The Department of Enterprise Trade and Investment (“the Department”) (1), is designated for the purposes of section 2(2) of the European Communities Act 1972 (“the 1972 Act”) (2) in relation to—

(a) the notification and control of substances and to measures relating to biocides (3);

(b) the regulation and control of classification, packaging and labelling of dangerous substances and preparations and for measures relating to consumer protection (4).

The Department, being the Department concerned (5) makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the 1972 Act (6) and Articles 17(1) to (6)(7) and 25(2) of, and paragraphs 1(1) and (4), 3(1), 5, 12(1) and 14(1) of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 (8) (“the 1978 Order”).

The Regulations give effect without modifications to proposals submitted to the Department by the Health and Safety Executive for Northern Ireland under Article 13(1A) (9) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)(10) of the 1978 Order.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Department 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 (11) concerning the making available on the market and use of biocidal products to be

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(1) Formerly the Department of Economic Development; see S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services; see S.I. 1982/846 (N.I.11), Article 3

(2) 1972 c.68

(3) S.I. 1981/1536 for the designation in relation to the notification and control of substances and S.I. 1999/2788 in relation to measures relating to biocides

(4) S.I. 1976/897 for the designation in relation to the regulation and control of classification, packaging and labelling of dangerous substances and preparations and S.I. 1993/2661 in relation to measures relating to consumer protection

(5) See Article 2(2) of S.I. 1978/1039 (N.I. 9)

(6) 1972 c.68; paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51)

(7) Article 17 shall be read with S.I. 1992/1728 (N.I.17), Articles 3(2) and 4(2)

(8) S.I. 1978/1039 (N.I. 9); the general purposes of Part II referred to in Article 17(1) were extended by S.I. 1992/1728 (N.I. 17), Articles 3(1) and 4(1). Article 35(2) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 19

(9) Article 13(1A) was substituted by S.I. 1999/2795 (N.I. 18), Article 4

(10) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18 and the Health Protection Agency Act 2004 (c.17), section 11 and Schedule 3 paragraph 10

(11) OJ No L167, 27.06.12, p1
construed as including references to Annexes I to IV of that Regulation as those Annexes are amended from time to time; and


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(13);

“the 2009 Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009(14);

“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;


(12) OJ No L353, 31.12.08, p1
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(15) 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.

(15) 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.

(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


(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;

(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(17) 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(18) in accordance with the Biocidal Products Regulations (Northern Ireland) 2001(19).

(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.

(17) S.R. 1997 No.269, as amended by Constitutional Reform Act 2005 (c.4)
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(20), 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(21).

(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.

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(20) 1968 c.67; section 75(8) was amended by S.I. 1968/1699
(21) 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(22);
(c) the Biocidal Products (Amendment) Regulations (Northern Ireland) 2007(23);
(d) the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010(24).

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.

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

(23) S.R. 2007 No.190
(24) S.R. 2010 No.163
SCHEDULE 1

Transitional, transitory and savings provisions

1. In this Schedule—

“COPR” means the Control of Pesticides Regulations (Northern Ireland) 1987(25)

“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;


“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—

(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—

(i) 28th February 2018 in relation to the making available of the biocidal product on the market; and

(ii) 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 (Northern Ireland) 2001 by virtue of regulation 22(a) of these Regulations, paragraph 13 of Schedule 12 to the Biocidal Products Regulations (Northern Ireland) 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 12 to the Biocidal Products Regulations (Northern Ireland) 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;
   (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 (Northern Ireland) 2001, the Biocidal Products (Amendment) Regulations (Northern Ireland) 2007 and the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010 by virtue of regulation 22(a), (c) and (d) 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 14(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 (Northern Ireland) 2001;
      (b) Regulations 2, 3, 4, 7, 8, 9, 10 and 19 of the Biocidal Products (Amendment) Regulations (Northern Ireland) 2007; and
      (c) Regulations 2(2) and 2(3) of the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010.

SCHEDULE 2

Regulation 18(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
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 3

Amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 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—

“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, 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.”.

SCHEDULE 4

Consequential Amendments

PART 1

ENACTMENTS

Wildlife (Northern Ireland) Order 1985

1. In Article 15B of the Wildlife (Northern Ireland) Order 1985(27), in subsection (3), for paragraph (c) substitute—

“(c) Regulation (EU) No 528/2012 of the European Parliament and of the Council(28); or”.

(27) 1985 No. 171 (N.I. 2); Article 15B inserted by Wildlife and Natural Environment Act (NI) 2011, 2011 c.15
(28) OJ No L167, 27.06.12, p.1.
PART 2
SUBORDINATE LEGISLATION

Control of Pesticides Regulations (Northern Ireland) 1987

2. In the Control of Pesticides Regulations (Northern Ireland) 1987(29), omit regulation 3(2)(j).

African Swine Fever Order (Northern Ireland) 2003


Diseases of Animals (Approval of Disinfectants) Order (Northern Ireland) 2008

4.—(1) The Diseases of Animals (Approval of Disinfectants) Order (Northern Ireland) 2008(31) is amended as follows.


(3) In Article 7(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”.

Environmental Liability (Prevention and Remediation) Regulations (Northern Ireland) 2009

5.—(1) The Environmental Liability (Prevention and Remediation) Regulations (Northern Ireland) 2009(32) are amended as follows.

(2) In Schedule 2, for paragraph 6(d) substitute—

“(d) biocidal products as defined in Article 3(1)(a) of 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 Schedule 3, paragraph 8, for “the Biocidal Products Regulations (Northern Ireland) 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”.

SCHEDULE 5
Regulation 3

Premises and Activities Within The Territorial Sea

1.—(1) In this Schedule—

“activity” includes a diving project and standing a vessel by;

(29) SR 1987 No. 414, as amended by SR 2001 No. 422
(30) 2003 No. 494
(31) 2008 No. 272
(32) SR 2009 No. 252
“designated area” means any area designated by Order under section 1(7) of the Continental Shelf Act 1964(33) and “within a designated area” includes over and under it;
“diving project” has the meaning assigned to it by regulation 2(1) of the Diving at Work Regulations (Northern Ireland) 2005(34) save that it includes an activity in which a person takes part as a diver wearing an atmospheric pressure suit and without breathing in air or other gas at a pressure greater than atmospheric pressure;
“gas importation and storage zone” has the meaning assigned to it by section 1(5) of the Energy Act 2008(35);
“offshore installation” shall be construed in accordance with paragraph 2(2) and (3);
“supplementary unit” means a fixed or floating structure, other than a vessel, for providing energy, information or substances to an offshore installation;
“vessel” includes a hovercraft and any floating structure which is capable of being navigated.

(2) For the purposes of this Schedule, any structures and devices on top of a well shall be treated as forming part of the well.

(3) Any reference in this Schedule to premises and activities includes a reference to any person, article or substance on those premises or engaged in, or, as the case may be, used or for use in connection with any such activity, but does not include a reference to an aircraft which is airborne.

Offshore installations

2.—(1) This paragraph shall apply to a designated area or a gas importation and storage zone to and in relation to—
(a) any offshore installation and any activity on it;
(b) any activity in connection with, or any activity immediately preparatory to an activity in connection with, an offshore installation, whether carried on from the installation itself, in or from a vessel or in any manner, other than an activity falling within sub-paragraph (4);
(c) a diving project involving—
(i) the survey and preparation of the sea bed for an offshore installation;
(ii) the survey and restoration of the sea bed consequent on the removal of an offshore installation.

(2) Subject to sub-paragraph (3), in this paragraph, “offshore installation” means a structure which is, or is to be, or has been, used while standing or stationed in water, or on the foreshore or other land intermittently covered with water—
(a) for the exploitation, or exploration with a view to exploitation, of mineral resources by means of a well;
(b) for undertaking activities falling within paragraph 6(2);
(c) for the conveyance of things by means of a pipe;
(d) for undertaking activities that involve mechanically entering the pressure containment boundary of a well; or
(e) primarily for the provision of accommodation for persons who work on or from a structure falling within any of the provisions of heads (a) to (d),

(33) 1964 c. 29; section 1 was amended by the Oil and Gas (Enterprise) Act 1982 (1982 c. 23), section 37 and Schedule 3, paragraph 1
(34) S.R. 2005 No. 45, as amended by S.R. 2007 No. 247
(35) 2008 c.32; section 1(5) is prospectively amended by the Marine and Coastal Access Act 2009 (c.23), Schedule 4 Part 1, paragraph 5(1) and (2). Section 1(5) of the Energy Act 2008 would continue to define the term “gas importation and storage zone” after the amendment.
together with any supplementary unit which is ordinarily connected to it, and all the connections.

(3) Any reference in sub-paragraph (2) to a structure or supplementary unit does not include—
   (a) a structure which is connected with dry land by a permanent structure providing access at all times and for all purposes;
   (b) a well;
   (c) a mobile structure which has been taken out of use and is not yet being moved with a view to its being used for any of the purposes specified in sub-paragraph (2);
   (d) any part of a pipeline; and
   (e) a structure falling within paragraph 8(c).

(4) Subject to sub-paragraph (5), the following activities fall within this paragraph—
   (a) transporting, towing or navigating an installation;
   (b) any of the following activities carried on in or from a vessel—
      (i) giving assistance in the event of an emergency;
      (ii) training in relation to the giving of assistance in the event of an emergency;
      (iii) testing equipment for use in giving assistance in the event of an emergency.
      (iv) putting or maintaining a vessel on stand-by ready for an activity referred to in any of sub-heads (i) to (iii).

(5) Sub-paragraph (4)(b) does not apply in respect of a vessel in or from which an activity is carried on in connection with, or any activity that is immediately preparatory to an activity in connection with, an offshore installation other than an activity falling within sub-paragraph 4(b).

Wells

3.—(1) Subject to sub-paragraph (2), this paragraph applies to and in relation to—
   (a) a well and any activity in connection with it; and
   (b) an activity which is immediately preparatory to any activity in head (a).

(2) Sub-paragraph (1) includes keeping a vessel on station for the purpose of working on a well but otherwise does not include navigation or an activity connected with navigation.

Pipelines

4.—(1) This paragraph applies to and in relation to—
   (a) any pipeline;
   (b) any pipeline works;
   (c) the following activities in connection with pipeline works—
      (i) the loading, unloading, fuelling or provisioning of a vessel;
      (ii) the loading, unloading, fuelling, repair and maintenance of an aircraft on a vessel, being in either case a vessel which is engaged in pipeline works; or
      (iii) the moving, supporting, laying or retrieving of anchors attached to a pipe-laying vessel including the supervision of those activities and giving of instruction in connection with them.

(2) In this paragraph—
   “pipeline” means a pipe or system of pipes for the conveyance of any thing, together with—
(a) any apparatus for inducing or facilitating the flow of any thing through, or through part of, the pipe or system;
(b) any apparatus for treating or cooling any thing which is to flow through, or through part of, the pipe or system;
(c) valves, valve chambers and similar works which are annexed to, or incorporated in the course of, the pipe or system;
(d) apparatus for supplying energy for the operation of any such apparatus or works as are mentioned in heads (a) to (c);
(e) apparatus for the transmission of information for the operation of the pipe or system;
(f) apparatus for the cathodic protection of the pipe or system; and
(g) a structure used or to be used solely for the support of a part of the pipe or system;

but not including a pipeline of which no initial or terminal point is situated in the United Kingdom, within the territorial sea adjacent to the United Kingdom, or within a designated area;

“pipeline works” means—
(a) assembling or placing a pipeline or length of pipeline including the provision of internal or external protection for it;
(b) inspecting, testing, maintaining, adjusting, repairing, altering or renewing a pipeline or length of pipeline;
(c) changing the position of or dismantling or removing a pipeline or length of pipeline;
(d) opening the bed of the sea for the purposes of the works mentioned in heads (a) to (c), and tunnelling or boring for those purposes;
(e) any activities incidental to the activities described in heads (a) to (d);
(f) a diving project in connection with any of the works mentioned in heads (a) to (e) or for the purpose of determining whether a place is suitable as part of the site of a proposed pipeline and the carrying out of surveying operations for settling the route of a proposed pipeline.

Mines

5.—(1) This paragraph applies to and in relation to a mine within the territorial sea or extending beyond it, and any activity in connection with it, while it is being worked.

(2) In this paragraph “mine” has the same meaning as in the Mines Act (Northern Ireland) 1969(36).

Gas Importation and Storage

6.—(1) Subject to sub-paragraph (3), this paragraph applies within a gas importation and storage zone to and in relation to any activities connected with or immediately preparatory to the activities set out in sub-paragraph (2).

(2) The activities are—
(a) the unloading of gas to an installation or pipeline;
(b) the storage of gas, whether temporary or permanent, in or under the shore or bed of any water;

(36) 1969 c. 6 (N.I.)
(c) the conversion of any natural feature for the purpose of storing gas, whether temporarily or permanently;
(d) the recovery of gas stored;
(e) exploration with a view to, or in connection with, the carrying on of activities within heads (a) to (d).

(3) Sub-paragraph (1) does not apply to an activity falling within sub-paragraph (2) if the provisions of this Schedule apply to or in relation to that activity by virtue of paragraph 2(1).

(4) In this paragraph—

“gas” means any substance which is gaseous at a temperature of 15°C and a pressure of 101.325 kPa (1013.25 mb); and

“installation” includes any floating structure or device maintained on a station by whatever means.

(5) For the purposes of sub-paragraphs (2) and (4), references to gas include any substance which consists wholly or mainly of gas.

Production of Energy from Water or Wind

7.—(1) This paragraph applies within a renewable energy zone to and in relation to any energy structure or activities connected with or preparatory to—

(a) the exploitation of those areas for the production of energy from water or wind,
(b) the exploration of such areas with a view to, or in connection with, the production of energy from water or wind, or
(c) the operation of a cable for transmitting electricity from an energy structure.

(2) In this paragraph—

“energy structure” means a fixed or floating structure or machine, other than a vessel, which is, or is to be, or has been, used for producing energy from water or wind; and

“renewable energy zone” has the meaning given by section 84(4) of the Energy Act 2004 and “within a renewable energy zone” includes over and under it.

Underground Coal Gasification

8. This paragraph applies within a designated area to and in relation to—

(a) underground coal gasification and any activity in connection with it;
(b) any activity which is immediately preparatory to any activity in sub-paragraph (a); and
(c) any fixed or floating structure which is, or is to be, or has been, used in connection with the carrying on of activities within sub-paragraphs (a) and (b).

Other activities

9.—(1) Subject to sub-paragraph (2), this paragraph applies to and in relation to—

(a) the construction, reconstruction, alteration, repair, maintenance, cleaning, use, operation, demolition and dismantling of any building, or other structure, not being in any case a vessel, or any preparation for any such activity;

(37) 2004 c.20; section 84(4) is prospectively amended by the Marine and Coastal Access Act 2009 (c. 23), Schedule 4, Part 1, paragraph 4. Section 84(4) of the Energy Act 2004 would continue to define the term “renewable energy zone” after the amendment.
(b) the transfer of people or goods between a vessel or aircraft and a structure (including a building) mentioned in head (a);
(c) the loading, unloading, fuelling or provisioning of a vessel;
(d) a diving project;
(e) the laying, installation, inspection, maintenance, operation, recovery or repair of a cable;
(f) the construction, reconstruction, finishing, refitting, repair, maintenance, cleaning or breaking up of a vessel except when carried out by the master or any officer or member of the crew of that vessel;
(g) the maintaining on a station of a vessel which would be an offshore installation were it not a structure to which paragraph 2(3)(c) applies;
(h) the transfer of people or goods between a vessel or aircraft and a structure mentioned in head (g).

(2) This paragraph does not apply—
(a) to a case where paragraph 2, 3, 4, 5, 6, 7 or 8 applies; or
(b) to vessels which are registered outside the United Kingdom and are on passage through the territorial sea.

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EXPLANATORY NOTE

(This note is not part of the Regulations)


These Regulations also provide for the enforcement, in respect of Northern Ireland, of the Biocides Regulation and the CLP Regulation and of certain provisions of these Regulations.

These Regulations additionally make provision for the competent authority in Northern Ireland 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 L 325, 11.12.2007, p. 3).

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 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.

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.

Provision is made for the coming into operation of the Regulations and to extend the application of the Regulations outside Northern Ireland in regulations 2 and 3 and Schedule 5.

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

Regulations 5 and 6 provide that the Health and Safety Executive for Northern Ireland (“the Executive”) and the Department of Enterprise, Trade and Investment are designated as the competent authority in relation to the Biocides Regulation and the CLP Regulation respectively.

Regulation 7 makes provision for the enforcement of the Biocides Regulation and regulations 11 and 12(2) of these Regulations by applying enforcement and penalty provisions of the Health and Safety At Work (Northern Ireland) Order 1978 (“the 1978 Order”) to the Biocides Regulation and regulations 11 and 12(2) of these Regulations as if they were health and safety regulations for the purposes of the 1978 Order.

Regulation 8 provides that the Biocides Regulation and regulations 11 and 12(2) are enforced either by the Executive or the district council, depending on the circumstances as set out in the regulation.

Regulation 9 limits the powers of an inspector to enter domestic premises in exercise of that inspector’s powers under the 1978 Order, as applied to the Biocides Regulation and regulations 11 and 12(2) of these Regulations by regulation 7.

Regulation 10 ensures that information provided to the competent authority under the Biocides Regulation is not treated as relevant information for the purposes of Article 30 of the 1978 Order.

Regulation 11 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 12 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 13 provides a right of appeal in relation to certain decisions of the competent authority made under the Biocides Regulation which is available to a class of persons defined in regulation 13.

Regulations 14 and 15 and Schedule 1 provide transitional measures to enable the continuation of existing procedures for a limited period of time.

Regulation 16 makes provision for the enforcement of the CLP Regulation by applying enforcement and penalty provisions of the 1978 Order to the CLP Regulation as if it were health and safety regulations for the purposes of the 1978 Order.

Regulation 17 provides that the CLP Regulation is enforced by the Executive, the district council or the Department of Health, Social Services and Public Safety, depending on the circumstances set out in the regulation. In the case of enforcement by the district council or the Department of Health, Social Services and Public Safety, 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.

Regulation 18 and Schedule 2 make provision for defence exemption certificates in respect of requirements and prohibitions contained in the Biocides Regulation and the CLP Regulation.

Regulation 19 disapplies the provisions of these Regulations where an enforcing authority takes a sample of a substance or mixture for enforcement purposes.
Regulation 20 sets out the penalties that apply for an offence under Article 31 of the 1978 Order, as applied to these Regulations and the Biocides Regulation and the CLP Regulation by provisions in these Regulations.

Regulation 21 provides for a defence of due diligence in any proceedings for an offence in respect of a breach of a requirement of regulations 11 and 12(2) of these Regulations, the Biocides Regulation and the CLP Regulation.

Regulation 22 revokes, or partially revokes, instruments that implemented Directive 98/8/EC in relation to biocidal products.

Regulation 23 and Schedule 3 amend the 2009 Regulations. These amendments provide for references to the EU Regulation on the export and import of hazardous chemicals to replace the references to the 2008 Regulation. The amendments also make provision for the advertising of dangerous preparations and bring penalties in line with the European Communities Act 1972. These amendments will have effect until the 2009 Regulations are revoked in accordance with Regulation 24.


Regulation 25 and Schedule 4 make consequential amendments to primary and secondary legislation.

In Great Britain the corresponding legislation is the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (S.I. 2013/1506). The Great Britain Health and Safety Executive has prepared a full impact assessment of the effect that the Regulations will have on the costs of business and the voluntary sector. A copy of that assessment is available from the Health and Safety Executive for Northern Ireland, 83 Ladas Drive, Belfast, BT6 9FR. A copy of the impact assessment has been placed in the library of the Northern Ireland Assembly and is annexed to the Explanatory Memorandum which is available alongside these Regulations at www.legislation.gov.uk.