

2007 No. 293

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2007

<i>Made</i> - - - -	<i>6th February 2007</i>
<i>Laid before Parliament</i>	<i>9th February 2007</i>
<i>Coming into force</i> - -	<i>6th April 2007</i>

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(a) (“the 1972 Act”) in relation to biocides.

The Secretary of State makes these Regulations—

(a) in exercise of the powers conferred on him by section 2(2) of, and paragraph 1A of Schedule 2 to, the 1972 Act; and sections 15(1), (2), and (8), and 82(3)(a) of, and paragraphs 1(1)(b) and (c), (4) and (5), 4(1), 13(1), 15(1) and 16 of Schedule 3 to the Health and Safety at Work Act 1974(b) (“the 1974 Act”), and

(b) for the purpose of giving effect to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act.

Before submitting proposals for these Regulations to the Secretary of State, the Health and Safety Commission has consulted the bodies that appeared to it to be appropriate, as required by section 50(3) of the 1974 Act.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for references in the Biocidal Products Regulations 2001(c) to Directive 98/8/EC of the European Parliament and the Council(d), Commission Regulation (EC) No.1896/2000(e) and Commission Regulation (EC) No.2032/2003(f) to be construed as references to those instruments as amended from time to time.

(a) 1972 c.68; Schedule 2 was amended by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51). As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c.46) which provides that, despite the transfer to the Scottish Ministers by virtue of section 53 of that Act of functions in relation to observing and implementing Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes of section 2(2) of the European Communities Act 1972.

(b) 1974 c.37; sections 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 6 and 16 respectively. Section 15(1) was also amended by S.I. 2002/794, art 5(2), Schedule 2. Section 50(3) was also amended by the Health Protection Agency Act 2004 (c.17), section 11(1), Schedule 3, paragraph 5.

(c) S.I. 2001/880, amended by S.I. 2003/429 and 2005/2451.

(d) OJ No. L123, 24.4.98, p.1.

(e) OJ No. L228, 8.9.2000, p. 6.

(f) OJ No. L307, 24.11.2003, p.1.

Citation and commencement

1. These Regulations may be cited as the Biocidal Products (Amendment) Regulations 2007 and shall come into force on 6th April 2007.

Amendment of the Biocidal Products Regulations 2001

2. The Biocidal Products Regulations 2001 are amended as follows.

3. In regulation 2(1)—

- (a) for the definition of “the 1994 Regulations” substitute—
““the 2002 Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002(a);”;
- (b) in the definition of “approved supply list”, for “the 1994 Regulations” substitute “the 2002 Regulations”;
- (c) in the definition of “classified”, for “regulation 5 of the 1994 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 “Scotland”, 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 3(2);
- (b) in paragraph (3), for “Schedule 3 to the 1995 Regulations” substitute “Schedule 4 to the 2005 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)”; and
- (d) in paragraph (8)—
 - (i) for sub-paragraph (a), substitute—
“(a) the 2005 Regulations” means the Plant Protection Products Regulations 2005(a); and”, and

(a) S.I. 2002/1689, amended by S.I. 2005/2571.

(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. 2005/1435.

- (ii) in sub-paragraph (b), for “Schedule 3 to the 1995 Regulations” substitute “Schedule 4 to the 2005 Regulations”.

5. After regulation 3, insert—

“**3A.**—(1) Subject to Schedule 13 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 12A shall apply to all biocidal products.”

6. In regulation 5, in paragraph (a)(ii) for “micro-organism” substitute “micro-organism”.

7. In regulations 4, 5, 6 and 7, for each reference to “new active substance” substitute a reference to “active substance”.

8. 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 Ministers, 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.”.

9. In regulation 10(7)(a)(ii), after “its proposed uses;” insert “or”.

10. 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 Ministers shall not authorise a biocidal product under paragraph (1) unless the Ministers have made the determinations referred to in Schedule 3 and either—

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

(b) they are 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).

11. 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 Ministers shall not register a biocidal product under paragraph (1) unless the Ministers have made the determinations referred to in Schedule 3 and either—

(a) S.I. 2005/1435.

- (a) in accordance with regulation 6(2), they have evaluated the new active substance contained in that biocidal product which is not included in Annex IA; or
- (b) they are 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).

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

13. After regulation 15, insert—

“Essential use authorisation

15A.—(1) Where a person submits an application under this regulation to the Ministers for the authorisation of an essential use biocidal product, the Ministers 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 Ministers shall grant an authorisation under paragraph (1) only if they are 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 Ministers 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 Ministers may extend an authorisation granted under paragraph (1) if the Commission makes a decision or adopts a regulation to that effect.”.

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

15. 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 Ministers shall revoke an authorisation made under regulation 15A where—

 - (a) they consider that the biocidal product no longer satisfies the requirement referred to in regulation 15A(3);
 - (b) they consider that any of the conditions set out in regulation 15A(4) and contained in the authorisation are not being complied with; or

(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.

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

16.—(1) In regulation 20, 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 Ministers, 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 Ministers, 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.”.

(2) After paragraph (3), insert—

“(3A) The Ministers 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

(3) In paragraph (5), after “paragraph (3)” insert “an authorisation under paragraph (3A)”.

17. In regulation 29(6) omit “NHS Trust”.

18. In regulation 32, for “regulations 9 to 15” substitute “regulations 9 to 15A”.

19. In regulation 34—

- (a) in paragraphs (2) and (5), after “in paragraph (1)” insert “or made under regulation 15A”; and
- (b) in paragraph (7)(a), after “regulation 9, 11, 13, 15”, insert “,15A”.

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

21. 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 Ministers.

(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.”.

22. In paragraph 13 of Schedule 4, for “the 1994 Regulations” substitute “the 2002 Regulations”.

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

24. In paragraph 6 of Schedule 6—

- (a) for “the 1994 Regulations”, substitute “the 2002 Regulations”; and
- (b) for “paragraph 18(1)” substitute “paragraph 6(1)”.

25. In paragraph 4 of Schedule 7, for “the 1994 Regulations” substitute “the 2002 Regulations”.

26. In paragraph 3 of Schedule 12, after sub-paragraph (h) insert—

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

27. In Schedule 12A—

- (a) in paragraph 4(a)(i), after “regulations 9 to 14” insert “or 15A”.
- (b) in paragraph 17, after “regulations 9 to 14” insert “or 15A”.

28. In Schedule 13—

- (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 12A,”; and
- (ii) omit sub-paragraph (c).

Signed by authority of the Secretary of State for Work and Pensions.

Bill McKenzie
Parliamentary Under Secretary of State,
Department for Work and Pensions

6th February 2007

(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 23

“

SCHEDULE 5A

Regulation 15A(2)

LIST OF ACTIVE SUBSTANCES AND THE ESSENTIAL USE

<i>1</i> <i>Active substance</i>	<i>2</i> <i>Use</i>	<i>3</i> <i>Date</i>
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.	14 th May 2008”

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Biocidal Products Regulations 2001 (S.I. 2001/880) (“the 2001 Regulations”) to make further provision as regards Great Britain 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 13 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. This 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 12A to, the 2001 Regulations.

6. Regulation 7 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 8 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 10 and 11 amend regulations 13 and 14 of the 2001 Regulations to allow the Ministers 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 13 inserts a new regulation 15A into the 2001 Regulations to allow the Ministers 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 23, inserting a new Schedule 5A, showing the essential use authorised for each substance;
- (b) regulation 26, amending Schedule 12 to allow a fee to be charged for the processing of these applications; and
- (c) regulation 27, amending Schedule 12A to make such applicants for essential use authorisations subject to the General Industry Charge.

10. Regulation 16(1) amends regulation 20 of the 2001 Regulations to ensure that where the Ministers propose to extend the uses to which a biocidal product can be put, they must ensure that any requirements on the use of the active substance set out in Annex I or IA remain satisfied. Furthermore, when the Ministers propose to modify any conditions of use in an authorisation, they must ensure that the requirements of Schedule 3 remain satisfied.

11. Regulation 21 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 28(a) amends paragraph 2 of Schedule 13 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 28(b) amends paragraph 4 of Schedule 13 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.

(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 coccidia, cryptosporidium and nematodes in livestock, (C (2006) 6707).

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