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(**a**), being the Department concerned(**b**), makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**c**) ("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(**d**) ("the 1978 Order").

The Department was designated(**e**) 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(**f**) after the Executive had carried out consultations in accordance with Article 46(3)(**g**) 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(**h**) to Directive 98/8/EC of the European Parliament and the Council(**i**), Commission Regulation (EC) No. 1896/2000(**j**) and Commission Regulation (EC) No. 2032/2003(**k**) to be construed as references to those instruments as amended from time to time.

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.

(**a**) 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
(**b**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**c**) 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)
(**d**) S.I. 1978/1039 (N.I. 9)
(**e**) 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
(**f**) Article 13(1A) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
(**g**) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18
(**h**) S.R. 2001 No. 422, as amended by S.R. 2002 No. 302, S.I. 2003/429 and S.I. 2005/2451
(**i**) OJ No. L123, 24. 4. 98, p. 1
(**j**) OJ No. L228, 8. 9. 2000, p. 6
(**k**) OJ No. L307, 24. 11. 2003, p. 1

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(**a**);";

(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(**b**);";

(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(**c**)";

(d) in paragraph (7)—

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

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

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

(**b**) 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"

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

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

"**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).

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(**a**).

(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".

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—

(**a**) 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

"(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.

(2) Before any tests referred to in paragraph (1) are carried out the applicant must carry out an evaluation into the adequacy of existing data and make a decision on the need to conduct tests, taking into account, among other things, the need to minimise testing on vertebrate animals.".

20. In paragraph 13 of Schedule 4, for "the 1995 Regulations" substitute "the 2002 Regulations".

21. After Schedule 5, add the Schedule set out in the Schedule to these Regulations.

22. In paragraph 6 of Schedule 6—

(a) for "the 1995 Regulations", substitute "the 2002 Regulations"; and

(b) for "paragraph 18(1)" substitute "paragraph 6(1)".

23. In paragraph 4 of Schedule 7, for "the 1995 Regulations" substitute "the 2002 Regulations".

24. In paragraph 3 of Schedule 11, after sub-paragraph (h) insert—

"(ha) an application under regulation 15A for the authorisation of a biocidal product for an essential use;"

25. In Schedule 11A—

(a) in paragraph 4(a)(i), after "regulations 9 to 14" insert "or 15A"; and

(b) in paragraph 17, after "regulations 9 to 14" insert "or 15A".

26. In Schedule 12—

(a) after paragraph 2 insert—

"**2A** In relation to those active substances to which the first sub-paragraph of Article 4.2 of the second review regulation(**a**) refers, a decision referred to in paragraph 2(b) of this Schedule not to include those active substances in Annex I, IA or IB shall be deemed to have taken effect, and these Regulations shall apply to a biocidal product which contains any of those active substances.";

(b) for paragraph 4 substitute—

"**4.** Where there is more than one unlisted active substance in a biocidal product, these Regulations shall not apply to that biocidal product until either—

(a) a decision referred to in paragraph 2(a) to include the last of those unlisted active substances in Annex I, IA or IB takes effect, provided that such a decision has been made to include all other active substances in that biocidal product in either Annex I, IA or IB; or

(b) a decision referred to in paragraph 2(b) not to include an unlisted active substance present in the biocidal product in Annex I, IA or IB takes effect.";

(c) in paragraph 14—

(i) in sub-paragraph (a), for "paragraph 10" substitute "paragraph 13" and omit "and" at the end; and

(ii) omit sub-paragraph (b); and

(d) in paragraph 15—

(i) after "other than regulation 29," insert "33, 39A or Schedule 11A,"; and

(ii) omit sub-paragraph (c).

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on 21st March 2007.

L.S.

Michael J. Bohill
A senior officer of the Department of Enterprise, Trade and Investment

(**a**) The first sub-paragraph of Article 4.2 of the second review regulation is substituted by Article 1.3 (b) of the third review regulation

SCHEDULE

Regulation 21

"SCHEDULE 5A

Regulation 15A(2)

List of active substances and the essential use

1 *Active substance*	*2* *Use*	*3* *Date*
Ammonia EC n°231-635-3 CAS n° 7664-41-7	Veterinary hygiene biocidal product for the prevention of infections by coccidia, cryptosporidium and nematodes in livestock; only when no other means with similar effect can be used	14th May 2008"

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Biocidal Products Regulations (Northern Ireland) 2001 (S.R. 2001 No. 422) ("the 2001 Regulations") to make further provision as regards Northern Ireland for the implementation of Directive 98/8/EC of the European Parliament and Council (OJ No. L123, 24.4.98, p.1.) concerning the placing of biocidal products on the market ("the Directive").

2. These Regulations —

(a) take account of the effects of three Commission Regulations on the transitional provisions in Schedule 12 to the 2001 Regulations for biocidal products on the market before 14 May 2000—

(i) Commission Regulation (EC) No. 1896/2000 (OJ No. L228, 8.9.2000, p. 6.) ("the First Review Regulation"),

(ii) Commission Regulation (EC) No. 2032/2003 (OJ No. L307, 24.11.2003, p.1.), ("the Second Review Regulation"), and

(iii) Commission Regulation (EC) No. 1048/2005, (OJ No. L178, 9.7.2005, p.1.) ("the Third Review Regulation");

(b) update references and make minor corrections in the 2001 Regulations; and

(c) take account of developments within the Directive that require further amendment to the 2001 Regulations.

3. The main changes made by these Regulations are as follows.

4. Regulation 3 amends the definitions of "existing active substance" and "new active substance"—

(a) the definition of "existing active substance" now reflects the definition in the First Review Regulation. A footnote refers to the effects of Article 4.3 of the Second Review Regulation. This deems those existing active substances, which have been neither identified nor notified to the European Commission, not to have been on the market before 14th May 2000. Consequently these substances should not be treated as existing active substances.

(b) the definition of "new active substances" has been amended so to include substances deemed by Article 4.3 of the Second Review Regulation not to be existing active substances; however note that provisional authorisations and registrations under regulations 13 and 14 of the 2001 Regulations should not be granted for biocidal products containing such active substances.

5. Regulation 5 inserts a new regulation 3A into the 2001 Regulations. The effect of this is that—

(a) a biocidal product can remain on the UK market under its existing national authorisation only if all active substances within it are existing active substances. The transitional provisions provide that when a decision takes effect as to whether to include the active substance(s) in that product in the Directive's annexes, the 2001 Regulations will then apply to that product;

(b) the transitional provisions will cease to apply on 14th May 2010; and

(c) the transitional provisions do not apply to regulation 33 (advertisements) in the same way as they do not apply to regulations 29 and 39A of, and Schedule 11A to, the 2001 Regulations.

6. Regulation 6 amends regulations 4, 5, 6 and 7 of the 2001 Regulations, in line with the Second Review Regulation, so that they apply to all active substances.

7. Regulation 7 amends regulation 9 of the 2001 Regulations so that it now contains the qualification contained in Article 8(5) of the Directive. This allows an applicant to omit from the dossier information that they consider unnecessary or not technically possible to supply.

8. Regulations 9 and 10 amend regulations 13 and 14 of the 2001 Regulations to allow the Executive to grant provisional authorisations or registrations where an application has been made to another competent authority. Certain conditions attached to granting these authorisations or registrations have been removed.

9. In order to implement a Commission Decision(**a**) regulation 12 inserts a new regulation 15A into the 2001 Regulations to allow the Executive to grant an authorisation to place a product on the market where the active substance in the product has been approved for an essential use under Article 4a.3 of the Second Review Regulation. A number of consequential amendments have been made to the 2001 Regulations as a result, including—

(a) regulation 21, inserting a new Schedule 5A, showing the essential use authorised for each substance;

(b) regulation 24, amending Schedule 11 to allow a fee to be charged for the processing of these applications; and

(c) regulation 25, amending Schedule 11A to make such applicants for essential use authorisations subject to the General Industry Charge.

10. Regulation 15(1) amends regulation 20 of the 2001 Regulations to ensure that where the Executive proposes to extend the uses to which a biocidal product can be put, it must ensure that any requirements on the use of the active substance set out in Annex I or IA remain satisfied. Furthermore, when the Executive proposes to modify any conditions of use in an authorisation, it must ensure that the requirements of Schedule 3 remain satisfied.

11. Regulation 19 amends regulation 37 of the 2001 Regulations so as to require an applicant, before he carries out any testing, to evaluate the existing data and to take into account among other things the need to minimise testing on animals.

12. Regulation 26(a) amends paragraph 2 of Schedule 12 to reflect the effect of Article 4(2) of the Second Review Regulation, as amended by the Third Review Regulation. From 1st September 2006, existing active substances that have been identified but not notified to the Commission can no longer be placed on the market.

13. Regulation 26(b) amends paragraph 4 of Schedule 12 to clarify that the transitional provisions cease to apply to biocidal products containing more than one existing active substance–

(a) either after a decision is made not to include one of those substances in Annex I, IA or IB, or

(b) after the decision has been taken to include all of those substances in Annex I, IA or IB.

14. In Great Britain the corresponding Regulations are the Biocidal Products (Amendment) Regulations 2007 (S.I. 2007/293).

(**a**) Commission Decision of 20/XII/2006 addressed to the United Kingdom, concerning the extension of the deadline for placing on the market of biocidal products containing ammonia for use as a veterinary hygiene biocidal product for the prevention of infections by coccidian, cryptosporidium and nematodes in livestock, (C (2006) 6707)

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