

D R A F T S T A T U T O R Y I N S T R U M E N T S

2023 No. XXXX

RETAINED EU LAW REFORM

PESTICIDES

**The Plant Protection Products (Miscellaneous Amendments)
Regulations 2023**

Made - - - -

Coming into force - - *31st December 2023*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 14(2), (4)(b) and (c) and (7) and 20(1)(a) and (b) of the Retained EU Law (Revocation and Reform) Act 2023 (“the 2023 Act”)(a).

The Secretary of State is a relevant national authority for the purposes of section 14(2) of the 2023 Act(b).

In accordance with paragraph 5(1) of Schedule 5 to the 2023 Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Plant Protection Products (Miscellaneous Amendments) Regulations 2023.

(2) These Regulations come into force on 31st December 2023.

(3) These Regulations extend to the United Kingdom, subject to paragraph (4).

(4) Any amendment or saving of a provision in an enactment has the same extent as the provision amended or saved.

Amendment of the Plant Protection Products Regulations 2011

2.—(1) The Plant Protection Products Regulations 2011(c) are amended as follows.

(a) 2023 c. 28.

(b) The term “relevant national authority” is defined in section 21(1) of the Retained EU Law (Revocation and Reform) Act 2023.

(c) S.I. 2011/2131. Regulation 20 was amended by S.I. 2019/306 (as amended by S.I. 2020/1376). There are other amending instruments but none is relevant.

(2) In regulation 11(1) (parallel trade permits and permits for trial purposes), for “Article 52(5)” substitute “Article 52A(8)”.

(3) In regulation 20(2)(e) (provision of information), after “Article” insert “52A(2) or”.

Amendment of the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019

3.—(1) Part 4 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019(a) (treated seeds) is amended as follows.

(2) For paragraph 14(4)(b) substitute—

“(b) 1st July 2027.”.

Amendment of Regulation (EC) No 1107/2009

4.—(1) Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market(b) is amended as follows.

(2) In Article 28(2)(e) (authorisation for placing on the market and use), for “Article 52” substitute “Article 52A and, for these purposes, a plant protection product subject to a grace period granted in accordance with Article 46 (as applied by Article 52A) is to be treated as though it were a product for which a parallel trade permit is in force”.

(3) Omit Article 52 (parallel trade).

(4) After Article 52 insert—

“Article 52A

Parallel trade

1. This Article applies in respect of a parallel trade permit which—

- (a) immediately before IP completion day was a permit of a description referred to in Article 52(4A), and
- (b) by virtue of Article 52(6)(b), ceased to be valid on 1st January 2023 (an “original parallel trade permit”).

2. The person to which an original parallel trade permit was issued may submit an application to the competent authority for the reinstatement of that permit as it had effect in relation to a constituent territory immediately before it ceased to be valid.

3. An application for the reinstatement of the original parallel trade permit must be made no later than 1st April 2024.

4. The application must be accompanied by—

- (a) a duplicate of the information that was submitted in connection with—
 - (i) the initial application for the original parallel trade permit, and
 - (ii) any subsequent application to amend that permit before it ceased to be valid;
- (b) where applicable, notification of any changes to the contact details supplied in connection with applications concerning the original parallel trade permit;
- (c) as regards the plant protection product authorised in the Member State of origin at the time of application for the original parallel trade permit—

(a) S.I. 2019/556. Part 4 of Schedule 1 to S.I. 2019/556 was amended by S.I. 2019/1410 and 2020/1376. There are other amending instruments but none is relevant.

(b) EUR 2009/1107. Articles 28 and 52 were amended by S.I. 2019/556 (as amended by S.I. 2019/1410 and 2020/1376). There are other amending instruments but none is relevant.

- (i) confirmation that the product remains authorised and available for sale in the Member State of origin at the time of application for the reinstatement of the permit,
 - (ii) confirmation that the label for the product as submitted with the application for the original parallel trade product remains unchanged as regards the identification of the product in the Member State of origin at the time of application for the reinstatement of the permit, and
 - (iii) photographs of the plant protection product container (including all sides of the container) with visible and readable label, showing the product as it is being marketed in the Member State of origin at the time of application for the reinstatement of the permit;
- (d) as regards the label for the plant protection product as it is to be marketed in the constituent territory concerned—
- (i) confirmation that the label for the product as submitted with the initial application for the original parallel trade product remains unchanged, or
 - (ii) notification of any change to the label for the plant protection product, together with the draft label which is to be attached to the product as it is to be marketed in the constituent territory concerned;
- (e) a declaration by the applicant that, to the best of that person's knowledge—
- (i) all information supplied in accordance with this paragraph is accurate, as it applies to the manufacture and placing on the market of the plant protection product in respect of which the application for reinstatement of the original parallel trade permit is made, and
 - (ii) for the purposes of paragraph (i), that the duplicate information supplied in accordance with subparagraph (a) continues to apply in respect of that product, subject to any changes required to be notified in accordance with this paragraph.

5. At any time after receiving an application and before determining it the competent authority may require the applicant to provide it with such further information as it reasonably considers necessary to determine the application.

6. The competent authority must grant the application for the reinstatement of the original parallel trade permit where—

- (a) at the time of application for that permit, the authorisation of the reference product granted prior to the application for the original parallel trade permit has not been withdrawn by that authority in relation to the constituent territory concerned;
- (b) the authority is satisfied that—
 - (i) the application complies with the requirements of paragraphs 2 and 3;
 - (ii) all information and documentation required to accompany the application in accordance with paragraphs 4 and 5 is complete;
 - (iii) where the applicant has notified a change to the label for the plant protection product in accordance with paragraph 4(d), that change—
 - (aa) is consistent with the proposition that the product must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product, or
 - (bb) is a minor change (such as a change of address) that is not material to the identity of that label with the label for the reference product;
 - (iv) the declaration made by the applicant in accordance with paragraph 4(e) is valid on the basis of all relevant information available to the authority concerning the plant protection product.

7. Where the reinstatement of a parallel trade permit is granted in accordance with this Article—

- (a) the competent authority must issue the parallel trade permit and must specify the date on which the permit has effect, and
- (b) the parallel trade permit is valid in relation to a constituent territory until the earlier of—
 - (i) the date on which the authorisation of the reference product expires in relation to that constituent territory;
 - (ii) the date two years after the day on which the permit was specified to have effect under this Article.

8. A plant protection product for which a parallel trade permit has been issued in accordance with this Article must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product.

9. The plant protection product for which the parallel trade permit has been issued may be the subject of a grace period granted in accordance with Article 46 as though the permit for the product concerned were an authorisation and, for these purposes, Article 46 applies—

- (a) where a parallel trade permit ceases to be valid in accordance with paragraph 7(b), or
- (b) where a parallel trade permit is withdrawn under paragraph 10(a).

10. A parallel trade permit that has been issued in accordance with this Article is to be treated as an authorisation for the purposes of Articles 44 and 45 and—

- (a) may be withdrawn—
 - (i) in accordance with either Article, or
 - (ii) without prejudice to Article 44, where the authorisation of the plant protection product in respect of which the original parallel trade permit was issued is withdrawn in the Member State of origin for safety or efficacy reasons;
- (b) may be amended in accordance with either Article, but only to the extent necessary to enable the product to be placed on the market and used in accordance with the provisions of the authorisation of the reference product.

11. The holder of a parallel trade permit must report any available information to the competent authority in accordance with Article 56(4) as though the authority had authorised the plant protection product concerned.

12. Chapters 6 to 10 apply in respect of any plant protection product for which a parallel trade permit has been granted in accordance with this Article, as if references in those Chapters to an authorisation were references to the parallel trade permit.

13. Subject to Chapter 6, each competent authority must take steps to make publicly available information which it holds about parallel trade permits.

14. In this Article—

“Member State of origin” means the Member State or EEA state which was the Member State of origin in accordance with paragraph 1 of Article 52 as it had effect immediately before IP completion day, as adapted by the EEA agreement as it had effect immediately before IP completion day;

“reference product” means the plant protection product which was already authorised in the United Kingdom prior to the application for the original parallel trade permit, and to which the product to which that permit relates (including that permit in its reinstated form), is identical in composition.”.

Savings

5. Article 52 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market is saved for the purposes of the references made by Article 52A of that Regulation to an original parallel trade permit.

	<i>Name</i>
	Parliamentary Under Secretary of State
Date	Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and replace Article 52 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (EUR 2009/1107, “the 2009 Regulation”) and modify transitional provisions in paragraph 14(4)(b) of Part 4 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556, “the 2019 Regulations”). The 2009 Regulation and the 2019 Regulations concern legislation in the field of pesticides and in particular plant protection products. Both the 2009 Regulation and Part 4 of Schedule 1 to the 2019 Regulations are secondary retained EU law within the meaning of section 11(2) of the Retained EU Law (Revocation and Reform) Act 2023 (c.28). These Regulations also amend the Plant Protection Products Regulations 2011 (S.I. 2011/2131) in consequence of the replacement of Article 52 of the 2009 Regulation and make saving provision in respect of Article 52 of that Regulation.

Regulation 3 amends the 2019 Regulations to extend the maximum period during which treated seeds not authorised for use in Great Britain may be placed on the market and used so that it expires on 1st July 2027.

Regulation 4 revokes Article 52 of the 2009 Regulation, which made provision for the continued use of parallel trade permits for a maximum period of two years ending on 1st January 2023. The Article 52 arrangements applied to permits which had been granted in respect of plant protection products authorised in a member State of the European Union, where the product was identical in composition to a plant protection product already authorised in the United Kingdom (the reference product), and had not expired before IP completion day. Regulation 4 also makes new provision under Article 52A for the reinstatement of parallel trade permits which had ceased to be valid under the Article 52 arrangements. Only the original permit holders may apply for the reinstatement of their permits. Applications must be submitted no later than 1st April 2024 and must be accompanied by evidence demonstrating that the plant protection product concerned remains substantively the same, subject to any changes made to ensure that the product has remained identical to the reference product. The permit issued under Article 52A is to be valid for two years from the date of issue, provided the authorisation of the reference product does not expire in the meantime.

Regulation 4 also amends Article 28 of the 2009 Regulation to refer to new Article 52A of that Regulation. An equivalent consequential amendment is made by regulation 2 to regulation 11 of the Plant Protection Products Regulations 2011, which makes it an offence to place on the market or use a plant protection product in contravention of Article 52A; and regulation 20 of those Regulations is amended so as to make it an offence to provide false information in connection with an application for a parallel trade permit under Article 52A.

A full impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from www.legislation.gov.uk and from the Department for Environment, Food and Rural Affairs, Seacole Building, 2 Marsham Street, London, SW1P 4DF.

© Crown copyright 2023

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of His Majesty's Stationery Office and King's Printer of Acts of Parliament.

£8.14

<http://www.legislation.gov.uk/id/ukdsi/2023/9780348252651>

ISBN 978-0-34-825265-1



9 780348 252651