



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Sanco/2971/2000
10/10/2000

Draft guidance document

on Voluntary Mutual Recognition

of

Minor Use Authorizations

(does not necessarily represent the view of the Commission Services)

Voluntary Mutual Recognition of Minor Use Authorizations

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This document

Directive 91/414/EEC concerning the placing of plant protection products on the market provides in Article 9(1) that Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that:

- the documentation and information to support an extension of the field of applications has been submitted by the applicant;
- they have established that the conditions referred to in Article 4(1)(b)(iii), (iv) and (v) are satisfied;
- the intended use is minor in nature;
- users are fully and specifically informed as to instructions for use, by means of an addition to the labelling or, failing that, by means of an official publication.

Article 10 provides for the obligation to grant mutual recognition to the extent that the Uniform Principles have been applied and only for plant protection products containing active substances already included in Annex I to the Directive.

However, since Member States do not have to apply the Uniform Principles when granting an extension of an authorization¹ for minor uses there is no obligation to grant mutual recognition for such authorizations.

The Guidance Document 9191/VI/97 has been composed as a helpful instrument in the process of voluntary mutual recognition of minor use authorizations. It proposes a standard method which may help the Designated National Authorities (DNA's) in their evaluation process when dealing with an extension of use according to article 9 of Directive 91/414. It facilitates voluntary mutual recognition for minor uses and facilitates the exchange of evaluations and decisions between Member States. Exchange of data may be a consequence but is not a purpose. The document furthermore provides applicants and Member States with advice on which information should be submitted in order to obtain an extension of use through voluntary mutual recognition.

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 the implementation of provisions concerned, nor any case law by the European Court of Justice.

¹ Several countries name the granted use according to article 9 an 'approval', others call it an 'authorization'. In this document we will use the term 'authorization' while also 'approval' can be read if applicable for your Member State

1. Introduction

1.1 Voluntary Mutual Recognition

Minor Use Problem

Plant protection products must be authorized before they can be used legally. Much research has to be done at very high costs to obtain all necessary data to ensure an efficacious product which can be used safely in respect of human health and the environment. For minor uses, national markets are mostly too small to recover these costs. As a result a lack of authorizations exists for many of these uses. The European harmonisation of registration requirements (Directive 91/414) has increased the burden on the registration process considerably which is having a large impact on minor use registrations where in the past data requirements were often minimal. A consequence of this problem is an increase in the illegal use of pesticides. Specific actions need to be taken to handle minor use problems and one of the proposed is a system for voluntary mutual recognition. This introduction sets out the first step towards the establishment of a Guidance Document which describes this system.

Voluntary Mutual Recognition

World-wide much national effort is given to the evaluation and authorization of plant protection products. Thorough evaluation is a necessity but work may be duplicated if countries are unable to recognise data or evaluations produced in other states. Voluntary mutual recognition will allow a Member State of the EU, when evaluating a minor use extension of an authorization, to follow other Member States in their decision to authorize the use. Member States are not obliged to follow this procedure as the decision will be made on national basis. Voluntary mutual recognition will make use of data and decisions already existing in other Member States and thus makes the authorization process less expensive. It therefore has the potential to reduce the problem of the authorization of minor uses.

1.2 Voluntary mutual recognition of what?

Article 9 of Directive 91/414

When discussing the possibility of voluntary mutual recognition of an authorized use the intention is that recognition will be from one country to a second. It always concerns an application for use in the second in accordance with Article 9 of Directive 91/414. This document gives guidance on the application of this Article.

According to Article 9(1) Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that:

- the documentation and information to support an extension of the field of applications has been submitted by the applicant;
- they have established that the conditions referred to in Article 4(1)(b)(iii), (iv) and (v) are satisfied;
- the intended use is minor in nature;
- users are fully and specifically informed as to instructions for use, by means of an addition to the labelling or, failing that, by means of an official publication.

As extension of use is involved there is a prerequisite that the plant protection product for which the extension of use is sought should already have an authorization in the recognising country (i.e. comparable formulation).

It is implied - and stated in the declarations of the Council when adopting the Uniform Principles - that this applies also to extension of use for minor uses applied for by companies. No difference is made in data requirements between an application made by grower groups or companies. Article 9(1) does not require an assessment of efficacy.

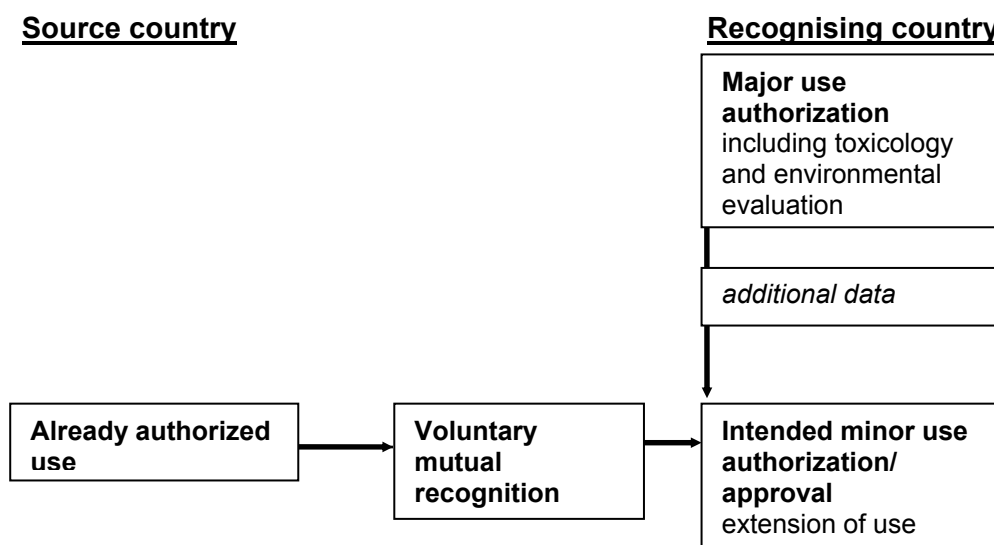
Definition of Minor Use

This Guidance Document does not provide a definition of minor use even though the document refers to the voluntary mutual recognition of minor uses. This is intentional because of the voluntary character of the mutual recognition process and because of the range of national definitions or interpretations of “minor use”. An acceptable European definition is hard to obtain. This Guidance Document refers to existing guidelines, guidance documents and procedures: where necessary (for example for residue issues) these documents address the issue of the definition of minor use within their own context. The decision on what is or is not a minor use will be a national decision, i.e. a decision of the Designated National Authority (DNA).

Which types of application will be dealt with?

Mutual recognition refers to the recognition of both evaluations and data. What situations can be considered when an applicant in a certain country asks for mutual recognition of a minor use of another country? In all cases the active substance must be the same and the formulation should be comparable. In ideal cases the agricultural (including pattern of use, i.e. method of application), plant health and environmental (including climatic) conditions are similar in both countries. Thus the evaluation in the recognising country will be straightforward as many data are comparable and usable. In other cases however there may be differences in the application between the two countries: for example the target pest, the pattern of use, environmental conditions, etc. may be different. Then it may be possible that through extrapolation, through additional research, etc. the recognition can be obtained. As it will be based on a case by case decision by the national DNA's it is not necessary to define criteria for the applications which may make use of the decision schemes. With the help of the flow-charts all aspects of the evaluation will be addressed in order to reach a justifiable decision.

In Figure 1 the intended use for which voluntary mutual recognition may be granted has been visualised.



*Figure 1. Overview of the procedure of voluntary mutual recognition. This document uses the term ‘recognising country’ for the country which has an intended use to be authorized. The country where the minor use already has an authorization will be used as a source for the evaluation and/or data. This country will therefore be named as ‘source country’. (However other countries/your own country may also be used for information/data and thus be a source). **The already authorized use** is the authorized use of a plant protection product in the source country and which use is applied for in a second country, **the intended use**. The purpose of this document is to authorize this intended use through (voluntary) mutual recognition (of the already authorized use). Additional data such as from the major use authorization in the recognising country, may be necessary for a positive decision on the authorization of the intended use.*

1.3 How to use this document?

When will it be used?

When a chemical industry or a growers' organisation is applying for an authorization of a minor use via voluntary mutual recognition this document can be used as a guide. Applications should clearly state that they are being made via this system of voluntary mutual recognition. In such case it is suggested that the application form (see Annex 1) can be used.

Who should use it?

It provides advice to the Designated National Authorities (DNA's) of the Member States in their decision making process in deciding whether to grant the authorization. The applicant may also use it to check which procedure is required.

How it should be used?

The aim of this document is to facilitate exchange of evaluations and decisions between Member States; exchange of data may be a consequence but is not a purpose. The document provides a standard method for the evaluation of an application and thus clarifies the evaluation process. It makes the method of evaluation transparent. In this way it will prevent the user from repeating evaluation work which has been done in another Member State. A final evaluation will always need to be done by the DNA of the Member State. The document uses the existing criteria and practices in Member States; it is not intended to add new criteria for evaluation.

Authorization may be granted in certain cases without further local evaluation. In other cases additional data may have to be generated and evaluated. Even then the system should provide benefits, as it shows clearly which additional data are required and how they may be obtained, i.e. through extrapolation or additional data (e.g. bridging studies). It is preferable that data and their positive evaluations (on a/o. worker protection and environment) are available. In many cases this will be the case. If, however, additional data need to be generated and evaluated this will, in many cases, produce a financial demand on the applicant. It is therefore preferred that applications remain within the conditions of use as evaluated for the major uses of the product concerned and the minor use in the source country which is to be recognised.

The guidance consists of several decision schemes which lead the user through the decision making process of mutual recognition. It works by means of a master key and several subkeys in which the whole evaluation process leading to authorization is covered (i.e. residues, environment, worker protection and efficacy). As the questions in the keys need to be kept brief, all questions are elaborated in detail in the explanatory text. Each key is accompanied by a flowchart. When using the decision schemes for a recognition of an application in the source country the question should be posed: on what is the authorization in that country based (i.e. as a result of data, extrapolation, a statement)? This makes the original decision transparent and might facilitate the recognition procedures. Thus the following questions should always be posed:

- Which data are required?
- What data were used by the source country?
- What data are available?
- Are the available data sufficient or are additional data necessary?

It should be realised that the system requires expert judgement on the level of flexibility and possible extrapolations from the DNA since a very strict and rigid use of this Guidance Document will not work. Member States should use this document in their own pragmatic way.

It will be stimulating for voluntary mutual recognition if the various DNA's maintain their contacts with sister organisations as this may lead to an easier understanding of the evaluation process in other Member States and shorter communication lines.

1.4 Starting Points

The decision on whether to operate this system of voluntary mutual recognition will be up to individual Member States. However several starting points have been identified which are given below.

Active Substance

1. There is a total of about 840 active substances to be evaluated at EU level. All active substances will be considered unless it is clear that the active ingredient will not be defended nor placed on Annex 1.
2. The active substance of the product to be recognised in the country of the intended use (the so called 'recognising country') should already have an authorization in this country (or it may be in the review phase). Also the plant protection product should already have an authorization, i.e. a plant protection product with a comparable formulation.
3. What if the recognised active substance in the source country is to be prohibited? When it concerns a decision at European level it will be prohibited in both countries while if the prohibition is a national decision it is up to the other Member State what to decide.

Underlying data

1. In the process of voluntary recognition world-wide data may be accepted if can be demonstrated that the research has been executed under comparable conditions and to suitable quality standards. For residue data for minor use extensions of authorizations at least GEP will be required (for the fieldpart of the trial). For the laboratory trials GLP is required. In case no official standards apply to these data they should be examined on a case by case for acceptability of quality. Public domain literature may be used. Transparency on how data have been obtained is necessary.
2. The decision on how to handle the 'efficacy' dossier is up to each Member State; Article 9(1) does not explicitly demands data. In case data are required and if no official data are available an efficacy evaluation may be done based on extrapolations from other uses and/or positive experience in the field during a number of years.
3. Article 13 of Directive 91/414 also counts for extensions of authorizations according to article 9 of this Directive. Data protection may inhibit voluntary mutual recognition because it may be that useful data cannot be used when they are legally protected. When the owner (official organisations, for example a growers' organisation or a rival firm) does not allow use elsewhere mutual recognition will not be possible. As far as data which are owned by growers' organisations is concerned discussions are now ongoing at the European level (COPA) how to handle this problem. For instance co-operation between growers organisations on data exchange is desirable. When commercial companies own the necessary data difficulties will occur when they are unwilling to cooperate.
4. Who is locating the data? Member States have to evaluate the information submitted to them. The applicant is responsible for searching for additional data and locating them in the different countries and at the different companies. Although the applicant is responsible for locating data but it may be sufficient to inform the DNA where additional data can be obtained without actually possessing them. Locating data will take a lot of time and may create problems when the applicant is a growers' organisation. The European Pesticide Information System which is in development may be helpful in locating data sources. The DNA may in some cases help in searching for and locating data.

1.5 Additional instruments

The application form

An application form may provide guidance to applicants unfamiliar with the regulatory process. This form will help the applicant, as well as the Designated National Authorities, in the operation of procedures for voluntary mutual recognition. It is not intended that the application form should replace the existing application forms already available in the DNA. It gives a *listing of characteristics specific to voluntary mutual recognition* which may not be generally available on existing application forms. It may be appropriate to add the guidance to existing national forms. See Annex 1.

The Summary Evaluation form

When a DNA is dealing with an application for voluntary mutual recognition a 'Summary Evaluation form' may be a helpful instrument. The DNA of the source country should already have prepared a record of the basis on which the 'already authorized use' has been granted. This will provide the necessary information for completing the 'Summary Evaluation Form' when this is requested by the 'recognising country'.

The aim of the form is to make visible to other DNA's how a decision on an authorization has been taken in the country where the extension has been given. Therefore this form summarizes the decision taken by the DNA and provides transparency on what information this decision has been based. It must provide the critical information underlying any authorization: what has been approved by whom in which way?

Such a form has been developed (see Annex 2). This form is only intended to be used for extensions of uses according to article 9 of 91/414. In article 9(5) it has been stated that 'Member States shall ensure that a file is compiled on each application ..'. In fact a summary evaluation form complies with part of this file requirement.

2. Key 1 Mutual recognition: no additional evaluation required

2.1 Key 1

Please read the general introduction and the explanation of the questions in 2.2.

1. Does the plant protection product which has the intended use and the already authorized use contain the same active substance and have a comparable formulation?
yes
2 no **mutual recognition not possible**

2. Does the intended use concern an extension of use which conforms to article 9, i.e. an authorization exists already for this active substance with a comparable formulation?
yes 3
no **mutual recognition not possible**

3. Has the active substance been included in Annex I?
no 4
yes 5

4. Is it clear that the active substance will not be placed on Annex 1 or is it known that the chemical company will not defend the active substance for placement on Annex 1?
no 5
yes **mutual recognition not possible**

5. Is an assessment on residue aspects required for the intended use?
yes **Key 2**
no 6

6. Is an assessment on worker protection required for the intended use?
yes **Key 3**
no 7

7. Is an assessment on environmental aspects required for the intended use?
yes **Key 4**
no 8

8. Is an efficacy assessment required for the intended use?
yes **Key 5**
no **mutual recognition possible**

2.2 General introduction and explanation of the questions of key 1

In this key and all other keys hereafter two terms are regularly used when talking about authorizations of plant protection products: the already authorized use and the intended use. **The already authorized use** is the authorized use of a plant protection product in the source country and which use is applied for in the recognising country (i.e. your own country), **the intended use**. See also figure 1 for these terms. The purpose of this document is to authorize this intended use through (voluntary) mutual recognition (of the already authorized use). **Use** means the pesticide application conforms to the label, for (a) certain target pest organism(s) in (a) certain crop(s). **Pattern of use** includes the dosage, number of applications, frequency, timing, equipment and method of application (application technique). The pattern of use thus includes the application which conforms to the label instructions. As already mentioned before the granting of an extension of use may be called an **authorization** or an **approval**, which differs between Member States. Only the term 'authorization' will be used here, while also an approval can be meant, depending on the country and situation.

The questions in this key provide a guide through the general evaluation process for authorization of a plant protection product. Questions 1 - 4 form the basic requirements for voluntary mutual recognition: the intended use and the already authorized use should contain the same active substance which is or will be placed on Annex 1; the products with these uses should have a comparable formulation and the intended use relates only to an extension of use.

The subsequent questions, i.e. question 5 - 8 mention all aspects which need to be evaluated for an authorization. In this key the already authorized use and intended authorized use are compared on their effects on consumption (residue data), worker protection, environment and, if needed, efficacy. Thereby the assumption has been made that the underlying data of the authorized use are complete and have been well evaluated. If the patterns of use are the same or comparable and the agricultural, plant health and environmental (including climatic) conditions are the same or comparable, the conclusion can be drawn that the effects will be comparable and thus a positive recommendation on mutual recognition can be given. In case further study is required reference will be made to the underlying keys 2 - 5, i.e. a more detailed evaluation of data is necessary. The result after using these subkeys may still be a positive recommendation for mutual recognition whether or not through submission of additional data or through extrapolation of data.

Explanation for each question

1. Does the plant protection product which has the intended use and the already authorized use contain the same active substance and have a comparable formulation?

In order to qualify for voluntary mutual recognition it is essential that the product to be authorized contains the same active substance(s) as the already authorized use. Some differences in respect of formulation are acceptable, it is up to the Member State to decide on what is a 'comparable' formulation.

2. Does the intended use concern an extension of use which conforms to article 9, i.e. an authorization exists already for this active substance with a comparable formulation?

'Conforms to' article 9' means here: the minor use extension concerns an active substance which will probably or has already been placed on Annex 1. This article 9 requirement implies that the active substance of the intended use should already have an authorization in this country (or it may be in the review phase). Also the plant protection product should already have an authorization, i.e. a plant protection product with a comparable formulation. Furthermore this intended use should be minor in nature according to article 9(1). Also see the introduction for more information on Article 9.

3. Has the active substance been included in Annex 1?

4. Is it clear that the active substance will not be placed on Annex 1 or is it known that the chemical company will not defend the active substance for placement on Annex 1?

The starting point here is that when an active substance has been placed on Annex 1 the evaluation of data of the intended use may be easier as the underlying data of the extended, already authorized use are well defined. As the evaluation of active substances for Annex 1 will take many years we

consider here both the active substances which have been placed already and the substances which will certainly or probably be defended by industry.

Those active substances which will certainly not be applied for an Annex 1 evaluation nor will be defended, will not be considered and thus mutual recognition will not be possible. Those uses which have been excluded from inclusion during the Annex 1 procedure will also not be considered. Thus when investigating the 'chances' of an active substance being supported proper communications with the chemical companies are essential.

5. *Is an assessment on residue aspects required for the intended use?*

This question refers to the need for residue data. In case the application occurs in a crop which is partly or completely, directly or indirectly consumed the evaluator has to go through Key 2 ('Residue data: products of plant origin'), i.e. when the application concerns a crop which is partly or wholly intended for human or animal consumption. An example of indirect consumption is milk consumption by man which may contain residues of pesticides when cereals have been treated by chemicals and the straw has been fed to cattle. The use of Key 2 is not necessary when dealing with those crops which are not grown for consumption.

This Key 2 is also not required when dealing with an active substance which has been placed on Annex 1 (with an evaluation of the authorized use during the process of drafting a review report on this active substance) and when the already authorized and the intended use have the same agricultural, plant health and environmental (including climatic) conditions relevant to the uses concerned. These conditions include the patterns of use.

6. *Is an assessment on worker protection required for the intended use?*

This question refers to the need for worker protection data. If the answer is 'no' the use of Key 3 ('Worker protection') will not be necessary. This will be the case when the active substance has been placed on Annex 1 and when the agricultural, plant health and environmental (including climatic) conditions (of the two countries involved) relevant to the use of the product concerned are comparable, including the patterns of use.

7. *Is an assessment on environmental aspects required for the intended use?*

This question refers to the need for data on environmental aspects. If the answer is 'no' the use of Key 4 ('Environment') will not be necessary. This will be the case when the active substance has been placed on Annex 1 and when the agricultural, plant health and environmental (including climatic) conditions (of the two countries involved) relevant to the use of the product concerned are comparable, including the patterns of use.

8. *Is an efficacy assessment required for the intended use?*

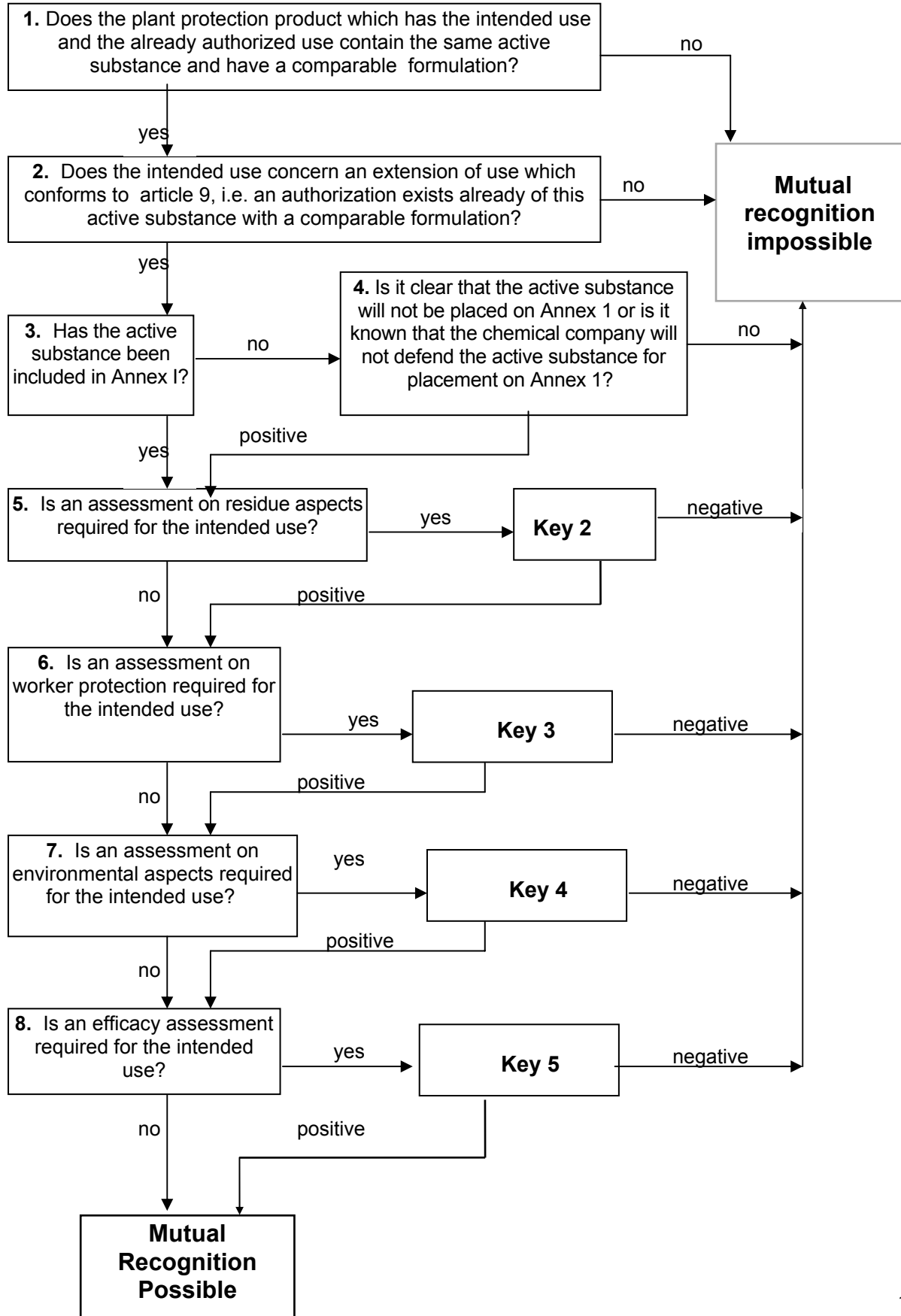
The question whether efficacy data are required should be answered by the DNA as article 9 of Directive 91/414 does not include assessment of efficacy as a prerequisite. If the DNA asks for an efficacy evaluation it might be possible to recognise the efficacy evaluation of the already authorized use. Therefore the agricultural (including patterns of use), plant health and environmental (including climatic) conditions relevant to the use of the product concerned should be comparable.

These conditions thus include the crop, crop destination and target organism(s), which should be the same or comparable. The crop should be defined on the agricultural level rather than on the taxonomic level since botanical species may contain rather different crops. On the variety level crops do not need to be identical, but in some cases, e.g. herbicides, caution may be necessary. In that case additional evaluation for phytotoxicity may be necessary.

In those cases where the DNA asks for a detailed evaluation and/or when the above mentioned conditions are not comparable, Key 5 should be chosen.

2.3 Flowchart 1 of Key 1

'Mutual Recognition: no additional evaluation required'



3. Key 2 Residue data: products of plant origin

3.1 Key 2

Please read the general introduction and the explanation of the questions in 3.2.

A. General

1. Is there any acceptable reason not to require residue data because it can be expected that residues will be below limit of determination?
yes **continue Key 1, no 6**
no 2
2. Has the active substance been placed on Annex 1?
yes4 (B)
no 3
3. Has the active substance been included in the systematic of the residue harmonisation (directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC)?
yes9 (C)
no 14 (D)

B. Active substance has been included in Annex 1

4. Has a comparable type of application of the active substance been excluded in the overall conclusion in the review report?
yes **mutual recognition not possible**
no 5
5. Are sufficient data available to evaluate the intended use?
yes 8
no 6
6. Is extrapolation possible in principle from another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?
yes 7
no **mutual recognition not possible**
7. Are data available which make it possible to evaluate the intended use?
yes8
no **mutual recognition not possible**
8. Is establishment of a MRL possible?
yes, establish MRL **continue Key 1, no 6**
no **mutual recognition not possible**

C. Active substance has not been included in Annex 1; has been included in the directives of the residue harmonisation

9. Has an MRL been established according to the systematic of the residue harmonisation (directives, see question 3) which can be taken over to the intended use?
yes **continue key 1, no 6**
no 10
10. Are sufficient data available to evaluate the intended use
yes 13
no 11

11. Is extrapolation possible in principle from a another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?
 yes 12
 no **mutual recognition not possible**
12. Are data available which make it possible to evaluate the intended use?
 yes 13
 no **mutual recognition not possible**
13. Is establishment of a MRL possible?
 yes, establish MRL **continue Key 1, no 6**
 no **mutual recognition not possible**

D. Active substance has not been included in Annex 1 nor in the directives of the residue harmonisation

14. Does a Codex CXL exist for the intended use?
 yes 15
 no 16
15. Have the underlying data (for establishment of the CXL for the intended use) been generated under comparable conditions of use?
 yes 23
 no 16
16. Is extrapolation possible in principle from another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?
 yes 17
 no 19
17. Does a Codex CXL exist for this “another crop” from which the minor use might be extrapolated?
 yes 18
 no 20
18. Have the underlying data (for establishment of this “another crop” CXL) been generated under comparable conditions of use?
 yes 23
 no 20
19. Does a national MRL exist for the intended use in a Member State?
 yes 22
 no **mutual recognition not possible**
20. Does a national MRL exist for the intended use in a Member State?
 yes 22
 no 21
21. Does a national MRL exist for the major crop application in a Member State?
 yes 22
 no **mutual recognition not possible**
22. Are data available which make it possible to evaluate the intended use?
 yes 23
 no **mutual recognition not possible**
23. Is establishment of a MRL possible?
 yes, establish MRL **Continue Key 1, no 6**
 no **mutual recognition not possible**

3.2 General introduction and explanation of the questions of key 2

This key clarifies the process of evaluation of residue data in the authorization procedure. The system described considers different situations concerning the MRL status of the active substance when applying for voluntary mutual recognition:

- the active substance has been placed on Annex 1;
- the active substance has not been placed on Annex 1 but has been included in the directives of the residue harmonisation;
- the active substance has not been placed on Annex 1 nor in the directives of the residue harmonisation.

Every situation requires another procedure to obtain a MRL for the intended use. Different possibilities to obtain a MRL can be distinguished, related to these situations. When the active substance involved has been included in Annex 1 and if extrapolation of data is possible (also regarding the comparability of the relevant conditions) no additional data will be required.

In case no European harmonisation of the required residue data has taken place yet other data can be used, i.e. data accepted by the Codex Alimentarius. These data may be suitable for extrapolation and will likely be accepted in the Annex 1 regime in future. If these data are not available or usable national data may possibly be used in the process of mutual recognition.

It should be emphasised that the data to be evaluated may greatly differ. When dealing with national MRL's it may happen that almost all data may need further evaluation while when dealing with an Annex 1 based MRL (MRL of a active substance of a certain crop placed on Annex 1) almost all data have been evaluated already and only a limited amount of additional data may need further evaluation.

Some countries require the evaluations and/or data of the other Member States to establish an MRL. Only when recent evaluations and adequate risk assessments are available it will not always be necessary to provide the trial data.

Explanation for each question

A. General

1. *Is there any acceptable reason not to require residue data because it can be expected that residues will be below limit of determination?*

In some cases the occurrence of residues will be most unlikely or negligible according to the internationally accepted views (for instance when dealing with some pre-emergence herbicides). No residues will be expected: the MRL will be below limit of determination (LOD). Member States may decide for these cases not to require residue data and a residue evaluation will not be necessary. In this case the evaluation should proceed in Key 1.

2. *Has the active substance been placed on Annex 1?*

In the case where the active substance has been placed on Annex 1 with a comparable pattern of use (for instance application rate, time and frequency of application, pre-harvest interval) extrapolation may be a possibility. Therefore it is necessary that the major crop from which minor use will be extrapolated has an authorization in a Member State with a harmonised MRL. All agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product should be comparable. These criteria will be treated in table B.

3. *Has the active substance been included in the systematic of the residue harmonisation (directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC)?*

In the case where the active substance has not been placed on Annex 1 (yet) mutual recognition and extrapolation may be possible. In many cases European MRL's exist for major uses of the active substance concerned. When the active substance has been placed on the residue directives a MRL may exist for the minor crop already and if not extrapolation may be possible from a major crop. When these situations do not occur a Codex CXL may exist which may be used.

B. Active substance has been included in Annex 1

4. *Has a comparable type of application of the active substance been excluded in the overall conclusion in the review report?*

The framework of the overall conclusion in the review report indicates which uses are not connected to placement of an active substance in Annex 1. If the type of application of the intended use is excluded no authorization is allowed.

5. *Are sufficient data available to evaluate the intended use?*

It may occur that enough data are available for the establishment of a MRL for the intended use. This possibility includes the situation that an European MRL has already been established for this use. It should be taken into account that the underlying data have been generated under official research standards (at least GEP for minor uses) and the conditions of use (between the region where the data come from and the region where the data are meant for) should be comparable. These conditions concern agricultural, plant health and environmental (including climatic) conditions. Of course the pattern of use is important (see Key 1 for a definition), including the pre-harvest interval.

6. *Is extrapolation possible in principle from another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?*

Document 7525/VI/95, Appendix D presents clear guidance for extrapolation of residue data from crop to crop. It gives an overview of the possibilities of extrapolation from major to minor crops with the number of trials necessary for extrapolation. When the answer to this question is 'no' mutual recognition is not possible.

7. *Are data available which make it possible to evaluate the intended use?*

First requirement is of course the availability of data. Furthermore the data must be generated under comparable agricultural, plant health and environmental (including climatic) conditions, in order to be valid. If data are only partly comparable the unsuitable data should be removed after which a judgement is possible or advice is given to generate additional (new) data.

Data must refer to a comparable pattern of use, see the explanatory text of Key 1 for a definition. Here it includes the pre-harvest interval. Individual differences for the factors mentioned may vary with approximately 25% as a maximum in one factor, but a variation of all factors towards intensification of risk with 25% each is certainly not acceptable. If the pattern of use in the source country differs too much suitable additional data must be available. See also the explanatory text of question 5 on data requirements.

8. *Is establishment of a MRL possible?*

Based on the available data (accepted, extrapolated and evaluated) a risk assessment should be performed after which a MRL can be established. Consequently the residue directive should be adapted. Establishment of a MRL is only possible when the expected intake of the active substance calculated with the European diet resulting from all uses remains below the ADI and acute RfD (reference dose). If risk is acceptable continue with the general evaluation in Key 1, question 6. If establishment of a MRL is not possible, or if the national diet does not allow more use of the active substance concerned the evaluation will end here and recognition of the authorization cannot be advised.

C. Active substance has not been included in Annex 1; has been included in the directives of the residue harmonisation

9. *Has an MRL been established according to the systematic of the residue harmonisation (directives, see question 3) which can be taken over to the intended use?*

It may be possible that a MRL already exists for the crop of the intended use. If this is the case, the DNA should always check whether the basis for this MRL can be used to recognize the intended use at national level.

10. Are sufficient data available to evaluate the intended use?

It may be possible that additional data are available which make it possible to establish a MRL for the intended use. Of course the proposition of the MRL should happen according the systematic of the residue harmonisation.

11. Is extrapolation possible in principle from another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?

See explanation question 6.

12. Are data available which make it possible to evaluate the intended use?

See explanation question 7. Of course the MRL should be established according the systematic of the residue harmonisation.

13. Is establishment of a MRL possible?

Based on the available data (accepted, extrapolated or evaluated) a risk assessment should be performed after which a MRL can be established. Establishment of a MRL is only possible when the expected intake of the active substance calculated with the European diet resulting from all uses remains below the ADI and acute RfD (reference dose). If risk is acceptable continue with the general evaluation in Key 1, question 6. If establishment of a MRL is not possible, or if the national diet does not allow more use of the active substance concerned the evaluation will end here and recognition of the authorization cannot be advised. When a MRL has been proposed the residue Directive has to be amended.

D. Active substance has not been included in Annex 1 nor in the directives of the residue harmonisation

14. Does a Codex CXL exist for the intended use?

In a number of cases a Codex MRL may exist for the minor crop. This MRL is not automatically acceptable for the European Union and thus should be evaluated at this level.

15. Have the underlying data (for establishment of the CXL of the intended use) been generated under comparable conditions of use?

See explanation question 7. If the conditions are comparable a national MRL can be established.

16. Is extrapolation possible in principle from another crop according to the extrapolation guidance document 7525/VI/95 rev. 5, Appendix D?

See explanation question 6.

17. Does a Codex CXL exist for this "another crop" from which the minor use might be extrapolated?

In a number of cases a Codex MRL may exist. This MRL is not automatically acceptable for the European Union and thus should be evaluated at this level.

18. Have the underlying data (for establishment of this "another crop" CXL) been generated under comparable conditions of use?

See explanation question 7.

19. Does a national MRL exist for the intended minor use in a Member State?

In some cases, especially for old active substances, only national MRL's exist. National MRL's are MRL's for products for which no European harmonised MRL has been established yet. These values may be scientifically perfectly sound and thus be extrapolated to other Member States and the European level without problem. This however will not always be the case. We therefore suggest that this type of national authorization demands a full evaluation in the process of mutual recognition. In doing so care should be taken not to repeat this full evaluation in all Member States and accept former evaluations of other Member States.

20. Does a national MRL exist for the intended minor use in a Member State?

See explanation question 19.

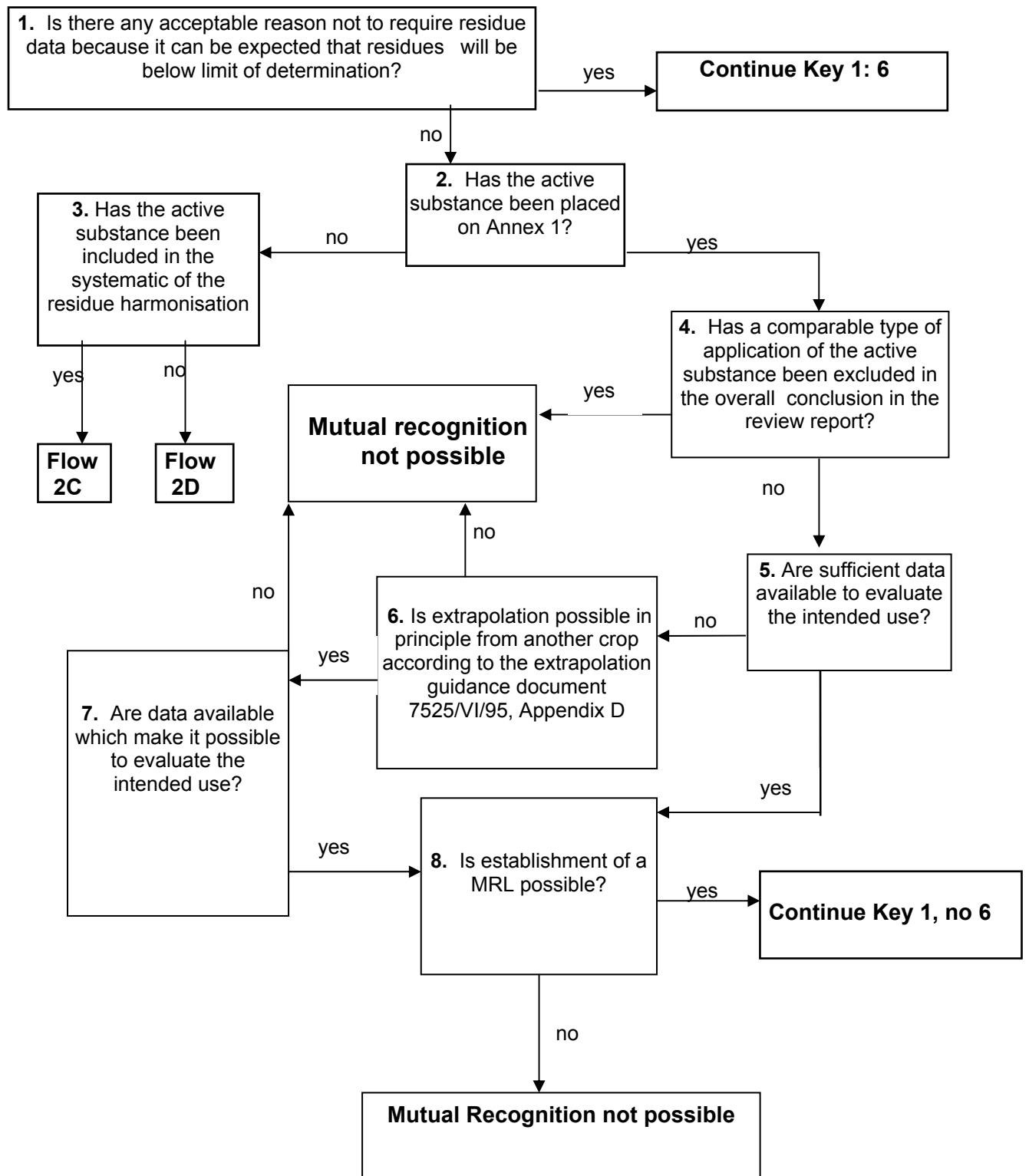
21.*Does a national MRL exist for the major crop application in a Member State?*
See explanation question 19.

22.*Are data available which make it possible to evaluate the intended use?*
See explanation question 7.

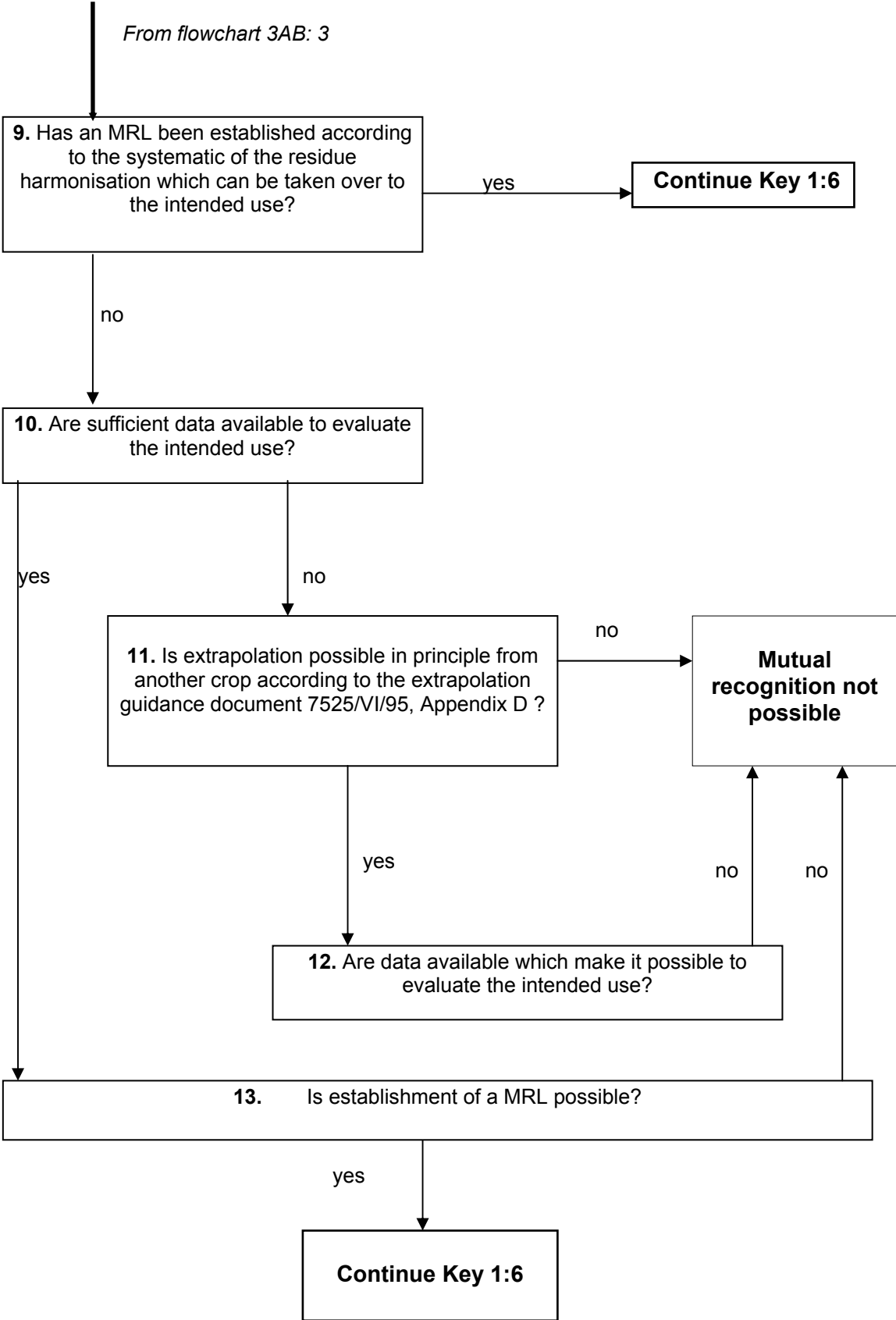
23.*Is establishment of a MRL possible?*

Based on the available data (accepted, extrapolated or evaluated) a national risk evaluation should be performed after which a national MRL can be established. Establishment of a MRL is only possible when expected intake of the active substance with the national diet resulting from all uses remains below the ADI and acute RfD (reference dose). If risk is acceptable continue with the general evaluation in Key 1, question 6. If establishment of a MRL is not possible, or if the national diet does not allow more use of the active substance concerned the evaluation will end here and mutual recognition is not possible.

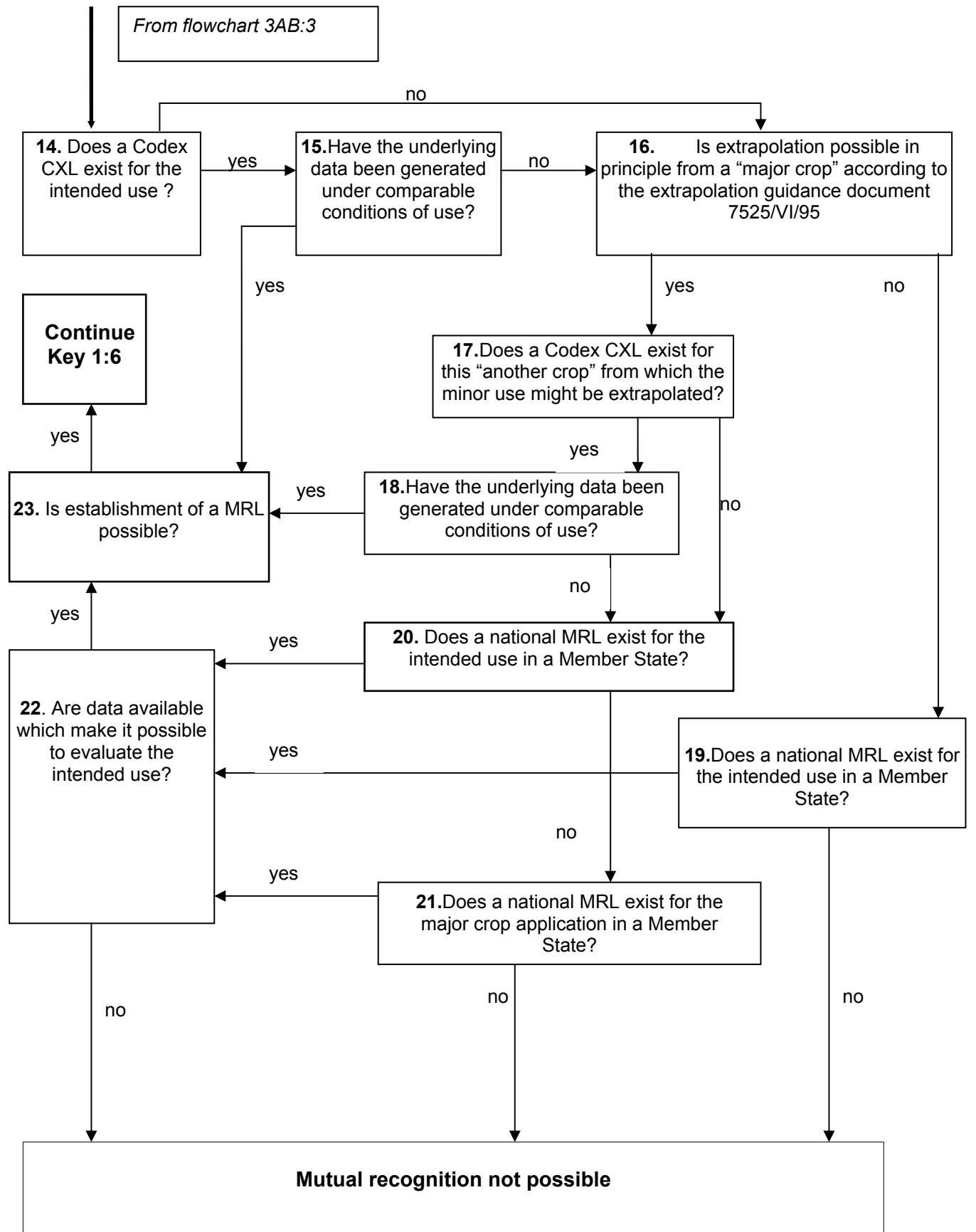
3.3 Flowchart 2 A, B of key 2 'Residue'



Flowchart 2 C of key 2 'Residue'



Flowchart 2 D of key 2 'Residue'



4. Key 3 Worker Protection

4.1 Key 3

Please read the general introduction and the explanation of the questions in 4.2.

1. Does the pattern of use of the intended use differ significantly from the already authorized use(s) in the Member State of intended use in a way as to likely cause a higher worker exposure either in total, or via any single route, and hence a higher workers risk?
yes 2
no **continue Key 1, no 7**

2. Does the pattern of use of the intended use differ significantly from the already authorized use in the source country in a way as to likely cause a higher worker's risk?
yes 3
no **continue Key 1, no 7**

3. Are any data available **and** is risk evaluation supporting the view that the higher exposure is acceptable?
yes **continue Key 1, no 7**
no **mutual recognition not possible**

4.2 General introduction and explanation of the questions of key 3

The general idea underlying this key is the notion that operator, worker and bystander risk (referred to as worker only, though all three are meant) is in principle not different as long as a similar exposure to a same active substance is concerned.

Important in this concept is the notion that the original risk evaluation is complete and up to date and that patterns of use and their evaluation are comparable. It is not unreasonable to expect that with some old active substances this may currently not be the case. If scientific defensible extrapolations are impossible additional data and their evaluation will be required.

Basic to all risk evaluation is besides the general toxicological properties of the active substance, the pattern of use of the product on which the risk evaluation is based. The general toxicological properties are known and do not change from application to application. Patterns of use however vary, and extrapolation of an authorization to another country may often mean small or large changes in pattern of use. A change in pattern of use may mean a difference to worker protection. Worker's exposure may be estimated by the use of the draft EUROPOEM models which are being validated currently.

Within the pattern of use differences in machinery are quite important. For example conventional sprays using vehicle mounted equipment versus hand-held equipment. Different worker conditions (safety clothing etc.), different application types (e.g. soil incorporated, leaf sprays, product treatments) may also lead to differences in worker protection risks. If there is no real difference, or the intended use is fundamentally more safe than the use the risk evaluation is based on in the recognising country a detailed evaluation may be not necessary.

It should be realised by applicants that voluntary mutual recognition is likely to proceed easily as long as extrapolation without additional information is possible. This will be the case a long as patterns of use and other relevant application conditions remain comparable to the patterns of use of the existing major uses.

Explanation for each question

1. *Does the pattern of use of the intended use differ significantly from the already authorized use(s) in the Member State of intended use in a way as to likely cause a higher worker exposure either in total, or via any single route, and hence a higher worker's risk?*

For voluntary mutual recognition of specific (minor) uses only active substances will be considered which have already been authorized for other (major) uses in the recognising state. This means that normally a risk evaluation of worker protection is available in the Member State of intended use. In most cases this risk evaluation will be better applicable to the intended use than the risk evaluation belonging to the already authorized use in the source country. This is because the first one (already existent in the recognising Member State) will take into account the specific risk factors of the recognising country and the second may only refer to specific conditions in the source country and to the specific risks connected to the already authorized use. Therefore: if possible use the existing risk estimate of the recognising country. If this estimate does not cover the intended authorized use the risk evaluation of the source country should be employed, if possible, in question 2.

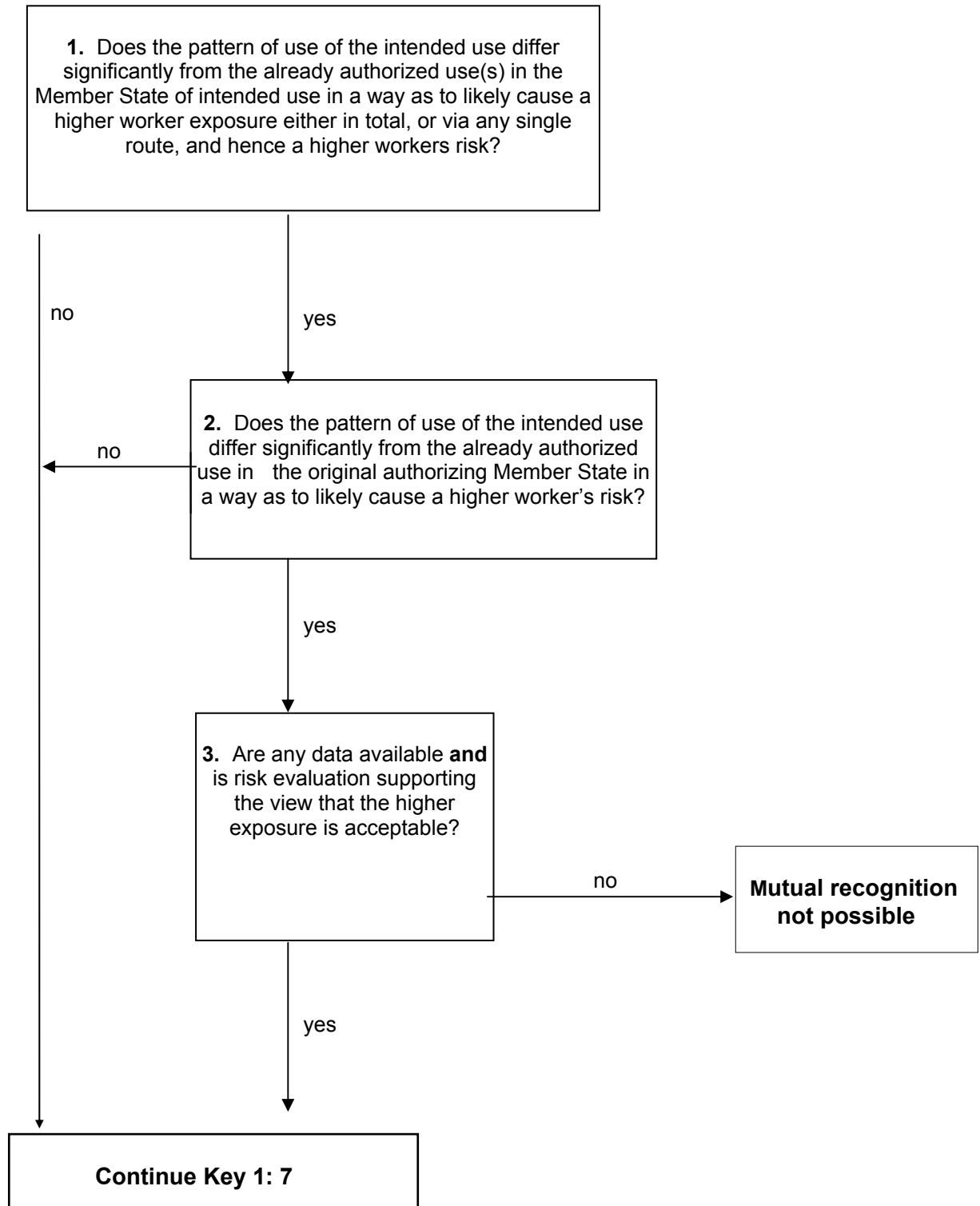
2. *Does the pattern of use of the intended use differ significantly from the already authorized use in the source country in a way as to cause a higher worker's risk?*

The intended use will normally not lead to higher worker exposure if the pattern of use and the application conditions remain comparable. But average application conditions, like weather, might differ in such a way as to cause a significantly increased risk, and so may different use contexts (such as the degree of mechanisation and hence the presence of workers in the field shortly after application). This applies as well to re-entry periods etc. Land use may influence field size and farm spatial structure and hence bystander risk: small fields in densely populated areas may create different risks for bystanders compared to large fields in sparsely populated countries. Presence or absence of wide unsprayed field boundaries creates similar differences to bystander risk. If patterns of use and/or other application conditions are different additional data and a risk analysis will be needed.

3. Are any data available *and* is risk evaluation supporting the view that the higher exposure is acceptable?

In case risk is estimated on basis of a comparison of the patterns of use to be significantly higher in the recognising state a new risk evaluation must be made for which additional data might be needed. This is also necessary if the evaluation criteria of the two states differ in a way that a higher risk is accepted in the source country of the already authorized use. In case the original data in combination with the evaluation of additional data supports the conclusion that the risk to workers is acceptable one should continue with Key 1 no 7. If worker's risk is not acceptable the process of mutual recognition ends here with a negative advice.

4.3 Flowchart 3 of key 3 'Worker protection'



5. Key 4 Environment

5.1 Key 4

Please read the general introduction and the explanation of the questions in 5.2.

1. Is it possible to use the 'environment' dossier of the already authorized use in the recognising country for the authorization of the intended use?
yes **mutual recognition possible**
no 2
2. Is the pattern of use of the already authorized use in the source country comparable to the conditions of the intended use in the recognising country?
yes
3
no
4
3. Are the agricultural, plant health and environmental (including climatic) conditions of the already authorized use comparable to the conditions of the intended use?
yes **mutual recognition possible**
no 4
4. Has the active substance of the intended use been placed on Annex 1?
yes 9
no 5
5. Have endpoints for the environmental parameters of concern been proposed within the EU?
yes
9
no 6
6. Are additional data available on environmental aspects in the recognising country on behalf of this intended use?
yes
9
no 7
7. Does the dossier of the authorized use in the source country contain additional information on environmental aspects to be used by the recognising country?
yes 9
no 8
8. Are data available on environmental aspects in the source country on behalf of this intended use in the recognising country?
yes 9
no **mutual recognition not possible**
9. Are higher environmental risks to be expected from the intended use in the recognising country?
yes 10
no **mutual recognition possible**
10. Does a higher risk mean that environmental decision criteria set within the Uniform Principles are exceeded?
no **continue key 1, no 8**
yes **mutual recognition not possible**

5.2 General introduction and explanation of the questions of key 4

Within an evaluation of environmental aspects three steps can be distinguished. First, assessment of the exposure of the environmental compartments water, soil (including ground water) and air. Secondly, the determination of the so called endpoints which are values for environmental parameters (LC50, LD50 and NOEC values representing toxicity to organisms like algae, fish, daphnia, birds, bees, etc.; and physical chemical parameters such as data on adsorption/desorption and others). The third step is the evaluation of hazards and risks. For the steps 2 and 3 the endpoints of step 1 are used, and matched with data on the proposed use of the pesticide under the relevant conditions of use.

The procedure presented in Figure 2 describes a commonly accepted stepwise approach in hazard/risk assessment on which evaluation of environmental acceptability of plant protection product use should be built.

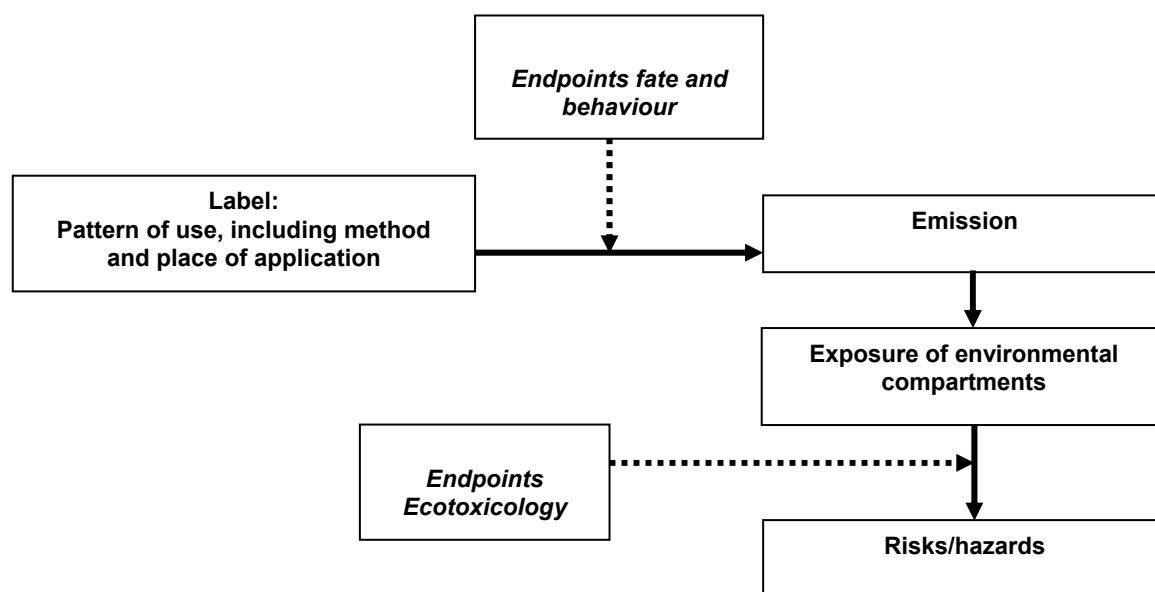


Figure 2. Commonly accepted stepwise approach in conducting hazard/risk assessment.

From Figure 2 it can be seen that the label is the basis for environmental risk assessment. Using endpoints on the fate of behaviour, the pattern of use determines the exposure of environmental compartments. By comparing exposure and ecotoxicity endpoints, risks/hazards can be calculated.

The environmental endpoints (with exclusion of PEC values) will in general not depend on the use of the pesticide in agricultural practice. So, for mutual recognition, a thorough evaluation of all the underlying data on the environmental endpoints is normally not expected to be necessary. This is especially true when the endpoints have already been set within the EU. However, some caution will be necessary since placement in Annex I may refer to only one use of a product which may be extremely different from the use to be recognised in respect of environmental impact. Good knowledge of the Annex I background is therefore indispensable. Where it is known for old products that very deviating systems may have been used in evaluation a more thorough evaluation of underlying data seems appropriate.

From Figure 2 it becomes clear that whenever endpoints on fate, behaviour and ecotoxicology are accepted voluntary mutual recognition is reduced to comparison of exposure. Exposure may differ due to differences in agricultural (including pattern of use), plant health and environmental (including climatic) conditions. Within this procedure it is necessary to consider these potential differences in order to facilitate a decision on mutual recognition.

When differences are distinguished between the authorized use in the source country and the intended use in the recognising country which might lead to higher risks a risk assessment is required. This assessment can range from simple extrapolations to detailed assessment. Again general insights in the risk assessment systems of the source country may be of great help in the acceptance of its evaluation without repeating the total evaluation, even when evaluation systems are not identical.

It is necessary to show for all environmental aspects that under relevant field conditions of use no higher risk resulting from the intended use in comparison to the already authorized use in the recognising country will be expected.

Throughout the key there is the possibility of making a decision based on additional data for those situations where the available dossier is lacking information; or where the available evaluation does not seem to be backed by sufficient or adequate information.

It should be realised by applicants that voluntary mutual recognition is likely to proceed easily as long as extrapolation without additional information is possible. This will be the case as long as patterns of use and other relevant application conditions are comparable to the patterns of use of the existing uses in the recognising country.

Explanation for each question

1. *Is it possible to use the 'environment' dossier of the already authorized use in the recognising country for the authorization of the intended use?*

If the active substance of the intended use is already authorized in the recognising country, the set of environmental endpoints may be complete and of adequate quality to decide on acceptance of the intended use. This may not always be the case, i.e.:

- When additional environmental endpoints need to be considered for the intended use (which were irrelevant to the already authorized use). The existing authorized use may relate to application in glasshouses, while the intended use is meant for field crops and thus additional data of effects on e.g. birds and mammals are required. These may not be available.
- When other emission routes get involved. An example might be the authorized use in a glasshouse while the intended use deals with a field crop; run-off and drift might become relevant then.

2. *Is the pattern of use of the already authorized use in the source country comparable to the conditions of the intended use in the recognising country?*

The pattern of use is the starting point for environmental risk assessment. This implies that a different pattern of use might result in a different outcome of such an assessment. Clearly different dose rates, application frequencies, application times, but also other ways of application of the pesticide could result in higher risks to the environment. In case the pattern of use in the recognising country will be comparable to that of the source country, the assessment of the source country should be acceptable in voluntary mutual recognition, unless the agricultural, plant health and environmental (including climatic) conditions appear not to be comparable.

3. *Are the agricultural, plant health and environmental (including climatic) conditions of the already authorized use comparable to the conditions of the intended use?*

Unless the agricultural, plant health and environmental (including climatic) conditions are not comparable, the risk evaluation of the source country should be recognised by the recognising country without additional evaluation or additional requirements. Within this key deviating environmental conditions have to be considered. Quite a number of possible deviations can be recognised. Examples with respect to ground water might be considerable, deviations in precipitation, ground water levels, or soil types (preferential flow). With respect to aquatic life, there may be considerable deviations in the number and type of waterbodies (width, depth, flowing velocity, macrophyte densities and others).

4. *Has the active substance of the intended use been placed on Annex 1?*

If the active substance has been placed on Annex 1, the environmental **effect** endpoints may be taken on without additional requirements. Effect endpoints do not depend on patterns of use nor agricultural, plant health or environmental (including climate) conditions. In case the pattern of use is comparable (question 2 answered "yes" and the environmental (including climate) conditions are comparable

(question 3 answered “yes”), the environmental fate and behaviour endpoints have to be adopted as well.

5. Have endpoints for the environmental parameters of concern been proposed within the EU?

Between adoption of environmental endpoints within the EU and placement on Annex 1, time elapses. It is not necessary to wait for placement on Annex 1. As soon as environmental endpoints have been proposed in the EU, these endpoints should be taken on.

6. Are additional data available on environmental aspects in the recognising country on behalf of this intended use?

When environmental endpoints have not been set within the EU yet (questions 4 and 5 answered “no”) and when it is not possible to use the dossier of the already authorized use in the recognising country (question 1 answered “no”), the next step is to investigate whether additional information can be used for the determination of the environmental endpoints. This additional information might come from public literature, databases around the world, the use of QSAR’s, the use of data from chemical closely related analogues, data from studies at national research institutes, etc. These data sources might provide useful data of acceptable quality.

7. Does the dossier of the authorized use in the source country contain additional information on environmental aspects to be used by the recognising country ?

The dossier of the source country is studied. It might contain data on environmental **effect** endpoints, as well as the environmental **fate and behaviour** endpoints to assess PEC values in environmental compartments, necessary to decide on acceptance of the intended use in the recognising country. PEC values set by the source country should be accepted by the recognising country, when the pattern of use as well as the environmental conditions are comparable (questions 2 and 3 answered “yes”). If these data have been qualified as insufficient they may be taken over as provisional endpoints with conditions for extension. When the dossier of the source country does not contain the necessary data on environmental endpoints necessary to decide on the intended use, the next stage of the scheme is reached.

8. Are data available on environmental aspects in the source country on behalf of this intended use in the recognising country?

See explanation question 6.

9. Are higher environmental risks to be expected from the intended use in the recognising country?

Taking the proposed pattern of use and using endpoints on fate and behaviour, predicted environmental concentrations in the different environmental compartments are calculated. These are compared with endpoints on toxicity to organisms in the environment to assess whether risks exist and to what extent. Higher risks deal in general with a higher degree of adverse effects. Ground water and surface water are exceptions because higher concentrations in itself are considered to be the risk.

When the pattern of use as well as the environmental conditions are not comparable (questions 2 and 3 answered “no”), environmental risks/hazards have to be assessed. This is an easy job in case differences in the pattern of use and the environmental conditions clearly lead to lower risks. In that case mutual recognition is possible. In all other cases a risk assessment, based on the values for relevant environmental endpoints, is required for a proper decision on acceptability of environmental risks. Higher risks may result from differences between the existing patterns of use, i.e.:

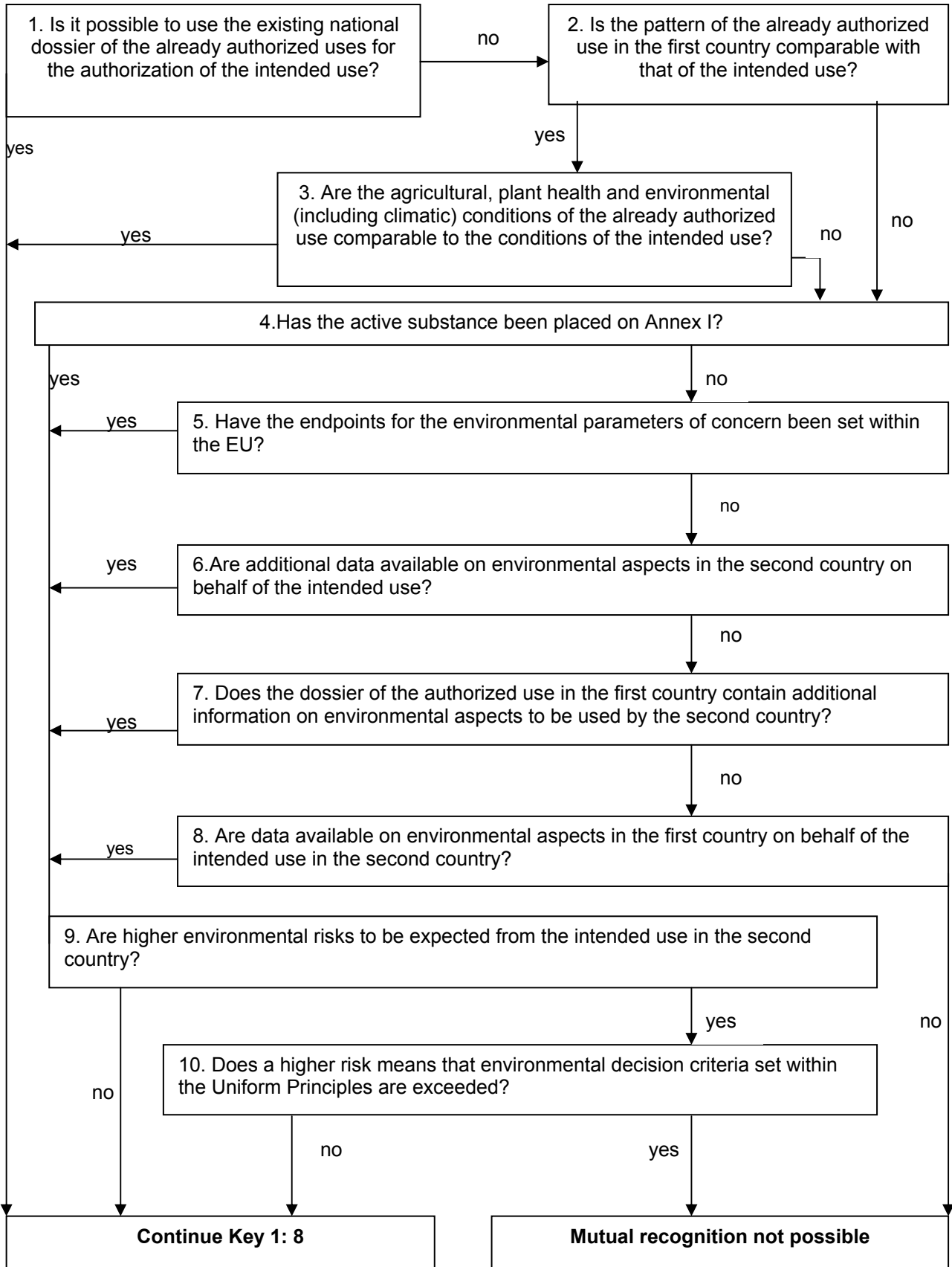
- the differences in application method (crop treatment, row treatment, soil treatment, flow system, drip irrigation, etc.);
- differences in place of treatment (in the glasshouse, outdoors, in closed areas);
- differences in other pattern of use aspects (dosage, interval, frequency, timing).

Higher risks may also result from differences in environmental conditions (like temperatures, precipitation, characteristics of waterways, etc.) between the source country and your recognising country. This risk assessment checks whether these differences result in a higher risk to an extent that is considered to be unacceptable to the environment. If this is the case mutual recognition is not possible.

10. Does a higher risk mean that environmental decision criteria set within the Uniform Principles are exceeded?

As soon as higher risks occur no mutual recognition is possible. In all other cases the evaluation may continue with Key 1, no 8.

5.3 Flowchart 4 of key 4 'Environment'



6. Key 5 Efficacy

6.1 Key 5

Please read the general introduction and the explanation of the questions in 6.2.

1. Does the intended use refer to the same crop(s) and if so, to the same product destination as in the already authorized use?
yes 2
no answer question 9 and continue if possible, with 2
2. Is the intended use meant for control of the same target organism(s) as in the already authorized use?
yes 3
no answer question 9 and continue if possible with 3
3. Are dose-rate, timing of the application, application technology and frequency of application the same as in the original pattern of use of the already authorized use?
yes 4
no answer question 9 and continue if possible with 4
4. Are negative efficacy effects to be expected in the recognising country due to different agricultural, plant health and environmental (including climatic) conditions compared to those for the already authorized use?
yes answer question 9 and continue if possible with 5
no 5
5. Do you expect any negative effect on succeeding crops?
yes answer question 9 and continue if possible with 6
no 6
6. Is impact on adjacent crops known to occur or otherwise to be expected, and are sensitive crops normally grown in the neighbourhood of the crop to be treated?
yes, if necessary **mutual recognition not possible**
yes, if possible **warning on label** and continue with 7
no 7
7. Is relevant phytotoxicity known to occur and how does it influence the crop or the resulting plant product?
yes, visual influence only 8
yes, reduction of yield answer question 9 and continue if possible with 8
yes, adverse effect on quality..... answer question 9 and continue if possible with 8
no 8
8. Does resistance risk evaluation indicate high, or very high risk on the occurrence of the development of resistance?
yes **formulate resistance management strategy on label; mutual recognition possible**

no **mutual recognition possible**

9. Is any data, knowledge or experience available, including bridging studies and extrapolations and is evaluation of these data supporting the view that authorization of the intended use in the recognising country is acceptable

yes **continue this key**
with the question following the one which led to
question 9; coming from 7: **mutual recognition possible**

no **mutual recognition not possible**

6.2 General introduction and explanation of the questions of key 5

Key 5 examines efficacy aspects of authorization which may be needed, though Directive 91/414, article 9, states that efficacy data are not needed per se in case of an extension of an authorization for minor uses. It is entirely up to the Member State to decide which information is necessary.

The flowchart has a rigid appearance at first glance, but provides flexibility through the explanation and interpretation of the questions. **Expert judgement** is needed to go through the key and it should be realised that in the key the conclusion “unacceptable” for one question automatically produces a negative decision on mutual recognition as a whole. Therefore the evaluator should always bear in mind the degree of relevancy of the question to authorization as a whole. In many cases negative points may be sufficiently covered by warnings or statements on labels which allow acceptance of a weak point in the pesticides performance as pinpointed with the key. The evaluator should also be aware of the total efficacy picture emerging as a combination of a number of minor negative details may produce as a whole an unacceptable profile of an intended pattern of use.

In this key minor or major adaptations from the already authorized use are to be accounted for. Additional data, consisting of bridging studies, field studies or field evidence and extrapolation of data, including those from open literature, may be needed for evaluation and subsequent authorization. Both the absence of data (in the sense of non-existing or not available) and a negative outcome of the evaluation lead to a negative decision on mutual recognition. However, required data may be produced by applicants for registration and their evaluation may provide a positive outcome at a later date.

Explanation for each question

1. *Does the intended use refer to the same crop(s) and if so, to the same product destination as in the already authorized use?*

This question is important to efficacy because mutual recognition is related to identical pesticide patterns of use. If the crop is not identical at least extrapolation will be necessary. We may point here to the very wide varieties within botanical species grown for the same or very different purposes, and to the fact that under one heading, such as salad, more botanical species may be found within Europe. In case the already authorized use refers to a crop group such as “cabbage” the intended use must refer to the same crops. In some cases additional data need to be submitted and evaluated. This question needs to be answered on the agricultural level rather than on the taxonomic level since botanical species may contain rather different crops. On the variety level crops do not need to be identical, but in some cases, e.g. herbicides, caution may be necessary.

If the destination, or use of the crop, is different the possibilities for pesticide use may be affected. For instance whether carrots are grown as a vegetable for direct consumption, or as a seed crop, will make obvious differences with regard to necessary efficacy and to acceptable soil persistence. Wherever different crop use affects (the demands on) pesticide use evaluation of additional efficacy data may be needed.

2. *Is the intended use meant for control of the same target organism(s) as in the already authorized use?*

Uses of pesticides are developed in relation to the control of specific pests. Efficacy on other pests may be poor. This warrants the requirement of additional data or bridging studies and their evaluation if the intended use relates to a different pest as compared to the already authorized use.

However, in many cases extrapolation from one pest to a (closely) related pest is possible and no additional data are needed.

3. *Are dose-rate, timing of the application, application technology and frequency of the application the same as in the original pattern of use of the already authorized use?*

These four aspects of the pattern of use are together the crucial active parts of any authorization. Any deviation of these aspects may mean differences in respect of selectivity to crop and pest. Any relevant change in these aspects should be accounted for with either a scientific justifiable extrapolation or evaluation of additional new data. The decision on "relevance" is to the Member States.

4. *Are negative efficacy effects to be expected in the recognising country due to different agricultural, plant health and environmental (including climatic) conditions compared to those for the already authorized use?*

In some cases (e.g. clearly different rotations, a clearly higher disease pressure, very different soil conditions or very different crop husbandry systems such as hydroponics or different climate) the occurrence of negative aspects due to these conditions cannot sufficiently be ruled out. In that case additional data need to be evaluated or expert judgement extrapolations be made.

5. *Do you expect any negative effect on succeeding crops?*

In many cases the intended use will take place in crop rotations which are different from the ones usually encountered in the country of already authorized use. In case of persistent active substances, such as some soil acting herbicides, effects on succeeding crops are likely. In some cases a warning on the label will suffice, in others the intended use does not fit into the local crop rotations and a negative advice on mutual recognition should be given. Currently there is no accepted European guidance system yet, but in most cases the draft guidance "impact on succeeding crops" may be helpful. Additional data, bridging studies or extrapolations may be useful.

6. *Is impact on adjacent crops known to occur or otherwise to be expected, and are sensitive crops normally grown in the neighbourhood of the crop to be treated?*

Especially certain herbicides having a high vapour pressure may cause extensive damage to nearby crops. Expectations can be based on available data on vapour pressure, on crop/weed sensitivity to the active substance, on local cropping structure and on information on the occurrence of damage to adjacent fields. If a risk on damage is clearly present a warning on the label (e.g. "do not apply within 200m from a cucurbit crop") will in most cases suffice. In extreme cases risk mitigation is not possible and mutual recognition is not advisable for this reason. Additional information such as field studies etc. are not required because there are no accepted methods for field studies on vapour (drift) damage, but circumstantial evidence on occurrence or absence of vapour drift may be accepted.

7. *Is relevant phytotoxicity known to occur and how does it influence the crop or the resulting plant product?*

- phytotoxicity is not known

The occurrence of phytotoxicity meant in this question is strictly limited to the treated crop only.

"Phytotoxicity" in this question should be taken as any negative effect of the plant production product on the crop or on the plant product.

- visual influence only

Many treatments produce slight symptoms during a short period after treatment without any measurable after-effects. These symptoms disappear after a short while. They are normally of no consequence. If there is good reason to suspect more prolonged effects additional data may be needed.

-reduction of yield

If this effect is known to occur occasionally in the source country it is in most cases advisable to require additional yield data for the recognising country. The need for additional data is judged to be larger if the geographical distance between already and intended use increases and also as the agricultural differences between the two systems increase.

- *adverse effects on quality*

The same reasoning as for yield applies here. Adverse effects on quality may also show as a visible spray deposit, which is undesirable in many ornamentals. Other negative quality effects may be on germination (seeds) smell, taste or keeping quality of the product.

8. *Does resistance risk evaluation indicate high or very high risk on the occurrence of the development of resistance?*

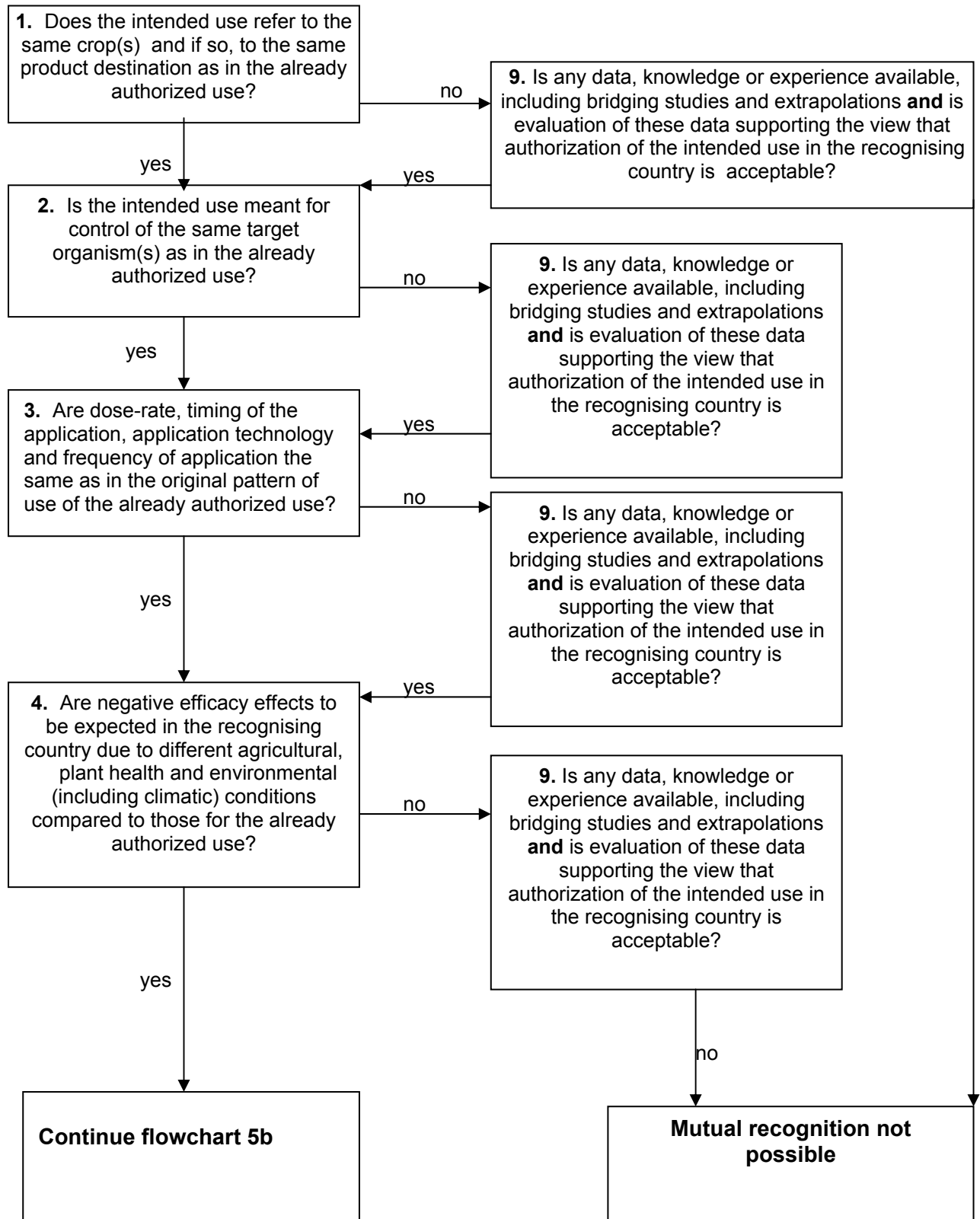
The EPPO guidance document for resistance risk evaluation may be of use here. If risk estimation of the intended use indicates elevated levels of risk on resistance the applicant should formulate a resistance avoidance strategy. This strategy should carry a lower risk on resistance development, and should be put on the label or in the instructions for use. For minor use it is generally not thought to be necessary to generate new or additional information as high resistance risks are normally tied to large uses and their resulting selection pressures.

9. *Is any data, knowledge or experience available, including bridging studies and extrapolations and is evaluation of these data supporting the view that authorization of the intended use in the recognising country is acceptable?*

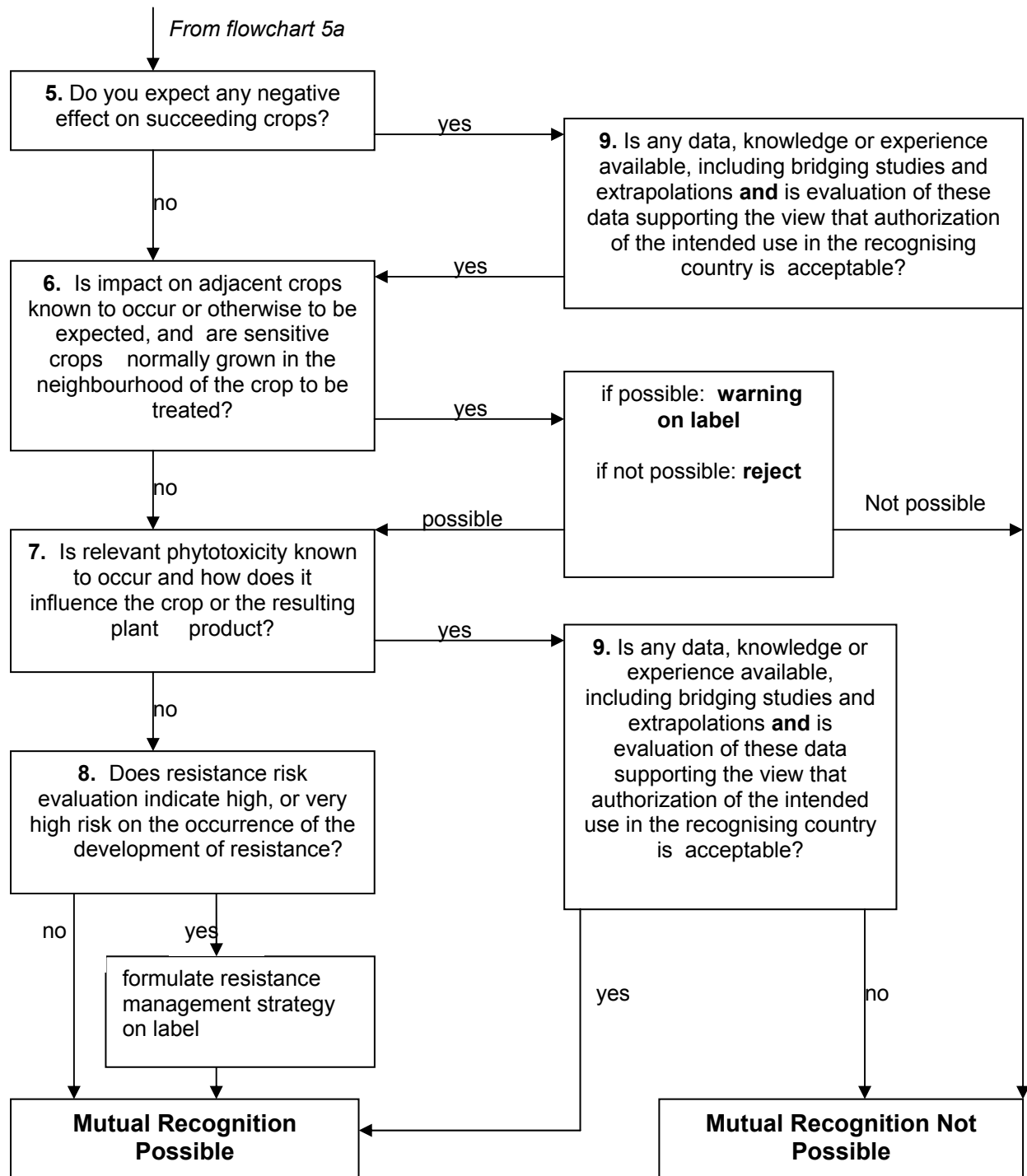
This question follows on most deviations of the already authorized use and ensures that the intended use is supported by sufficient information where necessary. The necessity is decided on by the DNA. Field experience gathered and described in a suitable way is also included in this question. The original dossier does not supply these data, because the question refers to a deviation of use between the authorizations. It is to the applicant to deliver these data, though in particular cases a DNA might help. Absence of data in cases where the local DNA requires data may mean a negative advice on mutual recognition.

Once data have been submitted these additional data will be evaluated by the recognising authority which may result in a positive or negative advice on mutual recognition.

6.3 Flowchart 5 A of key 5 'Efficacy'



Flowchart 5 B of key 5 'Efficacy'



ANNEXES

ANNEX 1

Application Form for Voluntary Mutual Recognition

of an extension of the field of application of an authorized plant protection product

To be completed by the Designated National Authority receiving this form

National registration number:

Date received:

Country where the use will be recognised from (the 'source country'):

Name, address, telephone, telefax and email address of authority and contact point in the above indicated EU Member State (the 'source country'):

Decision on approval:

Date:

Applicant

1. Name and address of the applicant:
2. Name, address, telephone, telefax and email address of contact person:

Identity of the active substance

3. Common name of the active substance(s):

Identity of the plant protection product

	source country	your own country (i.e. the recognising country)
4. Current trade name and approval number		
5. Manufacturer(s) of the plant production product		
6. Type of preparation and concentration(s)		
7. Function		

Use applied for

8. Extension of use applied for:
(provide proposed label attached)

9. Are there already authorised/approved uses of this (or a similar) plant protection product in this country (i.e. in the so called recognising country)?

10. EU Member State of authorization/approval to be recognised:
provide (translated) approved label or official information.

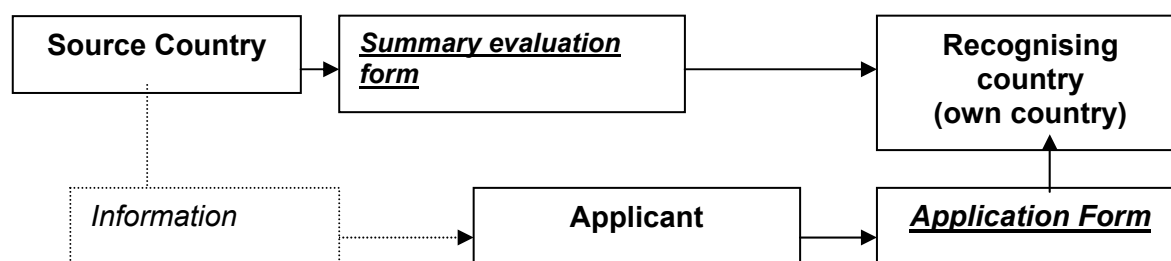
Application Form for Voluntary Mutual Recognition

Explanation

This form will help the applicant, as well as the DNA, in the procedure of voluntary mutual recognition. An application for voluntary mutual recognition asks for a special application form to facilitate the procedure and to make clear to all parties involved how to operate in the procedure. Completing the form is the first step in the process of voluntary mutual recognition.

The purpose of the application form is not to replace the forms which are already used by the Designated National Authorities. This form gives a *listing of characteristics specific to voluntary mutual recognition* which are not provided through the already available forms. This application form for voluntary mutual recognition might in some countries be presented as part of an already existing application form for label extensions. The language of this form is English. As this form has a national purpose only the applicant and DNA should agree upon the language which is required for completing this form. It is essential that the parties involved in a Member State communicate as efficiently as possible.

The position of the application form is illustrated below. In this scheme the applicant is the initiator. The use of the application form is intended as a means of communication between applicant and DNA on a national basis.



The numbering of the form will be followed below in elaborating the questions posed in the form.

Box: 'To be completed by the Designated National Authority receiving this form'

The application form starts with a box to be filled in by the DNA receiving this form. It facilitates the filing of the application in an efficient way and equally the procedure to be followed. Important in the procedure are for instance also the name and contact facilities of a contact person in the DNA of the EU Member State to be contacted (the so called 'source country'). See Annex 3 for a list of the contact points at every Member State.

Applicant

1. Name and address of the applicant

Applications may be submitted by either industry or third parties such as growers or their organizations according to Article 9 of Directive 91/414. It has been stated in this article as follows: "Official or scientific bodies involved in agricultural activities or professional agricultural organizations and professional users...".

2. Name, address, telephone, telefax and email address of contact person

In order to facilitate the communication between the DNA and the applicant, the full name and address and contact facilities of phone, fax and email of a contact person should be provided by the applicant.

Identity of the active substance and the plant protection product

3. Common name of the active substance(s)

As in all official dealings with plant protection products only the internationally officially approved common names should be stated here.

Identity of the plant protection product

4. Current trade name and approval number

The name(s) and number(s) should be provided by the applicant for both the source country and the own recognising country.

5. Manufacturer(s) of the plant protection product.

It should be realised that the manufacturer of the active substance does not need to be the same as the producer of the plant protection product, and that producers may differ between countries.

6. Type of the preparation and concentration(s)

In this question information should be provided on the formulation of the product ; e.g “wetttable powder” or “granulate”, according to GIFAP-terminology. Official codes may be presented as well as the complete composition of the product. One should be aware that information as “powder” or “liquid” is insufficient. In this section the concentration(s) should be presented in either g/kg or g/l active substance.

7. Function

Choose between Acaricide, Fungicide, Growth Regulator, Herbicide, Insecticide etc.

Use applied for

8. Extension of use applied for

Under this heading the proposed label text for your own (recognising) country should be provided as an attachment, or if necessary (such as in the case of off-label approvals) as additional information regarding this proposed use.

9. Are there already authorized/approved uses of this (or similar) plant protection product in this country (i.e. in the so called recognising country)?

This country is the Member State in which the application for extension of use is made. When dealing with voluntary mutual recognition it is required that other uses of the same product (or almost identical products) already exist in this country. The question itself is valuable to the applicant because when he answers here with “no”, he will know that voluntary mutual recognition is not possible and an application will make no sense.

10. EU member State of authorization/approval to be recognised

Under this heading one should mention the Member State (source country) one refers to in the application for voluntary mutual recognition. A copy of the label (or notice of approval) for the authorized/approved use should be added with a translation, if required, or any other EU language to be agreed upon by the local DNA.

ANNEX 2

‘Summary of the national evaluation’

Form for the procedure of Voluntary Mutual Recognition of an extension of the field of application of an authorized plant protection product

To be completed on request by the Designated National Authority of another EU Member State

Neither publications are allowed from a completed form nor can rights be derived from it.

General information

Name of the DNA filling in this form (including the country)

Name, address, telephone, telefax and email address of contact point of the DNA

1. Identity of the active substance(s) and the plant protection product

1.1 Common name of the active substance

1.2 Manufacturer(s) of the active substance(s)

1.3 Specification of purity of the active substance(s)

1.4 Current trade name of the plant protection product

1.5 Manufacturer(s) of the plant protection product

1.6 Type of the preparation and code

1.7 Other relevant information to decide on the comparability of the plant protection product

2. Information on the authorization/approval

- 2.1 Number of the authorization/approval (*national reference number*)
- 2.2 Name and address of authorization/approval holder
- 2.3 Name, address, telephone, telefax and email address of contact person at the company who is the approval holder or applicant
- 2.4 Knowledge or concerns on the withdrawal of the product
- 2.5 Expiry date of the authorization of the product
- 2.6 Type of decision on the use of the plant protection product
- 2.7 Information, if relevant, on the data protection, data ownership and confidentiality of data

3. Pattern of use

- 3.1 Field of use
- 3.2 Details of the use, e.g. types of harmful organism controlled and/or plants or plant products to be protected
- 3.3 (Maximum) application rate
- 3.4 Method of application
- 3.5 (Maximum) number and timing of applications
- 3.6 Proposed instructions for use (enclose national label)
- 3.7 Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used

4. Residue information

- 4.1 MRL (EU harmonized, Codex or national)
- 4.2 Number of residue trials and standards (i.e. GEP, GLP or otherwise)
- 4.3 Derived maximum residue value based on these data
- 4.4 Geographical/ecological zone(s) under which these residue data are applicable
- 4.5 Pre-harvest interval
- 4.6 List of endpoints, if available
- 4.7 Other relevant information

5. Worker protection information

- 5.1 Re-entry period
- 5.2 Information, if available, on the acute toxicity and operator exposure
- 5.3 Worker protective measures
- 5.4 List of endpoints, if available
- 5.5 Other relevant information

6. Environmental information

- 6.1 Information, if available, on fate and behaviour in the environment
- 6.2 Mitigating measures
- 6.3 Information, if relevant, on ecotoxicological studies

- 6.4 Mitigating measures
- 6.5 Other considerations
- 6.6 Geographical/ecological zone(s)
- 6.7 List of endpoints, if available

7. Efficacy information

- 7.1 Relevant information on the efficacy
- 7.2 Relevant information on the selectivity of the product and undesirable or unintended side-effects. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding/ adjacent crops
- 7.3 Other mitigating measures relevant for an efficacy evaluation
- 7.4 Are there data available on efficacy (including user derived evidence)?
- 7.5 Geographical zone

Name of the registrant

Date and place

Signature

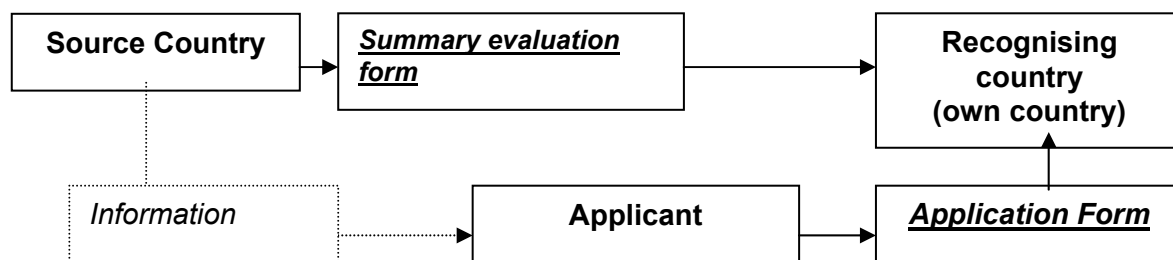
Form 'Summary of the national evaluation' for Voluntary Mutual Recognition

Explanation

This form is only meant for extensions of uses according to article 9 of 91/414. In article 9(5) it has been stated that 'Member States shall ensure that a file is compiled on each application ..'. In fact a summary evaluation form complies with part of this file requirement.

The aim of the form is to make visible to other DNA's how a decision on an authorization/approval has been taken in the country where the extension has been given. This form needs to summarise the decision taken by the DNA and gives details on what information/data this decision has been based. It must provide the critical information underlying any authorization: what has been approved by whom in which way? Such a form needs to be pragmatic and easy to use in order to ensure transparency.

The position of the summary evaluation form is illustrated below. In this scheme the applicant is the initiator.



The form is thus meant for the exchange of basic information between DNA's. The DNA of the recognising country asks for this completed form at the DNA of the source country when dealing with a request for voluntary mutual recognition. Thus the DNA which has given the authorization/approval of this certain use will complete the form. Use of one common language is essential: as this form is a communication instrument between two DNA's they should agree upon a common language.

The numbering of the form will be followed below in elaborating the questions posed in the form.

Box: 'General information'

Name of the DNA filling in this form (including the country)

The DNA receiving a request for voluntary mutual recognition (of the so called recognising country) should contact the source country for information on the executed evaluation. This source DNA thus completes this form. The name of your DNA as well as your country should be given here.

Name, address, telephone, telefax and email address of contact point of the DNA

Every DNA has a contact point for voluntary mutual recognition to facilitate the communication. Please give here details on this contact point as afterwards the other DNA (of the recognising country) may contact your contact point easily.

1. Identity of the active substance(s) and the plant protection product

1.1 Common name of the active substance

As in all official dealings with plant protection products only the internationally officially approved common names should be stated here.

1.2 Manufacturer(s) of the active substance(s)

Here it should be stated which company actually produces the active substance used in the making of the plant production product in your country. The question is relevant because the active substance in the recognising country may be from a different source in which case questions might arise on "similarity".

1.3 Specification of purity of the active substance(s)

The purity should be given in g/kg or g/l as appropriate.

1.4 Current trade name of the plant protection product

The name(s) and number(s) of the source country should be provided here.

1.5 Manufacturer(s) of the plant protection product

It should be realised that the manufacturer of the active substance does not need to be the same as the producer of the plant protection product, and that producers may differ between countries.

1.6 Type of the preparation and code

In this question information should be provided on the formulation of the product ; e.g "wetable powder" or "granulate", according to GIFAP-terminology. Official codes may be presented as well as the complete composition of the product. One should be aware that information as "powder" or "liquid" is insufficient. In this section the concentration(s) should be presented in either g/kg or g/l active substance.

1.7 Other relevant information to decide on the comparability of the plant protection product

The above mentioned questions have been posed to enable the DNA of the recognising country to decide on the comparability of the product. If additional information can be given which is relevant for this purpose please mention here.

2. Information on the authorization/approval

2.1 Number of the authorization/approval (*national reference number*)

The national DNA number should be given here to facilitate the communication afterwards.

2.2 Name and address of authorization/approval holder

The holder of the authorization or approval in your country should be given here: as well the name as the address. Afterwards the DNA, or other parties involved, may contact this holder for additional information.

2.3 Name, address, telephone, telefax and email address of contact person at the company who is the approval holder or applicant

To facilitate this communication please complete this question.

2.4 Knowledge or concerns on the withdrawal of the product

Only active substances which will (probably) be defended by industry will be considered in this procedure of voluntary mutual recognition. If it is known that the active substance or the product will be withdrawn (for several reasons) the possible recognition will have no future and thus no efforts should be taken to continue the procedure on voluntary mutual recognition.

2.5 Expiry date of the authorization of the product

The expiry date of the product at the source country is meant here.

2.6 Type of decision on the use of the plant protection product

For granting an authorization different ways are possible at the national level. For instance a standard authorization is possible, a provisional one or an extension of use. Furthermore this authorization may have been reached through mutual recognition, voluntary mutual recognition or through a 'normal' request. Furthermore the granting may be called an authorization or an approval.

2.7 Information, if relevant, on the data protection, data ownership and confidentiality of data

It may be important to have information on ownership of both active ingredient related and formulation related data (for instance when the approval holder of the source country is another one than the applicant of the recognising country). Therefore please indicate if data are protected and mention the data protection periods. If data or other information is confidential, please indicate here.

3. Pattern of use

3.1 Field of use

A description of the use is required here on two aspects:

- i.e. where is the use: in the field, glasshouse, food or feed storage or home garden
- i.e. is it a seed application, soil application, etc.

Use of the format given in document 1663/VI/94 Rev 8, 22 april 1998, Appendix 3, part I, form for use in reporting details of intended uses, is recommended.

3.2 Details of the use, e.g. types of harmful organism controlled and/or plants or plant products to be protected

The authorized use of the source country should be given here: against which harmful organism(s) in which crop(s) or plant product(s). If relevant also the height of the crop should be mentioned here (for instance relevant in fruit crops).

3.3 (Maximum) application rate

The rate should be given here as well as the maximum rate. Information should be given in maximum dose litres products/ha or kg product/ha and as maximum individual dose in terms of kg a.i./ha, /tonne, or /100 litres water.

3.4 Method of application

Relevant information on the method of application should be given here including the use of 'special equipment' if necessary for the application.

3.5 (Maximum) number and timing of applications

The maximum number of applications should be indicated and the spray intervals. Furthermore details on the period of application should be given if relevant: i.e. the season (summer, winter, etc.), the moment of application (the phenological stage of the crop; before flowering, pre-emergence, etc).

3.6 Proposed instructions for use (enclose national label)

The above mentioned information will already be partly covered by the label information. Furthermore information is required on recommendations for the use of the plant protection product which has not been asked for yet. For instance recommendations on the use of the product with other plant protection products and/or with adjuvants as a tank mix may be given here.

3.7 Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used

Certain conditions may influence the use of the product or measures should be taken to make the use possible. Only conditions which are relevant to know should be mentioned here, such as the national resistance strategy.

4. Residue information

4.1 MRL (EU harmonized, Codex or national)

To know the possibilities of residue extrapolation information should be given here on the basis of the residue data. Different sources are possible. The MRL can already be EU harmonized or the MRL can be based on data accepted by the Codex Alimentarius or national data. These Codex data may be suitable for extrapolation and will likely be accepted in the Annex 1 regime in future. If these data are not available or usable national data may possibly be used in the process of mutual recognition.

4.2 Number of residue trials and standards (i.e. GEP, GLP or otherwise)

The underlying data should be specified here to make a proper estimation possible in the recognising country on the utility of the data.

4.3 Derived maximum residue value based on these data

It may happen that the already mentioned MRL (5.1) is a rough indication based on old national grouping, while the maximum residue value based on the underlying data may be different. Therefore this question has been posed to know the eventual other value. This other value may be more appropriate to use by the recognising country.

4.4 Geographical/ecological zone(s) under which these residue data are applicable

For a proper interpretation of this completed evaluation form it is necessary to describe the ecological zone where the use has been authorized/approved. Especially for the residue evaluation it is necessary to describe your zone in terms of Northern or Southern Europe or Protected Cultivation.

4.5 Pre-harvest interval

The period between the last application and the harvest of the crop or plant product should be given here.

4.6 List of endpoints, if available

These endpoints may be useful to the recognising country in case the source country has already executed more work on these endpoints. Therefore, if available, please mention here the endpoints to make an estimation possible by the recognising country of the utility of these data.

4.7 Other relevant information

Any information relevant to know should be given here. For instance when it is known by the DNA of the source country that the MRL will be withdrawn this information should be given here.

5. Worker protection information

5.1 Re-entry period

If this information has not been given on the label yet please give the information here.

5.2 Information, if available, on the acute toxicity and operator exposure

It should be indicated here how the source country has decided on this authorization regarding the worker protection aspects. Has the source country made use of extrapolations or additional information for the decision for instance?

5.3 Worker protective measures

This information will probably already be given on the label. If this is not the case please mention here the measures.

5.4 List of endpoints, if available

These endpoints may be useful to the recognising country in case the source country has already executed more work on these endpoints. Therefore, if available, please mention here the endpoints to make an estimation possible by the recognising country of the utility of these data.

5.5 Other relevant information

Any other information can be given here.

6. Environmental information

6.1 Information, if available, on fate and behaviour in the environment

6.2 Mitigating measures

Measures concerning the fate and behaviour are mentioned here.

6.3 Information, if relevant, on ecotoxicological studies

It should be indicated here how the source country has decided on this authorization regarding the environmental aspects. Has the source country made use of extrapolations or additional information for the decision for instance?

6.4 Mitigating measures

Measures on the ecotoxicological criteria are mentioned here.

6.5 Other considerations

If relevant mention here additional information.

6.6 Geographical/ecological zone(s)

Different environmental criteria make use of different scenario's (for instance the FOCUS scenario's) to make an evaluation possible. Please indicate here additional information on the ecological zone relevant to know for the environmental evaluation.

6.7 List of endpoints, if available

These endpoints may be useful to the recognising country in case the source country has already executed more work on these endpoints. Therefore, if available, please mention here the endpoints to make an estimation possible by the recognising country of the utility of these data.

7. Efficacy information

7.1 Relevant information on the efficacy

Although not every Member State will ask for an efficacy evaluation it may help the DNA of the recognising country to have some information on efficacy. If relevant information is known to be there please mention here.

7.2 Relevant information on the selectivity of the product and undesirable or unintended side-effects. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding/adjacent crops

7.3 Other mitigating measures relevant for an efficacy evaluation

If known and relevant to mention please give the information such as the measures, related to the efficacy evaluation.

7.4 Are there data available on efficacy (including user derived evidence)?

As some Member States still want to have some data on efficacy it is relevant to mention here if data are available on which the evaluation is based. Also user derived evidence may be helpful and acceptable for the evaluation in the recognising country.

7.5 Geographical zone

Please describe the geographical zone here, relevant for the efficacy evaluation. Here not only the country is mentioned but also other relevant information such as the type of the soil (if relevant), the altitude, etc.

ANNEX 3

'CONTACT POINTS FOR EXTENSION OF MINOR USES'

Contact points in the different Member States

This list is provisional – a separate list will be available as soon as possible on our website.

	Contact	Fax Number	Telephone Number
A	Mr Lentsch	43 1 513 87 22	43 1 71100 28 70
B	Mrs A De Cock	32 2 208 38 66	32 2 208 38 60
D	Mr Zornbach	49 228 529 4406	49 228 529 4317
DK	Mrs Bennekou	45 32660 479	45 32 66 0576
E	Mr Martinez	34 91 3478316	34 91 3478274
F	Mr Vernede	33 1 4955 5949	33 1 4955 4955
FIN	Mr Blomqvist	358 9 5765 2780	358 9 5765 2770
EL	Mrs Niki Petsikos	30 1 80 77 506	30 1 80 78 324
I	Mr Marabelli	39 06 5994 3217	39 06 5994 3780
IRL	Mr Lynch	353 1 820 42 60	353 1 6072613
L	Mr Aschman	352 457172 340	352 457172 218
NL	Mr H.P.Kylstra	31-317 471 899	31 317 471 810
P	Mrs Silveira	351 21 4420 616	351 21 4464 085
S	Mrs Bernson	46 8 7357 698	46 8 7306768
UK	Mr Peter Chapman	44 1904 455 722	44 1904 455808

Mr. M. LENTSCH
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Abteilung VI/C/9
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Direcção-Geral de
Protecção das Culturas
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