European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

11-16651

An overview of EPPO discussion regarding mutual recognition and rationale for the EPPO Workshop on Zonal Efficacy Assessments

Over recent years, the issue of Mutual Recognition (MR) has been a regular agenda item in the agendas and discussions of the EPPO Panels and Working Party on Plant Protection Products. However, until 2009 these discussions generally concluded that there was no clear role for EPPO in this area, and therefore no scope for guidance development activity. Until this point in time there had been a provision for voluntary Mutual Recognition of authorizations under article 10 of Directive 91/414/EEC. To facilitate this provision, the EU post-Annex I working group developed a guidance working document to assist with MR issues (document: SANCO/00298/2006).

However, in 2009, when the scope of the new EC Regulation 1107/2009 became clearer on this subject, the EPPO Panels became increasingly active. Article 40 of the Regulation introduces a provision for Zonal Authorizations (also known as 'obligatory Mutual Recognition'), based on the division of European Member States into three 'Zones'.

At the same time as the agreement of the new Regulation, the EU post-Annex I working group also became active, developing a new draft Registration Report (dRR) for the submission of application for plant protection product dossiers. This new dossier format is intended to be a vehicle for all application types. As well as being used by national competent authorities, this is intended as a new format for company submissions and as such, additional guidance was generated to assist with dRR compilation.

One such associated guidance document (SANCO/6895/2009 rev 1) addresses the general layout and practicalities for completing the report, particularly in the framewok of Zonal Authorization processes. Importantly, it also outlines which areas of the risk assessment should be regarded as core (addressed by the Zonal Rapporteur), and which areas should be addressed nationally. However, at the 2009 EPPO Panel on Herbicides and Plant Growth Regulators (Zagreb, HR) the Panel members expressed concern regarding the efficacy data requirements. The Panel discussed that the document makes clear that, contrary to other data requirements (e.g. phys-chem properties, ecotox, environmental fate), efficacy assessments are a national requirement (see Appendix 1), i.e. stand alone data is required for each country.

In response to this EPPO corresponded with the EU post-Annex I working group to clarify this detail. It was explained that the aim with Zonal Authorization was very much to move towards worksharing, however, with regard to the area of efficacy, MS evaluators had provided very little feedback on this issue, and so for the time being, the document indicates efficacy as a national data requirement. It was highlighted that this was more an issue of lack of experience in this area, and that this may become a core data possibility as experience develops.

In response to this, the 2010 EPPO Working Party on Plant Protection Products (Slagelse, DK), highlighted the urgent need for efficacy guidance to facilitate Zonal Authorization in advance of the forthcoming entry into force of the new Regulation (June 2011). The key technical areas that were identified included guidance for the description of uses; core requirements for the dossier of the Rapporteurs; and the format in which the dossier should be drafted.

Shortly after this, an industry initiative led by ECPA aimed to elucidate some of the answers to these issues. An ECPA/Member State workshop was held in September 2010, after which there followed a consultation with applicant companies and Member State regulatory authorities. This made some progress in elucidating which data should and should not be integrated into the core dossier. It was also concluded that both industry and regulators need to work together to agree and reduce the number of national data requirements and then formalize this agreement.

Since this step was taken, EPPO Panel members have urged for an EPPO Workshop in advance of the date of entry into force of the new Regulation with experts from industry and regulators, in order to bring these developments together in order to make firm solutions to these issues.

The EPPO Workshop on Zonal Efficacy Assessments will take place in Berlin, on 2011-04-05/06 and sets out the following objectives:

- Provide guidance on a common format and content of the efficacy components of the dRR (draft Registration Report);
- Provide guidance on how to produce a zonal BAD (Biological Assessment Dossier);
- Agreement on core dossier requirements and which areas should be addressed by national addenda;
- Zonal data sets (number and location of trials for a zonal submission) and extra-zonal data (i.e. data from outside the zone);
- Understanding of general dossier submission procedures;
- Identification of the need to adapt existing EPPO standards and the need for new ones.

Appendix 1. Excerpt from document SANCO/6895/2009 rev 1: EU Guidance on the presentation and evaluation of registration dossiers in the framework of Zonal Authorization. Efficacy assessments are proposed as a national data requirement.