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Safety of the Food Chain
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Guidance document concerning the parallel trade of plant protection products

under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 *concerning the placing of plant protection product on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* (OJ EU L 309, 24.11.2009, p.1) hereinafter referred to as Regulation (EC) No 1107/2009.

COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

This document has been conceived as a working document of the Commission Services which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) 1107/2009 nor any case law developed with regard to this provision.

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1. Introduction & Background

One of the paramount pillars of the European Union is the free circulation of goods within the internal market. This is reflected in Article 34 of the Treaty On the Functioning of the European Union (O.J. EU C83, 30.3.2010, p.49) in which it is stated that:
"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States"

Nevertheless, further down in Article 36 of the Treaty a restriction on the free circulation of goods has been introduced that states:
"The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants;…." (underlining added by the author)

From the above it can be concluded that free circulation of plant protection products within the EU must be facilitated without posing any unnecessary barriers but at the same time safeguarding that the provisions in place do not pose any risk for human health, animals or the environment.

It must be stressed that in Article 28.2(e) of the Regulation (EC) 1107/2009 it is clearly stated that plant protection products for which a parallel trade permit has been issued are exempted from an authorisation. Therefore, the Regulation makes a clear distinction between applications for parallel trade permit and applications for authorisation of plant protection products. The requirements as well as the procedure for granting parallel trade permits are described in Article 52 of the Regulation (EC) 1107/2009.

The current guidance document is intended to facilitate the implementation of Article 52 of Regulation (EC) 1107/2009 of the European Parliament and of the Council in a harmonised and consistent way by Member States (hereafter MS) competent authorities.

This guidance document does not deal with matters which are covered by other legislation e.g. trademark law. Parallel traders should ensure that when an application for parallel trade is submitted to a MS that other relevant legislation is respected.

2. Legal Basis

This document has been conceived as a guidance document by the Commission Services, and was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009 nor any case law developed with regard to this provision. Nor does this document preclude the possibility that the European Court of Justice may give one or another provision direct effect in the Member States. The current version of the guidance document should be implemented as from XXXXX 2012 (date of noting of the original version by the Standing Committee on the Food Chain and Animal Health).

The Legal basis of this document is Article 52 of Regulation (EC) No 1107/2009 while the European Court of Justice (ECJ) decisions in this field have also been taken into

account, namely for example C-71/96, C-72/96, C-73/96, C-100/96, C-232/96, C-379/99,.

3. General principles for the application of the parallel trade provisions

From paragraph 1 of Article 52 of the Regulation (EC) 1107/2009 it is understood that three basic conditions must be met in order for a MS to grant a parallel trade permit.

These conditions are:

a) The plant protection product for which an application is submitted is authorised in the MS of origin and the reference product in the MS of introduction;

b) The product from the MS of origin and the reference product in the MS of introduction are of **identical composition** (see Chapter 4);

c) An **application** is submitted in the MS of introduction

Taking into account the above it can be concluded that introduction of a plant protection product in the following cases **does not** fulfil the general conditions for parallel trade:

i) Importation from third countries

It is not possible to grant a parallel trade permit for a product imported from and authorised in a third country. One of the conditions of Article 52(1) is not met.

ii) Introduction from a MS other than that stated in the parallel trade permit

Paragraph 1 of Article 52 makes reference to a plant protection product of identical composition from one Member State (MS of origin). The product must be introduced from the MS of origin as provided in the application for a permit. In the case the product is introduced from another MS, the permit holder is not complying with the terms of its permit.

iii) Parallel trade of parallel traded products

Article 52.1 makes clear that "*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*".

Therefore only plant protection products authorised under Article 28 of the Regulation or under national laws transposing Directive 91/414/EEC may be granted a parallel trade permit (see also section 9 of this document). Parallel traded products themselves do not have such an authorisation. Therefore a parallel trade permit cannot be granted on a product which is itself a parallel traded product.

Simplified procedure for granting parallel trade permits

Recital (31) of the Regulation states that *"Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products*" (underling added by the author).

This general provision has been translated into paragraph 2 of Article 52 of the Regulation where a very strict timeframe of 45 days for the examination and issuing a decision has been introduced. This period starts on the day when the application is considered as complete.

An application should allow identity with the reference product to be determined within the specified time-frame. Usually this is limited to a purely administrative check based on confirmatory information received from the MS of origin within 10 days of receiving the request.

4. Criteria for granting parallel trade permits

Article 52.3 of the Regulation specifies the particular criteria that must be fulfilled in order that a plant protection product for which an application for parallel trade has been submitted, can be considered as being identical to the reference product.

In the following paragraphs guidance is provided to MS as to how to apply these criteria in a harmonised and consistent way.

4.1 Manufacturer (Article 52.3 (a) of the Regulation)

The manufacturer as provided in Article 52.3(a) refers to the person(s) that manufacture plant protection products, in accordance with the same manufacturing process, for the authorisation holder. In the same paragraph the various forms of contracting manufacturing to other parties is also specified and are namely:
- associated undertaking or,
- under license.

In both cases it is a contract between two parties in which one party is always the manufacturer of the plant protection product while the other party varies depending on the form of contract used.

In the case of an “associated undertaking” contract the relationship between the manufacturer and the other company is quite strict in the sense that the manufacturer has direct control of the management of that company e.g. it is a subsidiary.

In the case of a contract “under license” the relationship of the manufacturer with the other company is not so strict in the sense that the manufacturer does not have control of the management of that company.

In this latter case it is possible that the other company is a manufacturer that in parallel with the manufacturing of his own product(s) is manufacturing the product(s) of another company according to a recipe supplied to him. Even in this case the manufacturer that bears the legal responsibilities coming from the authorisation certificate is the authorisation holder rather than the manufacturing company that is simply following the instructions supplied by him.

In practice when an application for parallel trade is received the following situations may occur:

- the manufacturer of the reference product and the parallel traded product is the same (parallel trade application fulfils this criterion)
- the manufacturer of the reference product is different from the manufacturer of the parallel traded product but information is provided from the MS of origin that this manufacturer operates as an “associated undertaking” or “under license” on behalf of the manufacturer of the reference product (parallel trade application fulfils this criterion)
- the manufacturer of the reference product is different from the manufacturer of the parallel traded product and no information is provided from the MS of origin that this manufacturer operates as an “associated undertaking” or “under license” on behalf of the manufacturer of the reference product (parallel trade application does not fulfil this criterion)

From the above it can be concluded that the two plant protection products that are compared during examination of the application for a parallel trade permit, should share a common origin (same manufacturer) with regard to the plant protection product. MS should bear in mind that when an application is assessed against this criterion it could be that the authorisation holder in the MS of introduction being different from the authorisation holder of the MS of origin. This is not a reason to conclude that the application does not fulfil this criterion.

During the assessment of an application for a parallel trade permit, the MS of introduction needs details of:

- the manufacturer(s) of the plant protection product

- the manufacturing plants and location and

- information (if available) whether the manufacturer operates “under license” or is an “associated undertaking” on behalf of the authorisation holder.

This information can be exchanged between the MS competent authorities in the context of the procedure foreseen in Article 52.2.

If common origin can be established on the basis of the documentation submitted by the applicant or/and the information exchanged between MS competent authorities, then the MS of introduction can proceed to check other aspects of identity as defined in Articles 52.3(b) and (c), as follows (Sections 4.2 & 4.3, below).

4.2 Specifications, content of a.s., safeners and synergists, type of formulation (Article 52.3(b) of the Regulation)

4.2.1 Specifications, content of a.s., safeners and synergists

Specifications refer to the minimum content of the a.s. and the maximum declared content of relevant and significant impurities expressed in g/kg of active substance in the technical active substance used to manufacture formulated products. Specifications of a.s. are assessed during the approval of the a.s. or during the equivalence check for other sources (i.e. plants where the a.s. is produced according to a defined specification) after approval, as conducted under Article 38 of the Regulation (EC) No 1107/2009 at EU level.

The content of the a.s. refers to the declared content of the a.s. in the formulated product and is expressed in different ways i.e. % w/w or v/v, g/kg, g/l depending on the physical state of the product. To facilitate the examination of applications for parallel trade the content should be expressed in the same way as in the reference product.

For the purposes of reviewing an application for parallel trade permit, safeners and synergists should be treated as for a.s. in that their nature and content must be identical, if a EU reference specification is established.

When an application for parallel trade is assessed against this criterion, the two products under examination should contain a.s., safeners or synergists from the same manufacturer from the same source or from other sources of this manufacturer that have been found equivalent previously under Article 38 of the Regulation (EC) No 1107/2009. When the equivalence of sources has not been assessed or accepted, the parallel trade application is refused.

4.2.2 Formulation type

This refers to the type of the plant protection product as placed on the market e.g. wettable powder, emulsifiable concentrate etc. In the context of an application for parallel trade the two products under examination must be identical in terms of formulation type as referred to in GIFAP[1] Technical Monograph 2, (6th edition revised May 2008).

In the context of an application for parallel trade differences in the manner in which the formulation type is expressed (i.e. different translation or interpretation of the same GIFAP[2] formulation types) shall not be considered a reason for refusing an application in case of identical products. In such cases the formulation type (code) of the reference product will be used in the decision for the parallel trade product.

4.3 Co-formulants, packaging size, material and form (Article 52.3(c) of the Regulation)

For these aspects Article 52.3(c) the Regulation (EC) 1107/2009 provides some flexibility for MS when they examine applications for parallel trade. This flexibility has been introduced with the phrase "the same or equivalent" which could give grounds to different interpretations. In the following paragraphs an effort is made to interpret this in order that MS assess applications for parallel trade in a harmonised and consistent way.

4.3.1 Co-formulants[3]

According to Article 52.3(c) of the Regulation under the term "*co-formulant*" are included all those substances that are contained in the formulated product other than active substances, safeners and synergists.
The nature and the content of co-formulants are submitted in the detailed quantitative and qualitative composition of plant protection products when companies apply for an authorisation. However, this information is confidential and parallel traders do not have access to it. Product formulation details including the nature and content of co-formulants are exchanged in the context of Article 52.2 of the Regulation and checked among MS competent authorities when assessing the identity of parallel trade permit applications.

In order to fulfil the criterion in Article 52.3(c) the co-formulants in the parallel traded products should either be identical or equivalent to those of the reference product. As a consequence variations in co-formulants permitted under the term "equivalent" in Article 52.3(c) should be within a limited range.

Co-formulants used in plant protection products fulfil a variety of roles and vary depending on a number of factors including the type of preparation, climatic conditions and mode of use. Some co-formulants are essential for the safety and efficacy of the product, others are needed to ensure its stability, whilst some are of lesser functional importance. To promote consistency of approach in assessing the significance of difference in co-formulants when assessing parallel permit applications it is proposed that the following criteria apply.

[1] Now Crop Life International
[2] Now Crop Life International
[3] For this section of the document please consult also the Guidance Document SANCO/12638/2011 dealing with "changing the chemical composition of authorised plant protection products" (under preparation)

Applications for parallel trade plant protection products should be considered as not equivalent, if the product under examination:

- Contains co-formulants which have never been assessed by the competent authority of the MS of introduction in the context of an authorisation of a plant protection product;
- Contains co-formulants that lead to a worse classification according to GHS (Globally Harmonised System) in view of safety or toxicity.
- Contains quantitative variations in all co-formulants that account for more than 10% of the formulation.

The application for a parallel trade permit is a simplified administrative procedure that excludes a risk assessment. As no deviation within the co-formulants requiring a risk assessment would be acceptable, criteria are required to enable the competent MS authorities to differentiate between different qualitative and quantitative deviations amongst the co-formulants. It is necessary to create categories of co-formulants and possible deviations to meet the requirements of a simplified procedure and the time frame of 45 working days. To facilitate the assessment of the identicality the different types of co-formulants are divided in two categories.

Category 1: Significant co-formulants

These co-formulants are essential for the functioning, the safety or stability of the plant protection product. Parallel traded plant protection products should contain the same **Category 1** co-formulants and quantitative variations should only be accepted within a small margin. For **Category 1** co-formulants formulations with qualitative differences in co-formulants or quantitative differences outside the tolerances below should be refused. Co-formulants which are named differently but are the same chemicals (same CAS number), are considered identical.

The significance of quantitative differences in the co-formulants present may be assessed using FAO tolerances (set out in Table 1 below) for active substances or applying a general tolerance of ±10% for any one co-formulant.

Declared content in g/kg or g/L at 20 °C ± 2 °C	Permitted deviation from the declared content
up to 25	± 15% for homogenous formulations (EC, SC, SL, etc.) ± 25% for heterogeneous formulations (GR, WG, etc.)
over 25 and up to 100	± 10%
over 100 and up to 250	± 6%
over 250 and up to 500	± 5%
over 500	± 25 g/kg or g/L i.e. a maximum of ± 5%

Category 2: Co-formulants which are considered non-significant for the assessment of identity according to article 52

These co-formulants, for example inert fillers and some dyes or odorants may have little functional role in the plant protection product and MS may exercise a greater degree of tolerance for both qualitative and quantitative changes in Category 2 co-formulants.

Examples of Co-formulants which may, fall into Category 1:
adhesive (sticker)
emetic
thickener
preservative
antioxidant
antifreeze
stabiliser
repellent
buffer
antifoaming agent
anti-caking agent
emulsifier
dispersing agent
propellant
wetting agent
solvent

Examples of Co-formulants which may, depending on the formulation type, fall into Category 2:
deodorant
dye
miscellaneous
free-flowing agent
carrier
binder

4.3.2 Packaging size, material and form

Information concerning the size, material and form of the packaging should always be provided in the context of an application for parallel trade and checked since differences might exist, even if re-packaging does not occur, that could compromise the safety of the product (e.g. material that in the MS of introduction is not authorised).

Regulation (EC) 1107/2009 does not prohibit re-packaging of plant protection products. Nevertheless, this is a crucial step in the parallel trade of plant protection products that usually creates the most concerns for MS. It is quite decisive for competent authorities to ensure traceability of the products, and especially whenever re-packaging occurs. A product repacked in a third country and imported to the EU cannot benefit from the provisions on parallel trade.

Parallel traders are obliged to provide the exact location of the re-packaging plant to the competent authority of the MS of introduction, once this information is available to them and well before re-packaging actually takes place, to provide this information to competent authority of the MS of introduction. A change in the re-packaging location

at a later stage should be reflected on the label (see also section 4.4 below) and notified to the competent authority of the MS of introduction.

Concerning the packaging size the basic principle that should be followed is that the same rules as for the authorisation of plant protection products shall apply to the products placed on the market via parallel trade.

In that respect there are basically two cases that occur in practice:

a) The size(s) of the packaging(s) of the reference product is specified in the authorisation certificate or examined during the authorisation process e.g. 1, 5, 10 L (or Kg) or

b) A range of packaging size(s) for the reference product is specified in the authorisation certificate or examined during the authorisation process e.g. under 1 L (or Kg), 1 and up to 20 L (or Kg) etc.

Proposed packaging sizes that are identical to those of the reference product (case a) above) or that fall into the range of size(s) (case b) above), will be accepted without any further examination.

In the case of deviations a decision will be taken on a case-by-case basis depending on the magnitude of the deviation and the experience from other similar cases. If the package size does not increase the risk associated with the product, the package could be considered equivalent.

Concerning the packaging material the usual practise is that in the authorisation certificate of the reference product a range of materials e.g. PET, HDPE etc. is assessed and approved.

In the context of an application for parallel trade it will be assumed that a packaging material is equivalent to the reference product if this is packed in one of the materials tested and approved for the reference product. Any other packaging materials that have not been tested during the assessment conducted for the reference product need the submission and assessment of storage stability tests. This goes beyond the scope of the parallel trade and therefore the application will be rejected after consideration of the nature of deviation.

Finally, with regard to the form of the packaging this usually refers to the form of the package as it is sold and used by end-users e.g. bottles, cans, drums etc. This should not be confused with the outer package that eventually is used for the transport of products.

In the context of an application for parallel trade it will be assumed that a packaging form is equivalent to the reference product if this is one of the forms tested and approved for the reference product. No differences in the form are allowed that would lead to significant differences in the application of the product.

Information concerning packaging size, material and form must be provided by the time of submission of an application for parallel trade in order to give the possibility to the competent authority to examine the equivalence.

4.4 Labelling

Article 52.4 of the Regulation provides for an optional obligation when an application for parallel trade is submitted this to be accompanied by the draft label for the product intended to be placed on the market and, if requested, the original label and the instructions of use of the product from the MS of origin.

Labelling of plant protection products that are subject to parallel trade should follow the same rules as those that have undergone the normal authorisation process and therefore should comply with the requirements of the implementing Regulation (EC) No 547/2011.

The name and address of the permit holder and the permit number should be included on the label.

With regard to the labelling of parallel traded products two different approaches are usually followed depending on whether the product to be introduced is subject to re-packaging or not. In the following paragraphs the details to be followed in each case are specified.

4.4.1 Labelling of parallel trade products introduced and placed on the market in their original package

The new label should contain exactly the same information as on the label of the reference product with regard to the agricultural conditions of use and safety instructions of use of the product (e.g. risk and safety phrases, instructions for use, applications rates and crops etc.) and must be in the national language(s) of the MS of introduction if required by the MS of introduction.

To facilitate inspections and traceability of parallel traded products it should be checked that the formulation batch number and the production date are clearly displayed on the label as required by the Commission Implementing Regulation (EC) 547/2011 (Annex I, point 1.f).

In any case, the parallel trader should adhere to the requirements of the MS of introduction and the new label must be properly affixed in order to avoid that it tears off during handling and use.

Parallel traders, when labelling, should pay attention to the rules on protection of intellectual property rights and in particular trademark.

4.4.2 Labelling of parallel trade products introduced and placed on the market after re-packaging

In this case the same rules apply as for the products introduced in their original package.
Nevertheless there are some differences that need to be checked. To ensure traceability of repacked products and compliance with the provisions of implementing Regulation (EC) 547/2011 (Annex I, point 1.f) the formulation batch number and the production date must be displayed on the label of the re-packaged product

The name and the address of the company that is responsible for the packaging and labelling should also be included on the label, as required in the implementing Regulation (EC) 547/2011 (Annex I, point 1.b).

Parallel traders could use their own batch numbering system and include this information on the label.

5. Procedure for the examination of applications for granting parallel trade permits

5.1 Submission of applications

Applicants are required to file an application in the form specified by each MS and, to submit this in the competent authority of the MS of introduction accompanied by the

respective fee (if applicable) and the background documents (i.e. original label, draft label etc.).A specimen of the product to be introduced and, if repackaging will occur, a specimen of the original product in its original package from the country of origin may be requested by MS competent authorities. It is preferable for each product that is intended to be introduced a separate application form should ~~must~~ be submitted.

For the sake of harmonisation it is proposed that information requested in the application forms is standardised and divided into sections in the following way:

Section 1: Identification of the applicant

e.g. the name of the company, postal address, contact details etc.

Section 2: Identification of the reference plant protection product

e.g. trade name, active substance(s) and content, formulation type, function, authorisation number etc

Section 3: Identification of the plant protection product from the MSs of origin

e.g. MSs of origin, trade name, active substance(s) and content, formulation type, function, authorisation number etc.

Section 4: Additional information for the product to be introduced

e.g. re-packaging/re-labelling company, packaging size, material, form etc.

5.2 Preliminary assessment of applications

MS receiving an application for parallel trade should, at a first stage, examine on the basis of the available information that the application does not fall into one of the cases of Section 3 of the present document otherwise it will be rejected without further examination.

Following that, a documentary check is performed to ensure that information required or a justification has been submitted and that the accompanying documents e.g. draft label are physically present.If at this stage missing information has been identified these should be communicated to the applicant asking him to submit it within a specified deadline otherwise the application is rejected.

For those applications which were found complete, a request for certain information is forward immediately to the competent authority of the MS of origin. In order to facilitate the exchange of information between MS competent authorities it is the Model Form of **Annex I** of the present document that can be used.

5.3 Taking a decision on parallel trade applications

Upon receipt of the information from the MS of origin, the MS of introduction is examining that all criteria of Article 52.3 are fulfilled. In that respect if one of the criteria is not fulfilled e.g. the manufacturer of the plant protection product is the same, the packaging size, material and form are identical or equivalent but the content in co-formulants deviates from the acceptable levels described in Section 4.3.1 of this document, the application will be refused.

Applications for parallel trade for which identity has been proven will be approved and a parallel trade permit will be issued. In this case the competent authority of the MS of introduction makes its decision publicly available, as stated in Article 52.11 by uploading the relevant information concerning the identification of the product and the permit holder on its website.

For those applications for which identity has not been proven a decision for refusal will be issued in which the reasons for refusal shall be stated. The applicant may choose to apply for an authorisation of the plant protection product.

6. Post-permit issues

6.1 Data base of approved parallel trade applications

To facilitate exchange of information between MS competent authorities as well as monitoring and control of parallel traded products, each MS should upload on its website a list containing information for all applications for parallel trade products for which a permit has been issued. In that list the following information should be included as a minimum:
-Trade name of the parallel traded product, permit number & holder, expiry date
- Trade name of the reference product

In order to facilitate enforcement of the provisions on parallel trade when MS competent authority comes along with any suspected case concerning a parallel traded product, they should communicate general information on that e.g. product concerned, brief description of the case etc. to the other MS. Details can be exchanged by interested MS on a bilateral basis.

Following the adoption of this guidance document each MS should appoint a contact person for parallel trade issues and its website where information on parallel trade shall be found. This information shall be communicated to the Commission and the other MS.

6.2 Withdrawal or amendment of parallel trade permits

Parallel trade permits granted are subject to an amendment or withdrawal if the reference product has been amended or withdrawn. It is suggested that, whenever this is applicable, MS competent authorities communicate any amendments in the authorisation of the reference product to the holder of the parallel trade permit setting the same deadline as for the authorisation holder to correct the label.

In the case of withdrawal of the authorisation of the reference product the same grace period for the disposal, storage, placing on the market and use of existing stocks shall be set for parallel trade products as for the reference product.

Nevertheless parallel trade permits will remain valid when the authorisation of the reference product has been withdrawn by the MS of introduction following a request from the authorisation holder in application with Article 45(1).

If the authorisation of the reference product is renewed according to Article 43.1 or if the expiry date of the authorisation of the reference product for administrative reasons is changed upon initiative of the MS competent authority according to Article 43.6, the expiry date of the parallel trade products will also be extended for the same period.

It should be noted also that Article 52.8 foresees that on a case by case basis parallel trade permits granted are subject to withdrawal whenever the authorisation of the product of introduction has been withdrawn by the MS competent authority of origin for safety or efficacy reasons.

To enforce this provision it is important that when a MS withdraws an authorisation for safety or efficacy reasons to communicate this information to all other MS competent authorities regardless the zone it belongs to.

It is in this case the responsibility of the MS of introduction to withdraw the parallel trade permit that was issued on the basis of that product.

Finally, parallel trade permits shall be withdrawn if one of the conditions of Article 44 of the Regulation (EC) 1107/2009 is met.

6.3 Penalties and infringements

Penalties and infringements for irregularities on plant protection products is generally under the responsibility of individual MS.

In an effort to increase the efficacy and transparency of control mechanisms, it is suggested that whenever MS of introduction comes along with an irregularity concerning a parallel traded product to communicate this information to the MS of origin briefly stating the infringement encountered and the penalty imposed.

6.4 Obligations of holders of parallel trade permits

Generally speaking, parallel permit holders have the same obligations as the authorisation holders. In that respect it should be noted that not only the obligations coming from Regulation (EC) 1107/2009 should be respected but also those coming from Directive (EC) 128/2009 concerning the sustainable use of pesticides.
In the following sections the obligations deriving from Regulation (EC) 1107/2009 are described.

6.4.1 Record keeping

Holders of parallel trade permits, like authorisation holders, are obliged according to the provisions of Article 67 of the Regulation (EC) 1107/2009 to keep records for at least 5 years of the plant protection products they introduce and they place on the market. For parallel traded products this information shall be made available to MS competent authorities of introduction upon request. They shall also provide MS competent authorities with all data relating to the volume of sales of plant protection products.

The details of the information that parallel traders should keep in their archives are specified by the individual MS in the context of the implementation of Regulation (EC) 1185/2009 concerning statistics on pesticides. Parallel traders, like authorisation holders, should follow the national provisions issued in this field by each MS with regard to the content of the information that should be kept as well as the procedure for communication of this to the competent authorities.

6.4.2 Information about potentially harmful or unacceptable effects

It is an obligation, for parallel trade permit holders, according to Articles 52(7) and 56(4) of the Regulation (EC) 1107/2009 to report annually to the competent authority of the MS if they have information available on lack of efficacy, development of resistance, and unexpected effects on plants, plant products or the environment. They may also report potential harmful effects on human or animal health or on ground water.

6.4.3 Stewardship programmes

In some cases competent authorities of MS of introduction may set in the authorisation certificate a condition for authorisation holders to conduct stewardship programs to monitor for instance the impact from the use of the product on groundwater. Such programmes are usually specified in the authorisation certificate

issued by the competent authority and the results of such stewardship programmes should be communicated to the competent authority.

Whenever there is an obligation in the authorisation of the reference product, such an obligation is applicable to the holders of parallel trade permits.

7. Parallel trade applications for personal use

Parallel trade of plant protection products for personal use is not carried out on a commercial basis as the products are not placed on the market. Furthermore, the product is introduced into the MS in the unchanged packaging from the MS of origin.

Parallel trade for personal use has to be considered as parallel trade and require a permit, but the following data cited in the guidance document are not required from the applicant:

- trade name of the parallel traded product;
- data on packaging/repackaging;
- data on labelling except, if required, a translation of the label in the official language of the MS of introduction,

In addition, the user who was granted a permit must use the product according to the conditions and restrictions as specified in the authorisation of the reference product.

In addition parallel trade permits holders in this case should keep records as required under Article 67(1) and use the products as required in Article 55.

8. Renewal of parallel trade permits

Upon the expiry date of a parallel trade permit a new application needs to be submitted according to the provisions of Article 52 of the Regulation (EC) No 1107/2009. The assessment of these applications against the criteria of Article 52 will be conducted considering them as new applications. Therefore, a complete set of documents needs to be submitted.

9. Transitional measures

As from 14 June 2011, Regulation (EC) No 1107/2009 applies. As a consequence both authorisations granted under Regulation (EC) No 1107/2009 and under national laws transposing Directive 91/414/EEC should be considered for the granting of parallel trade permits under Article 52.

Up to that date a number of parallel trade permits will have been granted by MS. It is assumed that these permits, will be considered as parallel trade permits under the provisions of Regulation No 1107/2009 and will remain valid as far as common origin is given and as long as the authorisation of the reference product or/and the authorisation of the plant protection product from the MS of origin are not withdrawn. Permits that were only valid for limited quantities to be introduced will expire when that quantity is reached or at their actual expiry date. Following that, new applications need to be submitted according to the provisions of Regulation (EC) 1107/2009.

To facilitate the implementation of the provisions of Article 52.8, MS shall communicate information concerning the withdrawal of authorisations to all other MS competent authorities regardless the zone they belong to.

ANNEX I

MODEL FORM FOR THE EXCHANGE OF INFORMATION CONCERNING PARALLEL TRADE APPLICATIONS FOR PLANT PROTECTION PRODUCTS

SECTION 1 – Information about the application (to be completed by the MS receiving the application)

1.	Application number/date	
2.	Applicant name & address	
3.	Trade name of the product in the MS of origin /authorisation number	
4.	Active substance(s) & content	
5.	Formulation type	

SECTION 2 – Information about the plant protection product to be introduced (to be completed by the MS of origin)

STATEMENT: Is this product subject to a parallel trade permit? (tick as appropriate)

YES ☐ **NO** ☐

1	Authorisation holder	
2.	Manufacturer(s) of the active substance (name and address)	
	Location of the plants (name and address)	
3.	Manufacturer(s) of the plant protection product (name and address)	
	"under licence" or an "associated undertaking"? (tick as appropriate)	YES ☐ No information available ☐
	Location of the plants (name and address)	
4	Expiring date of the authorisation:	

SECTION 2.1 – Composition of the formulation

Information on the content of the technical active substance, safeners or synergists in the plant protection product.

(please add a row of each a.s, safener or synergist contained in the product)

content of technical active substance, safener or synergist :	g /l or g/kg
Minimum purity:	

Composition of …….(insert trade name of plant protection product)

Chemical name	CAS no, CIPAC no. or EINECES no. or ELINCES no.	Function: -active substance (herbicide, fungicide, insecticide, safener etc.) -formulant (adhesive, carrier, dye etc.)	g/kg or g/l	% w/w
<active substance 1>				
<active substance 2>				
<formulant 1>				
<formulant 2>				
<formulant 3>				
<formulant 4>				
<formulant 5>				

SECTION 2.2 – Information about packaging (if available)

Authorised size(s):	
Material:	
Form:	

Date: Signature: