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GUIDANCE DOCUMENT ON Mutual Recognition of Plant Protection Products under Council Directive 91/414/EEC

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Mutual Recognition of Plant Protection Products

1. Aim of this guidance document

Theoretically, mutual recognition can be seen as a cost, time and energy saving procedure, both on the side of the applicant, who would not have to repeat tests according to specific requirements of Member States, and on the side of the competent authority of the receiving Member State, who would not have to repeat evaluation of the dossier. In practice, it is however seen that both interested parties have difficulties in applying the principle of mutual recognition. Furthermore, to Commission and Member States it is not clear which procedure to follow in case of refusal of an application for mutual recognition.

This guidance document aims to clarify the conditions to be met and the procedures to be followed in order to pave the way to a more frequent application of the principle of mutual recognition, and hence to work-saving for all Member States.

First the legal context is described (chapter 2), followed by a summary of experiences till now (chapter 3). In chapter 4 the need and possibilities for work sharing in the framework of mutual recognition are described. In chapter 5 is detailed which data should be submitted for applications for mutual recognition.

2. Legal context

Taking into account the wording of Articles 10 and 11 of Council Directive 91/414/EEC concerning applications for plant protection product, it can be stated that following conditions have to be met in order to apply mutual recognition:

- the active substances contained in the plant protection product are listed in Annex I of Directive 91/414/EEC.
- the product applied for is identical to the authorised product ("the reference product").
- the product is (re-) authorised in a Member State (the "reference Member State") with comparable agro-climatic, plant health and environmental conditions after evaluation according to the Uniform Principles and taking into account the endpoints of the Review Report.
- the uses applied for are identical with the uses evaluated by the reference Member State.

When a Member State does not wish to approve an application for mutual recognition, it should inform the Commission as soon as possible of the invoked reasons. It is then up to the Commission to decide what should be done.

3. Experience until now

Although the legal context seems very clear and easy to apply, in reality it is seen that mutual recognition is often thought “not to work”. As a result of a workshop on work sharing (York; November 2005) the Commission launched a questionnaire. Based on the results of this questionnaire the commonly encountered problems are summarized below.

The number of applications for mutual recognition is very different according to Member States. And in total, there is still a limited number of applications on mutual recognition. Reasons for this may be:

- in the beginning, only a very limited number of active substances were listed in Annex I. The importance of mutual recognition was hence underestimated by some Member States, resulting in no or very late actions to foresee the possibility of mutual recognition in Member States. As a consequence, there is poor transparency in the authorisation procedure: what does a company has to do in order to apply for mutual recognition ? which documents have to be submitted and which procedure has to be followed ?
- although mutual recognition should by definition go faster and easier than a normal application, this is not the case in some Member States because extra data are requested or the procedures to be followed include additional steps.
- some Member States use mutual recognition for re-registration following Annex I inclusion of the active substance, and others don't.
- different marketing strategies of the companies (regional, global aspects) are resulting in different formulations or different agricultural practises, including different crops or uses, registered in different Member States and so prohibiting mutual recognition.
- many applicants act on a local basis, with local strategies, ignoring evaluation and authorisation status for the same products elsewhere.

When evaluating the applications for mutual recognition submitted until now in different Member States, it is concluded that in many cases the conditions for a valid application (as mentioned in chapter 2) were not fulfilled.

Even if all conditions are met, still other problems occur when applying for mutual recognition:

- the registration reports were not available, or written in another language.
- the registration reports did not take into account all points of the Uniform Principles.

- the evaluation by the reference Member State was not detailed enough, done according to other models, or taking into account other parameters (reflecting the local agricultural practices or climatic and environmental conditions). This refers to national specific data.
- the evaluation by the reference Member State was based on other endpoints than determined by the Review Report for the active substance.

The fact that Mutual Recognition is obligatory pushes Member States rather in the direction of refusing the application (and keeping silent on it) than of applying Mutual Recognition with certain flexibility.

Member States refusing applications are not tending to report on this, as the procedure meant in art. 10 is unclear, and is estimated to lead to an administrative burden.

4. Mutual recognition and work sharing

In finding solutions we have to consider the advantages for Member States in applying mutual recognition. The biggest incentive for Member States is that mutual recognition can lead to work saving. This work saving is especially present on the level of the evaluation of the dossiers. The experts should use the available registration reports (= the work already done) as much as possible. If remodelling is necessary, the same endpoints for the formulation as determined by the reference Member State should be used.

Furthermore, this remodelling with the national models/parameters could be done by the applicant, but then again using the endpoints of the reference Member State (not those of the dossier of the applicant). This would lead to even more work saving for the Member States.

Industry will be interested in applying for mutual recognition if the procedure is clearly described (e.g. in a guidance document) and indeed will lead to a faster procedure and therefore reduced costs.

In the same interest of work sharing, mutual recognition should not be limited to applications for authorisation, but could e.g. also be possible for applications for extension of use.

A crucial point for work sharing is the availability of acceptable evaluation/registration reports. All Member States should prepare their evaluation/registration reports using a common format and language. The following points should be considered:

- Availability of registration reports in English (considered as the only language understandable to all Member States) or in a language understandable in all Member States with the same agro-climatic, plant health and environmental conditions (see 5.1).

- Availability of 'registration reports' in accordance with the "*Guidance Document on the re-registration of plant protection products following inclusion of an existing active substance in annex I of Council Directive 91/414/EEC*" (SANCO 10798/2003)". This document gives only a model of such a registration report. What is however essential, is an evaluation report in which all points of the annex III dossier and the uniform principles are covered.
- Clear indication of the endpoints, the parameters and the models used, to allow for interpretation and/or remodelling if necessary.
- Cross-reference to other evaluation/registration reports (for other products...)
- Use of the endpoints of the review report.

It may require more work to write an evaluation report according to the above-mentioned points. However once such an evaluation report will be available in one Member State, a wide range of other Member States can use it.

The above mentioned guidance document SANCO 10798/2003 was designed for re-registration but should also be used for new registrations. Registration Reports available to this model would allow for work sharing opportunities and can facilitate mutual recognition.

As a work saving method for the Member State, it could be considered to:

- appoint a contact person;
- disclose registration reports, including the confirmation of evaluation according to the Uniform Principles and the composition of the plant protection product.

This information should be made available via national websites and preferably also via CIRCA.

Industry should be convinced that putting different formulations on the European Market will jeopardise work sharing activities -including mutual recognition- for new and existing authorisations. Member States will have fewer resources available for new authorisation evaluation, slowing down the whole authorisation process.

A separate "*Guidance Document on Work sharing*" is in preparation.

5. Application of the principle of mutual recognition

As stated before, the following conditions should be met in applying mutual recognition:

- the authorized plant protection product is identical to the one applied for.
- the authorized (and hence evaluated) fields of use are comparable to the ones applied for.
- agro-climatic, plant health and environmental conditions are comparable.

In practice, it is seen that the conditions for mutual recognition in the strict sense of article 10 (“pure” mutual recognition) are rarely met. Almost for every application, some (minor) deviations are noticed.

If a Member State concludes that an application for mutual recognition does not fulfill the criteria of Article 10, the Member State should refuse such an application and not authorize the plant protection product on the basis of a Mutual Recognition request. However on request of the applicant -and if allowed by national rules- the application can be shifted to a ‘normal’ application.

By shifting to a normal application, a refusal of the application and the need for notification of this refusal (as imposed by Articles 10 and 11) can be avoided. At the same time this does not prevent Member States to benefit as much as possible from the work done by other Member States (via work sharing).

However, for both kinds of applications, the procedure should be as simple as possible in order to allow for faster and easier registration. Only in this way, industry will be motivated to apply for mutual recognition, leading to work saving for Member States.

5.1. Mutual recognition

The applicant has to submit the following documentation to prove that all conditions are fulfilled:

- The information concerning the identity of the product (point 1 of annexe III), including full composition of the product and of the active substance, as well as information on the manufacturer of the product and of the active substance.
- Original label/official instructions for use (original and respective national translation) of the reference member state.
- Proposed label/instructions for use adapted for placing on the market in the Member State concerned
- A comparison between the requested GAP and the GAP authorised in the reference Member State. The field of application must refer to identical intended uses.
- A (certified) copy of the authorisation granted by the reference MS.
- A statement and/or evidence of comparability of the relevant agricultural-climatic, plant health and environmental conditions.

On request, the applicant should also submit complete documentation for application in accordance with Annex III of Directive 91/414/EEC and/or a copy of the evaluation/registration report (if necessary, translated in English) from the reference member state.

The receiving member state should seek confirmation from the competent authority of the reference Member State that the product was authorised with reference to the Uniform Principles following inclusion of the active substance in Annex I of Directive 91/414/EEC, and ask for the composition of the authorised product.

The mutual recognition of authorisations is related to the comparability of agricultural, plant health and environmental conditions. There are still different approaches on this subject depending on the test area, including risk mitigation measures.

National conditions in the test area `efficacy` are often comparable in various countries of the EC, particularly if conditions are similar in respect to cultivation/storage conditions and climate. The international plant protection organisation EPPO has now submitted a study on comparability based on comparable regions for efficacy.

In another test area, `fate and behaviour in the environment`, the comparability of conditions to assess concentrations in soil, on soil, and plant surfaces, in groundwater, surface water and air is, as a rule, only given if climate and other parameters relate to the respective `realistic worst case`. The comparability of these conditions (both environmental and use parameters) must be proved by the applicant by submitting appropriate data. On the other hand, it is widely known which Member States have comparable conditions in this matter.

The observed differences in residue behaviour seem to make a regional distribution of residue studies advisable. Until the enforcement of new regulations, the following applies (see also guideline of the EU, document 1607/VI/97 rev.1):

- The required comparability for field applications can be achieved by dividing Europe into 2 zones
 - Northern and Central Europe
 - Southern Europe
- World-wide zoning is not necessary for storage application;
- For use in greenhouses, regional zoning in Europe is not necessary.

For ease of applying mutual recognition, each Member State should consider providing a clear list of Member States with comparable conditions that allow for mutual recognition.

5.2. Work sharing

As soon as one of the conditions for mutual recognition (article 10) is not met, the application should be considered as a normal application. In that case, there is no obligation to grant authorisation or to notify refusal of such an application. However, the receiving member state should take the opportunity to use the work of the reference member state as much as possible. On the other hand, this allows requiring additional data compared to what is required for mutual recognition.

Each condition that is not fulfilled should be the subject of an expert judgement.

It is highly recommended that the applicant pinpoints out all differences and submits an argumentation or explanation for each difference.

Following conditions could be at stake :

- Comparability of the product composition : A small difference in the composition could still allow for using a major part of the dossier and of the risk assessments available for the evaluated composition. If a composition change is still ongoing in the reference Member State, and the same application for composition change is added to the application for mutual recognition (containing all necessary data), it could also be considered to combine mutual recognition together with an own evaluation of the composition change.
- Comparability of uses : Any differences in the field of use should be justified (e.g. non-relevance of certain pests/diseases etc.). What is important is that the evaluation of the reference Member State can be used for the uses applied for. Hence, a (slightly) lower application rate, a lower number of applications... could be accepted. An application for other crops, other application stages, higher doses,... will need an own evaluation, but even in that case some parts of the evaluation could be taken over and the same end points of the formulation could be used for own risk assessments.

Following data or information could be required on top of what is required for pure mutual recognition:

- A copy of the evaluation/registration report (of necessary, translated in English) from the reference member state.
- Analytical methods for monitoring and/or reinforcement purposes.
- Efficacy data, or any other additional study
- Calculations according to national exposure models and taking into account national specific criteria. This can be the case for e.g.:
 - operator exposure;
 - groundwater modelling;
 - calculation of the risk for water organisms, non-target arthropods, non-target plants... via leaching, drift...

The registration report allows to check whether the evaluation of the reference member state (used models, parameters,...) is valid for the application in the receiving member state.

Additional calculations allow to verify if local conditions are respected.

Additional data could be required to confirm any aspect of the dossier, or to allow for reinforcement of (national) legislation.