

7th December 2011

Parallel Trade in Plant Protection Products – Information Note for Applicants

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC came into force on 14th June 2011.

Article 52 of these Regulations outlines the criteria and conditions applicable for Parallel Trade.
(For information, the complete text is included in Appendix 2 to this note)

This Information Note outlines for applicants the process of obtaining a Parallel Trade Permit in Ireland.

NB: Approval must be obtained before any importation of product takes place.

1. Product Eligibility:

The product to be imported must be identical to a product already on the Irish market.

In accordance with Article 52 of the Regulations, Parallel Trade is limited to products that are authorised in another Member State. Product sourced outside the EU cannot be granted a Parallel Trade Permit.

A Parallel Trade Permit will not be granted on a product which is itself a parallel traded product in the country of origin.

2. Application

Application for a Parallel Trade Permit must be made to the Pesticide Registration & Control Division, Department of Agriculture, Food and the Marine, Backweston Campus, Celbridge, Co Kildare, using the application form in **Appendix 1** to this Information Note.

The following must be submitted with the application form:

- a. A draft label for the product intended to be placed on the market in Ireland.
- b. A copy of the approved product label from the country of origin.
- c. A Material Safety Data Sheet for the product to be placed on the market.
- d. A sample of the product to be placed on the market, in its original container with original label from the country of origin attached (To be submitted before placing the product on the Irish market).

Following receipt of an application, the applicant will be invoiced for the appropriate fee, which must be paid prior to commencement of the evaluation. This fee is non-refundable.

NB: Products, previously approved as ‘roll over’ registrations under SI 83 of 2003 as amended, will require a new Parallel Trade Permit based on a new application and will be assigned a new PCS number.

3. Permit

For each application approved, a Permit will be issued by the Department of Agriculture, Food and the Marine. This Permit will outline the terms and conditions which apply to the marketing and use of the product concerned.

4. Duration of the Permit

Subject to the payment of an annual registration maintenance fee, Parallel Trade Permits will remain valid for the duration of the authorisation of the reference product in Ireland.

In the event of the authorisation of the reference product being withdrawn for reasons other than for the protection of health and/or the environment and the requirements of Article 29 remain fulfilled, the duration of validity of the Permit shall expire on the date which the authorisation of the reference product would normally have expired taking into account the approval status of the active substance(s) concerned.

In the event of the product authorization being withdrawn in the Member State of origin because of safety or efficacy reasons, the Permit issued here may also be withdrawn.

Expiry dates for active substances can be accessed at

http://ec.europa.eu/sanco_pesticides/public/index.cfm

5. Changes in details

The Department of Agriculture, Food and the Marine must be notified of any changes in the details specified in the application form.

Changes which require an amendment of the Parallel Trade Permit will be dealt with as an application for a trivial amendment and will be subject to a fee.

Changes not requiring an amendment to the Permit must be notified in writing and may not be subject to a fee.

6. Label

A printed version of the product label must be approved by the Department of Agriculture, Food and the Marine prior to the product being placed on the market in Ireland.

All product placed on the market in Ireland must carry the approved label.

Holders of Parallel Trade Permits must be aware that changes may be required to the product label in the event of new legislative requirements or amendments to the reference product label (e.g. changes in GAP as a result of MRL changes or to changes in risk and safety information of the reference product, etc). The onus is on the holder of a Parallel Trade Permit to ensure that the product label is up-to-date and is consistent with the current label on the reference product.

7. Records

In accordance with Article 67 of Regulations (EU) No. 1107/2009, records must be retained, of plant protection products imported, exported, stored or placed on the market for at least 5 years. Among the records required to be retained are purchase records (Invoices, consignment notes, etc.) stores records (stock records) sales records, (delivery dockets, etc.). Records of batch numbers of original consignments must be retained and where appropriate, correlated with any new batch numbers being assigned to the product.

These records must be made available to the Department of Agriculture, Food and the Marine on request in accordance with the relevant legislation.

8. Enforcement

As indicated at 2(d) above, a reference sample of the original product in its original container with its original label intact must be provided to the Department of Agriculture, Food and the Marine prior to the product first being placed on the market.

In addition, the Department of Agriculture, Food and the Marine may at any subsequent time take further sample(s) of the product at wholesale, retail or end user level to ensure compliance with the conditions of the Permit issued.

Appropriate action will be taken if, at any time, evidence becomes available indicating that the product does not fulfil the terms and conditions of the Parallel Trade Permit granted.

9. Own Use Parallel Trade

Applications for “own use” Parallel Trade Permits must be made using the same application form and criteria outlined above with the following differences:

- a. No need for a product Trade name.
- b. Whilst it will be necessary to demonstrate that the directions for use of the product will be in accordance with Irish GAP, re-labelling of the product will not be required.
- c. A sample of the product to be imported is not required at the time of application.
- d. Appropriate records of use must be maintained.
- e. The product may not be supplied to or used by third parties.
- f. Product imported under an Own use Parallel Trade Permit cannot be repackaged.

Appendix 1

Application form for a Parallel Trade Permit in accordance with Article 52 of Regulation (EC) No 1107/2009.

Application for:

Supply for sale:

Own Use: (tick as appropriate)

Part A1 – Identification of applicant

1	Applicant	Contact name	
		Company name	
		Address	
		Telephone	
		E mail	

Part A2 – Identification of the reference product (in Ireland)

2	Reference Product trade name	
	Identity and content of Active Substance(s)	
	Formulation type	
	PCS Number	
	Authorisation holder	

Part A3 – Identification of the plant protection product from the Member State of Origin

3	EU Country of Origin	
	Product name in country of origin	
	Formulation type	
	Authorisation Number (country of origin)	
	Authorisation holder	
	Packaging size(s) and type	

Part A4 – Further information about the product to be placed on the market

4	Proposed Trade Name	
	Name and address of supplier	
	Will the product being imported be re-packaged?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Name and address of the re-packaging company	
	Proposed packaging type/material	
	Proposed pack size(s)	

Part A5 - Declaration

I, hereby declare that all entries made by me above are true and correct and I hereby apply for a Parallel Trade Permit for the plant protection product detailed above.

Signature of Applicant: _____ Date: _____

Article 52 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Parallel trade

1. A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.
2. From receiving a complete application, a parallel trade permit shall be granted in a simplified procedure within 45 working days if the plant protection product to be introduced is identical in terms of paragraph 3. Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request. The procedure for granting a parallel trade permit is interrupted from the day the request for information is sent to the competent authority of the Member State of origin until the complete information required is delivered to the competent authority of the Member State of introduction.
3. Plant protection products shall be considered as identical to the reference products if:
 - (a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;
 - (b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and
 - (c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.
4. The application for a parallel trade permit shall include the following information:
 - (a) the name and registration number of the plant protection product in the Member State of origin;
 - (b) the Member State of origin;
 - (c) the name and address of the authorisation holder in the Member State of origin;
 - (d) the original label and instructions for use with which the plant protection product to be introduced is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction. This competent authority may require a translation of the relevant parts of the original instructions for use;
 - (e) the name and address of the applicant;
 - (f) the name to be given to the plant protection product to be distributed in the Member State of introduction;
 - (g) a draft label for the product intended to be placed on the market;
 - (h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;
 - (i) the name and registration number of the reference product.

The information requirements may be amended or completed and further details and specific requirements shall be established in cases of application for a plant protection product for which a parallel trade permit has already been granted and in cases of an application for a plant protection product for a personal use in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5. A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the

authorisation of the reference product. To facilitate monitoring and controls the Commission shall set out specific control requirements for the product to be introduced in a Regulation referred to in Article 68.

6. The parallel trade permit shall be valid for the duration of authorisation of the reference product. If the authorisation holder of the reference product applies for a withdrawal of authorisation in accordance with Article 45(1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit shall expire by the date on which the authorisation of the reference product would normally have expired.
7. Without prejudice to specific provisions of this Article, Articles 44, 45, 46, and 55 and Article 56(4) and Chapters VI to X shall apply to parallel traded plant protection products correspondingly.
8. Without prejudice to Article 44, a parallel trade permit may be withdrawn if the authorisation of the introduced plant protection product is withdrawn in the Member State of origin because of safety or efficacy reasons.
9. Where the product is not identical, in terms of paragraph 3, to the reference product, the Member State of introduction may only grant the authorisation required for placing on the market and use in accordance with Article 29.
10. The provisions of this Article shall not apply to plant protection products which are authorised in the Member State of origin in accordance with Article 53 or 54.
11. Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits.