
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 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 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 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 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.

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(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.

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