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Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009

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Revision history

When	What
Rev 7 of 1 February 2013	Applications for zonal and inter-zonal uses Notification form included as an appendix MR of amended GAP Acceptance of comparability assessments Not commenting on all applications Zonal independent areas of the risk assessment Updated info on steering committees Clarification where refused by zRMS New schematic including MRL notification
Rev 8 of 16 July 2013	Appendix 5 regarding types of applications and commenting requirements has been included.
Rev 9 of 11 July 2014	Clarification regarding Art. 37(3) has been added in chapter 2.2.6.1.

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1. Background

This guidance document has been developed to elaborate the procedures contained in Regulation (EC) No 1107/2009 for zonal evaluation (Articles 33 – 39) and mutual recognition (Articles 40 – 42). The Regulation (EC) No 1107/2009 provides for a more efficient system of mutual recognition, which is built on the assumption that any assessment which was already done by one Member State (MS) shall not be repeated by another MS when recognising an authorisation, except for clearly defined circumstances.

The Regulation (EC) No 1107/2009 provides for a general system of zonal evaluation. Mutual recognition is an important part of this. Under Regulation (EC) No 1107/2009 an authorisation in one MS can be used for mutual recognition in another MS. Therefore it seems appropriate to set out procedures for the zonal evaluation in more detail.

It applies for applications which are made, or due to be made, after the date of application of the Regulation (EC) No 1107/2009 (14 June 2011). Transitional measures are also covered in the document.

2. Zonal authorisations

2.1 Legal basis

Procedure to be followed when an application for authorisation is submitted is described in Articles 33-39 of the Regulation (EC) No 1107/2009.

In the special case of low-risk PPPs (Article 47) a similar guideline will be developed once low risk active substances have been identified.

Summary of the legal provisions:

An applicant shall apply to each MS where the plant protection product is intended to be placed on the market.

It is clear from the wording of Article 33 par. 2 (a) that applications for authorisation shall include all the intended uses in each zone and the MS to which they intend to apply.

When an application is submitted **applicants should also make a proposal as to which MS he expects to evaluate the application (the zonal RMS) in each concerned zone** (Article 33 par. 2(b)). In principle, the MS that was originally proposed by the applicant will act as zonal RMS **unless another MS in the same zone agrees to examine it. The other MS in the same zone to which an application has been submitted shall, at the request of the zonal RMS, cooperate to ensure a fair division of the workload** (Article 35).

In case of applications for use in:

- a. Greenhouses as defined in Article 3 par. 27

- b. post-harvest treatment as defined in Article 3 par. 28
- c. treatment of empty storage rooms
- d. seed treatment

only one MS shall evaluate the application considering all zones (Article 33.2 b).

The same principle applies to MRLs, which according to Regulation (EC) No 396/2005 are linked to the active substance and the critical GAP of each crop in all zones

Once the zonal RMS has been appointed the other MS (“concerned MS”) in the zone **shall refrain from proceeding with the assessment of their applications, waiting for the assessment from the zonal RMS** (Article 35 third subparagraph), in order to avoid duplication of work.

In those cases that an application for authorisation of a PPP is submitted at the same time in more than one zone, the **zonal RMS** in the different zones shall come to an agreement as to which MS will evaluate the data which are not related to the environmental and agricultural conditions (the core dossier) (Article 35 subparagraph 4).

During the assessment of an application the zonal RMS shall give all MS in the same zone the opportunity to submit **comments for consideration in the assessment** (Article 36 par. 1).

The zonal RMS shall **decide within twelve months of receiving the application** whether the requirements for authorisation are met making use of the Uniform Principles. When additional data are requested, **this period is prolonged for a maximum of six months and shall cease at the moment when the additional information is received by the MS. If the applicant has not submitted the missing elements, the application is inadmissible** (Article 37 par. 1). **Subsequent submission of further information or studies after this prolongation period is not allowed.**

In line with Article 37.2, in case of applications for authorisation of PPPs containing **sources other than those assessed for approval**, the deadlines for taking a decision are suspended while applying the procedure of Article 38 (assessment of equivalence) for not more than 60 days.

In those cases where an application is received for the representative product containing an active substance that has not yet been approved, the zonal RMS in each zone should start its assessment as soon as it has received the DAR from the RMS for the active substance. In this case and if the application refers to the **same formulation and the same uses, the zonal RMS should decide on the authorisation at the latest within six months of the active substance being approved** (Article 37.3). If the formulation or uses are different, however, the twelve month timeline would apply.

The zonal RMS, once it has concluded its assessment of the application, shall **make available its assessment** to the other MS of the zone.

The other MS of the zone on the basis of the conclusions of the assessment of the zonal RMS shall grant or refuse an authorisation at the latest within 120 days of receipt of the assessment report and the copy of the authorisation (Articles 36.2 and 37.4).

By way of derogation, appropriate conditions and other risk mitigation measures may be imposed deriving from specific conditions of use (Article 36.3 and 37.4).

In case of refusal of an authorisation because of unacceptable risk to human or animal health or the environment the MS who refused the authorisation is obliged **to inform immediately the applicant and the Commission providing a technical or scientific justification**.

For the special case of **low risk products** –once identified- the procedure remains the same as for the conventional products but the timeframe is reduced (120 days + max 6 months if additional data are requested).

In principle, the same procedure (1 year evaluation plus possibly extended by up to 6 months) shall be followed for applications for amendment of an existing authorisation e.g. extension of use or change of composition, although where no technical assessment is involved shorter timelines may apply (see GD on renewal, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 – SANCO 2010/13170 and GD on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 – SANCO 12638/2011).

2.2 Timelines, procedures and communication

2.2.1 Steering Committees

Communication within zones and between zones is critical to effective operation of the zonal system and is facilitated by the establishment of the following structure:

- One inter-zonal steering committee
- Three zonal steering committees
- Two zonal contact point per MS

Frequency and organisation

Within each MS there are two zonal contact points identified, which are recorded in the [EU contacts list](#) which is available on CIRCABC.

A Zonal Steering Committee in each zone will be in place in which each MS in the zone will participate. The Zonal Steering Committee will meet by routine teleconference (or other remote meeting tool) every 2 months to discuss specific applications and issues arising which should be fed into the Inter Zonal Steering Committee. They should also meet face to face at least once a year. It is envisaged that these meetings will be organised and chaired by the participating MS on a yearly rotating basis.

An Inter-zonal Steering Committee attended by 2 representatives from each of the Zonal Steering Committees (the chair and the in-coming chair) and the Commission will address issues between the zones. This Committee will meet every 2 months remotely following the zonal steering committees, and at least once a year face to face. In particular this Committee will have to address co-ordination between zones and co-ordinate who

evaluates which parts of the dossier where these are shared. It will also co-ordinate the evaluation of applications for use in greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment. These meetings will be organised and chaired by the Commission in association with the participating Member States.

The remit and organisation of the inter-zonal and zonal steering committees are detailed in Appendix 1 and 2 respectively.

2.2.2 Applications and authorisations database

[An application and authorisations database is currently under development in the Commission, together with experts from MS. A link to that database together with rules on use and some information will be inserted as soon as the project is more advanced]

Until the data-base is functional, it is important that all MS are informed about future and ongoing applications. To ensure best exchange of information between MS, the zRMS is required to complete and update the spreadsheet of ongoing applications/appropriate zonal database (for links see below). This information is particularly important for interzonal applications (and to facilitate sharing of non-zonal elements of assessment (See 2.2.4.1 Application second para). The chair and/or the incoming chair is responsible for updating the spreadsheet based on the information given by the individual MS.

Inter-zonal applications – see

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:idcl=FormPrincipal: id3&FormPrincipal_SUBMIT=1&id=cc7a5d91-bb03-4090-819f-dd159d73230c&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAIyMnB0ACsvanNwL2V4dGVuc2lvbi93YWkvbmF2aWdhdGlubi9jb250YWluZXIuanNw

Central zone – see

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:idcl=FormPrincipal: id3&FormPrincipal_SUBMIT=1&id=f885309e-3289-40f2-a773-2e02811e7f80&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAIyNHB0ACsvanNwL2V4dGVuc2lvbi93YWkvbmF2aWdhdGlubi9jb250YWluZXIuanNw

Northern Zone – see

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:idcl=FormPrincipal: id3&FormPrincipal_SUBMIT=1&id=b4ee626d-befb-4706-87c7-05829a8661af&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAIyNnB0ACsvanNwL2V4dGVuc2lvbi93YWkvbmF2aWdhdGlubi9jb250YWluZXIuanNw

Southern Zone - see

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:idcl=FormPrincipal: id3&FormPrincipal_SUBMIT=1&id=de349373-e654-4938-9046-399d78c3c2c1&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAIyOHB0ACsvanNwL2V4dGVuc2lvbi93YWkvbmF2aWdhdGlubi9jb250YWluZXIuanNw

2.2.3 Before industry submits an application (pre-application)

At least six months before the application is due to be made it is recommended that the applicant should submit to all zonal contact points in MS in the zone a summary of the products for which authorisation will be sought, detailing in which MSs the authorisation is envisaged. A common format (“notification form”) has been developed which should be used by applicants (Appendix 3). This will help organise the allocation of work to MS and speed up the process. In future, the applicant shall also feed this information into the database.

The Regulation (EC) No 1107/2009 states that the application must also include a proposal for the zonal RMS. However, for efficient operation of the system the zonal RMS should be appointed before the application arrives. Therefore it is expected that a proposal for the zonal RMS is already included in the pre-application. Based on this proposal the zonal steering group will make a recommendation who will act as zonal RMS which will be fed back to the applicant.

Already during the pre-application the applicant should identify which studies could fall under the provisions to avoid duplicative testing and sharing of tests involving vertebrate animals (Article 62). The zonal RMS should make an indicative list of studies available to all applicants on request.

To make the zonal system work (organise the allocation of work and speed up the process) the applicant should make his application to each MS where an authorisation is envisaged at the same time. Whilst the applicants’ preference for choice of zonal RMS should be taken into consideration wherever possible the final decision may also need to take into account a fair and proportional distribution of applications amongst MS in the zone. In addition the following, should also be taken into account:

- identity of the original RMS for the approval of the active substance (noting that it will not always be possible to allocate the work to the original RMS),
- MS where authorisation is sought,
- relevance/importance of the products in each MS,
- impact of products containing more than one active substance (e.g. if a MS has evaluated a product containing one of the active substances and thereby gained knowledge it would be efficient if the same MS also evaluated the next product),
- resource availability in each MS, and
- if a MS has previously examined the application and rejected the application due to the fact that the missing data could not be received within the time limits.

For greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment, only one zonal RMS should be proposed.

For products with multiple uses (outdoor and greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment) the application might be split up by the applicant and in any case only one zonal RMS shall examine the greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment uses for which

a separate dRR needs to be submitted. The identification of the RMS for the interzonal evaluation could be facilitated by the inter-zonal steering committee.

MS should discuss possible problems in the proposed zonal application with the applicants in order to improve the quality of, and review the strategy for, the zonal application. In order to facilitate this, requests for pre-submission meetings, to be held around 6 months prior to submission, should be addressed to the envisaged zonal RMS. Pre-submission meetings are not obligatory but highly recommended for complex applications/groups of applications.

Applicants should consider the use of the **risk envelope** approach, where appropriate, 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. Choice of uses should be optimised to best reflect uses across the zone and possible differences in risk mitigation. The risk envelope is a concept which exploits the idea that within a group of products and uses, there will be certain uses which represent the *worst-case situation* in each area of assessment/compartment. This can be different for the various areas of the assessment. The assessment of this worst-case product/use will cover all other situations where the GAP is less critical or the same. By establishing the risk envelope, it is possible to minimise the number of individual product/use assessments that need to be completed. The risk envelope concept is laid down in a separate guidance document [SANCO/11244/2011 rev. 5, 14 March 2011] and it will be further developed in light of experience.

Applicants are required, in the context of the work sharing framework, to propose the uses and critical GAPs which establish the zonal risk envelope in each area of the assessment (whilst also highlighting *all* the uses authorised/required within the zone). Assessors should consider the proposal to establish the risk envelope as part of their assessment, taking into account also the assessment available of the representative use submitted under the approval procedure. Note however that the core assessment should cover all uses applied for in the whole zone, in order to allow the concerned MS within the zone to decide on their uses within the 120 day period. This approach should take minor uses into account.

It should be noted that it may be difficult to define a risk envelope for all areas of the assessment (e.g. for fate and ecotoxicology there are for the time being still national assessment requirements which mean that it is not always possible to define a risk envelope relevant to the zone). In this case the MS requesting additional information should explain the additional request to the applicant and justify why he considers the risk envelope approach not applicable in this particular case.

Given the large number of national assessment requirements, further work is necessary to harmonise national requirements at EU level.

These difficulties are expected to diminish as information exchange and harmonisation is increasing between MS under the procedure set out in articles 33-42 of the Regulation (EC) No 1107/2009 (see also "further steps" in chapter 4 of this guidance document).

2.2.4 Industry application

2.2.4.1 Application

To make the zonal system work (organise the allocation of work and speed up the process) the applicant should make its application in each MS where an authorisation is envisaged at the same time. The application has to include a list of all intended uses in each MS of the zone where the applicant has made or intends to make an application. Differences within the same use for different MS should be justified. The application should include the core assessment and the national addenda as foreseen by Guidance document [SANCO/6895/2009 on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (to be replaced by resp. GD under 1107/2009)]. The application must also include a proposal for zonal RMS (see pre-submission arrangements above).

In those cases that an application for authorisation of a PPP is submitted at the same time in more than one zone, the **zonal RMS** in the different zones have to come to an agreement as to which MS will evaluate the data which are not related to the environmental and agricultural conditions (the core dossier, sections concerned are physchem properties, analytical methods, confidential information, toxicology, all study evaluations) (Article 35 subparagraph 4). Industry should identify candidate applications and time their submissions to help Member States share zonal independent areas of the assessment. Industry should send to all the zRMS the relevant contact details for that application within the other zone(s).

2.2.4.2 Dossier to be submitted

Basic requirements for an application are set out in Article 33.

The draft registration report format will be required for each product as set out in SANCO guidance 6895/2009. Also required will be:

- Covering letter,
- Data underlying the core assessment,
- Other national requirements (application forms etc) relevant to the receiving MS, and
- Confidential information.

For products with multiple uses (outdoor and greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment), separate draft registration reports will need to be prepared for the inter-zonal uses (to be submitted to a single zonal RMS) and the zonal outdoor uses.

Language

The application should be prepared in English. Whenever information is not provided in English, a translation into English should be provided. Information on use, label and instructions for use must be provided in the national language of the MS in which an authorisation is applied for.

Quality of the dRR

It should be noted, that the quality of the dRR prepared by the applicant influences the time keeping process and resource efficiency of MS. In particular, this means:

- One product – one dRR
- Each active of the product to be addressed
- Reference to EFSA conclusion and DAR including a short summary and justification why appropriate
- dRR prepared by a generic company/3rd parties: to include in the dRR as much as possible (use “official” documents like EFSA conclusion, DAR)
- Contains in principle only information relevant for the applied uses

2.2.5 Completeness check

A completeness check is not a direct legal requirement in Regulation (EC) No 1107/ 2009. However the Regulation (EC) No 1107/2009 does set out in Article 33 and 34 the requirements for the application. If any of these elements are missing then the application should not be accepted which implies that a completeness check to establish the completeness of the application is carried out.

This completeness check has to be conducted within the overall timeframe for evaluation and should therefore be confined to an administrative check to establish that the required elements of the application are present (see 2.2.4.2). The check shall be conducted by the zonal RMS and should be finalised within 6 weeks.

At this stage a further exchange of information between MS and including, if necessary, the applicant will be required on the basis of the actual dossier to establish that the decisions on work allocation taken before submission of the application are still valid.

2.2.6 Zonal RMS evaluation

2.2.6.1 Timelines

There is a total of one year to complete the evaluation from the date the application is submitted. This period may be extended by 6 months if further information is requested.

In addition the timelines can be suspended if the procedure in Article 38 (assessment of equivalence) is necessary.

In order to allow for the commenting phase envisaged in Article 36(1) the initial assessment should be completed within 8 months of the date of submission of the application.

During the assessment it is not uncommon to have issues to resolve with the applicant. This can be simple clarification or may involve the submission and assessment of new data. Whilst both are acceptable the zonal RMS should specify a maximum time period of six months for the clarification of these issues/submission of new data by the applicant. The zonal RMS should set the deadline at a realistic length in light of the additional information required. If the missing information will take longer than six months to provide the application shall be refused at that stage and a new application required or continued with only those uses that can be supported. Where further information is required the initial 1-year assessment period will be extended by the additional period granted by the zonal RMS. However in order to allow sufficient time to deal with new information in the evaluation it is recommended that further requirements are identified no later than 6 months after the submission of the application. Several requests for information can be made, including after the commenting period to clarify points, up to a maximum of six months plus further minor clarifications can be permitted without 'stopping the clock'. If the information is not provided within the required timeframe, the application shall be refused at that stage and a new application required or the evaluation shall be completed for those uses that can be authorised without the requested information.

Where the missing information is submitted at a later date the MS should accept a new application containing the missing data and refer to the refused application, in order to continue the evaluation work. The twelve month assessment period re-start in such cases although it is recommended that the evaluation time should be appropriate to the amount of missing data requiring evaluation.

In line with Article 37.2, in case of applications for authorisation of PPPs containing **sources other than those assessed for approval**, the deadlines for taking a decision are suspended while applying the procedure of Article 38 (assessment of equivalence) for not more than 60 days, unless the equivalence check has already been performed. The procedure for the assessment of the equivalence of new sources of technical materials according to Article 38 Regulation (EC) No 1107/2009 is described in SANCO/10597/2003).

In line with Article 37.3 an applicant should be able to apply for non-representative products/uses before the entry into force of the approval regulation, but the 12 month timeline for taking a decision only applies from the date of entry into force of the Regulation on the approval of the active substance.

It is important that the zRMS alerts other MS to requests for further information which impact upon the target delivery date. The ZRMS should update the zonal database/application spreadsheet accordingly.

A schematic representation is in Appendix 6.

2.2.6.2 Contingency measures

The expectation is that the zonal RMS will deliver their evaluation within the deadline specified. However if due to unforeseen circumstances the zonal RMS is unable to deliver their assessment they should alert the Zonal Steering Committee as soon as possible. The Zonal Steering Committee will consider whether re-allocation or assistance to zonal RMS is possible and appropriate. This may present some practical difficulties, including fees, which would have to be resolved between MS.

2.2.6.3 Assessment format

The evaluation should be presented according to the registration report format by the zonal RMS.

The Uniform Principles must be applied for the assessment of a product and its uses, and should only cover all the uses intended in the zone. The risk assessment should reflect guidance applicable at the date that the application was received by the zonal RMS. Assessments must be supported by appropriate data, and reflect consideration of all active substances in the product.

In cases where a MS clearly identified specific national assessment requirements (differing from or extending the core assessment) which are necessary due to its specific environmental or agricultural circumstances, that MS must complete a national addendum to Part B of the Registration Report based on the core assessment. However, all parts of the assessment of the zonal RMS shall be used by other MS in the zone as a basis for national regulatory decisions. It is not the responsibility of the zonal RMS to evaluate all the national addenda. In the longer term, further harmonisation will be necessary.

The Part B core assessments (and national addenda where appropriate) are then used to determine risk mitigation measures and other restrictions or conditions which are due to specific conditions of use in that MS (reported in Part A of the Registration Report).

Language

The registration report should be prepared in English. Where necessary, translation into the national language for Part A and national addenda (Part B) can be added. The national authorisations (issued on completion of the assessment) will be prepared in national language.

2.2.6.4 Comments on zonal RMS draft

The zonal RMS draft registration report should be uploaded to the authorisation data base, for the time being CIRCA, for comments by all other MS belonging to the same zone.

A standard format table has been developed to notify other MS that the assessment is available for commenting and the deadline for comments (Appendix 4). This also includes details of the concerned MS within the zone.

If possible both Part A and Part B of the registration report should be made available, although if Part A is not available then the preliminary conclusions of the RMS with regard to whether or not authorisations are likely to be granted should be included in the aforementioned commenting notification table.

Further details and guidance on uploading document and naming conventions can be found at:

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:_idcl=FormPrincipal:_id3&FormPrincipal_SUBMIT=1&id=cc7a5d91-bb03-4090-819f-dd159d73230c&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAIyMnB0ACsvanNwL2V4dGVuc2lvbi93YWkvb250YWluZXIuanNw

A 6 week period should be provided for MS comments using a reporting table format, and the comments should be submitted to the zRMS. The final reporting table should be uploaded on CIRCA by the zRMS (in future: in the database). In case of differing opinions on technical issues, the zonal RMS and the MS concerned shall try to reach a compromise. If a compromise is not possible, this shall be recorded in the Reporting Table. The Reporting Table shall therefore be handled as a supplement to the Registration Report, for transparency reasons.

At the same time as uploading to CIRCA the draft Registration Report should also be sent to the applicant to provide comments in the same format. It shall be clearly communicated to the applicant, which information is required (factual issues only) and that further information which was not requested would not be taken into account.

In principle, all applications for new authorisations should be dealt with via the full zonal procedure and thus be subject to commenting from other MS in the zone. It is clear, however, that certain types of applications (minor pack changes, identical products etc) are dealt with via a more administrative procedure, and are not supported by a technical assessment. Such applications should be dealt with via a simplified procedure and should be processed to shorter timelines given the fact that there is no need for commenting. In Appendix 5 the types of applications are listed and it is indicated if commenting is required or not.

Other MS should be informed, however, of the amendment that has been made via CIRCA/the authorisations database. Applications requiring technical assessment should follow the zonal procedure.

It should be noted that commenting should focus on critical issues that affect the risk assessment and not to minor points that do not change its outcome.

2.2.6.5 Finalisation and Decisions

Decisions by zonal RMS

Once the comments have been received the zonal RMS should finalise their assessment and make their decision on authorisation in accordance with Article 37(1). It is still possible to seek further clarifications from the applicant at this stage within the overall six month period for requests for further information. The zonal RMS may grant or refuse the

authorisation. Either way, the conclusions of the assessment of the zonal RMS should still be used by the concerned MS as the basis for their decisions. Therefore, if the zonal RMS has come to the unambiguous conclusion that the use of a given plant protection product is acceptable in the zone in principle, but not in its own territory for conditions specific to that territory, this conclusion should be considered a positive assessment by the "zonal Rapporteur". On the basis of this positive assessment the Member States in the zone to which an application was sent shall grant authorisations unless the provisions of Article 36(3) are applicable.

Authorisation by other MS in the zone

The concerned MS have to issue an authorisation or refuse the authorisation within 120 days of receipt of the zonal RMS assessment and decision.

Other MS must not re-evaluate the application but shall restrict the assessment to their national requirements described under article 36(3) and national data protection. In particular, formulation comparability assessments conducted by the zonal RMS with respect to zonal applications for generic products should simply be accepted by the other MS, not re-assessed, provided the reference products in both MS are the same.

There may be opportunities for further work sharing between MS at this stage if national specific requirements are shared.

Harmonisation of authorisation format

The basic information contained in an authorisation as well as the format for information to be kept available for public access should be harmonised to facilitate information sharing and to this end an application and authorisation database is being developed, Obligatory information is clearly described in Article 31 par. 1, 2 and 3 and in Article 57.

2.2.6.6 Publication

The finalised Registration Report (including the reporting table) should be sent to the applicant and uploaded on CIRCA, replacing previous versions.

In principle Registration Reports could be published to increase transparency and openness if legal provisions in the individual MS allow. Removing confidential information (see article 63) and appropriate redaction would be required.

3. Mutual recognition

3.1 Legal basis

As of 14 June 2011, mutual recognition in the sense of Article 40 applies to all authorisations in MS, which were either granted under Directive 91/414/EEC in compliance with Annexes II, III and VI of that Directive or under Regulation (EC) No 1107/2009.

The procedure to be followed when an application for mutual recognition of an authorisation is submitted is described in Articles 40-42 of the Regulation (EC) No 1107/2009 while the extension of authorisations for minor uses is included in Article 51 in general and more specifically in Article 51.7

Specific provisions have also been included for some special cases like low-risk products (Article 47) and products containing substances that are included in the list of “candidates for substitution” (Article 50).

Applications for mutual recognition between MS belonging to different zones are possible.

3.2 Different cases for mutual recognition

The situations under which mutual recognition can be applied for are very clearly described in Article 40.1, with the prerequisite that the reference authorisation needs to have been granted in accordance with Article 29:

1. authorisations between MSs belonging to the same zone.
2. authorisations between MSs belonging to different zones with the provision that this authorisation is not used for mutual recognition in another MS within the same zone e.g. UK authorisation (central zone) can be mutually recognised by Sweden (northern zone) however Denmark (also northern zone) may only mutually recognise the same product from the UK and not from Sweden to avoid the 'domino effect'.
3. authorisations between any MS (regardless the zone it belongs to) where the application concerns use in greenhouses or post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products or for seed treatment.

There are a number of cases for which mutual recognition is **optional**. These are namely the following (Article 41.2):

1. an application has been submitted for an authorisation that has been granted in accordance with case 2 above (voluntary mutual recognition between countries that belong to different zones);
2. the product contains a substance that is included in the list of candidates for substitution;
3. the application concerns a provisional authorisation;
4. the application concerns a product that contains a substance that has been approved under the derogation of Article 4.7 (substances for which there are no alternatives).

Mutual recognition according to article 40(1) and 41 is also applicable to minor uses. In this specific case, an applicant applies for the mutual recognition of a minor use from one MS in another MS under the precondition that the product has a regular authorization in both MS.

3.3 Timelines, procedures and communication

For mutual recognition the principles applied are the same as those outlined above for zonal authorizations in the concerned MS. However, in this circumstance it is necessary to underline an important difference between the zonal evaluation and the mutual recognition. According to Article 40 Regulation (EC) No 1107/2009, mutual recognition can only be based on an existing authorisation. Therefore, the statement of the zonal rapporteur according to which the use would be acceptable in the concerned MS in the zone in principle, but not under the special conditions of its own territory, can not be used for an application under Article 40 of the Regulation.

Authorisations given on the basis of mutual recognition must be clearly identified to avoid the ‘domino effect’. The central database on applications and also the database according to Article 57 should help MS receiving the application. MS should also state in their authorisation certificate that this authorisation is based on mutual recognition under Regulation (EC) No 1107/2009.

MS have 120 days to decide on authorisation or refusal of a mutual recognition application. They shall avoid re-evaluation of the application other than to fulfil the requirements of article 36(3). In principle, this timeline applies to applications for mutual recognition of the same product and same use under comparable agricultural conditions. Whilst there may be some flexibility to accept slight changes within an application for mutual recognition (e.g. where no technical assessment would be required to support the differences i.e. no new risk assessment to be performed), more significant changes would be dealt with as new zonal applications. In order not having to refuse systematically applications for mutual recognition, MS should consider making their national requirements available, so that they can be taken into account by the applicant by submission for the application for mutual recognition in the format of national addenda to the dRR. Although this possibility is not explicitly foreseen by Regulation (EC) No 1107/2009, it can be understood to be in line with the spirit of the Regulation (EC) No 1107/2009 as it is foreseen in the zonal evaluation system.

4. MRL setting in the context of zonal evaluation

4.1 Legal provisions

Two legal provisions on the authorisation of PPPs in Regulation (EC) No 1107/2009 refer to the MRL setting under Regulation (EC) No 396/2005:

- Art. 33(3)(e) of Regulation (EC) No 1107/2009: “the application shall include the following: (...) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information”;
- Art. 29(1)(i): “... a plant protection product shall only be authorised where (...) it complies with the following criteria: (...) for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005”.

In addition the following legal provisions of Regulation (EC) No 396/2005 are relevant in this context:

- Articles 6 to 9: where there is a need to set or modify an MRL in the context of an application for authorisation, the evaluating MS shall draft an evaluation report and submit it to the Commission and EFSA; there is no time limit for the evaluating MS to do so;
- Article 11: EFSA has 3 months to draft a reasoned opinion on the MRL; where more detailed evaluations are needed, this time period may be extended to 6 months; where supplementary information is needed, the time limit shall be suspended;
- Article 14: upon receipt of the reasoned opinion, the Commission shall prepare within 3 months a Regulation on the setting or modification of the MRL, for submission to the Standing Committee.

4.2 Coherence of zonal application and MRL setting or modification

Considering the timelines set out in chapter 2.2.6.1 (see also appendix 1) and the time lines under Regulation (EC) No 396/2005 (or the absence of a time limit for the evaluating MS to draft the evaluation report), it is obvious that it might be very difficult to achieve an MRL setting or modification within 12 months as of the application.

Several elements can contribute to achieving the goal of an MRL setting or modification within 12 months after the PPP application:

- It should be avoided that detailed evaluations are needed by EFSA, leading to a time line of 6 instead of 3 months for the finalisation of the reasoned opinion. Such detailed evaluations can be needed for instance where new metabolism studies need to be evaluated, where there are new methods of analysis, etc. It is therefore recommended to applicants to submit to the extent possible all available information that may be needed for later MRL settings with the application for the active substance approval (or the renewal of the approval), even if this information is not essential for the representative uses;
- The need to apply for new or modified MRLs in the context of applications for plant protection products should be avoided to the extent possible. It should be recommended to applicants to submit to the extent possible already in the context of the application for the active substance approval (or the renewal of the approval) all MRL applications they foresee, and not to submit only those MRL applications relevant to the representative uses.

Even when these recommendations are implemented, there will always be a need to set or modify MRLs in the context of new PPP authorisation applications. And even if the time limit of 3 months for EFSA to draft a reasoned opinion can be applied, it might be difficult to fit the MRL setting/modification procedure within the 12 months period. In order to streamline the procedure as much as possible, consideration also needs to be given to the two aspects in chapters 4.3 and 4.4.

4.3 Member State performing the evaluation

Two scenarios should be considered:

4.3.1 Applications are limited to one zone

The zonal RMS shall perform the evaluation for the MRL setting/modification.

4.3.2 Applications are made in 2 or 3 zones

Following the chapters above, in this case 2 or 3 zonal RMSs would normally evaluate the application. Each of them would also prepare an evaluation report with a view of setting/modifying MRLs.

However, this would clearly result in a duplication of effort for the MSs involved which would also complicate the follow-up work for EFSA. Any MS should be able (from the technical/scientific point of view) to evaluate the studies needed for the setting/modification of MRLs, even if the MRL applied for is not relevant for the zone to which it belongs. It is therefore recommended that all MRL related studies are evaluated by one zonal RMS for all three zones. It would be logical to allocate this task to the MS which will be responsible for the evaluation of data which are not related to the environmental and agricultural conditions, or the zonal RMS of that zone, to which the new – higher – MRL belongs should act as the evaluating MS considering the MRL setting according to Regulation (EC) No 396/2005).

This approach will have the further advantage that this zonal RMS will have the complete overview of all GAPs and will be able to identify the critical GAP for a certain crop. This will help avoiding that divergent MRLs are being proposed by the 3 zonal RMSs for the same commodity.

4.4 Timelines

The time needed between the submission of the evaluation report and the publication of the Regulation setting/modifying the MRL is about 9 months (and more where EFSA needs to perform more detailed evaluations). In order to meet the time limit of 12 months for the granting of the authorisation by the zonal RMSs, it should be recommended that the evaluating ZRMS submits the evaluation report to EFSA within 3 months after the receipt of the application.

It is recommended that the applicant submits the application for MRL setting in advance to the application for authorization of a plant protection product to the relevant evaluating MS/zonal RMS.

5. Procedures for low-risk PPPs (Article 47)

To be inserted at a later stage

6. Harmonisation

Harmonisation of risk assessments is a medium term aim. A number of steps were proposed during the workshop in Braunschweig in January 2010 and were followed up in a separate document.

7. Transitional measures

Re-registration applications will be processed in accordance with the timelines set out under Directive 91/414/EEC and using the [voluntary re-registration work-sharing](#) guidance if appropriate (SANCO/6896/2009).

If an application relates to a PPP which is a new product in one MS (12 month zonal deadline applies) but an existing PPP in another MS (2 year re-registration deadline applies), the timing of evaluations will depend on the choice of zonal RMS and this should be discussed at the pre-submission phase.

Applications for provisional authorisations containing new active substances (NAS), for which Article 80.1.a of Regulation 1107/2009 applies, are still possible and can be processed using the voluntary registration worksharing.

Appendix 1: The interzonal Steering Committee

Remit of the interzonal Steering Committee (izSC)

- The izSC is a co-ordination body dealing with issues of work-sharing. In this respect the izSC will address and co-ordinate issues between the zones.
- The izSC takes over the role of the zSC for applications for use in greenhouses, post harvest treatment, treatment of empty storage rooms and for seed treatment. In this respect the izSC may take a role in the allocation of the Member State who will undertake the core evaluation of a particular product on behalf of the other MS – the interzonal Rapporteur Member State (izRMS).
- The izSC facilitates the harmonisation of national risk assessments relevant between the zones, i.e. by initiating the development of respective harmonised guidance by a particular expert group.
- The izSC contributes to relevant guidance documents.
- The izSC discusses any general issues relating to the efficiency of the system.
- The izSC ensures transparency and gives a formal feedback of its work to all MS and also communicates to Stakeholders.

Organisation of the interzonal Steering Committee

- Representatives for izSC will be the chair and the in-coming chair of the zSC.
- Meetings of the izSC should preferably take place every 2 months by teleconference / remote meeting tool. They should take place in even months.
- There should be a face to face meeting at least once a year, which should in principle take place in Brussels and will be funded by the Commission.
- The chair will be provided by the Commission.
- The responsibilities of the chair are
 - organisation of teleconferences and at least one face to face meeting,
 - preparing the necessary agenda,
 - providing feedback to the Standing Committee,
 - managing the updating of the overview table on interzonal applications (*transitionally done by AT*),
 - managing the contribution to relevant guidance documents.
- Preparation of the minutes of the teleconferences/meetings (preferably within 2 weeks) will be shared amongst the attendees of the izSC (until question of secretariat solved) and circulated to all MS via CIRCA.

- An additional summary of the minutes, excluding confidential information, will also be prepared by the same MS preparing the minutes, which is foreseen to be made publically available.

Appendix 2: The zonal Steering Committees

Remit of the Zonal Steering Committees (zSC)

- The zSC co-ordinates work sharing activities within zones, which is seen to be the **key function** of the group.
- The zSC is a co-ordination body dealing with issues of work-sharing; it does not address questions on product specific risk assessments.
- The zSC takes a role in the allocation of the Member State who will undertake the core evaluation of a particular product on behalf of the other MS in the zone – the Zonal Rapporteur Member State (zRMS). In principle the applicant's choice is followed. But in case of unbalanced distribution, the zSC should be involved at a very early stage (preferably before detailed pre-submission meetings) to look for an alternative zRMS. The zRMS should be known at the time of detailed pre-submission meetings, in order to respect the deadlines and avoid duplication of work.
- The zSC ensures that all MS are involved in the evaluation of PPP applications. In doing so the zSC will take into account the capacity of the MS to act as zRMS. MS should inform the zSC of their capacity in general, and of their capacity to take additional applications on board.
- The zSC discusses any general issues relating to the efficiency of the system.
- The zSC contributes to relevant guidance documents.
- The zSC does not get involved in disagreements between zRMS and a commenting MS regarding an assessment (this should be dealt at expert level). The zSC can recommend an expert meeting to solve the disagreements.
- The zSC facilitates the harmonisation of national risk assessments relevant within the zone, i.e. by initiating the development of respective harmonised guidance by a particular expert group.
- The zSC ensures transparency and gives a formal feedback of its work to all MS in the zone.

Organisation of the zonal Steering Committees

- Each MS in the zone should participate in the zSC.
- Within each MS two zonal contact points should be nominated. They are
 - contact point for mutual communication and information,
 - contact point for the commenting procedures on dRRs,

- most likely the attendees of zSC meeting (but may also be other MS representative).
- Meetings of the zSC should preferably take place every 2 months by teleconference / remote meeting tool. They should take place in uneven months.
- There should be a face to face meeting at least once a year, which should in principle take place in the MS of the chair (decision up to the chair).
- In principle every MS should be willing to be the chair. Two MSs could co-chair at the same time. With this option small member states which may not have the resources to chair but who wish to do so can coordinate with another small MS or even with one of the larger MSs and they can chair concurrently.
- The chair will change on a yearly rotating basis.
- The responsibilities of the chair are
 - organisation of teleconferences and at least one face to face meeting,
 - preparing the necessary agenda,
 - preparation the minutes of the teleconferences/meetings (preferably within 2 weeks) and to circulate them to the other MS of the zone,
 - attendance of the inter-zonal Steering Committee,
 - manage the updating of the overview table on zonal applications,
 - collecting remarks and comments on relevant guidance documents and discuss them in the zSC,
- Representatives for the interzonal steering committee (izSC) will be the chair and the in-coming chair of the zSC.

*Form to notify intended zonal applications under Regulation (EC)
No 1107/2009*

Send to contact points of zonal Rapporteur(s) (**zRMS**) **and** concerned MS (**cMS**)
¹ preferably via e-mail

1. Product (name(s) and/or product code(s)), type of formulation:

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2. Name, content and status at EU-level of active substance(s) (name all actives):

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3. Applicant:

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4. Intended zones, proposal for zRMS and proposed dates for submission of the application to zRMS and cMS:

Northern zone:	submission date:
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Central zone:	submission date:
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Southern zone:	submission date:
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5. Summary of uses.

a For general overview of products within each zone, please complete table in appendix A.

b For details of all national GAPs within each zone, please complete table in appendix B.

¹ For list of contact points see on Commission Website
http://ec.europa.eu/food/plant/protection/evaluation/contact_points_en.xls

c For each zone, which MS approval represents the critical GAP – and thus can be used to establish the risk envelope. Please give brief details or complete table in appendix C.

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6. Is the source of the active substance(s) identical with the one(s) evaluated for the inclusion?

If not, provide information if an equivalence assessment has already been carried out (name MS, including the date).

If no assessment has been conducted, appendix E would need to be completed and ***should be send separately or provided in the pre-meeting²***.

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Please note.

A short but sufficiently descriptive summary should be provided together with this form highlighting critical aspects and potential areas of concern.

Detailed technical questions should be submitted separately in time prior to pre-meetings with zRMS (or cMS, if relevant).

² In cases that the applicant has no access to these data, the specification could be sent directly from the respective applicant/manufacture to the zRMS/cMS with a clear reference.

Appendix A - General overview of products within each zone

MS	Product name	Product code	Active substance(s) and content (g/L or g/kg)	Crop(s)	Authorisation holder of registered product ³	Authorisation number of registered product ³	Comments

³ For new products not yet authorised this field is not applicable.

Appendix B - details of all national GAPs within each zone (to be sorted by crop)

(For further information regarding filling the table see appendix D)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1													
2													
3													
4													
Field uses													
1													
2													
EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to article 51													
5													
6													

Appendix C – critical intended uses within each zone

Table A: Operator/worker/bystander/resident exposure risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Table B: Dietary risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Table C: Environmental risk assessment (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Table D: Ecotoxicological risk assessment* (copy of relevant use(s) from appendix B)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

*) For the ecotoxicological risk assessment the critical organism should be indicated under remarks.

Appendix D – guidance for filling the GAP table

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data) – not relevant for the notification form.

The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops).

All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.

Make use of existing standards like EPPO and BBCH.

Product:

Please indicate the specific variant of the active substance if relevant.

If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks.

As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions / location of use).

Formulation:

Type:

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International)¹⁾.

Conc. of as:

g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

¹⁾ http://www.croplife.org/files/documentspublished/1/en-us/PUB-TM/4147_PUB-TM_2008_05_01_Technical_Monograph_2_-_Revised_May_2008.pdf

Safener/Synergist:

Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s):

All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:**No.:**

Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s):

For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table. Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation:

The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).

If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones.

Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use:

Outdoor or field use (F), glasshouse application (G) or indoor application (I)
"Glasshouse" indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.

[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled:

Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.

In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code, ...) – period, first and last treatment.

Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”.

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

- a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
- b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

- a)-(Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
- b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/l per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (l/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given. The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated. Information concerning the sowing method (precision drilling, ...) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

- a)-(Maximum) as rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
- b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations.

In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials. If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

PHI (days) – minimum pre harvest interval

PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks:

Remarks may include: amount of safener/synergist per ha or extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

Additional recommendations:

For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 "Harmonized basic information for databases on plant protection products"
- EPPO Standard PP1/ 248 "Harmonized classification and coding of the uses of plant protection products"

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

For EPPO-Guidelines, see: <http://archives.eppo.org/EPPOStandards/efficacy.htm>

Use EPPO extrapolation tables, see <http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm>

For EPPO Plant Protection Thesaurus, see: <http://eppt.eppo.org/>

Appendix E – Specification of the used technical material

(Document should be sent separately or provided in the pre-meeting)

Name of the active substance or variant:

Manufacturer:

Location of the manufacturing site:

Chemical name/code	CAS number, if available	Structural formula	Specified levels Minimum purity (as) Maximum content (impurities) [g/kg]

Appendix 4 - standard e-mail table to notify MS that an assessment is available for commenting (includes a row detailing the zRMS conclusion)

Product name (product code)	
Active substances	
Applicant	
Application reference code of zRMS (if available)	
Application for (type of application)	
Concerned Member States	
Direct link to the completed assessment uploaded to CIRCA	
Direct link to part C uploaded to CIRCA	
6 weeks deadline for comments	
zRMS conclusion	<p>E.g.</p> <p>An authorisation has been recommended for use on X, Y and Z</p> <p>An authorisation has been recommended for use on X and Y and it is recommended that use on Y is refused due to insufficient <i>[insert brief details why refusal has been recommended]</i></p> <p>No authorisation can be recommended due to insufficient <i>[insert brief details why refusal has been recommended]</i></p>

Appendix 5 - Types of application and commenting requirements

	Type of application	description	Requirement for commenting Y/N
1a	Duplicate authorisation (from data owner)	<p>Identical product (same formulation manufacturer and source of a.s)– same authorisation holder</p> <p>-Changes applied may include, commercial name, marketing company (see extract from SANCO/2010/13170 rev. 7 below).</p> <p>-Same or reduced label claims</p> <p>Article 34(ish)</p>	N
1b	Duplicate authorisation (with access agreement)	<p>Same product – different authorisation holder (will usually require data access agreement).</p> <p>-Identical product (same formulation manufacturer and source of a.s)– In addition to the authorisation holder Changes applied may include, commercial name, marketing company (see extract from SANCO/2010/13170 rev. 7 below).</p> <p>-Same or reduced label claims as original product</p> <p>Article 34(ish)</p>	N

	Type of application	description	Requirement for commenting Y/N
2a	Generic authorisation – no technical assessment	<p>From non-notifying company.</p> <p>New product referencing an existing authorisation but with different source of a.s. (previously found technically equivalent) and different formulating company.</p> <p>Same or reduced GAP and label claims as reference product.</p> <p>Formulation differences from the reference product are non-significant (SANCO/12638/2011).</p> <p>Reference product data are unprotected in the evaluating MS or relevant data access agreement is in place.</p> <p>Article 34 (using Guidance document on significant and non-significant changes of the chemical composition)</p>	<p>N –</p> <p>Assessments of formulation comparison should be accepted by other MSs.</p> <p>Concerned MS will need to consider data protection / data access in their MS and whether the reference product is authorised in their MS.</p>
2b	Generic authorisation with technical assessment	<p>From non-notifying company.</p> <p>New product referencing an existing authorisation but with different source of a.s. (previously found technically equivalent) and different formulating company.</p> <p>Formulation differences from the reference product are usually significant with specific formulation data provided for some areas of the assessment (SANCO/12638/2011).</p> <p>Additional data may be required to cover differences from the original product or to match protected data</p> <p>Article 33</p>	Y
3a	Minor change of existing authorisation (no data required)	<p>Change of authorisation within existing risk envelope. E.g. non-significant formulation change / packaging change</p> <p>Article 45</p>	N

	Type of application	description	Requirement for commenting Y/N
3b	Change of existing authorisation (new data are required)	More significant changes to e.g. formulation / packaging where new data or risk assessment is required. Article 33	Y
4a	Additional crop or pest control claim (no data required)	When extrapolation from assessment for existing crop/pest is acceptable (MRL check required) Article 45	N
4b	Additional Crop	Technical assessment required Article 33	Y
5	New product with complete data package	Article 33	Y
6	Concerned MS application	Concerned MSs national 120 day assessment Article 36(2)	N
7	Mutual recognition	National 120 day assessment submitted after zRMS assessment is complete Article 40	N
8	Application to address product data gap	Where authorisation previously granted with minor data gap (most commonly shelf life data) Ideally this would be assessed by original zRMS at the next significant application.	N (unless a concern has been identified)
9	Technical equivalence	Assessment of a new source of active substance Article 38	Y
10	New crop (minor use)	New use on minor crop based on new data and or/risk assessment Article 51	Y
11	Parallel permit	Article 52	N
12	Emergency authorisation for 120 days	Article 53	N (must inform COM)
13	Product containing a GMO	Article 48	Y
14	Permit for trials purposes	Article 54	N

Zonal evaluation and Mutual recognition under Regulation (EC) No 1107/2009 (ART. 33 – 42)

