1994 No. 6

HEALTH AND SAFETY

Notification of New Substances Regulations (Northern Ireland) 1994

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

Coming into operation . . *28th February 1994*

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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