

SCHEDULE 1

Amendment of Titles 1 to 15

PART 7

Amendment of Title 7: Authorisation

Chapter 1 of Title 7

- 43.** In Article 55, for “internal market” substitute “market in the United Kingdom”.
- 44.**—(1) Article 56 is amended as follows.
- (2) In paragraph 4—
- (a) in point (a), for “[Directive 91/414/EEC](#)” substitute “[Regulation \(EC\) No 1107/2009](#)”;
- (b) in point (b), for “[Directive 98/8/EC](#)” substitute “[Regulation \(EU\) No 528/2012](#)”;
- (c) in point (c), for “[Directive 98/70/EC](#)” to the end substitute “the Motor Fuel (Composition and Content) Regulations 1999(1)”.
- (3) In paragraph 5(a), for “[Directive 76/768/EEC](#)” substitute “[Regulation \(EC\) No 1223/2009](#)”.
- 45.**—(1) Article 58 is amended as follows.
- (2) In paragraph 1, for the subparagraph before point (a) substitute—
- “**1.** The Secretary of State may, by regulations, include in Annex 14 substances referred to in Article 57. The regulations must specify for each substance:”.
- (3) In paragraph 2, omit “Community”.
- (4) In paragraph 3—
- (a) in the first subparagraph, omit “, taking into account the opinion of the Member State Committee,”;
- (b) in the second subparagraph, in the second sentence, for “1 June 2009” substitute “1 June 2020”.
- (5) In paragraph 4, for “Commission” substitute “appropriate authorities”.
- (6) In paragraph 7, omit “Community”.
- (7) For paragraph 8 substitute—
- “**8.** The Secretary of State may, by regulations, remove from Annex 14 substances which as a result of new information no longer meet the criteria of Article 57.”.
- (8) After paragraph 8, insert—
- “**9.** Regulations under paragraph 1 or 8 are to be made by statutory instrument; and a statutory instrument containing regulations under paragraph 1 or 8 is subject to annulment in pursuance of a resolution of either House of Parliament.
- The function of making regulations under paragraph 1 or 8 is subject to the consent requirement in Article 4A.”.
- 46.**—(1) Article 59 is amended as follows.

(1) [S.I. 1999/3107](#), amended by [S.I. 2001/3896](#), [2003/3078](#), [2007/1608](#), [2010/3035](#), [2012/2567](#), [2013/2897](#), [2014/3076](#), [2015/1630](#), 1796.

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- (2) After paragraph 1, insert—
 - “1A. The Agency must include in its candidate list every substance that is included in ECHA’s candidate list under Article 59(1) of EU REACH immediately before exit day.”.
- (3) In paragraph 2—
 - (a) for “The Commission” substitute “An appropriate authority”;
 - (b) in the last sentence for “Member States” substitute “appropriate authorities”.
- (4) In paragraph 3—
 - (a) for “Any Member State” substitute “The Agency”;
 - (b) omit “and forward it to the Agency”;
 - (c) in the last sentence for “within 30 days of receipt to the other Member States” substitute “to the appropriate authorities”.
- (5) Omit paragraph 5.
- (6) In paragraph 6, omit “or make”.
- (7) In paragraph 7—
 - (a) omit “made or”;
 - (b) for the words from “shall” to the end substitute “must consider the comments and make a decision on the identification of the substance within 45 days of the deadline specified in paragraph 4”.
- (8) Omit paragraphs 8 and 9.

Chapter 2 of Title 7

47.—(1) Article 60 is amended as follows.

- (2) In paragraph 1—
 - (a) for “Commission” substitute “Secretary of State”;
 - (b) at the end, insert—

“That responsibility of the Secretary of State is subject to the provisions of this Title which make the exercise of certain functions subject to the consent requirement in Article 4A.”.
- (3) In paragraph 2—
 - (a) for “Committee for Risk Assessment” substitute “Agency so far as the opinion relates to the elements”;
 - (b) for “Commission”, in each place it occurs, substitute “Secretary of State”;
 - (c) in the second subparagraph, for “Council [Directive 90/385/EEC](#)” to the end substitute “the Medical Devices Regulations 2002(2)”.
- (4) In paragraph 4, for “the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis” substitute “the elements”.
- (5) In paragraph 5, for “Commission” substitute “Secretary of State”.

48.—(1) Article 61 is amended as follows.

- (2) In paragraph 1—
 - (a) for “Commission” substitute “Secretary of State”;

(2) [S.I. 2002/618](#), amended by [S.I. 2003/1400](#), [1697](#), [2005/2759](#), [2909](#), [2007/400](#), [610](#), [803](#), [2008/530](#), [2936](#), [2009/383](#), [2010/557](#), [2012/1426](#), [2013/525](#), [2327](#), [2017/207](#).

- (b) after the fifth subparagraph, insert—

“The function of deciding under this paragraph whether to amend or withdraw the authorisation is subject to the consent requirement in Article 4A.”.
- (3) In paragraph 2—
 - (a) in the second subparagraph, for “Commission” substitute “Secretary of State”;
 - (b) after the second subparagraph, insert—

“Any of the other appropriate authorities may request the Secretary of State to carry out a review of an authorisation under this paragraph.”.
- (4) In paragraph 3—
 - (a) for “Commission”, in each place it occurs, substitute “Secretary of State”;
 - (b) after the second subparagraph, insert—

“Where the Secretary of State is carrying out a review of an authorisation under this paragraph, any of the other appropriate authorities may request the Secretary of State to suspend the authorisation while the review is being carried out.

The function of deciding under the first subparagraph whether to amend or withdraw the authorisation, and the function of deciding under the second subparagraph whether to suspend the authorisation, are subject to the consent requirement in Article 4A.”.
- (5) In paragraph 4, omit “referred to in [Directive 96/61/EC](#)”.
- (6) In paragraph 5—
 - (a) after “If the” insert “river basin”;
 - (b) omit “as referred to in Article 4(1) of [Directive 2000/60/EC](#)”.
- (7) In paragraph 6, for “Commission” substitute “Secretary of State”.
- (8) After paragraph 6, insert—

“7. In this Article—

 - (a) “environmental quality standard” means the set of requirements which must be fulfilled at a given time in relation to a given environment or particular part thereof, as set out in retained EU law;
 - (b) “river basin district in Northern Ireland” means a river basin district as defined by the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017(3);
 - (c) “river basin district in Scotland” means an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003(4);
 - (d) “river basin environmental objectives” means—
 - (i) in relation to the Northumbria River Basin District, the environmental objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003(5);
 - (ii) in relation to the Solway Tweed River Basin District, the environmental objectives as defined in regulation 2 of the Water Environment (Water

(3) [S.I. 2017/81](#).

(4) [2003 asp 3](#).

(5) [S.I. 2003/3245](#), amended by [S.I. 2016/139](#), [2017/407](#); there are other amending instruments but none is relevant.

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- Framework Directive) (Solway Tweed River Basin District) Regulations 2004⁽⁶⁾;
- (iii) in relation to any other river basin district within the meaning of the WFD Regulations, the environmental objectives referred to in those Regulations;
 - (iv) in relation to a river basin district in Scotland, the environmental objectives set under section 9(1)(a)⁽⁷⁾ of the Water Environment and Water Services (Scotland) Act 2003;
 - (v) in relation to a river basin district in Northern Ireland, the environmental objectives set under regulation 12, in accordance with regulation 13, of the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017; and
- (e) “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017⁽⁸⁾.”.

49.—(1) Article 62 is amended as follows.

(2) In paragraph 5—

- (a) in point (b)(i), for “was granted in accordance with [Directive 96/61/EC](#)” substitute “to carry out an activity referred to in Annex I to [Directive 2010/75/EU](#) was granted in accordance with retained EU law”;
- (b) for point (b)(ii) substitute—
 - “(b) (ii) discharges of a substance from a point source governed by retained EU law that transposed the requirement for prior regulation referred to in Article 11(3)(g) of [Directive 2000/60/EC](#)⁽⁹⁾ and [Directive 2008/105/EC](#) of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy⁽¹⁰⁾.”.

(3) In paragraph 6, for “Directives [90/385/EEC](#), [93/42/EEC](#) or [98/79EC](#)” substitute “the Medical Devices Regulations 2002”.

50.—(1) Article 64 is amended as follows.

(2) In paragraph 1, for the second sentence substitute “The Agency must give its draft opinion within ten months of the date of receipt of the application”.

(3) For paragraph 3 substitute—

“**3.** In preparing its opinion, the Agency must first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Agency must request additional information to bring the application into conformity with the requirements of Article 62. The Agency may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Agency, and any scientific adviser providing the Agency with scientific knowledge and advice in relation to the opinion, must take into account any information submitted by third parties.”.

(4) After paragraph 3 insert—

⁽⁶⁾ [S.I. 2004/99](#), amended by [S.I. 2016/139](#); there are other amending instruments but none is relevant.

⁽⁷⁾ Section 9(1)(a) was amended by section 54(4)(a) of the Aquaculture and Fisheries (Scotland) Act 2013 ([asp 7](#)). Section 9 was applied with modifications by [S.I. 2003/3245](#) and [2004/99](#).

⁽⁸⁾ [S.I. 2017/407](#), to which there are amendments not relevant to these Regulations.

⁽⁹⁾ Article 11(3)(g) has been transposed by various pieces of legislation, including the Environmental Permitting (England and Wales) Regulations 2016 ([S.I. 2016/1154](#)).

⁽¹⁰⁾ OJ No. L 348, 24.12.2008, p. 84, as last amended by [Directive 2013/39/EU](#) (OJ No. L 226, 24.8.2013, p. 1).

3A. In paragraph 3 “scientific adviser” means a person who the Agency has commissioned (in compliance with the duty imposed by Article 77(A1)) to provide it with scientific knowledge and advice.”.

- (5) In paragraph 4—
- (a) in the first sentence, for “opinions” substitute “opinion”;
 - (b) in point (a), omit “Committee for Risk Assessment.”;
 - (c) in point (b), omit “Committee for Socio-economic Analysis.”.
- (6) In paragraph 5—
- (a) in the first subparagraph, for “these draft opinions” substitute “its draft opinion”;
 - (b) in the second subparagraph, for “these opinions to the Commission, the Member States” substitute “its final opinion to the appropriate authorities”;
 - (c) in the third subparagraph—
 - (i) for “Committees” substitute “Agency”;
 - (ii) for “their” substitute “its”;
 - (iii) for “opinions”, in both places it occurs, substitute “opinion”;
 - (iv) for “Commission, the Member States” substitute “appropriate authorities”.
- (7) In paragraph 6, for “opinions” substitute “opinion”.
- (8) For paragraph 8 substitute—
- 8.** The Secretary of State must make a decision granting or refusing the authorisation within six months of receipt of the opinion from the Agency.
- The function in this paragraph of deciding whether to grant or refuse the authorisation is subject to the consent requirement in Article 4A.”.
- (9) In paragraph 9—
- (i) for “Commission decisions” substitute “decisions of the Secretary of State”;
 - (ii) for “in the Official Journal of the European Union” substitute “by the Secretary of State”.

Chapter 3 of Title 7

51. In Article 65, in the first sentence, omit the words from “without prejudice” to the end of that sentence.

52. In Article 66(2), in the second sentence, for “competent authorities of the Member States” substitute “appropriate authorities”.