

SCHEDULE 1

Amendment of Titles 1 to 15

PART 10

Amendment of Title 10: Agency

Title 10

61. Omit Articles 75 and 76.

62.—(1) Article 77 is amended as follows.

(2) Before paragraph 1, insert—

“**A1.** When forming opinions the Agency must take relevant scientific knowledge and advice into account (including any relevant knowledge and advice relating to socio-economic matters).

A2. The Agency may take any such knowledge or advice into account when forming an opinion only if—

- (a) the knowledge or advice has been commissioned by the Agency, from one or more suitably qualified or experienced persons who are independent of the Agency, for the purposes of forming the opinion concerned, or
- (b) the knowledge or advice—
 - (i) is already in existence (whether within the Agency or externally),
 - (ii) is produced within the Agency for the purposes of forming the opinion concerned, or
 - (iii) is, in accordance with Article 2B, produced by the Environment Agency or one of the other environmental regulators in connection with the Agency forming the opinion concerned and then passed on to the Agency, and the Agency considers that it is appropriate to take it into account, rather than to commission knowledge or advice in compliance with point (a).

The knowledge or advice that the Agency may take into account in compliance with point (b) (i) includes knowledge or advice which has previously been commissioned by the Agency from one or more suitably qualified or experienced persons who are independent of the Agency for the purposes of forming a previous opinion on any matter.

A3. The Agency must comply with this paragraph if —

- (a) it is forming—
 - (i) an opinion in connection with deciding whether to grant an authorisation under Article 60,
 - (ii) an opinion under Article 70 as to whether suggested restrictions are appropriate in reducing the risk to human health or the environment, or
 - (iii) an opinion under Article 71 on suggested restrictions and on the related socio-economic impact, and
- (b) it only takes into account knowledge or advice that is not commissioned in compliance with paragraph A2(a) for the purposes of forming that opinion.

The Agency must—

- (a) produce an explanation of why it considered that it was appropriate to take only that knowledge or advice into account,
- (b) publish the explanation, and
- (c) send a copy of the explanation to the appropriate authorities.

A4. When exercising its functions, the Agency must act in a way that ensures a high degree of transparency.

A5. The Agency must produce and publish a statement of how it will comply with paragraphs A1, A2 and A4.

The Agency must produce and publish the first statement within the period of 3 months beginning with the day after exit day.

The Agency must consult such persons as it considers appropriate before producing the first, or any subsequent, statement.

A6. The statement must include—

- (a) information about the qualifications or relevant experience that are suitable in order for persons to be commissioned to provide knowledge or advice to the Agency,
- (b) examples of situations in which the Agency envisages that it might be appropriate to take existing knowledge or advice (rather than knowledge or advice commissioned as mentioned in paragraph A2(a)) into account.

A7. Paragraphs A1 to A6 do not limit the Agency’s duties under Article 2B.”.

(3) In paragraph 1, for “Member States and the institutions of the Community” substitute “appropriate authorities”.

(4) In paragraph 2—

- (a) in the words before point (a), for “The Secretariat” substitute “The Agency”;
- (b) omit points (a) to (d);
- (c) in point (e)—
 - (i) in the first sentence omit the words from “, the classification” to the end;
 - (ii) omit the final sentence.
- (d) omit point (h);
- (e) in point (i), omit “including Member State competent authorities”;
- (f) in point (l)—
 - (i) omit “Commission’s”;
 - (ii) after “request” insert “of any appropriate authority”;
 - (iii) for “between the Community, its Member States,” substitute “with”;
- (g) in point (m), omit “based on conclusions from the Member State Committee”.

(5) Omit paragraphs 3 and 4.

63. Omit Articles 78 to 82.

64.—(1) Article 83 is amended as follows.

(2) For the heading substitute “Annual report by the Agency to the appropriate authorities”.

(3) Omit paragraphs 1 and 2.

- (4) In paragraph 3—
- (a) in the words before point (a)—
 - (i) for “Executive Director” substitute “Agency”;
 - (ii) for “Management Board” substitute “Secretary of State”;
 - (b) in point (a)—
 - (i) for “received by the Agency and opined upon” substitute “prepared by the Agency”;
 - (ii) after “restricted;” insert “the Agency’s compliance with Article 77(A1) by taking into account scientific knowledge and advice (including knowledge and advice relating to socio-economic matters);”;
 - (iii) omit “; an overview of the activities of the Forum”.
 - (c) for the last two subparagraphs substitute—

“The Agency must provide any draft submitted to the Secretary of State under points (a) to (e) to the other appropriate authorities at the same time it is submitted to the Secretary of State.

The Secretary of State must consult the other appropriate authorities before giving approval to any draft submitted under points (a) to (e).”.

65. Omit Articles 84 to 87.

66.—(1) Article 88 is amended as follows.

(2) For paragraph 1 substitute—

“1. The details of the suitably qualified or experienced persons that provide advice to the Agency under Article 77(A2)(a) must be made public. Individuals may request that their names not be made public if they believe that such publication could place them at risk. The Agency must decide whether to agree to such requests. When details are published, the professional qualifications of each suitably qualified or experienced person must be specified.”.

(3) In paragraph 2, in the first sentence, for the words from “Members of the Management Board” to “the Forum” substitute “Suitably qualified or experienced persons that provide advice to the Agency pursuant to Article 77(A2)(a)”.

(4) Omit paragraph 3.

67. Omit Articles 89 and 90.

68.—(1) Article 91 is amended as follows.

(2) In paragraph 1, for “Article 30(2) and (3) and Article 51” substitute “Article 51 and Article 52”.

(3) After paragraph 1 insert—

“1A. An appeal pursuant to paragraph 1 lies to the First-tier Tribunal.”.

(4) After paragraph 2 insert—

“3. On an appeal pursuant to paragraph 1, the First-tier Tribunal—

- (a) may dismiss the appeal, or
- (b) if it allows the appeal may—
 - (i) quash the decision and (if appropriate) remit the matter to the Agency, or

(ii) substitute for the decision any other decision which could have been made by the Agency.”.

69.—(1) Article 92 is amended as follows.

- (2) In the heading, omit “, time-limits, fees and form”.
- (3) Omit paragraphs 2 and 3.

70.—(1) Article 93 is amended as follows.

- (2) For the heading substitute “Change of decision where appeal made”.
- (3) For paragraph 1 substitute—

“1. If—

- (a) an appeal against a decision is brought pursuant to Article 91, and
- (b) the Agency considers the appeal to be admissible and well founded,

the Agency may rectify the decision within the period of 30 days beginning with the day when the appeal is brought.”.

- (4) Omit paragraphs 2 to 4.

71. Omit Article 94.

72.—(1) Article 95 is amended as follows.

(2) In paragraph 1, for “bodies established under Community Law, including Community Agencies,” substitute “public bodies”;

(3) In paragraph 3—

- (a) omit “and the body concerned is a Community Agency or a scientific committee”;
- (b) for “Commission” substitute “appropriate authorities”.

73. Omit Articles 96 to 107.

74. In Article 108, for the words from “Management Board” to “and” substitute “Agency must develop appropriate contacts with”.

75. In Article 109, for the words from “Management Board” to “Commission,” substitute “Agency must”.

76.—(1) Article 110 is amended as follows.

(2) In the heading and in paragraph 1, for “Community” substitute “public”;

(3) In paragraph 2—

(a) in the first subparagraph—

(i) for the words from “Executive” to “Authority,” substitute “Agency, having consulted the Food Standards Agency(1) and Food Standards Scotland(2),”;

(ii) omit the last sentence;

(b) in the second subparagraph, for “European Food Safety Authority” substitute “Food Standards Agency and Food Standards Scotland”.

(1) The Food Standards Agency was established by section 1 of the Food Standards Act 1999 (c. 28).

(2) Food Standards Scotland was established by section 1 of the Food (Scotland) Act 2015 (asp 1).

(4) In paragraph 3, for “European Medicines Agency” substitute “Medicines and Healthcare products Regulatory Agency⁽³⁾”.

(5) Omit paragraph 4.

77. In Article 111, for “Member States, manufactures” substitute “Manufacturers”.

(3) The Medicines and Healthcare products Regulatory Agency was created on 1 April 2003 through the merger of the Medicines Control Agency and the Medical Devices Agency.