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 and 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.