STATUTORY INSTRUMENTS

2010 No. 745

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2010

Made - - - - 10th March 2010

Laid before Parliament 16th March 2010

Coming into force - - 6th April 2010

The Secretary of State is a Minister designated(1) for the purposes of section 2(2) of the European Communities Act 1972(2) ("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 the 1972 Act; and sections 15(1), (2), and (8), and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (4), 4 (1), 13(1) and 15(1) of Schedule 3 to the Health and Safety at Work etc. Act 1974(3), ("the 1974 Act"), and
- (b) for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Executive under section 11(3) of the 1974 Act.

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

Citation and Commencement

1. These Regulations may be cited as the Biocidal Products (Amendment) Regulations 2010 and come into force on 6th April 2010.

Amendment of the Biocidal Products Regulations 2001

2. The Biocidal Products Regulations 2001(4) are amended as follows.

⁽¹⁾ S.I. 1999/2788.

^{(2) 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 Scotlish 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.

^{(3) 1974} c.37. Sections 15(1) and 50(3) are amended by the Employment Protection Act 1975 (c. 71), paragraphs 6 and 16 respectively. Section 15(1) is further amended by S.I. 2002/794, art 5(2), Schedule 2. Section 50(3) is further amended by the Health Protection Agency Act 2004, Schedule 3, paragraph 5(1) and (3) and S.I. 2008/960, which also inserts section 50(1AA).

⁽⁴⁾ S.I. 2001/880; relevant amending instruments are S.I. 2003/429, 2005/2451, 2007/293.

3.—(1) In regulation 2(1)—

(a) after the definition of "feedingstuff", insert—

""the fifth review regulation" means Commission Regulation (EC) No 1451/2007;";

- (b) in the definition of "new active substance", substitute "fifth" for "second";
- (c) for the definition of "placing on the market" substitute—

""placing on the market" means—

- (a) any supply, whether in return for payment or not, within Great Britain; or
- (b) importation of a biocidal product into Great Britain; or
- (c) any subsequent storage other than storage followed by—
 - (i) consignment from the customs territory of the European Community or
 - (ii) disposal,

and "place on the market", "placed on the market" and "on the market" shall be construed accordingly; and" and

- (d) omit the definition of "the second review regulation".
- (2) In regulation 2(2)(a), omit "and the Minister of Agriculture, Fisheries and Food, acting jointly".

4. In regulation 3—

- (a) for paragraph (3) substitute—
 - "(3) These Regulations shall not apply to a biocidal product which is a relevant plant protection product where and to the extent that the biocidal product is placed on the market or used for a purpose over which—
 - (a) but for the provisions of Schedule 4 to the 2005 Regulations, control under the 2005 Regulations would otherwise be exercisable; or
 - (b) but for the provisions of Schedule 4 to the 2005 (Scotland) Regulations, control under the 2005 (Scotland) Regulations would otherwise be exercisable.";
- (b) in paragraph (8)(a), omit the word "and";
- (c) after paragraph (8)(a), insert—
 - "(aa) "the 2005 (Scotland) Regulations" means the Plant Protection Products (Scotland) Regulations 2005(5); and"; and
- (d) in paragraph (8)(b), for "in paragraph 8 of Schedule 4 to the 2005 Regulations" substitute "in paragraph 12 of Schedule 4 to the 2005 Regulations".

5. In regulation 3A—

- (a) in paragraph (1), for "which contains no active substances other than existing active substances" substitute "where all the active substances in that product are existing active substances.";
- (b) For paragraph (2) substitute—
 - "(2) subject to paragraph (4), paragraph (1) shall cease to apply on 14th May 2014"; and
- (c) after paragraph (3) insert—
 - "(4) Where a decision under Article 16(2) to include an existing active substance in Annex I or IA sets a date for compliance with Article 16(3) which is later than 14th May

2014, paragraph 1 shall continue to apply in relation to biocidal products that include that active substance until the date set in that decision.".

- **6.** In regulation 23, for each reference to "2010", wherever it appears, substitute "2014".
- 7. In regulation 24, for each reference to "2010", wherever it appears, substitute "2014".
- 8. In Schedule 2—
 - (a) Omit paragraph (g) and (j); and
 - (b) after paragraph (u), insert—
 - "(v) the Medical Devices Regulations 2002(6);
 - (w) the Plant Protection Products Regulations 2005; and
 - (x) the Plant Protection Products (Scotland) Regulations 2005.".
- 9. In Schedule 13—
 - (a) in paragraph 1, for the definition of "COPR biocidal product", substitute—

""COPR biocidal product" means any substance, preparation or organism prepared or used for any of the purposes listed in regulation 3(1) of COPR 1986, which is not a plant protection product;

"Plant protection product" has the same meaning as in Regulation 2(1) of the Plant Protection Products Regulations 2005"; and;

- (b) after paragraph 1, insert—
 - "1A. This Schedule applies only in relation to a biocidal product where all the active substances in that product are existing active substances.";
- (c) in paragraph 2A, for "the first sub-paragraph of Article 4.2 of the second review regulation" substitute "Article 4.1 of the fifth review regulation";
- (d) in paragraph 5, for "not later than 3 months after that decision takes effect" substitute "not later than the date that decision takes effect"; and
- (e) in paragraph 8, for "not later than 3 months" substitute "not later than 2 months".

Signed by authority of the Secretary of State for Communities and Local Government

William D. McKenzie
Parliamentary Under Secretary of State,
Department for Work and Pensions

10th March 2010

EXPLANATORY NOTE

(This note is not part of the Regulations)

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 (OJNo. L123, 24.4.98, p.1.) concerning the placing of biocidal products on the market.

These Regulations—

- (a) implement Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods ("the Amending Directive");
- (b) update references and make minor corrections in the 2001 Regulations; and
- (c) take account of developments that require further amendment to the 2001 Regulations.

The main changes made by these Regulations are as follows.

Regulation 3 amends the definitions of "new active substance" and "placing on the market" and substitutes the "fifth" for the "second" review regulation.

Regulation 4 corrects a cross reference.

Regulation 5 amends time periods.

Regulation 6 extends the data protection periods for active substances from 14th May 2010 to 14th May 2014.

Regulation 7 extends the data protection periods for biocidal products from 14th May 2010 to 14th May 2014.

Regulation 8 adds the Medical Devices Regulations 2002, the Plant Protection Products Regulations 2005 and the Plant Protection Products (Scotland) Regulations 2005 to Schedule 2 and removes the Medical Devices Regulations 1994 and the Plant Protection Products Regulations 1995.

Regulation 9 clarifies that a biocidal product can only remain on the UK market under its existing national authorisation if all the active substances within it are existing active substances and changes specific time periods.

A full regulatory impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen. A copy of the transposition note in relation to the implementation of the Amending Directive can be obtained from the Health and Safety Executive, International Branch, Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS. Copies of these documents have been placed in the Library of each House of Parliament.