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Guideline developed within the Standing Committee on Plant Health concerning parallel trade of plant protection products within the EU and the EEA

Introduction

The aim of this document is to provide guidance to the Member States' authorities which are responsible for the processing of parallel imports in their territory.

This document has been conceived as an opinion of the Commission Services and elaborated in co-operation with the Member States. It does not however intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State in relation to the subject matter of the document, nor any case law by the European Court of Justice.

Commission services received complaints from economic operators about the way the procedure for parallel imports was drafted and applied in several Member States. These guidelines are an attempt to set out general rules which, if applied in all Member States, would lead to the removal of barriers to parallel trade.

The most important practical issue that the document is attempting to tackle is setting out the criteria of "identity" between the master and the parallel plant protection product. Once these criteria are established and agreed, their practical application will be of great importance for the positive outcome of this undertaking. Member States are, therefore, strongly encouraged to establish an informal network of exchange of information and mutual consultation on the practical questions in relation to those criteria. Finally, this informal and evolving process may lead to the definition of a "Best Practice" in this area.

The process initiated by this Working Document should be reviewed after 2 years of its adoption and on the basis of the experience and results obtained by the Member States' contacts, possible amendments and clarifications could be made.

1. Definition of parallel trade or parallel import

Parallel trade in a plant protection product means:

The importation into a Member State of a plant protection product which is identical, under the terms of this document (see point 3), to a plant protection product (hereafter "reference product") already authorised in the importing Member State.

"Member State" means a Member State of the European Community or an EFTA State which is a Contracting Party to the Agreement on the European Economic Area.

2. Legal framework for parallel imports of plant protection products

Directive 91/414/EEC on the marketing of plant protection products contains no specific provisions on parallel imports of plant protection products. The European Court of Justice confirmed this in its preliminary ruling of 11 March 1999 in case C-100/96, "Agrochemicals" (paragraphs 31 and 32). The case was referred to the Court by the UK High Court of Justice which put questions on the interpretation of Directive 91/414/EEC.

It is, thus, for the national legislative authority in the importing Member State to adopt rules on parallel imports that comply with the principles of Community law, i.e. Articles 28 to 30 of the EC Treaty.

3. Simplified procedure for parallel imports of plant protection products

3.1. Establishing a simplified procedure

In case C-100/96, "Agrochemicals", the European Court of Justice confirmed the need for a simplified procedure for parallel imports of plant protection products. The Court declared that checks by the authorities of the importing Member States should concern only the identity ("simplified procedure") of the imported product with a product already authorised by the competent authorities in the importing Member State.

In particular, as the Court stated, the objective of this simplified procedure should be the following: "*… the competent authority should verify, apart from the existence of a common origin, that the two plant protection products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and also have the same effect with due regard, in particular, to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product*" (par. 33).

3.2. Aspects of the simplified procedure and its practical application

3.2.1. Information which may be requested from the parallel importer

Pursuant to the Court's Judgment in the Agrochemicals case (C-100/96), national authorities of the importing Member States may not ask parallel importers to provide any information other than what is accessible to them.
As a guide, this information may include the following elements:

- name of the product in the Member State of origin and in the importing Member State
- names and addresses of the authorisation-holders of the imported product and the reference product
- name and address of the parallel importer
- authorisation numbers for the imported product and the reference product
- Member State of origin of the imported product
- other useful information in their possession, such as:
  - content of active ingredient in the imported product
  - type of formulation
- its label and, when necessary, a sample of the imported product
- a draft label to be used
- If necessary, for the protection of the user, information on and/or a sample of the package.

How much of the above information shall be requested is up to the national authorities to decide. Under normal circumstances, the parallel importer will be in a position to supply all of the above. On the other hand, the authorities should restrict their requests for information from the parallel importer to the above points.

Should the parallel importer not be able to provide some of the information which the national authorities of the importing Member State consider necessary, these authorities should have other ways of obtaining it (see case C-100/96, Agrochemicals, paragraphs 34-35):

- In this regard, the proper functioning of the information exchange mechanism between the Member States, as provided for in Articles 9.5 and 12 of Directive 91/414/EEC, is of paramount importance. These provisions are designed to enable the competent authority of the Member State of importation to obtain the documents necessary for verification.
Moreover, the competent authority may consult the file submitted in connection with the application for marketing authorisation for the plant protection product already authorised ("reference product").

- If, nevertheless, the information provided by the parallel importer and the contacts with the other regulatory authorities do not help, there is another route in order to verify that the conditions for the parallel import approval are met:
The competent authority of the Member State of importation has available to it legislative and administrative means capable of compelling the manufacturer, his duly appointed representative or the licensee for the reference product which is already covered by marketing authorisation to supply information in their possession which the authority considers to be necessary. Nevertheless, such an approach should be avoided, when the parallel importer does not agree to the involvement of the manufacturer or his representative in the processing of his application.

3.2.2. Time limits for dealing with parallel imports

The purpose of the procedure is to verify the identity of the imported product with the reference product (see point 3.1.). The simplified procedure should be completed

within a reasonable time period (for example, 45 working days). This limit starts to run when all the information the parallel importer can provide has reached the national authority. The 45-day time limit excludes the time during which authorities of other Member States or third parties are being consulted.

The authorities of the various Member States should actively co-operate with each other to supply any information requested by authorities for assessing the identity of an imported product with the reference product within a reasonable time. Third parties (e.g. the manufacturer) should also co-operate within a reasonable time limit. National authorities may inform manufacturers that failure to provide the necessary information within a specified time limit will be regarded as an implicit agreement to the identity of the parallel product. As already mentioned above (3.2.1), approaches to third parties should only take place with the agreement of the parallel importer.

3.2.3. Fees and scope of the verification procedure for parallel imports

The application of high fees creates an unjustified obstacle to parallel imports. If a fee is applied, the amount of the fee must be established in a transparent manner and must correspond to the actual cost of the administrative processing (and, if necessary, technical examination) of a parallel import application.

The amounts charged should also take into account the scope of the parallel import approval (e.g. lower fees for one-year than for ten-year approval).

3.2.4. Concept of "identity"

The simplified procedure aims solely at checking whether the imported product is "identical" to the reference product.

As already stated above (3.2.1), according to the European Court of Justice in the Agrochemicals case (par. 33), *"the competent authority should verify, apart from the existence of a common origin, that the two plant protection products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and also have the same effect with due regard, in particular, to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product"*.

On the basis of the above mentioned case-law of the European Court of Justice and the practice followed in the Member States, the following definitions of the crucial elements of "identity", can be given. It must be stressed that these definitions are given as a guide, with the aim of eliminating barriers to trade stemming from different definitions in Member States.

- *"Identity" and "Common origin"*

Plant protection products share a common origin when they (active substance and formulated product) "*have been manufactured by the same company or by an associated undertaking or under licence"* (paragraph 40).

- *“Identity” and “Same formulation”*

The formulation type of the “reference” and the “parallel” products should be the same. As regards the type and amount of the ingredients, the batch-to-batch variations that can be expected in the manufacturing process are acceptable and should not lead to the denial of “identity”.
As regards formulants, further variations should only be accepted if the two products for which “identity” is sought, continue to have the same effect with due regard to differences which may exist in conditions relating to agriculture, human and plant health and the environment, in particular climatic conditions, relevant to the use of the products.

- *“Identity” and “same active ingredient”*

The active substance must have the same specifications and common origin as that already authorised in the Member States of importation.
Batch-to-batch variations in the amount, as can be expected in the manufacturing process (see FAO Guidelines and Annex VI of Directive 91/414), can be accepted.

3.2.5. Re-packaging and replacement of a trade mark

The European Court of Justice has clearly recognised that its relevant case law on parallel imports of pharmaceuticals can, by analogy, be applied to parallel imports of plant protection products (Judgment C100/96, par.29).

In the field of pharmaceuticals, recent case law indicates that the parallel importer of a pharmaceutical may re-package the imported product and replace a trade mark on it provided certain conditions are met (see cases C-232/94, MPA Pharma, C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb, and C-71/94, C-72/94 and C-73/94, Eurim-Pharm, judgments of 11 July 1996 with regard to re-packaging; case C-379/97, Pharmacia & Upjohn, Judgment of 12 October 1999 with regard to replacement of a trade mark).

According to this case law, the trade-mark owner may not invoke its intellectual property right to prevent the marketing of an imported product in the importing Member State under the following conditions:

- if the use of the trade mark rights would contribute to artificial partitioning of the markets between Member States, as happens if:
  - the same product is put on the market in different packaging or with different trade marks in more than one Member State or,
  - the re-packaging or the replacement of the trade mark is necessary in order to be able to market the product in the importing Member State;
- if the re-packaging is such that the reference state of the product is not altered;
- if the re-packager and the holder of the authorisation are identified on the product;
- if the re-packaged product is not presented in a way which could damage the reputation of the trade mark or its owner and,
- if the parallel importer informs the trade mark owner in advance of the re-packaged product being marketed and if he, upon request, transmits a copy of the re-packaged product to the trade mark owner.

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Any other trade-mark used by the parallel importer has to comply with the legislation of the importing Member State.

3.2.6. Labelling requirements

Refusal of a parallel import on the basis of non-substantive differences in the labelling, constitutes an unjustified barrier to trade.
On the other hand, parallel imported products should not carry any use instructions or safety notices other than the ones included on the label of the reference product.

Differences between Member States in the classification of the same product may occur under the current system of national authorisations. In that event, the national legislation of the importing Member State will apply and the parallel imported product will have to follow the classification of the reference product.
However, a parallel imported product is identical to the reference product when it fulfils the above (explained under 3.2.4) criteria of identity. The same classification is not one of these criteria and, therefore, any classification differences should not influence the verification of identity carried out by the regulatory authorities of the Member States.