

**Report of the EPPO Workshop
on the Interpretation and Use of the EPPO Standard on Resistance Risk Analysis**

Bologna, IT, 2004-10-19/20

Introduction and Background

This report presents the conclusions and recommendations made by the EPPO Workshop on the Interpretation and Use of the EPPO Standard on Resistance Risk Analysis, held in Bologna, Italy, on 19 and 20 October 2004.

The purpose of the Workshop was to present the revised EPPO Standard on Resistance Risk Analysis (PP 1/213) to representatives of the national authorities in EPPO member countries responsible for the registration of plant protection products and to representatives of the crop protection industry. The meeting was not concerned with the theories or principles of resistance at a scientific level.

The workshop was organized in response to recommendations made by a previous EPPO workshop on resistance risk analysis held in Poznan, Poland in June 2000. One recommendation was for EPPO Secretariat and the *Ad hoc* Panel on Resistance Risk Assessment to revise the Standard and, in due course, to organize another workshop. The initiative for this workshop came from the Resistance Action Committees. It was supported by ECPA and organized with the assistance of the members of the *Ad hoc* Panel on Resistance Risk Assessment.

The workshop was hosted by the Plant Protection Service of Emilia-Romagna region and DIPROVAL (Dipartimento di Protezione e Valorizzazione Agroalimentare), Faculty of Agronomy, Bologna University and special thanks are due to Mr Buggiani and Mrs Collina for the most successful local organization. The participants were welcomed by Prof. Marangoni from Bologna University. Approximately 50 people attended. The majority were officials from national regulatory agencies of 14 EPPO countries. The other participants were representatives of crop protection companies and researchers/scientists from different Institutes and Universities. The list of workshop participants is available on the EPPO web site.

Workshop Focus

The Workshop was primarily intended to clarify any existing misunderstandings on the interpretation of EPPO Standard PP 1/213, both within industry and in the regulatory community.

The workshop addressed the following discussion subjects: Test methods, Availability of data, Sensitivity data, Acceptability of resistance risk, Resistance management, Details and flexibility of label, EPPO role/ future activities of the *Ad hoc* Panel on Resistance Risk Assessment.

Workshop Organization

The Workshop was organized in alternating lecture sessions, smaller working groups and plenary discussion sessions.

Lecture session

The speakers are listed below and summaries of their presentations are available at EPPO web page.

The lecture session started with Ton Rotteveel's (PPS, Wageningen, NL) presentation of the Standard and its rationale, followed by Antony Straszewski's (ECPA, Efficacy Expert Group) talk about the experience of industry with the authorities when implementing the standard. The lecture session then provided a variety of perspectives on status and use of the Standard PP 1/213 in Germany (Udo Heimbach, BBA, Braunschweig), France (Robert Delorme, INRA Versailles and Annie Micoud, DRAF-SRPV Rhône-Alpes), Italy (Piero Cravedi Agricultural Faculty, University of Piacenza and Ivan Ponti PPS of Emilia-Romagna, presented by Emanuele Mazzoni) and in the UK (Oliver Macdonald, PSD York). Round table discussion gave the opportunity for every country representative briefly to present the situation and problems with resistance in their country.

Implementation of resistance management strategies was presented by the Fungicide Resistance Action Committee chairman Karl-Heinz Kuck, Insecticide Resistance Action Committee chairman Robert Dutton and Anne Thomson chairman of Herbicide Resistance Working Group within the EWRS. They also covered the past and current activities and accomplishments of their organizations.

The practical application and communication of resistance management strategies in Italy for fungicides and insecticides was addressed by Riccardo Buggiani (PPS, Emilia-Romagna region) and for herbicides by Maurizio Sattin (Institute of Agro-Environmental and Forest Biology, Legnaro (Padova)) who also explained activities of the Italian Herbicide Resistance Working Group. More about the importance of local expert groups in the implementation of resistance management programmes was heard from James Clarke (chairman of the UK Weeds Resistance Action Group). He explained the role of the resistance action groups, what they do, how they interact with RACs and how they interface with the registration process. These presentations were an incentive for other participants to envisage similar organization of the activities on resistance in their countries.

One of the main discussion subjects, baseline sensitivity, was addressed in a lively debate "*For*" and "*Against*" the requirement to provide sensitivity data, in which the speakers had inverse roles. Ton Rotteveel (PPS, Wageningen, NL) argued in favour of industry and was therefore against, whereas Antony Straszewski (ECPA Efficacy Expert Group Chairman) strongly represented the regulatory point of view. Their extreme positions (opinions) generated a very interesting discussion, which proved that a mutual agreement was achievable and that sometimes conflicting interests can be weighed up and balanced.

Working group sessions

Working group sessions, in which the workshop participants split up into six groups (two for each discipline: herbicide, insecticide, fungicide), allowed for more detailed discussion of the workshop subjects.

The participants had the opportunity to practice use of the Standard on three fictitious plant protection products, discuss the implications for registration authorities and industry and make proposals for further development. The groups studied that part of the dossier concerned with resistance risk analysis to decide if it allowed a clear evaluation of risk and the

preparation of a realistic management strategy. They also studied how the dossier would be evaluated by the registration authority.

The working group sessions were followed by a plenary session in which the groups gave a short report on their discussion and conclusions. The individual working groups' reports are available on EPPO web site.

Plenary session

The final session of the Workshop developed its conclusions and recommendations, which it hoped would be noted by the registration authorities and the crop protection industry, and by the EPPO Working Party on Plant Protection Products in deciding its future programme in this area.

The Workshop found once again that the Standard on Resistance Risk Analysis was a very useful document, needed at the stage of registration of plant protection products, in particular in the context of mutual recognition. It facilitates the evaluation of resistance risk and the preparation of risk management strategies and, especially for the registration authority, the evaluation of the dossier concerned with resistance risk. The Workshop agreed that this meeting had been a good opportunity to develop an understanding of how to implement the standard.

WORKSHOP CONCLUSIONS & RECOMMENDATIONS

The Workshop

- Welcomed the existence of the EPPO Standard PP 1/213 Resistance Risk Analysis and believed that it facilitates the evaluation of risk and the preparation of risk management strategies for registration of plant protection products
- Recommended that it should be used by the registration authorities in all EPPO member countries and by crop protection companies when preparing a dossier for registration.
- Recommended that the dossier concerned with resistance and the evaluation by the registration authority of this aspect of the dossier should follow the format of the guideline.
- Recommended that any conclusions drawn in the dossier or the evaluation should be clearly explained.
- Recommended that a more flexible approach to registration should be adopted to allow label requirements to be altered in the light of more recent information on resistance development.
- Believed that early discussion between applicant and regulatory authority are to be encouraged from both sides as they avoid potential difficulties later in the approval process.
 - The applicant and the registration authority should agree on the specific requirements needed in the Annex III dossier at an early stage prior to dossier submission;
 - The applicant should provide sufficient details and interpretation for regulator to understand data in a dossier;
 - In the event of disagreement between the applicant and the regulator expert judgement will be required in order to make satisfactory decisions;

The Workshop also agreed on the following.

- Understanding and managing resistance is a complex process, important for sustainable use of plant protection products;
- A diverse toolbox of products is essential for resistance management;
- Further use restrictions are likely to increase resistance management problems: loss of active substances in the EU, loss of targets (restricted uses); loss of product diversity (not limited to minor crops); one alternative is probably not sufficient for resistance management;
- Resistance usually starts as a local issue. It is important to have a regional approach for resistance strategies and if necessary work towards getting common strategies, by networking on the European level;
- Management strategies should be adapted to individual regions (countries) and should include an emergency plan of action in case the strategy is not working;
- Modifiers should also be discussed with advisory services (responsibility on industry to carefully analyse and decide on resistance risk strategies);
- Encourage local regulatory authorities to organize training courses, seminars or other communication which can be of benefit to both large and small companies making submissions;

- The formation of national / regional expert groups on resistance should be encouraged (e.g. IRAG and FRAG-UK);
- It is important to engage the Food Chain organisations on the importance of resistance management when developing farmer protocols;

The Workshop agreed that a new revision of the EPPO standard on Resistance Risk Analysis was not required, but, the EPPO *ad hoc* Panel on Resistance Risk Assessment should explore possibilities to issue more advisory information on

- Sampling procedures (when, which pest, which crop, where in a crop, outside crop (e.g. air sampling) in what conditions, treated/untreated
- Appropriate new testing methods for testing responses of pests to plant protection products, including molecular methods, for publication in *Bulletin OEPP/EPPO Bulletin* and EPPO web site.

Other sources of information on resistance

Resistance Action Committees

FRAC – Fungicide Resistance Action Committee (www.frac.info)

IRAC – Insecticide Resistance Action Committee (www.irc-online.org)

HRAC – Herbicide Resistance Action Committee (www.plantprotection.org/HRAC/)

RRAC – Rodenticide Resistance Action Committee

(www.croplife.org/website/pages/RRAC.aspx)

EWRS-HRWG – European Weed Research Society-Herbicide Resistance Working Group
(www.ewrs.org/ewrs-hr.htm)

National Resistance Action Groups

UK RAGs (www.pesticides.gov.uk/rags_home.asp)

GIRE - Il Gruppo Italiano di Lavoro sulla Resistenza agli Erbicidi

Resistance Databases

Arthropod Resistance Database (University of Michigan) (www.pesticideresistance.org/DB/)

HRAC/Weed Science Society of America: worldwide survey of herbicide resistant weeds
(www.weedscience.org)