STATUTORY INSTRUMENTS

2001 No. 880

The Biocidal Products Regulations 2001

PART I

GENERAL

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(1), 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(2).

(2) Subject to Schedule 13, 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 1995 Regulations, control under the 1995 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(**3**), 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(4).

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

- (7) These Regulations shall not extend to Northern Ireland.
- (8) In this regulation—
 - (a) "the 1995 Regulations" means the Plant Protection Products Regulations 1995(5); and
 - (b) "relevant plant protection product" shall have the meaning assigned to it in paragraph 8 of Schedule 3 to the 1995 Regulations.

⁽¹⁾ OJ No. L214, 24.8.93, p. 1.

^{(2) 1968} c. 67; section 58B was added by the Medicines Act 1968 (Amendment) (No. 2) Regulations 1992 (S.I.1992/3271).

⁽³⁾ S.I. 1994/3142, to which there are amendments not relevant to these Regulations.

⁽⁴⁾ S.I. 1994/2987, to which there are amendments not relevant to these Regulations.

⁽⁵⁾ S.I. 1995/887, as amended by S.I. 1997/7, 1997/2499, 1999/3430.

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