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STATUTORY INSTRUMENTS

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**2023 No. 1321**

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

**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<sup>(1)</sup> 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—

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<sup>(1)</sup> 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;

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**Status:** *This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

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“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.”.