

## SCHEDULE 1

### Transitional provisions and savings

## PART 4

### Ongoing MRL assessments

#### **Ongoing EFSA assessments under Article 12 of Regulation (EC) No 396/2005**

11.—(1) This paragraph applies where—

- (a) before exit day, the European Food Safety Authority is required to provide a reasoned opinion in respect of an active substance, in accordance with Article 12(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, and
- (b) immediately before exit day, either—
  - (i) such an opinion has not been provided in accordance with Article 12(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, or
  - (ii) such an opinion has been provided, but a regulation or decision made as a result of that reasoned opinion under Article 14(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day has not come into force.

(2) A competent authority may produce a reasoned opinion within a period of 36 months beginning with 1st April 2019 in respect of that active substance in relation to its constituent territory, except where sub-paragraph (3) applies.

(3) Where at the end of the 36 month period described in sub-paragraph (2) there are outstanding renewals of authorisations under Article 43 of Regulation (EC) No 1107/2009 relating to that active substance in relation to its constituent territory, a competent authority may instead produce a reasoned opinion before the end of the period of 6 months beginning with the date on which the last of those outstanding renewals is concluded.

(4) Articles 12(3) to (6) and 14 of Regulation (EC) No 396/2005 apply to a reasoned opinion under sub-paragraph (2) as they apply to a reasoned opinion under Article 12(1) of that Regulation.

(5) In providing a reasoned opinion under sub-paragraph (2), the competent authority may also consider relevant information provided by an interested person, including (but not limited to)—

- (a) the GAP;
- (b) evidence of an authorisation;
- (c) relevant assessments undertaken in other countries;
- (d) data required by regulations made under Article 8(4) of Regulation (EC) No 1107/2009, including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well as plant and animal metabolism data.

(6) In sub-paragraph (5), “interested person” includes manufacturers, growers, importers and producers of products listed in a list in Part 1 of the MRLs register in relation to the competent authority’s constituent territory.

(7) In this Article, “Regulation (EC) No 1107/2009” means Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.