
STATUTORY INSTRUMENTS

2013 No. 1506

HEALTH AND SAFETY

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

Made - - - - 18th June 2013

Laid before Parliament 27th June 2013

Coming into force in accordance with regulation 2

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(1) (“the 1972 Act”) in relation to—

- (a) biocides(2);
- (b) the regulation and control of classification, packaging and labelling of dangerous substances and preparations (3);
- (c) measures relating to consumer protection(4);
- (d) the control of the import and export of goods(5); and
- (e) the notification and control of substances(6).

The Secretary of State makes these Regulations—

- (a) in exercise of the powers conferred by section 2(2) of, and paragraph 1A(7) of Schedule 2 to, the 1972 Act; and sections 15(1), (2), (3)(c), 5(b), (6), (8) and (9), and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (4), 2(1), 4(1), 6, 13(1) and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(8) (“the 1974 Act”), and
- (b) for the purposes of giving effect without modifications to proposals submitted to him by the Health and Safety Executive under section 11(3)(9) of the 1974 Act.

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

(1) 1972 c.68. Section 2(2) was amended by section 27 of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3 of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7). The power of Ministers to make regulations in relation to matters in or regards Scotland is preserved by section 57(1) of the Scotland Act 1998 (c.46).

(2) S.I. 1999/2788.

(3) S.I. 1976/897.

(4) S.I. 1993/2661.

(5) S.I. 1983/1706.

(6) S.I. 1981/1536.

(7) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51).

(8) 1974 c.37; sections 15 and 50 were amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 6 and 16 respectively.

(9) Section 11(3) was amended by the Legislative Reform (Health and Safety Executive Order) 2008 (S.I.2008/960).

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 these Regulations to—

- (a) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012⁽¹⁰⁾ concerning the making available on the market and use of biocidal products to be construed as including references to Annexes I to IV of that Regulation as those Annexes are amended from time to time;
- (b) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008⁽¹¹⁾ on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006, to be construed as including references to Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29, 35(2) second and third sub-paragraphs and Annexes I to VII of that Regulation as those Articles and Annexes are amended from time to time; and
- (c) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012⁽¹²⁾ concerning the export and import of hazardous chemicals to be construed as including references to Annexes I, II, V and VI of that Regulation as those Annexes are amended from time to time.

PART 1

INTRODUCTION

Citation, commencement and extent

1. These Regulations may be cited as the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

2.—(1) Except as provided by paragraphs (2) to (5), these Regulations come into force on 1st September 2013.

(2) Chapter 2 of Part 3 of these Regulations comes into force on 1st June 2015.

(3) In so far as they apply to Chapter 2 of Part 3 of these Regulations or the CLP Regulation, regulations 4, 30 to 32 and 33(1) and Schedule 3 come into force on 1st June 2015.

(4) Chapter 3 of Part 3 of these Regulations, regulations 7, 33(2) and 34(f) and Part 1 of Schedule 4 come into force on 1st March 2014.

(5) In so far as they apply to Chapter 3 of Part 3 of these Regulations or the PIC Regulation, regulations 4, 31, 32 and 33(1) come into force on 1st March 2014.

3.—(1) These Regulations shall not extend to Northern Ireland except as provided by paragraphs (2) and (3).

(2) Regulations 1, 2(1), (4) and (5), 7, 33(2) and 34(f) and Chapter 3 of Part 3 of these Regulations shall extend to Northern Ireland.

(3) In so far as regulations 4, 31, 32 and 38 apply to Chapter 3 of Part 3 of these Regulations or the PIC Regulation, they shall extend to Northern Ireland.

⁽¹⁰⁾ OJ No L167, 27.06.12, p.1.

⁽¹¹⁾ OJ No L353, 31.12.08, p.1.

⁽¹²⁾ OJ No L201, 27.07.12, p.60.

(4) Except for the regulations listed in paragraph (5), these Regulations apply outside Great Britain as sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 2013(13).

(5) The regulations referred to in paragraph (4) are—

- (a) regulation 7;
- (b) Chapter 3 of Part 3; and
- (c) regulations 4, 31, 32 and 33 in so far as they apply to Chapter 3 of Part 3 or to the PIC Regulation.

Interpretation

4.—(1) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974;

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978(14);

“the Great Britain Executive” means, for the purposes of regulation 7 and Chapter 3 of Part 3, the Health and Safety Executive established under section 10(15) of the 1974 Act;

“the 1998 Regulations” means the Health and Safety (Enforcing Authority) Regulations 1998(16);

“the 2006 Regulations” means the Health and Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006(17);

“the 2009 Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009(18);

“the Biocides Regulation” means Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, of which Annexes I to IV are to be read as amended from time to time;

“the CLP Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, of which Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29, 35(2) second and third sub-paragraphs and Annexes I to VII are to be read as amended from time to time;

“the Commission” means the Commission of the European Union;

“competent authority” means the authority or authorities appointed in a Member State for the purpose of carrying out the duties of a competent authority under the Biocides Regulation or the CLP Regulation;

“contravention” includes a failure to comply and “contravene” has a corresponding meaning;

“devolved administration” means the Scottish Ministers or the Welsh Ministers;

“inspector” means—

- (a) a person appointed under section 19 of the 1974 Act; or
- (b) for the purposes of Chapter 3 of Part 3, a person falling within paragraph (a) or a person appointed under Article 21 of the 1978 Order;

(13) S.I. 2013/240.

(14) S.I. 1978/1039 (N.I. 9).

(15) Section 10 was amended by S.I. 2008/960.

(16) S.I. 1998/494, to which there are amendments not relevant to these Regulations.

(17) S.I. 2006/557, as amended by S.I. 2006/2739, 2007/320, 2007/1573 and 2008/2323.

(18) S.I. 2009/716, as amended by S.S.I. 2011/228; S.I. 2011/1043 and 2011/2131.

“local authority” means—

- (a) in relation to England, a county council so far as it is the council for an area for which there are no district councils, a district council, a London borough council, the Common Council of the City of London, the Sub-Treasurer of the Inner Temple, the Under-Treasurer of the Middle Temple, or the Council of the Isles of Scilly;
- (b) in relation to Wales, a county council or county borough council; and
- (c) in relation to Scotland, a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994⁽¹⁹⁾;

“local weights and measures authority” has the meaning in section 69 of the Weights and Measures Act 1985⁽²⁰⁾;

“the Northern Ireland Executive” means the Health and Safety Executive for Northern Ireland established under Article 12 of the 1978 Order;

“the PIC Regulation” means Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, of which Annexes I, II, V and VI are to be read as amended from time to time;

“work” shall be construed in accordance with section 52 of the 1974 Act.

(2) Expressions used in both—

- (a) Chapter 1 of Part 3 of, or Schedule 2 to, these Regulations; and
- (b) the Biocides Regulation,

have the same meaning in these Regulations as they have in the Biocides Regulation.

(3) Expressions used in both—

- (a) Chapter 2 of Part 3 of these Regulations; and
- (b) the CLP Regulation,

have the same meaning in these Regulations as they have in the CLP Regulation.

(4) Expressions used in both—

- (a) regulation 7 or Chapter 3 of Part 3 of these Regulations; and
- (b) the PIC Regulation,

have the same meaning in these Regulations as they have in the PIC Regulation.

PART 2

APPOINTMENT OF COMPETENT AUTHORITIES AND DESIGNATED NATIONAL AUTHORITIES

Competent authorities and designated national authorities

5.—(1) Subject to paragraph (2), for the purposes of Article 81(1) of the Biocides Regulation the competent authority is—

- (a) in England, the Secretary of State;
- (b) in Scotland, the Scottish Ministers; and
- (c) in Wales, the Welsh Ministers.

⁽¹⁹⁾ 1994 c.39.

⁽²⁰⁾ 1985 c.72; as amended by the Local Government (Wales) Act 1994, s.66(6), Sch 16, para 75 and the Local Government (Scotland) Act 1973, s.149(6) Sch 1, para 144.

(2) In relation to matters outside the competence of a devolved administration, the competent authority is the Secretary of State.

6.—(1) Subject to paragraph (2), for the purposes of Article 43 of the CLP Regulation the competent authority is—

- (a) in England, the Secretary of State;
- (b) in Scotland, the Scottish Ministers; and
- (c) in Wales, the Welsh Ministers.

(2) In relation to matters outside the competence of a devolved administration, the competent authority is the Secretary of State.

7. The Great Britain Executive and the Northern Ireland Executive are the designated national authorities—

- (a) to act for the performance of the administrative functions required by the PIC Regulation, in accordance with Article 4 of that Regulation; and
- (b) to have the responsibility for controlling the export and import of chemicals listed in Annex I of the PIC Regulation, in accordance with Article 18 of that Regulation.

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\(21\)](#).

(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—

(21) OJ L 325, 11.12.2007, p. 3.

- (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.

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\(22\)](#) in accordance with the Biocidal Products Regulations 2001(23).

(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.

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

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

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

(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⁽²⁴⁾, 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⁽²⁵⁾.

(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)—

⁽²⁴⁾ 1968 c. as amended by S.I. 2010/231, art 68, Sch. 4.

⁽²⁵⁾ 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.

- (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”.

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⁽²⁶⁾, 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⁽²⁷⁾ 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⁽²⁸⁾ 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).

⁽²⁶⁾ S.I. 1996/1921 (N.I. 18).

⁽²⁷⁾ S.I. 2004/1861.

⁽²⁸⁾ S.R. 2005 No. 150, as amended by S.R. 2005 No. 578 and S.R. 2011 No.161.

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(**29**)(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.

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.

PART 4

REVOCATIONS, AMENDMENTS AND REVIEW

Revocations and amendments

- 34.** Subject to paragraph 10 of Schedule 2, the following regulations are revoked:
- (a) except for regulations 39 and 39A and Schedules 12 and 12A, the Biocidal Products Regulations 2001;
 - (b) in so far as they apply to Great Britain and except for regulation 3(c) and Schedule 1, the Biocidal Products (Amendment) Regulations 2003⁽³⁰⁾;
 - (c) in so far as they apply to Great Britain, the Biocidal Products (Amendment) Regulations 2005⁽³¹⁾;
 - (d) the Biocidal Products (Amendment) Regulations 2007⁽³²⁾;
 - (e) the Biocidal Products (Amendment) Regulations 2010⁽³³⁾; and
 - (f) the Export and Import of Dangerous Chemicals Regulations 2008⁽³⁴⁾.
- 35.** The 2009 Regulations are amended in accordance with the provisions of Schedule 4.
- 36.** The following provisions of the 2009 Regulations are revoked—
- (a) regulation 5;
 - (b) regulations 4, 6 to 11 and 13, with effect from 1st June 2015;
 - (c) except to the extent that they continue to apply for the purposes of enforcing regulation 12 of the 2009 Regulations, regulations 14 to 18, with effect from 1st June 2015; and
 - (d) regulations 1 to 3, and 12, with effect from 1st June 2018.
- 37.** The enactments, or instruments made by the Scottish Parliament, specified in Schedule 5 are amended to the extent specified in that Schedule.

Review

- 38.**—(1) The Secretary of State must from time to time—
- (a) carry out a review of regulations 5 to 33,
 - (b) set out the conclusions of the review in a report, and

⁽³⁰⁾ S.I. 2003/429.
⁽³¹⁾ S.I. 2005/2451.
⁽³²⁾ S.I. 2007/293.
⁽³³⁾ S.I. 2010/745.
⁽³⁴⁾ S.I. 2008/2108.

- (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to the measures taken to implement rules on enforcement and appointment of authorities in relation to the PIC, CLP and Biocides Regulations in other Member States.
- (3) The report must in particular—
 - (a) set out the objectives intended to be achieved by the measures taken to implement rules on enforcement and appointment of authorities in relation to the PIC, CLP and Biocides Regulations,
 - (b) assess the extent to which those objectives are achieved, and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (4) The first report under this regulation must be published before 1st September 2018.
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

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

18th June 2013

Mark Hoban
Minister of State,
Department for Work and Pensions

SCHEDULE 1

Regulation 14(4)

Biocidal products appeals

PART 1

DEFINITIONS AND ARRANGEMENTS FOR AN APPEAL

1. In this Schedule—
 - (a) “appeal” means an appeal under regulation 14;
“appellant” means a person who has brought an appeal;
“appointed person” means a person appointed in accordance with paragraph 2;
“appropriate person” has the same meaning as it has in regulation 14(8);
“hearing” means a hearing to which Part 2 of this Schedule applies;
“the parties” means the appellant and the competent authority;
 - (b) a reference to “government department” includes, in the case of an appeal relating to a decision of the competent authority—
 - (i) in or as regards Scotland, a reference to the Scottish Administration or any part thereof; and
 - (ii) in or as regards Wales, a reference to the Welsh Ministers;
 - (c) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.
2. The appropriate person must—
 - (a) direct that an appeal shall be determined by a person appointed by the appropriate person for that purpose; and
 - (b) notify the parties in writing of the name of the appointed person.
3. Before the determination of an appeal, the appointed person must ask the parties whether they wish to appear and be heard on the appeal and—
 - (a) the appeal may be determined without a hearing if the parties express a wish not to be heard;
 - (b) the appointed person must, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing, in which case the provisions of Part 2 of this Schedule shall apply.
4. An appointed person may give such directions as that appointed person thinks appropriate to give effect to a determination.
5. The appropriate person may pay to an appointed person such remuneration and allowances as the appropriate person may determine.

PART 2

APPEAL PROCEDURES

6. An appeal brought pursuant to regulation 14(1)(q) must be heard in private.

7.—(1) Subject to the following sub-paragraphs of this paragraph, a date, time and place for the holding of the hearing shall be fixed, and may be varied, by the appointed person, who must give not less than 42 days' notice in writing of such date, time and place to the parties.

(2) With the consent of the parties, the appointed person may give such lesser period of notice as shall be agreed with the parties, and in that event, the appointed person may specify a date for service of the statement referred to in paragraph 8(1) later than the date determined in accordance with that paragraph.

(3) Where it becomes necessary or advisable to vary the time or place fixed for the hearing, the appointed person shall give such notice of the variation as may appear to the appointed person to be reasonable in the circumstances.

(4) Without prejudice to sub-paragraphs (1) to (3), the appointed person may require the competent authority to take one or more of the following steps, namely—

(a) to serve such notice of the hearing, in such form and on such persons or classes of persons as the appointed person may direct;

(b) to give such other notice of the hearing, in such form as the appointed person may direct, and the requirements as to the period of notice contained in sub-paragraph (1) shall not apply to any such notices.

8.—(1) Not later than 28 days before the date of the hearing, or such later date as the appointed person may specify in accordance with paragraph 7(2), the competent authority must serve on the appellant a written statement of any submission which the competent authority proposes to put forward at the hearing and shall supply a copy of the statement to the appointed person.

(2) Where a government department has expressed in writing to the competent authority a view in support of the decision of the competent authority and the competent authority proposes to rely on such expression of view in its submission at the hearing, the competent authority must include the expression of view in its statement and must supply a copy of the statement to the government department concerned.

(3) Where the competent authority intends to refer to, or put in evidence at the hearing, documents (including photographs), the statement of the competent authority must be accompanied by a list of such documents, together with a written notice stating the times and place at which the documents may be inspected by the appellant; and the competent authority shall afford the appellant a reasonable opportunity to inspect and, where practicable, to take copies of the documents.

(4) If so required by the appointed person, the appellant must—

(a) serve on the competent authority and on the appointed person, within such time before the hearing as the appointed person may specify, a written statement of the submissions which the appellant proposes to put forward at the hearing; and such statement must be accompanied by a list of any documents (including photographs) which the appellant intends to refer to or put in evidence at the hearing; and

(b) afford the competent authority a reasonable opportunity to inspect and, where practicable, to take copies of such documents as are referred to in paragraph (a).

9.—(1) The parties shall be entitled to appear at the hearing.

(2) Any other person may appear at the discretion of the appointed person provided that that person has, not later than 7 days before the date of the hearing, served on the competent authority a statement of that person's proposed submissions.

(3) The competent authority must send a copy of every statement served on the competent authority in accordance with sub-paragraph (2) to the appointed person and to the appellant.

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(4) A body corporate may appear by its clerk or secretary or by any other officer appointed for the purpose by that body, or by counsel or a solicitor.

(5) A Scottish partnership (other than a limited liability partnership), may appear by a partner or other person in charge, or locally in charge, of the partnership's affairs.

(6) A person may appear on that person's own behalf or be represented by counsel, a solicitor or any other person.

(7) Where there are two or more persons having a similar interest in the subject matter of the hearing, the appointed person may allow one or more persons to appear for the benefit of some or all persons so interested.

10.—(1) Where a government department has expressed in writing to the competent authority a view in support of the decision of the competent authority and the competent authority has included this view in the statement referred to in paragraph 8(1), the appellant may apply in writing to the appointed person, not later than 14 days before the date of the hearing, for a representative of the government department concerned to be made available at the hearing.

(2) The appointed person must send an application made to the appointed person under sub-paragraph (1) to the government department concerned, who must make a representative of the department available to attend the hearing.

(3) A representative of a government department who, in pursuance of this paragraph, attends a hearing, shall be called as a witness by the competent authority and shall state the reasons for the view expressed by the representative's department and included in the statement of the competent authority under paragraph 8(1) and shall give evidence and be subject to cross-examination to the same extent as any other witness.

(4) Nothing in sub-paragraph (3) shall require a representative of a government department to answer any question which, in the opinion of the appointed person, is directed to the merits of government policy or to matters which affect the safety of the State, and the appointed person must disallow any such question.

11.—(1) Except as otherwise provided in this Part of this Schedule, the procedure at the hearing must—

- (a) be determined at the discretion of the appointed person, subject to consideration of any submission by the parties at the commencement of the hearing; and
- (b) be communicated by the appointed person to the parties at the commencement of the hearing.

(2) Unless in any particular case the appointed person, with the consent of the appellant, otherwise determines—

- (a) in the case of an appeal to the Secretary of State, the appellant shall be heard first and shall have the right of final reply; and
- (b) in the case of an appeal to the Secretary of State and the Scottish Ministers, or the Secretary of State and the Welsh Ministers, acting jointly—
 - (i) the appellant shall be heard first;
 - (ii) the other persons entitled or permitted to appear shall be heard in such order as the appointed person may determine; and
 - (iii) any closing statements shall be made in the same order, unless the appointed person otherwise determines.

(3) The parties shall be entitled to make an opening statement, to call evidence and to cross-examine persons giving evidence, but any other person appearing at the hearing may do so only to the extent permitted by the appointed person.

(4) Subject to sub-paragraph (5), any evidence may be admitted at the discretion of the appointed person, who may direct that documents tendered in evidence may be inspected by any person entitled or permitted to appear at the hearing and that facilities be afforded to that person to take or obtain copies of those documents.

(5) The appointed person shall not require or permit the giving or production of any evidence, whether written or oral, which would be contrary to the public interest.

(6) The appointed person may allow the competent authority or the appellant, or the parties, to alter or add to the submissions contained in any statement served under paragraph 8(1) or (4), or to any list of documents which accompanied such statement, so far as may be necessary for the purpose of determining the questions in controversy between the parties, but must (if necessary by adjourning the hearing) give the appellant or the competent authority, as the case may be, an adequate opportunity of considering any such fresh submission or document.

(7) If any person entitled to appear at the hearing fails to appear, the appointed person may proceed with the hearing at the appointed person's discretion.

(8) The appointed person shall be entitled to take into account any written representations or statements received by the appointed person before the hearing from any person, subject to disclosure of such representations or statements at the hearing.

(9) The appointed person may from time to time adjourn the hearing, and where the appointed person does so, shall give reasonable notice to every person entitled or permitted to appear at the hearing of the date, time and place of the adjourned hearing.

12.—(1) Where, after the close of the hearing, the appointed person proposes to take into consideration—

- (a) any new evidence, including expert opinion on a matter of fact; or
- (b) any new issue of fact, not being a matter of government policy or a matter affecting the safety of the State,

which was not raised at the hearing and which the appointed person considers to be material to the decision, the appointed person must not come to a decision without first notifying the parties of the substance of the new evidence or of the new issue of fact and affording them an opportunity of making representations on the new evidence or new issue in writing within 21 days or of asking within that time for the re-opening of the hearing.

(2) If the appointed person thinks fit, the appointed person may cause the hearing to be re-opened and must cause it to be re-opened if asked to do so in accordance with sub-paragraph (1).

(3) Where the hearing is re-opened, paragraphs 7(1) and 7(4) apply as they applied to the original hearing with the substitution in paragraph 7(1) of “28” for “42”.

13. The appointed person must notify the determination on the appeal, and the reasons for the determination, in writing to the parties and to any person who, having appeared at the hearing, has asked to be notified of the decision.

SCHEDULE 2

Regulation 16

Transitional, transitory and savings provisions

1. In this Schedule—

“COPR” means the Control of Pesticides Regulations 1986(35);

(35) S.I. 1986/1510, amended by S.I. 1997/188.

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

“Plant protection product” has the same meaning as in Article 2(1) of Regulation (EC) No 1107/2009⁽³⁶⁾ of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC;

“Unlisted active substance” means an existing active substance which has not been subject to a decision to approve or not approve it in accordance with Article 9 of the Biocides Regulation.

2.—(1) Following a decision that an unlisted active substance shall be approved in accordance with Article 9(1)(a) of the Biocides Regulation, COPR shall cease to apply to a COPR biocidal product containing that active substance on the dates determined in accordance with paragraphs 4 to 6.

(2) Where there is more than one unlisted active substance in a COPR biocidal product, the decision in sub-paragraph (1) shall be taken to mean the decision in relation to the last of the unlisted active substances in the COPR biocidal product.

3. Following a decision that an unlisted active substance shall not be approved in accordance with Article 9(1)(b) of the Biocides Regulation, COPR shall cease to apply to a COPR biocidal product containing that active substance from the date or dates upon which the biocidal product may no longer be placed on the market or used pursuant to that decision.

4.—(1) Where—

- (a) there is a decision referred to in paragraph 2; and
- (b) no application is submitted in accordance with the Biocides Regulation for authorisation or mutual recognition in parallel in respect of the COPR biocidal product on or before the date of approval of the active substance,

COPR shall cease to apply to the COPR biocidal product in accordance with sub-paragraph (2).

(2) For the purposes of sub-paragraph (1), COPR shall cease to apply to the COPR biocidal product at the expiry of—

- (a) 180 days from the date of approval, in relation to the placing on the market of the biocidal product; and
- (b) 365 days from the date of approval, in relation to the disposal and use of existing stocks of the biocidal product.

5.—(1) Where—

- (a) there is a decision referred to in paragraph 2; and
- (b) an application is submitted in accordance with the Biocides Regulation for authorisation or mutual recognition in parallel of the COPR biocidal product on or before the date of approval of the active substance,

COPR shall cease to apply to the COPR biocidal product in accordance with sub-paragraphs (2) to (4).

(2) Where a decision is taken to authorise the COPR biocidal product, COPR shall cease to apply to the biocidal product from the date of that decision.

(3) Where the application referred to in sub-paragraph (1)(b) is rejected, COPR shall cease to apply to the COPR biocidal product at the expiry of—

⁽³⁶⁾ OJ No. L309, 24.11.2009, p.1.

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- (a) 180 days from the date of the decision to reject the application, in relation to the placing on the market of the biocidal product; and
 - (b) 365 days from the date of the decision to reject the application, in relation to the disposal and use of existing stocks of the biocidal product.
- (4) Where a decision is taken not to authorise the COPR biocidal product, COPR shall cease to apply to the COPR biocidal product at the expiry of—
- (a) 180 days from the date of that decision in relation to the placing on the market of the biocidal product; and
 - (b) 365 days from the date of that decision in relation to the disposal and use of existing stocks of the biocidal product.

6.—(1) Following an application for authorisation under the Biocides Regulation on or before 1st September 2017 in respect of a COPR biocidal product which falls within Article 93(1) of the Biocides Regulation, COPR ceases to apply to that biocidal product in accordance with sub-paragraphs (2) to (5).

(2) Where a decision is taken to authorise the COPR biocidal product, COPR shall cease to apply to the biocidal product from the date of that decision.

(3) Where the application referred to in sub-paragraph (1) is rejected, COPR shall cease to apply to the COPR biocidal product from the date of rejection.

(4) Where a decision is taken not to authorise the COPR biocidal product, COPR shall cease to apply to the biocidal product at the expiry of—

- (a) 180 days from the date of that decision in relation to the placing on the market of the biocidal product; and
- (b) 365 days from the date of the decision or 1st September 2018 (whichever is the later) in relation to the disposal and use of existing stocks of the biocidal product.

(5) Where no application for authorisation of the COPR biocidal product has been made by 1st September 2017, COPR shall cease to apply to the biocidal product after—

- (a) 28th February 2018 in relation to the making available of the biocidal product on the market; and
- (b) 1st September 2018 in relation to the disposal and use of existing stocks of the biocidal product.

7. Despite the revocation of the Biocidal Products Regulations 2001 by virtue of regulation 34(a) of these Regulations, paragraph 13 of Schedule 13 to the Biocidal Products Regulations 2001 is preserved so that COPR shall continue not to apply to COPR biocidal products where, by virtue of that paragraph, it previously ceased to apply.

8.—(1) Where a certificate of exemption—

- (a) was issued under paragraphs 6 to 12 of Schedule 13 to the Biocidal Products Regulations 2001; and
- (b) has not expired or been revoked prior to 1st September 2013,

that certificate is hereby revoked.

(2) Where a certificate is revoked pursuant to sub-paragraph (1), the competent authority may issue a new certificate of exemption which exempts any person or class of person or any biocidal product or class of biocidal product from Article 17(1) of the Biocides Regulation.

9. A certificate of exemption granted pursuant to paragraph 8(2)—

- (a) must be in writing;

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- (b) must be granted for a period of time not exceeding the time period allowed for the continuation of the current system or practice, including any phase out period, allowed for under Article 89 of the Biocides Regulation;
- (c) may be granted subject to conditions; and
- (d) may be revoked by certificate in writing at any time.

10.—(1) Despite the revocation of the Biocidal Products Regulations 2001, the Biocidal Products (Amendment) Regulations 2007 and the Biocidal Products (Amendment) Regulations 2010 by virtue of regulation 34(a), (d) and (e) of these Regulations, the regulations listed in sub-paragraph (2) shall continue to apply for the purposes of evaluating applications for biocidal product authorisations pursuant to regulation 15(1) of these Regulations.

- (2) The regulations referred to in sub-paragraph (1) are—
 - (a) Regulations 2, 3, 9, 10, 11, 12, 13, 14, 15, 17, 18, 25, 32, 34, 35 and 37 of, and Schedules 3, 4, and 5 to, the Biocidal Products Regulations 2001;
 - (b) Regulations 2, 3, 4, 8, 9, 10, 11 and 21 of the Biocidal Products (Amendment) Regulations 2007; and
 - (c) Regulations 3 and 4 of the Biocidal Products (Amendment) Regulations 2010.

SCHEDULE 3

Regulation 30(2)

Defence Exemption Certificates

- 1.** The Secretary of State may decide that it is necessary in the interests of defence for a person to be exempt from compliance with a requirement or prohibition in the Biocides Regulation or the CLP Regulation.
- 2.** The Secretary of State may decide to apply the exemption—
 - (a) to a person, including the Secretary of State, or a category of persons;
 - (b) to one or more requirement or prohibition at the same time;
 - (c) prospectively;
 - (d) for a limited or unlimited period;
 - (e) generally or to a particular case;
 - (f) subject to such limitations and conditions as the Secretary of State sees fit.
- 3.** A decision by the Secretary of State to apply the exemption must be evidenced in writing by a certificate.
- 4.** A certificate—
 - (a) must contain sufficient particulars of the persons to whom, and the matters to which, it relates; and
 - (b) may be varied or revoked in writing.
- 5.** The Secretary of State may provide to a person who has the benefit of a certificate—
 - (a) the certificate;
 - (b) a copy of it; or
 - (c) a copy of a relevant extract of the certificate.

6. A person who claims the benefit of a certificate must produce to the person listed in paragraph 7, when reasonably requested to do so—

- (a) the certificate;
- (b) a copy of it made by the Secretary of State; or
- (c) a copy made by the Secretary of State of a relevant extract of the certificate.

7. The persons referred to in paragraph 6 are—

- (a) an enforcing authority;
- (b) a competent authority;
- (c) the equivalent of an enforcing authority of another Member State;
- (d) the European Chemicals Agency.

8. Unless the contrary is proved—

- (a) a certificate;
- (b) a copy of it made by the Secretary of State; or
- (c) a copy made by the Secretary of State of a relevant extract of the certificate,

is conclusive evidence of the matters to which it relates.

9. A person who fails to comply with paragraph 6 shall not be exempt from compliance with a requirement or prohibition in the Biocides Regulation or the CLP Regulation in the interests of defence.

SCHEDULE 4

Regulation 35

Amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009

PART 1

References to Regulation (EU) No 649/2012

1. In paragraph (ii) of the Preamble, for “Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals, of which Annexes I and V are as amended from time to time”, substitute “Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, of which Annexes I, II, V and VI are as amended from time to time”.

2. In regulation 3(3)(c), for “Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals, of which Annexes I and V are as amended from time to time”, substitute “Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, of which Annexes I,II,V and VI are as amended from time to time”.

PART 2

Advertisements for dangerous preparations and penalties

3. After regulation 5 insert—

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“Advertisements for dangerous preparations

5A.—(1) Subject to paragraph (2), a person who supplies a dangerous preparation shall not advertise that preparation, or arrange for the production of any such advertisement, unless mention is made in the advertisement of the type of hazard indicated on the label.

(2) Paragraph (1) shall apply only in respect of a dangerous preparation where the advertisement enables a person, otherwise than in the course of a business, to conclude a contract to purchase the dangerous preparation before that person has seen the label relating to the dangerous preparation.

(3) In this regulation, “supply” has the same meaning as it has in section 46 of the Consumer Protection Act 1987.”.

4. After regulation 14(1) insert—

“(1A) The maximum penalty for an offence under this regulation is—

(a) on summary conviction—

(i) in England and Wales, 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.”

SCHEDULE 5

Regulation 37

Consequential Amendments

PART 1

ENACTMENTS

Wildlife and Countryside Act 1981

1. In section 15A of the Wildlife and Countryside Act 1981⁽³⁷⁾, in subsection (2), for paragraph (b) substitute—

“(b) Regulation (EU) No 528/2012 of the European Parliament and of the Council⁽³⁸⁾.”.

Natural Environment and Rural Communities Act 2006

2. In section 43 of the Natural Environment and Rural Communities Act 2006⁽³⁹⁾, in subsection (3), for paragraph (c) substitute—

“(c) Regulation (EU) No 528/2012 of the European Parliament and of the Council;”.

⁽³⁷⁾ 1981 c. 69.

⁽³⁸⁾ OJ No L167, 27.06.12, p.1.

⁽³⁹⁾ 2006 c. 16.

PART 2

SUBORDINATE LEGISLATION

Control of Pesticides Regulations 1986

3. In the Control of Pesticides Regulations 1986(40), omit Regulation 3(2)(j).

African Swine Fever (England) Order 2003

4. In Article 12(2) of the African Swine Fever (England) Order 2003(41), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

African Swine Fever (Scotland) Order 2003

5. In Article 12(2) of the African Swine Fever (Scotland) Order 2003(42), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

African Swine Fever (Wales) Order 2003

6. In Article 12(2) of the African Swine Fever (Wales) Order 2003(43), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

Diseases of Animals (Approved Disinfectants) (England) Order 2007

7.—(1) The Diseases of Animals (Approved Disinfectants) (England) Order 2007(44) is amended as follows.

(2) In Article 3(2)(b), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

(3) In Article 6(1)(d), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

Diseases of Animals (Approved Disinfectants) (Wales) Order 2007

8.—(1) The Diseases of Animals (Approved Disinfectants) (Wales) Order 2007(45) is amended as follows.

(2) In Article 3(2)(b), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

(40) [S.I. 1986/1510](#) as amended by [S.I. 2001/880](#).

(41) [S.I. 2003/2913](#).

(42) [S.S.I. 2003/586](#).

(43) [S.I. 2003/3273](#).

(44) [S.I. 2007/448](#) as amended by [S.I. 2011/1509](#).

(45) [S.I. 2007/2803](#).

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(3) In Article 6(1)(c), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008

9.—(1) The Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008⁽⁴⁶⁾ is amended as follows.

(2) In Article 3(2)(b), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

(3) In Article 6(1)(b)(iii), for “the Biocidal Products Regulations 2001” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”.

Health and Safety (Fees) Regulations 2012

10. In the Health and Safety (Fees) Regulations 2012⁽⁴⁷⁾, for Regulation 24(16)(c) substitute—
“(c) the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013; and”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, in respect of Great Britain, provide for the appointment of competent authorities in relation to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (“the Biocides Regulation”; OJ No L167, 27.06.12, p.1) and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (“the CLP Regulation”; OJ No. L353, 31.12.08, p.1).

These Regulations, in respect of the United Kingdom, provide for the appointment of designated national authorities in relation to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (“the PIC Regulation”; OJ No. L201, 27.07.12, p.60).

These Regulations also provide for the enforcement, in respect of Great Britain, of the Biocides Regulation and the CLP Regulation and in respect of the United Kingdom, of the PIC Regulation, and of certain provisions of these Regulations.

These Regulations additionally make provision for the competent authorities in Great Britain to authorise biocidal products for essential use, following the granting of a derogation by the European Commission under [Commission Regulation \(EC\) No 1451/2007](#) (OJ No. L325, 11.12.2007, p. 3).

⁽⁴⁶⁾ S.S.I. 2008/219.

⁽⁴⁷⁾ S.I. 2012/1652.

The Biocides Regulation repeals Directive [98/8/EC](#) of 16 February 1998 (OJ No. L123, 24.4.98, p.1) concerning the placing of biocidal products on the market, which laid down harmonised rules for the placing on the market of biocidal products. The Biocides Regulation lays down revised harmonised rules for the approval of active substances and the making available on the market of biocidal products. Its main purpose is to improve the free movement of biocidal products within the European Union, while maintaining the high level of protection of both human and animal health and the environment established in Directive [98/8/EC](#).

The CLP Regulation replaces Council Directive [67/548/EEC](#) (OJ No L196 16.8.67, p.1) and Council Directive [1999/45/EC](#) (OJ No L200 30.7.99, p.1). The main purpose of the CLP Regulation is to adopt within the European Community the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) published by the UN Social and Economic Council (Fourth Revised Edition ISBN-978-92-1-117042-9). The UN GHS is a result of an international agreement made at the United World Conference on Environment and Development in Rio de Janeiro in 1992, and the World Summit on Sustainable Development in Johannesburg in 2002. It sets out internationally accepted definitions and criteria to identify the hazards of chemicals and to communicate those hazards via labels and safety data sheets. The GHS is a voluntary international agreement and countries may keep national requirements that are not covered by the GHS provided that they do not contradict it. The CLP Regulation requires dutyholders to classify, label and package hazardous chemicals before placing them on the market in accordance with its provisions.

The PIC Regulation is a recast of Regulation (EC) No [689/2008](#) (OJ L204, 31.7.08, p.1), deemed necessary in the interests of clarity as a result of several substantial amendments to other European chemicals legislation. The PIC Regulation implements the UN Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade, establishes a procedure by which chemicals qualify for prior informed consent ('PIC') status and maintains in force a common export notification procedure for chemicals either banned or severely restricted within the European Union. The European Commission acts, on behalf of all Member States, as the central administrative authority for contact with the secretariat, other parties and non-parties to the Convention.

Provision is made for the coming into force of the Regulations and to extend the application of the Regulations outside Great Britain in Regulations 2 and 3.

Most of the terms and expressions used in these Regulations are defined in regulation 4.

Regulations 5 and 6 provide that the Secretary of State in relation to England, the Scottish Ministers in relation to Scotland, and the Welsh Ministers in relation to Wales are designated as the competent authorities in relation to the Biocides Regulation and the CLP Regulation. Where a matter is outside the competence of the Scottish Ministers or the Welsh Ministers, the competent authority is the Secretary of State.

Regulation 7 provides that the Great Britain Executive and the Northern Ireland Executive are the designated national authorities with responsibility for the performance of administrative functions required by the PIC Regulation and for controlling the import and export of chemicals listed in Annex I of the PIC Regulation. Regulation 4 provides that the "Great Britain Executive" means the Health and Safety Executive and the "Northern Ireland Executive" means the Health and Safety Executive for Northern Ireland.

Regulation 8 makes provision for the enforcement of the Biocides Regulation and regulations 12 and 13(2) of these Regulations by applying enforcement and penalty provisions of the Health and Safety at Work etc. Act 1974 ("the 1974 Act") to the Biocides Regulation and regulations 12 and 13(2) of these Regulations as if they were health and safety regulations for the purposes of the 1974 Act, subject to the exceptions in the regulation.

Regulation 9 provides that the Biocides Regulation and regulations 12 and 13(2) are enforced either by the Health and Safety Executive, the Office of Rail Regulation, the local weights and measures authority or the local authority, depending on the circumstances as set out in the regulation.

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Regulation 10 limits the powers of an inspector to enter domestic premises in exercise of that inspector's powers under the 1974 Act, as applied to the Biocides Regulation and regulations 12 and 13(2) of these Regulations by Regulation 8.

Regulation 11 ensures that information provided to the competent authorities under the Biocides Regulation is not treated as relevant information for the purposes of section 28 of the 1974 Act.

Regulation 12 requires that information required to be shown on the label of a biocidal product by Article 69(2) of the Biocides Regulation must be in English.

Regulation 13 enables the competent authority 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 5 of [Commission Regulation \(EC\) No 1451/2007](#) (OJ L 325, 11.12.2007, p. 3).

Regulation 14 and Schedule 1 provide a right of appeal and the appeal procedure in relation to certain decisions of the competent authorities made under the Biocides Regulation which is available to a class of persons defined in regulation 14.

Regulations 15 and 16 and Schedule 2 provide transitional measures to enable the continuation of existing procedures for a limited period of time.

Regulation 17 makes provision for the enforcement of the CLP Regulation by applying enforcement and penalty provisions of the 1974 Act to the CLP Regulation as if it were health and safety regulations for the purposes of the 1974 Act.

Regulation 18 provides that the CLP Regulation is enforced by the Health and Safety Executive, the Office of Rail Regulation, the local weights and measures authority or the General Pharmaceutical Council, depending on the circumstances set out in the regulation. In the case of enforcement by the local weights and measures authority or the General Pharmaceutical Council, the provisions of section 12 of the Consumer Protection Act 1987 apply to the CLP Regulation as if it were a safety regulation for the purposes of that Act.

Regulations 19 and 20 provide that the PIC Regulation and regulation 28 of these Regulations are enforced by the Great Britain Executive in Great Britain and the Northern Ireland Executive in Northern Ireland and that the provisions of the 1974 Act, as regards Great Britain, and the 1978 Order, as regards Northern Ireland, are applied to the PIC Regulation and regulation 28 as if they were health and safety regulations for the purposes of the 1974 Act in Great Britain and the Health and Safety at Work (Northern Ireland) Order 1978 ("the 1978 Order") in Northern Ireland. The powers of officers in relation to chemicals or articles under section 25A of the 1974 Act and Article 27A of the 1978 Order, as applied to the PIC Regulation by regulations 19 and 20, enables them to withhold customs clearance pending examination or further action by the Great Britain Executive or the Northern Ireland Executive, who will take charge of the chemical or article from the point that it is handed over.

Regulation 21 provides that a failure to discharge a duty placed by the PIC Regulation on a designated national authority or 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.

Regulation 22 provides that the Great Britain Executive and Northern Ireland Executive must make adequate arrangements for the enforcement of regulation 28 of these Regulations and the PIC Regulation.

Regulations 23 to 28 make provision for enforcement notices to be served by inspectors in respect of a contravention of a provision in the PIC Regulation, and for an appeal process in respect of enforcement notices.

Regulation 29 provides for service of enforcement notices.

Regulation 30 and Schedule 3 make provision for defence exemption certificates in respect of requirements and prohibitions contained in the Biocides Regulation and CLP Regulation.

Regulation 31 disapplies the provisions of these Regulations where an enforcing authority takes a sample of a substance or mixture for enforcement purposes.

Regulation 32 sets out the penalties that apply for an offence under section 33 of the 1974 Act and Article 31 of the 1978 Order, as applied to these Regulations and the Biocides Regulation, the CLP Regulation and the PIC Regulation by provisions in these Regulations.

Regulation 33 provides for a defence of due diligence in any proceedings for an offence in respect of a breach of a requirement of regulations 12 and 13(2) of these Regulations, the Biocides Regulation, the CLP Regulation and the PIC Regulation.

Regulations 34 revokes, or partially revokes, instruments that implemented Directive 98/8/EC in relation to biocidal products, and the Export and Import of Dangerous Chemicals Regulations 2008, which provided for the enforcement and appointment of designated national authorities in respect of Regulation (EC) No 689/2008.

Regulation 35 and Schedule 4 amend the 2009 Regulations. These amendments update references to the PIC Regulation, make provision for the advertising of dangerous preparations and provide for penalties in line with the European Communities Act 1972. These amendments will have effect until the 2009 Regulations are revoked in accordance with Regulation 36.

Regulation 36 revokes provisions of the 2009 Regulations on various dates so that the domestic provisions which implemented Council Directive 67/548/EEC and Council Directive 1999/45/EC are revoked in accordance with the time periods allowed for the transition to the CLP Regulation.

Regulation 37 and Schedule 5 make consequential amendments to primary and secondary legislation.

Regulation 38 requires the Secretary of State to review the operation and effect of these Regulations and to publish a report within five years after they come into force and within five years thereafter. Following each review, the Secretary of State, in consultation with the devolved administrations, will decide whether the Regulations should remain as they are, or be revoked or amended. A further instrument would be needed to revoke the Regulations or to amend them.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. A copy of this document has been placed in the Library of each House of Parliament and is annexed to the Explanatory Memorandum which is available alongside these Regulations at www.legislation.gov.uk.