

SCHEDULE 2

Regulation 8

Amendment of Schedule 2 to the 2019 Regulations

1. Schedule 2 to the 2019 Regulations (Amendments to retained direct EU legislation) is amended in accordance with paragraphs 2 to 72.

Amendments relating to Regulation (EC) No 1907/2006 (“the REACH Regulation”)

2. In the following paragraphs, in each place it occurs, for “UK” substitute “GB”—
- (a) paragraph 2 (amendment of Article 3 of the REACH Regulation);
 - (b) paragraph 3 (amendment of Article 15 of the REACH Regulation);
 - (c) paragraph 4 (amendment of Article 59 of the REACH Regulation);
 - (d) paragraph 5 (amendment of Annex I to the REACH Regulation);
 - (e) paragraph 6 (amendment of Annex II to the REACH Regulation);
 - (f) paragraph 7 (amendment of Annex XVII to the REACH Regulation);
 - (g) paragraph 8 (amendment of the foreword to Appendices 1 to 6 to the REACH Regulation);
 - (h) paragraph 10 (amendment of Appendix 2 to the REACH Regulation).

Amendments relating to Regulation (EC) No 1272/2008 (“the CLP Regulation”)

3. In paragraph 13 (amendment of Article 1 of the CLP Regulation⁽¹⁾)—
- (a) in sub-paragraph (2)(c), for “UK” substitute “GB”;
 - (b) in sub-paragraph (2)(d)—
 - (i) for “UK” substitute “GB”;
 - (ii) for “exit day” substitute “IP completion day”;
 - (c) in sub-paragraph (3)(a), omit “and the Ionising Radiations Regulations (Northern Ireland) 2017”.
4. For paragraph 14 (amendment of Article 2 of the CLP Regulation) substitute—
- “14. In Article 2—
- (a) for point 10 (definition of “producer of an article”), substitute—

“10. “producer of an article” means any natural or legal person—

 - (a) who makes or assembles an article within Great Britain;
 - (b) who makes or assembles an article within Northern Ireland which is a qualifying Northern Ireland good and which is placed directly on the market in Great Britain;”;
 - (b) for point 15 (definition of “manufacturer”) substitute—

“15. “manufacturer” means any natural or legal person—

 - (a) established in Great Britain, who manufactures a substance within Great Britain;”;
 - (b) established in Northern Ireland, who manufactures a substance which is a qualifying Northern Ireland good and which is placed directly on the market in Great Britain;”;

(1) Here and in other parenthesised text throughout this instrument, “CLP” stands for “classification, labelling and packaging”.

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(c) for point 16 (definition of “import”) substitute—

“**16.** “import” means the physical introduction into Great Britain, except where the goods are qualifying Northern Ireland goods;”;

(d) for point 17 (definition of “importer”) substitute—

“**17.** “importer” means any natural or legal person established within Great Britain who is responsible for import;”;

(e) in point 19 (definition of “downstream user”), for “within the Community” substitute “within Great Britain, or within Northern Ireland in the case of qualifying Northern Ireland goods which are placed directly on the market in Great Britain”;

(f) in point 20 (definition of “distributor”), for “within the Community” substitute “within Great Britain, or within Northern Ireland in the case of qualifying Northern Ireland goods which are placed directly on the market in Great Britain”;

(g) in point 23 (definition of “the Agency”), for the words from “European Chemicals Agency” to the end substitute “Health and Safety Executive”;

(h) in point 24 (definition of “competent authority”), for “established by the Member States to carry out the obligations arising from this Regulation” substitute “appointed to carry out the obligations arising from this Regulation by the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013”;

(i) after point 37 (definition of “intermediate packaging”) insert—

“**38.** “GB mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A;

39. “GB notification database” means the database established in accordance with Article 42;

40. “European Chemicals Agency” means the Agency established by Article 75 of Regulation (EC) No 1907/2006 as it has effect in EU law;

41. “EU 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/EEC, and amending Regulation (EC) No 1907/2006, as it has effect in EU law;

42. “Devolved Authority” means—

- (a) the Scottish Ministers, or
- (b) the Welsh Ministers;

43. “qualifying Northern Ireland goods” has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.”.

5. For paragraph 15 (amendment of Article 4 of the CLP Regulation) substitute—

“**15.** In Article 4—

(a) in paragraph 3—

(i) in the first subparagraph—

(aa) for “harmonised” substitute “mandatory”;

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- (bb) for “Part 3 of Annex VI” substitute “the GB mandatory classification and labelling list”;
 - (ii) in the second subparagraph, for “Part 3 of Annex VI” substitute “the GB mandatory classification and labelling list”;
 - (b) in paragraph 5, after “distributors” insert “who are established within Great Britain”;
 - (c) in paragraph 6, after “downstream users” insert “who are established within Great Britain”.
6. In the following paragraphs, in each place it occurs, for “UK” substitute “GB”—
- (a) paragraph 17 (amendment of Article 10 of the CLP Regulation);
 - (b) paragraph 18 (amendment of Article 15 of the CLP Regulation);
 - (c) paragraph 21 (amendment of Article 18 of the CLP Regulation);
 - (d) paragraph 22 (amendment of Article 21 of the CLP Regulation);
 - (e) paragraph 24 (amendment of Article 25 of the CLP Regulation);
 - (f) paragraph 25 (amendment of Article 26 of the CLP Regulation);
 - (g) paragraph 30 (amendment of the heading for Title V of the CLP Regulation);
 - (h) paragraph 32 (amendment of Article 36 of the CLP Regulation).
7. For paragraph 33 (amendment of Article 37 of the CLP Regulation) substitute—
- “33. For Article 37 substitute—

“Article 37 Procedure for mandatory classification and labelling where the EU Risk Assessment Committee publishes an opinion

1. This Article applies in relation to a substance—
 - (a) on which the Committee for Risk Assessment of the European Chemicals Agency (“the Committee”) publishes an opinion under Article 37(4) of the EU CLP Regulation on or after IP completion day, or
 - (b) on which the Committee has published an opinion under Article 37(4) of the EU CLP Regulation before IP completion day, but which has not, as at IP completion day, been included in Part 3 of Annex VI of the EU CLP Regulation.
2. Within 6 months of the publication of the Committee’s opinion, the Agency must publish a technical report on the Committee’s opinion.
3. Within 12 months of the publication by the Agency of the technical report, the Agency must publish its own opinion.
4. Where the Agency’s opinion recommends aligning with the Committee’s opinion that there should be a change—
 - (a) within 12 months of the publication of its opinion, the Agency must—
 - (i) submit a recommendation to the Secretary of State to give effect to the classification and labelling requirement set out in the Agency’s opinion, and
 - (ii) send a copy of that recommendation to the Devolved Authorities;
 - (b) within 3 months of the recommendation being submitted by the Agency, the Secretary of State must—

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- (i) decide whether to accept the recommendation;
- (ii) publish that decision, together with reasons for the decision;
- (iii) where the decision referred to in paragraph (i) is to accept the recommendation, specify (alongside the decision and the reasons for the decision) the date from when any new or revised classification and labelling requirement must be complied with;
- (iv) notify the Agency of the decision and details referred to in paragraphs (ii) and (iii);
- (c) the Secretary of State's functions under paragraph (b)(i) and (iii) are subject to the consent requirement in Article 53B;
- (d) within one month of the Secretary of State notifying the Agency of a decision in accordance with paragraph (b)(iv), the Agency must update the GB mandatory classification and labelling list accordingly, making clear the date from when the new or revised classification and labelling requirement must be complied with.

5. Where the Agency's opinion does not recommend aligning with the Committee's opinion the Agency may produce a proposal under paragraph 2 of Article 37A for a new or revised mandatory classification and labelling requirement.”.”.

8. For paragraph 34 (insertion of Article 37A of the CLP Regulation) substitute—

“34. After Article 37 insert—

“Article 37A Procedure for mandatory classification and labelling of substances where Article 37(1) does not apply

1. This Article—

- (a) applies in relation to substances to which Article 37(1) does not apply;
- (b) does not apply to manufacturers, importers or downstream users established in Northern Ireland who supply qualifying Northern Ireland goods directly to Great Britain.

2.—(1) The Agency may produce a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(2) A competent authority may submit to the Agency a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(3) A proposal under subparagraphs (1) or (2) must follow the format set out in Part 2 of Annex VI and must contain the relevant information provided for in Part 1 of Annex VI.

3.—(1) A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for a mandatory classification and labelling of that substance and, where appropriate, specific concentration limits or M-factors, where there is no entry in the GB mandatory classification and labelling list for such substance in relation to the hazard class or differentiation covered by that proposal;

(2) A manufacturer, importer or downstream user who has new information which may lead to a change of the mandatory classification and labelling elements

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of a substance in the GB mandatory classification and labelling list must submit a proposal to the Agency for a revised classification.

(3) A proposal under subparagraph (1) must follow the format set out in Part 2 of Annex VI and must contain the relevant information provided for in Part 1 of Annex VI.

(4) Where a proposal under subparagraph (1) concerns the mandatory classification and labelling of a substance in accordance with Article 36(3), it must be accompanied by a fee.

4. Within 12 months of a proposal being received by or produced by the Agency, during which time the parties concerned must be given an opportunity to comment, the Agency must publish a technical report on the proposal.

5. Within 6 months of publishing the technical report, the Agency must publish an opinion on the proposal.

6. In exceptional circumstances, the 6 month time limit referred to in paragraph 5 may be extended to 12 months.

7. Where the Agency considers that it is appropriate to recommend that a new or revised mandatory classification and labelling requirement is imposed, within 12 months of the opinion being published, the Agency must—

- (a) submit a recommendation to the Secretary of State to give effect to the opinion, and
- (b) send a copy of that recommendation to each of the Devolved Authorities.

8.—(1) Within 3 months of the recommendation being submitted by the Agency, the Secretary of State must—

- (a) decide whether to accept the recommendation;
- (b) publish that decision, together with reasons for the decision;
- (c) where the decision referred to in paragraph (b) is to accept the recommendation, specify (alongside the decision and the reasons for the decision) the date from when any new or revised classification and labelling requirement must be complied with;
- (d) notify the Agency of the decision and details referred to in paragraphs (b) and (c).

(2) The Secretary of State's functions under subparagraphs (1)(a) and (c) are subject to the consent requirement in Article 53B.

9. Within one month of the Secretary of State notifying the Agency of a decision in accordance with paragraph 8(d), the Agency must update the GB mandatory classification and labelling list accordingly, making clear the date from when any new or revised classification and labelling requirement must be complied with.”.”.

9. In the following paragraphs, in each place it occurs (including in new provisions being inserted and headings), for “UK” substitute “GB”—

- (a) paragraph 35 (amendment of Article 38 of the CLP Regulation);
- (b) paragraph 36 (insertion of Article 38A into the CLP Regulation);
- (c) paragraph 37 (amendment of the heading for Chapter 2 of the CLP Regulation);

10. In paragraph 39 (amendment of Article 40 of the CLP Regulation)—

- (a) in sub-paragraph (a), for “UK” substitute “GB”;

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- (b) in sub-paragraph (b), for “exit day” substitute “IP completion day”.
- 11. In paragraph 40 (amendment of Article 41 of the CLP Regulation), for “UK” substitute “GB”.
- 12. In paragraph 41 (amendment of Article 42 of the CLP Regulation)—
 - (a) in each place it occurs (including in the amendment to the heading), for “UK” substitute “GB”;
 - (b) in point (e), for “37(3)(b) and Article 37A(6)” substitute “37(4)(b) and Article 37A(8)”.
- 13. In paragraph 45 (amendment of Article 45 of the CLP Regulation)—
 - (a) in sub-paragraph (b), in the new paragraph 1A which it inserts, for “Scotland, Wales or Northern Ireland” substitute “Scotland or Wales”;
 - (b) for paragraph (d) substitute—
 - “(d) for paragraph 4 substitute—
 - “4. The Secretary of State may by regulations specify the information relating to emergency health response and preventative measures required for the purposes of this Article, following consultation with relevant stakeholders as referred to in paragraph 5.
 - 5. Before making regulations, the Secretary of State must consult—
 - (a) the body or bodies appointed under paragraph 1,
 - (b) any person or body who the Secretary of State considers is representative of importers, if any,
 - (c) any person or body who the Secretary of State considers is representative of downstream users, if any, and
 - (d) any other person who the Secretary of State considers appropriate.
 - 6. The Secretary of State’s regulation-making function under paragraph 4 is subject to the consent requirement in Article 53B.”.
- 14. For paragraph 48 (amendment of Article 49 of the CLP Regulation) substitute—
 - “48. In Article 49—
 - (a) in paragraph 3—
 - (i) in the first subparagraph, for “competent authority or the enforcement authorities of a Member State in which a supplier is established” substitute “competent authorities, enforcing authorities”;
 - (ii) in the second subparagraph, after “authority” insert “in question”;
 - (b) after paragraph 3 insert—
 - “4. For the purposes of this Article, “enforcing authorities” has the meaning given by regulation 18 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.”.
- 15. In paragraph 51 (amendment of Article 52 of the CLP Regulation), in the new Article 52 which it substitutes—
 - (a) in paragraph 1(b), for “paragraphs 6 to 10” substitute “paragraphs 6 to 8”;
 - (b) omit paragraph 6(d) (and the semicolon before it);
 - (c) omit paragraphs 9 and 10.
- 16. In paragraph 53 (insertion of Articles 53A and 53B into the CLP Regulation), in the new Article 53B which that paragraph inserts, omit paragraphs 4 to 7.

17. In the following paragraphs, in each place it occurs, for “UK” substitute “GB”—

- (a) paragraph 55 (amendment of Annex I to the CLP Regulation);
- (b) paragraph 56 (amendment of Annex II to the CLP Regulation);
- (c) paragraph 57 (amendment of Annex VI to the CLP Regulation).

Amendments relating to Regulation (EU) No 544/2011 (Regulation on data requirements for active substances)

18. In paragraph 58 (amendment of the Annex to Regulation (EU) No 544/2011(2)), in both places it occurs, for “UK” substitute “GB”.

Amendments relating to Regulation (EU) No 545/2011 (Regulation on data requirements for PPPs)

19. In paragraph 59 (amendment of the Annex to Regulation (EU) No 545/2011(3)), in each place it occurs, for “UK” substitute “GB”.

Amendments relating to Regulation (EU) No 547/2011 (Regulation on labelling requirements for PPPs)

20. In paragraph 60 (amendment of Annex I to Regulation on labelling requirements for PPPs), in both places it occurs, for “UK” substitute “GB”.

Amendments relating to Regulation (EU) No 528/2012 (“the Biocides Regulation”)

21. In paragraph 62 (amendment of Article 1 of the Biocides Regulation), in sub-paragraph (3)—

- (a) in paragraph (a), for “United Kingdom” substitute “Great Britain”;
- (b) in paragraph (c), for “the United Kingdom” substitute “Great Britain”.

22. In paragraph 63 (amendment of Article 2 of the Biocides Regulation), for sub-paragraph (2) substitute—

“(2) In paragraph 2, in the first subparagraph—

- (a) in the opening sentence omit “Union”;
- (b) for point (b) substitute “the Medical Devices Regulations 2002”;
- (c) for point (c) substitute “the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012”;
- (d) for point (k) substitute “the Toys (Safety) Regulations 2011”.

23. In paragraph 64 (amendment of Article 3 of the Biocides Regulation), in sub-paragraph (2)—

(a) for paragraph (d) substitute—

“(d) in point (k), for “the Union” substitute “Great Britain”;

(b) in paragraph (f), in the new point (n) which it substitutes, for “exit day” substitute “IP completion day”;

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- (2) [Commission Regulation \(EU\) No 283/2013](#) repealed Regulation (EU) No 544/2011, but made transitional provision in Article 3 (Transitional measures as regards procedures concerning active substances) and Article 4 (Transitional measures as regards procedures concerning plant protection products) preserving the effect of Regulation (EU) No 544/2011 in relation to certain authorisations that were applied for before specified dates, of which some are still in effect.
 - (3) [Commission Regulation \(EU\) No 284/2013](#) repealed Regulation (EU) No 545/2011, but made transitional provision in Article 3 (Transitional measures as regards procedures concerning active substances) and Article 4 (Transitional measures as regards procedures concerning plant protection products) preserving the effect of Regulation (EU) No 545/2011 in relation to certain authorisations that were applied for before specified dates, of which some are still in effect.

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- (c) in paragraph (h)(ii), for “the United Kingdom” substitute “Great Britain”;
- (d) in paragraph (k)—
 - (i) for the new point (ai) which it inserts, substitute—
 - “(ai) “appropriate fee” means the fee payable for the activity concerned in regulations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;”;
 - (ii) after the new point (ai) which it inserts, for point (ah) (the second time this point number is used) substitute—
 - “(aj) “Devolved Authority” means—
 - (i) the Scottish Ministers, or
 - (ii) the Welsh Ministers.”.

24. In paragraph 69 (insertion of Article 8A into the Biocides Regulation), in the new Article 8A which it inserts, in both places it occurs (including the heading), for “UK” substitute “GB”.

25. In paragraph 70 (amendment of Article 9 of the Biocides Regulation), in sub-paragraph (4), in the new paragraph 2 which it substitutes, for “UK” substitute “GB”.

26. In paragraph 75 (amendment of Article 14 of the Biocides Regulation), in sub-paragraph (6), in the new paragraph 4A which it inserts, for “UK” substitute “GB”.

27. After paragraph 78 (amendment of Article 17 of the Biocides Regulation), insert—

“**78A.** After Article 17 insert—

“Article 17A NI Product Market Access

1. Subject to paragraphs 5-8, a biocidal product is to be treated as if it was authorised by the competent authority under Article 30 or, where relevant, Article 26, under the same terms and conditions as the product is authorised or permitted in Northern Ireland where—

- (a) each of the following conditions are met—
 - (i) the biocidal product—
 - (aa) is a qualifying Northern Ireland good, and
 - (bb) has a Relevant NI Permission at that time;
 - (ii) the authorisation holder or the person with a Relevant NI Permission (as the case may be) is established in Northern Ireland;
 - (iii) all the active substances in the biocidal product are entered in—
 - (aa) the list prepared pursuant to Article 8A (the GB List), or
 - (bb) the list prepared pursuant to Article 24A (the Simplified Active Substance List);
 - (iv) the person referred to in point (a)(ii) notifies the competent authority no later than 90 days in advance of making the biocidal product available on the market by submitting in full to the competent authority the information that the person submitted in their application under Regulation (EU) No 528/2012 as it has effect in EU law to the evaluating competent authority, reference

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- Member State⁽⁴⁾ or Northern Ireland competent authority (as the case may be), for the Relevant NI Permission together with a copy of any relevant NI authorisation or permit;
- (v) the competent authority takes no action pursuant to paragraph 2;
- (b) if the person referred to in point (a)(ii) intends to make any changes to the product, that person notifies the competent authority no later than 90 days in advance of the date on which such changes will apply, with the information submitted to the reference Member State pursuant to Article 5 of Commission Implementing Regulation (EU) No 354/2013 as it has effect in EU law, or for administrative changes other than those referred to in the second subparagraph of Article 6(2) of that Regulation, that person notifies the competent authority within 12 months of making the change;
- (c) if the person referred to in point (a)(ii) intends to renew the authorisation of the product in Northern Ireland, that person notifies the competent authority no later than 90 days in advance of the date of renewal by submitting in full the information that the person submitted to the reference Member State pursuant to Articles 31(1) or 45(1) of Regulation (EU) No 528/2012 as it has effect in EU law or, where relevant, Article 2 of Commission Delegated Regulation (EU) No 492/2014 as it has effect in EU law.
2. The competent authority may prohibit a biocidal product notified under paragraph 1 from being made available on the market in Great Britain where—
- (a) such action can be justified on any of the following grounds—
- (i) the protection of the environment,
- (ii) public policy or security,
- (iii) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants,
- (iv) the protection of national treasures possessing artistic, historic or archaeological value,
- (v) the target organisms not being present in harmful quantities, or
- (b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.
3. The competent authority may amend the terms and conditions under which a biocidal product may be made available on the market in Great Britain where—
- (a) this can be justified on the grounds in paragraph 2(a), or
- (b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.
4. Where the competent authority intends to take action under paragraphs 2 or 3, or identifies concerns as to whether the biocidal product meets the criteria in Articles 19 or 25, the competent authority—
- (a) must inform the notifier, and
- (b) may request additional information.

(4) “reference Member State” has the meaning given by Article 33 of Regulation (EU) No 528/2012 as it has effect in EU law.

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5. The period of 90 days referred to in paragraphs 1(a)(iv), (b) and (c) is suspended—

- (a) where the competent authority takes action under paragraph 4(b), until the competent authority receives the additional information, and
- (b) from the point when the competent authority receives the additional information, for a further period of 90 days to allow the competent authority to consider that additional information.

6. Where any information submitted to the competent authority under this Article includes one or more letters of access, the competent authority may reject the letter of access⁽⁵⁾ where it does not hold the relevant data.

7. Where the additional information has not been submitted to the competent authority within 90 days of a request under paragraph 4(b), the notification made under paragraph 1 is to be treated as withdrawn.

8. Where the competent authority has amended the terms and conditions under which a biocidal product may be made available on the market under paragraph 3, that product must not be made available and used in Great Britain other than under those amended terms and conditions.

9. Where a biocidal product has been treated as authorised due to meeting the requirements of paragraph 1 but ceases to satisfy those requirements—

- (a) there is deemed to be a cancellation of the authorisation of that product by the competent authority, and
- (b) the period of grace provided for in Article 52 applies.

10. For the purposes of this Article—

- (a) “NI competent authority” means the competent authority appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013;
- (b) “qualifying Northern Ireland good” has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;
- (c) “Relevant NI Permission” means any of the following—
 - (i) a national authorisation granted by the NI competent authority under Article 30 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 5 of Regulation (EU) No 414/2013 as it has effect in EU law;
 - (ii) an authorisation granted by mutual recognition by the NI competent authority under Articles 33 or 34 of Regulation (EU) No 528/2012 as it has effect in EU law;
 - (iii) a Union authorisation granted by the Commission under Article 44 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 6 of Regulation (EU) No 414/2013 as it has effect in EU law;
 - (iv) an authorisation granted by the NI competent authority under the simplified procedure in accordance with Article 26 of Regulation (EU) No 528/2012 as it has effect in EU law or Article 6a of Regulation (EU) No 414/2013 as it has effect in EU law;

(5) “Letter of access” has the meaning given by Article 3(1)(t) of Regulation (EU) No 528/2012 as it has effect in EU law.

- (v) a biocidal product permitted on the market by the NI competent authority under the Parallel Trade procedure in Article 53(1) of Regulation (EU) No 528/2012 as it has effect in EU law;
- (vi) a critical use permit granted in Northern Ireland under Article 55(1) of Regulation (EU) No 528/2012 as it has effect in EU law;
- (vii) a provisional authorisation under Article 55(2) of Regulation (EU) No 528/2012 as it has effect in EU law;
- (viii) a cultural heritage authorisation granted under Article 55(3) of Regulation (EU) No 528/2012 as it has effect in EU law;
- (ix) an essential use authorisation granted under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013.”.”.

28. In paragraph 102 (amendment of Article 55 of the Biocides Regulation), in the new Article 55 which it substitutes—

- (a) omit paragraph 4(d) (and the semicolon which precedes it);
- (b) omit paragraphs 7 and 8;
- (c) re-number paragraph 9 as paragraph 7;
- (d) in paragraph 7 (previously paragraph 9), in the second sentence, for “Devolved Authorities” substitute “Devolved Authority”.

29. In paragraph 107 (amendment of Article 60 of the Biocides Regulation), in paragraph (3), in the new paragraphs 4 and 5 which it inserts, in each place it occurs, for “exit day” substitute “IP completion day”.

30. For paragraph 108 (amendment of Article 62 of the Biocides Regulation), substitute—

“**108.** In Article 62(2)—

- (a) in the first subparagraph, after point (b)—
 - (i) in the first place it occurs, for “Agency” substitute “competent authority”;
 - (ii) omit “Agency or to a”;
 - (iii) after “under this Regulation” insert “or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day”;
 - (iv) for “The Agency shall” substitute “The competent authority must”;
 - (v) at the end, insert “and whether the competent authority has access to the tests or studies”;
- (b) in the second subparagraph—
 - (i) omit “Agency or to a”;
 - (ii) after “under this Regulation” insert “or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day”;
 - (iii) for “the Agency shall” substitute “and where the competent authority has access to the tests or studies the competent authority must”.”.

31. In paragraph 111 (amendment of Article 65 of the Biocides Regulation), in sub-paragraph (3), for paragraph (b) substitute—

- “(b) in the second subparagraph, for “on the Union market” substitute “on the market in Great Britain”.”.

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32. In paragraph 115 (amendment of Article 69 of the Biocides Regulation), in sub-paragraph (3), for paragraph (b) substitute—

“(b) in point (o), for “[Directive 2000/45/EC](#)” substitute “the Control of Substances Hazardous to Health Regulations 2002.”.

33. In paragraph 119 (amendment of Article 77 of the Biocides Regulation), in the new Article 77 which it substitutes, for paragraph 1 substitute—

“1. Decisions of the competent authority taken pursuant to this Regulation may be appealed against in accordance with regulation 14 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.”.

34. In paragraph 123 (amendment of Article 81 of the Biocides Regulation), in paragraph (3), for the new paragraph 1 which it substitutes, substitute—

“1. The competent authority responsible for the application of this Regulation—

- (a) is the competent authority as appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013, and
- (b) must have a sufficient number of suitably qualified and experienced staff to enable the obligations provided for in this Regulation to be carried out efficiently and effectively.”.

35. In paragraph 125 (insertion of new Articles 83A and 83B of the Biocides Regulation), in the new Article 83B which it inserts—

- (a) in new paragraph 1, for “paragraphs 2 to 4” substitute “paragraphs 2 and 3”;
- (b) omit new paragraphs 4 to 7.

36. In paragraph 129 (amendment of Article 88 of the Biocides Regulation), in the new Article 88 which it substitutes—

- (a) in paragraph 2, at the end, for “paragraphs 3 to 7” substitute “paragraphs 3 to 5”;
- (b) omit paragraph 3(d) (and the semicolon which precedes it);
- (c) omit paragraphs 6 and 7;
- (d) re-number paragraph 8 to become paragraph 6;
- (e) in paragraph 6 (re-numbered from paragraph 8), in the second sentence, for “other Devolved Authorities” substitute “other Devolved Authority”.

37. In paragraph 135 (amendment of Article 94 of the Biocides Regulation), in sub-paragraph (2) (b), in both places it occurs, for “exit day” substitute “IP completion day”.

38. Omit paragraph 137 (insertion of Articles 95A to 95L into the Biocides Regulation)(6).

39. In paragraph 143 (amendment of Annex VI to the Biocides Regulation)—

- (a) in sub-paragraph 12, for “United Kingdom” substitute “Great Britain”;
- (b) for sub-paragraph 14 substitute—

“(14) In paragraph 77, for “the Member State or, where appropriate, in the Union” substitute “Great Britain”.”.

(6) The provisions that were inserted into the Biocides Regulation by paragraph 137 of Schedule 2 to [SI 2019/720](#) are replaced, with amendments, by Schedule 4 to this instrument.

Amendments relating to Regulation (EU) No 649/2012 (“the PIC Regulation”)

40. For paragraph 145 (amendment of Article 1 of the PIC Regulation) substitute—

“**145.** In Article 1—

(a) in paragraph 1, in the second subparagraph—

(i) for “the Union” substitute “Great Britain”;

(ii) for “to Parties and other countries” substitute “to Parties, other countries and Northern Ireland”;

(b) in paragraph 2—

(i) for “the Member States” substitute “Great Britain”;

(ii) for “to other Parties or other countries” substitute “to other Parties, other countries or Northern Ireland”;

(iii) for “of those Parties or other countries” substitute “of those Parties, other countries or Northern Ireland”.”.

41. In paragraph 146 (amendment of Article 2 of the PIC Regulation)—

(a) for sub-paragraph (2) substitute—

“(2) In paragraph 1, in point (b), for “the Union or a Member State” substitute “Great Britain”.”;

(b) in sub-paragraph (3)—

(i) in paragraph (a), omit “and the Ionising Radiations Regulations (Northern Ireland) 2017”;

(ii) in paragraph (b), for the words from “, the Waste (Scotland)” to the end substitute “and the Waste (Scotland) Regulations 2011”;

(iii) in paragraph (c), for the words from “(Scotland) Regulations 2002” to the end substitute “(Scotland) Regulations 2002 and the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002”;

(c) for sub-paragraph (4) substitute—

“(4) In paragraph 3—

(a) in the first subparagraph, after “each importing country” insert “, or to Northern Ireland”;

(b) in the second subparagraph, for “using the Database referred to in Article 6(1) (a)” substitute “from the exporter’s Designated National Authority”.”.

42. In paragraph 147 (amendment of Article 3 of the PIC Regulation)—

(a) in sub-paragraph (4)(b), for “the UK PIC list” substitute “the GB PIC list”;

(b) in sub-paragraph (5), for paragraphs (b) and (c) substitute—

“(b) in the second sentence—

(i) for “the Union” substitute “Great Britain”;

(ii) for “Annex I” substitute “the GB PIC list”.”;

(c) in sub-paragraph (6)(b), for “UK PIC list” substitute “GB PIC list”;

(d) in sub-paragraph (7), for paragraph (b) substitute—

“(b) in point (b), for “Union” substitute “Great Britain”.”;

(e) in sub-paragraph (8), for paragraph (b) substitute—

“(b) in point (b), for “Union” substitute “Great Britain”.”;

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- (f) in sub-paragraph (11), in the new point (16) which it substitutes—
 - (i) in the first place it occurs, for “the United Kingdom” substitute “Great Britain”;
 - (ii) in point (a), for “section 35 or 36” substitute “sections 33(4), 35 or 36”;
 - (iii) in the second place it occurs, for “the United Kingdom” substitute “Great Britain”;
 - (g) in sub-paragraph (12), in both places the words occur, for “the United Kingdom” substitute “Great Britain”;
 - (h) for sub-paragraph (13) substitute—
 - “(13) In point (18)—
 - (a) in point (a)—
 - (i) for “Party or other country” substitute “Party, other country or Northern Ireland”;
 - (ii) for “the customs territory of the Union” substitute “Great Britain”;
 - (b) in point (b), for “the customs territory of the Union” substitute “Great Britain”;
 - (c) in point (c), in both places it occurs, for “the Union” substitute “Great Britain”;
 - (i) for sub-paragraph (14) substitute—
 - “(14) In point (19), for “the customs territory of the Union” substitute “Great Britain”;
 - (j) in sub-paragraph (17), in the new point (26) which it inserts, for “UK PIC list” substitute “GB PIC list”.
- 43.** In paragraph 149 (amendment of Article 5 of the PIC Regulation), in sub-paragraph (4), in the new paragraphs 1 to 3 which that sub-paragraph substitutes—
- (a) paragraphs 1, 2 and 3 become paragraphs 2, 2A and 2B respectively;
 - (b) in the paragraph re-numbered as paragraph 2, in subparagraph (a)—
 - (i) for “United Kingdom” substitute “Great Britain”;
 - (ii) for “other Parties and countries” substitute “other Parties, countries and Northern Ireland”;
 - (c) in the paragraph re-numbered as paragraph 2A, in subparagraph (c), for “United Kingdom” substitute “Great Britain”.
- 44.** In paragraph 151 (amendment of Article 7 of the PIC Regulation), in sub-paragraphs (3), (4) and (5), in each place it occurs, for “UK PIC list” substitute “GB PIC list”.
- 45.—**(1) Paragraph 152 (amendment of Article 8 of the PIC Regulation) is amended as follows.
- (2) For sub-paragraph (2) substitute—
- “(2) In paragraph 1—
 - (a) for “Annex I” substitute “the GB PIC list”;
 - (b) for the words from “importing Party” to the end substitute “importing Party, other country or Northern Ireland”.
- (3) In sub-paragraph (3)—
- (a) in paragraph (a)—
 - (i) for paragraph (i) substitute—
 - “(i) for “the Union” substitute “Great Britain”;
 - (ii) paragraphs (ii) to (iv) become paragraphs (iii) to (v);
 - (iii) after paragraph (i) insert a new paragraph (ii) as follows—

- “(ii) for “to a Party or other country” substitute “to a Party, other country or Northern Ireland”,”;
 - (b) for paragraph (c) substitute—
 - “(c) in the third subparagraph—
 - (i) for “The Agency shall, on behalf of the Commission” substitute “The Designated National Authority must”;
 - (ii) after the words “designated national authority of the importing Party” insert “or Northern Ireland”,”;
 - (c) in paragraph (d)—
 - (i) for paragraph (v) substitute—
 - “(v) for “importing Parties and other countries” substitute “importing Parties, other countries and Northern Ireland”,”;
 - (ii) after paragraph (v) insert—
 - “(vi) for “by means of the Database” substitute “via its website”.”.
- (4) For sub-paragraph (4) substitute—
 - “(4) In paragraph (3)—
 - (a) in the first place it occurs, for “Agency” substitute “Designated National Authority”;
 - (b) for “importing Party or other country” substitute “importing Party, other country or Northern Ireland”;
 - (c) for “Annex I” substitute “the GB PIC list”;
 - (d) in the first place it occurs, omit “, on behalf of the Commission,”;
 - (e) in the second place it occurs, for “Agency” substitute “Designated National Authority”;
 - (f) in the second place it occurs, omit “, on behalf of the Commission,”;
 - (g) after “of the importing Party” insert “or Northern Ireland”.”.
- (5) For sub-paragraph (6) substitute—
 - “(6) In paragraph 5—
 - (a) in both places the words occur, for “the importing Party or other country” substitute “the importing Party, other country or Northern Ireland”;
 - (b) for the words from “designated” to the end substitute “exporter’s Designated National Authority”.”.
- (6) For sub-paragraph (7) substitute—
 - “(7) In paragraph 6—
 - (a) in the first subparagraph—
 - (i) in point (b), at the end, insert “, or in the case of Northern Ireland where such a response has been provided to the Secretariat indicating whether or not it consents to the import of the chemical”;
 - (ii) in point (c)—
 - (aa) for “Commission” substitute “Designated National Authority”;
 - (bb) omit the words from “and has forwarded” to the end”;

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- (b) in the second subparagraph, at the end, insert “, or in the case of Northern Ireland, where export notification by exporting Parties is explicitly required through the import decision relating to Northern Ireland or otherwise”;
 - (c) in the third subparagraph—
 - (i) in point (a), after “designated national authority of the importing Party”, insert “or Northern Ireland”;
 - (ii) in point (b)—
 - (aa) for “Commission” substitute “Designated National Authority”;
 - (bb) after “designated national authority of the importing Party” insert “or Northern Ireland”;
 - (cc) for the words from “and has forwarded” to the end substitute “and has made it publicly available via its website”.
- (7) For sub-paragraph (8) substitute—
- “(8) In paragraph 7—
- (a) for the words from “The Commission” to “Agency” substitute “The Designated National Authority”;
 - (b) for “importing Parties and other countries” substitute “importing Parties, other countries and Northern Ireland”.
- 46.** In paragraph 153 (amendment of Article 9 of the PIC Regulation)—
- (a) in sub-paragraph (2)(b)(ii)—
 - (i) for “the United Kingdom” substitute “Great Britain”;
 - (ii) for the words “under a Party’s or other country’s legislation” substitute “under the legislation of a Party, other country or Northern Ireland”;
 - (b) after sub-paragraph (2)(b)(ii) insert—
 - “(iii) for the words from “each Party” to the end substitute “each Party, other country or Northern Ireland”.
- 47.** In paragraph 154 (amendment of Article 10 of the PIC Regulation), for sub-paragraph (2) substitute—
- “(2) In paragraph 1—
- (a) in the first subparagraph
 - (i) in point (a), for “Annex I” substitute “Part 1, 2 or 3 of the GB PIC list”;
 - (ii) in point (c), for “Annex I” substitute “the GB PIC list”;
 - (iii) in the words which follow point (c)—
 - (aa) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (bb) for “each Party or other country” substitute “each Party, other country or Northern Ireland”;
 - (cc) for “a Party or other country” substitute “a Party, other country or Northern Ireland”;
 - (b) in the second subparagraph, in both places it occurs, for “the Union” substitute “Great Britain”.
- 48.** In paragraph 155 (amendment of Article 11 of the PIC Regulation)—
- (a) in sub-paragraphs (2)(b), (3)(a) and 4(a)(ii), for “UK PIC list” substitute “GB PIC list”;

- (b) in sub-paragraph (7)(b)(iii), for the words from “, the Welsh Ministers” to the end substitute “and the Welsh Ministers”.

49. In paragraph 156 (amendment of Article 12 of the PIC Regulation), for “UK PIC list” substitute “GB PIC list”.

50. In paragraph 157 (amendment of Article 13 of the PIC Regulation), in sub-paragraph (6)(b), for the words from “, the Welsh Ministers” to the end substitute “and the Welsh Ministers”.

51.—(1) Paragraph 158 (amendment of Article 14 of the PIC Regulation) is amended as follows.

(2) For paragraph (6) substitute—

“(6) In paragraph (6)—

(a) in the first subparagraph—

(i) in the first line, for “Annex I” substitute “the GB PIC list”;

(ii) in point (a)—

(aa) for the words from “designated national authority of the exporter’s” to “Agency” substitute “exporter’s Designated National Authority”;

(bb) after “importing Party” insert “or Northern Ireland”;

(iii) in point (b)—

(aa) for “Annex I” substitute “the GB PIC list”;

(bb) at the end, insert “, or in the case of Northern Ireland the European Union has given consent to import”;

(b) in the second subparagraph—

(i) for “Annex I” substitute “the GB PIC list”;

(ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;

(iii) omit “in consultation with the Commission and on a case-by-case basis,”;

(c) in the third subparagraph—

(i) in the first two places it occurs, for “Agency” substitute “Designated National Authority”;

(ii) for “shall, on behalf of the Commission,” substitute “must”;

(iii) for the words from “unless” to “forwarded it to the Agency” substitute “to the designated national authority of the importing Party or Northern Ireland or to an appropriate authority in the importing other country”;

(iv) in the last place it occurs, for “Agency” substitute “Designated National Authority”.”.

(3) For paragraph (7) substitute—

“(7) In paragraph (7)—

(a) in the first subparagraph—

(i) in the first place it occurs, for “Annex I” substitute “the GB PIC list”;

(ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;

(iii) omit the words from “in consultation” to “case-by-case basis and”;

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- (iv) in the opening sentence and in point (a), for “importing Party or other country” substitute “importing Party, other country or Northern Ireland”;
- (v) in point (b)—
 - (aa) for “a Party or other country” substitute “a Party, other country or Northern Ireland”;
 - (bb) for “Annex I” substitute “the GB PIC list”;
 - (cc) at the end, insert “or used in or imported into Northern Ireland (as appropriate)”;
- (b) in the second subparagraph, for “Annex I” substitute “the GB PIC list”;
- (c) in the third subparagraph—
 - (i) for “Annex I” substitute “the GB PIC list”;
 - (ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (iii) omit “, in consultation with the Commission assisted by the Agency,”;
 - (iv) for “importing Party or other country” substitute “importing Party, other country or Northern Ireland”;
 - (v) omit the words from “, and submit” to the end.”.
- (4) For paragraph (10) substitute—
 - “(10) In paragraph 11—
 - (a) for “importing Party or other country” substitute “importing Party, other country or Northern Ireland”;
 - (b) for “Union legislation” substitute “retained EU law”.”.
- 52.** In paragraph 159 (amendment of Article 15 of the PIC Regulation)—
 - (a) in sub-paragraph (a), for “UK PIC list” substitute “GB PIC list”;
 - (b) in sub-paragraph (b)—
 - (i) for paragraph (i) substitute—
 - “(i) for “the Union” substitute “Great Britain”,”;
 - (ii) in paragraph (ii), for “UK PIC list” substitute “GB PIC list”.
- 53.** In paragraph 160 (amendment of Article 16 of the PIC Regulation), in sub-paragraph (a)(i), for “UK PIC list” substitute “GB PIC list”.
- 54.** In paragraph 161 (amendment of Article 17 of the PIC Regulation)—
 - (a) after sub-paragraph (a)(ii) insert—
 - “(iii) for “the importing Parties or other countries” substitute “importing Parties, other countries or Northern Ireland”,”;
 - (b) in sub-paragraph (b), for “UK PIC list” substitute “GB PIC list”;
 - (c) after sub-paragraph (b) insert—
 - “(c) in paragraph 3, for “Party or other country” substitute “Party, other country or Northern Ireland”.”.
- 55.** In paragraph 162 (amendment of Article 18 of the PIC Regulation), in sub-paragraph (3)(a)(ii), for “UK PIC list” substitute “GB PIC list”.
- 56.** In paragraph 164 (amendment of Article 20 of the PIC Regulation), for paragraphs (a) and (b) substitute—

- “(a) in paragraph 1—
 - (i) in the first subparagraph, for the words from the beginning to “Member States” substitute “The Secretary of State”;
 - (ii) in the second sub-paragraph—
 - (aa) for the words from the beginning to “Agency as necessary” substitute “The Secretary of State.”;
 - (bb) in point (b), for “Parties and other countries” substitute “a Party, other country or Northern Ireland”;
- (b) in paragraph 2—
 - (i) for the words from the beginning to “Agency” substitute “The Secretary of State and the Designated National Authority”;
 - (ii) for “a Party or other country” substitute “a Party, other country or Northern Ireland”.”.

57. In paragraph 167 (amendment of Article 23 of the PIC Regulation), in sub-paragraphs (a), (b)(ii), (c)(ii) and (d)(ii), for “UK PIC list” substitute “GB PIC list”.

58. In paragraph 168 (insertion of Articles 23A and 23B into the PIC Regulation), in the new Article 23B that it inserts—

- (a) in paragraph 1, for “paragraphs 2 to 4” substitute “paragraphs 2 and 3”;
- (b) omit paragraphs 4 to 7.

59. In paragraph 171 (amendment of Annex II to the PIC Regulation)—

- (a) in sub-paragraphs 3(a) and (4), for “UK PIC list” substitute “GB PIC list”;
- (b) for sub-paragraph (6) substitute—
 - “(6) In paragraph 8—
 - (a) in the first line, for “the Union” substitute “Great Britain”;
 - (b) in paragraph (a), for “Union” substitute “Great Britain”;
 - (c) in paragraph (b), for “Annex I of the Regulation” substitute “Parts 1, 2 and 3 of the GB PIC list”.”.

60. For paragraph 173 (amendment of Annex IV to the PIC Regulation) substitute—

“**173.** In Annex IV, in paragraph 1, in point (f), for “the Union” substitute “Great Britain”.”.

Amendments relating to Regulation (EU) No 283/2013 (Regulation on data requirements for active substances)

61. In paragraph 176 (amendment of the Annex to the Regulation on data requirements for active substances), in both places it occurs, for “UK” substitute “GB”.

Amendments relating to Regulation (EU) 284/2013 (Regulation on data requirements for PPPs)

62. In paragraph 177 (amendment of the Annex to the Regulation on data requirements for PPPs), in each place it occurs, for “UK” substitute “GB”.

Amendments relating to Regulation (EU) No 354/2013 (“the Changes Regulation”)

63. In paragraph 179 (amendment of Article 2 of the Changes Regulation)—

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- (a) for paragraph (a) substitute—
 - “(a) in the first subparagraph, for “Agency” substitute “competent authority”.”;
- (b) for paragraph (b) substitute—
 - “(b) for the second subparagraph substitute—
 - “The opinion must be delivered within 45 days following receipt of the request and payment of the appropriate fee. In this Regulation, “appropriate fee” means the fee payable for the activity concerned in relations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.”;
- (c) after paragraph (b) insert—
 - “(c) in the third subparagraph, for “Agency” substitute “competent authority”.”.

Amendments relating to Regulation (EU) No 414/2013 (“the Same Products Regulation”)

- 64.** For paragraph 195 (amendment of Article 1 of the Same Products Regulation) substitute—
 - “**195.** In Article 1—
 - (a) after “which has been authorised and registered” insert “in the United Kingdom”;
 - (b) after “and of the Council or” insert “authorised or registered in the United Kingdom in accordance with”;
 - (c) after “Regulation (EU) No 528/2012,” insert “or authorised or registered in Great Britain in accordance with this Regulation,”.
- 65.** In paragraphs 197 (amendment of Article 3 of the Same Products Regulation), for sub-paragraphs (3) and (4) substitute—
 - “(3) In paragraph 1—
 - (a) after “by national authorisation” insert “in the United Kingdom (before IP completion day) or in Great Britain (from IP completion day)”;
 - (b) after “for such an authorisation” insert “in Great Britain”;
 - (c) omit the words from “that has granted” until the end.
 - (4) Omit paragraph 1a.
 - (5) In paragraph 2, for “paragraphs 2 and 4” substitute “paragraph 2”.

Amendments relating to Regulation (EU) No 88/2014 (“the Annex I Regulation”)

- 66.** In paragraph 209 (amendment of Article 4 of the Annex I Regulation), for sub-paragraph (2) substitute—
 - “(2) In paragraph 1—
 - (a) in the first subparagraph—
 - (i) omit “evaluating”;
 - (ii) for “assessment report and the conclusions of its evaluation” substitute “opinion”;
 - (iii) for the words from “European Chemicals Agency” to “(“the Agency”)” substitute “Secretary of State, the Scottish Ministers and the Welsh Ministers”;

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- (iv) in the first place it occurs, for “Annex I to” substitute “the Simplified Active Substance List under”;
- (v) in the first place it occurs, for “the assessment report and the conclusions” substitute “the opinion”;
- (vi) in the second place it occurs, for “Annex I to” substitute “the Simplified Active Substance List under”;
- (vii) in the second place it occurs, for “the assessment report and the conclusions” substitute “the opinion”;
- (b) in the second subparagraph—
 - (i) for “conclusions” substitute “opinion”;
 - (ii) for “Agency” substitute “Secretary of State, the Scottish Ministers and the Welsh Ministers,”;
 - (iii) in the first place it occurs, omit “evaluating”;
 - (iv) for “assessment report and on the conclusions of the evaluation” substitute “opinion”;
 - (v) in the second place it occurs, omit “evaluating”;
 - (vi) for “evaluation” substitute “opinion”.

67. In paragraph 210 (amendment of Article 5 of the Annex I Regulation), in sub-paragraph (3), for the words “the Scottish Ministers, the Welsh Ministers and a Northern Ireland Department” substitute “the Scottish Ministers and the Welsh Ministers”.

Amendments relating to Regulation (EU) No 1062/2014 (“the Review Regulation”)

68. Paragraph 214 (amendment of Article 2 of the Review Regulation) is amended as follows—

- (a) in sub-paragraphs (2) and (3), in each place it occurs, for “exit day” substitute “IP completion day”;
- (b) for sub-paragraph (4) substitute—
 - “(4) For point (d), substitute—
 - “(d) “competent authority” means the authority appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;”;
- (c) for sub-paragraph (5) substitute—
 - “(5) After point (d) insert—
 - “(e) “the consent requirement” means the requirement for consent in accordance with Article 83B of Regulation (EU) No 528/2012;
 - (f) “appropriate fee” means the fee payable for the activity concerned in regulations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;
 - (g) “Devolved Authority” means—
 - (i) the Scottish Ministers, or
 - (ii) the Welsh Ministers.”.

69. In paragraph 218 (amendment of Article 6 of the Review Regulation), in paragraph 2(a), in the new point (b) which that paragraph substitutes, for “exit day” substitute “IP completion day”.

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70. In paragraph 227 (amendment of Article 15 of the Review Regulation)—

- (a) in sub-paragraphs (3) and (4), in each place it occurs, for “exit day” substitute “IP completion day”;
- (b) in sub-paragraph (4), in the new point (aa) which it inserts, at the end insert “or in new, authoritative guidance published by the Competent Authority”.

71. In paragraph 234 (amendment of Article 22 of the Review Regulation), in the new Article 22 which that paragraph substitutes—

- (a) in new paragraph 1, at the end, for “Article 89(8)” substitute “Article 89(7)”;
- (b) in new paragraph 3—
 - (i) for “the United Kingdom” substitute “Great Britain”;
 - (ii) for “paragraph 10” substitute “paragraph 8”;
 - (iii) at the end, for “paragraphs 4 to 8” substitute “paragraphs 4 to 6”;
- (c) omit new paragraph 4(d) (and the semicolon which precedes it);
- (d) omit new paragraphs 7 and 8;
- (e) re-number paragraphs 9 and 10 as 7 and 8 respectively
- (f) in the paragraph renumbered as paragraph 7 (previously paragraph 9)—
 - (i) for “grants the derogation” substitute “exercises the derogation”;
 - (ii) in the second place it occurs, for “Devolved Authorities” substitute “Devolved Authority”.

72. In paragraph 235 (insertion of Articles 22A to 22D of the Review Regulation), in the new Articles 22A to 22D which it inserts—

- (a) in new Article 22A—
 - (i) in the heading, and in new paragraph 1, in each place it occurs, for “exit day” substitute “IP completion day”;
 - (ii) in new paragraph 2, in each of subparagraphs (a) and (b)—
 - (aa) in the first place it occurs, for “exit day” substitute “IP completion day”;
 - (bb) after “United Kingdom” insert “competent authority”;
 - (cc) for “Member State” substitute “competent authority”;
 - (dd) in the second place it occurs, for “exit day” substitute “30 March 2019”;
 - (iii) after paragraph 2 insert—

“3. Where the applicant does not meet the requirements of this Article, the application is to be treated as having been withdrawn under Article 11(1)(b).”;
- (b) in new Articles 22B and 22C, in each place it occurs, for “exit day” substitute “IP completion day”;
- (c) in new Article 22D—
 - (i) in the heading, and in new paragraph 1, for “exit day” substitute “IP completion day”;
 - (ii) in new paragraph 2, for points (a) and (b), substitute—

“(a) 90 days of IP completion day, where the United Kingdom competent authority was the evaluating competent authority before 30 March 2019,
or

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(b) 180 days of IP completion day, where the United Kingdom competent authority was not the evaluating competent authority before 30 March 2019”;;

(iii) after paragraph 2 insert—

“**3.** Where the applicant does not meet the requirements of this Article, the application will be treated as having been withdrawn under Article 11(1)(b).”.