Plenary discussion on revision of the EPPO guidelines/risk assessment scheme

H.M.Thompson

Dusts from seed treatments

Oomen, chairman: The dust issue is likely to be a realistic risk also in countries other than Germany, France, Slovenia and Italy. Therefore should the meeting recommend to regulatory authorities in other member states that they should consider this risk?

Forster: In Germany the seed quality approach is in principle the same as in France. Dusts will be limited to 4g/100kg seed or lower, the sowing technique is amended to prevent the spread of dust and to reduce dusts as much as possible. The amount of dust should be reduced by 99% by these two methods; a risk assessment then can be conducted based on 1% dust to identify whether there is still a potential risk.

Oomen: Then the statement should be phrased that it is a general recommendation on behalf of the ICPBR symposium to the authorities in the EU to be aware of the potential risk and to take measures to reduce the risk from dusts from seed treatments liaising with BVL, JKI and AFSSA on appropriate approaches to the issue.

Forster: Seed trade is very flexible in the EU and so imported seed can be used if the exporting country has authorisation. There is therefore a need to ensure that all EU member states have a similar level of quality for seed treatments.

Alix: The risk manager needs to be included in discussions as well as the risk assessor to ensure that appropriate batch analysis rules are in place and to encourage the adaptation of machinery.

Lortsch: Will these minutes be in draft and circulated?

Oomen: Only the final minutes will be published.

Thompson: The organising committee will review the draft minutes.

Lewis: France and Germany have significant expertise in this area of seed treatments; we need to ensure that the information and guidance is passed to authorities.

Oomen: Is it a good idea for the ICPBR meeting to act as intermediaries?

Nienstedt: The Commission and member states have been informed of the issue.

Forster: They are aware of the incident but not aware how the problem is being addressed. The example of dust in seed bags can be used to highlight quality criteria with respect to dust in bags and the redesign of sowing machines should also be considered.

Brasse: France and Germany have addressed the issue but Italy reported a similar issue in 2002 and this has not been addressed there - the information needs to go to the governments.

Giffard: In France the issue has been addressed for dusts but not for the redesign of sowing machines.

Oomen: *The conclusion of the meeting is that the risk of dusts from seed treatments should be brought to the attention of authorities in all member states and the solutions being developed in France and Germany brought to their attention.*

Revision of the EPPO guidelines and risk assessment for honeybees

Oomen: The role of the ICPBR Bees and Pesticides Group is to address problems as we perceive them and to use working groups to develop proposals. There is a need to integrate the three working group proposals highlighted at this meeting into the existing EPPO risk assessment scheme and to develop these as a new scheme. We therefore need to discuss these three proposals.

The field and semi-field testing guideline

Kievits: On the tunnel effects there is a need for a toxic standard for compounds more toxic than dimethoate.

Lewis: It is important to be clear what the toxic standard is for – it is only to ensure the system is working and to show sensitivity and it is not intended to compare effects relative to the treatment (this view was endorsed by Coulson).

Kievits: What is the toxic standard for toxic contaminants in nectar – for a systemic compound?

Becker: You need to distinguish what the test is for, an IGR, a sprayed product or systemic effects and design the test appropriately.

Alix: For systemic compounds it is more difficult, due to the exposure issue - the residue is transferred to nectar and this varies by crop type and even by variety. This is why the toxic standard is used to show the study design has worked and the system is sensitive. A toxic standard for systemics is then very difficult to identify. Therefore we use residue analysis to check exposure to the treatment for systemic compounds.

Candolfi: When setting the validity criteria for the control and toxic standard you need to insert a concrete figure or omit the approach of validity criteria.

Coulson: This was discussed and the group didn't consider setting a fixed number for validity criteria for the toxic standard - addressing this may be an action of the meeting.

Lewis: Critical analysis of the acceptability of the study is required.

Candolfi: *There is a need to analyse data for toxic standards from existing studies.*

Coulson: *Agreed. The group should take action to look at developing a database, with a view of developing validity criteria of field and semi-field tests.*

Stevenson: The need for expert judgement in analysing data has been identified, e.g. an experienced beekeeper.

Brasse: Which country would allow the use of a toxic standard in a field study? This use should be avoided.

Coulson: Felt he couldn't make the statement but the meeting was able to raise this issue.

Kievits: Tunnel tests can't assess issues with contaminated pollen which may be stored, fermented and consumed weeks or even months later.

Coulson: The intention is that the study takes into account the chemistry of the molecule and the test is designed to address the issues raised.

Bruneau: The quantity of pollen from a tunnel test is low and additional pollen after the test is conducted is likely to dilute this further.

Coulson: How could this be addressed?

Bruneau: By using a PEC/PNEC approach.

Oomen: The use of laboratory or model derived data raises the issue of extrapolation to the field while a field test addresses this directly.

Bruneau: The field test should be repeated to ensure the results are statistically valid.

Oomen: The honeybee risk assessment scheme is the only EPPO scheme which has been validated and data over many years has shown it to be reliable.

Bruneau: This is true for sprays but the problem is with systemics.

Alix: *You may have delayed exposure with pollen – we are aware storage may occur - but this is reflected in the duration of the study. Studies cannot represent every condition; they aim to determine that effects do not occur under the conditions of a field study which cannot cover all situations. A wider range of conditions of use is only possible through monitoring and this is currently occurring in France to help to confirm the risk assessment is correct.*

Bakker: The strong technical guidance on cage size in the semi-field study may be too restrictive - smaller cages can be useful and the paragraph needs rewording.

Coulson: This guideline is for standard tests – we are supportive of smaller cages for special designed studies.

Lewis: *Smaller cages are recognised as useful for addressing specific questions.*

Giffard: Larger cages are needed, smaller cages are OK for acutely toxic insecticides but not for colony studies, sizes need to increase to 100-150 m^2.

Coulson: The minimum was set for the standard study but the guidance allows for smaller cages for specific studies. Is 40 m^2 sufficient?

Brasse: There is a need to relate the size of the colony used to the area of forage available, but you also need a minimum size of colony to see effects.

Lewis: There is a need to balance the level of detail in the guideline with being too prescriptive.

Pistorius: There is a need to identify the colony size by size of frames and a rough estimate of numbers of bees and brood cells.

Wallner: Some data suggest for fields that the minimum area is 3 ha and, rather than monoculture of *Phacelia*, that clover is sown to flower at the same time to ensure mixed forage and thus ensure attractiveness to bees.

Tornier: For winter oilseed rape the minimum is 1 ha with 4 colonies, this is the same stocking rate as a commercial beekeeper uses. *Phacelia* is much later flowering, in central Europe mid June-July, and there are very few other flowering crops which reduces alternative forage.

Bruneau: There has been a problem with *Phacelia* in Germany in that the bees don't only forage on the *Phacelia*.

Tornier: The *Phacelia* needs to be irrigated to ensure it is attractive as forage for bees.

Maus: For systemic compounds the effect on honeybees is addressed in the real crop, not *Phacelia*.

Karise: *The guideline should state that it is ensured there are no large apiaries nearby rather than recording their presence.*

Coulson: Agreed.

Lortsch: What is the definition of behaviour?

Coulson: Behaviour within the tent or field.

Laves: You are not assessing the foraging behaviour of the bees in the guideline but the number of bees per m^2; they aren't necessarily foraging.

Coulson: The word foraging should be removed and replaced with number of bees/m^2.

Lewis: Appropriate behavioural observations need to be made for the bees on the crop.

Forster: You still need to know the number of foraging bees.

Lewis: You need to count the numbers of bees on and above crop but if the behaviour is to be recorded you need to know what the bees are actually doing.

Lortsch: We do not agree to the field and semi-field schemes as it is not a final text for systemics.

Alix: *It is a wide framework which highlights which observations should be made, based on observations at earlier stages of testing so that the study design is tailor made to the issues to be addressed.*

Lortsch: This answers my concern.

Brasse: The guideline is not a word-by-word guide, it needs to leave areas open to allow the design of the study to address a specific question.

Nienstedt: *We need to ensure that the terms methods, guidance documents and guidelines are not mixed.*

Zlof: It may help if I provide an outline of the EPPO procedure for guidelines. EPPO is an international organisation founded in 1951, there are 50 member countries, the whole of the EU, Russia and the ex-Soviet countries and North Africa. The remit relates to phytosanitary regulations and plant protection products with the aim of facilitating regulators in authorisation and industry in registration by harmonising procedures. The Environmental Risk Assessment Working Panel published a scheme which covers all aspects of the environment, soil/water and organisms in 2002-2003. Member countries have recently asked EPPO to revise the standard and risk assessment scheme for honeybees. Schemes are adopted into national legislation and EPPO is meant as the minimum requirements. All documents are developed by specialist groups of experts, not national representatives. They are then sent to the member countries for comments which are reviewed by the experts and then the documents are sent to the Working Party on Plant Protection Products. The aim is for the honeybee guidelines and scheme under discussion here to be approved in May 2009. I would like to thank the organising committee and working groups for their activities.

Systemic risk assessment

Candolfi: Can the data from which the TER values were calculated be seen?

Alix: We started from acute toxicity data in the Agritox database and a high default residue level of 1 mg/kg for pollen and nectar. We then made the TER calculations for all substances whatever the mode of action. We compared the 48hr LD50 with the 10 day LC50 (UK PSD funded study) and a factor of 10 covers the range of values. We tested the relevance of the trigger values in the TER calculations. The proportion of substances going to tier 2 for all compounds based on 1 mg/kg and a trigger value of 10 was 16% and included almost all insecticides, so this was a check for false positives. We also checked that the only insecticides that passed, were the IGRs and non-bee-toxic insecticides. We will provide the background in the proceedings.

Kievits: The TER of 10 is too low, we propose better screening at tier 1 including persistence – we have to find a better method of screening.

Alix: Persistency is included in the scheme, even if it is not directly related to the treated crop, e.g. effects in a following crop. The safety factor is based on an acute effect in the right species (we are not trying to extrapolate to another species) and the concentration in nectar and pollen we are using (1mg/kg) has never been observed at this level and is therefore extreme. The concern is actually only for a few substances, many of the insecticides are toxic but not systemic. We therefore need to ensure we don't over-cover the systemic issue so as to be consistent with the rest of the Ecotox risk assessment. For the substances of concern these are all triggered as values are well below 10.

Oomen: Is there agreement with the proposal of the working group on systemic risk assessment?

Kievits: We have a lot of points of concern but agree with the global structure of the risk assessment; our concerns will be sent direct to the working group.

Alix: *Please send each concern, illustrated with data, in a table format to allow a response on each issue.*

Brood effects

Oomen, chairman: Are there questions for the brood group?

Barrett: There is stated lack of validation data for the Oomen method, the bee brood feeding study has been used for many years by many labs and we need to pull together data into a single place to show the level of use and data available.

Becker: I agree this is a good way forward.

Barrett: It would be a powerful database for a range of compounds and doses.

Becker: *The working group wants to reconsider the Oomen method (bee brood feeding studies) including reviewing such data.*

Bruneau: The trigger of 30% decrease in brood levels in a tunnel test - where does the data come from?

Becker: There is a need for expert judgement on this as lower levels of decline may be an issue and may trigger a need for a field test.

Barrett: Under what conditions would the test be needed – for all products?

Becker: Not for all products but for IGRs and systemics, or if data from efficacy or ecotox studies show effects in juvenile or larval stages of arthropods.

Oomen: Do we agree to the proposal of the working group on brood effects?

Lortsch: Long term effects are not covered in the proposal.

Becker: The effects to 7 days are in the tunnel but evaluation is up to 28 days and can be extended through 2 brood cycles, this is the same as for field studies for long term effects.

Bruneau: There is still the problem of diluting effects of other pollen sources in the tunnel.

Tornier: I agree for the tunnel, this is why there are control and positive control treatments.

Bruneau: The variability is high, so results are not significant - so what does an effect mean?

Tornier: Do you have a proposal for an alternative?

Becker: Tunnel tests are not always perfect. There are likely to be a number of tests and together these are unlikely to completely mask effects. If there is still concern there is still the option to monitor colonies in real use.

Alix: The duration of the flowering is the exposure driver, but bees will also forage elsewhere. Therefore we maximise exposure by placing the bees within the test field for the complete duration of flowering.

Becker: If there are still concerns please send them to the working group.

Bruneau: Agree.

Oomen, chairman: *The working groups will consider the points raised and the final versions of the schemes will be circulated in mid January for final comment (2 week deadline) prior to submission to EPPO.*

He then thanked the organisers and participants and closed the meeting.