STATUTORY RULES OF NORTHERN IRELAND

2007 No. 190

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations (Northern Ireland) 2007

Made - - - - 21st March 2007

Coming into operation 30th April 2007

The Department of Enterprise, Trade and Investment(**1**), being the Department concerned(**2**), makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**3**) ("the 1972 Act") and 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(**4**) ("the 1978 Order").

The Department was designated(**5**) for the purposes of section 2(2) of the 1972 Act in relation to the notification and control of substances and to measures relating to biocides.

The Regulations give effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A) of the 1978 Order(**6**) after the Executive had carried out consultations in accordance with Article 46(3)(**7**) of the 1978 Order.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Department of Enterprise, Trade and Investment that it is expedient for references in the Biocidal Products Regulations (Northern Ireland) 2001(**8**) to Directive 98/8/EC of the European Parliament and the Council(**9**), Commission Regulation (EC) No. 1896/2000(**10**) and Commission Regulation (EC) No. 2032/2003(**11**) to be construed as references to those instruments as amended from time to time.

(**1**) Formerly the Department of Economic Development; *see*S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services, *see*S.I. 1982/846 (N.I. 11), Article 3
(**2**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**3**) 1972 c. 68: the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51)
(**4**) S.I. 1978/1039 (N.I. 9)
(**5**) S.I. 1981/1536 for the designation in relation to the notification and control of substances and S.I. 1999/2788 in relation to measures relating to biocides
(**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
(**8**) S.R. 2001 No. 422, as amended by S.R. 2002 No. 302, S.I. 2003/429 and S.I. 2005/2451
(**9**) OJ No. L123, 24. 4. 98, p. 1
(**10**) OJ No. L228, 8. 9. 2000, p. 6
(**11**) OJ No. L307, 24. 11. 2003, p. 1

Citation and commencement

1. These Regulations may be cited as the Biocidal Products (Amendment) Regulations (Northern Ireland) 2007 and shall come into operation on 30th April 2007.

Amendment of the Biocidal Products Regulations (Northern Ireland) 2001

2. The Biocidal Products Regulations (Northern Ireland) 2001 shall be amended as follows.

3. In regulation 2(1)—

(a) for the definition of "the 1995 Regulations" substitute—

> ""the 2002 Regulations" means the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002(**12**);";

(b) in the definition of "approved supply list", for "the 1995 Regulations" substitute "the 2002 Regulations";

(c) in the definition of "classified", for "regulation 5 of the 1995 Regulations" substitute "regulation 4 of the 2002 Regulations";

(d) in the definition of "the Directive", after "16th February 1998" insert "as from time to time amended,";

(e) for the definition of "existing active substance", substitute—

> ""existing active substance" means an active substance on the market in the European Community before 14th May 2000 as an active substance of a biocidal product for a purpose other than process-orientated research and development or scientific research or development(**13**);";

(f) in the definition of "first review regulation", after "Commission Regulation (EC) 1896/2000" add "as from time to time amended";

(g) for the definition of "new active substance" substitute —

> ""new active substance" means an active substance which is not an existing active substance, but in regulations 13 and 14 shall not include any active substance that is deemed not to have been placed on the market in the European Community for biocidal purposes before 14th May 2000 by virtue of the second review regulation;"; and

(h) after the definition of "scientific research and development", insert—

> ""the second review regulation" means Commission Regulation (EC) No. 2032/2003 as from time to time amended;".

4. In regulation 3—

(a) omit paragraph (2);

(b) in paragraph (3), for "Schedule 3 to the PPP Regulations" substitute "Schedule 4 to the PPP Regulations";

(c) in paragraph (5), for "regulation 5(1)(c) of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994" substitute "paragraph 2(c) of Schedule 4 to the Veterinary Medicines Regulations 2005(**14**)";

(**12**) S.R. 2002 No. 301, amended by SR. 2005 No. 463

(**13**) References to an existing active substance in these Regulations are affected by the provisions of Article 4.3 of the second review regulation, as amended by the Commission Regulation (EC) no. 1048/2005 (OJ No. L178, 9.7.2005, p.1.) ("the third review regulation"), which states that "from the date of entry into force of this Regulation, any active substance not listed in Annex I or Annex VII shall be deemed not to have been placed on the market for biocidal purposes before 14 May 2000"

(**14**) S.I. 2005/2745

(d) in paragraph (7)—

(i) for sub-paragraph (a), substitute

"(a) "the PPP Regulations" means the Plant Protection Products Regulations (Northern Ireland) 2005(**15**); and"; and

(ii) In sub-paragraph (b), for "Schedule 3 to the PPP Regulations" substitute "Schedule 4 to the PPP Regulations".

5. After regulation 3, insert—

"**3A.**—(1) Subject to Schedule 12 and paragraphs (2) and (3) below, these Regulations shall not apply to a biocidal product which contains no active substances other than existing active substances.

(2) Paragraph (1) shall cease to apply on 14th May 2010.

(3) Notwithstanding paragraph (1) above but subject to regulation 3, regulations 29, 33, 39A and Schedule 11A shall apply to all biocidal products."

6. In regulations 4, 5, 6 & 7, for each reference to "new active substance" substitute a reference to "active substance".

7. In regulation 9—

(a) at the beginning of paragraph (4), insert "Subject to paragraph (6A)"; and

(b) after paragraph (6), insert—

"(6A) Where the applicant justifies the omission to the satisfaction of the Executive, the applicant may omit from a dossier submitted in accordance with paragraph (4)(a) information which—

(a) is not necessary owing to the nature of—

(i) the biocidal product, or

(ii) its proposed uses; or

(b) it is not scientifically necessary or technically possible to supply".

8. In regulation 10(7)(a)(ii), after "its proposed uses;" insert "or".

9. In regulation 13—

(a) in paragraph (1), after "regulation 5" add ", or to a competent authority under Article 11";

(b) for paragraph (2), substitute—

"(2) The Executive shall not authorise a biocidal product under paragraph (1) unless the Executive has made the determinations referred to in Schedule 3 and either—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex I or Annex IA; or

(b) it is satisfied that an evaluation has been carried out by a competent authority of the new active substance contained in that biocidal product which is not included in Annex I or Annex IA."; and

(c) in paragraph (4)—

(i) omit "and", and

(ii) omit sub-paragraph (b).

(**15**) S.R. 2005 No. 526

10. In regulation 14—

(a) in paragraph (1)(a), after "regulation 5" add ", or to a competent authority under Article 11;";

(b) for paragraph (2), substitute—

"(2) The Executive shall not register a biocidal product under paragraph (1) unless the Executive has made the determinations referred to in Schedule 3 and either—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex I or Annex IA; or

(b) it is satisfied that an evaluation has been carried out by a competent authority of the new active substance contained in that biocidal product which is not included in Annex IA."; and

(c) in paragraph (5)—

(i) omit "and", and

(ii) omit sub-paragraph (b).

11. In regulation 15(6), in sub-paragraphs (a) and (b) after "regulation 9, 11, 13" insert ",15A".

12. After regulation 15, insert—

"**Essential use authorisation**

15A.—(1) Where a person submits an application under this regulation to the Executive for the authorisation of an essential use biocidal product, the Executive may authorise the placing on the market of that product(**16**).

(2) In this regulation, an "essential use biocidal product" means a biocidal product containing an active substance listed in column 1 of the table in Schedule 5A for the use listed in column 2 of that table.

(3) The Executive shall grant an authorisation under paragraph (1) only if it is satisfied that the essential use biocidal product has no unacceptable effect on human or animal health or on the environment.

(4) An authorisation granted under paragraph (1) shall include the following conditions —

(a) that the biocidal product is placed on the market only for the essential use set out in column 2 of the table in Schedule 5A;

(b) all risk reduction measures that the Executive consider appropriate for that product are imposed;

(c) that the label of the biocidal product shows that it is intended only for the essential use set out in column 2 of the table in Schedule 5A.

(5) An authorisation granted under paragraph (1) shall expire on the date specified in column 3 of the table in Schedule 5A.

(6) The Executive may extend an authorisation granted under paragraph (1) if the Commission makes a decision or adopts a regulation to that effect.".

13. In regulation 16(9)(a), after "regulation 9, 11, 13" wherever it appears insert ", 15A".

(**16**) Authorisations may only be made under this regulation following a decision made by the European Commission under Article 4a.3 of the second review regulation to allow the United Kingdom to grant an approval for a biocidal product containing the active substance to be placed on the market for certain essential uses

14. In regulation 19—

(a) in paragraph (2)—

(i) in sub-paragraph (a), for "or 13" substitute ", 13 or 15A", and

(ii) in sub-paragraph (b), after "15" add ", 15A";

(b) after paragraph (10), insert—

"(10A) The Executive shall revoke an authorisation granted under regulation 15A where—

(a) it considers that the biocidal product no longer satisfies the requirement referred to in regulation 15A(3);

(b) it considers that any of the conditions set out in regulation 15A(4) and contained in the authorisation are not being complied with; or

(c) a Commission decision requires the authorisation to be revoked.".

15. In regulation 20—

(a) after paragraph (2) insert—

"(2A) Where a modification of the conditions of use, proposed under paragraphs (1) or (2) above, would result in an extension of uses to which the biocidal product can be put, the Executive, in modifying the conditions of use, shall ensure that any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product remain satisfied.

(2B) The Executive, in modifying the conditions of use subject to which an authorisation or a registration is granted under these Regulations, shall ensure that the requirements referred to in paragraphs 1(a)-(d) and 4(b) of Schedule 3 remain satisfied.".

(b) After paragraph (3), insert—

"(3A) The Executive may review an authorisation of a biocidal product granted under regulation 15A at any time if there are indications that—

(a) the biocidal product no longer satisfies the requirement referred to in regulation 15A(3); or

(b) any of the conditions contained in the authorisation set out in regulation 15A(4) are not being complied with;" and

(c) in paragraph (5), after "paragraph (3)" insert "an authorisation under paragraph (3A)".

16. In regulation 32, for "regulations 9 to 15" substitute "regulations 9 to 15A".

17. In regulation 34—

(a) in paragraphs (2) and (5), after "in paragraph (1)" insert "or granted under regulation 15A"; and

(b) in paragraph (7)(a), after "regulation 9, 11, 13, 15", insert ",15A".

18. In regulation 36(1) in sub-paragraphs (d) to (g), for "regulations 9 to 15" wherever it appears substitute "regulations 9 to 15A".

19. For regulation 37, substitute—

"**37.**—(1) Every test carried out in support of an application under regulations 9 to 15A and 17 shall be conducted in accordance with such guidance as may be issued by the Executive.