SCHEDULE 1 Regulation 28

Transitional provisions

PART 1

Interpretation

Interpretation

1. In this Schedule—

"Regulation (EU) No 844/2012" means Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market;

"plant protection product" has the meaning given by Article 2(1) of Regulation (EC) No 1107/2009.

PART 2

Active substances, basic substances, low-risk active substances and candidates for substitution

Existing approvals of active substances, etc.: general

2.—(1) An active substance, basic substance, low-risk active substance or candidate for substitution which is set out in an entry in a table in the Annex is deemed to have been approved by each competent authority in relation to its constituent territory under Article 13 of Regulation (EC) No 1107/2009 in accordance with sub-paragraphs 2(3) and 2(4).

(2) Sub-paragraph (1) does not apply to the following entries in the table in Part A of the Annex—

(a) entry 21 (Cyclanilide);

(b) entry 33 (Cinidon-ethyl);

(c) entry 43 (Ethoxysulfuron);

(d) entry 45 (Oxadiargyl);

(e) entry 49 (Cyfluthrin);

(f) entry 56 (Mecoprop);

(g) entry 72 (Molinate);

(h) entry 87 (Ioxynil);

(i) entry 94 (Imazosulfuron);

(j) entry 100 (Tepraloxydim);

(k) entry 113 (Maneb);

(l) entry 120 (Warfarin);

(m) entry 143 (Flusilazole);

(n) entry 144 (Carbendazim);

(o) entry 151 (Glufosinate);

(p) entry 157 (Fipronil);

(q) entry 159 (Spodoptera exigua nuclear polyhedrosis virus).

(3) An active substance, basic substance, low-risk active substance or candidate for substitution to which sub-paragraph (1) applies is deemed to have been approved—

(a) from the date of approval stated in the relevant entry in the Annex;

(b) until the existing expiration date, except—

(i) for a basic substance, or

(ii) as provided for in sub-paragraph (4);

(c) subject to the specific provisions stated in the relevant entry in the Annex as modified in accordance with paragraph 3.

(4) Where the existing expiration date for an approval is 31st March 2022 or earlier, approval is taken instead to expire at the end of a period of three years beginning with the existing expiration date.

(5) In this paragraph—

"the Annex" means the Annex to Commission Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances as it had effect immediately before exit day;

"existing expiration date" means the date for the expiration of approval stated in the relevant entry in the Annex.

Existing approvals: Annex modifications

3.—(1) For the purposes of paragraph 2(3)(c), the Annex is modified in accordance with this paragraph.

(2) In the Annex—

(a) a reference to Member States is to be read as a reference to competent authorities;

(b) a reference to Article 29(6) of Regulation (EC) No 1107/2009 is to be read as a reference to Article 29(6)(a) of that Regulation;

(c) a requirement on a notifier to submit, or on a member State to ensure that a notifier submits, further studies, data or information to the Commission, one or more member States or the Authority within a period of time which has expired before exit day is to be ignored;

(d) a requirement on member States to inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 is to be ignored;

(3) The entries in the table in Part A of the Annex are modified as follows—

(a) in entry 46 (Cyazofamid), in the seventh column, in the second paragraph, in the second sentence, the second indent is to be read as if "especially for Northern European regions" were omitted;

(b) in entry 173 (Difenoconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The notifier must submit to each competent authority the information set out in point (d) within 2 years from the issuing of specific guidance.";

(c) in entry 175 (Imazaquin), in the seventh column, Part B is to be read as if, for the third paragraph there were substituted—

"The notifier must submit to each competent authority the information set out in point (b) within 2 years from the issuing of specific guidance.";

(d) in entry 176 (Lenacil), in the seventh column, Part B is to be read as if, in the fourth paragraph, in the second sentence, for "the Commission" there were substituted "each competent authority";

(e) in entry 210 (Abamectin), in the seventh column, in Part B, the fourth paragraph is to be read as if for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(f) in entry 211 (Epoxiconazole), in the seventh column, Part B is to be read as if, for the third paragraph there were substituted—

"The notifier must submit to each competent authority further studies addressing the potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.";

(g) in entry 217 (Metazachlor), in the seventh column, Part B is to be read as if, in the fifth paragraph, for "the Commission" there were substituted "each competent authority";

(h) in entry 268 (Tebuconazole), in the seventh column, Part B is to be read as if for the second paragraph there were substituted—

"The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.";

(i) in entry 269 (Triadimenol), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of triadimenol within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.";

(j) in entry 282 (Chlorsulfuron), in the seventh column, Part B is to be read as if, in the fourth paragraph, for "the Commission" there were substituted "each competent authority";

(k) in entry 284 (Dimethachlor), in the seventh column, Part B is to be read as if, in the fifth paragraph, for "the Commission" there were substituted "each competent authority";

(l) in entry 289 (Triflusulfron), in the seventh column, Part B is to be read as if, in the third paragraph, for "the Commission" there were substituted "each competent authority";

(m) in entry 307 (Sulfuryl fluoride), in the seventh column, Part B is to be read as if, in the fourth paragraph—

(i) for "Commission, Member States and the Authority" there were substituted "each competent authority";

(ii) for "2017" there were substituted "2022";

(n) in entry 315 (Fenbuconazole), in the seventh column, Part B is to be read as if, for the sixth paragraph there were substituted—

"The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of febuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.";

(o) in entry 318 (Bromuconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of bromuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.";

(p) in entry 327 (Oryzalin), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (4) within six months of notification of a decision classifying oryzalin.";

(q) in entry 328 (Tau-fluvalinate), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority confirmatory information addressing the possible impact on the environment of the potential enantio-selective degradation in environmental matrices, within two years after the issuing of specific guidance.";

(r) in entry 335 (Fluometuron), in the seventh column, Part B is to be read as if—

(i) in the third paragraph, in the words before point (a), for "the Commission" there were substituted "each competent authority";

(ii) for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (d) within six months of notification of a decision classifying fluometuron.";

(s) in entry 337 (Carboxin), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (h) within six months of notification of a decision classifying carboxin.";

(t) in entry 338 (Cyproconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (e) within two years of the issuing of specific guidance.";

(u) in entry 344 (Diclofop), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (b) within two years of the issuing of a specific guidance document on evaluation of isomers mixtures.";

(v) in entry 348 (Paclobutrazol), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority—

(a) the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption, and

(b) the information set out in point (5) within two years after the issuing of specific guidance.";

(w) in entry 352 (Hexythiazox), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (d) within two years after the issuing of specific guidance.";

(x) in entry 354 (Flurochloridone), in the seventh column, Part B is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for "the Commission" there were substituted "each competent authority";

(ii) for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption.".

(4) The entries in the table in Part B of the Annex are modified as follows—

(a) in entry 7 (Sprioxamine), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (a) within two years after the issuing of specific guidance.";

(b) in entry 10 (Tefluthrin), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a specific guidance document on evaluation of isomers mixture.";

(c) in entry 16 (Terbuthylazine), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (4) within six months of the notification of the classification decision for terbuthylazine.";

(d) in entry 19 (Acrinathrin), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (4) within two years after the issuing of specific guidance.";

(e) in entry 20 (Prochloraz), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the adoption of the OECD test guidelines on endocrine disruption.";

(f) in entry 48 (Sedaxane), in the seventh column, Part B is to be read as if for the sixth paragraph there were substituted—

"The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for sedaxane.";

(g) in entry 49 (Emamectin), the seventh column is to be read as if for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the relevant information within two years after the issuing of a specific guidance document on evaluation of isomers mixtures.";

(h) in entry 51 (Fluopyram), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (2) within two years after the adoption of the OECD test guidelines on endocrine disruption.";

(i) in entry 55 (Penflufen), in the seventh column, Part B is to be read as if in the fourth paragraph for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(j) in entry 57 (Penthiopyrad), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for penthiopyrad.";

(k) in entry 60 (Spirotetramat), the seventh column is to be read as if in the fourth paragraph—

(i) for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for "Community agreed test guidelines" there were substituted "test guidelines set by the competent authority";

(l) in entry 67 (Spinetoram), the seventh column is to be read as if in the fifth paragraph, for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(m) in entry 69 (Amisulbrom), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (5) within two years after the adoption of OECD test guidelines on endocrine disruption.";

(n) in entry 73 (Ipconazole), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority—

(a) the information set out in point (c) of the fourth paragraph within two years after the issuing of a specific guidance document on evaluation of isomer mixtures, and

(b) the information set out in point (d) of the fourth paragraph within two years after the adoption of OECD or national test guidelines on endocrine disruption.";

(o) in entry 80 (Meptyldinocap), the seventh column is to be read as if , for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (b) within two years after the issuing of specific guidance.";

(p) in entry 91 (Flupyradifurone), the seventh column is to be read as if , for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(q) in entry 97 (Pinoxaden), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for pinoxaden.";

(r) in entry 99 (Cyantraniliprole), the seventh column is to be read as if for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water

within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(s) in entry 100 (Isofetamid), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(t) in entry 104 (Thifensulfuron-methyl), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (4) within six months of the notification of the classification decision for thifensulfuron-methyl.";

(u) in entry 105 (thiabendazole), the seventh column is to be read as if in the fourth paragraph for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(v) in entry 107 (Iodosulfuron), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (2) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(w) in entry 108 (Flazasulfuron) and entry 111 (Mesosulfuron), the seventh column is to be read as if for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(x) in entry 112 (Mesotrione), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(y) in entry 114 (Propoxycarbazone), the seventh column is to be read as if for the fourth paragraph there were substituted—

"The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(z) in entry 121 (Silthiofam), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point 1, for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) in the fifth paragraph—

(aa) for "Commission" there were substituted "competent authority";

(bb) for the words from "one year" to the end there were substituted "six months of the notification of the classification decision for Silithiofam";

(aa) in entry 123 (Zoxamide), the seventh column is to be read as if, in the fourth paragraph—

(i) for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for "Commission" in the second place it appears there were substituted "competent authority";

(bb) in entry 124 (Trifloxystrobin), the seventh column is to be read as if—

(i) for the fifth paragraph, there were substituted—

"The applicant must submit to each competent authority the information set out in point (1) within six months of the notification of the classification decision for trifloxystrobin.";

(ii) in the sixth paragraph, for "the Commission" there were substituted "each competent authority";

(cc) in entry 125 (Carfentrazone-ethyl), the seventh column is to be read as if—

(i) for the fifth paragraph, there were substituted—

"The applicant must submit to each competent authority the information set out in point (1) within six months of the notification of the classification decision for carfentrazone-ethyl.";

(ii) in the sixth paragraph, for "the Commission" there were substituted "each competent authority";

(dd) in entry 126 (Fenpicoxamid), the seventh column is to be read as if—

(i) in the fourth paragraph, in point 3, ", as amended by Commission Regulation (EU) 2018/605," were omitted;

(ii) in the fifth paragraph—

(aa) for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(bb) for "Commission" in the second place it occurs there were substituted "competent authority";

(ee) in entry 127 (Pethoxamid), in the seventh column, Part B is to be read as if—

(i) in the fourth paragraph, in the words before point 1, for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) in the fifth paragraph, for the words from "one year" to the end there were substituted "six months of the notification of the classification decision for pethoxamid";

(iii) in the sixth paragraph, for "Commission" there were substituted "competent authority";

(iv) in the seventh paragraph, the words from "in accordance with" to the end were omitted.

(5) The entries in the table in Part E of the Annex are modified as follows—

(a) in entry 4 (Benzovindiflupyr), the seventh column is to be read as if, for the fifth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(b) in entry 7 (Pendimethalin), the seventh column is to be read as if—

(i) in the fifth paragraph, in the words before point (1), for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for the sixth paragraph there were substituted—

"The applicant must submit to each competent authority the information set out in point (2) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.";

(c) in entry 9 (Propyzamide), the seventh column is to be read as if—

(i) in the fifth paragraph, in the words before point (1), for "the Commission, the Member States and the Authority" there were substituted "each competent authority";

(ii) for the sixth paragraph there were substituted—

"The applicant must submit to each competent authority—

(a) the information set out in point (2) by 30th April 2019;

(b) the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.".

(6) In this paragraph, "the Annex" has the meaning given in paragraph 2(5).

Existing approvals: supplementary

4.—(1) When implementing the uniform principles as referred to in Article 29(6)(a) of Regulation (EC) No 1107/2009 for a plant protection product which contains an active substance, basic substance, low-risk active substance or candidate for substitution to which paragraph 2(1) applies, the competent authority must take into account the conclusions of the review report on that substance or candidate, and in particular Appendices 1 and 2 of that report.

(2) Each competent authority must make available on request a free copy of a review report for an active substance, basic substance, low-risk active substance or candidate for substitution to which paragraph 2(1) applies.

(3) Sub-paragraph (2) does not apply—

(a) to any confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009;

(b) otherwise, from the earliest of the following—

(i) the date on which the approval of that substance or candidate is renewed;

(ii) the date on which the approval of that substance or candidate is withdrawn or expires.

Existing candidates for substitution under Commission Implementing Regulation (EU) 2015/408

5.—(1) An active substance which immediately before exit day is set out in the Annex to Commission Implementing Regulation (EU) 2015/408 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution is taken to have been approved by each competent authority in relation to its constituent territory under Article 13 of Regulation (EC) No 1107/2009 as a candidate for substitution.

(2) Sub-paragraph (1) does not apply for the purposes of applications for plant protection products—

(a) which were submitted before 4th April 2018, where the plant protection product contains 8-hydroxyquinoline;

(b) otherwise, which were submitted before 1st August 2015.

Ongoing active substance approval applications

6.—(1) This paragraph applies in relation to an application for approval of an active substance, or for amendment of the conditions of such an approval, where—

(a) before exit day, that application was submitted to the United Kingdom as rapporteur Member State under Article 7 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, and

(b) immediately before exit day, a Regulation adopted under Article 13(2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to that application has not entered into force.

(2) An application in relation to which this paragraph applies is taken as being made on the day on which it was made—

(a) where the application is for approval of an active substance, under Article 7(1) of Regulation (EC) No 1107/2009;

(b) where the application is for amendment of the conditions of approval of an active substance, under Article 7(1A) of Regulation (EC) No 1107/2009.

(3) The relevant competent authority is the assessing competent authority for an application to which this paragraph applies.

(4) Anything done before exit day in relation to an application to which this paragraph applies—

(a) by the rapporteur Member State;

(b) by the European Food Safety Authority under Article 10 or 12 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day;

is taken to have been done by the relevant competent authority as the assessing competent authority.

(5) In sub-paragraphs (3) and (4), the "relevant competent authority" is the Secretary of State, subject to sub-paragraphs (6) to (8).

(6) The Secretary of State may appoint another competent authority as the relevant competent authority for an application to which this paragraph applies with the agreement of that competent authority.

(7) The relevant competent authority must notify the applicant following an appointment under sub-paragraph (6).

(8) An appointment in accordance with sub-paragraph (6) does not affect anything done by the Secretary of State as assessing competent authority prior to appointment.

(9) In this paragraph—

"assessing competent authority" has the same meaning as in Subsection 2 of Section 1 of Chapter 2 of Regulation (EC) No 1107/2009;

"rapporteur Member State" has the meaning given by Article 3(22) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

Ongoing active substance renewal applications

7.—(1) This paragraph applies in relation to an application for renewal of the approval of an active substance where—

(a) before exit day, that application was submitted to the United Kingdom as rapporteur Member State or co-rapporteur Member State in accordance with Article 1 of Regulation (EU) No 844/2012 as it had effect immediately before exit day, and

(b) immediately before exit day a Regulation adopted under Article 20(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to that application has not entered into force.

(2) An application in relation to which this paragraph applies is taken as being made under Article 1 of Regulation (EU) No 844/2012 on the date on which it was made, and the relevant competent authority is the assessing competent authority for that application.

(3) Anything done before exit day in relation to an application to which this paragraph applies—

(a) by the rapporteur Member State or the United Kingdom as co-rapporteur Member State;

(b) by the European Food Safety Authority under Regulation (EU) No 844/2012 as it had effect immediately before exit day;

is taken to have been done by the relevant competent authority as the assessing competent authority.

(4) In sub-paragraphs (2) and (3), the "relevant competent authority" is the Secretary of State subject to sub-paragraphs (5) to (7).

(5) The Secretary of State may appoint another competent authority as the relevant competent authority for an application to which this paragraph applies.

(6) The relevant competent authority must notify the applicant following an appointment under sub-paragraph (5).

(7) An appointment in accordance with sub-paragraph (5) does not affect anything done by the Secretary of State as assessing competent authority prior to appointment.

(8) In this paragraph—

"assessing competent authority" has the meaning given by Article 15(1) of Regulation (EC) No 1107/2009;

"co-rapporteur Member State" means the co-rapporteur Member State for the active substance which is the subject of the application as set out in the third column in the Annex to Commission Implementing Regulation (EU) No 686/2012 as it had effect immediately before exit day;

"rapporteur Member State" means the rapporteur Member State for the active substance which is the subject of the application as set out in the second column in the Annex to Commission Implementing Regulation (EU) No 686/2012 as it had effect immediately before exit day.

Requirement to provide existing maximum residue level applications in support of new active substance approval or renewal applications

8.—(1) Sub-paragraph (2) applies where—

(a) on or after exit day an application is made—

(i) for approval of an active substance or the amendment of the conditions of such an approval in accordance with Article 7(1) or (1A) of Regulation (EC) No 1107/2009, or

(ii) for renewal of approval of an active substance in accordance with Article 15 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 8(1)(g) of Regulation (EC) No 1107/2009 or Article 7(1)(i) of Regulation (EU) No 844/2012 (as the case may be) 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 an obligation to provide a copy of the application described in sub-paragraph (1)(b).

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 sub-paragraph (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

(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 sub-paragraph (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.

PART 4

Treated seeds

Treated seeds

14.—(1) Article 49(1) of Regulation (EC) No 1107/2009 applies to seeds to which sub-paragraph (2) applies as it applies to seeds to which Article 49(1) applies.

(2) This sub-paragraph applies to—

(a) seeds treated before exit day with a plant protection product which at the time of treatment was authorised for that use in at least one member State or EEA state but not the United Kingdom;

(b) seeds treated on or after exit day with a plant protection product which immediately before exit day was authorised for that use in at least one member State or EEA state but not the United Kingdom.

(3) But sub-paragraph (2) does not apply to the extent that immediately before exit day the sale or use of such seeds was restricted or prohibited by measures adopted in the United Kingdom or by the European Commission in accordance with Regulation (EC) No 1107/2009 as it had effect immediately before exit day (as adapted by the EEA agreement as it had effect immediately before exit day).

(4) Sub-paragraphs (1) and (3) cease to have effect in respect of seeds to which sub-paragraph (2) applies in relation to a constituent territory on the earliest of the following dates—

(a) the date on which the plant protection product used to treat the seeds is no longer authorised for that use in at least one member State or EEA state;

(b) 1st April 2022.

(5) In this paragraph, "EEA state" does not include the Principality of Liechtenstein.

PART 5

Existing guidance

Existing guidance

15.—(1) Sub-paragraph (2) applies to a guidance document which relates to Regulation (EC) No 1107/2009 as it had effect immediately before exit day, where—

(a) before exit day, the guidance document was noted by the Committee, and

(b) immediately before exit day, that guidance document had not been withdrawn or replaced.

(2) A guidance document to which this sub-paragraph applies is taken to have been issued by each competent authority in relation to its constituent territory in accordance with Article 77(1) of Regulation (EC) No 1107/2009.

(3) Where the guidance document to which sub-paragraph (2) applies relates to scientific methods referred to in Article 4(2)(a) or (3)(b) or (e) of Regulation (EC) No 1107/2009, those methods are taken to have been accepted by each competent authority in accordance with Article 4(8).

(4) In sub-paragraph (1)(a), "the Committee" means the Standing Committee described in Article 79(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.