particulars previously notified and of changes in the quantity of the substance placed on the market. In the case of a substance that had previously been notified at least 10 years previously only limited information need be provided (regulation 11).

By regulation 12, in the case of substances manufactured outside the European Communities for which more than one notification has been made the duty to notify additional information under regulation 5 is imposed on each notifier established in Northern Ireland unless the manufacturer has appointed a sole representative when that duty is only imposed on that sole representative if established in Northern Ireland.

By regulation 13, where a substance has already been notified under the Directive, the competent authority may agree that a subsequent notifier may make use of the particulars previously notified with the consent of the previous notifier. For the purpose of avoiding the duplication of animal testing, a prospective notifier of a new substance is required to enquire from the competent authority whether the substance which he intends to notify has already been notified to the competent authority of any member State. If this is the case the prospective notifier is required to try to reach agreement with the previous notifier to share information with a view to reducing the amount of animal testing.

By regulation 14, the notifier is required to ensure that any tests carried out for the purpose of these Regulations conform to the principles of good laboratory practice. By regulation 15 notifications and reports submitted to the competent authority for Northern Ireland are required to be in English.

Part III Rights and duties of the competent authority — Regulations 16 and 17

By regulation 16, in the case of notifications received, the competent authority is required to carry out and keep up to date an assessment of the risks to human health and the environment created by the substance.

By regulation 17, the competent authority is required to send information about notifications and reports received to the European Commission in relation to the substance concerned.

Part IV Disclosure of information — Regulations 18 to 20

By regulation 18, a notifier may ask that information that is commercially sensitive is kept confidential, but certain information specified in the regulation cannot be kept confidential. Regulation 19 sets out the way in which confidential information is to be treated and by regulation 20, in certain circumstances, a new substance which has been notified may appear in the European List of Notified Chemical Substances (''ELINCS'') in the form of its trade name.

Part V Miscellaneous and General — Regulations 21 to 25

Regulation 21 makes provision for enforcement and provides for the Department of Economic Development to be the enforcing authority for the Regulations. By regulation 22 the placing on the market of substances that have not been duly notified is prohibited. Regulation 23 provides for exemption from the requirements of the Regulations in certain circumstances, and regulation 24 specifies fees to be charged for specified purposes.

Regulation 25 revokes the Notification of New Substances Regulations (Northern Ireland) 1985 (as amended) and provides for consequential amendments to the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993. This regulation also contains transitional provisions. In addition regulation 25 amends regulation 19(3) of the Chemicals (Hazard Information and Packaging) Regulations (Northern Ireland) 1993 to conform with the enabling power contained in section 2(2) of the European Communities Act 1972.

A person who contravenes the Regulations is guilty of an offence under Article 31 of the Health and Safety at Work (Northern Ireland) Order 1978.