#### SCHEDULE 1

### Transitional provisions

#### PART 3

### Plant protection products

### Ongoing plant protection product authorisation applications where a member State is examining the application under Article 35 of Regulation (EC) No 1107/2009

- **9.**—(1) This paragraph applies in relation to an application for authorisation to place a plant protection product on the market in the United Kingdom or the amendment of such an authorisation where—
  - (a) before exit day—
    - (i) that application was made in accordance with Article 33 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day,
    - (ii) a member State or EEA state had agreed to examine that application in accordance with the first paragraph of Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, and
  - (b) immediately before exit day a decision to grant or refuse the application had not been made by a competent authority in accordance with Article 36(2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.
- (2) An application in relation to which this paragraph applies is taken to have been made in accordance with Article 33 of Regulation (EC) No 1107/2009—
  - (a) where the member State or EEA state described in sub-paragraph (1)(a)(ii) had made its assessment available to the United Kingdom before exit day in accordance with the third subparagraph of Article 36(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, on the date on which the application was made,
  - (b) otherwise, on exit day.
- (3) Where sub-paragraph (2)(a) applies to an application, anything done by the member State or EEA state in respect of the examination of application before exit day is taken to have been done by a competent authority.
- (4) In this paragraph, a reference to an Article of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in respect of an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.

# Requirement to provide existing maximum reside level applications in support of new plant protection product authorisation applications

- 10.—(1) Sub-paragraph (2) applies where—
  - (a) on or after exit day an application is made for authorisation of a plant protection product or amendment of such an authorisation in accordance with Article 33 of Regulation (EC) No 1107/2009, and
  - (b) before exit day a relevant application for a maximum residue level was made in accordance with Article 7 of Regulation (EC) No 396/2005 as it had effect immediately before exit day.
- (2) Where this sub-paragraph applies, the obligation in Article 33(3)(e) of Regulation (EC) No 1107/2009 to provide a copy of a relevant application for a maximum residue level in Article 7 of

Regulation (EC) No 396/2005 is to be read as including a copy of the application described in subparagraph (1)(b).

### Assessment of equivalence under Article 38(1) of Regulation (EC) No 1107/2009 where active substance last approved before exit day

- 11.—(1) Sub-paragraph (2) applies where—
  - (a) it is necessary to assess equivalence of an active substance in accordance with Article 38 of Regulation (EC) No 1107/2009, and
  - (b) the active substance was last approved before exit day in accordance with Regulation (EC) No 1107/2009 as it had effect immediately before exit day.
- (2) Where this sub-paragraph applies, the assessing competent authority for the purposes of Article 38 of Regulation (EC) No 1107/2009 is the Secretary of State, subject to sub-paragraphs (3) to (5).
- (3) The Secretary of State may appoint another competent authority as the assessing competent authority for the purposes of Article 38 of Regulation (EC) No 1107/2009.
- (4) The assessing competent authority must notify the applicant for the authorisation of the plant protection product to which the assessment of equivalence relates following an appointment under sub-paragraph (3).
- (5) An appointment in accordance with sub-paragraph (3) does not affect anything done by the Secretary of State as assessing competent authority prior to that appointment.

## Compliance checks or assessment of information under Article 43(3) of Regulation (EC) No 1107/2009 where product examined before exit day

- 12.—(1) Sub-paragraph (2) applies where—
  - (a) it is necessary to complete compliance checks of a plant protection product or assess information relating to the renewal of that product in accordance with Article 43(3) of Regulation (EC) No 1107/2009, and
  - (b) before exit day a member State or EEA state examined the application for that plant protection product in accordance with the first paragraph of Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.
- (2) Where this sub-paragraph applies, the competent authority which examined the application for the purposes of Article 43(3) of Regulation (EC) No 1107/2009 is taken to be the Secretary of State.
- (3) In sub-paragraph (1)(b), the reference to Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.

### Ongoing evaluations under Article 56(3) of Regulation (EC) No 1107/2009

- 13.—(1) Sub-paragraph (2) applies where—
  - (a) before exit day the holder of an authorisation of a plant protection product had notified a competent authority in accordance with Article 56(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day,
  - (b) in accordance with the first subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, a member State or EEA state was obliged to evaluate the information received, and

**Draft Legislation:** This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 No. 556

- (c) immediately before exit day that member State or EEA state had not informed the competent authority in accordance with the first or second subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.
- (2) Where this sub-paragraph applies, the first subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 applies in respect of that notification as if the reference to the competent authority which first granted the authorisation were a reference to the competent authority referred to in subparagraph (1)(a) of this paragraph.
- (3) In sub-paragraph (1)(b) and (c), the reference to Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.