1985 No. 63

HEALTH AND SAFETY

Notification of New Substances Regulations (Northern Ireland) 1985

Made . . . . . *27th March 1985*

Coming into operation . . . *8th May 1985*

ARRANGEMENT OF REGULATIONS

1. Citation and commencement.
2. Interpretation.
3. Application of these Regulations.
4. Notification of new substances.
5. Notification to be made of material change of circumstances.
6. Requirement for further testing.
7. Use of the results of studies carried out by other notifiers.
8. Particulars to be sent to the Department of the Environment.
9. Particulars to be sent to the Commission of the European Communities and other member States.
10. Disclosure of information notified.
11. Tests under these Regulations to conform to the principles of good current laboratory practice.
12. Certificates of exemption for certain substances supplied for use as pesticides.
13. Regulation of unnotified substances.
14. Enforcement.
15. Defence in proceedings for the contravention of certain Regulations.
16. Information supplied to the Department to be in the English language.
17. Transitional provision.

SCHEDULE 1. (Which reproduces the requirements of Annex VII to the Directive). Information required for the technical dossier referred to in regulation 4(1)(*a*).

SCHEDULE 2. PART I (Which reproduces the provisions of Article 2(2) of the Directive). Definitions of substances which are dangerous.

PART II (Which reproduces the requirements of Part I of Annex VI to the Directive). Criteria for classification as very toxic, toxic or harmful.

SCHEDULE 3. (Which reproduces the requirements of Article 16(2) of the Directive). Labelling data for substances which are dangerous.

SCHEDULE 4. Categories of substances subject to regulation 4(3).

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

The Department of Agriculture, the Department of Economic Development, the Department of the Environment and the Department of Health and Social Services being Departments 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 the notification and control of substances, acting jointly in exercise of the power conferred on them by the said section 2 and acting jointly as the Department concerned(**c**) in exercise of the powers conferred by Articles 17(1), (2), (3), (5) and (6) and 55(2) of, and paragraphs 1(1), (4) and (5) and 14(1) of Schedule 3 to the Health and Safety at work (Northern Ireland) Order 1978(**d**) and of every other power enabling them in that behalf, after consultation with the Health and Safety Agency for Northern Ireland and such other bodies as appear to them to be appropriate, hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Notification of New Substances Regulations (Northern Ireland) 1985 and shall come into operation on 8th May 1985.

Interpretation

2.—(1) In these Regulations—

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

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

"the Department" means the Department of Economic Development;

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

"importer" means a person who imports a new substance into Northern Ireland whether that substance comes through Great Britain or is imported directly from somewhere other than Great Britain; and importation shall be construed accordingly;

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

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

"new substance" means any substance except a substance which had been supplied (either alone or as the component of a preparation) to a person in a member State at any time in the period from 1st January 1971 to 18th September 1981;

(**a**) S.I. 1981/1536
(**b**) 1972 c. 68
(**c**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**d**) S.I. 1978/1039 (N.I. 9)
(**e**) OJ No. L196, 16.8.67, p. 1 (OJ/SE 1967, p. 234)
(**f**) OJ No. L68, 19.3.69, p. 1; OJ No. L59, 14.3.70, p. 33 (OJ/SE 1970 p. 147); OJ No. L74, 29.3.71, p. 15 (OJ/SE 1971 p. 180); OJ No. L167, 25.6.73, p. 1; OJ No. L183, 14.7.75, p. 22; OJ No. L360, 30.12.76, p. 1; OJ No. L88, 7.4.79, p. 1
(**g** OJ No. L259, 15.10.79, p. 10
(**h**) 1974 c. 37

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

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

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

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

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

(*b*) commercial sample,

and includes importation into Northern Ireland;

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

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

Application of these Regulations

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

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

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

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

(*b*) any quantity of a substance which is supplied exclusively as, or exclusively for use in, food within the meaning of section 70(1) of the Food and Drugs Act (Northern Ireland) 1958(**c**);

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

(*d*) a radioactive substance within the meaning of regulation 2 of the Ionising Radiations (Sealed Sources) Regulations (Northern Ireland) 1969(**e**);

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

(i) in a member State other than the United Kingdom in as far as that substance is subject to the provisions of Article 1(4)(*b*) of the Directive, or

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

(**a**) 1954 c. 33 (N.I.)
(**b**) 1968 c. 67
(**c**) 1958 c. 27 (N.I.)
(**d**) 1970 c. 40
(**e**) S.R. & O. (N.I.) 1969 No. 318

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

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

(ii) notified it in accordance with regulation 4(1) or Article 6(1) of the Directive; and

(*g*) a substance to which the Explosives Acts (Northern Ireland) 1875 to 1970(**a**) or the Explosives (Northern Ireland) Order 1972(**b**) applies.

Notification of new substances

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

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

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

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

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

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

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

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

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

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

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

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

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

---

(**a**) 1875 c. 17; 1924 c. 5 (N.I.); 1970 c. 10 (N.I.)
(**b**) S.I. 1972/730 (N.I. 3)

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

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

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

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

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

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

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

Notification to be made of material change of circumstances

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

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

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

(ii) the properties of the substance; and

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

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

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

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

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

Requirement for further testing

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

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

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

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

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