STATUTORY RULES OF NORTHERN IRELAND

2013 No. 206

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

PART 1

INTRODUCTION

Citation and commencement

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

2.—(1) Except as provided by paragraphs (2) and (3) these Regulations shall come into operation on 1st September 2013.

(2) Chapter 2 of Part 3 of these Regulations shall come into operation 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, 18 to 21 and Schedule 2 shall come into operation on 1st June 2015.

Application within the territorial sea

3. Within the territorial sea these Regulations shall apply only to and in relation to the premises and activities to which any of paragraphs 2 to 9 of Schedule 5 applies.

Interpretation

4.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the Executive" means the Health and Safety Executive for Northern Ireland;

"the 1999 Regulations" means the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999(**1**);

"the 2009 Regulations" means the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009(**2**);

"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;

(**1**) S.R. 1999 No.90, as amended by S.R.2000 No. 375, S.R. 2003 No. 33, S.R. 2006 No. 205, S.R. 2006 No. 425, S.R. 2007 No. 31, S.R. 2007 No. 291, S.R. 2009 No. 238 and S.R. 2012 No. 179

(**2**) S.R. 2009 No.238, as amended by S.R. 2009 No. 273. S.R. 2010 No. 160 and S.R. 2011 No. 295

"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;

"the Department" means the Department of Enterprise, Trade and Investment;

"the Department concerned" has the same meaning as in Article 2(2) of the 1978 Order;

"inspector" means a person appointed under Article 21 of the 1978 Order;

"territorial sea" means the territorial sea of the United Kingdom adjacent to Northern Ireland and "within the territorial sea" includes on, over and under it;

"work" shall be construed in accordance with Article 2(4) of the 1978 Order.

(2) Expressions used in both—

(a) Chapter 1 of Part 3 of, or Schedule 1 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) The Interpretation Act (Northern Ireland) 1954(**3**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

PART 2

APPOINTMENT OF COMPETENT AUTHORITIES

Competent authorities

5. For the purposes of Article 81(1) of the Biocides Regulation the competent authority shall be the Executive.

6. For the purposes of Article 43 of the CLP Regulation the competent authority shall be the Department of Enterprise, Trade and Investment.

(**3**) 1954 c.33 (N.I.)

PART 3

CHAPTER 1

BIOCIDAL PRODUCTS

Application of the 1978 Order

7.—(1) The following provisions of the 1978 Order shall apply to regulations 11 and 12(2) of these Regulations and the Biocides Regulation as if they were health and safety regulations for the purposes of that Order, subject to the following provisions of this Chapter and to the extent that they would not otherwise do so—

(a) Articles 20 to 28 (in relation to enforcement);

(b) subject to regulations 20 and 21, Articles 31 to 39 (in relation to offences); and

(c) Article 43(2) (in relation to civil liability).

(2) The Articles of the 1978 Order 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 Article 31(1)(c) of the 1978 Order.

(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 Executive or the Department concerned under any provision of the 1978 Order 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 Order.

(6) The Articles of the 1978 Order which are applied to the Biocides Regulation by paragraph (1) shall 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) Articles 24 and 27 of the 1978 Order shall apply to the Biocides Regulation as if the reference to serious personal injury in those Articles 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

8.—(1) Notwithstanding the 1999 Regulations, and subject to paragraphs (2) to (6), the enforcing authority for regulations 11 and 12(2) of these Regulations and the Biocides Regulation shall be the Executive.

(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 11 of these Regulations and for the Articles of the Biocides Regulation listed in paragraph (3) shall be the district council for the district in which the biocidal product or treated article is placed on the market or made available on the market.

(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 shall be the district council for the district in which the biocidal product is placed on the market.

(5) Subject to paragraph (6), the 1999 Regulations shall 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,

shall be the district council for the district in which the use occurs.

Limitation on entry to domestic premises in certain circumstances

9.—(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).

(2) An inspector may not enter domestic premises in the exercise of that inspector's powers under the 1978 Order, as applied to the Biocides Regulation by virtue of regulation 7(1)(a) of these Regulations, in respect of an activity which is not, or is not related to, an activity involving work, unless a lay magistrate has issued a warrant authorising the inspector to enter and exercise that inspector's powers in those premises.

(3) A lay magistrate may not issue such a warrant unless, on an application made by the inspector, the lay magistrate 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

10. Information provided to the competent authority under the Biocides Regulation shall not be treated as relevant information for the purposes of Article 30 of the 1978 Order.

Labelling

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

Essential use

12.—(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(**4**).

(2) A person shall 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 shall—

(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

13.—(1) Subject to paragraphs (3) and (4), a person ("P") may appeal to the Department 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;

(**4**) OJ L 325, 11.12.2007, p.3.

(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) shall 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) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(**5**) shall apply where P appeals to the Department.

(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.

Applications for biocidal product authorisations prior to 1st September 2013

14.—(1) The competent authority shall evaluate applications for biocidal product authorisations submitted before 1st September 2013 for the purposes of Directive 98/8/EC(**6**) in accordance with the Biocidal Products Regulations (Northern Ireland) 2001(**7**).

(2) Where, following an evaluation carried out in accordance with 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 shall be taken in accordance with the Biocides Regulation.

Transitional, transitory and savings provisions

15. Schedule 1 shall have effect.

(**5**) S.R. 1997 No.269, as amended by Constitutional Reform Act 2005 (c.4)
(**6**) OJ No. L123. 24.4.98, p.1.
(**7**) S.R. 2001 No. 422, as amended by S.R. 2002 No. 302, S.I. 2003/429, S.I. 2005/2451, S.R. 2007 No. 190, S.R. 2009 No. 238, S.R. 2010 No. 163, S.R. 2011 No. 295

CHAPTER 2

CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

Application of the 1978 Order

16.—(1) The following provisions of the 1978 Order shall apply to the CLP Regulation as if it were health and safety regulations for the purposes of that Order, except that those Articles shall not apply to duties placed by the CLP Regulation on the competent authority or the Member State—

(a) Articles 20 to 30 (in relation to enforcement);

(b) subject to regulations 20 and 21, Articles 31 to 39 (in relation to offences); and

(c) Article 43(2) in relation to civil liability.

(2) Any function of the Executive or the Department concerned under any other provision of the 1978 Order 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 Order.

Allocation of enforcement responsibility

17.—(1) Notwithstanding the 1999 Regulations and subject to paragraphs (2) to (4), the enforcing authority for the CLP Regulation shall be the Executive.

(2) The enforcing authority for the CLP Regulation shall be the district council for the district in which are situated the premises in or from which such a substance, mixture or article is placed on the market—

(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 section 75 of the Medicines Act 1968(**8**), the enforcing authority shall be the Department of Health, Social Services and Public Safety.

(4) In every case where, by virtue of this regulation and the CLP Regulation, the CLP Regulation is enforced by the Department of Health, Social Services and Public Safety or by a district council, it shall be enforced as if it were a safety regulation made under section 11 of the Consumer Protection Act 1987(**9**).

(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.

(**8**) 1968 c.67: section 75(8) was amended by S.I. 1968/1699
(**9**) 1987 c. 43; section 11(7)(c) was amended by SI 1996/275 (N.I. 2), Article 71(1) and Schedule 6

CHAPTER 3

EXEMPTIONS, PENALTIES, DUE DILIGENCE DEFENCE

Exemptions

18.—(1) A person shall be 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 2 (defence exemption certificates) shall have effect.

19.—(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 or the CLP Regulation.

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

Penalties

20. The maximum penalty for an offence under Article 31 of the 1978 Order as applied by these Regulations to the Biocides Regulation, the CLP Regulation and regulations 11 and 12(2) of these Regulations shall be—

(a) on summary conviction, imprisonment for a term not exceeding three 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

21. In any proceedings for an offence under Article 31(1)(c) of the 1978 Order, as applied by these Regulations to regulations 11 and 12(2), the Biocides Regulation and the CLP Regulation, it shall be 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 AND AMENDMENTS

Revocations and amendments

22. Subject to paragraph 10 of Schedule 1, the following Regulations are revoked:

(a) except for regulations 39 and 39A and Schedules 11 and 11A, the Biocidal Products Regulations (Northern Ireland) 2001;

(b) the Biocidal Products (Amendment) Regulations (Northern Ireland) 2002(**10**);

(**10**) S.R. 2002 No.302

(c) the Biocidal Products (Amendment) Regulations (Northern Ireland) 2007(**11**);

(d) the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010(**12**).

23. The 2009 Regulations are amended in accordance with the provisions of Schedule 3.

24. 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.

25. The enactments or Regulations specified in Schedule 4 are amended to the extent specified in that Schedule.

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on 2nd August 2013.

L.S.

D Sterling
A senior officer of the Department of Enterprise,
Trade and Investment

(**11**) S.R. 2007 No.190
(**12**) S.R. 2010 No.163