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

Background

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 recognizing an authorization, except for clearly defined circumstances.

Under Regulation (EC) No 1107/2009 an authorization in one MS can be used for mutual recognition in another MS.

PPP Zonal authorization

Legal basis

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

applications for authorization shall include all the intended uses in each zone and the MS to which they intend to apply (art.33).

applicants should also make a proposal as to which MS 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).

PPP Zonal authorization

In case of applications for the following use only one MS shall evaluate the application considering all zones (Article 33.2 b).

- Greenhouses as defined in Article 3 par. 27
- Post-harvest treatment as defined in Article 3 par. 28
- treatment of empty storage rooms
- seed treatment

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

PPP Zonal authorization

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 (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).

PPP Zonal authorization

The zonal RMS shall decide within 12 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 6 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.

PPP Zonal authorization

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 (stop the clock).

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 12 month timeline would apply.

PPP Zonal authorization

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 authorization at the latest within 120 days of receipt of the assessment report and the copy of the authorization (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).

PPP Zonal authorization

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.

low risk products**:** 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).

PPP Zonal authorization

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).

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:

1 inter-zonal steering committee

3 zonal steering committees

2 zonal contact point per MS

Within each MS there are 2 zonal contact points identified, which are recorded in the EU contacts list which is available on CIRCABC.

Zonal Steering Committee

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 organized and chaired by the participating MS on a yearly rotating basis

Inter-zonal Steering Committee

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 organized and chaired by the Commission in association with the participating Member States.

Applications and authorisations database

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 inter-zonal 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.

Before industry submits an application (pre-application)

At least 6 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 authorization is envisaged. A common format ("notification form") has been developed which should be used by applicants.

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.

Notification form

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:

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

3. Applicant:

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

Northern zone:	submission date:
Central zone:	submission date:
Southern zone:	submission date:

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.

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.

Pre-submission meetings are not obligatory but highly recommended for complex applications/groups of applications.

products with multiple uses

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 1 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.

Application

applicant should make its application in each MS where an authorization 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

Dossier to be submitted

The draft registration report format for each product (SANCO guidance 6895/2009).

Covering letter

Data underlying the core assessment

Other national requirements (application forms etc) relevant to the receiving MS

Confidential information.

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 authorization is applied for.

Quality of the dRR

quality of the dRR prepared by the applicant influences the time keeping process and resource efficiency of MS.

1 product – 1 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

Completeness check

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.

The check shall be conducted by the zonal RMS and should be finalized within 6 weeks.

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 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.

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.

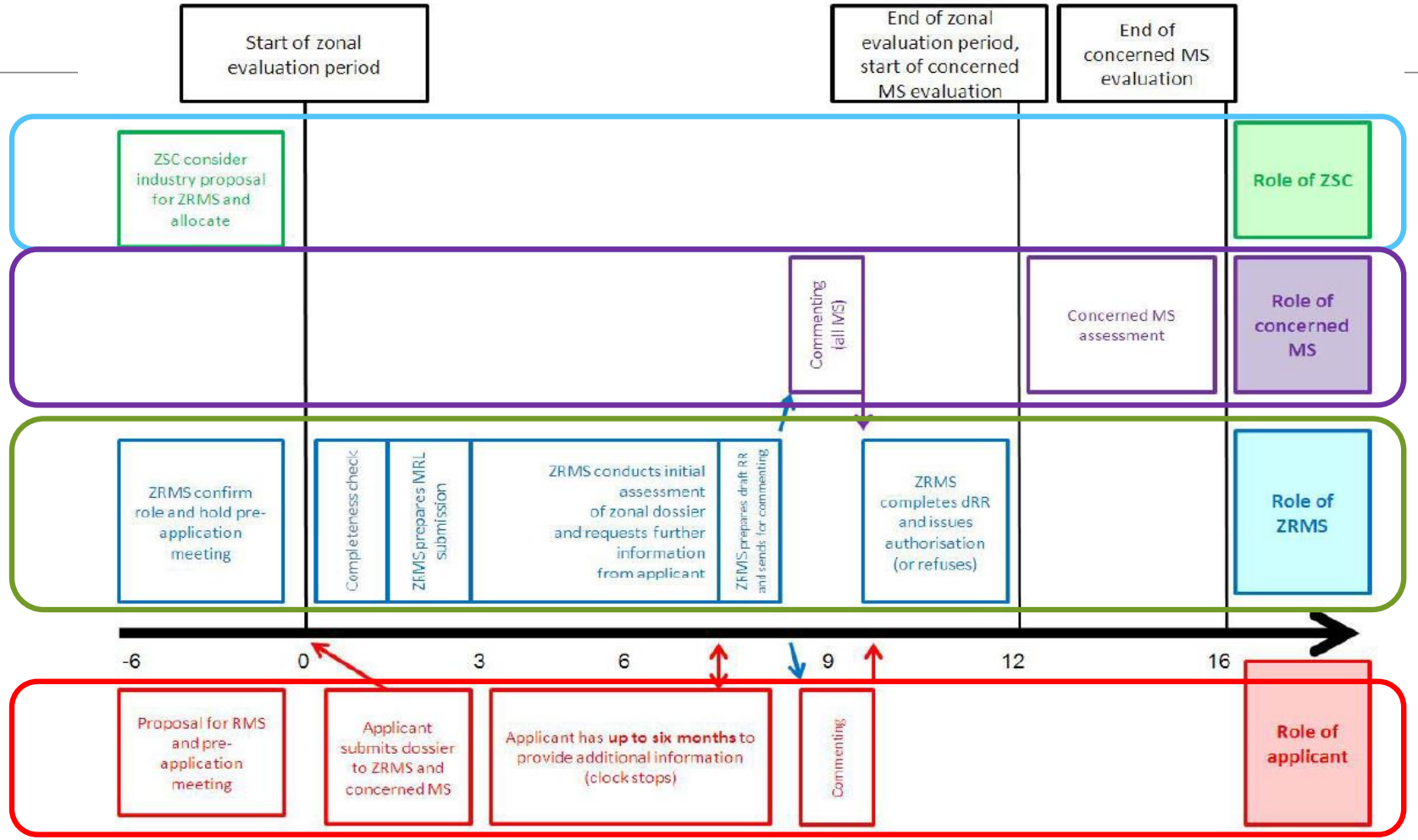
Timelines

In line with Article 37.2, in case of applications for authorization 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.

Timelines zonal evaluation and mutual recognition



Comments on zonal RMS draft

The zonal RMS draft registration report should be uploaded to the authorization 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.

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.

Decisions by zonal RMS

The concerned MS have to issue an authorization or refuse the authorization 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.

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

Authorisation by other MS in the zone

Once the comments have been received the zonal RMS should finalize 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 6 month period for requests for further information.

The zonal RMS may grant or refuse the authorization. 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 authorizations unless the provisions of Article 36(3) are applicable.