

SCHEDULE 1

Amendment of Titles 1 to 15

PART 7

Amendment of Title 7: Authorisation

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—

“**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—

Changes to legislation: There are currently no known outstanding effects for the The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 50. (See end of Document for details)

- (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 ”.

Commencement Information

- II** Sch. 1 para. 50 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see **reg. 1(1)**

Changes to legislation:

There are currently no known outstanding effects for the The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 50.