
DRAFT STATUTORY INSTRUMENTS

2019 No.

The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019

PART 2

Amendment of retained direct EU legislation

CHAPTER 1

Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Chapter 3

5.—(1) Chapter 3 is amended as follows.

(2) In Article 28—

(a) in paragraph 1—

(i) after “used” insert “in a constituent territory”;

(ii) for “in the Member State concerned” substitute “by the relevant competent authority”;

(b) in paragraph 2—

(i) in point (c)—

(aa) for “another Member State” substitute “the constituent territory of another competent authority”;

(bb) for the words from “in that Member State” to the end substitute “by that other competent authority for that constituent territory”;

(ii) in point (d)—

(aa) for “in a third country” substitute “outside the United Kingdom”;

(bb) for the words from “the Member State” to “inspection requirements” substitute “there are inspection requirements in place”;

(cc) for “its territory” substitute “the United Kingdom”;

(iii) in point (e), for “has been granted” substitute “is in force”.

(3) In Article 29—

(a) in paragraph 1—

(i) in the words before point (a), after “paragraph 6” insert “for the constituent territory of authorisation”;

(ii) in point (a), for “have been approved” substitute “are approved in the constituent territory of authorisation, and approval is not suspended in accordance with Article 69”;

- (iii) in point (b)(i), for the words from “included in” to “synergist” substitute “of that substance, safener or synergist as approved in the constituent territory of authorisation”;
- (iv) in point (c), for “in Annex III” substitute “on the unacceptable co-formulants register in relation to the constituent territory of authorisation”;
- (v) in point (g), for “all Member States” substitute “the United Kingdom”;
- (vi) in point (i), after “modified” insert “in relation to the constituent territory of authorisation”;
- (b) in paragraph 3, for “zone” substitute “areas of the United Kingdom”;
- (c) omit paragraphs 4 and 5;
- (d) in paragraph 6—
 - (i) for the first subparagraph substitute—
 - “(a) The appropriate authority may, by regulations, prescribe uniform principles for the evaluation and authorisation of plant protection products.”;
 - (ii) the existing second subparagraph becomes point (b).
- (4) Article 31 is amended in accordance with paragraphs (5) to (7).
- (5) In paragraph 2—
 - (a) in the first subparagraph, in the second sentence—
 - (i) for “Regulation approving” substitute “approval of”;
 - (ii) at the end, insert “in the constituent territory of authorisation”;
 - (b) in the second subparagraph—
 - (i) in the first sentence, for “[Directive 1999/45/EC](#)” substitute “[Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council”;
 - (ii) in the second sentence—
 - (aa) for “Member States” substitute “A competent authority”;
 - (bb) for “[Directive 1999/45/EC](#)” substitute “[Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council”.
- (6) In paragraph 4(a), for “Community provisions” substitute “retained EU law”.
- (7) After paragraph 4 insert—
 - “5. For the purposes of paragraph 4(c), Article 14 of [Directive 2009/128/EC](#) is to be read as if—
 - (a) obligations on Member States were obligations on the competent authorities;
 - (b) paragraph 3 were omitted.”.
- (8) In Article 32(1), in the second subparagraph—
 - (a) after “approval” insert “in the constituent territory of authorisation”;
 - (b) at the end, insert “in the constituent territory of authorisation”.
- (9) In Article 33—
 - (a) for paragraph 1, substitute—
 - “1. An applicant or a representative of the applicant may apply to the competent authority for authorisation to place a plant protection product on the market in a constituent territory.

- 1A.** An applicant or a representative of the applicant may apply to the competent authority which granted an authorisation to amend that authorisation.”;
- (b) in paragraph 2—
- (i) in point (a), for the words from “in each zone” to “Member States where” substitute “and the competent authorities to whom”;
 - (ii) omit point (b);
 - (iii) in point (c), for “in a Member State” substitute “by a competent authority”;
 - (iv) in point (d), for “Member State” substitute “competent authority”;
- (c) in paragraph 4, in the third subparagraph—
- (i) for “Member State” substitute “competent authority”;
 - (ii) after “application” insert “(see Article 35)”;
- (d) in paragraph 5—
- “**5.** Where permitted by the competent authority, the applicant may submit an application in a language other than English.”;
- (e) in paragraph 6, for “Member State” substitute “competent authority”.
- (10) In Article 34—
- (a) in paragraph 1—
- (i) for the words from “Member state” to “application is made” substitute “competent authority examining the application”;
 - (ii) at the end insert “, or where paragraph 3 applies”;
- (b) in paragraph 2—
- (i) in point (a), after “declaration that” insert “, in respect of each constituent territory to which the application relates,”;
 - (ii) in point (b), after “approved” insert “in respect of each constituent territory to which the application relates”;
 - (iii) in point (c), for “concerned Member State” substitute “competent authority examining the application”;
- (c) after paragraph 2 insert—
- “**3.** This paragraph applies where another competent authority has the test and study reports concerned.
- 4.** Where paragraph 3 applies—
- (a) the competent authority examining the application must request those reports from the competent authority which has those reports, and
 - (b) the competent authority which has those reports must send them to the competent authority examining the application as soon as reasonably practicable.”.

(11) For Article 35 substitute—

“Article 35

Competent authority examining the application

- 1.** For the purposes of this Subsection “the competent authority examining the application” is the competent authority which receives the application under Article 33.

2. But a competent authority may examine an application on behalf of one or more of the other competent authorities (and consequently for the purposes of this Subsection is “the competent authority examining the application”) where—
- (a) each competent authority receives the same application;
 - (b) each competent authority agrees which competent authority is to examine the application;
 - (c) each active substance, safener or synergist in the plant protection product to which the application relates—
 - (i) is approved in relation to the constituent territory of each competent authority, and the conditions of each approval are compatible with the proposed authorisation, and
 - (ii) has an equivalent technical specification in relation to each constituent territory, where necessary as determined in accordance with Article 38;
 - (d) any co-formulant in the plant protection product to which the application relates is not included on the unacceptable co-formulants register in relation to the constituent territory of each competent authority; and
 - (e) any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) and any guidance relating to those requirements or principles are the same in relation to the constituent territory of each competent authority.
3. Where paragraph 2 applies in relation to an application—
- (a) the competent authority examining the application must inform the applicant that it is to examine the application;
 - (b) the other competent authorities must —
 - (i) not proceed to determine the application pending assessment by the competent authority examining the application;
 - (ii) at the request of the competent authority examining the application, cooperate to ensure a fair division of the workload.”.
- (12) In Article 36—
- (a) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) in the first sentence, for “Member State” substitute “competent authority”;
 - (bb) in the second sentence, for “It shall give all Member States in the same zone” substitute “Where Article 35(2) applies in relation to an application, the competent authority examining the application must give the other competent authorities”;
 - (ii) in the second subparagraph—
 - (aa) for “Article 29(6)” substitute “Article 29(6)(a)”;
 - (bb) omit “in the same zone”;
 - (iii) for third subparagraph substitute—

“Where Article 35(2) applies in relation to an application, the competent authority examining the application must make available its assessment to the other competent authorities.”;
 - (b) in paragraph 2—

- (i) for “The Member States concerned” substitute “Where Article 35(2) applies in relation to an application, the competent authorities which received that application”;
 - (ii) for “Member State” substitute “competent authority”;
- (c) in paragraph 3—
 - (i) in the first subparagraph, for “Community” substitute “retained EU”;
 - (ii) in the second subparagraph—
 - (aa) for “Member State” in the first place it occurs substitute “competent authority”;
 - (bb) omit “national”;
 - (cc) for “a Member State” in the second place it occurs substitute “that competent authority”;
 - (dd) after “its” insert “constituent”;
 - (iii) in the third subparagraph—
 - (aa) for “Member State” substitute “competent authority”;
 - (bb) for “Commission” substitute “other competent authorities”;
 - (iv) omit the fourth subparagraph.
- (13) In Article 37—
 - (a) in paragraphs 1 and 3, for “Member State” in each place it occurs substitute “competent authority”;
 - (b) in paragraph 3, in the first sentence, for the words from “it has received” to the end substitute “the draft assessment report for that active substance is circulated in accordance with Article 12(1)(a)”;
 - (c) after paragraph 3 insert—

“**3A.** Where Article 35(2) applies in relation to an application, the requirement in paragraph 3 to decide on the application within 6 months of the active substance being approved is to be read as a requirement to decide on the application within 6 months of the earliest date on which the active substance is approved by one of the competent authorities which received the application for authorisation.”;
 - (d) in paragraph 4—
 - (i) for “The Member States concerned” substitute “Where Article 35(2) applies in relation to an application, the competent authorities which received the application for authorisation”;
 - (ii) for “Member State” substitute “competent authority”.
- (14) For Article 38 substitute—

“Article 38

Assessment of equivalence under Article 29(1)(b)

1. This Article applies where it is necessary in relation to an application to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process or location complies with Article 29(1)(b).

1A. Where this Article applies, equivalence—

- (a) may be assessed by a competent authority examining the application, where—

- (i) each of the other competent authorities examining the application consents to that competent authority assessing equivalence, and
 - (ii) in relation to the active substance, safener or synergist for which equivalence is to be assessed, any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6) (a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority examining the application;
- (b) otherwise, must be assessed by each competent authority examining the application.

1B. The applicant must submit all necessary data to each competent authority assessing equivalence.

2. A competent authority assessing equivalence must—

- (a) give the applicant the opportunity to submit comments,
- (b) prepare a report on the competent authority’s conclusion on equivalence within 60 days from receiving the application, and
- (c) provide a copy of that report to—
 - (i) the applicant, and
 - (ii) where the assessment is undertaken in accordance with paragraph 1A(a), the other competent authorities examining the application.

3. Where an assessment is undertaken in accordance with paragraph 1A(a), a competent authority examining the application which does not agree with the conclusion in the report provided in accordance with paragraph 2(c)(ii) must notify the competent authority which assessed equivalence, the other competent authorities examining the application and the applicant, stating its reasons for not agreeing.

3A. Following a notification under paragraph 3, the competent authorities concerned must—

- (a) give the applicant the opportunity to submit comments, and
- (b) try to reach agreement on whether Article 29(1)(b) is complied with.

4. Article 29(1)(b) is deemed not to be complied with where the competent authorities concerned under paragraph 3A do not reach agreement within 45 days of the latest date on which a notification from a competent authority is communicated in accordance with paragraph 3.”

(15) In Article 39—

- (a) in paragraph 1—
 - (i) in the words before point (a)—
 - (aa) for “Member States” substitute “A competent authority”;
 - (bb) after “application” insert “it receives”;
 - (ii) in point (b), omit the words from “the format” to “Article 79(2).”;
 - (iii) in point (c), for “Member State” substitute “competent authority”;
- (b) in paragraph 2—
 - (i) for “Member States” in the first place it occurs substitute “a competent authority”;
 - (ii) for “Member States, the Commission and the Authority” substitute “competent authorities”;

- (c) in paragraph 3, for “Member States, the Commission and the Authority” substitute “the competent authorities”;
 - (d) omit paragraph 4.
- (16) In Subsection 3—
- (a) in the heading, at the beginning insert “Ongoing applications for”;
 - (b) omit Article 40;
 - (c) before Article 41 insert—

“Article 40A

Application and interpretation

1. This Subsection applies where—
 - (a) before exit day the holder of an authorisation of a plant protection product granted by a member State or EEA state in accordance with Article 29 as it had effect immediately before exit day had applied for—
 - (i) authorisation of the same product in the United Kingdom in accordance with Article 40 as it had effect immediately before exit day, or
 - (ii) authorisation of the same product for minor uses in accordance with Articles 40 and 51(7) as those Articles had effect immediately before exit day, and
 - (b) immediately before exit day that application had not been determined.
 2. In this Subsection—
 - (a) a reference to an Article as it had effect immediately before exit day in relation to an EEA state is a reference to that Article as adapted by the EEA Agreement as it had effect immediately before exit day;
 - (b) “reference state” means the member State or EEA state referred to in paragraph 1(a).”;
- (d) in Article 41—
- (i) in paragraph 1—
 - (aa) for “Member State” in the first place it occurs substitute “competent authority”;
 - (bb) after “Article 40” insert “as it had effect immediately before exit day”;
 - (cc) for “Member State examining the application” substitute “reference state”;
 - (ii) after paragraph 1 insert—

“1A. But where the application was for authorisation of minor uses in accordance with Article 51(7) as it had effect immediately before exit day, the competent authority must authorise such uses, except where—

 - (a) Article 36(3) applies, or
 - (b) the competent authority considers that those uses are not minor.”;
 - (iii) in paragraph 2—
 - (aa) in the words before point (a), for “paragraph 1, the Member State” substitute “paragraphs 1 and 1A, the competent authority”;
 - (bb) in point (a), after “Article 40(1)” insert “as it had effect immediately before exit day”;

- (cc) in point (b), at the end insert “or”;
 - (dd) omit point (c).
- (17) Article 42 is amended in accordance with paragraphs (18) to (20).
- (18) In paragraph 1—
- (a) in point (a)—
 - (i) for “Member State” in the first place it occurs substitute “state”;
 - (ii) for the words from “an official language” to the end substitute “English or another language permitted by the competent authority”;
 - (b) in point (b), for “Member State” substitute “state”;
 - (c) in point (c), for “when requested by the Member State” substitute “as it had effect immediately before exit day, when requested by the competent authority”;
 - (d) in point (d), for “Member State” substitute “state”.
- (19) In paragraph 2—
- (a) for “Member State” substitute “competent authority”;
 - (b) for “an application under Article 40” substitute “the application”.
- (20) For paragraph 3 substitute—
- “3. Where permitted by the competent authority, the applicant may submit an application in a language other than English.”.
- (21) After Subsection 3 insert—

“Subsection 3A

Mutual recognition of authorisations within the UK

Article 42A

Mutual recognition

1. This Subsection applies where a plant protection product has been authorised by a competent authority in accordance with Article 29 (the “reference competent authority”).
2. The following persons may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices within the constituent territory of another competent authority—
 - (a) the holder of the authorisation granted by the reference competent authority;
 - (b) an official or scientific body involved in agricultural activities or a professional agricultural organisation—
 - (i) with the consent of the authorisation holder, or
 - (ii) where consent is refused, with the consent of the competent authority to which the application is made on the grounds of public interest.
3. An applicant under paragraph 2(b) must demonstrate that the use of such a plant protection product is of general interest within the constituent territory of the competent authority.
4. An application may not be made under paragraph 2 where—
 - (a) the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is not approved in relation to the constituent territory of the other competent authority;

- (b) the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is approved in relation to the constituent territory of the other competent authority, but—
 - (i) the conditions of that approval are incompatible with the product to which the application relates, or
 - (ii) the technical specification relating to that approval is not equivalent to the technical specification of the approval of the same substance, safener, synergist or candidate in relation to the constituent territory of the reference competent authority, where necessary as determined in accordance with Article 38;
- (b) the plant protection product contains a co-formulant which is entered on the unacceptable co-formulants register in relation to the constituent territory of the other competent authority; or
- (c) the relevant data requirements specified in regulations made under Article 8(4)(a) and (b), the relevant uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) or any guidance issued under Article 77 relating to those requirements or principles are not the same in relation to the constituent territory of each competent authority.

Article 42B

Authorisation

1. The competent authority to which an application under Article 42A(2) is submitted, having examined the application and the accompanying documents referred to in Article 42C(1), and as appropriate with regards to the circumstances in its constituent territory, must authorise the plant protection product concerned under the same conditions as the reference competent authority, except in accordance with paragraph 2 or 3.
2. The competent authority may authorise the plant protection product where it contains a candidate for substitution or a substance approved in accordance with Article 4(7).
3. Paragraphs 1 and 2 do not apply where Article 36(3) applies.

Article 42C

Procedure

1. An application under Article 42A must be accompanied by the following—
 - (a) a copy of the authorisation granted by the reference competent authority;
 - (b) a formal statement that the plant protection product is identical to that authorised by the reference competent authority;
 - (c) a complete or summary dossier as required in Article 33(3) when requested by the competent authority;
 - (d) an assessment report of the reference competent authority containing information on the evaluation and decision on the plant protection product.
 2. The competent authority to which an application under Article 42A is submitted must decide on the application within 120 days.”
- (22) In Article 43—
- (a) in paragraph 2—
 - (i) in the words before point (a)—

- (aa) after “approval” insert “in relation to a constituent territory”;
- (bb) after “product” insert “authorised in that constituent territory”;
- (cc) after “information” insert “to the competent authority for that constituent territory”;
- (ii) in point (d), for “out in the Regulation” substitute “by the competent authority”;
- (b) in paragraph 3—
 - (i) the existing first subparagraph becomes point (a);
 - (ii) in that point (a)—
 - (aa) for “Member States” substitute “The competent authority examining the application”;
 - (bb) for the words from “in the Regulation” to the end substitute “on renewal of the approval of the active substance, safener or synergist”;
 - (iii) for the second subparagraph substitute—
 - “(b) The competent authority which examined the plant protection product application in accordance with Article 35(2) may coordinate the compliance check and assessment of the information submitted for all competent authorities which receive an application for renewal of authorisation for the same product, provided that the conditions in Article 35(2) apply in relation to the renewal application.”;
- (c) omit paragraph 4;
- (d) in paragraph 5, for “Member States” substitute “The competent authority examining the application”;
- (e) in paragraph 6, for “Member State in question” substitute “competent authority examining the application”.
- (23) In Article 44—
 - (a) in paragraph 1—
 - (i) in the first subparagraph, for “Member States” substitute “A competent authority”;
 - (ii) in the second subparagraph—
 - (aa) for “Member State” substitute “competent authority”;
 - (bb) for “objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of [Directive 2000/60/EC](#)” substitute “environmental objectives of a river basin district”;
 - (b) in paragraphs 2 and 3, for “Member State” substitute “competent authority”;
 - (c) in paragraph 4—
 - (i) in the first sentence—
 - (aa) for “Member State” substitute “competent authority”;
 - (bb) for “, the other Member States, the Commission and the Authority” substitute “and the other competent authorities”;
 - (ii) in the second sentence—
 - (aa) for “Member States belonging to the same zone shall” substitute “competent authorities may”;
 - (bb) for “national conditions” substitute “conditions in its constituent territory”;
 - (cc) for “, third or fourth” substitute “or third”;

(d) after paragraph 4 insert—

“5. In paragraph 1, “environmental objectives”—

- (a) in relation to the Northumbria River Basin District, means the objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003(1);
- (b) in relation to the Solway Tweed River Basin District, means the objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004(2);
- (c) in relation to any other river basin district, within the meaning of the WFD Regulations, has the same meaning as in those regulations;
- (d) in relation to a river basin district in Scotland, means the objectives set under section 9(1)(a)(i) of the Water Environment and Water Services (Scotland) Act 2003(3);
- (e) in relation to a river basin district in Northern Ireland, means the objectives set under regulation 12, in accordance with regulation 13, of the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017(4).

6. In paragraph 4, the “conditions” in the constituent territory of a competent authority include—

- (a) any data requirements specified in regulations made under Article 8(4)(a) or (b) in relation to that constituent territory;
- (b) any uniform principles prescribed by regulations made under Article 29(6)(a) in relation to that constituent territory;
- (c) any guidance issued under Article 77 in relation to that constituent territory.

7. In this Article—

- (a) “river basin district” means any of the following—
 - (i) the Northumbria River Basin District;
 - (ii) the Solway Tweed River Basin District;
 - (iii) a river basin district within the meaning of the WFD Regulations;
 - (iv) in relation to Scotland, an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;
 - (v) in relation to Northern Ireland, a river basin district within the meaning of the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017;
- (b) “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017(5).”.

(24) For Article 46 substitute—

(1) S.I. 2003/3245, amended by S.I. 2016/139 and 2017/407.
(2) S.I. 2004/99, amended by S.I. 2016/139; there are other amending instruments but none is relevant.
(3) 2003 asp 3. Section 9(1) was amended by section 54(1) and (4)(a)(i) of the Aquaculture and Fisheries (Scotland) Act 2013 (asp 7).
(4) S.R. 2017 No.81.
(5) S.I. 2017/407.

“Article 46

Grace period

1. A competent authority may grant a grace period for the disposal, storage, placing on the market and use of existing stocks of a plant protection product in its constituent territory where—

- (a) the authority withdraws, amends or does not renew authorisation for the plant protection product, and
- (b) the reasons for withdrawal, amendment or non-renewal are not related to the protection of human and animal health or the environment.

2. The grace period—

- (a) for the sale and distribution of the existing stocks must not exceed six months;
- (b) for the disposal, storage, and use of the existing stocks must be consecutive to the period described in point (a) and must not exceed one year.”.

(25) In Article 47

- (a) in paragraph 1(a), at the end insert “in relation to the constituent territory of application”;
- (b) in paragraph (3)—
 - (i) in the first subparagraph, for “The Member State” substitute “A competent authority”;
 - (ii) in the second and third subparagraphs, for “Member State” in both places it occurs substitute “competent authority”.

(26) In Article 48—

- (a) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) for “an organism falling within the scope of [Directive 2001/18/EC](#)(6)” substitute “a genetically modified organism”;
 - (bb) for “that Directive” substitute “the examination legislation”;
 - (ii) in the second subparagraph, for “, as referred to in Article 19 of [Directive 2001/18/EC](#),” substitute “to market the genetically modified organism under section 111(1) of the Environmental Protection Act 1990(7) or Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(8)”;
- (b) after paragraph 2 insert—
 - “3. In paragraph 1, “the examination legislation” means—
 - (a) in relation to England, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002(9);
 - (b) in relation to Wales, regulation 24(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(10);
 - (c) in relation to Scotland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(11);

(6) OJ No L 106, 17.4.2001, p 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p 30).

(7) [1990 c.43](#).

(8) [S.I. 1991/1714 \(N.I. 19\)](#), to which there are amendments not relevant to these Regulations.

(9) [S.I. 2002/2443](#), to which there are amendments not relevant to these Regulations.

(10) [S.I. 2002/3188 \(W 304\)](#), to which there are amendments not relevant to these Regulations.

(11) [SSI 2002/541](#), to which there are amendments not relevant to these Regulations.

- (d) in relation to Northern Ireland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(12).”.
- (27) In Article 49—
- (a) in paragraph 1—
- (i) for “Member States” substitute “A competent authority”;
- (ii) for “in at least one Member State” substitute “by at least one competent authority”;
- (b) for paragraph 2 substitute—
- “2. The appropriate authority may, by regulations, implement measures to restrict or prohibit the use or sale of treated seeds as referred to in paragraph 1 where the appropriate authority has substantial concerns that—
- (a) the treated seeds are likely to constitute a serious risk to human or animal health or to the environment, and
- (b) such risk cannot be contained satisfactorily by measures taken by the competent authorities concerned.
- 2A. Before making regulations in accordance with paragraph 2, the appropriate authority may obtain independent scientific advice where the appropriate authority considers it appropriate to do so.”;
- (c) omit paragraph 3;
- (d) in paragraph 4—
- (i) for “Community legislation” substitute “retained EU law”;
- (ii) for “[Directive 1999/45/EC](#)” substitute “[Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council”.
- (28) In Article 50—
- (a) in paragraph 1, in the words before point (a)—
- (i) in the first sentence—
- (aa) for “Member States” substitute “a competent authority”;
- (bb) at the end insert “in relation to its constituent territory”;
- (ii) in the second sentence, for “Member States” substitute “A competent authority”;
- (b) in paragraph 2—
- (i) for “Member States” substitute “a competent authority”;
- (ii) for “that Member State” substitute “the United Kingdom”;
- (c) in paragraph 4—
- (i) in the first subparagraph, for “Member States” substitute “a competent authority”;
- (ii) in the second subparagraph, for “Member States” substitute “the competent authority”;
- (d) in paragraph 5—
- (i) for “Member State” in both places it occurs substitute “competent authority”;
- (ii) after “substitution” insert “in relation to its constituent territory”.
- (29) In Article 51—
- (a) in paragraph 1, for “in the Member State concerned” substitute “by a competent authority”;

(12) [S.R. 2003 No. 167](#), to which there are amendments not relevant to these Regulations.

- (b) in paragraph 2, for “Member States” substitute “The competent authority”;
 - (c) in paragraph 3, for “Member States” substitute “A competent authority”;
 - (d) in paragraph 4, omit the words from “, in accordance with” to the end;
 - (e) in paragraph 5—
 - (i) in the first subparagraph—
 - (aa) for “Member States grant” substitute “the competent authority grants”;
 - (bb) for “they” substitute “the competent authority”;
 - (ii) in the second subparagraph, for “Member States” substitute “competent authority”;
 - (f) in paragraph 7—
 - (i) in the first sentence, for the words from “Article 40(1)” to the end substitute “Article 42A, except where one or more of the conditions in Article 42A(4) are met”;
 - (ii) in the second sentence—
 - (aa) for “Member States” in the first place it occurs substitute “The competent authority which receives such an application”;
 - (bb) for “Article 41” substitute “Article 42B”;
 - (cc) for “in the Member States of application” substitute “by that competent authority”;
 - (g) in paragraph 8, for “Member States” substitute “Each competent authority”.
- (30) In Article 52—
- (a) omit paragraphs 1 to 4;
 - (b) before paragraph 5 insert—

“**4A.** This Article applies to a parallel trade permit issued before exit day by the United Kingdom as the Member State of introduction in accordance with this Article as it had effect immediately before exit day, where immediately before exit day the validity of that permit had not expired.”;
 - (c) in paragraph 5, in the second sentence—
 - (i) for “the Commission shall” substitute “the appropriate authority may”;
 - (ii) for “a Regulation” substitute “regulations”;
 - (iii) for “Article 68” substitute “Article 68(3)”;
 - (d) for paragraph 6 substitute—

“**6.** The parallel trade permit is valid in relation to a constituent territory until the earlier of—

 - (a) the date on which the authorisation of the reference product expires in relation to that constituent territory;
 - (b) 31st March 2021.

6A. Paragraph 6B applies to a parallel trade permit where—

 - (a) the authorisation holder of the reference product for that permit applies for a withdrawal of authorisation in accordance with Article 45(1), and
 - (b) the requirements of Article 29 are still fulfilled in respect of the product to which that permit relates.

6B. Where this paragraph applies, the date of expiry of the reference product for the purposes of paragraph 6(a) is deemed to be the date on which the authorisation of the

reference product would have expired if the application under Article 45(1) had not been made.

6C. In paragraphs 4 to 6B, “reference product” means the plant protection product which was already authorised in the United Kingdom prior to the application for the parallel trade permit under paragraph 1 of this Article as it had effect immediately before exit day, and to which the product to which that permit relates is identical in composition.”;

(e) after paragraph 8, insert—

“8A. In paragraph 8, “Member State of origin” means the member State or EEA state which was the Member State of origin in accordance with paragraph 1 of this Article as it had effect immediately before exit day, as adapted by the EEA agreement as it had effect immediately before exit day.”;

(f) omit paragraphs 9 and 10;

(g) in paragraph 11, for “Member State” substitute “competent”.

(31) In Article 53—

(a) in paragraph 1—

(i) in the first subparagraph—

(aa) for “Member State” substitute “competent authority”;

(bb) after “controlled use” insert “in its constituent territory”;

(ii) in the second subparagraph—

(aa) for “Member State” substitute “competent authority”;

(bb) for “Member States and the Commission” substitute “other competent authorities”;

(b) omit paragraphs 2 and 3;

(c) in paragraph 4—

(i) for “Paragraphs 1 to 3” substitute “Paragraph 1”;

(ii) for “[Directive 2001/18/EC](#)” substitute “section 111(1) of the Environmental Protection Act 1990 or article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991”.

(32) In Article 54—

(a) in paragraphs 1 and 2—

(i) for “Member State” in each place it occurs substitute “competent authority”;

(ii) after “in whose” insert “constituent”;

(b) in paragraph 1, in the first subparagraph, at the end insert “in relation to that constituent territory”;

(c) in paragraph 3, for “[Directive 2001/18/EC](#)” substitute “section 111(1) of the Environmental Protection Act 1990 or article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991”;

(d) in paragraph 4, for “Member State” substitute “competent authority”;

(e) omit paragraph 5.

(33) In Article 55—

(a) the existing first and second paragraphs become paragraphs 1 and 2;

(b) in that paragraph 2, omit the words from “, which shall apply” to the end;

(c) after that paragraph 2 insert—

“3. For the purposes of this Article, Article 14 of [Directive 2009/128/EC](#) is to be read as if—

- (a) obligations on Member States were obligations on the competent authorities;
- (b) paragraph 3 were omitted.”.

(34) In Article 56—

- (a) in paragraph 1—
 - (i) in the first subparagraph, for “the Member States” substitute “each competent authority”;
 - (ii) in the fourth subparagraph, for “third” substitute “other”;
- (b) in paragraph 3—
 - (i) in the first subparagraph—
 - (aa) for “Member States” in the first place it occurs substitute “competent authorities”;
 - (bb) for “the Member State” substitute “where paragraph 3A applies, the competent authority”;
 - (cc) omit “within each zone”;
 - (dd) for “Member States, belonging to the same zone” substitute “competent authorities which granted authorisation for the plant protection product”;
 - (ii) in the second subparagraph—
 - (aa) for “Member State” substitute “competent authority”;
 - (bb) for “Member States and the Commission” substitute “competent authorities”;
- (c) after paragraph 3 insert—

“3A. This paragraph applies where—

 - (a) each competent authority which granted authorisation agrees which competent authority is to evaluate the information;
 - (b) each active substance, safener or synergist in the plant protection product to which the information relates has the same conditions of approval in relation to the constituent territory of each competent authority concerned;
 - (c) any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed by regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority concerned.”;
- (d) in paragraph 4, omit “of the Member States”.

(35) In Article 57—

- (a) in paragraph 1—
 - (i) in the words before point (a), for “Member States” substitute “A competent authority”;
 - (ii) in point (e), for the words from “to [Directive 1999/45/EC](#)” to the end substitute “with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and any regulations made under Article 65(1A)”;

(b) omit paragraph 3.