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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

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**GUIDANCE DOCUMENT
ON THE PROCEDURES RELATING TO THE AUTHORISATION
OF PLANT PROTECTION PRODUCTS FOLLOWING
INCLUSION OF AN EXISTING ACTIVE SUBSTANCE IN ANNEX
I OF COUNCIL DIRECTIVE 91/414/EEC**

*Commission working document - does not necessarily represent the views of the
Commission services.*

This document has been conceived as a guidance document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

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1. Legal Status

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2. Introduction

This document is intended to give guidance to the Competent Authorities of the Member States on the authorisation of plant protection products post-Annex I inclusion, and has been developed primarily with respect to products containing existing active substances. The aims are:

- to establish a harmonised approach in this area in order to avoid unnecessary duplication of effort
- to improve co-operation between the Competent Authorities of the Member States such that the limited resources of the Member States are used in a more efficient way, and
- to improve consistency in decision making between Member States.

This document identifies the key steps in the re-registration process where harmonisation of procedures across Member States (MS) could be achieved. As with all such guidance documents, it will not be a statutory requirement for all MS to adopt the procedures, although it is recommended that generally the procedures should be adopted in order to improve mutual recognition and facilitate the development of a re-registration work-sharing programme. All MS will, of course, retain the right to request data more urgently and take decisions earlier if necessary.

It is intended that after the document has been used by the Member States in the context of the re-registration process it might be updated as a result of their experience.

3. The Re-registration process

Re-registration relates to the evaluation, following the inclusion of an active substance on Annex I of Directive 91/414/EEC, of plant protection products containing that active substance in accordance with Annexes II, III and VI of the Directive.

There are **two key steps**:

Step 1 – to check that the conditions and restrictions of the Annex I inclusion Directive are met, including the equivalence of the technical specification of the active substance and demonstration of access to a complete Annex II dossier.

Step 2 – involves the submission of a dossier satisfying the requirements set out in Annex III, and its assessment in accordance with Annex VI of the Directive, the Uniform Principles.

Associated with these key steps are **three key dates**:

- i) the 'Entry into force' date, or Step 1 submission deadline, when the active substance is actually included in Annex I of the Directive.
- ii) the 'Compliance deadline', by which MS are required to have completed Step 1, the compliance check and, where necessary, to have amended or withdrawn existing authorisations in line with the Annex I conditions. This is usually 6 months after the 'Entry into force' date of the inclusion directive that includes any of the active substances contained in a plant protection product in Annex I.
- iii) the 'Final deadline' for amending or withdrawing national authorisations as a result of the full, Step 2 assessment. This is usually 4 years after the 'Entry into force' date of the inclusion directive that includes the last active substance contained in a plant protection product in Annex I.

Where appropriate, Member States where authorisations exist should inform all affected authorisation holders once an active substance has been included in Annex I, setting out the deadlines to be met and the requirements of each stage of the process. Member States should also explain the action that will be taken where the requirements are not met.

This information should be sent as soon as possible once the relevant dates are known. This is usually after publication of the inclusion Directive but could be earlier if the dates are included in the draft directive that has been voted on.

The RMS should confirm at the time of voting that they will undertake the Step 1 check (and if not another designated MS (DMS) should be allocated).

MRL review

Article 12(1) of Regulation (EC) No 396/2005 provides that EFSA shall, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC, submit a reasoned opinion on:

- Existing MRLs for that active substance set out in the Annexes I and III to the Regulation (EC) No 396/2005;
- The necessity of setting new MRLs for that active substance, or its inclusion in Annex IV to the Regulation (EC) No 396/2005;
- Specific processing factors as referred to in Article 20(2) of regulation (EC) No 396/2005 that may be needed for that active substance;
- MRLs which the Commission may consider including in Annex II and/or Annex III to Regulation (EC) No 396/2005 and on those MRLs which may be deleted related to that active substance.

In order to assist EFSA in its tasks, the RMS for an active substance included or not-included in Annex I is requested to undertake within three months after the entry into force of the directive for inclusion or the decision of non-inclusion the following actions:

- The submission of an evaluation report addressing the above mentioned issues (the format of the evaluation report is available on the PRAPeR/MRL Workspace of EFSA's Extranet);
- To complete the PROFile for the active substance in line with the user guide available on the PRAPeR/MRL Workspace of EFSA's Extranet.

4. General issues

With the move to considering only a limited number of representative uses for Annex I inclusion, the workloads now facing most Member States in terms of re-registration of uses post Annex I Inclusion has increased considerably.

Initially different Member States had different deadlines for the submission of data for the different stages of the process (compliance checking, Annex III submissions). This will clearly lead to a duplication of effort with several Member States evaluating the same or similar data at different times. Procedures were therefore harmonised to facilitate the development of a structured work programme for re-registration.

The main proposals for harmonisation were as follows:

- Harmonisation of 'compliance check' submissions to facilitate the possibilities for sharing this work.
- Harmonisation of Annex III re-registration procedures, to improve mutual recognition and facilitate the development of a work-sharing programme.
- Use of standard templates for the Annex III assessments, to facilitate mutual recognition and the development of a work-sharing programme.
- Harmonisation of standard 'sell-out' periods, to improve transparency and create a level playing field for growers across the EC.

5. Harmonised approach to re- registration.

5.1 Compliance checking (Step 1)

5.1.1 General procedure

There are two key aspects to the compliance check; the check for compliance with Annex I conditions and restrictions specified in Annex I of the Directive, including the assessment of the equivalence of the technical specification of the active substance

compared with that considered for Annex I inclusion, and the 'access to protected Annex II data' check.

In the interest of efficiency the original RMS should perform the compliance check. Only in those cases where the original RMS is not able to undertake the work in time should another MS (designated MS) perform the compliance check. This check primarily (but not exclusively) relates to alternative sources of an active substance that were not considered during the assessment for Annex I inclusion.

Each authorisation holder for a plant protection product or producer of an active substance on their behalf must send a Step 1 Compliance check submission to each MS that has authorised products containing that source, with a copy of the submission also being copied to the original RMS/DMS for the substance. Due to the tight deadlines, all data must be submitted by the Step 1 submission deadline. -. -The RMS/DMS should then inform the contact person for the Equivalence and Compliance table of all applicants and the sources submitted (including the sources evaluated in the DAR) and whether the sources are identical to the one evaluated in the DAR.

Details of the submission dates and RMS/DMS for each active substance due to be re-registered can be found at the [Equivalence and Compliance Table](http://circa.europa.eu/Members/irc/sanco/pest/library?l=/technical_evaluation/overview_tables&vm=detailed&sb=Title&cookie=1) on CIRCA at http://circa.europa.eu/Members/irc/sanco/pest/library?l=/technical_evaluation/overview_tables&vm=detailed&sb=Title&cookie=1.

The RMS/DMS then has 4 months to prepare the Step 1 compliance check report for each source involved (equivalence of technical material and access to protected Annex II data). These reports for both compliant and non-compliant sources are then made available via CIRCA (uploaded by RMS/DMS) and all MS informed via an Email to the contact points for re-registration and the contact person for the Equivalence and Compliance table should be informed in accordance with the Technical Equivalence Guidance Document (SANCO/10597/2003 rev. 8.1).

Details of the re-registration contact for each MS can be found in the Commission's Contact points list at http://ec.europa.eu/food/plant/protection/evaluation/dir91-414eec_en.htm (click on 'Contact Points' near the bottom of the page).

The completed report of the assessment (including the consideration of any further data submitted) should be available to all MS 4 months after the date of entry into force.

Other MS then have 2 months to consider the opinion of the RMS/DMS and make their own decision on Step 1 compliance.

5.1.2 Assessment

Compliance with the Annex I inclusion

The Step 1 check involves checking the technical specification / impurity profile of the active substance for compliance with the specification established in the Annex I inclusion, and also that the field of use of the products is appropriate (herbicide, fungicide etc) and that any restrictions associated with the Annex I inclusion are met. For the '**technical specification compliance**' check, a standard format for the report on equivalence of the technical specifications has been developed, which would also serve

to act as the notification required under Article 13.5 of the Directive where new sources or new manufacturing processes are identified and the active substance is deemed to be equivalent to the one listed in Annex I of Directive 91/414/EEC. In deciding on compliance, the guidance document on assessment of equivalence of technical materials, Sanco/10597/2003 rev. 8.1, should be used. The reports on equivalence of the technical specifications should be uploaded on CIRCA (in the separate post-Annex I section with restricted access due to the confidential nature of the uploaded data) by the RMS/DMS.

The technical equivalence of a source should be determined by comparison with the reference source. The reference source is the source on which the risk assessment in the Draft Assessment Report was based and for which a regulatory decision has been taken by the Commission.

Further information can be found in the “Guidance document on the finalisation of the reference specification for technical active substances after the peer review (SANCO/6075/2009 rev.3)”.

The responsibility of the RMS/DMS, in terms of evaluating any alternative sources of an active substance for equivalence with that considered for Annex I inclusion, ends at Step 1. Following the Step 1 compliance check, any new sources should be evaluated by the Member State receiving the application for authorisation of that new source. However, in view of the experience of the RMS/DMS and in order to maintain consistency in decisions, assessment of a new source by the RMS/DMS could still be considered.

The specific restrictions (Part A) such as rate restrictions, indoor use only etc must be taken into account at Step 1, but this can only be done via product authorisations at the MS level.

Microorganisms and other natural substances

In general RMS/DMS should adopt, where possible, a practical approach to microorganisms and other natural substances as it is not always possible to set a defined reference specification. The emphasis should be confirming that there are no safety issues and the source complies with the inclusion condition rather than conducting a full equivalence check. It should be noted that according to the guidance document SANCO/10754/2005 rev.5 microorganisms should be included into Annex I at the strain level. A similar approach can also be adopted for certain list 4 substances e.g. plant extracts, quartz.

Variants

Whilst it is clear that any salts and esters not considered for Annex I inclusion should be checked to see that they are compliant or fit within the Annex I inclusion at Step 1, it is also clear that the variants will not be chemically equivalent, such that further data would be required to demonstrate equivalence in line with tier 2 of the equivalence guidance document, and it is unlikely that this assessment could be undertaken within four/six months. It has therefore been agreed that the full assessments of variants should be left to Step 2 of the re-registration process. Where possible the original RMS should undertake the assessment on behalf of the others, in line with the ‘new Annex II data post-Annex I inclusion’ guidance document (SANCO/10328/2004 rev. 6).

To avoid any confusion, it must be reported back to the applicants with variants at Step 1 that the technical equivalence of the variants was not fully evaluated during the compliance check and that they will have to submit all the necessary data to establish the equivalence of the variant for each area of the risk assessment in the Annex III dossier at Step 2.

Access to protected Annex II data

Applicants are required to provide information to demonstrate access to protected Annex II data. This may be achieved in a number of ways:

- By reference to information previously submitted on the active substance to support inclusion in Annex I which is not protected in accordance with Article 13 of Directive 91/414/EEC.
- By providing evidence of access to the information submitted to support inclusion in Annex I which is protected in accordance with Article 13 of Directive 91/414/EEC. A new letter of access would be required, dated after the date of the decision on inclusion, clearly referencing the data required for Step 1.
- By providing alternative and equivalent studies, including published studies, to those protected.
- By providing a case justifying why certain data are not relevant to the uses which are claimed to be supported.

The applicant may find useful information in this respect in the DAR (detailed evaluations, lists of studies) or in evaluations performed by other organisations (e.g. JMPR).

Where alternative and equivalent studies are submitted, the onus will be placed on the applicant to demonstrate the equivalence of those studies in terms of their support of the agreed end-points and the data protection status of such studies in accordance with Article 13 of Directive 91/414/EEC. A standard format for such submissions is given at **Appendix I**.

The information provided at Step 1 should be checked to confirm that access to the protected Annex II data is available. For sources other than those considered for Annex I inclusion this would involve checking that any cases for non-submission of data are acceptable, and that any equivalent studies have been conducted to GLP (where appropriate) and the correct protocol, such that there is a reasonable prospect that if evaluated the information/studies would satisfactorily address the regulatory requirement(s) in an equivalent way to the protected study.

Note if another applicant derives a significantly more critical end-point from their study, then they are under obligation to report this to the COM as adverse data (a procedure for dealing with adverse data is described in the guidance document on new Annex II data post-Annex I inclusion, SANCO/10328/2004 rev. 6).

If the study has been conducted to the correct protocol, to GLP and the source has been deemed equivalent, the study may be accepted as equivalent. Where an older, non-GLP compliant study has been cited, the equivalence of the study should be checked. This is where the RMS knowledge and experience of the active substance from the original Annex I assessment will help in the determination of the equivalence of studies. Studies in progress or interim reports of ongoing studies will not be accepted as equivalent studies and this must be highlighted to MS by the RMS/DMS at the 4 month stage. MS should check individually whether the final reports are received and accepted as equivalent before the Step 1 deadline.

Where it is considered that the equivalence of alternative studies is not adequately demonstrated, or the arguments for non-provision of data are not accepted, the applicant must be informed as soon as possible to allow them time to address the deficiency. It should be noted, however, that the report of the Step 1 compliance check should be available 2 months before the compliance deadline. All additional submissions should also be sent to the original RMS/DMS to undertake the check on behalf of the other MS. However it may be that these additional information will need to be considered individually at MS level, if it is not submitted in time for the RMS/DMS to complete its report in time.

Generally the opinion of the RMS/DMS will in no way be binding and MS have the possibility to check the information themselves. It may be that justifications for the non-provision of data will need to be considered individually at MS level, as the arguments may relate to specific environmental or agronomic conditions in each MS.

Letters could be sent to all authorisation holders informing them of the outcome of the compliance check for their products by the concerned MS.

5.1.3 Revocation of unsupported products/uses

Where products are not adequately supported at this stage (with the exception of vertebrate data – see below), any existing authorisations should be revoked and it is suggested that a standard period of grace of 18 months be applied:

Where nothing at all is received by the entry into force date or where data / information is provided but the products are not supported, revocation action should occur at the compliance deadline, with the immediate revocation of authorisations for the authorisation holders, a further 6 month period for those other than the authorisation holders to sell and supply existing stocks already in the supply chain followed by a further 12 months for the storage and use only of those existing stocks.

In general, where an active substance / product is supported at Step 1 and has passed the compliance check, all authorised uses should be allowed to continue pending the full re-assessment of all uses at Step 2. Where it is clear that a particular use is not supported or has not passed the compliance check, however, that use should be revoked at the compliance deadline.

This will be the case for limited inclusions, where the including Directive limits the uses that can be authorised or where specific concerns were raised in relation to a particular use during the Annex I assessment, such that the use was subject to specific restrictions

in the including Directive. It may also occur where new Annex II data (e.g. metabolism and residues data) were provided to support a use considered for Annex I inclusion and gained protection, and access to those data are not available to other notifiers. This should also be checked by the RMS/DMS and reported in the Step1 compliance check report.

In these cases labels must be amended. Old labels should be immediately revoked for the authorisation holders, and allowed a further 6 month period for those other than the authorisation holders to sell and supply existing stocks of products containing old labels already in the supply chain followed by a further 12 months for the storage and use only of those existing stocks. Re-labelling should be allowed.

In cases where MS are satisfied that the Annex II dossier, other than the vertebrate data is complete, and negotiations on access are in progress with the data holder a more flexible approach may be taken, e.g. provisionally maintaining or suspending authorisations pending the completion of those negotiations.

5.1.4 New authorisations

Where products or uses are not adequately supported during the Step 1 compliance check, they will be revoked (or suspended) as above. New authorisations for those products or uses could only be granted where equivalence was checked and they were supported by a complete Annex II and Annex III dossier, assessed in accordance with the Uniform principles (Annex VI).

5.2 Annex III assessment (Step 2)

Where necessary, MS are required to amend or withdraw all national authorisations by the final deadline specified in the inclusion Directive. All products and uses must, by that date, have been assessed in accordance with the requirements of Annexes II, III and VI of Directive 91/414/EEC.

5.2.1 Submissions

The latest deadline for submission of a full Annex III dossier should be 2 years prior to the final deadline specified in the Directive, which should allow time for the full Annex III assessment and for zonal evaluations/work-sharing and/or mutual recognition of the authorisations by other MS (see below). Submissions could always be received before that deadline, e.g. where early re-registration is sought by the applicants or where MS have specific concerns about particular products or uses. Submissions can also be made after the deadline, although then it may be that the assessment would not be completed by the final re-registration deadline, or in time to allow for mutual recognition of the assessment by other MS.

General guidance on the format of full Annex III submissions in the format of a (draft) registration report is given in guidance document SANCO/6895/2009 rev. 1. This format should be used from October 2010 although applicants are encouraged to use this format (and MS should accept this format) from now on.

In making such submissions, applicants must inform the MS of the other countries to which submissions have also been made, so allowing the MS to contact other MS to discuss the timelines for evaluation and the possibilities for work-sharing. General guidelines on work-sharing are given in guidance document SANCO/6896/2009 rev 1.

Where possible applicants should rationalise their submissions, harmonising the products and GAPs being supported across a number of Member States. Step 2 submissions should then cover all the products and GAPs being supported, allowing the MS the possibility to adopt an approach for grouping intended uses (e.g., the risk envelope approach) in the core assessment to minimise the number of individual uses assessed, and maximise the value and relevance of the core assessment to all MS. The risk envelope concept will be further developed in light of experience and will be covered by a separate guidance document... In addition if possible, all uses should be covered by the submissions, including any minor uses or 'off-label' uses, so that these can also be assessed under the risk envelope approach.

It must also be made clear which revision of the Guidance Documents for risk assessment have been used.

Timing of submissions is also proving to be critical in determining whether or not work sharing arrangements are a possible route for approval, with internal targets within MS for the completion of applications often preventing them from awaiting the assessment of another MS. Improved information exchange with regard to applications made to other MS would help alleviate this problem and in the longer term a database should be developed.

5.2.2 Assessment

Step 2 of the re-registration process is primarily concerned with the evaluation of full Annex III dossiers in accordance with Annex VI, the Uniform Principles, to support existing national authorisations. Increasingly, however, new Annex II data are being submitted for evaluation, increasing the work required for the evaluation of these submissions. There are several reasons for the provision of these new Annex II data; for re-registration of new uses not considered for Annex I inclusion, to address data gaps identified in the review report or inclusion Directive or they may be submitted as adverse data. Further information on the evaluation of Annex II data post-Annex I inclusion can be found in the guidance document SANCO/10328/2004 rev. 6.

In principle, the evaluation of further data should be left for the review of the Annex I inclusion. Data submitted in support of revised end-points should only be evaluated where authorisations could not be granted using the original agreed EU end-point established during the consideration for Annex I inclusion.

Where new Annex II data are necessary, they should be evaluated by the original RMS/DMS on behalf of the other MS, in the interest of efficiency. Where the assessment results in the need to amend a critical end-point (ADI, AOEL, ARfD), the new end-point must be agreed via EFSA and the Standing Committee.

Where new values are established for other end-points, however, the assessment should be uploaded on CIRCA (post-Annex I folder for the active substance) and other MS informed. Further details relating to the procedures to be adopted for the evaluation of new Annex II data post-Annex I inclusion can be found in the Guidance document SANCO/10328/2004 rev.6-

Where the applicant has submitted a (draft) registration report this standard template should be used by MS (see SANCO/6895/2009 rev.1). In the meantime, following the evaluation of the full Annex III dossier, the standard template for Annex III assessment reports (Guidelines for the preparation of Registration Reports, SANCO/10798/2003) should be used to report the results, to improve the transparency of the assessment and thus facilitate zonal work-sharing and mutual recognition. It must also be made clear which revision of the Guidance Documents for risk assessment have been used.

The Registration Reports should be made available as soon as they are finalised and, if possible, at least 6 months prior to the final Commission deadline to allow the assessments to be used as the basis for decisions in other MS. Where a zonal submission has been made the evaluation should be made available within one year of submission (see see the Guidance Document on intra and inter-zonal work-sharing – SANCO/6896/2009 rev. 1).

Green route actives (3rd and 4th lists)

In principal the MS should use the endpoints and list of protected studies in the DAR for the data matching check (as referred to in the review report) highlighting that outcomes may change if peer review concludes different end-points.

5.2.3 Revocation of unsupported products/uses

Where products/uses are not adequately supported at this stage, any existing authorisations must be revoked or amended and it is suggested that a standard period of grace be applied, with the immediate revocation of authorisations for the authorisation holders, a further 6 month period for those other than the authorisation holders to sell and supply existing stocks already in the supply chain followed by a further 12 months for the storage and use only of those existing stocks.

As stated above, the Step 2 submission deadline is an administrative deadline, and it is possible that submissions could be accepted past the deadline although there would then be no guarantee that the re-registration assessment would be completed by the final deadline. Given that later applications can still be submitted, and that a full 4 year period is allowed for the re-registration process, authorisations should not be revoked for failure to meet the Step 2 submission deadline. All authorisations passing the Step 1 compliance check should, therefore, continue until the final re-registration deadline, when they will need to be revoked.

5.3 Amending the Annex I inclusion

On occasion, it may be necessary to amend the inclusion directive, particularly if the specific provisions in Part A prevent the authorisation of an otherwise acceptable source/use. For example the inclusion directive may restrict the use of the product as an acaricide when nematocidal uses are also acceptable.

The formal procedure for amending the Annex I inclusion directive is the comitology procedure described in Article 19 of Directive 91/414/EEC. In order to amend the inclusion directive the notifier has to submit data/justifications to show that the requirements in Article 5 of Directive 91/414/EEC are fulfilled and to demonstrate that the change is 'risk neutral'. The data/justifications shall be evaluated by the responsible MS/RMS and the final decision will be taken in the Standing Committee.

6. Confirmatory data

Some inclusion Directives require specific data, identified in the inclusion directive, to be provided within a limited period in order to support continued inclusion in Annex 91/414. These data are known as confirmatory data.

Further details of the procedures for dealing with confirmatory data can be found in the Guidance document on the procedures for the submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC (SANCO/5634/2009 rev. 3).

7. Mutual recognition

The major efficiency gains in terms of reduced workloads will arise from mutual recognition and an organised work-sharing programme for the consideration of Annex III packages, with a limited number of MS undertaking the assessment of the full Annex III packages on behalf of the others who received a request for authorisation. Ideally this would be one MS on behalf of all but more realistically, using the zonal mutual recognition concept detailed in Guidance Document SANCO/00298/2006, rev. 9b, it would be one MS conducting the full assessment on behalf of the others in the same 'zone'.

Different MS have different procedures for re-registration of authorisations. Following the assessment of the Annex III dossier in accordance with Annex VI, some MS issue new authorisations under the different legislation implementing the Directive, while others allow the original authorisations to continue. For the purposes of mutual recognition, it would be useful if there was some way of identifying that the authorisation to be recognised is based on a full Annex II, Annex III and Annex VI assessment.

Although Article 10 of Directive 91/414/EEC requires that an authorisation (assessed using EC-harmonised methods) in one MS be recognised in other MS where the conditions are comparable, it does provide for conditions or restrictions to address concerns relating to the exposure of workers and consumers, and non-comparable agricultural, plant health or environmental conditions.

Some MS have identified areas of the risk assessment where they would expect companies to provide further information to address particular concerns relating to that MS. Details of these further requirements should be published and easily available to

applicants. Additional national requirements such as these, however, must be kept to a minimum.

A number of initiatives have been introduced to facilitate more work-sharing via mutual recognition. The use of the standard Registration Report format for reporting assessments continues to be important in further improving the use of mutual recognition.

According to legal instructions some MS are obliged to publish their decisions including the underlying risk assessments. An important condition in facilitating work-sharing is that registration reports obtained from other MSs are not kept confidential and can be disclosed and published on websites. They should be available, in principle, at least 6 months prior to the final Commission deadline to allow them to be used as the basis for decisions in other MS. Also in cases where an authorisation is rejected because a risk to human or animal health or the environment cannot be excluded should be made available to other MS.

Timing of submissions is also proving to be critical in determining whether or not mutual recognition is a possible route for approval, with internal targets within MS for the completion of applications often preventing them from awaiting the assessment of another MS. Improved information exchange with regard to applications made to other MS would help alleviate this problem.

Further details can be found in the Work-sharing Guidance Document SANCO/6896/2009 rev. 1.

Appendix I – Format for submission demonstrating access to a complete Annex II package

MATCHING PROTECTED ANNEX II DATA FOR [ACTIVE SUBSTANCE]

Active substance source =

Annex point / reference number	Title of study or case for which data protection has been claimed	Year	Title of alternative study or case referenced / submitted by applicant	Year	In EC review	Reason for equivalence / justification for non-provision	MS Opinion

Notes on completion of table

1. The list of studies for which data protection has been claimed in Appendix III A of the review report must be checked, in particular the column detailing previous use in granting national authorisations. Where the report indicates that the studies were used as the basis of a regulatory decision in a Member State *prior* to the Commission dossier submission date (specified in the review report), these are not eligible for protection in accordance with Article 13(3)(d) and do not need to be matched by an alternative source.
2. Any alternative studies / cases submitted or referenced by the applicant must *match* those Annex points with data / information *protected* at Community level. Checks should establish that they satisfactorily address the regulatory requirement (e.g. any studies follow an appropriate protocol, or correct parameters are used in any modelling, etc); and

Where assessments have already been carried out at Community level for studies or cases made in the EC review, documents supporting the review report may provide an indication as to their acceptability.

3. Opinion on the acceptability of the data / information provided or referenced should be provided in the final column.