HSE

Health and Safety Executive

# Parallel Trade Permit Procedure – Guidance for introduction, use and placing on the UK market of parallel trade products

## Contents

## 1. Introduction

This Guidance applies for applications received from 1 October 2015 and sets out the provisions for granting parallel trade permits under the parallel trade procedure for placing plant protection products on the market in the UK (i.e. for commercial purposes). It is based on the provisions of Article 52 of Regulation (EC) No 1107/2009 (1107/2009), and the EU guidance document concerning the parallel trade of plant protection products (SANCO/10524/2012) (the EU guidance document).

Applications for parallel trade permits for products placed on the market in the Member State of origin under their parallel trade permit arrangements will also be processed via the provisions set out in this Guidance. However, the target times set out in Article 52 of 1107/2009 may not be achievable as it will be necessary to trace the permitted source product back to the original authorised product in order to verify that the permitted source product is identical to the UK reference product.

Different guidance is available for "own-use" parallel trade products.

## 2. Definitions

**Source product** – a plant protection product authorised or permitted in another EU Member State, but not the UK.

**Parallel trade product** – a source product for which a permit has been granted to allow its introduction, placing on the market or use in the Member State of introduction (for the purpose of this Guidance, to allow it to be parallel traded into the UK).

**Reference product** – a plant protection product authorised in the EU Member State of introduction (for the purpose of this Guidance, the UK), to which the parallel trade product is deemed by that Member State to be identical in composition.

**Member State of origin** – the EU Member State from which a source product is obtained.

**Member State of introduction** – the EU Member State into which a parallel trade product is permitted to be introduced, placed on the market or used (for the purpose of this Guidance, the UK).

## 3. What is parallel trade?

Parallel trade is the trade of a plant protection product which is:

- authorised in the Member State from which it is obtained (the Member State of origin) and is
- determined, by the Member State of introduction, to be identical in composition to one that is already authorised in the Member State of introduction (i.e. identical to the reference product).

Article 52 of 1107/2009 regulates parallel trade.

The parallel trade permit provisions do not require an applicant to provide evidence to prove that the product is safe and efficacious. As a result, the parallel trade permit procedure is cheaper, quicker and simpler than for a normal plant protection product authorisation.

## 4. When parallel trade provisions do not apply

The parallel trade permit provisions do not apply for introduction into the UK of:

- any plant protection products which are imported from outside the EU;
- plant protection products obtained in the EU but re-packaged and/or re-labelled outside the EU;
- products which do not fall within the definition of "plant protection products" within Article 2 of 1107/2009, because they are not in the form in which they are supplied to the end user (e.g. where the product is not already packaged in an authorised container for sale to the end user).

Further guidance can be found in the EU guidance document (section 4.3.2 Packaging size, material and form).

## 5. How are products determined to be identical?

A key requirement of the parallel trade permit provisions is that the product to be introduced, placed on the market or used in the UK (the parallel trade product) is identical to the UK reference product.

A parallel trade permit will only be granted where the product to be traded has been determined by HSE to be identical to the UK reference product.

Article 52(3) of 1107/2009 provides the criteria for establishing whether plant protection products are identical to the reference product, namely 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* (more familiarly known as having a 'common origin');

(b) *they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation* (e.g. granule, emulsifiable concentrate); *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*.

The general criteria employed by HSE in determining whether the products are identical are set out in Annex A of this Guidance.

HSE will use a number of verification procedures to determine whether the source product is identical to the UK reference product. These are set out at Annex B of this Guidance.

## 6. Information not accepted as evidence of identical composition

Data from formulation analysis of source products will not be accepted in support of parallel trade permit applications. Reliance on such data would be outside the scope of the parallel trade provisions, which enable the trading of identical products without recourse to additional data being required.

In cases where the applicant needs to submit data in support of their application, or in cases where common origin cannot be established, the applicant will need to apply for an authorisation under a different application stream. In these cases the parallel trade permit application will be refused.

## 7. Applying for a new or amended parallel trade permit

Applicants must complete and submit application form CRD5 when seeking a new or amended parallel trade permit. Further information on what to include in an application is available in The Applicant Guide.

### Applying for a parallel trade permit for a new product

Applicants applying for a parallel trade permit for a new product are required to provide information as explained in section 9 of this Guidance.

HSE will verify the source product named in the application for a new parallel trade product. If the source product has been determined to be identical to an existing UK reference product in the last 24 months, a verification fee will not be charged. However, if the source product has not been so determined, HSE will contact the competent authority in the Member State of origin to verify the source product and a verification fee will be charged (see section 13 for further information).

### Applying for administrative changes to existing parallel trade permits

Applicants with existing parallel trade permits can apply for the following administrative changes:

- change of product name;
- change of permit holder (see the paragraph below on ‘assignment or transfer’ for more information);
- change of marketing company.

Transfer or assignment of a parallel trade permit is permissible only via application to HSE. It is a condition of each parallel trade permit that the permit is for the benefit of the named permit holder only. While this does not prevent transfer or assignment of the parallel trade permit, a condition of the permit will be breached if the permit is used for the benefit of anyone other than the named permit holder. Breach of a condition of the parallel trade permit may result in withdrawal of the permit in accordance with Article 44(3) of 1107/2009. An application to HSE, by the existing permit holder, for transfer or assignment of a parallel trade permit must be submitted to HSE at least a calendar month prior to the date that the permit holder wishes the transfer or assignment to take effect. The application for change of permit holder must be supported in writing by the proposed new permit holder.

### Administrative changes that result in new MAPP numbers (product registration numbers)

Product registration numbers (MAPP numbers) are sometimes changed by HSE. Information about the situations in which they might be changed can be found in the Applicant Guide.

When an administrative change results in a new MAPP number for a parallel trade product, a new parallel trade permit will be issued to replace the existing permit which will be withdrawn with grace periods to allow existing labelled stock to be sold and used. This means that existing stock of the parallel trade product will not need to be re-labelled, until the end of the grace period, with the new MAPP number or any other details that might be necessary, e.g. change of permit holder or marketing company.

See 'The Applicant Guide: Withdrawal of Authorisations and Permits' for further information about withdrawals.

### When an application for amendment to the parallel trade permit is not required

Permit holders do not need to apply for changes to the parallel trade permit where the following changes have been made to the authorisation for the reference product, as these will apply automatically:

- addition of crops or recommendations;
- extension of expiry dates, e.g. following the submission of confirmatory data.

Change of company address should be notified to HSE in writing. A revised parallel trade permit with the new company address will be issued by HSE.

## 8. Maximum of one source product for each new parallel trade permit

HSE will only accept one source product in each application for a new parallel trade permit. This means that a new product to be introduced into the UK can only be sourced from one Member State of origin, but may be obtained from more than one distributor in that Member State.

### What will happen to older existing parallel trade permits containing more than one source product per parallel trade product?

Older parallel trade permits will not be affected, in that permitted parallel trade products with more than one source product granted under previous guidance will continue to be permitted in line with the existing permit. Administrative changes listed in section 7 above will be allowed to older parallel trade permits. However, applicants are required to list all existing source products in the application form for an administrative change, and to declare that those source products are still authorised in the Member State(s) of origin.

Further information on procedures for parallel trade permit applications is available in Annex C of this Guidance.

## 9. Information to be supplied by the applicant

Article 52(4) of 1107/2009 states that an 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.*

### HSE's requirements

HSE require the information detailed in (a)-(c), (e)-(g) and (i) above to be provided on the application form. Information about HSE's requirements for provision of (d) the original label and (h) a sample of the product are explained directly below.

### Original label of source product

HSE require the original label from the container of the source product actually marketed in the Member State of origin, for example, to help:

- determine whether the product is identical to the UK reference product;
- provide evidence of the applicant's access to the source product to be imported;
- aid monitoring of compliance and traceability.

An original label should be supplied in electronic format, either as a scanned copy or photograph of the original label. The front of the label or label wrap may be sufficient, provided that the information supplied in the application form can be identified on the source product label e.g. product name, authorisation holder, registration number. Downloaded copies from company websites will not be acceptable as an original label.

### Draft UK label

Although CRD do not check draft labels at the time of application, except for minimal information such as the product name, the draft label may be referred to at a later date

should it be necessary for compliance purposes. However, parallel traders are responsible for labelling the parallel trade product in accordance with the UK reference product (see section 17 of this Guidance for further information).

If applicants require a label check by CRD, this should be requested in the covering letter, accompanied by a Compatibility Assurance Statement (if tank mixes are to appear on the label). See The Labelling Handbook and the guidance document on tank-mixes for further information. Please note that there will be an additional fee for a label check.

### Additional information that may be required – product sample

Under Article 52(4)(h) of 1107/2009, a sample of the source product may be required from an applicant.

Where a sample of the source product is requested, this should be provided in its original container, with its original label and seals intact. Samples of the UK reference product are not acceptable.

The authorisation holder of the UK reference product, the authorisation holder of the source product in the Member State of origin and the competent authority are not under any legal obligation to provide parallel trade permit applicants with samples of products.

### Information required about the final packager and/or labeller

In addition to the information mentioned above, HSE also require the applicant to provide the exact location of the re-packaging/re-labelling site, to help:

- determine that the plant protection product to be imported will be re-packaged and/or re-labelled in the EU;
- simplify and improve monitoring of compliance and traceability.

EU guidance expands further on this requirement in sections 4.3.2 to section 5.

The company legally responsible for:

- the final packaging and labelling; or
- the final labelling,

of the parallel trade product, if not the permit holder or marketing company, must appear on the label of the permitted product as required by Commission Regulation (EU) No 547/2011 Annex I, (1)(b) regarding the labelling of plant protection products.

### Providing false information, or failing to disclose anything of relevance

Applicants, and their representatives, should be aware that a number of offences are listed in the Plant Protection Product Regulations 2011 (PPPR 2011) relating to the provision of any false information, and to the failure to disclose information, in relation to an application for a parallel trade permit.

## 10. Reasons for HSE refusing an application

HSE may refuse to process an application for a parallel trade permit for the following, non-exhaustive, reasons:

- where, on completion of its standard civil debt recovery procedures, HSE has been unable to secure the timely payment of the invoiced fees for that application (see section 14 of this Guidance);
- where it transpires that a product claimed to be a source product is not authorised in the Member State of origin;
- where a source product is not determined by HSE to be identical to the UK reference product. Reasons for refusal will be given as far as commercial confidentiality considerations will allow.

## 11. Granting of parallel trade permit

Under Article 52(1) of 1107/2009, parallel trade products will not receive an authorisation but will be granted a 'permit'. When an application reaches a successful conclusion the parallel trade product will receive a MAPP number and its details will be included on the 'e-@pprovals' database available on the HSE website (Pesticides Databases).

The parallel trade permit will specify the permit holder, the UK reference product, the Member State of origin from which the source product must be obtained, the source product's registration number and the name of the authorisation holder in that Member State.

### What happens when changes are made to the UK reference product?

Article 52(5) of 1107/2009 states that 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 reference product.

Parallel trade permits consequently automatically mirror changes made to the provisions of the UK reference product's authorisation. For example, if the following changes were made to the UK reference product's authorisation:

- change of authorisation holder or marketing company where they do not result in a change of MAPP (registration) number (see section 7 of this Guidance);
- individual uses/recommendations withdrawn;
- change or addition of container (not including returnable or refillable containers);
- addition of crops or recommendations;
- alteration of any condition of use or marketing;
- extension of expiry dates, e.g. following the submission of confirmatory data,

then no amendment of the parallel trade permit would be necessary. The permit would be deemed to incorporate the same changes.

It is therefore imperative that permit holders keep up-to-date with changes made to the relevant reference product authorisation. Amendments to these authorisations will be published within 7 days following amendment, and will be available to the public via searching the 'e-@pprovals' database on the HSE website (Pesticides Databases).

While no practical change is required to be made to the parallel trade permit issued to the permit holder, because changes to the provisions of the reference product's authorisation are deemed to apply automatically, the changes may well result in additional obligations for the permit holder, e.g. the requirement to alter product packaging or labelling.

### What happens if the UK reference product is withdrawn?

Article 52(6) of 1107/2009 provides that where the reference product has been withdrawn at the request of the authorisation holder, a parallel trade product may continue to be valid until the expiry date that the reference product would normally have expired. This is provided that the requirements for authorisation of the reference product are still fulfilled (Article 29).

Further information about the impact on parallel trade permits following the withdrawal of reference product authorisations can be found in Annex C of this Guidance.

### What happens if the source product is withdrawn?

When a source product is withdrawn, permit holders must notify HSE not more than 6 months after the expiry date for sale of that product. Where permit holders have not notified HSE about the withdrawal of a source product, but HSE becomes aware that a source product has been withdrawn, HSE will take the same action that it takes in response to notifications received by the permit holder, as described further below.

Where all source products for a parallel trade product have been withdrawn from the market for reasons not related to the protection of human and animal health or the environment, HSE will withdraw the parallel trade permit allowing a period of time for sale of existing stock in the UK market and a further 'use up' grace period for product users.

Where there are multiple source products for older existing parallel trade products, but at least one source product listed on the parallel trade permit continues to be authorised and available in one or more Member States of origin, the existing permit will remain extant and not be amended. The parallel trade permit will only be withdrawn when all source products listed in the permit are no longer authorised.

See 'The Applicant Guide: Withdrawal of Authorisations and Permits' for further information.

### Further information/sampling that may be required after the parallel trade permit has been granted

Article 67 of 1107/2009 requires, amongst others, importers of plant protection products to keep records of the products that they import, export, store or place on the market for at least five years. The relevant information contained in these records must be produced to HSE on request. To ensure that parallel trade products continue to meet the requirements of the parallel trade permit, and in particular the criteria regarding being identical, HSE may require the provision of such information at any time after the permit has been granted for a plant protection product.

As is the case for authorised products, HSE will routinely obtain samples and carry out chemical analysis of parallel trade products to determine whether they are consistent with their parallel trade permits. The permit holder will only be contacted in the event of a concern being identified as a result of this analysis and may be required to provide information on the origin of batches of the product (see section 18 of this Guidance on record keeping for further information).

## 12. Reasons for amending or withdrawing parallel trade permits

HSE may withdraw a parallel trade permit if the authorisation or permit of the source product is withdrawn in the Member State of origin because of safety or efficacy reasons (Article 52(8) of 1107/2009 refers, but without prejudice to Article 44).

In addition, on the basis that Article 44 of 1107/2009 (withdrawal or amendment of an authorisation) applies to parallel traded products via the operation of Article 52(7), HSE shall withdraw or amend a parallel trade permit, as appropriate, for any of the following reasons:

(a) the requirements of Article 29 (for authorisation for placing on the market) are not or are no longer satisfied. For example, the reference product is renewed (also known as re-registered) following EU renewal of the active substance;

(b) false or misleading information was supplied concerning the facts on the basis of which the permit was granted;

(c) a condition included in the permit has not been met. For example, the source product is no longer available in the Member State of origin;

(d) the manner of use and amounts used can be modified on the basis of developments in scientific and technical knowledge;

(e) the permit holder fails to comply with its obligations under 1107/2009.

Further information can be found in Annex C of this Guidance.

## 13. Fees and processing times

Following receipt of an application, HSE will ensure that the application form has been completed correctly and that necessary supporting documents accompany the application. This process is known as the Applications Sift and will identify the processing fees to be charged for the application.

### Applications for parallel trade permits for new products

The fees for a new parallel trade permit application include processing fees for:

- the Applications Sift;
- verification of the source product (if not verified within the last 24 months in any UK parallel trade product); and
- co-ordination of the application.

Applicants will be invoiced these processing fees following the Applications Sift. Any fees charged or deadlines set for processing parallel trade permit applications will be in accordance with published guidelines operating at the time of the application (see Fees Charged, and Application Streams and Targets).

Article 52(2) of 1107/2009 provides that applications shall be granted within 45 working days from receipt of a complete application if the parallel trade product is identical to the reference product. This target time does not include the time required to liaise with competent authorities* in other Member States. It also excludes any time waiting for payment of outstanding fees for the application if they have not been paid by the time the application is completed, but also see section 14 of this Guidance below.

Where HSE have not been able to confirm identical composition, applicants will be offered the option of the appeal procedure, where the applicant requests HSE to contact the UK reference product authorisation holder for confirmation that the formulations of the source and UK reference products are identical. This process is not subject to a target processing time and will result in the verification fee being charged to the applicant. Annex B of this Guidance provides further information.

* Article 52(2) of 1107/2009 says that Member States' competent authorities shall, within 10 working days of receiving a request, provide each other with the information necessary to assess whether products are identical. These target times may not apply to applications where the source product is placed on the market in the Member State of origin under a parallel trade permit.

### Applications for changes to existing parallel trade permits

Administrative changes to existing parallel trade permits, as described in section 7 of this Guidance, will result in the applicant being invoiced for the following processing fees:

- the Applications Sift, and
- administrative changes.

## 14. Late or non-payment of fees

Formal processing of correct applications will usually start after the Applications Sift, prior to payment of the invoice for that application being received. However, in cases where HSE has been unable to secure the timely payment of previously invoiced fees, companies may be informed that processing of a new application will not commence until payment for that new application has been received in full.

Following non-payment of the initial invoice for an application, a second reminder for payment will be issued 60 days after the invoice date (30 days after the payment deadline on the invoice). Applicants should note that non-payment of invoiced fees following this second reminder may result in their application not being processed.

## 15. Batch variation

The parallel trade product will be granted allowance for the same batch-to-batch variation in formulation as is granted to the corresponding UK reference product.

## 16. Packaging requirements

In accordance with Article 52(3) (c) of 1107/2009, and section 4.3.2 of EU guidance, the form, material and size of the packaging of the parallel trade product must be the same or equivalent as that for the reference product. Re-packaging of the source product may be permitted provided that the original condition of the product, including its safety (for human or animal health or the environment) and its efficacy, is not adversely affected. For example:

- re-packaging must not adversely affect the storage stability of the product;
- the chosen container design must not adversely affect operator safety.

Where products are permitted to be re-packaged, permit holders must ensure:

- each container contains only material from one batch of the source product; and
- the product is re-packaged in the EU (the exact location of the site where re-packaging takes place must be provided to HSE, see section 9 of this Guidance).

Returnable or refillable containers are not allowed for parallel trade products in the UK, so re-packaging of such products into standard containers as authorised for the UK reference product would be required for a parallel trade permit to be granted.

## 17. Labelling requirements

All plant protection products, including parallel trade products, must be labelled in accordance with Commission Regulation (EU) No 547/2011 ("547/2011") which implements Article 65(1) of 1107/2009. EU guidance expands on this requirement in section 4.4 Labelling. Permit holders, among other things, are required to add the following to the parallel trade product label:

- the name and address of the permit holder and marketing company (if relevant);
- product registration number (MAPP number in the UK);
- the formulation batch number and production date of the source product;
- the name and address of the company legally responsible for final packaging and labelling, or final labelling, if different from that of the permit holder or marketing company.

The instructions and classification on the label of the parallel trade product must be consistent with those on the UK reference product; for example, they must not make any additional claims regarding use and safety.

Permit holders can add their own batch number to the label should they wish to do so, but this is in addition to the requirement to add the source product formulation batch number and production date.

Permit holders should be aware that it is an offence under PPPR 2011 to fail to comply with labelling requirements specified within PPPR 2011 (combined effect of regulations 17 and 23).

## 18. Record keeping

Article 67(1) of 1107/2009 applies to parallel traded products via the operation of Article 52(7). Thus, permit holders must keep records for at least 5 years of the plant protection products they import, export, store or place on the market. Article 67 does not specify the nature of the records to be kept, however, HSE has set out below examples of records that may assist compliance with Article 67(1):

- dates of purchase of source product;
- details of company or individual selling source product;
- name and authorisation/registration number of source product purchased;
- formulation batch number and production date of source product purchased;
- amount of each batch of source product purchased and imported;
- date of entry of each batch of source product into the UK;
- storage location(s) prior to placing on the market;
- details of where re-packaged and/or re-labelled;
- sales information – including for export out of the UK (similar to above).

Invoices may contain some of the above information and so it is advisable that these are retained.

HSE may request information under Article 67 at any time, for example for:

- regulatory purposes; or
- as a result of a concern regarding the parallel trade product's compliance with the provisions of its parallel trade permit; or
- to ensure that the formulation of the product continues to be supported by an authorisation in the Member State of origin.

Permit holders should be aware that it is an offence under PPPR 2011 to fail to comply with the record keeping requirements specified in PPPR 2011 (combined effect of regulations 19 and 23).

## 19. Transport and handling

All Permit holders should ensure that they comply with any legislation controlling the transportation and handling of chemical substances.

## Further Information Links

Regulation (EC) No 1107/2009 – concerning the placing of plant protection products on the market

EU Guidance Document (SANCO/10524/2012) – concerning the parallel trade of plant protection products

Commission Regulation (EU) No 547/2011 – labelling requirements for plant protection products

Plant Protection Products Regulations 2011 – domestic legislation underpinning the operation of Regulation (EC) No 1107/2009 in the UK

The Plant Protection Products (Fees and Charges) Regulations 2011 – domestic legislation that sets the fees and charges relating to plant protection products in the UK

Council Directive 91/414/EEC – concerning the placing of plant protection products on the market (replaced by Regulation (EC) No 1107/2009)

## Annex A

### Parallel Trade Permit procedure: Criteria to be used by HSE to verify that the formulation of the product to be introduced into the UK (source product) and the authorised UK product (reference product) are identical.

These guidelines are **not** exhaustive. Decisions will be based on the information HSE has obtained regarding the formulation of the source products concerned (see Annex B of this Guidance for Verification procedures). Every application will be considered on a case-by-case basis.

The issue of whether a source product is identical to a reference product is for the relevant Member State's competent authority to decide. In the UK, the competent authority is HSE.

HSE will **not** consider source and reference products to be different in composition from each other where:

- differences in the formulation are due to rounding up or down of co-formulant values between countries;
- there are non-significant changes in co-formulant levels when the imported formulation is specified in g/l and the formulation details for the UK reference product are % w/w or vice versa;
- the only difference in co-formulants is that they are named differently (i.e. they have different trade names but are the same chemical);
- the only difference is the manner in which the formulation type is expressed (i.e. different translations of the same GIFAP formulation types);
- changes are made to dye, pigment or colouring material, provided the new dye is already approved in existing preparations, the dye is present at <5% of the preparation, and the new dye is on the EU approved list;
- differences in the percentage of co-formulants within the source product compared to the UK reference product are deemed by HSE to be insignificant, and do not need to be supported by the submission of data. When considering such differences, HSE will apply the same criteria used to decide whether a change to the reference product's authorisation should be supported by data (see SANCO/12638/2011).

HSE **will** consider source and reference products to be different from each other where:

- the source and the reference product do not share a common origin (see section 5 of this Guidance);
- there is any difference in the specification and content of the of the active substance(s), safeners and synergists within the formulations;
- the co-formulants are not the same or equivalent in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment due to solvents, dispersal agents, anti-foaming agents and preservatives;

- differences in the percentage of co-formulants within the formulations would require supporting data for the source product to be introduced to the UK;
- differences in the formulations would require different hazard and/or risk phrases to be specified;
- formulation types are different.

At the time of application, the source product to be parallel traded must be authorised in the country of origin and packaged and labelled in a form that is authorised for sale to a **user in that country**.

Where HSE do not consider the source product to be identical to the UK reference product, the parallel trade permit application will be refused and reasons for refusal will be given to the extent that disclosure does not, for example, undermine commercial interests (Article 63 of 1107/2009). In such cases it is open to the applicant to apply for authorisation supported by an appropriate data package, via a different application stream. This will not be a parallel trade permit application (Article 52(9) of 1107/2009).

# Annex B

## Verification procedure

### Assessment of information provided by the applicant

In the first instance, HSE will consider the information supplied by the applicant to see whether it provides a sufficient basis to determine whether the relevant source product is identical to the UK reference product.

### Contact with the Regulatory Authorities in the Member State of origin

HSE will contact the competent authority in the Member State of origin, from which the applicant intends to obtain the source product, to request the following information:

1. formulation details of the source product;
2. the name and address of the manufacturer of the formulation;
3. the name and address of the manufacturer of the active substance(s);
4. the purity of the active substance(s);
5. details of the containers for the authorised source product;
6. whether the source product is itself a parallel trade product.

A comparison of products will then be made using the information provided by the applicant and the competent authority in the Member State of origin, and the formulation details of the UK reference product.

In accordance with Article 52(2) of 1107/2009, the time taken in contacting the competent authority in the Member State of origin (see section 13 of this Guidance), to secure information will be excluded from the stated processing time target. Member States are required to supply this information within 10 working days; where this information is not received in time, HSE will follow the matter up with the competent authority in the Member State of origin.

Applicants will be informed when these actions are taken. Where there are likely to be delays, the applicant will be informed as soon as possible, and a revised target date for processing the application will be confirmed.

HSE will also ask the competent authority in the Member State of origin that a check be made to ensure that the formulation details provided by that authority are up to date, and take account of all formulation changes that have been notified to it.

### Contact with the UK reference product authorisation holder (appeal procedure)

In some cases, there may be a delay in obtaining the information from the Member State of origin, or the information provided by the Member State of origin might not result in HSE being able to determine that the source product is identical to the UK reference product.

In such situations, HSE will contact the applicant to enquire if they want HSE to contact the authorisation holder of the UK reference product to obtain written evidence that the formulation of the source product is identical to that of the UK reference product.

An additional verification fee will be charged where HSE is asked to contact the authorisation holder of the UK reference product.

### Additional evidence

Apart from the above, HSE may make additional enquiries and/or request further evidence, if it believes that they will assist with its evaluation of an application for a parallel trade permit. But, as stated above, the authorisation holder for the UK reference product will only be approached by HSE provided the applicant directs that such an approach be made and is willing to pay the additional verification fee.

## Annex C

## Examples of the impact on parallel trade permits following changes to the reference or source product

| **Amendment to/withdrawal of the Reference Product which does not give rise to safety or efficacy concerns** | **Effect on the Parallel Trade Permit** | **Comments** |
|---|---|---|
| The reference product authorisation is amended e.g. extension of authorisation, addition/removal of crops, changes to rates of application, change of container (excluding returnable or refillable containers). | The parallel trade permit automatically mirrors changes to the reference product authorisation.<br>The permit holder is responsible for keeping up-to-date with changes to the reference product authorisation. | No application required. |
| The reference product authorisation is withdrawn at Step 1 or Step 2 of re-registration or following Article 43 renewal because continued authorisation is not supported e.g. no application or insufficient data to support re-registration/renewal. | The parallel trade permit is withdrawn in line with the reference product authorisation. | |
| The reference product authorisation is withdrawn and a new reference product authorisation is granted following successful re-registration or Article 43 renewal. | The parallel trade permit is withdrawn in line with the reference product authorisation. | The permit holder must apply for a new parallel trade permit following re-registration/renewal of the reference product. |
| The reference product is withdrawn for 'commercial reasons' under Article 45. | The parallel trade permit is unaffected and continues until the reference product would normally have expired e.g. product re-registration/ renewal deadlines, providing all other conditions of Article 29 are still met. | The parallel trade permit will continue to mirror the last authorisation for the reference product. A copy of the last relevant authorisation will still be available via the public search on the 'e-@pprovals' database on the HSE website (Pesticides Databases). |

| **Amendment to/withdrawal of the Reference Product which gives rise to safety or efficacy concerns** | **Effect on the Parallel Trade Permit** | **Comments** |
|---|---|---|
| The reference product authorisation is amended or withdrawn as a result of safety or efficacy concerns. | The parallel trade permit automatically mirrors amendments to the reference product authorisation.<br><br>The permit holder is responsible for keeping up to date with changes to the reference product.<br><br>Where the reference product is withdrawn, the parallel trade permit is withdrawn in line with the reference product authorisation. | |
| The reference product is amended or withdrawn following evaluation of confirmatory data or data are not provided. | The parallel trade permit automatically mirrors amendments to the reference product authorisation.<br><br>The permit holder is responsible for keeping up to date with changes to the reference product.<br><br>Where the reference product is withdrawn, the parallel trade permit is withdrawn in line with the reference product authorisation. | |

| Withdrawal of the Source Product | Effect on the Parallel Trade Permit | Comments |
|---|---|---|
| The source product is no longer available in the Member State of origin e.g. the source product is no longer authorised for sale in the Member State of origin (for reasons other than that its authorisation has been withdrawn on safety or efficacy grounds). | The parallel trade permit will be withdrawn (in accordance with Article 44(3)(c) of 1107/2009) with grace periods to allow existing stock to be used up where appropriate. | The permit holder must notify HSE when the source product has been withdrawn in the Member State of origin (see section 11 of this Guidance). |
| The source product is withdrawn in the Member State of origin, on safety or efficacy grounds. | The parallel trade permit may be withdrawn in accordance with Article 52(8) of 1107/2009, or amended or withdrawn in accordance with Article 44. | The permit holder must notify HSE when the source product has been withdrawn in the Member State of origin, as above. |