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.

⁽¹⁾ 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.

CHAPTER 2

CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

Application of the 1974 Act

17.—(1) The following provisions of the 1974 Act apply to the CLP Regulation as if it were health and safety regulations for the purposes of that Act, except that those sections shall not apply to duties placed by the CLP Regulation on the competent authority or the Member State—

- (a) sections 18 to 28 (in relation to enforcement); and
- (b) subject to regulations 32 and 33(1), sections 33 to 42 (in relation to offences).

(2) Any function of the Health and Safety Executive under any other provision of the 1974 Act in respect of health and safety regulations (including their enforcement) shall be exercisable as if the CLP Regulation were health and safety regulations for the purposes of that Act.

Allocation of enforcement responsibility

18.—(1) Notwithstanding the 1998 Regulations and subject to paragraphs (2) to (4), the enforcing authority for the CLP Regulation is the Health and Safety Executive or the Office of Rail Regulation, determined in accordance with the provisions of the 2006 Regulations.

- (2) The enforcing authority for the CLP Regulation is the local weights and measures authority—
 - (a) where a substance, mixture or article is placed on the market within the meaning of the CLP Regulation (other than in the circumstances referred to in paragraph (3))—
 - (i) in or from any shop, mobile vehicle, market stall or other retail outlet; or

⁽²⁾ OJ No. L123, 24.4.98, p.1.

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

- (ii) otherwise to members of the public, including by way of free sample, prize or by mail order; and
- (b) for Articles 35(2) and 48 of the CLP Regulation.

(3) Subject to paragraph (4), where a substance, mixture or article is placed on the market in or from premises which are registered under sections 74A to 74L of the Medicines Act 1968(4), the enforcing authority shall be the General Pharmaceutical Council.

(4) In every case where, by virtue of this regulation and the CLP Regulation, the CLP Regulation is enforced by the General Pharmaceutical Council or the local weights and measures authority, it shall be enforced as if it were a safety regulation made under section 11 of the Consumer Protection Act 1987(5).

(5) The provisions of section 12 of the Consumer Protection Act 1987 shall apply to the CLP Regulation as if it were a safety regulation for the purposes of that Act and as if the maximum period of imprisonment on summary conviction specified in subsection (5) of section 12 of that Act were 3 months instead of 6 months.

CHAPTER 3

EXPORT AND IMPORT OF HAZARDOUS CHEMICALS

Application of the 1974 Act

19.—(1) The provisions of the 1974 Act specified in paragraph (2) shall apply for the purposes of the enforcement in Great Britain of regulation 28 and the PIC Regulation as if they were health and safety regulations for the purposes of that Act, and any function of the Great Britain Executive under any provision of that Act in respect of health and safety regulations (including their enforcement) shall be exercisable as if regulation 28 and the PIC Regulation were, to the extent that they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) The provisions referred to in paragraph (1) are—

- (a) sections 19 and 20 (appointment and powers of inspectors);
- (b) section 21 (improvement notices) and sections 23 and 24 (supplementary provisions and appeals) to the extent that they relate to an improvement notice served under section 21;
- (c) section 25A to 28 (customs officer's power to detain articles and substances, power to indemnify inspectors, power to obtain information, information communicated by the Commissioners of Revenue and Customs and restrictions on disclosure of information); and
- (d) subject to regulations 32 and 33(1), sections 33 to 42 (provisions as to offences).
- (3) For the purposes of paragraph (1)—
 - (a) section 25A shall have effect as if, in subsection (1) of that section, after the word "substance" there were inserted "or any article bound for export or any substance bound for export"; and
 - (b) section 27A shall have effect as if, in subsection (1) of that section, after "imports" there were inserted "or exports".

(4) 1968 c. as amended by S.I. 2010/231, art 68, Sch. 4.

^{(5) 1987} c. 43, as amended by SI 2005/1803, reg 46(1), (3). Amendments made to section 11 by other instruments are not relevant for these purposes.

Application of the 1978 Order

20.—(1) The provisions of the 1978 Order specified in paragraph (2) shall apply for the purposes of the enforcement in Northern Ireland of regulation 28 and the PIC Regulation as if they were health and safety regulations for the purposes of that Order, and any function of the Northern Ireland Executive under any provision of that Order in respect of health and safety regulations (including their enforcement) shall be exercisable as if regulation 28 and the PIC Regulation were, to the extent that they would not otherwise be so, health and safety regulations for the purposes of that Order.

- (2) The provisions referred to in paragraph (1) are—
 - (a) Articles 21 and 22 (appointment and powers of inspectors);
 - (b) Articles 23 (improvement notices), and Articles 25 and 26 (supplementary provisions and appeals) to the extent that they relate to an improvement notice served under Article 23;
 - (c) Articles 27A to 30 (customs officer's power to detain articles and substances, power to indemnify inspectors, power to obtain information, information communicated by the Commissioners of Revenue and Customs and restrictions on disclosure of information); and
 - (d) Subject to regulations 32 and 33(2), Articles 31 to 39 (provisions as to offences).
- (3) For the purposes of paragraph (1)—
 - (a) Article 27A shall have effect as if, in paragraph (1) of that Article, after "substance", there were inserted "or any article bound for export or any substance bound for export"; and
 - (b) Article 29A shall have effect as if, in paragraph (1) of that Article, after "imports", there were inserted "or exports".

Duties on designated national authorities and Member States

21. A failure to discharge a duty placed by the PIC Regulation on a designated national authority or the Member State is not an offence under section 33(1)(c) of the 1974 Act or under Article 31(1) (c) of the 1978 Order.

Allocation of enforcement responsibility

22. It shall be the duty of the Great Britain Executive and the Northern Ireland Executive to make adequate arrangements for the enforcement of regulation 28 and the PIC Regulation, and references to the enforcing authority in the provisions applied for those purposes by regulations 19 and 20 shall be construed as references to the Great Britain Executive and the Northern Ireland Executive.

Enforcement notice

23. If an inspector is of the opinion that a person has contravened, is contravening or is likely to contravene a requirement placed on that person by the PIC Regulation, the inspector may serve on that person an enforcement notice.

24.—(1) An enforcement notice must—

- (a) state that the inspector is of the opinion referred to in regulation 23;
- (b) specify the matters constituting the contravention or the matters making it likely that the contravention will arise, as the case may be;
- (c) specify the steps that must be taken to remedy the contravention or to remedy the matters making it likely that the contravention will arise, as the case may be; and
- (d) specify the period within which those steps must be taken.

(2) Steps specified pursuant to paragraph (1)(c) may include the prohibition of further movement or the recall of chemicals and articles.

25. An enforcement notice may contain provision prohibiting the export of chemicals and articles until steps specified under regulation 24(1)(c) have been taken or the notice has been withdrawn.

26. Where an enforcement notice has been served but is not to take immediate effect—

- (a) the notice may be withdrawn by an inspector at any time before the end of the period specified therein;
- (b) the period so specified may be extended or further extended by an inspector at any time when an appeal against the notice is not pending.

27.—(1) A person on whom an enforcement notice is served may, within 21 days from the date of its service, appeal to—

- (a) an employment tribunal, where the notice is served by an inspector appointed under section 19 of the 1974 Act; or
- (b) an industrial tribunal established under Article 3 of the Industrial Tribunals (Northern Ireland) Order 1996(6), where the notice is served by an inspector appointed under Article 21 of the 1978 Order,

and on such an appeal the tribunal may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the tribunal in the circumstances thinks fit.

(2) Schedule 4 to the Employment Tribunals (Constitution and Rules of Procedure) Regulations 2004(7) applies to an appeal to an employment tribunal under paragraph (1)(a).

(3) An enforcement notice is to be treated under paragraph (2) in the same way as an improvement notice for the purposes of that Schedule.

(4) Schedule 5 to the Industrial Tribunals (Constitution and Rules of Procedure) Regulations (Northern Ireland) 2005(8) applies to an appeal to an industrial tribunal under paragraph (1)(b).

(5) An enforcement notice is to be treated under paragraph (4) in the same way as an improvement notice for the purposes of that Schedule.

(6) Subject to paragraph (7), the bringing of the appeal shall not affect the operation of the enforcement notice.

(7) Where an appeal under this regulation is brought against an enforcement notice within the period allowed under paragraph (1), the tribunal may, on the application of the appellant, direct that the bringing of the appeal shall have the effect of suspending the operation of the notice until the appeal is finally disposed of or, if the appeal is withdrawn, until the withdrawal of the appeal.

28. A person shall not contravene any requirement or prohibition imposed by an enforcement notice (including any such notice as modified on appeal).

Service of enforcement notices

29.—(1) Section 46 of the 1974 Act shall apply to an enforcement notice served by an inspector appointed under section 19 of the 1974 Act as if it were an improvement notice.

(2) Section 24 of the Interpretation Act (Northern Ireland) 1954(9)(service of documents) shall apply to regulations 23 to 27 in their application to Northern Ireland as if they were provisions of an Act of the Northern Ireland Assembly.

⁽⁶⁾ S.I. 1996/1921 (N.I. 18).

⁽⁷⁾ S.I. 2004/1861.

⁽⁸⁾ S.R. 2005 No. 150, as amended by S.R. 2005 No. 578 and S.R. 2011 No.161.

^{(9) 1954} c. 33 (N.I.).

CHAPTER 4

EXEMPTIONS, PENALTIES AND DUE DILIGENCE DEFENCE

Exemptions

30.—(1) A person is exempt from compliance with provisions imposing requirements or prohibitions in the Biocides Regulation or the CLP Regulation, if that person—

- (a) has the benefit of a defence exemption certificate made by the Secretary of State in respect of that provision; or
- (b) can demonstrate that the appropriate authorities of another Member State have exempted that person from compliance in the interests of defence.
- (2) Schedule 3 (defence exemption certificates) has effect.

31.—(1) These Regulations shall not apply to a substance or mixture which is a sample taken by an authority responsible for the enforcement of any requirement of, or prohibition imposed by or under, the Biocides Regulation, the CLP Regulation or the PIC Regulation.

(2) In this regulation, "substance" and "mixture" have the same meaning as they have in the CLP Regulation.

Penalties

32.—(1) The maximum penalty for an offence—

- (a) under section 33 of the 1974 Act, as applied by these Regulations to the Biocides Regulation, the CLP Regulation, the PIC Regulation and regulations 12,13(2) and 28 of these Regulations; or
- (b) under Article 31 of the 1978 Order as applied by these Regulations to the PIC Regulation and regulation 28 of these Regulations,

shall be determined in accordance with paragraph (2).

- (2) The penalty referred to in paragraph (1) shall be—
 - (a) on summary conviction—
 - (i) in England, Wales and Northern Ireland, imprisonment for a term not exceeding three months or a fine not exceeding the statutory maximum, or both;
 - (ii) in Scotland, imprisonment for a term not exceeding twelve months or a fine not exceeding the statutory maximum, or both; and
 - (b) on conviction on indictment, imprisonment for a term not exceeding two years, or a fine or both.

Due diligence defence

33.—(1) In any proceedings for an offence under section 33(1)(c) of the 1974 Act, as applied by these Regulations to regulations 12 and 13(2), the Biocides Regulation, the CLP Regulation and the PIC Regulation, it is a defence for the person charged to prove that that person took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) In any proceedings for an offence under Article 31(1)(c) of the 1978 Order, as applied by these Regulations to the PIC Regulation, it is a defence for the person charged to prove that that person took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

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