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EPPO Workshop on herbicide resistance analysis in the framework of zonal evaluation

Berlin, 2012-10-23/25

CONCLUSIONS and RECOMMENDATIONS

Introduction and Background

Herbicide resistance has become an increasingly significant problem in agriculture. In the framework of the new EC Regulation 1107/2009 (replacing 91/414/EEC), mutual recognition and zonal authorizations are core principles of the authorization of plant protection products. Many of the technical details for conducting zonal evaluations including resistance risk analysis still need to be harmonized among EPPO member countries.

The aim of the workshop was to bring together regulators, scientists and industry participants in order to better understand the present herbicide resistance situation in Europe, and to consider how to address resistance risk analysis across EU authorization zones.

There were 56 participants from 15 EPPO countries (including delegates from research institutions, universities, national regulatory bodies, agricultural advisory organizations, agrochemical and consulting companies).

The main discussion points and proposals are summarized. Open points are to be addressed by the relevant EPPO Panels.

Sensitivity data

- The Workshop considered the sources of data that may be used in order to consider changes in sensitivity over time. These may include 'true' baseline sensitivity data, efficacy data from field trials, data gained from bioassays (dose response data), public domain/literature survey information.
- Depending on the case, i.e. the active substance-crop-pest situation, certain methods tend to be more appropriate. It was therefore proposed that EPPO guidance could be very useful to provide a more objective method for the selection of acceptable information regarding sensitivity.
- With co-formulations, it is not clear whether information on the active substances or specific information on the product is needed. This should be elaborated by EPPO.

Standardization of methods:

- Sampling strategies: could sampling be conducted in the same fields and under the same zonal approach as for the efficacy trials package? How many samples are needed? Random sampling vs. sampling of resistance 'hot spots'? The importance of EPPO climatic zones?
- When dose response data are used, what number and sampling strategy should be employed and hos should the results be provided e.g. ED_{50} or ED_{90}?

- Could sensitivity information be a standard component of an efficacy submission?

Resistance risk assessment

- It was felt that the EPPO Standard PP1/213 *Resistance risk analysis* was difficult to use for herbicide resistance risk assessment. Since the guidance is insufficiently detailed, it was felt that there was some subjectivity in the approach to the risk assessments. Further guidance will help with harmonization and consistency in approach.
- Some more specific guidance or a decision support scheme for resistance risk analysis for herbicides could be helpful to provide a more objective approach. This could employ modeling or quantitative/semi-quantitative methods. It is noted that one such system for herbicides had been developed by Moss *et al*., and by Pavely *et al*. for fungicides.
- It was felt that there was a need for independent guidelines, i.e. one for fungicide, one for herbicide and one for insecticide risk analysis in order to provide better tailored guidelines for each subject.
- Another open point identified was how co-formulations should be addressed. It was agreed that this should be addressed on a case by case basis.
- The basic risk assessment should be described in the CORE dossier. National addenda may be presented if there are significant differences in a given cMS, e.g. pest pressure.

Resistance management and monitoring

- The Workshop proposed that the zonal rapporteur member state (ZRMS) may be able to provide general prompts for candidate good management practices and modifiers, e.g. rotation, diversification of actives, soil management. This could form a 'toolbox of modifiers'. Politics and economics may be driving factors on what may be done nationally when the national decisions are made. Therefore, it was proposed that National Addenda should reflect those differences.
- EPPO may be able to elaborate the concept of 'toolbox of modifiers'. These may be split into general and more specific modifiers.
- Where should management restrictions/comments/modifiers be summarized: in the core dossier or national addenda?
- There are many different methods for monitoring. Can these be harmonized into a 'best practice' for monitoring? Ideally, baseline information from the original registration could be used and compared at any following registration. It was agreed that results from complaint samples are best relevant, i.e. there is no need to conduct a random survey. Else, the importance of the structure that would performed the analysis had been pointed out, i.e. public institute vs. agrochemical companies.
- The Workshop urged a collaborative approach and sharing of data.
- Is it possible to agree a harmonized approach for addressing the requirements of Article 56(4) of EC Regulation 1107/2009 regarding the reporting of changes in sensitivity to competent authorities?
- When should restrictions be imposed? In general, it was proposed that failures as an outcome of monitoring or complaints could trigger a modification of the label.
- It was proposed that failures should be notified as a component of the quantity of the active used, i.e. reporting should be more quantitative.

- The Workshop expressed the importance of the label as statutory requirements and communication to the end-user so that restrictions can be applied. It was agreed that the MoA (HRAC group) should be printed on the label.

Summary of actions

1. Dialogue with the European Commission

- Core/national issues – some additional guidance can be proposed for the development of the Sanco guidance document which is being developed regarding core/national addenda:
    - For sensitivity testing and resistance risk assessment, as much as possible should be addressed in the core dossier.
    - For resistance management, the core dossier could include general proposals for good management practices and modifiers, e.g. rotation, diversification of actives, soil management. This could form a 'toolbox of modifiers' and individual countries could consider these when elaborating their national addenda.

2. EPPO Panel on resistance and the EPPO Panel on herbicides and PGRs

- How to develop the EPPO Standard PP1/213 Resistance risk analysis:
    - Proposed guideline for herbicides – could be an appendix to the guideline. The case studies used for the Workshop Working groups may be elaborated as examples.
    - EPPO guidance to provide a more objective method for the selection of acceptable information regarding sensitivity, and standardization of sampling methods.
    - Specific guidance or a decision support scheme for resistance risk analysis for herbicides could be helpful to provide a more objective approach. EPPO resistance Panel to provide steering, mindful of similar current activities for fungicides.
    - EPPO to clarify whether information on the active substance or specific information on the product is needed for the steps of resistance risk analysis.
    - Elaborate the concept of 'toolbox of modifiers'.