STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

HEALTH AND SAFETY

Biocidal Products Regulations (Northern Ireland) 2001

Made - - - - 5th December 2001

Coming into operation 16th January 2002

The Department of Enterprise, Trade and Investment(**1**) being a Department designated(**2**) for the purpose of section 2(2) of the European Communities Act 1972(**3**) in relation to the notification and control of substances and to measures relating to biocides, in exercise of the powers conferred on it by the said section 2(2) and, being the Department concerned(**4**), in exercise of the powers conferred on it by Articles 17(1), (2), (3) and (5), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (4) and (5), 3(1), 12(1), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**5**) and of every other power enabling it in that behalf, and for the purpose of giving effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A) of that Order(**6**), after the carrying out by the said Executive of consultations in accordance with Article 46(3)(**7**) of that Order, hereby makes the following Regulations:

Part I

General

Citation and commencement

1. These Regulations may be cited as the Biocidal Products Regulations (Northern Ireland) 2001 and shall come into operation on 16th January 2002.

Interpretation

2.—(1) In these Regulations—

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

(**1**) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5)
(**2**) S.I. 1981/1536 and S.I. 1999/2788
(**3**) 1972 c. 68
(**4**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**5**) S.I. 1978/1039 (N.I. 9)
(**6**) Article 13(1A) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
(**7**) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18

"the 1995 Regulations" means the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 1995(**8**);

"active substance" means a substance or micro-organism having a general or specific action on or against harmful organisms;

"approved supply list" has the same meaning as it has in the 1995 Regulations;

"biocidal product" means an active substance or a preparation containing one or more active substances, in the form in which it is supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical or biological means;

"classified" means classified in accordance with regulation 5 of the 1995 Regulations;

"the Commission" means the Commission of the European Communities;

"Commission decision" means a decision taken in accordance with the procedures set out in Article 28(2);

"competent authority" means the authority appointed in a member State for the purpose of carrying out the duties of a competent authority under the Directive;

"the Directive" means Directive 98/8/EC of the European Parliament and the Council of 16th February 1998 concerning the placing of biocidal products on the market(**9**);

"the Executive" means the Health and Safety Executive for Northern Ireland;

"existing active substance" means an active substance which was on the market in the European Community before 14th May 2000 for a purpose other than process-orientated research and development or scientific research and development;

"feedingstuff" means feedingstuff for animals, birds or fish;

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

"the Great Britain Regulations" means the Biocidal Products Regulations 2001(**11**)

"harmful organism" means an organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment;

"letter of access" means a document—

(a) permitting the use by the Executive of information, which is—

  (i) subject to the provisions of regulation 23 or 24, and

  (ii) specified in that document; and

(b) signed by the owner of that information;

"low-risk biocidal product" means a biocidal product—

(a) which does not contain any active substance other than an active substance included only in Annex IA;

(b) which does not contain a substance of concern; and

(c) which, under the conditions subject to which that biocidal product may be used, poses a low risk to humans, animals and the environment;

"member State" means a member State of the Communities, except the United Kingdom;

(**8**) S.R. 1995 No. 60, amended by S.R. 1996 No. 376, S.R. 1997 No. 398, S.R. 1998 No. 459, S.R. 1999 No. 150, S.R. 1999 No. 303 and S.R. 2001 No.168
(**9**) O.J. No. L123, 24.4.98, p.1
(**10**) 1974 c. 37
(**11**) S.I. 2001/880

"micro-organism" includes a fungus and a virus;

"the Ministers" has the meaning assigned to it by regulation 2(2) of the Great Britain Regulations;

"new active substance" means an active substance which is not an existing active substance;

"placing on the market" means—

(a) any supply, whether in return for payment or not, within Northern Ireland, including importation into Northern Ireland; or

(b) any subsequent storage,

other than a supply for storage followed by consignment from the customs territory of the European Community or followed by disposal, and "on the market" shall be construed accordingly;

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

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

"product-type" means one of the product-types specified in column 1, and described in column 2, of Schedule 1;

"residue" means a substance present in a biocidal product which remains as a result of the use of that biocidal product, including the metabolites of, and products resulting from the degradation or reaction of, such a 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;

"substance" means a chemical element and its compounds 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;

"substance of concern" means a substance, other than an active substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present in or produced in a biocidal product in sufficient concentrations to create such an effect; and

"territorial waters" means United Kingdom territorial waters adjacent to Northern Ireland and "within territorial waters" includes on, over and under them.

(2) In these Regulations, any requirement to submit or provide information, including information comprising, or included in, a dossier, in support of an application for the authorisation or the registration of a biocidal product under these Regulations, may be satisfied in whole or in part by—

(a) the submission of a letter of access in respect of that information; or

(b) a reference to information which the Executive or a competent authority already holds and which, by virtue of regulation 23 or 24, the Executive or the competent authority is entitled to use for the benefit of persons other than the persons who submitted that information.

(3) In these Regulations, a reference to "frame-formulation" is a reference to specifications for a group of biocidal products which—

(a) have the same use;

(b) are used by the same type of user; and

(c) contain the same active substances of the same specification,

and whose composition, when compared, subject to paragraph (4), with the composition of a biocidal product which has been authorised or registered in accordance with these Regulations, is the same as the composition of that biocidal product.

(4) In carrying out the comparison referred to in paragraph (3), there shall be disregarded a variation which does not reduce the efficacy of, nor affect the level of risk associated with, the biocidal products in question.

(5) In paragraph (4), "variation" means one or more of the following, that is to say—

(a) a lower percentage of each active substance;

(b) a change in the percentage of each substance which is not an active substance;

(c) the replacement of pigments, dyes or perfumes by other pigments, dyes or perfumes having the same or a lower risk.

(6) In these Regulations, any reference to the name of an active substance is a reference to—

(a) the name of that active substance as listed in Part I of the approved supply list; or

(b) if the name is not listed in Part I of the approved supply list, the name of that substance as given in the European Inventory of Existing Chemical Substances(**12**); or

(c) if the name—

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

the International Organisation for Standardisation common name of that active substance; or

(d) if the name—

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

and there is no International Organisation for Standardisation common name for that active substance, the chemical designation of that active substance according to International Union of Pure and Applied Chemistry rules.

(7) In paragraph (6),

(a) "International Organisation for Standardisation" means the institution of that name founded in 1947 and currently having its headquarters at 1 rue de Varembé, CP56, 1211 Geneva 20, Switzerland, and

(b) "International Union of Pure and Applied Chemistry" means the institution of that name founded in 1919 and currently having its headquarters at Bank Court Chambers, 2–3 Pound Way, Templars Square, Cowley, Oxford OX4 3YF.

(8) In these Regulations, a reference to a biocidal product which contains an active substance shall include a reference to a biocidal product which is an active substance.

(9) In these Regulations a reference to a numbered Article or Annex is a reference to the Article in or Annex to the Directive so numbered.

(10) The Interpretation Act (Northern Ireland) 1954(**13**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

(**12**) A copy of the European Inventory of Existing Chemical Substances may be obtained from the European Communities Information Office, 8 Storey's Gate, London SW1P 3AT

(**13**) 1954 c. 33 (N. I.)

Application

3.—(1) These Regulations shall not apply to a biocidal product where and to the extent that the biocidal product is placed on the market or used for a purpose over which control is exercised under —

(a) any of the Regulations set out in Schedule 2;

(b) Council Regulation (EEC) No. 2309/93(**14**), laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; or

(c) sections 32 to 39 or section 58B of the Medicines Act 1968(**15**).

(2) Subject to Schedule 12, these Regulations, except regulation 29, shall not apply to a biocidal product which contains an existing active substance.

(3) These Regulations shall not apply to a biocidal product which is a relevant plant protection product where and to the extent that that biocidal product is placed on the market or used for a purpose over which, but for the provisions of Schedule 3 to the PPP Regulations, control under the PPP Regulations would otherwise be exercisable.

(4) These Regulations shall not apply to a biocidal product which, by virtue of regulation 19(1) of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**16**), continues to have a product licence under section 7 of the Medicines Act 1968 so long as that licence remains in force.

(5) These Regulations shall not apply to the placing on the market of a biocidal product prepared extemporaneously in the circumstances described in regulation 5(1)(*c*) of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**17**).

(6) Regulations 30 to 32 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

(7) In this regulation—

(a) "the PPP Regulations" means the Plant Protection Products Regulations (Northern Ireland) 1995(**18**); and

(b) "relevant plant protection product" shall have the meaning assigned to it in paragraph 8 of Schedule 3 to the PPP Regulations.

Part II

Active Substances

Placing on the market of active substances

4.—(1) Subject to paragraph (2), a person shall not place on the market for use in a biocidal product a new active substance unless—

(a) an application has been made to the Executive, the Ministers or to a competent authority for the inclusion of that new active substance in Annex I, IA or IB; and

(**14**) O.J. No. L214, 24.8.93, p. 1
(**15**) 1968 c. 67; section 58B was added by the Medicines Act 1968 (Amendment) (No. 2) Regulations 1992 (S.I. 1992/3271)
(**16**) S.I. 1994/3142, to which there are amendments not relevant to these Regulations
(**17**) S.I. 1994/2987, to which there are amendments not relevant to these Regulations
(**18**) S.R. 1995 No. 371, as amended by S.R. 1996 No. 456, S.R. 1997 No. 471, S.R. 1997 No. 507, S.R. 1999 No. 57 and S.R. 1999 No. 282