Pesticides and Honey Bees — The Risk Assessment Process in the EU

Introduction

Honey bees have a long-standing place in pesticide regulation in Europe. They have been the subject of regulatory data requirements for pesticides at national level within the EU for more than forty years, and the International Commission for Plant Bee Relationships (ICPBR) Bee Protection Group has been the recognised European expert forum addressing risks of pesticides to bees for thirty years. The Bee Protection Group meets formally every two or three years and is an open meeting with representatives from academia, regulators and industry (there were over eighty delegates from fifteen countries at the 2008 meeting). Apart from publication of the scientific papers presented at the meetings the primary outputs are review and revision, as appropriate, of European and Mediterranean Plant Protection Organisation (EPPO) honey bee testing guidelines and risk assessment schemes, which are used in European pesticide regulation. This article provides an introduction to how the toxicity and exposure of honey bees is assessed and recent updates to risk assessment in Europe.

All European pesticide risk assessment schemes use a tiered approach moving from laboratory to increasing levels of realism, with higher tier field data taking precedence over laboratory-derived data. This is because sublethal effects seen under artificial laboratory conditions, such as using the proboscis extension reflex in the honey bee, may not be relevant to real life; if they are important then effects will be observed in higher tier studies. All studies are required to comply with Good Laboratory Practice, which is co-ordinated by the Organisation for Economic Cooperation and Development (OECD) and in the UK is a legal Statutory Instrument. In addition, more routine studies must be run to recognised guidelines. Risk assessments for sprayed and systemic (e.g., seed treatments, such as neonicotinoids) pesticides are considered separately as the exposure of honey bees differs.

Assessing sprayed pesticide risks

Hazard assessment

Initially risk assessments were based only on laboratory derived toxicity data (LD50; the dose that kills 50% of adult workers over a 48-hour period, see Figure 1) i.e. they measured hazard. The data are generated using internationally agreed OECD guidelines to ensure their worldwide acceptability. However, many years ago toxicity data were shown not to be a good indicator of effects in the field when used on their own. The level of exposure has a significant influence on the actual risk posed. Therefore, a Hazard Quotient (HQ) approach to risk assessment was developed in the mid-1980s for sprayed pesticides. The HQ takes into account both the application rate and the toxicity of the pesticide, i.e. it is a measure of risk and acts as a gateway to determine which pesticides require further evaluation in semi-field or field studies.

Figure 1. Laboratory testing of pesticide toxicity. Pesticides are applied in selected doses for different periods of exposure. The number of deaths at each dose and the duration of exposure are recorded for comparative analyses.

This approach is incorporated into European legislation as: 'no authorisation shall be granted if the hazard quotients for oral or contact exposure of honey bees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honey bee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use'.

If the HQ is <50, there are no indications of major sublethal effects and the active substance in the product is not an insect growth regulator, then there is no need for further consideration. However, if any of the three criteria are not met then:

- It is a condition of approval that the product is not used on the flowering crop.
- The risk must be assessed further, which will require higher tier data.

Insect growth regulators, which are designed to affect insect development are assessed separately using studies in which pesticides are fed directly to brood as they usually have low toxicity to adult insects. However, if effects are observed higher tier studies are required.

These higher tier data, which over-ride laboratory-generated data, are produced from studies run to guidelines. Higher tier studies replicate realistic exposure and encompass sublethal as well as acute effects.

Cage or tunnel studies

Cage or tunnel studies are outdoor studies with small hives of bees allowed to forage freely within a cage (approx 10m x 5m). These studies allow mortality and behaviour to be readily assessed and observations made of hive health in the short term when the bees are forced to forage on the treated crop (see Figure 2). If effects are observed field studies are required, which represent more realistic conditions.

Figure 2. Tunnel testing of pesticide toxicity. Bees housed in small hives forage freely within the tunnel and the effects of pesticide treatments can be measured within this closed system. Photo by Selwyn Wilkins.

Field studies

Field studies may be run based on results of laboratory studies or if cage studies show effects. Hives of bees are allowed to forage naturally on the treated crop and bee losses, behaviour, structure and development of the population are assessed (see Figure 3). These studies are designed to encompass specific individual factors, e.g. behaviour, based on the results of the lower tier studies. In addition residues of pesticides assessed in bees, food and plants can be assessed to aid in the risk assessment.

Figure 3. Field testing of pesticide toxicity on natural forage. Photo by Selwyn Wilkins.

All data are evaluated by the regulatory authorities at both European and national level. In the UK risk assessments are undertaken by the Chemicals Regulation Directorate (CRD) and independent expert advice is also available from Defra's Advisory Committee on Pesticides and its Environmental Panel.

Such refinements of the risk assessment processes, together with the post-registration monitoring in the UK — the honey bee poisoning incident scheme — have significantly reduced the risks posed to honey bees as shown by the reduction in numbers of pesticide incidents involving bees over the last two decades (illustrated in Figure 4).

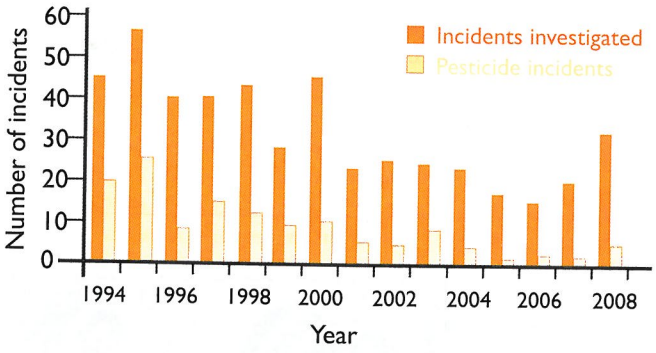

Figure 4. Number of honey bee poisoning incidents reported and number attributable to pesticides.

Systemic non-sprayed products

Recent work by the Bees and Pesticides Group has been in developing risk assessments for systemic non-sprayed products, such as seed dressings. This has included revision of the guidelines for tunnel and field studies to incorporate recommendations for studies using systemic pesticides. The proposals have been adopted by EPPO and they have also been submitted to European Food Safety Authority (EFSA) for consideration for use at European level. Full details are available on the EPPO website (www.eppo.org/PPPRODUCTS/honeybees/honeybees.htm).

Systemic pesticides are those applied as sprays, soil drenches, seed treatments or granules, which may result in residues in the growing plant. The application of such directed treatments has obvious environmental advantages over widespread spray applications. However, there is the potential for residues to be present in substrates that are attractive to honey bees, e.g. nectar or pollen. These types of pesticides have received increased publicity over the last ten years with linkage, but without robust scientific evidence, to pollinator declines. However, over this period there has been no EU/EPPO guidance available on how to assess risks to bees posed by substances with systemic properties (although national authorities have been undertaking risk assessments using their own approaches).

As for the sprayed pesticides the risk assessment scheme for systemic pesticides is based on a stepwise approach, starting with simple calculations based on existing data in dossiers and progressing to higher tier semi-field and field studies.

The first stage of the scheme is identification of potential exposure. Plant protection products (pesticides) applied as seed coatings and soil applications (bare soil) are intended to concentrate the product in or on plant parts to be protected, or where pests are most abundant. This approach potentially reduces exposure of most non-targets when compared to spray applications, but if the product has systemic properties then growing plants may contain residues and exposure to bees may arise if significant amounts of residues reach nectar and or pollen. Thus, if there is the potential for transfer to nectar or pollen and the plant is attractive to bees or, if the product is persistent and plants used in the rotation are attractive, then exposure is likely to occur. Obviously systemic uses where the crop is harvested before flowering are not of significant concern unless there are flowering weeds present.

Generating residue data for pollen and nectar, where levels are likely to be very low, is both very expensive and complicated. Therefore, at the first tier, the group decided to use the residues in the green parts of plants as the default value as translocation of pesticides to fruiting structures is less effective than to other plant parts. Information from residue studies and plant metabolism studies can be used to identify if the substance will be transferred to the plant during growth. A review of the data showed that the majority of the residues in plants were (in terms of active ingredient; ai) less than 1 mg ai kg-1 active substance, therefore this value could be used as the default. In all cases where data were available the residues in pollen and nectar were less than 0.1 mg ai/kg.

In terms of toxicity, oral toxicity data for adults are readily available but there are only limited data available on the relative sensitivity of adult honey bees and larvae (brood). Until more data are generated to allow prediction of the relative sensitivity of different life stages risk assessments for adults and brood will be considered separately for systemic pesticides.

Photo by Selwyn Wilkins.

The proposed risk assessment scheme follows the approach of comparing toxicity and exposure (based on daily intake of pollen and nectar) both for adults and brood separately with a trigger value set to identify compounds of concern. The trigger value of ten was set and evaluated with both systemic and non-systemic compounds with a wide range of toxicity. This showed that the trigger was failed by a subset, which included insecticides (e.g. neonicotinoids) and fungicides and no compound that was considered a potential risk passed. Where the trigger is failed by compounds increasing realism is introduced with semi-field and field studies, which address both mortality and sub-lethal effects on adults and brood.

Dusts — not a risk assessment issue

At the 2008 meeting the Bee Protection Group discussed concerns over dusts that had resulted in honey bee mortality in Germany and France. These mortalities had occurred following the drift of

Dr Pettis Puts the Case at Parliament

Dr Jeff Pettis of the US Department of Agriculture joined Dominic Dyer (Crop Protection Association), Chris Hartfield (NFU) and Tim Lovett (BBKA) at the meeting of the All Party Parliamentary Group on Science and Technology in Agriculture.

Dr Pettis had been invited from the USA to give more detail on his, as yet unpublished, work on possible interactions between pesticides and *Nosema ceranae*. This was the work cited in the somewhat alarmist article by Mike McCarthy in the *Independent* in March 2011 in which it was implied that publication was being suppressed. Dr Pettis was at pains to deny any whiff of conspiracy and went into some detail on his work, which shows that honey bees fed the neonicotinoid imidocloprid were 3–4 times mores susceptible to nosema infection when exposed to nosema spores than control bees. Yet again, he emphasised the the difficulty of translating laboratory results to the reality of the field but concluded that pests and diseases together with habitat loss and poor forage may interact with pesticide exposure when it occurs, to damage bee health. He also reported the interesting phenomenon that had been observed that bees seem able to identify contaminated pollen, entombing it with a thick wax capping in cells to prevent use in the colony.

Dominc Dyer (CPA) reminded the packed room that use of agro-chemicals in delivering the ever-growing levels of food production needed due to population growth was unavoidable. Plant protection agents are responsible for up to 40% enhanced productivity. He pointed to the cost, some £300M in bringing new chemicals through the regulatory process to market. Chris Hartfield (NFU) spoke on behalf on the Bee Farmers who are affiliated to the NFU. He was of the view that the regulatory process for approving new chemicals should be revisited but was anxious that the current alarm over neonicotinoids should not divert attention from the key issue of bee pests and diseases.

Big Ben and Portcullis House. Parliamentary copyright image, reproduced with the permission of Parliament.

Tim Lovett concluded the presentations by giving the BBKA's position, which is that 'risk' based as opposed to 'hazard' based research, seeking robust evidence before action is what is needed. He said that the BBKA did not support the precautionary principle; there being no new convincing evidence to date and being concerned that suspension of neonicotinoids would actually inhibit the review of these agents by taking the heat off the authorities. .Also the possible worsening of the situation, by forcing farmers to resort to older, 'dirtier' chemicals putting bees at greater risk than that with the newer systemic agents.

There was a lively Q&A session with, as expected, strong views emerging on both sides of the argument. We await Jeff Pettis' full paper when published with interest.

Tim Lovett

dust during drilling from poorly treated seed onto nearby flowering crops. The issues were less around risk assessment and more in ensuring the dusts generated from seed treatments are minimised. Both Germany and France have instigated requirements for reduction of dust in bags of treated seed and ensuring vents from drilling equipment are directed towards the soil to minimise drift; these two modifications are estimated to reduce dust generated during drilling by 99%. These have recently been taken up by European requirements together with a requirement for post-registration monitoring of exposure of honey bees to neonicotinoid pesticides following use as seed treatments to ensure that the risks associated with their use are acceptable.

Summary

In summary the pesticide risk assessment for honey bees is accordance with other practices in the EU in being a stepwise approach, which discriminates between substances requiring further assessment and those of low concern — thus making best use of available resources. The new systemic risk assessment for honey bees is based on evidence of exposure and uses existing data on toxicity and exposure to avoid a default requirement for field studies for all systemic pesticides. The EPPO guidance documents for semi-field and field studies have also been updated with special emphasis on seed or soil treatments. The ICPBR Bees and Pesticides Group will continue to use scientific evidence to review the risk assessments and study guidelines and to ensure that the risks posed to honey bees by pesticides are fully evaluated.

Dr Helen Thompson, Team leader — Environmental Risk Assessment Team, within Fera's Chemical Safety Programme