STATUTORY INSTRUMENTS

## 2013 No. 1506

# The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013

### PART 3

#### CHAPTER 1

#### **BIOCIDAL PRODUCTS**

#### Application of the 1974 Act

**8.**—(1) The following provisions of the 1974 Act apply to regulations 12 and 13(2) of these Regulations and the Biocides Regulation as if they were health and safety regulations for the purposes of that Act, subject to the following provisions of this Chapter and to the extent that they would not otherwise do so—

- (a) sections 18 to 26 (in relation to enforcement); and
- (b) subject to regulations 32 and 33(1), sections 33 to 42 (in relation to offences).

(2) The sections of the 1974 Act referred to in paragraph (1) shall not apply to duties placed by the Biocides Regulation on the competent authority or Member State.

(3) A failure by any person to discharge a duty referred to in paragraph (4) shall not constitute an offence under section 33(1)(c) of the 1974 Act.

(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1) 13(1), (2)(b) and (3), 20(1) and (3), 26(1), 29(1), 31(1), 33(1), 34(1) and (2), the second and third sub-paragraphs of 39(1), 43(1), 45(1), (2)(b) and (3), 50(2), the second and third sub-paragraphs of 53(1), 53(4), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), the second sub-paragraph of 79, the second sub-paragraph of 89(3), 93(1) and 95(1) of the Biocides Regulation.

(5) Any function of the Health and Safety Executive under any provision of the 1974 Act in respect of health and safety regulations (including their enforcement) shall be exercisable as if this Chapter and the Biocides Regulation were, to the extent that they would not otherwise be so, health and safety regulations for the purposes of that Act.

(6) The sections of the 1974 Act which are applied to the Biocides Regulation by paragraph (1) apply to the Biocides Regulation as if any reference to—

- (a) danger, or danger to health and safety, were a reference to danger to the health or safety of humans or animals or to danger to the environment; and
- (b) harm were a reference to harm to humans, animals or the environment.

(7) Sections 22 and 25 of the 1974 Act apply to the Biocides Regulation as if the reference to serious personal injury in those sections were a reference to—

- (a) serious personal injury to humans;
- (b) a breach of the Biocides Regulation and serious injury to animals; or
- (c) a breach of the Biocides Regulation and serious harm to the environment.

#### Allocation of enforcement responsibility

**9.**—(1) Notwithstanding the 1998 Regulations, and subject to paragraphs (2) to (6), the enforcing authority for regulations 12 and 13(2) of these Regulations and the Biocides Regulation is the Health and Safety Executive or the Office of Rail Regulation, determined in accordance with the provisions of the 2006 Regulations.

(2) Where a biocidal product or treated article is placed on the market or made available on the market—

(a) in or from any shop, mobile vehicle, market stall or other retail outlet; or

(b) otherwise to members of the public, including by way of free sample, prize or mail order,

the enforcing authority for regulation 12 of these Regulations and for the Articles of the Biocides Regulation listed in paragraph (3) is the local weights and measures authority.

(3) The Articles referred to in paragraph (2) are—

- (a) Article 17(1), in so far as it relates to making biocidal products available on the market;
- (b) Article 58(2) to (6);
- (c) Article 69(1) and (2); and
- (d) Article 95(3).

(4) The enforcing authority for Article 72 of the Biocides Regulation is the local weights and measures authority.

(5) Subject to paragraph (6), the 1998 Regulations apply to the enforcement of Article 17(1) (in so far as it relates to the use of biocidal products) and Articles 17(5), 56(1) and (2) of the Biocides Regulation.

(6) The enforcing authority for Article 17(1) (in so far as it relates to the use of biocidal products) and Article 17(5) of the Biocides Regulation—

- (a) in respect of any use not related to an activity involving work; or
- (b) in respect of any use by a domestic servant in a private household,

is the local authority for the area in which the use occurs.

#### Limitation on entry to domestic premises in certain circumstances

**10.**—(1) In this regulation—

"domestic premises" means premises occupied as a private dwelling (including any garden, yard, garage, outhouse or other appurtenance of such premises which is not used in common by the occupants of more than one such dwelling); and

"justice" means-

- (i) in relation to England and Wales, a justice of the peace; and
- (ii) in relation to Scotland, a sheriff, stipendiary magistrate or justice of the peace.

(2) An inspector may not enter domestic premises in the exercise of that inspector's powers under the 1974 Act, as applied to the Biocides Regulation by virtue of regulation 8(1)(a) of these Regulations, in respect of an activity which is not, or is not related to, an activity involving work, unless a justice has issued a warrant authorising the inspector to enter and exercise that inspector's powers in those premises.

(3) A justice may not issue such a warrant unless, on an application made by the inspector, the justice is satisfied—

(a) that the inspector has reasonable grounds for believing that there is present in the domestic premises anything to which those powers relate; and

#### (b) that—

- (i) it is not practicable to communicate with any person entitled to grant entry to those premises;
- (ii) a person entitled to grant entry to those premises has unreasonably refused an inspector entry;
- (iii) entry to those premises is unlikely to be granted unless a warrant is produced; or
- (iv) the purpose of entry may be frustrated or seriously prejudiced unless an inspector arriving at those premises can secure immediate entry to them.

#### Confidentiality

**11.** Information provided to the competent authority under the Biocides Regulation must not be treated as relevant information for the purposes of section 28 of the 1974 Act.

#### Labelling

**12.** The information required by Article 69 of the Biocides Regulation to be shown on the label of a biocidal product must be in English, whether or not it is also in another language.

#### **Essential use**

13.—(1) In this regulation—

"essential use active substance" means an active substance in respect of which the Commission has granted a derogation for essential use under Article 5 of the fifth review regulation; and

"the fifth review regulation" means Commission Regulation (EC) No 1451/2007(1).

(2) A person must not place on the market a biocidal product containing an essential use active substance without an authorisation under this regulation.

(3) Where a person submits an application under this regulation to the competent authority for the authorisation of a biocidal product, the competent authority may authorise the placing on the market of that product.

(4) The competent authority may only grant an authorisation under this regulation if it concludes that, taking into account all available information, it is reasonable to assume that continued use of that biocidal product does not have any unacceptable effect on human or animal health or on the environment.

(5) An authorisation granted under this regulation must—

- (a) require that the biocidal product is placed on the market only for the essential use allowed for by the derogation;
- (b) impose any risk reduction measures that the competent authority considers appropriate for that product; and
- (c) be granted for a period of time not exceeding that permitted by the derogation granted by the Commission.

(6) The competent authority may extend an authorisation if the Commission makes a decision or adopts a regulation to extend the derogation.

(7) An authorisation granted under this regulation may impose labelling requirements.

<sup>(1)</sup> OJ L 325, 11.12.2007, p. 3.

#### Appeal

14.—(1) Subject to paragraphs (3) and (4), a person ("P") may appeal to the appropriate person if P is aggrieved by a decision of the competent authority under any article of the Biocides Regulation listed in paragraph (2).

- (2) The decisions referred to in paragraph (1) are—
  - (a) to stipulate conditions in an authorisation under Article 22(1);
  - (b) to issue a prohibition or restriction under Article 23(3);
  - (c) not to grant an authorisation under Article 26(3);
  - (d) not to grant an authorisation under Article 30;
  - (e) not to renew an authorisation under Article 31;
  - (f) to refuse to grant an authorisation under Article 37(4);
  - (g) not to grant an authorisation under Article 39(2);
  - (h) to cancel or amend an authorisation under Article 48;
  - (i) not to cancel an authorisation under Article 49;
  - (j) not to amend an authorisation under Article 50;
  - (k) not to grant a parallel trade permit under Article 53(1);
  - (l) to withdraw a parallel trade permit under Article 53(8);
  - (m) not to issue or not to extend a provisional authorisation under Article 55(2);
  - (n) to prohibit, or impose conditions on, a test or experiment under Article 56(3);
  - (o) not to allow P to refer to data provided by a previous applicant under Article 64(1);
  - (p) to refuse access to information under Article 66(2); or
  - (q) to refuse a request under Article 66(4) that information not be made available.

(3) Paragraph (1) does not apply where the decision of the competent authority in question is made to give effect to a Commission decision.

(4) P may only appeal a decision under paragraph (1) where—

- (a) in relation to paragraph 2(a) to (g), (j), (m) and (o), the decision relates to an application by P, or by someone on behalf of P;
- (b) in relation to paragraph 2(h) and 2(l), the decision relates to an authorisation or permit held by P;
- (c) in relation to paragraph 2(n), the decision relates to a notification to the competent authority by P, or by someone on behalf of P; and
- (d) in relation to paragraph 2(i), (k) and (q), the decision relates to a request made by P, or by someone on behalf of P.
- (5) The provisions of Schedule 1 apply where P appeals to the appropriate person.

(6) Where an appeal is brought in respect of a decision under paragraph (2)(h), the decision in question shall be suspended pending the final determination of the appeal.

(7) Where an appeal is brought under paragraph (2)(q), pending final determination of the appeal, the competent authority shall not disclose the information except to the Commission or another competent authority, or otherwise to the extent necessary to enable the appeal to be dealt with.

- (8) In this Regulation, subject to paragraph (9), "the appropriate person" means—
  - (a) in the case of a decision by the competent authority in England, the Secretary of State;

- (b) in the case of a decision by the competent authority in Scotland, the Secretary of State and the Scottish Ministers acting jointly; and
- (c) in the case of a decision by the competent authority in Wales, the Secretary of State and the Welsh Ministers acting jointly.

(9) In relation to matters outside the competence of a devolved administration, the "appropriate person" means the Secretary of State.

#### Applications for biocidal product authorisations prior to 1st September 2013

15.—(1) The competent authority must evaluate applications for biocidal product authorisations submitted before 1st September 2013 for the purposes of Directive 98/8/EC(2) in accordance with the Biocidal Products Regulations 2001(3).

(2) Where, following an evaluation carried out under paragraph (1), the competent authority proposes to make a decision to—

- (a) authorise a biocidal product; or
- (b) refuse to authorise a biocidal product,

that decision must be taken in accordance with the Biocides Regulation.

#### Transitional, transitory and savings provisions

**16.** Schedule 2 has effect.

<sup>(2)</sup> OJ No. L123, 24.4.98, p.1.

<sup>(3)</sup> S.I. 2001/880, as amended by S.I. 2003/429, S.I. 2005/2451, S.I. 2007/293 and S.I. 2010/745.