Department of Agriculture, Food and the Marine
An Roinn Talmhaíochta, Bia agus Mara

Final report

EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation

2-4 June 2015, Dublin Castle, Ireland

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Executive summary

EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation

2-4 June 2015, Dublin Castle, Ireland

Background

In Regulation (EC) No 1107/2009 it is indicated that the principle of mutual recognition is one of the means of ensuring the free movement of goods within the European Union. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the European Union has been divided into zones with such comparable conditions in order to facilitate such mutual recognition.

Before Regulation (EC) No 1107/2009 became applicable a workshop was organized in January 2010, hosted by BVL in Braunschweig (Germany), to set the framework for the zonal system. As a result two draft guidance documents were prepared. The *Guidance Document on Zonal Evaluation and Mutual Recognition* and the *Guidance Document on Renewal, Withdrawal and Amendment* were the concrete output of this workshop.

The experience that EU Member States and industry have with the zonal system differs. There are good examples e.g. were authorizations are granted within the 120 days deadline, but there are also many situations where for several reasons deadlines were not met or the provisions for mutual recognition were not applied properly. Now, more than 5 years after the entry into force of Regulation (EC) No 1107/2009, it was time to take stock.

The zonal system is a reality of which the principles are laid down in Regulation (EC) No 1107/2009. The European Commission is dedicated to the principle of zonal evaluation and

mutual recognition and is keen to enhance its functioning. The Commission has organised this workshop also in light of the upcoming review of Regulation (EC) No 1107/2009, where the Commission is asked to evaluate the functioning of mutual recognition and the division of the European Union in three zones. This event was aimed at an improvement of the zonal system to ensure that a consistent and workable approach will be applied across Member States.

Objectives of the workshop

In summary, the main workshop objectives were:

- provide an overview of current achievements in working with the zonal system
- discuss problems that Member States and applicants face with the zonal system
- identify regulatory solutions to those identified problems
- suggest harmonised solutions to facilitate the zonal process
- draw conclusions and recommendations for Commission, Member States, and applicants.

Workshop participants were requested to discuss concrete solutions which should contribute to a consistent and workable approach for applicants as well as Member States.
The following main areas of discussion were identified:

- Remit of the zonal Steering Committees;
- Remit of the interzonal Steering Committee;
- Necessity of national specific requirements;
- Interzonal Worksharing;
- Quality of evaluations;
- Need for a Zonal secretariat;
- Usefulness of the PPP Application Management System ('Authorisation database');
- Managing the re-authorisation process (Article 43).

Outcomes of the workshop

Zonal System and Mutual Recognition

The focus of the discussion was on how to improve the implementation of the zonal system and the principle of Mutual Recognition (according to SANCO/13169/2010 rev. 9 - 11 July 2014 “Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009”).

The discussion and recommendations focused on three key topics:

- Zonal evaluation and national specific requirements
- Worksharing
- Mutual Recognition

Zonal Evaluation and National Specific Requirements

Efficacy

Although the EU has been divided in 3 zones where agricultural, plant health and environmental (including climatic) conditions are considered comparable, these zones don't match the EPPO zones. Guidance is needed to provide a harmonised approach for the inclusion of efficacy trials for different EPPO Zones in a zonal dossier.

National Specific Requirements

The national specific requirements have been collected in the Northern Zone, Central Zone and Southern Zone. It would be helpful to update this list to increase transparency. MSs should consider how they can remove their national specific requirements and this will need further discussion with the Directors' Consultation Group of the zones (or equivalent group). Key questions to be asked are: 'What is necessary from a regulatory point of view?' and 'Are national evaluations indispensable?'.

EFSA could be requested to evaluate whether the national specific requirements have a scientific basis. EFSA also offered to develop a tool for risk characterization in EU regions (areas not necessarily limited to the borders of a MS) considering the main crops of EU.

Endpoints

Prerequisite is that Member States for granting national authorisations use the EU agreed endpoints. Furthermore the Guidance Document SANCO/10328/2004– rev 8 on the evaluation of new active substance data post approval shall be followed by MS. The use of different endpoints contributes to the lack of harmonization. The suggestion from EFSA to develop a database of all AS and PPP endpoints was welcomed.

Worksharing

Zonal and Interzonal Steering Committees

There should be a harmonised and consistent way for publishing minutes and decisions of the steering committees to provide better transparency and clarity to industry and other stakeholders on decisions taken. This should improve the ways of working with industry and as a consequence should enhance the quality of future dossiers.

Risk Envelope and draft Registration Report

The principle of the risk envelop is generally working well. The potential for taking a risk envelope approach across products was discussed to see if it could reduce workload and create efficiency in dossier production and evaluation. However, it can also create additional complexity. Therefore the strategy for a group of products needs to be clear and agreed with zRMS in pre-submission meetings. The registration reports are expected to be a stand-alone document in order to facilitate mutual recognition and worksharing in general. The new dRR format (March 2015) is a good tool to improve the quality of applications.

Interzonal Evaluation of Common Sections of the Dossier

Interzonal evaluation of indoor uses and common sections (e.g. phy chem, tox) needs to be further explored. This concept would reduce workload for MS. There has been limited success in this area to date.

Commenting
Commenting is considered by MSs an important step in understanding each other approach in risk assessment and can serve as a basis for building trust. An efficient commenting process is critical to this. Key challenges are the submission of additional data during the commenting period and the acceptance by the cMSs of the evaluation as prepared by the zRMS. Once the commenting period starts, there is not an opportunity to submit additional data. CMSs should accept the evaluation made by the zRMS and make a decision. There is no possibility to stop the clock during the 120 day period for a national assessment.
In general, improved quality of dossiers would help MSs to meet the timelines.

Mutual Recognition
Under Regulation (EC) No 1107/2009 an authorisation granted by one Member State should be accepted by other Member States if the application is made for the same product, the same use and under comparable agricultural, plant health and environmental (including climatic) conditions.
Although Member States should accept authorisations granted according to Uniform Principles under Directive 91/414, they apply in some cases different approaches.

Some difficulties in mutual recognition are frequently related to:

- Availability of a Registration Report (in English)
- Quality of the risk assessment
- When comments on the original application/authorisation have not been taken into account
- or when MSs don't have the resources at all to comment on the original application/ authorisation
- Different interpretation of (technical) guidance documents
- Data protection

More and earlier involvement of Member States in the development of technical guidance documents for both active substance and product assessment, improvement of zonal Registration Reports and support from Director's consultation groups (or equivalent group) could improve harmonization and facilitate mutual recognition.

Development of harmonised risk mitigation measures would also facilitate mutual recognition (e.g. MAGPIE).

Regarding data protection a database of references relied upon and the status of data protection for each decision taken should be available at Member State level.
It is not totally clear from Regulation (EC) No 1107/2009 as to when the 120 days' timeline starts (at the time of submission of the application or when the application is considered complete).

In order to achieve more harmonization within and between zones an exchange platform for experts would be helpful. CIRCABC could be used for this purpose. (e.g. the 'Newsgroups' as already used by the MS).

Re-authorisation – Article 43
A revised guidance document has been developed to clarify the procedures contained in Regulation (EC) No 1107/2009 for just the renewal of authorisations according to Article 43 of Regulation (EC) No 1107/2009. The 3-months timeframe may be too short to submit all necessary data. In this case the applicant may justify the lack of data by the fact that it could not anticipate this request before EFSA conclusions for the substance were available and a MS may find it justified to apply Article 43(6) and extend the authorisation and delay the re-authorisation.

This approach is described in detail in the draft **Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009** (SANTE/2010/13170 rev. 12; 20 March 2015).

The following points were discussed. Conclusions were reached, which are the basis of rev. 13 of the Guidance document for noting in the SCoPAFF in July 2015. It is important to have a harmonised procedure for Art. 43 applications as applications will be received by March 2016.

- Due to **seasonal studies** the applicant may be unable to provide the authorities with a complete application within the 3 months deadline because the time to conduct these studies (necessary because of e.g. changed end points) is too long ("category 4 studies"). These studies should be submitted as soon as possible, taking into account the time necessary to conduct the studies (generally within 2 years), to the zRMS who will evaluate the completed dossier within 6 months after submission. All MS should take a decision within 3 months. An initial indication of agreement on the studies which are needed and where possible an expected timeframe should be provided and agreed upon with the zRMS at the latest 2 months after publication of EFSA conclusion.

- The evaluation and assessment should focus only on the **new information** in those sections, for which changed endpoints and new data requirements have been considered. Also the conditions or restrictions in the renewal regulation, including the issues mentioned in the renewal regulation ("MS shall pay particular attention to....") should be considered.

- The new information is to be assessed using the Guidance documents in force at the time of application according to Article 43.

- No assessment of **efficacy data** is necessary if the GAP remains unchanged. Only the aspect of the possible development of resistance or cross-resistance should be assessed by the zRMS.

- Because of changes of end-points it might be necessary to lower the application rate, while still being above the effective dose. In this case new or additional efficacy data (reflecting the new GAP) might be needed (which will also be considered as seasonal or "category 4" studies).

- **Data matching check** is based on the list of studies relied upon for the renewal of the active substance and has to be performed by the active substance RMS as soon as possible after the 3 months deadline for application.

- **Allocation of the zRMS**
  The applicant should propose a zRMS 2 years before the application date, according to Article 43. The final allocation of the zRMS should be notified to the applicant preferably before the publication of the EFSA conclusion.

This adaptation of the Guidance Document allows for a pragmatic implementation based on the limitations of Art. 43.

Zonal Secretariat
A need for a secretariat is acknowledged by the workshop participants.

The secretariat should have exclusively administrative tasks, focusing on managing the current Plant Protection Products Application Management System (PPPAMS) system of which the funcitionalities need to be extended, and on maximizing efficiency of the zonal process. A pilot project should be run by a Commission focused working group, to determine best remit for the secretariat.

The establishment of a permanent secretariat would help solving the problems presently extant in the process of authorisation of PPP.

It is concluded that a secretariat could be helpful in removing the administrative burden, thus giving the Member States the opportunity to focus on core business: applications assessment and decision-making.

The role could be achieved as administrator of the current PPPAMS system. However, the current system would not fully cover the needs of an effective organisation of evaluations and its functionalities would hence need to be extended into an interactive workspace for both applicants and evaluators.

In recognition that the development of an extended system would take time, it is recommended to consider a more immediate pilot project to define the roles of the secretariat more fully. This would also encourage the use of the current system by Member States and applicants in collaboration.

The pilot project could also explore possibilities for future legislative status and funding for the secretariat role.

Next Steps
A list of action points can be found in chapter 1 of the report..

1 Summary table of actions

Annex I

Action points

Topic	Proposed Action	Short/ Medium/ Long term	Responsibility
"**National Specific Requirements**"	**Efficacy** COM and MSs to co-ordinate with EPPO. EPPO needs to identify the minimum number of trials. This should then provide the basis for guidance for a harmonised approach for the inclusion of efficacy trials for different EPPO Zones in a zonal dossier. Post workshop note: Belgium has proposed to organise a workshop on this issue early 2016.	Medium term	Belgium to liaise through Post Approvals issues (PAI) group and EPPO.
	National Specific Requirements Member States (MSs) (N-C-S Zone) to evaluate whether their national specific requirements could be removed.	Medium term	Member State.
	Chair of Zonal steering Committee to report to Directors meeting (or equivalent) for consideration and agreement.	Short term	Chairs of zonal steering committees (ZSC).
	ZSC and iZSC to discuss EFSA´s offer to evaluate the basis of the national specific requirements and their justification	Medium term	ZSC, iZSC.
	MSs to report to zonal steering committee by end of 2015 and to Directors meeting (or equivalent group) in 2016 on progress.	Medium term Medium term	Member State ZSC, iZSC, EFSA

Topic	Proposed Action	Short/ Medium/ Long term	Responsibility
	ZSC and iZSC to discuss EFSA's offer to develop a tool for risk characterization in EU regions considering the main crops of EU. EFSA to provide information to iZSC on what is possible and by when. **Endpoints:** ZSC and iZSC to discuss EFSA's offer to develop a database of AS and PPP endpoints and the process for updating it. EFSA to provide information on what is possible and by when.	Medium	ZSC, iZSC, EFSA
Zonal Steering Committees	ZSCs and iZSC to discuss a harmonised and consistent method for publishing sanitized minutes and decisions to provide better transparency and clarity to industry and other stakeholders on decisions taken. This should improve the ways of working with industry and as a consequence should enhance the quality of future dossiers..	Short term	Chairs of zonal steering Committees
Risk envelop Approach	Industry to explore this possibility, for article 43 submissions, recognising the need for a complete dossier of high quality with reference lists. Zonal RMS's to adopt approach where ever possible.	Medium term	Industry and ZRMS
Worksharing between Zones	ECPA will consider building a proposal for how interzonal worksharing could work and identify (re-registration) projects which could be pilots and come back to the ZSCs and iZSC with a proposal. **Worksharing based on indoor uses and common sections in the dossier (e.g. phy chem, tox):** Needs to be further discussed in the Zonal and Interzonal Steering Committees.	Short/ Medium term Short term	ECPA ZSC's /iZSC

Topic	Proposed Action	Short/ Medium/ Long term	Responsibility
Commenting Periods	PAI group to consider and amend the guidance document on Zonal Evaluation and Mutual recognition. PAI group to draft guidance document to accompany the new dRR templates to provide guidance to applicants on what is required for each section. (Post workshop note: A "dummy" example of a dRR using the new template will be prepared by Germany)	Short term Short term	PAI dRR group/ Germany
Mutual recognition between zones	Member States to look at real solutions to ensure implementation of this legal requirement. Report from this workshop to go to the Directors meetings (or equivalent group) in each zone.	Short - Medium term	Member State Chairs of ZSC's
Mutual Recognition within the zone	Improvement of technical guidance development procedure. Improvement of zRMS registration reports to enable mutual recognition. Update guidance document on zonal evaluation and mutual recognition Promote harmonization and mutual recognition at "political" level. Chairs of Zonal Steering Committees to report to Directors meeting (or equivalent). Member State experts to use and develop experts forum on CIRCABC for communication Harmonized risk mitigation measures (e.g MAGPIE)	Short Term Short –Medium term Short- Medium term Short - Medium term Short - Medium term Medium term	Pesticide Steering Network Member States PAI group Chairs of Zonal Steering Committees. MS experts MS experts via workshops and working groups

Topic	Proposed Action	Short/ Medium/ Long term	Responsibility
Lists of studies	Every MS should have a database with list of studies relied up for every decision taken.	Short - Medium Term	Member States
Time lines for mutual recognition	Clarify in guidance document on zonal evaluation and mutual recognition when 120 days should start	Short- Medium term	PAI group
Data protection	Finalize amendments of guidance document	Short term	PAI group
Zonal Secretariat	Directors to decide if there is support for a pilot project and propose participating Member States during June meeting of central zone. Industry to consider support for pilot. Request Member States and industry support (financial and resource) for the pilot. Proposal to the Central Zone Directors meeting for participation in pilot scheme. If agreed Central Zone to lead a pilot project with new PPPs, involving all 3 zones. Pilot project team to: Draft remit after the pilot is completed (to be included in PPP management system user guide Evaluate budget needs after the pilot project is completed Commission to reflect on legal status when drafting the legislation on the PPP system. Check options organising work (ZRMS) in Central Zone	Short term Medium term Short- Medium term Short term Medium term Short –Medium term	Chair of central Zone steering group Industry Pilot project team Chair of breakout group D Pilot project team and Central Zone Steering Committee Pilot project team

Topic	Proposed Action	Short/ Medium/ Long term	Responsibility
	for Article 43 applications Commission to reflect on funding when drafting the legislation on the PPP system	Short –Medium term	COM
PPP management system (database)	Organise a working group by the end of 2015 on what would be needed from an interactive workspace – with participation of Member States, industry and the developers of the current system Extend functionalities of the current PPP management system to make it an interactive workspace (directions to be considered at the working group mentioned earlier)	Medium term	**Commission**
Renewal of Authorisation (Article 43 of Reg. 1107/2009)	Revised version of draft Guidance Document to be circulated for consideration and possible note taking at July 2015 Standing Committee.	Short	Com/ MS

2 Breakout Group A (Zonal system)

2.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States

Background

The main purpose of the Regulation (EC) No 1107/2009 is described in **preamble 8** and states that *the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture.*
This follows by **article 1.3** - *The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production*.

Zones

*In **preamble 29** it is stated that "the Community should be **divided into zones** with such **comparable conditions** in order to facilitate such mutual recognition."*

The definition of such zones is found in **article 3.17**– *zone means a group of Member States as defined in Annex I. For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment the zone means all zones defined in Annex I.*

Annex I states that there are three zones:
Zone A — North: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden
Zone B — Centre: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom
Zone C — South: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia

The division of the EU into three zones is related to Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Although, EPPO has developed a **guidance on comparable climates (EPPO guidance PP 1/241)** for the efficacy evaluations of plant protection products. They have divided Europe into 4 different zones.

Work sharing and appointing zonal rapporteur

The procedure to appoint a zonal rapporteur (zRMS) is described in article 33 and 35.

***Article 33.2b** states that the application shall include a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned.*
*Further on in **article 35** it states that the application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine*

it. At the request of the Member State examining the application, the other Member States in the same zone to which an application has been submitted shall cooperate to ensure a fair division of the workload.

Work sharing according to Guidance document

In the **guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev.9)** the zonal steering committees (one per zone and one interzonal) are outlined. The establishment of zonal steering committee is to facilitate the communication within and between the zones to make the zonal system as effective as possible. The remit of the interzonal steering committee and the zonal steering committee are detailed in **appendix 1 and 2** to the guidance document.

Procedure

The evaluation procedure is described in art 35, 36 and 37.

*In **article 35** it is written that the other Member States within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application.*

*And in **article 36.1** The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.*

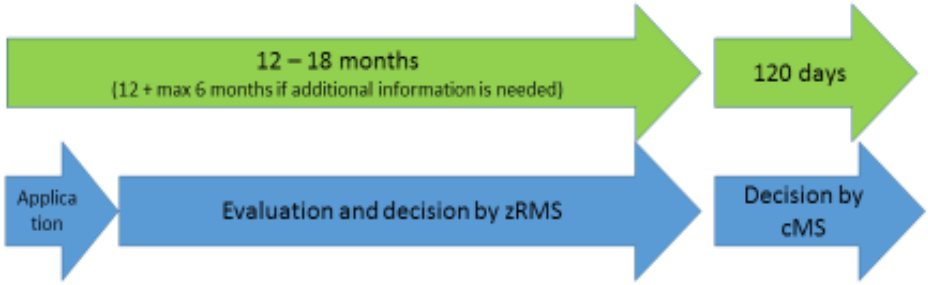
It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The examination for authorisation in a concerned member state (cMS) should be according to article 36.2 and they shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32.

***Article 36.3** gives the member states the possibility to impose appropriate condition of use with respect to the requirements referred to in art 31.3 and 31.4 and other risk mitigation measures deriving from specific conditions of use.*
It also states that *where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.*

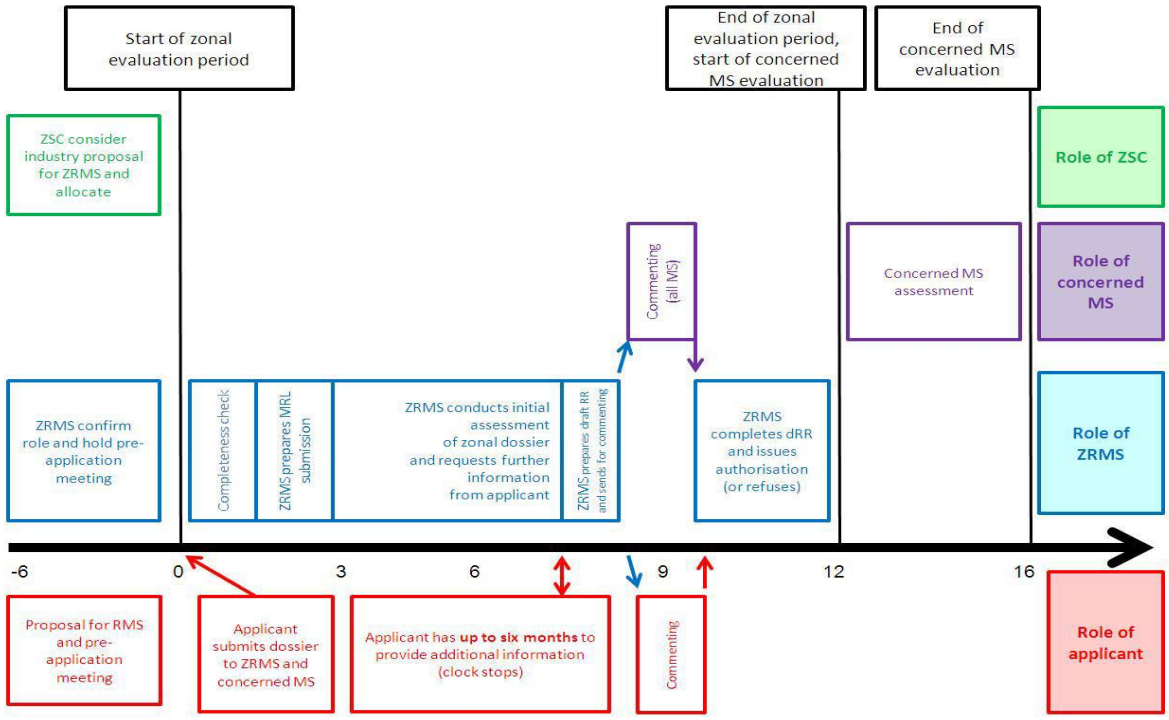
The timelines for the assessment of both the evaluating member states as well as for concerned member states are given in **article 37.1** and **article 37.4**. According to this *the Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met. The other Member States concerned shall at the*

latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).



Procedure and timelines according to Guidance document

In the **guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev.9** the zonal process is further described with more specified deadlines for different goals in the evaluation process.



- This process contains the step of pre-notification, which is not mandatory for the applicant since it is not stated in the regulation but highly recommended. The pre-notification should be at least 6 months ahead submission of the application.
- Within 6 months from submission of the application further requirements should be identified. The deadline for submission should be of realistic length, but not exceeding 6 months.
- The assessment should be completed and sent out for commenting within 8 months (excl. stop the clock time) after submission of the application.
- A commenting period of 6 weeks should be provided both to cMS and applicant

- During the cMS 120 days any evaluation regarding national requirements as well as decision making have to take place

Discussion points

Zones

1. The main reason for dividing the EU into different zones is to facilitate mutual recognition, since the Member States within a zone should have comparable conditions as regards agricultural, plant health and environmental (including climatic) conditions. Why do Member States, although they belong to the same zone, consider themselves still 'different' from their neighbours?

2. Is possible to achieve the prerequisites in preamble 8, regarding safeguard the competitiveness of European Union agriculture, with the division into two larger zones and one small?

Work sharing

3. Is the zonal steering committees workable? What can be improved? Is there anything in the remit that needs changing?
4. Pre-notifications, are they a good instrument for planning and appointing zRMS? Are they complete with the information needed? Do minor applicants use them? If not, how will the process of appointing zRMS work smoothly if an application just is submitted?
5. The appointment of zRMS is done differently between the zones. Some zones just accept the proposal and other have more difficulties to find a zRMS. How does the zones appoint a zRMS when the proposed zRMS refuse to be zRMS? Volunteers? Are they easy to find? Does the appointing of zRMS work? What can be improved?
6. Are the GAPs harmonised as much as possible with in a zone, if not is that a problem in the sense of work sharing?
7. Is the risk envelope approach working as an efficient option to reduce the workload of the assessment?
8. Work sharing between zones is that a realistic option, when it comes to certain areas of the evaluation?
9. How can the comments contribute to the harmonisation?. Are Zonal guidance documents for the risk assessment and risk management useful for the harmonization? Do they contribute to harmonisation within the zone or between zones? Which are the priorities?

Process and timelines

10. The Regulation contains a working process for the examination of applications with strict deadlines. Is it feasible to keep these timelines, both for MS and IND?
11. Where in the process is it most likely that the breaking of the timeline occurs? Confirmation/appointing of zonal rapporteur? Evaluation? Requesting further information? Decision making? New data received after the commenting period, that implies new assessment and perhaps a new commenting period?
12. How can the process be improved?
13. How is commenting working? Does the zRMS get any comments? What about the quality? Do the commenting MSs feel that their comments are taken into

consideration? Is a system needed to solve resulting disagreements? Does IND just comment on factual issues?

14. How does the changing of application dates from the date stated in the notification affect the planning in a zRMS?
15. In appendix 5 of the GD SANCO/13169/2010 rev. 9 on zonal evaluation and MR there is a table on which types of applications that require commenting. Do MS and IND have the capacity to comment on all these and does the commenting contribute to the evaluation.
16. The cMS has only 120 days for evaluation of national requirements and decision making. Is it possible to manage in time? If further information is needed regarding national requirements is the clocked stopped? How is keeping track of time used done, so that the 6 months are not exceeded?
17. National requirements, do they serve a purpose, because of difference in environment or agricultural practise or are they just old habits? Can the amount of NR be reduced? Are the national data requirements scientifically justified?

2.2 Summary report

1. Introduction

Purpose: The focus of the group was on how to improve the implementation of the zonal system (according to SANCO/13169/2010 rev. 9 - 11 July 2014 "Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009").
The discussion and recommendations focused on three key topics:

- Zonal evaluation and the challenge of national requirements
- Worksharing
- The zonal process and timelines

2. Zonal Evaluation and the Challenge of National Requirements

Efficacy
The 3 zones are regulatory zones and don't match the EPPO zones which match the agronomic and environmental conditions in a more realistic way. However, agronomic and environmental conditions might widely differ within a Member State as well . Guidance is needed to provide a harmonised approach for the inclusion of efficacy trials for different EPPO Zones in a regulatory zonal dossier.

Fate and Ecotox
The national requirements have already been collected in the North Zone, Central Zone and South Zone. MSs should first consider how they can remove their national requirements and this might need discussion with the Directors' Consultation Group. EFSA could be requested to evaluate whether the national requirements have a scientific basis. EFSA also offered to develop a tool for risk characterization in EU regions considering the main crops of EU.

Endpoints
For PPP evaluations in principle no active substance data need to be evaluated. Only to show a safe use they could be considered. Examples are mesocosm studies. The use of different endpoints contributes to the lack of harmonization. EFSA could develop a database of AS and PPP endpoints, to promote consistency and to prevent double work.

3. Worksharing

Zonal and Interzonal Steering Committees
From industry's perspective there is a lack of clarity and transparency of the discussions and decisions in the Steering Committees. The CZSC is publishing their agreements relevant for industry ('Bullet points') on the public PPP map on CIRCABC however. The SZSC will consider if they can also publicly communicate their agreements.

Risk Envelope

The principle of the risk envelop is good and generally it is working well.

The potential for taking a risk envelope approach across products was discussed to see if it could reduce workload and create efficiency in dossier production and evaluation. It was concluded that it could be an opportunity to reduce the workload. However, it can also create additional complexity. Therefore the strategy for a group of products needs to be clear and agreed with zRMS in pre-submission meetings. A standalone dRR per product is essential but could include risk envelope across products with special justification. It may be more appropriate for Fate, Ecotox, Residues than other sections. It could be difficult if additional refinement is needed. It is also important to clarify the approach for data protection in the pre-submission meeting. This could be an opportunity for art 43 renewals, when many products based on the same active are re-evaluated at the same time.

Interzonal Evaluation of Common Sections of the Dossier

- The MSs are very interested in this concept with a view to worksharing and reducing workload. However, it has not worked well in pilots so far, mostly due to the lack of coordination capacity. It could apply to products applied for in different zones, where some sections of the core dossier are common eg. phys chem., analytical methods, tox, residues, ecotox, fate.

Interzonal evaluation of indoor uses needs to be further evaluated now that the EFSA GD on protected uses is available.

Commenting
Commenting is viewed by the MSs to be important in building an understanding of each other and as a basis for building trust. It is the aspiration of Authorities to meet the timelines. An efficient commenting process is critical to this. Key challenges are:

- Submission of additional data during the commenting period. It was broadly agreed that this creates complexity, slows down the process and creates additional work. The applicant has an opportunity to respond to questions from the zRMS before the commenting period and to be involved in the commenting period. Once the commenting period starts, there is not an opportunity to submit additional data.
- cMSs who have not been involved in the commenting phase find it difficult to manage the 120 day timeline without a stop-clock period. cMSs should accept the evaluation by the zRMS and make a decision on this, if necessary with extra measures or restrictions + the national addenda in 120 days.

Quality of dRRs submitted by industry
If MSs will need to start to make stricter decisions in order to meet the timelines of the Regulation, greater clarity is needed between MSs and Industry about the quality of the dossier. This is consistently raised by MSs as an issue.

4. The Zonal Process and Timelines

Meeting the Timelines
The aspiration is to meet the timelines but this is still work in progress as the MSs are still building experience. MSs will not meet the timelines for Article 43.

It is considered that many of the actions above will support MSs in reducing workload, smoothing the process and thereby meeting the timelines for Article 33 applications.

5. Summary

The following are considered to be key factors in the zonal process working:

- Harmonisation of the evaluation, besides ecotox and fate especially for efficacy more harmonized approaches need to be developed
- Co-operation between zones supported by the iZSC and interzonal worksharing
- Quality of Guidance Documents including practicability in implementation
- Shared understanding of quality of the dRR and dossier requirements between MSs and Industry
- Transparency of ZSCs and iZSC, communication of agreements relevant to industry
- Not opening the box for mutual recognition
- Smoothing the commenting process and stop-clock period

2.3 Summary table

Summary of Discussion and Conclusions

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
ZONES				
Question 1: The main reason for dividing the EU into different zones is to **facilitate mutual recognition**, since the Member States within a zone should have comparable conditions as regards agricultural, plant health and environmental (including climatic) conditions. **Why do Member States, although they belong to the same zone, consider themselves still 'different' from their neighbours?**	**Efficacy** The 3 zones are political zones and don't match the EPPO zones which match the realities of agronomic and environmental conditions. GAPs are more similar within EPPO Zones than political zones. The question is how to integrate the EPPO system into the Regulatory zones. But Slovenia is across three EPPO zones and has to make this work and does not find it to be a big issue. The zonal dossier could contain efficacy trials from different EPPO Zones in the Zonal dossier. **Fate and Ecotox** For fate and ecotox, it is not the same issue as the core + addenda can fit with a zonal approach. National scenarios are used for refinement. For some products, there could be more work sharing as not	**Efficacy** Guidance is needed to provide a harmonised approach for the inclusion of efficacy trials for different EPPO Zones in a regulatory zonal dossier. **Fate and Ecotox** The national requirements have already been collected in the North Zone, Central Zone and South Zone.	**Efficacy** Efficacy needs work for harmonisation. COM and MSs to co-ordinate with EPPO. EPPO needs to identify the minimum number of trials. Then applicant will have guidance how to include efficacy trials from different EPPO Zones in the zonal dossier. **Fate and Ecotox** MSs (C Zone) to evaluate whether their national requirements could be removed (this may need discussion with the Directors' Consultation	Medium term Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	complex and the GAPs are well harmonised. In FR, concluded that FOCUS covered the national scenarios so use FOCUS and only national scenarios if refinement is needed. Is it possible to harmonise as protection goals are different?	MSs should first consider how they can remove their national requirements and this will need discussion with the Directors' Committee. EFSA could be requested to evaluate whether the national requirements have a scientific basis. EFSA offered to develop a tool for risk characterization in EU regions considering the main crops of EU. MS to consider this necessity. As a final and long term goal to have an EU CORE DOSSIER	Group.) EFSA can help to understand whether national requirements have a scientific basis. CZSC and iZSC to discuss EFSA's offer to develop a tool for risk characterization in EU regions considering the main crops of EU.	Long term
	Endpoints EFSA: List of endpoints to be included in a database. Could include updated endpoints for the AI and Product based on data submitted at the national level. EFSA would need to receive the original studies and be involved in the peer review. But this would be a continual updating of the AI.	**Endpoints** MSs to apply the GD on Annex II data – only evaluate if necessary to demonstrate safe use – could be provided to EFSA to amend the list of endpoints.	**Endpoints** CZSC and iZSC to discuss EFSA's offer to develop a database of AI and Product endpoints and the process for updating it.	Long term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Question 2: Is possible to achieve the prerequisites in preamble 8, regarding safeguard the competitiveness of European Union agriculture, with the division into two larger zones and one small?	Not discussed.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
WORK SHARING				
Zonal Steering Committees Question 3: Is the zonal steering committees workable? What can be improved? Is there anything in the remit that needs changing?	Limited discussion only. From industry perspective, there is a lack of transparency. The bullet point minutes are published by the C Zone on the CIRCABC. This also contains the messages which it is important for industry to know. However, industry is not aware that the intention from the CZSC is that these notes should be considered by industry as a communication of decisions. The SZSC communicate key decisions directly with applicants. They will discuss at the next meeting to publish bullet point minutes on CIRCABC to increase the transparency for industry.		ZSCs and iZSC to discuss a harmonised and consistent method for publishing minutes and decisions to provide better transparency and clarity to industry on decisions with the intention to improve the ways of working with industry and the future quality of the dossier.	Short term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Pre-notifications, Question 4: Are they a good instrument for planning and appointing zRMS? Are they complete with the information needed? Do minor applicants use them? If not, how will the process of appointing zRMS work smoothly if an application just is submitted?	Not discussed.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Appointment of ZRMS Question 5: The appointment of zRMS is done differently between the zones. Some zones just accept the proposal and other have more difficulties to find a zRMS. How does the zones appoint a zRMS when the proposed zRMS refuse to be zRMS? Volunteers? Are they easy to find? Does the appointing of zRMS work? What can be improved?	Not discussed.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Haromization of GAPs/risk envelope Question 6: Are the GAPs harmonised as much as possible with in a zone, if not is that a problem in the sense of work sharing?	Not discussed.			
Question 7: Is the **risk envelope approach** working as an efficient option to reduce the workload of the assessment?	The principle of the risk envelop is good and generally it is working well. The risk envelope may be different for one product in different sections of the dossier. It is not always possible to identify one worst case meaning that several need to be evaluated. There may also be one conclusion for Part B and one for Part A considering the national uses. If zRMS, what happens if worst case is not safe but other uses in cMSs may be? FR: request industry to provide a refinement. Don't accept to totally change the GAP.	Could be an opportunity to reduce the workload. However, it can also create additional complexity. Therefore the strategy for a group of products needs to be clear and agreed with zRMS in pre-submission meetings. A standalone dRR per product is essential but could include risk envelope across products with special justification. It may be more appropriate for Fate, Ecotox, Residues than other sections. It could be difficult if	Applicants to explore this possibility recognising the need for a complete dossier of high quality with reference lists and the need to create efficiency and effectiveness and not complexity for applicant and evaluators.	Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	The potential for taking a risk envelope approach across products was discussed to see if it could reduce workload and create efficiency in dossier production and evaluation. The concept would be to identify the risk envelope across a group of products and use the worst case for one product to cover another product. This could be relevant for Product Renewal programmes for a group of products where the deadline is triggered by the approval of an active substance. Taskforce dossier with a transversal risk envelope for Fate and Ecotox for copper has worked (FR) Risk envelope across products could help to save work by reviewing one evaluation. However, it is critical that there is a standalone dRR for each product. This could include a copy and paste of the evaluation based on the worst case GAP for another product. This means that the worst case GAP could be from a different product. In discussion, it's clear that it can	additional refinement is needed. It is also important to clarify the approach for data protection in the pre-submission meeting.		

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	become very complex (cross referencing, not similar compositions, data protection) and these factors would need to be considered. Conclusion that it could provide an efficiency gain for some products in the areas of Fate, Ecotox and Residues. The strategy would need to be clearly thought through and discussed with zRMS at pre-submission meetings. Taskforces could be an opportunity. (Very important to explain any non-standard approach in the dRR.)			
<u>Work sharing between zones</u> Question 8: Work sharing between zones is that a realistic option, when it comes to certain areas of the evaluation?	There are two potential situations for worksharing: • Indoor uses • Same product in different zones but some sections of the dossier are common eg. phys chem., analytical methods, tox, residues, ecotox, fate **Worksharing based on common areas of the dossier:** The Authorities are very interested in		**Worksharing based on common areas:** Kerry Gamble to take the discussion up within ECPA to build a proposal for how interzonal worksharing could work and identify (re-registration) projects which could be pilots and come back to the ZSCs and iZSC with a proposal.	Short term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	this concept as it has the potential to reduce workload. Between the Zonal Steering Committees, have tried to have a pilot but due to lack of capacity and co-ordination between the zones, it did not work. It was difficult to reach the co-ordinator in the other zones which cost time and therefore it was less efficient than doing the work separately. Also the need for commenting adds complexity to the process. The MSs are open to re-starting the pilot. However, it needs a co-ordination but capacity for this is low. Submission of the application needs to happen at the same time and the zones need to work at the same time during the evaluation process. It is important that the processes are synchronized in order for it to be efficient and effective. Need to choose similar products with similar GAP. It could be an interesting pilot for some re-registration projects companies will be prepared to take a risk of the process being problematic; where GAPs are harmonised and the deadline is the same in all the zones.		**Worksharing based on indoor uses:** Needs to be further discussed in the Zonal and Interzonal Steering Committees.	Short term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	The areas of the dossier where work-sharing can easily be applied are not the work intensive ones eg. phys chem., tox and ecotox data and therefore the risk is that this can create more work in co-ordination than is saved in evaluation. It is therefore preferred to also be able to share the work on fate and ecotox. This could work if there is a core dossier containing EU and FOCUS models which could be evaluated by one zRMS. A pilot project would be interesting and the applicant could take an active role in the co-ordination between the MSs. For commenting, one zRMS would make the evaluation and circulate to all MSs for comment. zRMS for other zones would need to be sure that they meet the legal requirements for their role. **Worksharing based on indoor uses** EFSA GD on protected crops in which there is a classification for different situations. 1107 identifies protected uses			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	in closed systems which is only 20% of the uses as most are not closed. CZSC: If open uses, then the three zone approach needs to be used.			
<u>Commenting Period</u> Question 9: How can the comments contribute to the harmonisation? Are Zonal guidance documents for the risk assessment and risk management useful for the harmonization? Do they contribute to harmonisation within the zone or between zones? Which are the priorities?	Comments are a very good step to share knowledge between MSs and create understanding for the evaluation. If you only receive a few comments, it's not clear whether MSs had no time to comment or that they agree with the evaluation. It's also important for the zRMS to get this feedback. When there is no agreement between the MSs on the comments, how is this solved? Disagreement with small impact on the final conclusion – easy for zRMS to respond to the comment and explain why. Disagreement with impact on the evaluation of safe use - will have a bilateral discussion but duty of zRMS to decide. This is considered to be a rare event.	It is the aspiration of Authorities to meet the timelines. An efficient commenting process is critical to this. Key challenges are: Submission of additional data during the commenting period. It was broadly agreed that this creates complexity, slows down the process and creates additional work The applicant has an opportunity to respond to questions from the zRMS before the commenting period and to be involved in the commenting period. Once the commenting period starts, there is not an opportunity to submit additional data. cMSs who have not been	How to consistently apply the stop the clock and manage the commenting phase should be clarified in the Zonal GD (submission of information and data during the review process especially during/after the commenting phase). Zonal and Interzonal Steering Committees: Quality of dossier would help MSs meet the timelines. Guidance to accompany the dRR Templates could provide guidance to applicants on quality. Zonal Guidance and completeness checks would also help industry. This could be updated with shared knowledge from Authorities and Industries on common issues experience by	Short term Short term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	The small Authorities have little time therefore the volume of comments from large compared to small MSs is very different. Small Authorities are selective (if not cMS then don't comment; otherwise select specific products or sections to comment on eg. Fate, Efficacy) The process of commenting works but the issue is to have the capacity for commenting. There is also no fee for the commenting so it is a challenge to find the capacity. If Authorities take time for commenting, it's important that the zRMS responds to this. Where solutions between MSs cannot be found based on comments, this could be discussed in the Director's Group. However, there has only been one case per year in CZone and none in SZone so this does not need a specific procedure. The role of the applicant with regards to responding to the commenting is not harmonised. Most MSs prefer not to receive additional data during the commenting. If the 6 month stop the	involved in the commenting phase find it difficult to manage the 120 day timeline. cMSs should accept the evaluation by the zRMS and make a decision on this + the national addenda in 120 days. If MSs will need to start to make stricter decisions in order to meet the timelines of the Regulation, greater clarity is needed between MSs and Industry about the quality of the dossier. This is consistently raised by MSs as an issue.	providing guidance.	

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	clock is not complete, the applicant could still be allowed to submit data. This is according to the GD. However, it is not efficient for the Authorities as a new commenting period could be needed. The GD allows for factual information only and not data to be submitted during the commenting period. Would it be more efficient to send the zRMS dRR to the applicant to give them the opportunity to comment and submit additional data before the commenting period? Not agreed. zRMS FR sends a letter with an outline of the requests and asks the applicant to update the dRR. The stop the clock is for 2 months or as proportionate to the request. Then finalises the RR for commenting by cMSs and applicant but no further data can be submitted. zRMS then finalises the RR considering the comments. NL provides the dRR relevant for the section to be updated and requests the dRR to be updated. This is then copied into the zRMS dRR. Only updates specific to the request are taken into			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	consideration. There are currently different approaches by different MSs. In some MSs, the law obliges additional data to be accepted. Broad agreement that new data during the commenting period is problematic. But new information from the applicant should be accepted. How to manage the stop the clock during the cMS 120 day period? During the commenting phase, the cMS should check the zRMS dRR and if a strong disagreement make a comment and check how it has been addressed by the zRMS. If not addressed, the cMS has the option to refuse or restrict the registration. Any national addenda would be considered during this phase. For the national evaluation, have to manage during the time available. However, smaller MSs are not always able to comment during the commenting phase and find issues when they start to review during the 120 days. Could refuse the registration but this does not seem reasonable (especially in			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	consideration of applicant fees). Proposal that instead of evaluating the poor quality trials, can advise to put on the label that the efficacy for certain uses has not been demonstrated. This enables the timeline to be managed without refusing the registration. But the cMS should rely on the evaluation of the zRMS and therefore minimise the work needed during the 120 days. If zRMS has not used EU endpoints, cMS needs to re-evaluate. If additional data is needed, cMS could refuse the registration until the data is available and applicant would need to reapply when the data is available. Industry would fully support MSs meeting the timelines but would rather timelines are extended than registrations are refused. If the process will be stricter, there needs to be much better clarity about the required quality of the dossier. New Guidance Documents do not help as they create uncertainty during the submission and evaluation process. DE has issued a completeness			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	check document to help applicants with the quality of the dossier. BE also has a checklist.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
PROCESS AND TIMELINES				
Question 10: The Regulation contains a working process for the examination of applications with strict deadlines. Is it feasible to keep these timelines, both for MS and INDUSTRY?	It is a challenge to meet the timelines. It is more complex for MSs and Industry than under 91/414. The ambition is to meet the timeline but it is very difficult. Difficult to plan the work as a cMS as it's not known when zRMS will produce the dRR for commenting or for the 120 day timeline. Delays from industry do not have too much impact on Authorities as there is already plenty to do. In small MSs, it is a challenge for the experts to meet the timelines given the volume of work. The only possibility for very small MSs is mutual recognition or resources are consumed with one application. For a simple dossier, it is not a problem to respect the timelines. For complex dossiers, we have to question whether the timelines can be reached. Improvements in the quality of the	The aspiration is to meet the timelines but this is still work in progress as the MSs are still building experience. It is considered that many of the actions above will support MSs in reducing workload, smoothing the process and thereby meeting the timelines for Article 33 applications.	See action under question 9 on quality of the dossier.	

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	dossier would help a smoother process. For Art 43, it will not be possible to keep the timelines.			
Question 11: Where in the process is it most likely that the breaking of the timeline occurs? (Confirmation/appointing of zonal rapporteur? Evaluation? Requesting further information? Decision making?) **New data received after the commenting period**, that implies new assessment and perhaps a new commenting period?	Not discussed.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Question 12: How can the process be improved?	Find the equilibrium between the role as the zRMS and as the cMS. The new dRR format will help. Industry should support the transition as much as possible from 1 Jan 2016 (including for AIR2 PR).			
Question 13: How is commenting working? Does the zRMS get any comments? What about the quality? Do the commenting MSs feel that their comments are taken into consideration? Is a system needed to solve resulting disagreements? Does IND just comment on factual issues?	Refer to answers under Question 9.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Question 14: How does the changing of application dates from the date stated in the notification affect the planning in a zRMS?	Refer to answers under Question 9.			
Question 15: In appendix 5 of the GD SANCO/13169/2010 rev. 9 on zonal evaluation and MR there is a table on which types of applications that require commenting. Do MS and IND have the capacity to comment on all these and does the commenting contribute to the evaluation.	Refer to answers under Question 9 and 10.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Question 16: The cMS has only 120 days for evaluation of national requirements and decision making. Is it possible to manage in time? If further information is needed regarding national requirements is the clocked stopped? How is keeping track of time used done, so that the 6 months are not exceeded?	Refer to answers under Questions 9 and 10.			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Question 17: **National requirements,** do they serve a purpose, because of difference in environment or agricultural practise or are they just old habits? Can the amount of NR be reduced? Are the national data requirements scientifically justified?	Refer to answers under Question 1.			

2.4 Presentation

Breakout group A Zonal System Presentation to Plenary.pdf

3 Breakout Group B (Mutual Recognition)

3.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States

1.Introduction

The principle of Mutual Recognition (MR) is one of the means of ensuring the free movement of goods within the European Union.
With MR art.40 of Regulation (EC) N.º 1107/2009 aims:

- to avoid any duplication of work,
- to reduce the administrative burden for industry and for Member States (MS) and,
- to provide for more harmonised availability of plant protection products.

Under Regulation (EC) N.º 1107/2009 an authorisation granted by one MS should be accepted by other MS where agricultural, plant health and environmental (including climatic) conditions are comparable. The division of the EU into three zones is related to Member States where agricultural, plant health and environmental (including climatic) conditions are comparable.
However, environmental circumstances specific to the territory of one or more MS might require that, on application, MS recognise or amend an authorisation issued by another MS, or refuse to authorise the plant protection product in their territory, where justified as a result of specific environmental circumstances or where the high level of protection of both human and animal health and the environment required by this Regulation cannot be achieved.

The guidance document has been developed to elaborate the procedures contained in Regulation (EC) N.º 1107/2009 for zonal evaluation (Articles 33 – 39) and MR (Articles 40 – 42).

After four years of implementation of the Regulation it's necessary to discuss some practical issues related to the implementation of MR.

2. Complying with the prerequisites

The situations under which MR can be applied for are very clearly described in Article 40.1, in which it is stated that the holder of an authorisation may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, with the prerequisite that the reference authorisation needs to have been granted in accordance with Article 29:

a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone;
b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State 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';

c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

MS have different interpretations and procedures regarding the implementation of the prerequisites established in the Regulation.

3. Granting authorisations under optional Mutual Recognition

According to Article 41.2 there are a number of cases for which MR is optional. These are namely the following:

- an application has been submitted for an authorisation that has been granted in accordance with case 2 above (voluntary MR between countries that belong to different zones);
- the product contains a substance that is included in the list of candidates for substitution;
- the application concerns a provisional authorisation;
- 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).

Authorisations given on the basis of MR must be clearly identified to avoid the 'domino effect'. With this aim MSs should also state in their authorisation certificate that this authorisation is based on MR under Regulation (EC) n.º 1107/2009.

MSs have different interpretations and procedures regarding the implementation of the **optional MR** established in the Regulation.

4. Repetition of the evaluation made by the Reference MS

The Regulation (EC) n.º 1107/2009 provides for a more efficient system of MR, 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, except for clearly defined circumstances.

They shall avoid re-evaluation of the application and may only restrict MR fulfilling the requirements of article 36(3).

Whilst there may be some flexibility to accept slight changes within an application for MR (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 some MS the evaluation made by the Reference Member state is re-evaluated by the competent authorities in some areas of evaluation.
As example: is MR mandatory if a particular pest or a particular crop is non-existent in the MS where MR is sought? Should an Art.36(3) notification be sent to the COM in these cases?

Is MR mandatory for applications where the reference authorization is being renewed under Art.43? If MR is granted then the deadline for asking renewal has already passed (AIR1 4 years after approval- AIR2, AIR3 supposedly with 1 year lag).

5. Acceptance of authorisations granted under Directive 91/414/ECC

As referred in the guidance, as of 14 June 2011, MR 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) n.º 1107/2009.
Article 40.1 describes the situations under which MR can be applied for, with the prerequisite that the reference authorisation needs to have been granted in accordance with Article 29.
Some MS do not grant an authorization if the authorization to be mutually recognized did not comply with the Article 29, for them the MR only applies for applications which are made, or due to be made, after the date of application of the Regulation (EC) n.º 1107/2009 (14 June 2011).

For PPPs authorized under Directive 91/414/EEC, Southern Zone MSs request to the Reference MS to provide the following documents:

- the total composition of the formulated PPP(s);
- confirmation that the authorisation(s) was(were) granted according to the Uniform Principles, set out in Regulation (EC) n.º 546/2011, and in accordance with the conditions of approval of the active substance(s) or a certificate of the authorisation that includes a confirmation of this information;
- a registration report, whenever available.

The application is only considered complete and the evaluation only starts when all these documents have been received. The availability of a registration report in the current format is limited.

6. Authorisation of minor uses

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

7. Data protection

Some MS are facing some issues after granting a MR authorization.
As an example, subsequently to the issue of the authorization, the owner of a competitor product sometimes challenges the decision and demands withdrawal of the mutually recognized product, on the basis that the Reference MS core assessment was based upon insufficient residues studies.
Further examples of open issues are:

- A reference authorization was granted based on studies no longer protected made reference to from another dossier – in the MS where the MR application is made those studies might be still protected or not available at all.

- How is data protection made when the CA in the MS receiving the MR application does not ask for the dossier that supported the reference authorization? (data protection is a national issue, starts from the date of authorization and applies to the studies that support the authorization)
- Is data protection to be carried out in these cases and how?
- Where is the "list of studies relied upon" of the reference authorization, when a Registration Report is not available (Directive 91/414/EEC authorizations)?

What is expected to be done in these situations?

8. Biological Assessment Dossier (BAD) quality

Some MSs have refused several applications for authorization due to the poor quality of the BAD. But according to article 36.3 efficacy is not a reason to refuse a Mutual Recognition Authorisation.

The quality of BADs is an issue that keeps coming up. It was felt that often the problem was the amount of resource that companies spent on the preparation of the documents and also the different levels in quality that competent authorities were prepared to accept.

In general MSs feel that the standards on the EPPO website are clear enough but that there is a difference in how these are implemented.
PAI Group proposed that the efficacy expert group be encouraged to discuss this issue among themselves and prepare some clear guidance with minimum standards for BADs (or for Efficacy Chapter of the dRR (B7)) that can be shared with companies. Once these are set then all MS should refer to this and only accept BADs that conform to these standards.

Can all MSs agree on this?
Which MS can take the lead?

9. Timelines and the central database

MS have 120 days to decide on granting authorisation or refusal of a MR application.
In southern zone the application is only considered complete, and the examination of the application only starts when all these documents have been received.
This is reflected in the accounting of time considered by the industry and different competent authorities.
The central database on applications and also the database according to Article 57 should help MS receiving the application.

10. Notification

According art 36.3 where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures a Member State may refuse authorisation of the plant protection product, in these cases Member State shell immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification.

Specific reasons - like national specific elements but also other thresholds - sometimes identify a risk which leads to the refusal of mutual recognition. The process of 'notification' is then entered.
Notification is a 2-step process with little room for the exchange of views.
Would it be possible to build in a third step in which all MSs may participate, in order to exchange views? This will not only reduce the number of actual notifications, but will also help building harmonisation.

Discussion points

Zones

(1) The main reason for dividing the EU into different zones is to facilitate mutual recognition, since the Member States within a zone should have comparable conditions as regards agricultural, plant health and environmental (including climatic) conditions. Why do Member States, although they belong to the same zone, consider themselves still 'different' from their neighbours?

(2) Is possible to achieve the prerequisites in preamble 8, regarding safeguard the competitiveness of European Union agriculture, with the division into two larger zones and one small?

Work sharing

(3) Is the zonal steering committees workable? What can be improved? Is there anything in the remit that needs changing?

(4) Pre-notifications, are they a good instrument for planning and appointing zRMS? Are they complete with the information needed? Do minor applicants use them? If not, how will the process of appointing zRMS work smoothly if an application just is submitted?

(5) The appointment of zRMS is done differently between the zones. Some zones just accept the proposal and other have more difficulties to find a zRMS. How does the zones appoint a zRMS when the proposed zRMS refuse to be zRMS? Volunteers? Are they easy to find? Does the appointing of zRMS work? What can be improved?

(6) Are the GAPs harmonised as much as possible with in a zone, if not is that a problem in the sense of work sharing?

(7) Is the risk envelope approach working as an efficient option to reduce the workload of the assessment?

(8) Work sharing between zones is that a realistic option, when it comes to certain areas of the evaluation?

(9) How can the comments contribute to the harmonisation?. Are Zonal guidance documents for the risk assessment and risk management useful for the harmonization? Do they contribute to harmonisation within the zone or between zones? Which are the priorities?

Process and timelines

(10) The Regulation contains a working process for the examination of applications with strict deadlines. Is it feasible to keep these timelines, both for MS and IND?

(11) Where in the process is it most likely that the breaking of the timeline occurs? Confirmation/appointing of zonal rapporteur? Evaluation? Requesting further information? Decision making? New data received after the commenting period, that implies new assessment and perhaps a new commenting period?

(12) How can the process be improved?

(13) How is commenting working? Does the zRMS get any comments? What about the quality? Do the commenting MSs feel that their comments are taken into consideration? Is a system needed to solve resulting disagreements? Does IND just comment on factual issues?

(14) How does the changing of application dates from the date stated in the notification affect the planning in a zRMS?

(15) In appendix 5 of the GD SANCO/13169/2010 rev. 9 on zonal evaluation and MR there is a table on which types of applications that require commenting. Do MS and IND have the capacity to comment on all these and does the commenting contribute to the evaluation.

(16) The cMS has only 120 days for evaluation of national requirements and decision making. Is it possible to manage in time? If further information is needed regarding national requirements is the clocked stopped? How is keeping track of time used done, so that the 6 months are not exceeded?

(17) National requirements, do they serve a purpose, because of difference in environment or agricultural practise or are they just old habits? Can the amount of NR be reduced? Are the national data requirements scientifically justified?

3.2 Summary report

Breakout group B (Mutual Recognition – Regulation 1107 of 2009)

The principle of Mutual Recognition (MR) is one of the means of ensuring the free movement of goods within the European Union.
With MR art.40 of Regulation (EC) N.º 1107/2009 aims:

- to avoid any duplication of work,
- to reduce the administrative burden for industry and for Member States and,
- to provide for more harmonised availability of plant protection products.

Under Regulation (EC) N.º 1107/2009 an authorisation granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. The division of the EU into three zones is related to Member States where agricultural, plant health and environmental (including climatic) conditions are comparable.

Regulation 1107/2009 states that the reference authorization need to have been granted in accordance with article 29.
Member States have different approaches and can, in some cases, accepts authorisations granted under uniform principles under Directive 91/414.

According to Member States and applicants, the difficulties in mutual recognition are frequently related to:

- Availability of Report
- Quality of risk assessment
- New applications where comments are not taking in account where no harmonised assessment (ex. Comments just "noted" or "to be dealt at national level")
- Some Member States don't comment because of resources.
- Different interpretation of the guidance (Greenhouses)
- Different opinions on when new endpoints should be applied.
- Data protection
- Problem of inconsistency in national authorisations.

For solving these difficulties the breakout group proposes the following action:

- Improvement of guidance procedure (More involvement of Member States and faster procedure)
- Improvement of zonal Registration Report (With Mutual Recognition objective)
- Director's consultation group action (harmonized on "political" level)
- Agreement on ZSC on guidance issues
- Initiate and develop experts meetings.
- Harmonized risk mitigation measures (MAGPIE)

About national requirements there were 3 general topics:
1. Need to define clearly what is national requirement.
2. Are they scientifically justified?
3. .Are they publicly available at zonal level?

Because some increased need of transparency, a zonal document regrouping all national requirements was proposed to be issued in a short term.

Regarding data protection the group agreed on the fact that a database of protected studies should be available at Member State level.
The group stated that registration reports are expected to be a stand-alone document in order to facilitate mutual recognition and work-sharing in general.
Furthermore, the SANCO/13169/2010 guidance should precise when the 120 days timeline should start (at the time of application or when application is considered complete by Member State).

An electronic version of the dossier available for Member States would help. Commission stated that it would not be feasible in short/medium term.
As the 3 regulatory zones are not matching the 4 EPPO zones some complementary efficacy data is needed. There are also efficacy dossier quality that are not matching Member State standards.

For these issues harmonisation of trials format is needed and some supportive data can be accepted by some Member States.

In order to achieve more harmonization within and between zones the group required an exchange platform. Because it could be useful for sharing experiences and increase level of acceptance, decreasing requirement. CIRCA BC could be used for this purpose, so a commission training and access for Member State will be done in the next few months.

Applicants and Member States thinks new dRR format is a good tool to improve the quality of applications. In order to get better applications, all Member States are encouraged to comment in details the new dRR template.

3.3 Summary table

Summary of Discussion and Conclusions

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Mutual recognition between zones	• Not accepted in all MS. • Not many applications made			
Difficulties MR within the zone with "old" dossiers	• "old 91/414" authorisations • Availability of Report • Quality of RA • Some MS are investigating some parts of the dossier and adapts labels to the national condition.	• Most of MS accepts old application if there were granted with Uniform principles • Each MR is treated case by case in the light of what information is available • Some MS let the possibility to add information (mostly efficacy and Efate) • Possibility to submitting just complementary information but not comply 120 days	• Be more pragmatic • Define if, when and what additional information can be accepted and delays	Short Term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Difficulties with new applications	• New applications where comments are not taking in account where no harmonised assessment (ex. Comments just "noted" or "to be dealt at national level") • Some MS don't comment because of resources. • Different interpretation of the guidance (Greenhouses) • Different opinions on when new endpoints should be applied. • Data protection • Risk mitigation measures are not a problem because MS adapt to their conditions. • Problem of inconsistency in national authorisations.	• GD to be used at the time of application are to harmonised and enforced ones. • If no harmonized GD is available some MS will take the latest document available. • Step1:Having General Guidance • Step2 : zonal conditions of this guidance (Zonal Guidance) • Step3 : experts meeting for stating common risk assessment. • More and earlier involvement of MS in drafted guidance. • Testing phase should be issued • In RR there should be conclusions and	• Improvement of guidance procedure (More involvement of MS and faster procedure) • Improvement of zRMS RR (thinking MR) • Director's consultation group action (harmonized on "political" level) • Agreement on ZSC on guidance issues • Initiate and develop experts meetings. • Harmonized risk mitigation measures (MAGPIE)	Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
		options for other to choose (PPE, mitigation measures,...) • No authorisation granted for provisional authorisation. • zRMS should have MR in mind when writing RR.		
Need of zonal and national requirements	• There 3 general topics: 1. Need to define clearly what is national requirement: 2. Are they scientifically justified 3.Are they publicly available at zonal level? • In every zone there are clear national requirements maybe need of formal document in Center Zone. • EFSA protection goals is a fine step to develop new guidance.	Lack of information and transparency for applicant Source of mistrust between MS	Zonal document regrouping all national requirements	Short Term
Data Protection	• -National issue: Problems for generics and some adapted claims.	• Applicant should have a letter of access valid for the application in	Every MS should have a database with protection status of the studies.	Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	• List of studies is available in pdf and not in workable format. • -Data protection guidance is quite clear but there are issues for "old" products	the country. • It is MS competence to determine what is protected or not but applicants could help MS to manage. Portugal have issued an Excel file stating protection status of all Annex III studies.	Finalize data protection guidance	Short term
Availability of RR and timelines	120 days starts not in the same time for every MS: -Some MS are requesting full dossier. - Some MS accept only if RR available. Cross-referencing dRR are an issue and be considered incomplete. Electronic version of the dossier would help but not feasible according to commission in short term.	RR should be a stand alone document.	Clarifying guidance for when 120 days should start Applicants should issue stand alone dRR Database with electronic dossiers	Short term Short Term Long term
Minor uses	Problem where the use is minor in reference country but not in MR country. No MS have received applications under article 40.2.	Should have improvements in EPPO guidance for minor use. Need of criteria to define what is a minor use or not	EPPO guidance update Definition by Minor use secretariat	Medium term Medium term
Efficacy	Needed trials in EPPO zones. In some MS efficacy is a reason for rejection of MR or at least reducing	Need of Harmonisation of trials format	EPPO to define what is the minimum quality of trials	Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	GAPs. Possibility to add "supportive data" in MR by MS. Quality of the trials is important.	Some MS accepts supportive data	All MS should be involved on commenting the new dRR template	Short term
Exchange forum	Could be useful for sharing experiences and increase level of acceptance., decreasing requirement and achieve more harmonisation	Possibility of using CIRCA BC as discussion forum.	Commission to give access and training to MS	Short Term
New dRR format	MS should state clearly what is needed in RR. "example" of dRR should be issued.	All MS should state clearly what is needed in RR. "example" of dRR should be issued.	All MS should be involved on commenting the new dRR template	Short term
Reporting	Information about being more pragmatic needs to be reported at director's level	Conclusions of the workshop have to be reported to consultation directors group	Send the executive summary and tables to consultation directors group	Short Term

3.4 Presentation

Breakout group B Mutual Recognition Presentation to Plenary.pdf

4 Breakout Group C (Re-authorisation, article 43 of Regulation 1107/2009)

4.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States

Background

The writing in Article 43(1) is that an authorization shall be renewed upon an application, provided that the requirements referred to in article 29 are still met.

Article 43(2) indicates that an authorisation holder should submit an application within 3 months from the date of entry into force of the decision on the renewal of the approval of an active substance. This application should include any new product data with evidence that new data are required as a result of new data requirements/ new or changed endpoints or criteria or are necessary to amend original conditions of approval.

A guidance document (SANCO/2010/13170) was developed in 2011 to elaborate the procedures for renewal, withdrawal and amendment of authorisations. A revision of this GD in now under development. This revised guidance document has been developed to clarify the procedures contained in Regulation (EC) No 1107/2009 for just the renewal of authorisations according to Article 43 of Regulation (EC) No 1107/2009. The basic principle is that products which will be renewed under Regulation (EC) No 1107/2009 have already been authorised in accordance with the Regulation (EC) No 1107/2009 or the Directive 91/414/EEC, and therefore comply with the data requirements of that Directive/Regulation and were assessed under the Uniform Principles applicable for the time of the assessment.

The 3-months timeframe may be too short to submit all necessary data. In this case the applicant may justify the lack of data by the fact that it could not anticipate this request before EFSA conclusions for the substance were available and a MS may find it justified to apply Article 43(6) and extend the authorisation and delay the re-authorisation.

This approach is described in detail in the draft **Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009** (SANTE/2010/13170 rev. 12; 20 March 2015). The procedures described in this guidance document only apply to renewals of authorisations based on active substances for which approval is renewed under the Regulation (EC) No 1107/2009.

Introduction

The revised GD on Article 43 was prepared by a small expert´s meeting (including participants of industry, MSs, COM) and discussed several times in PAI meetings. It was the

intention that the GD should have been noted in the Standing Committee meeting in March 2015. However, due to strong reservations from a number of MSs this was not the case.

The aim of the GD was to give registration holders information about the procedure of re-registration of PPP according Art 43, with details about the required information and studies, timelines, allocation of zRMS etc. One of the major points of discussion in the GD, was about the necessary studies which could not be conducted considering the short time between the date of application of the renewal regulation of the active substance (DoA) and the time of the submission of the application for re-authorisation of the PPP, at a later stage (with reference to Article 43.6).

In addition, the large number of applications to be expected (> 10.000 products considering AIR 3 only), the short time frames for evaluation by the zRMS (6 months) and the capacities of both (authorities and industry) shows an urgent need for an harmonized and pragmatic approach on how to deal with Article 43 applications.
Most likely, as a consequence:

- MS will not meet the timelines given in Reg. 1107/2009;
- MS might be overloaded with Article 43 applications;
- there may be no capacity for MS acting as zRMS for new products;
- there may be major delay in decisions of Article 43 applications;
- there may be major delay in the assessment of new products.
- there might be less products on the market since holders will not have the capacity to do applications that fulfills the requirements and therefore will not apply

Discussion

Basis for the discussions and the conclusion is the draft GD mentioned. The following issues are to be discussed in particular:

Preconditions for Article 43 applications:

- No formulation change [exception: non-significant change according to GD SANCO/12638/2011]
  The GD on non-significant change is very strict. What about formulation changes, which are significant changes in the sense of the GD, but nevertheless no additional risk assessment is required since comparable for sections ecotox, tox?
- Accepted to include those formulation changes into article 43 applications as well?
- No change in the authorized GAPs within the respective zone [remark: the change of GAPs necessary because of new endpoints has to be elaborated separately]
- No additional use/crop as originally authorized with in the zone. Crop/use should be understood as a crop-pest combination
- No cMS included for which the product is new
- For uses new in one MS (even if the PPP is registered in that MS for other uses) - not to be considered for that MS (as cMS) under Article 43
- If one of the preconditions mentioned above are not met, the procedure according to Article 33 or Article 40 of Regulation 1107/2009 applies.

Reasons for insisting on existing/already registered) GAPs/uses:

- Not to re-open the efficacy file as all PPPs are authorized according UP (only resistance management will be considered) – see separate chapter "efficacy"
- Experiences of the voluntary work-sharing (Step 2 re-registrationss; Article 80) show enormous time and work load
- Tight time lines for Article 43 evaluations
- MS capacities blocked for new PPP evaluation
- Internal priority setting by authorities?

What about studies. If the applicant is unable to provide the authorities with a complete application within time of 3 months because conduction of studies necessary (based on e.g. changed end points; application of new guidance) is too long (e.g. new residue trials, mesocosm studies, field studies), how should that be dealt with? Allow Industry up to 2 years to provide the studies depending on the type of study needed (Or even longer? In case of new residue trials, 2 years for trials are necessary – not considering the season, which may extend the time once the studies are made available)? Evaluation once all studies are made available? dRR once all studies are made available?

To what extent should the evaluation be performed (and consequently the dRR provided by the applicant/registration holder)? The premise is that PPP are in the market after a evaluation following Uniform Principles, taking into account the short and strict deadline for the assessment and re-authorisation, is it reasonable to perform a complete assessement of the PPP or under a more pragmatic and efficient point of view only those sections, for which changed endpoints and new data requirements are to be considered?

Is it useful to have a full dRR in which the applicant includes the new information and identify the new information?.zRMS will evaluate only the new information?

Some MS may think it might be useful to have a full dRR (for PPPs containing more than 1 active: even evaluation of the 2nd active which expires more than 1 year after the first active?) because of their problems with granting mutual recognitions (Article 40), for the case that no evaluation report of the reference MS is available.
Question: May Article 43 really be considered a suitable tool for solution of issues with regard to mutual recognition?

Which Guidance Document to be applied? The guidance in force at the time of the submission of the supplementary dossier (Article 13 of Reg. (EU) No 844/2012), the guidance in force at the time of the renewal of the active ("frozen guidance") (What will be the legal basis in this case?) or the guidance in force at the time of submission of the application for renewal of the PPP?

Expiry dates of the actives? In the case of PPP containing more than one active substance, the suggestion in the GD is that if 2 actives expire within 1 year, the renewal of the second active is to be awaited before product renewal according to article 43.
- If the expiry dates are within 1 year and e.g. 2 months? Acceptable to await second active´s renewal?
- If the expiry dates change? Consideration of the following consequences:
  - Actives, which expire not within one year, may expiry within one year
  - Actives, which expire within one year, may not expiry within one year (i.e. changes of expiry dates may not be realized a posteriori and therefore the application is not complete?)

No predictability possible for both, authorities and industry.
May the expiry date at the time of taking note of the GD been used (even if the expiry date may change in future)?

Assessment of efficacy:

Already discussed and concluded for the situation, if the GAPs remain unchanged:
No assessment of efficacy except "Possible development of resistance or cross-resistance" (OECD KIII6.2.8)

- need for a new resistance risk analysis
- do we need a dRR (Section B 7) addressing resistance (OECD KIII6.2.8) only or a complete dRR (section B7) summarising previous national efficacy assessments.
- GAP table including all uses to be renewed (crop-pest combination)
- no need for an updated BAD to be provided by the applicant

It might be possible, that previous authorised GAP has to be changed (i.e. it is considered necessary to lower the application rate/ha) because of risk assessment issues. In this case new efficacy trials (reflecting the new GAP) might be necessary. The following option may be applied:
A later submission of those trials necessary (because of changed end points) may be justified (Cat 4 studies according to the GD rev. 12) and therefore wait until efficacy trials are made available.

Explore in detail what to be assessed when (as regards the individual sections of the risk assessment) – compiled like appendix II of GD on Article 43

PPPs containing 1 active only:
Studies reflecting new data requirements (with the exception of products containing AIR 2 actives) and changed endpoints. For these studies and evaluation (and the corresponding risk assessment) the latest guidance (guidance applicable at the time of application or guidance applicable at the time of renewal of the active?) to be applied. The remaining issues that remain unchanged are not to be assessed.

PPPs containing 2 actives which expire within 1 year:
Studies reflecting new data requirements (with the exception of products containing AIR 2 actives) and changed endpoints . For these studies and evaluation (and the corresponding risk assessment) the latest guidance (guidance applicable at the time of application or guidance applicable at the time of renewal of the active?) to be applied. The remaining issues that remain unchanged are not to be assessed.
When? Once the second active is renewed.

PPPs containing 2 actives which expires > 1 year:
After the **first active**´s renewal, studies reflecting new data requirements (with the exception of products containing AIR 2 actives) and changed endpoints. For these studies and evaluation (and the corresponding risk assessment) the latest guidance (guidance applicable at the time of application or guidance applicable at the time of renewal of the active?) to be applied. The remaining issues that remain unchanged are not to be assessed.

The **second active** is not to be looked at, since no new endpoints are available. Consequently, product data only to be assessed:

- physchem, identity: Nothing, only if the specifications of the substance has changed with regard to relevant impurities a storage stability of the PPP might considered necessary.
- Analytical methods: only if a new relevant impurity was included into the reference specification
- Analytical method for that impurity in the formulation
- Toxicology: formulation toxicity and dermal resorption
- Residues: actives data – no need to look at the second active
- Fate: actives data – no need to look at the second active
- Ecotox: formulation studies as regards e.g.: bees, arthropods, earthworms, plants, aquatic organisms,
- Part C: Composition of the PPP, manufacturer and manufacturing site; possible bridging concepts (if necessary); MSDS of co-formulants

After the second active´s renewal, analogy to the above mentioned.
Principles:

- not look at the second active after the 1st active´s renewal
- once the second is renewed, no need to look at the first active again

Combitox (ecotox and mammalian tox):

- once an EU-wide harmonized approach necessary
- if available, perform combitox after the second active´s renewal even if the second active expires > 1 year

Revocation of the product?

When to be revoked? If no application 3 month after EIF of the renewal of the active.

- Revocation 1 year after EIF of the renewal of the active
- period of grace (according to Article 46):
    - for sale and distribution: 0.5 year
    - for disposal, storage and use: 1 year

The draft GD on product renewal (rev 12) may be used as basis for discussions. Conclusions may be included directly into the draft GD.

4.2 Summary report

A guidance document (SANCO/2010/13170) was developed in 2011 to elaborate the procedures for renewal, withdrawal and amendment of authorisations. A revision of this GD in now under development. This revised guidance document has been developed to clarify the procedures contained in Regulation (EC) No 1107/2009 for just the renewal of authorisations according to Article 43 of Regulation (EC) No 1107/2009. The basic principle is that products which will be renewed under Regulation (EC) No 1107/2009 have already been authorised in accordance with the Regulation (EC) No 1107/2009 or the Directive 91/414/EEC, and therefore comply with the data requirements of that Directive/Regulation and were assessed under the Uniform Principles applicable for the time of the assessment.

The 3-months timeframe may be too short to submit all necessary data. In this case the applicant may justify the lack of data by the fact that it could not anticipate this request before EFSA conclusions for the substance were available and a MS may find it justified to apply Article 43(6) and extend the authorisation and delay the re-authorisation.

This approach is described in detail in the draft **Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009** (SANTE/2010/13170 rev. 12; 20 March 2015). The procedures described in this guidance document only apply to renewals of authorisations based on active substances for which approval is renewed under the Regulation (EC) No 1107/2009.

The following important points were discussed during the BOG sessions. Conclusions were reached, which are the basis of rev. 13 of the Guidance document for noting in the SCoPAFF in July 2015. It is important to have a harmonised procedure for art. 43 applications, which will start by March 2016.

- **What about seasonal studies for which the applicant is unable to provide the authorities with a complete application within time of 3 months because conduct of studies necessary (based on e.g. changed end points) is too long ("category 4 studies")?**

  These data should be submitted as soon as possible, taking into account the time necessary to conduct the studies (generally within 2 years), to the zRMS who will evaluate the completed dossier within 6 months after submission. All MS should take a decision within 3 months. A proof for conducting such studies should be provided and agreed upon with the zRMS at the latest 2 months after publication of EFSA conclusion).

- **To what extent should the evaluation be performed (and consequently the dRR provided by the applicant/registration holder)? The premise is that PPP are in the market after a evaluation following Uniform Principles, taking into account the short and strict deadline for the assessment and re-authorisation, is it reasonable to perform a complete assessment of the PPP or under a more pragmatic and efficient point of view only those sections, for which changed endpoints and new data requirements are to be considered?**

Assessment is to be focussed on new information, conditions or restrictions in the renewal regulation, including the issues mentioned in the renewal regulation ("MS shall pay particular attention to....").

- **Which Guidance Document to be applied? The guidance in force at the time of the submission of the supplementary dossier (Article 13 of Reg. (EU) No 844/2012), the guidance in force at the time of the renewal of the active ("frozen guidance") (What will be the legal basis in this case?) or the guidance in force at the time of submission of the application for renewal of the PPP?**
  The new information is to be assessed using the Guidance documents in force at the time of application according to Article 43.

- **Assessment of efficacy:**
  No assessment of efficacy data is necessary if the GAP remains unchanged. Only the aspect of the possible development of resistance or cross-resistance should be assessed by the zRMS.
  It might be necessary to lower the application rate because ofchanges of end-points, while still being above the effective dose. In this case new or additional efficacy data (reflecting the new GAP) might be needed.

- **Data matching check to be performed by the active substance RMS as soon as possible after the 3 months deadline for application.**
  Data matching step is based on the list of studies relied upon for the renewal of the active substance.

- **Allocation of the zRMS**
  The applicant should propose an zRMS 2 years before the application date, according to Article 43. The final allocation of the zRMS should be notified to the applicant preferably before the publication of the EFSA conclusion.

  It is proposed that one zRMS for Europe may assess all products containing the concerned active substance (guide: <10 products containing that substance). If more products (>10) are to be assessed, one zRMS within each zone should do the assessment of the products. This proposal will be further discussed at the June PAI meeting.

This adaptation of the Guidance Document allows for a pragmatic implementation based on the limitations of Art. 43.

4.3 Summary table

Summary of Discussion and Conclusions

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Preconditions for Article 43 applications	Preconditions were confirmed. No label extension from professional to home and garden uses is allowed. If one of the preconditions mentioned above are not met, the procedure according to Article 33 or Article 40 of Regulation 1107/2009 applies.	Already indicated in the GD, agreement of the group.	none	
Access to protected data:	This is the responsibility of each MS once the ZRMS has made the assessment of new data. In order to ensure a harmonised process there needs to be published a list of the protected studies (both for substance renewed, and the products).	To be amended in the GD	COM to make the list electronically available (Commissions website) at the time of availability of the EFSA conclusion (Remark: List to be submitted bz RMS to COM first)	
Seasonal studies (cat. 4 studies)	Agreed to take the 2-year period as an example. Agreed to allow a prolongation period, when necessary, sufficient for the studies to be generated and provided (agreement between zRMS and applicant needed during the	No changes of the scope of the definition of cat. 4 data.	none	

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	presubmission meeting 2 months after publication of EFSA conclusion).			
What to assess?	Assessment is to be focussed on new information, conditions or restrictions in the renewal regulation .	Proposal to amend section 3.5 "Assessment bz zRMS" to take into account the issue mentioned in the renewal regulation ("MS shall pay particular attention to....".		
full dRR?	Stand alone document containing everz section (the sections or oart of the sections which are newly assessed/amended to be highlighted. zRMS to assess only new information (highlighted parts of the dRR)	No need to amend the GD / already mentioned.	none	
Which Guidance Document to be applied?	The new information is to be assessed using the Guidance documents in force at the time of application according to Article 43.	No need to amend the GD / already mentioned.	none	
Mixed products	Agreement to assess products containing 2 actives expire within less than a year. Uncertainties regarding possible modification of	Agreement to assess products containing 2 actives expire within less than a year. Uncertainties	none	

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	expiry dates of the actives in one direction or another.	regarding possible modification of expiry dates of the actives in one direction or another. Anyway, flexibility needed. Clarified in the GD.		
Assessment of efficacy:	Already discussed and concluded for the situation, if the GAPs remain unchanged: No assessment of efficacy except "Possible development of resistance or cross-resistance" Assessment of resistance only by the zRMS. It might be possible, that previous authorised GAP has to be changed (i.e. it is considered necessary to lower the application rate/ha) because of risk assessment issues. In this case new efficacy trials (reflecting the new GAP) might be necessary. The following option may be applied: A later submission of those trials necessary (because of changed end points) may be justified (Cat 4 studies according to the GD rev. 12) and therefore wait until efficacy	No change of the GD needed.		

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	trials are made available. If the GAP is to be changed because of new end points, a new efficacy package may be regarded as "Cat 4 studies" .			
What to be assessed when (as regards the individual sections of the risk assessment) – compiled like appendix II of GD on Article 43	Need to set a table what/when to assess?	Appendix II of GD on Article 43 is agreed (what to provide when by the applicant), A table indicating what to be assessed when is not considered necessary		
Combitox (ecotox/toxicology)	when necessary, a combitox assessment is to be performed.	amended in the GD.	none	
Revocation of the product?	If no submission within 3 months after DoA, withdrawal after 9 months, with a period of grace period according to Article 46. Application to all uses of a product or partial revocation of some uses. Application of restrictions indicated	no need to amend the GD.	none	

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	in the renewal regulation: to be considered before 12 months after EIF of the renewal regulation.			
Data matching	data matching check to be performed by the acitive substance RMS as soon as possible after the 3 months deadline for application.	Amended in the GD	None	
Allocation of the zRMS	the proposal by the applicant to be provided 2 years before the application according to Article 43. The final allocation of the zRMS should be notified to the applicant preferably before the publication of the EFSA conclusion.	Amended in the GD.		
Allocation of the zRMS (2)	Proposal, that one zRMS for Europe has to assess all products containing one active substance to be further discussed at PAI (guide: <10 products containing that substance). If more products (>10) are to be assessed, one zRMS within each zone should do the assessment of the products containing one active.		To be discussed further at PAI meeting	Short term

4.4 Presentation

Breakout group C Presentation to Plenary.pdf

5 Breakout Group D (Zonal Secretariat)

5.1 Thought starter

The following document has been prepared as a thought starter to initiate discussions in the Breakout Groups and should in no way be conceived as the official position of the European Commission or the Member States

Background

There are voices stating that the establishment of a permanent secretariat would help solving the problems presently extant in the process of authorisation of PPP.
This workshop will investigate the value of this notion, and if it is true, which problems can actually be solved.
We then have to determine what the added value of a secretariat would be when compared to the present situation. After all, if member states (MSs) already have difficulty with the coordination at a national level, would coordination at an international level be possible at all? Would raising a permanent secretariat simplify, or rather complicate matters?
And finally, if relevant, we can decide what other helpful duties the secretariat might fulfil.
Only then the actual 'shape' of a secretariat can be determined.

1. Problems solvable by a secretariat

As a start, we'll focus on the problems that exist (or don't exist).
The table below serves for the identification of the problems (that might be solved by a permanent secretariat) in the process of application, assessment, authorisation and mutual recognition.

	Is this a problem?		Solvable by a permanent secretariat?	
	Yes	No	Yes	No
Finding a zRMS				
Even distribution of the workload				
Harmonised quality check of the received dossier				
Work sharing: distribution of work within one application over several MSs within a zone				
Work sharing: non-zonal work for applications in more zones				
Respecting the timelines – transparency of the progress, necessary for cMSs				
Communication with applicants				
Harmonised assessment dossiers by zRMSs				
Commenting rounds				
Mutual recognition (cMS-type)				
Assessment inter-zonal applications				
[other issues in the process of application, etc?]				

When decided on the usefulness of a secretariat, 3 factors first need to be checked.

2: Support for a permanent secretariat

Is there at all a need for a secretariat felt with:

- competent authorities
  - at a managerial level?
  - at a procedural level?
  - at a technical level?
- Commission?
- industry?
- consultants?

3: Purpose of a permanent secretariat apart from facilitation and easing the application process

What we (could) need in general terms is the facilitation of, to name a few examples

- reinforcement mutual trust
- coordination of EU-wide reactions to new 'hot' information (e.g. on indoxacarb)
- coordination of practical Q&A's (cf. Helpnet/ECHA)
- permanent recording and disclosure of agreements (from workshops, Newsgroups, PAI, zonal steering committees, etc.) – rather like ECHA's role via Helpnet
- substantive steering on the realisation of agreements

For a more exhaustive list, see the next pages that outline the possible benefits of a permanent secretariat to manage the zonal process within Regulation 1107/2009.

Bearing in mind that in order to be effective, its tasks should be as simple/uncomplicated as possible, which of all possibilities would be useful and feasible for a permanent secretariat?

4: Impact force of the secretariat

A permanent secretariat presently has not legal status.

In order to be effective, it would need some sort of authority, accepted by all MSs involved. However, the execution of voluntary mutual recognition has shown how difficult this is. Therefore, a secretariat can only operate successfully of it is granted certain legal competences.

In due time, this could be laid down in the revised regulation: the permanent secretariat in whatever shape, could be taken up to ensure its statutory basis.

For the time being we need another solution.

Germany/BVL came with a position paper, proposing a way forward for a more efficient work of the regulatory bodies working on the authorisations of PPP. This proposal could well be the basis for that solution.

Do you have any proposal as to the legal feasibility and EU-wide practicability of a permanent secretariat, in the light of its basic responsibilities as discussed under 1, and its extra responsibilities as discussed under 3?

5: Realisation of a permanent secretariat

- who would have the end-responsibility of the secretariat?
- what should the secretariat look like – office in Brussels, or a virtual office?
- How many FTE?
- How to raise the necessary funds?
- etcetera

Appendix to the thought starter on a Permanent Secretariat
Background

Regulation (EC) No 1107/ 2009 came into force in 2011 and with this a new process for evaluation and authorisation of plant protection products within the zones started as outlined in the Regulation. Three steering committees (Northern, Central and Southern) and an inter zonal steering committee, were set up on a voluntary basis as laid down in the Guidance document (SANCO/13169/2010).

Current situation and issues facing the steering committees and MS within the zones.
The zonal steering committees are working hard on harmonisation of processes and risk assessment but there are many obstacles and resource issues.
Current issues:

- The steering groups have little time for actual planning.
- Reliance on excel lists (will over time be replaced by the PPP IT system)
- Continuing reliance on excel sheets for voluntary work sharing (for applications under Dir 91/414)
- Different approaches from MS to voluntary work sharing (under Dir 91/414), new products and extension of uses (zonal) and amendments.
- Article 43 – Concern but no clear insight into how it will proceed.
- Different approaches from MS to risk assessment and national requirements – lack of EU quality system.
- Inter-zonal work sharing not sufficiently utilized (duplication of work e.g. phys/chem and ecotox/tox)
- Reliance on chair of steering committees and MS to provide resources to develop process. (resources may be switched back to MS priorities at expense of zonal system)
- Article 43 renewal will attract additional zonal coordination work, at levels far in exceedance of new product work handled thus far.
- In the different zones and elsewhere, agreements are reached, but since they're not recorded officially, they tend to be ignored.
- the (inter)zonal system will only work if we all assess in the same way, but presently, there is no benchmark so different approaches grow profusely.
- The secretariat could act as the information desk for the progress of submissions for authorisation and thus represent a direct contact point for applicants.

Possible benefits of a permanent secretariat.

For member states

- The secretariat could maintain the lists of applications.

For example:

- E.g. the applications that cannot yet be taken up in the PPP IT System like extension of use, amendment to conditions of authorisations,
- new zonal and inter-zonal applications that could not yet be uploaded in the EU data-base,
- applications in more than one zone where work sharing may take place,
- Co-ordination of Article 43 applications, (the article 43 process may need separate consideration and guidance)

- The secretariat could act as the information desk for distributing information on expert consultations within zonal authorization procedures working out harmonized assessment approaches, thus setting the benchmark – this would also help mutual trust.

- The secretariat could negotiate in distributing assessment work for zone-independent aspects of applications submitted in more than one zone.

- The secretariat could identify the availability of expert resource where specific additional support may be needed by zRMS. This may be for country-specific uses in the core section or if some MS had resources problems in a particular expert area or if a MS had excess capacity in an expert area they could consult the secretariat.

- The secretariat could act as a link between the steering committees, the post approvals issues group, EFSA (re new guidance etc) and the Commission (standing committee etc).

- The secretariat could manage the new PPP IT System for PPP applications

- The secretariat could identify MS capacities on an annual basis.

- The secretariat could coordinate and re-allocate work on the basis of the real capacities available, , and/or

- Coordinate and re-allocate work on the basis of specialised expertise.

- The secretariat could provide advice to applicants regarding making the most of the zonal system, for example where products are new in some MS and existing in others.

- The secretariat could contribute to a more harmonised and considered system which could be defended easily to NGO's etc.

- The secretariat could mediate in disagreements.

- The secretariat could coordinate, record and disclose Q&A's and other agreements (from workshops, Newsgroups, PAI, zonal steering committees, etc.) – rather like ECHA's role in Helpnet.

- The secretariat could steer on the content of agreements.

- The secretariat could coordinate in the signalling and dissemination of 'hot' topics (e.g. for indoxacarb).

In a "coordination role" the secretariat could

- Track and disclose the progress of the assessment, thus keeping informed the cMSs (helping them with their planning).
- Keep track of the planned submission of dossiers, thus keeping informed the zRMS and cMSs (helping them with their planning).
- send request for comments and sets deadline.
- collect the comments.
- send e-mail to zRMS with table containing the collected comments + request for comment by zRMS
- coordinate teleconferences.
- do or don't draw a final conclusion, (scientific role up to the zRMS?).

For Applicants:

- The secretariat could identify and coordinate available evaluation resources.
- The secretariat could act as a Helpdesk (One point of contact for planning issues)
- The secretariat could collect relevant national information
- The secretariat could develop and maintain an overview of
- expected future workload
- MS capabilities
- resources.
- Help notifiers identify a zRMS

For European citizens:

- A more harmonised system and scientifically peer reviewed process which gives more confidence to the process.

For Commission:

- Acceleration towards harmonisation.
- Confidence in the process.

Example of a possible way forward

How would a secretariat work in practice (applications only)

1. **Pre submission contact**

   No legal requirement but under guidance, applicants asked to submit details to secretariat. (Applicant may also contact MS which they wish to act as zonal RMS)

   Secretariat to link MS and zones and consider worksharing (in phys/chem and tox and other)

2. **Application**

   Legal requirement: Applicant to apply to all MS where they wish to have an authorisation or are seeking re-registration.

   Under guidance, requested to copy to the secretariat.

   Secretariat drafts a work schedule for the zonal RMS's and other MS involved (e.g zonal RMS to complete all area's or maybe sections divided). Some sections not to be duplicated in each zone.

   Agreement from MS as to which guidance documents/ template etc to be used.

   PPP IT System to be used (for the new product part.

   Secretariat adds to planning list and contacts the 4? MS involved to confirm or establish the zonal RMS.

3. **Evaluation**

   Secretariat to alert each zonal RMS at key points during the evaluation (eg, post acceptance latest date for start of commenting?). Issues to be resolved (e.g. reallocation of work if resource issues arise).

   ZRMS shall inform secretariat when additional information is required to the applicant and the deadline for submission (stop clock). Secretariat shall keep track of this.

4. **Commenting period**

   ZRMS to send DRR to secretariart for uploading on CIRCABC and start the commenting period,

   Secretariat to follow the commenting period (using PPP IT System?) and ensure that all relevant MS were contacted.

   Secretariat to collect all the comments in the reporting table and send to ZRMS

   Or could the secretariat co-ordinate the commenting period? Might be difficult in 6 weeks.

   Could the secretariat organise a peer review (teleconference among experts of ZRMS and cMS) for solving discrepancies and to agree the final evaluation?

5. **Authorisation**

   Zonal RMS to send a copy of authorisation/ final assessment to the secretariat for uploading and circulation of details to all MS.

5.2 Summary report

The breakout group agreed a secretariat is needed and recommended to have one for all zones.
The secretariat should have exclusively administrative tasks, focusing on managing the current PPPARMS system that needs to be extended, and maximizing efficiency of the zonal process. A pilot project should be run by a Commission focused working group, to determine best functionality for the secretariat.

The establishment of a permanent secretariat would help solving the problems presently extant in the process of authorisation of PPP.

The breakout group considered the need for a secretariat and concluded that it could be helpful in removing the administrative burden, thus giving the Member States the opportunity to focus on core business: applications assessment and decision-making.

The role could be achieved as administrator of the current PPPARMS system. However, the current system would not fully cover the needs of an effective organisation of evaluations and its functionalities would hence need to be extended into an interactive workspace for both applicants and evaluators.

In recognition that the development of an extended system would take time, it was necessary to consider a more immediate pilot project to define the roles of the secretariat more fully. This would also encourage the use of the current system by Member States and applicants in collaboration.

The article 43 renewal programme will not be considered under the remit of the pilot project since other organisational strategies have been applied to this work.

The pilot project would also explore possibilities for future legislative status and funding for the secretariat role.

Commission are already managing the current PPPARMS and therefore it would be logical for responsibility for the secretariat to also be held by the Commission.

A number of actions were agreed to progress this initiative:

In the short term: obtain Member States and industry agreement for participation in the pilot scheme; run a pilot project with new PPPs (where work sharing efficiencies could be found), involving all 3 zones – and with Central Zone lead
In the medium term: organise and conduct a focused working group to look at the possibilities of building an interactive workspace based on the current PPPARMS – with participation of Member States, industry and the developers of the current system;
Commission to reflect on legal status of secretariat and funding thereof when drafting the legislation on the PPP system and via article 78(2).

In the long term: after the pilot project is completed, the pilot project team should develop a remit for the secretariat, evaluate budget needs, and launch the extension of the system functionalities.

5.3 Summary table

Summary of Discussion and Conclusions

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Do we need a secretariat at all?	It has to be discussed whether a secretariat for each zone, or one to service all zones	YES. Rather speak about one for all zones as need broad coordination	Run a pilot project with new PPPs, involving all 3 zones - Central Zone to lead **Action: Directors to determine participating Member States (June meeting)**	Short term
	DK: NZ rather working; however other zones are not so far	Need more coordination		
	Too many working groups (note: not all participants know abbreviations and remits of SCOPAFF, PAIG, ZSCs…)	Need to organise		
PPP database (management system)	Member States training for one IT person per country only: impossible for Member States to work on it obligatory; based on R4BP for biocides	Member States and industry need to use the current system to get experience		

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Problems solvable by a secretariat	Sticker session on questions from thought starter (table in section 1)	Identified main issues are: • Finding a ZRMS (not solvable by the secretariat) • Even distribution of the workload (solvable by secretariat) • Work sharing – zonal (solvable) • Work sharing – non zonal (solvable) • Respecting timelines (not solvable) • Harmonised assessment by ZRMS (not solvable) • Assessment inter-zonal applications (solvable)		
Finding a ZRMS	This is difficult for companies Member States do not think a secretariat could decide on a ZRMS	Not sure whether Member States would accept the decision on ZRMS allocation from the secretariat		
Assessment of inter-zonal applications: one zone e.g. glasshouse, seed treatment	Is a problem when evaluators need to wait for each other Also some Member States do not trust the evaluation from the inter-zonal RMS and do the evaluation again	Avoid work duplication Cannot be solved by secretariat		

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Assessment of inter-zonal applications : one PPP with one GAP for all 3 zones	Duplication of work For new active substances, applicant has to identify zone-independent areas of assessment; for re-authorisations (article 43), all Member States are concerned at the same time and can coordinate	Can be solved by secretariat		
Support for a permanent secretariat	Voting session on identified need for a secretariat among stakeholders	• Authorities - managerial level: neutral • Authorities - procedural level: yes • Authorities - technical level: neutral • Commission: yes • Industry: yes • Consultants: yes	Check support from management (Member States and industry) for pilot project **Action: Directors June meeting; A Dhaussy for industry**	Short term
Communication between experts	Workshops would be needed between experts from all Member States on technical issues	Does not concern the secretariat		

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
PPP management system (database)	Updating the system is time-consuming, Member States lack time for this task During the training session, Member States raised the concern that there is duplication as each of them have their own system to manage R4BP is often mentioned as reference but it is not completely satisfactory (will be overruled by a new system) An expanded system would decrease workload for both Member States and industry	Task of supporting the organisation of evaluations should be handed over to secretariat Proposed name for the workspace: **PACT Pesticides Application Coordination Tool**	Organise a working group by the end of 2015 on what would be needed from an interactive workspace – with participation of Member States, industry and the developers of the current system **Action: Commission**	Medium term
	Using the system as an interactive workspace would limit email exchanges between parties and the multiple working groups, saving time for Member States to focus on evaluations Adding functionalities to the current system could help reduce the time for its development into an interactive workspace; this would also require a body to be dedicated to the system development.	The system should be an interactive workspace and the core task of the secretariat would be to act as administrator Adapting the system may need time but a solution is needed in the meantime to manage article 43!	Check options with breakout group C for organising work (ZRMS) in Central Zone for Article 43 applications **Action: A Smits**	Short term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Tasks for a secretariat	Stickers session to prioritize possible tasks for the secretariat between "must have", "nice to have" and "no way" It was discussed whether the system could be used to complete the Member States' task to notify some decisions (under article 36(3), 44, 53) and the companies' task to notify potential harmful effects (article 56). However the Member States decisions need to be noted in the SCoPAFF hence uploading them on the system would be a duplication of work	Must have: Coordinate zone-independent work • Identify available resources • Communication between the existing working groups • Helpdesk to collect questions and answers Nice to have: • Distribute information in experts consultations to support harmonisation • Reallocate work following available expertise No way • Mediate in disagreements • Arbitrate between Member States assessments • Draft assessment conclusions Signal "hot topics"	Draft remit after the pilot is completed (to be included in PPP management system user guide) **Action: pilot project team**	Long term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Helpdesk	It would take work away from Member States if the secretariat could act as helpdesk	The secretariat should collect questions and answers related to applications but also related to using the workspace		
Legal status	To be effective, the secretariat would need some kind of authority – currently It has no legal status	The secretariat could be included in the Regulation on PPP management system, or via article 78(2)	Commission to reflect on legal status when drafting the legislation on the PPP system **Action: Commission**	Medium term
Funding	What happened to article 76 (Commission expenditures)? Deleted by article 53 of Regulation 652/2014	Industry would agree to fund as long as it is delivering (Note: it may be difficult for SMEs)	Commission to reflect on funding when drafting the legislation on the PPP system **Action: Commission**	Medium term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
Post-it session: needs to be fulfilled by an interactive workspace	Start of the evaluation process : Pre-notifications (expected submissions for all concerned Member States to plan resources), including timing – industry must be able to update when needed / modify entry Notifications (new PPPs and article 43) Applicant proposal for ZRMS Facilitate pre-submission meetings Application and dossier submission in one central point (upload all uses for all concerned Member States) Upload letters of access Identify when same dossier submitted in several zones – to allow common project Maintain list of applications Extension of the current PPP management system Information/ advice to applicants e.g. where PPP is new System to handle confidential information	Workspace to contain all information needed for all stakeholders to use, and Member States / Zonal Steering Committees to take decisions	Extend functionalities of the current PPP management system to make it an interactive workspace (directions to be considered at the working group mentioned earlier)	Long term

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	During the evaluation: Track evaluations progress (including dates of compliance and completeness checks) Allow commenting Discussion platform (already exist in CIRCA) Register of experts contact details (in-house and external) Library of guidance documents Library of working groups (zonal steering committees, PAI…) documents and decisions Upload national data requirements Upload critical GAP Upload formulation composition Facilitate inter-zonal work and avoid repetition of evaluations			
	After the evaluation: Upload of the evaluations of the different sections for consolidation Upload the registration reports (RR) and lists of studies – publicly available to avoid individual requests for access Upload registration certificates			

Topic	Summary of Discussion	Conclusion	Proposed Action	Short/ Medium/ Long term
	Outside the evaluation process: Email alerts (allow to set preferences) Support data protection (list of protected studies) Library of guidance documents interpretations and precedents Link to the national databases Allow alignment ZRMS, ECHA, EFSA on classification	Store these issues	Discuss these issues in the working group on the workspace	Medium term
Realisation of the secretariat	No need for expenditures on an office, a Member State could lend desks when needed – can be virtual Commission is already managing the current PPP management system Industry willing to support	Virtual office Commission are already responsible for the current system, and should therefore be responsible for the secretariat (e.g. sign contracts)	Request Member States and industry support (financial and resource) for the pilot. Proposal to the Central Zone Directors meeting for participation in pilot scheme required as soon as possible **Action: A Smits to draft, T Roberts, AM Dillon and A Dhaussy to review**	Short term
	Staff: expected 3 FTEs Budget: from current Member States fees (to be increased) or separate fee to be set up in the Regulation that will formalize the current PPP management system	Regulation to formalize the current PPP management system should include provisions on the funding	Evaluate budget needs after the pilot project is completed	Long term

5.4 Presentation

Breakout group D Zonal Secretariat Presentation to Plenary.pdf

6 Final agenda

Department of Agriculture, Food and the Marine
An Roinn Talmhaíochta, Bia agus Mara

EU WORKSHOP on Zonal Evaluation, Mutual Recognition and Re-authorisation of Plant Protection Products

2-4 June 2015

Dublin Castle, Ireland

Final

WORKSHOP AGENDA

Hosted by:
The Irish Department of Agriculture Food and the Marine, Pesticides Registration and Control Division

Tuesday 2 June 2015		
08.30-09.00		**Registration**
09.00-09.20	Plenary session	**Welcome and introductions (Irish Department of Agriculture Food and the Marine)** **By Mr Dermot Ryan (Deputy Chief Inspector of the Department of Agriculture, Food and the Marine)** **Housekeeping announcements. Anne-Marie Dillon, Pesticides Registration and Control Division**
09.20-10.00		**Setting the scene** • Introduction and framework of the workshop • Objectives of the workshop • FVO presentation **Wolfgang Reinert and Jeroen Meeussen, European Commission, DG SANTE**
Experience of EU Member States and industry with the zonal system		
10.00-10.40	Short overviews and experiences, EU Member States and industry	*Chaired by Wolfgang Reinert* • Presentation 1 (Dr. Martin Streloke, Germany) • Presentation 2 (Mr Panos Theodoris, Greece)
10.40-11.10	Coffee break	
11.10-12.30	Short overviews and experiences, EU Member States and industry - continued	• Presentation 3 (Ms. Vibeke Møller, Denmark) • Presentation 4 (Mr Hans Mattaar, ECCA) • Presentation 5 (Martyn Griffiths ECPA) • Presentation 6 (Mr David Cary, IBMA)
12.30-13.45	Lunch	
13.45-14.45	Short overviews and experiences, EU Member States and industry – continued + plenary discussion	• Presentation 7 (Mr Donal Lynch, Ireland) • Plenary discussion. **Wolfgang Reinert, European Commission, DG SANTE**

14.45-14.55		Introduction to Breakout Groups. **Anne-Marie Dillon, Ireland**
14.55-15.30	Coffee break	

<table>
<tr><td colspan="3">Breakout Groups (BOGs)</td></tr>
<tr><td>15.30-17.00</td><td>Break-out group session #1

(1h30)</td><td>1.5 hours for group to set out what they want to discuss and to allow group to reflect over night for work in day 2.
4 BOGs; chairs to lead discussions
(Background paper and outline for each breakout group will be available prior to the workshop)

<table>
<tr><th></th><th>Main topics</th></tr>
<tr><td>1</td><td>Zonal System (general)
Allocation of ZRMS;
Role of ZSC/ IZSC;
Commenting - how to close comments
Harmonization of Risk assessment / RMM
Extension of uses; minor uses; generic products; comparative assessment….
Improvements to Guidance doc on Zonal evaluation and mutual recognition</td></tr>
<tr><td>2</td><td>Mutual recognition
Difficulties that have been identified and posible solutions
Need for national /Zonal requirements
Improvements to Guidance doc on Zonal evaluation and mutual recognition
Data Protection
Availability of RR;
how to move from the zonal evaluation to mutual recognition……</td></tr>
<tr><td>3</td><td>Re-authorisation (article 43):
Guidance document on renewal of authorisation
Allocation of ZRMS
Risk envelope
New endpoints and guidance
Availability of RR
comparative assessment
data protection
Withdrawal of authorizations and period of grace</td></tr>
<tr><td>4</td><td>Zonal secretariat
Function and role
Coordination/ allocation of ZRMS
Distribution of work
Peer review/commenting period….</td></tr>
</table>
</td></tr>
<tr><td>18.30</td><td>Workshop Dinner</td><td>Participants at the invitation of The Irish Department of Agriculture Food and the Marine</td></tr>
</table>

Wednesday 3 June 2015		
Breakout Groups (BOGs) – continued		
9:00 – 11.00	BOG session #2 (2h)	Cont'd from previous day
11.00-11.30	Coffee break	
11:30 – 13.00	Plenary session	Initial feedback from BOGs (Chaired by Jeroen Meeussen) (15 mins x 4 BOGs +30mins discussion)
13.00-14.30	Lunch	
Breakout Groups (BOGs) – continued		
14.30-16.30 (coffee break will be at 15.15)	BOG session #3 (2h)	Cont'd from morning session
16:30-17.00	Plenary session	**Article 82 review** **Wolfgang Reinert, European Commission, DG SANTE**
17.00-17.30	Plenary session	Questions/discussions

Thursday 4 June 2015		
Suggestions for improvements		
9.00-10.00	Plenary session	*BOG presentations in plenary (*Chaired by Jeroen Meeussen) *Questions and clarifications*
10.00-10.45	Plenary session	Final plenary discussion
10.45-11.15		Coffee break
Workshop summary and conclusions		
11.15-12.45	Plenary session	*Summary and Conclusions – written draft document* (Presented by each BOG and chaired by Jeroen Meeussen) Proposals for recommendations and activities, and the way forward
12.45-13.00	Closing remarks	The way forward, **Wolfgang Reinert, workshop chair**

7 List of participants

List of Member States, EEA-States, and stakeholders participating at the worskhop

IBMA, ECPA, FVO, ESA, APHA-Ireland, ECCA-Ireland, DG COMM

Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, UK

8 Workshop outline

Workshop Outline

Introduction and framework of the workshop

In Regulation (EC) No 1107/2009 it is indicated that the principle of mutual recognition (as well as the system of "concerned MS") is one of the means of ensuring the free movement of goods within the European Union. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the European Union has been divided into zones with such comparable conditions in order to facilitate such mutual recognition.

Before Regulation (EC) No 1107/2009 became applicable a workshop was organized in January 2010, hosted by BVL in Braunschweig (Germany), to set the framework for the zonal system. As a result two draft guidance documents were prepared. The *Guidance Document on Zonal Evaluation and Mutual Recognition* and the *Guidance Document on Renewal, Withdrawal and Amendment* were the concrete output of this workshop.

The experience that EU Member States and industry have with the zonal system differs. There are good examples e.g. were authorizations are granted within the 120 days deadline, but there are also many situations where for several reasons deadlines were not met or the provisions for mutual recognition (as well as the system of "concerned MS") were not applied properly. Now, more than 5 years after the entry into force of Regulation (EC) No 1107/2009, it is time to take stock.

The zonal system is a reality of which the principles are laid down in Regulation (EC) No 1107/2009. The European Commission is dedicated to the principle of zonal evaluation and mutual recognition and is keen to enhance its functioning. The Commission is organizing this workshop also in light of the upcoming review of Regulation (EC) No 1107/2009, where the Commission is asked to evaluate the functioning of mutual recognition and the division of the European Union in three zones (zonal system in general). This event should aim at an improvement of the zonal system to ensure that a consistent and workable approach will be applied across Member States.

Objectives of the workshop

In summary, the main workshop objectives will be to:

- provide an overview of current achievements in working with the zonal system
- discuss problems that Member States and applicants face with the zonal system
- identify regulatory solutions to those identified problems
- suggest harmonised solutions to facilitate the zonal process

- draw conclusions and recommendations for Commission, Member States, and applicants.

Workshop participants should discuss concrete solutions which should contribute to a consistent and workable approach for applicants as well as Member States and which can be implemented in the relevant guidance documents.

Based on the experiences gained so far need the remit of the zonal Steering Committees and the interzonal Steering Committees to be updated? Regulation (EC) No 1107/2009 should provide for a more harmonised availability of plant protection products across the zones. However, are we by applying 'national specific requirements' not moving away from harmonisation? Applicants and Member States are facing a huge workload as regards application for the re-authorisation of PPPs. Would a 'Zonal Secretariat' be the solution? The release of the PPP Application Management System ('Authorisation database') already provides for a clear overview of the applications in the different zones. It is envisaged that this system will make the workload (more) manageable. Also the use of the new draft Registration Report (dRR)-template will contribute towards further harmonization.

In summary, the main areas where discussion is needed are:

- Remit of the zonal Steering Committees;
- Remit of the interzonal Steering Committee;
- Necessity for Member States to have specific requirements;
- Need for a Zonal secretariat;
- Usefulness of the PPP Application Management System ('Authorisation database');
- Managing the re-authorisation process (Article 43).

Scope of the workshop

The workshop is limited to the procedures related to zonal evaluation, mutual recognition and re-authorisation according to Articles 33-46 of Regulation (EC) No 1107/2009.

Structure of the workshop

The workshop will be structured in plenary and break-out group sessions to allow more interaction between the participants. It will last 2.5 days starting on Tuesday 2 June in the morning and finishing on Thursday 4 June by mid-day.

Outcomes of the workshop

The report of the workshop, its conclusions and recommendations, including the presentations will be made available on CIRCABC.

The workshop recommendations could cover:

- Better implementation of the zonal system and the procedure for mutual recognition and re-authorisation of PPPs
- Pros and cons of setting up a zonal secretariat
- Suggestions for improvement of the *GD on Zonal Evaluation and Mutual Recognition*

- Suggestions for improvement of the *GD on the Renewal of Authorisations according to Article 43*
- Suggestions for the review according to Article 82 of Regulation (EC) No 1107/200

9 Plenary presentations

Plenary presentation.zip