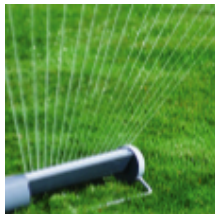




**ECPA's position on the implementation of the zonal authorisation and mutual recognition systems included in the new Regulation on the authorisation of plant protection products**



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## Introduction

This document aims to provide the industry view on the development of processes to support the system of zonal authorisation and mutual recognition for plant protection products. With the adoption of the new Authorisation Regulation, there is now a clear need to further consider the measures necessary to ensure the successful implementation of the zonal approach and ECPA supports the initiative for a workshop to discuss these issues to develop common processes and guidance in order to achieve this goal.

The **Standing Committee agreement on the format of a (draft) registration report (SANCO/6895/2009 rev 1)** is a major step forward to support worksharing and mutual recognition between Member States. This work highlights the importance and the benefit of close cooperation between industry and authorities in developing workable processes to benefit all parties. This document is expected to evolve as we gain greater experience and this will be important to improve the process. In particular, there will be a need to better understand what documentation will be considered as 'core', and what will be additional data that will form part of national addenda.

The agreement at the October 2009 Standing Committee meeting on **Guidance Document SANCO/6896/2009 rev 1 on the functioning of the zonal system** is also a positive and welcome development, setting out a clear framework to assist the functioning of the zonal system, both in the short term (under Directive 91/414/EEC) and in the longer term (under the new Authorisation Regulation). We acknowledge that this guidance document is not intended at present to cover the whole process in detail, but we would like to highlight areas which need further consideration and where the development of additional guidance will be extremely helpful.

While the current document highlights a number of areas which need to be further considered, we would stress that this sets out the interim view of industry and we hope to develop our thinking to support workable solutions for implementation. ECPA hopes to be fully involved in the development of this process, and will look to provide the necessary expertise to ensure that both Member State authorities and industry can make the most of the opportunities available.

## Harmonisation: Dealing with national requirements under the new authorization Regulation

While the procedures for implementing zonal worksharing for authorisations under Directive 91/414/EEC provide a necessary degree of flexibility for taking national requirements into account, further clarity is needed on how this will evolve under the new Regulation.

Currently, a number of Member States have national data requirements, risk assessments and decision making criteria that deal with specific climatic or geographical conditions in their country. Under Directive 91/414/EEC, these requirements can be considered in the national supplement provided by the notifier, and the Member States have sufficient time to undertake a scientific assessment prior to authorisation. Transitioning to the new Regulation, Article 37(4) and Article 42(2) require a decision by Member States in a 120 day period, based on the assessment of the zonal rapporteur Member State (ZRMS). In this period national risk mitigation measures shall be established, but assessment of specific national data is not foreseen.

In line with the stated aim of the Regulation, minimising such requirements will be the key element in ensuring a functional zonal system and the preferred solution for industry is the harmonisation of data requirements and risk assessment procedures. Such a process should ensure that sensible

compromise requirements are put in place – and not the sum of each of the current individual national requirements which would lead to an unnecessary increase in the cost and burden of authorisation. It is also important to ensure that balanced decisions are made considering views of all Member States within the zone and that decisions do not necessarily reflect the most severe assessment.

In order to make progress towards harmonisation, ECPA makes a number of suggestions below with relation to:

- safety data for humans, animals and the environment, and
- biological performance.

### **Safety data:**

Some examples of how risk assessments could start to be harmonised are provided below:

- **Environment:** Agreement should be reached at least at the zonal level on models and input parameters to be used for calculations.
- **Chronic and acute dietary risk:** If an EU MRL has been granted, there is a strong case not to undertake national risk assessments during the national authorisation as the EFSA assessment will take into account the worst cases.
- **Operator:** The use of absolute worst case scenarios by a number of Member States is problematic and further consideration must be given to ensuring the use of realistic scenarios in the decision making process.

### **Biological performance**

Being unable to ascertain that biological performance data is equivalent across national borders has been one of the major reasons for Mutual Recognition provisions under Directive 91/414/EEC not being widely used. Industry accepts that there is a need for a realistic transition period to allow Member States to adapt and accept this paradigm change.

Consideration needs to be given to situations where specific national efficacy testing should be avoided and industry believes that such guidance needs to be developed at a European level, taking full account of the existing EPPO guidelines. A number of Member States provide national guidance with examples of situations where additional testing is not necessary and these documents would provide useful input into developing guidance at the EU level. A starting point would be identification of the common elements of biological performance which should be accepted by all Member States, such as resistance management and crop safety.

### **Development of the risk envelope**

Developing a common understanding of identifying and communicating the risk envelope for both industry and Member States is one key element to the successful implementation of the zonal system. Although the risk envelope is a simple, logical concept, the practical application is a paradigm change to the way applicants and Member States have approached product authorisation. There is therefore a need to provide guidance to cover a number of issues to assist the further development of the risk envelope approach. Guidance would in particular be required for a number of areas including:

- GAP harmonisation
- Defining the risk envelope for each compartment, with examples
- Making use of the risk envelope over a number of formulations

Guidance would also be helpful in dealing with 'less risky' GAPs. Industry believes that in such cases, these lower risk GAPs would not need to be modelled, even if the risk envelope used in the evaluation is not authorised in the country concerned. It would also be useful to include guidance for a situation where the critical GAP is higher than that given in the core dossier. We believe that in certain situations it would be possible to take decisions on GAPs with a slightly higher use rate compared to the core dossier, without requiring submission of substantial additional information and/or studies.

## Residue data

As an EU MRL has to be set before the product can be placed on the market, industry would propose that data already assessed in granting the MRL should not be re-assessed during the zonal worksharing or the zonal authorisation process. This would include plant and animal metabolism, crop residues, processing studies and livestock feeding studies. At the present time, some Member States are requesting residue tests even though the GAP in the country is lower than that used to set the MRL. For the efficient use of resources and effective application of both zonal worksharing and zonal authorisations, Member States should refrain from such requests.

To support zonal worksharing, additional guidance may be required for countries that are located in different zones for residues evaluations. For instance, France is located within the southern zone under the new Regulation and in both zones for residues testing whereas Romania is located within the central zone under the new Regulation and in the southern zone for residues testing.

Given this situation, ECPA believes that the evaluation of all the proposed MRLs should be carried out by only one of the ZRMSs – including when the proposed MRLs is not applicable in that ZRMS. Such a system will ensure greater efficiency and streamlining of the work. The process should equally apply when applications are made for new MRLs, or there is a need to amend existing MRLs due to a new residue definition or an increase in the GAP.

## Other considerations in improving harmonisation and worksharing

### *Zonal steering team and coordination secretariat*

To improve coordination within each zone, industry would support a system where a secretariat is put in place. Such a secretariat would have a coordinating role and would be the first contact point for both the authorities and notifiers when issues require clarification. In addition, industry would welcome a cross-zone steering team and secretariat to track development of the zonal process, to promote and assist worksharing between the zones and to facilitate the assessment of single zone uses (e.g. glasshouses).

### *Ensuring timely zonal evaluations for products containing new active substances*

For products containing new active substances, the new Authorisation Regulation requires the Member State evaluating the application to start the evaluation as soon as it has received the draft assessment report being circulated by EFSA (Article 37.3), and to decide within 12 months if the requirements for authorisation are met. This is an important element of the new Regulation that is supported by industry in order to ensure the granting of timely authorisations for products containing new active substances. Industry's aim would be to ensure effective implementation of article 30 with the granting of provisional authorisations when the active substance evaluation has not been completed in 30 months. At the same time, the timely completion of the evaluation by the

ZRMSs would provide the necessary information to allow all Member States to authorise within 6 months of the active substance approval (as required under Article 37.3).

### ***Harmonisation for confidential information***

Article 63 of the new Authorisation Regulation deals with the information to be considered as confidential. To minimise the risk of different interpretation between Member States, a clear set of guidelines are required at the EU level to ensure harmonised processes and decisions in all Member States. Industry would also support a system whereby the decision on confidential information is taken by the ZRMS and that decision should be accepted by all other Member States within the zone.

### ***Re-allocation of evaluation and standardisation of national evaluation fees***

While Industry supports the proposal in the Guidance Document for a system with a reasonable sharing of the workload, there is some concern with any proposal for the re-allocation of the evaluating authority, especially as regards the fee that may be charge for the evaluation. The re-allocation of the work would impact on the predictability and overall cost of the process. Industry do take great care in choosing their lead evaluating Member States, and have close dialogue with the chosen Member State well in advance of any submission, ensuring that the authority is in a position to carry out a timely evaluation. Given this situation, we believe that a re-allocation of the dossiers to another authority should be an exceptional situation that would require clear justification to the notifier.

Whilst we recognise the provisions of Article 74, allowing Member States certain flexibility in the setting of fees, it would be helpful for further guidance to be given to standardise the level of the fees charged as much as possible when the new Regulation fully applies. Such guidance should also consider the lower workload (and therefore a lower fee) for a decision on mutual recognition as compared to the full evaluation work carried out by the ZRMS.

### ***The role of PRAPeR & PPR Panel***

One key element for the success of the Zonal authorisation process resides with PRAPeR and PPR panel. PRAPeR conclusions and PPR Panel opinions need to be clear and must be based on relevant criteria that will support decision making on products at the national/zonal level.

The requirement to assess the DAR according to guidance adopted by the Standing Committee at the time of dossier submission is crucial to provide consistent active substance approval decisions, with a high degree of clarity for the ZRMSs.

Frequent modifications to guidance will not facilitate worksharing and zonal authorisations, and any changes must be based on a clear and relevant benefit for human and animal health or the environment. To ensure predictability, any changes to guidance (including changes brought about by PPR opinions or discussions at PRAPeR) must be agreed by the Standing Committee and be published with a clear implementation timeframe to be adhered to in the evaluation of active substances and products.

### ***Mutual recognition***

Guidance document SANCO/6896/2009 currently deals with the zonal approach only and not with a situation where the mutual recognition procedure is used. Under the new Regulation, it will be important to ensure that the guidance document should be developed to cover both situations, ensuring that both processes are the same wherever possible.

***Flexibility between zones***

Under the new authorisation regulation, ensuring flexibility between zones will be key in dealing with specific situations; for example, where the GAP for the north differs significantly from the south (e.g. use in the north could be mainly low crops with use in the south mainly high crops). To deal with such cases, flexibility will ensure that the relevant data and evaluations are made available in a timely manner in order to complete national evaluations. Such situations will require excellent communication within and between zones in advance of any submission to ensure the most efficient evaluation and to avoid a duplication of effort.