STATUTORY INSTRUMENTS

1993 No. 3050

The Notification of New Substances Regulations 1993

PART I

INTERPRETATION AND GENERAL

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances Regulations 1993 and shall come into force on 31st January 1994.

Interpretation

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

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

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

"the competent authority" means—

(a) for Great Britain, the Secretary of State for the Environment and the Executive acting jointly; or

(b) for Northern Ireland or another member State, the authority appointed inaccordance 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 Great Britain;

"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 scientic 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 Directive" means Council Directive No.67/548/EEC, relating to the classification, packaging and labelling of dangerous substances(**2**) as amended in particular for the seventh time by Council Directive No.92/32/EEC(**3**);

"EINECS" means the European Inventory of Existing Commercial Chemical Substances(**4**);

(**1**) S.I.1993/1746.
(**2**) OJ No. L196, 16.8.67, p. 1 (OJ/SE 1967 p. 247).
(**3**) OJ No. L154, 5.6.92, p. 1.
(**4**) OJ No. C146A, 15.6.90, p. 1.

"ELINCS" means the European List of Notified Chemical Substances(**5**);

"the Executive" means the Health and Safety Executive;

"importer" means a person who imports a new substance into the Communities' customs territory and "importation" and "import" shall be construed accordingly;

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

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

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

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

(a) in the case of a substance manufactured within the Communities by the manufacturer who places the substance either on its own or in a preparation on the market; or

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

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

  (ii) by the sole representative of its manufacturer, and

"notify" and "notifier" shall be construed accordingly;

"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 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; and for the purposes of this definition "monomer unit" means the reacted form of a monomer in a polymer;

"preparations" means mixtures or solutions 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 Communities, means a person established in the Communities who has been appointed by the manufacturer of the substance for the purpose of notifying that 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 1982(**6**) as then in force by reason that it was reasonably considered by the person placing the substance on the market to be a polymer;

(**5**) OJ No. C130, 10.5.93, p. 1.
(**6**) S.I.1982/1496, amended by S.I.1984/1244, 1985/1333, 1986/890, and 1991/1914.

"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) In these Regulations, unless the context otherwise requires—

(a) a reference to a numbered Part, regulation or Schedule is a reference to the Part, regulation or Schedule in these Regulations so numbered; and

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

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 preparations.

(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, either—

(i) a medicinal product as defined in section 130 of the Medicines Act 1968(**7**), or

(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 section 1 of the Food Safety Act 1990(**8**) 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 Agriculture Feeding Stuffs Regulations 1991(**9**) 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(**10**) 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 1985(**11**);

(f) a substance in the form of waste which is covered by Council Directive No. 91/156/EEC(**12**) or Council Directive No. 91/689/EEC(**13**);

(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(**14**);

(h) a new substance which is in transit through the United Kingdom under customs control and which does not undergo any treatment or processing within the United Kingdom;

(**7**) 1968 c. 67.
(**8**) 1990 c. 16.
(**9**) S.I. 1991/2840.
(**10**) OJ No. L230, 19.8.91, p. 1.
(**11**) S.I. 1985/1333.
(**12**) OJ No. L75, 26.3.91, p. 32.
(**13**) OJ No. L377, 31.12.91, p. 20.
(**14**) S.I. 1989/2233.

(i) subject to Council Regulation EC 2455/92(**15**) 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 of the Communities; or

(j) a new substance which is a substance no longer polymer.

(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 Northern Ireland or another member State.

(4) These Regulations shall not extend to Northern Ireland except insofar as they relate to the importation of new substances into the United Kingdom.

PART II

NOTIFICATIONS

Full notifications

4. Subject to regulations 6 and 7, a person 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 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 Communities, where appropriate, a statement by the manufacturer that the notifier has been appointed, for the purpose of submitting 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 (avoidance of animal testing) for a period which shall not exceed one year from the date of the notification.

(**15**) OJ No. L251, 29.8.92, p. 13.

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 or studies or both 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 or studies or both 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 an alternative test or study would be preferable;

(c) when the quantity of the substance placed on the market reaches 1000 tonnes per year from a single manufacturer or when the total quantity of the substance reaches 5000 tonnes per manufacturer; the competent authority shall then draw up a programme of tests or studies or both according to Schedule 3, 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 of this regulation 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 below, 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 registered 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, 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 the customer's staff 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 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 Schedule 2, Part A, in addition to the label deriving from such tests, the label shall carry the warning "Caution-substance not yet fully tested".

(8) In the case of a notifier who has submitted a reduced notification dossier in conformity with paragraph (2), he shall before the quantity of the substance 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 Schedule 2.

(9) In the case of a notifier who has submitted a reduced notification dossier in conformity with paragraph (1), he 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, submit to the competent authority a full notification in conformity with regulation 4.

Notifications relating to polymers

7. Subject to regulation 6(4)(a), for polymers the specific provisions relating to the technical dossiers contained in notifications under regulation 4 or 6(1) or (2) shall be those in Part D of Schedule 2.

Placing of notified substances on the market

8.—(1) Substances 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) Substances 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 that 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 Articles 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) changes in the annual or total quantity of the substance placed on the Communities' market, by him or in the case of a substance manufactured outside the 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 of which he may be aware for the substance;

(d) any change in the composition of the substance as given in paragraph 1.3 of Schedule 2, Part A, B, or C 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 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 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 10 years previously, a subsequent notifier need not provide the information included in Schedule 2, Part A, B or C with the exception of that specified in paragraphs 1 and 2 of the relevant Part.

Substances manufactured outside the Communities

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

(a) more than 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 underArticles 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 Great Britain 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 Great Britain.

(3) Where in accordance with paragraph (1), the obligation to carry out further testing falls upon one or more notifiers established in Great Britain, the competent authority shall inform each such notifier of the identities of other notifiers within the 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 or 6(1) or (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 or studies or both included in the technical dossier forwarded 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 or 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 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 first notifier had not requested in accordance with regulation 4(f) a temporary exemption from the provisions of this regulation 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) In a case in which 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 first 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(**16**) 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, before the tests are commenced the notifier shall 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 set out in Annex B of Commission Directive 90/18/EEC(**17**) adapting to technical progress the Annex to Council Directive 88/320/EEC(**18**) 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 substances 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 inArticle 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 made 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.

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 supplementary 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 the dossier or information in pursuance of the regulation concerned or, in each case, a summary thereof.

(2) Where the competent authority has required further information from the notifier in accordance with regulation 5 or 9(1), the competent authority for Great Britain 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.

(**16**) OJ No. L15, 17.1.87, p. 29.
(**17**) OJ No. L11, 12.1.90, p. 37.
(**18**) OJ No. L145, 11.6.88, p. 35.

(4) The competent authority shall send to the European Commission a copy of any risk assessment made 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 underArticle 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 the foregoing paragraphs of this regulation, 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 of these Regulations

18.—(1) Subject to the following paragraphs of this regulation, in so far 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 section 28 of the Health and Safety at Work etc.Act 1974.

(2) Where a person making 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 substance 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 1993; and

(i) in the case of substances 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 prepare the risk assessment; or

(d) for the purposes 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 confidential, it shall also treat that information as confidential and shall not disclose it except in accordance with paragraph (1).

Substances appearing in the list of notified 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(**19**)—

(a) subject to paragraph (2), the provisions of the Health and Safety at Work etc.Act 1974 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 section 15 of that Act; 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 3 of the Health and Safety (Enforcing Authority) Regulations 1989(**20**) and subject to regulation 22(2), the enforcing authority for these Regulations shall be the Executive.

Prohibition of importation and placing on the market of unnotified substances

22.—(1) Where a new substance is required to be notified under regulation 4 or 6, the importation of that substance into the United Kingdom is prohibited unless it has been duly notified in accordance with that regulation.

(2) Any contravention of paragraph (1) shall be punishable under the Customs and Excise Management Act 1979(**21**) and not as a contravention of a health and safety regulation.

(3) Where the Executive 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 provisions imposed by the Communities in respect of the notification, control and regulation of substances, the Executive 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 Executive 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 enactments which apply 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.

(**19**) 1972 c. 68.
(**20**) S.I. 1989/1903.
(**21**) 1979 c. 2.

Fees for notifications etc.

24. The fee fixed by column 2 of Schedule 4 shall be payable in advance by a notifier to the Executive 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 revoked—

(a) the Notification of New Substances Regulations 1982(**22**);

(b) the Notification of New Substances (Amendment) Regulations 1986(**23**); and

(c) the Notification of New Substances (Amendment) Regulations 1991(**24**).

(2) In the Chemicals (Hazard Information and Packaging) Regulations 1993—

(a) in regulation 5(3)—

(i) for "the Notification of New Substances Regulations 1982", there shall be substituted "the Notification of New Substances Regulations 1993 (S.I.No.3050)", and

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

(b) in regulation 18(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 21(4) shall be revoked.

(3) After 31st January 1994, notifications made under the Notification of New Substances Regulations 1982 as in force immediately before that date shall be treated as notifications made under these Regulations and the requirements of these Regulations shall apply to such notifications as they apply to notifications made after that date.

(4) Between 31st January 1994 and 31st July 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 1982 as in force immediately before the coming into force of these Regulations, and other additional information required under these Regulations by 31st July 1994.

(5) In the case of a new substance which was not required to be notified under the Notification of New Substances Regulations 1982 as for the time being in force 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 July 1994.

Signed by order of the Secretary of State.

Department of Employment
15th December 1993

Michael Forsyth
Minister of State,

(**22**) S.I. 1982/1496.
(**23**) S.I. 1986/890.
(**24**) S.I. 1991/1914.

Department of the Environment
15th December 1993

John Gummer
Secretary of State,