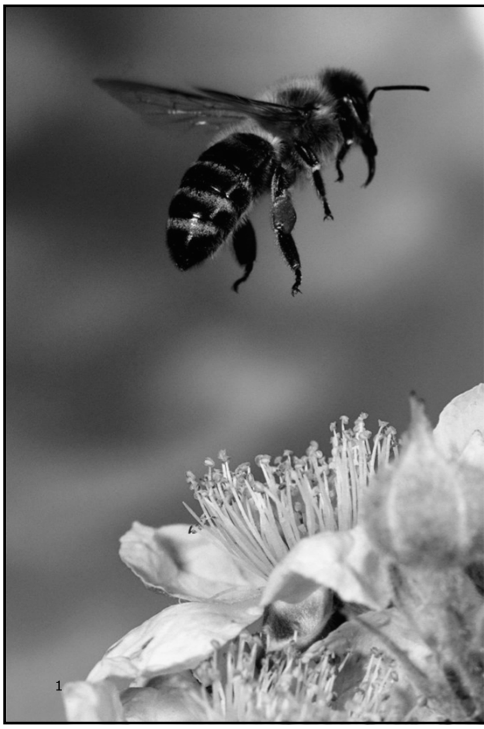


EFSA and bees

Robert Luttik

EFSA

The EFSA has a number of panels

One panel deals with plant protection products:

The Panel on Plant Protection Products and their Residues (PPR).

Three different types of questions:

1. Questions from the European Commission
2. Questions from the EFSA (related to the assessment of compounds),
3. Questions from the Panel (self tasking),

Bee question

Request for a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (Apis mellifera and Bombus spp.) and to prepare a guidance document on the risk assessment of plant protection products on bees

After consultation with DG SANCO it was proposed to define the term of reference as follows:

A scientific opinion of the PPR Panel on the science behind the development of a risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) and a guidance of EFSA on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees).

Issues to be assessed

- The assessment of the acute and chronic effects of plant protection products on bees, including the colony survival and development.
- The estimation of the long term effects due to exposure to low concentrations.
- The development of a methodology to take account of cumulative and synergistic effects.
- The evaluation of the existing validated test protocols and the possible need to develop new protocols, especially to take account of exposure of bees to pesticides through nectar and pollen.

Working group members

- Gérard Arnold, National Center of Scientific Research, France.
- Jos Boesten, Alterra , The Netherlands
- James Creswell, University of Exeter, Belgium
- Robert Luttik, National Institute of Public health and the Environment, NL
- Jens Pistorius, Julius Kühn Institute, Germany
- Fabio Sgolastra, University of Bologna, Italy
- Noa Simon Delso, Centre Apicole de Recherche et Information, Belgium
- Walter Steurbaut, Ghent University, Belgium
- Helen Thompson, Food and Environment Research Agency, UK

- Agnes Portais, EFSA, Emerging Risk Unit
- Jean-Lou, EFSA, Emerging Risk Unit
- Csaba Szentes, EFSA, Pesticide Unit
- Franz Streissl, EFSA, Secretaris of working group

Hearing expert:
- Ann Alix, Dow Chemical, UK

Protection goals

For the development of robust and efficient environmental risk assessment procedures it is crucial to know what to protect, where to protect it and over what time period.

"A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: *[….]*

– *(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:*

– *(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;*
– *(ii) its impact on non-target species, including on the ongoing behaviour of those species;*
– *(iii) its impact on biodiversity and the ecosystem"*

Protection goals

"an active substance, a plant safener or a synergist should be approved only if it is established that, the use of PPP that contain the active substance, safener or synergist under the intended conditions for use and after an appropriate risk assessment based on European or international adopted test guidelines.

will lead to a negligible exposure of the honey bees or

will not lead to unacceptable acute or chronic effects on the survival and development of the colonies, taking into account the effects on larvae and honey bee behaviour."

Protection goals

The working group identified pollination, biodiversity and hive products (for honey-bees only) as relevant ecosystem services.

Besides food/feed (i.e. honey, pollen, larvae in some countries, wax for food processing, propolis in food technology, royal jelly as a dietary supplement and ingredient in food), honeybees' products are also used as natural medicines (i.e. honey as an ingredient in medicine-like products, pollen, wax as a coating agent, propolis, royal jelly), cosmetic (i.e. pollen, wax, propolis, royal jelly), preservatives (i.e. for the tobacco industry), treating agents (i.e. for meat packing and coating coffee), textiles (i.e. beeswax is used to waterproof textiles and papers; emulsions containing beeswax for leather treatment).

Propolis is a resinous mixture that honey bees collect from tree buds, sap flows, or other botanical sources. It is used as a sealant for unwanted open spaces in the hive.

Royal jelly is a secretion from the glands in the heads of worker bees that is used in the nutrition of larvae.

Protection goals

Many agricultural crops depend on pollination.

About 70% of the main crops used directly for human consumption in the world are insect pollinated.

The economic value for the contribution of pollinators to the production of crops used directly for human consumption (excluding the value of non-food agricultural production, cattle raising and natural vegetation) was estimated as € 153 billion, which is about 9.5% of the total value of the production of human food worldwide.

Protection goals

There is a trade-off between plant protection and protecting the ecosystem services pollination, hive products and biodiversity.

From a farmers point of view plant protection may be more important than hive products.

While for beekeepers hive products are of greater importance.

Society may give a high value to protection of biodiversity (to ensure delivery of other ecosystem services such as aesthetic values, cultural services and genetic resources).

Protection goals

In-field, pollination service of crop plants,
- Ecological entity: Foragers of a colony / colony
- Attributes: Behaviour of foragers, survival, abundance
- Magnitude: Negligible effects up to small effects / negligible effects on colonies
- Temporal scale: 10 days for small

Off-field, pollination of non-crop plants
- Ecological entity: Foragers of a colony / colony
- Attributes: Behaviour of foragers, survival, abundance
- Magnitude: negligible effects
- Temporal scale: not relevant

In-field and off-field, Food provision service - hive products
- Ecological entity: colony
- Attributes: behaviour, survival/growth, abundance/biomass, reproduction
- Magnitude: negligible effects,
- Temporal scale: not relevant

Cumulative and synergistic effects

Normally environmental risk assessment is based on the formulation.

Not taken into account:

- Applications of compounds (+additives) in tank mixes
- Sequential use of compounds/formulations on the same field
- The use of compounds by neighbors

Cumulative and synergistic effects

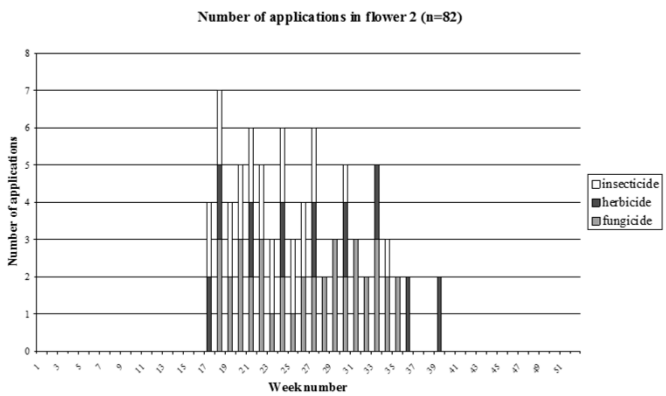
Tank mixes

After Fryday, Thompson and Garthwaite (2011)

Crop type	Compounds in mixture		Mean a.i. in mixture	Unique combinations	% of total treated area	Year
Arable	2-9		6.15	5992	66	2008
Vegetable	2-7		2.81	1519	53	2007
Orchards	2-8		3.09	1099	60	2008
Soft fruit	2-6		3.24	891	46	2006

Cumulative and synergistic effects

Sequential use of plant protection products



Cumulative and synergistic effects

There is evidence that concentration addition (CA) is a conservative method for assessing the toxicity of mixtures.

When comparing estimates using CA, it has been estimated that the majority of estimates do not deviate by more than a factor of 2 – 3 (mainly based on aquatic studies).

Applying such a default uncertainty factor to the threshold of toxicity for honey bees would be premature (research to underpin whether this is also applicable to bees is needed).

In most cases, synergism of pesticides in honey bees can be either predicted or assumed based on chemical class information (e.g. EBI fungicides and insecticides) and knowledge of the mode of action/molecular targets of the individual pesticides in the mixtures.

Complicating factors: diseases (e.g. Varroa) and malnutrition

Cumulative and synergistic effects

- Assessing the potential risk of tank mixes is possible.
- Assessing the potential risk of sequential use not jet possible

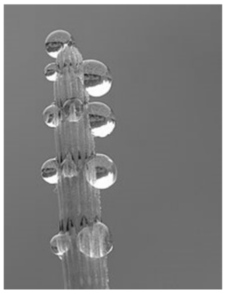
- Many unique possibilities
- Difficult implications for legislation

Exposure

Spray applications:
- Over spraying
- Contact (e.g. contaminated leaves, flowers)
- Oral (e.g. nectar, pollen, propolis or water)
- Inhalation
- Exposure to contaminated soil (e.g. bees nesting in the soil)
- Exposure to contaminated nesting material

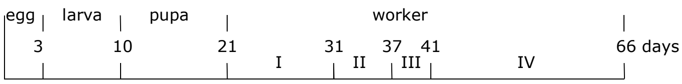
Granular applications and seed treatments:
- Exposure by dust (contact, oral, inhalation)

Systemic compounds
- Pollen
- Nectar
- Guttation droplets



Toxicity tests available for risk assessment

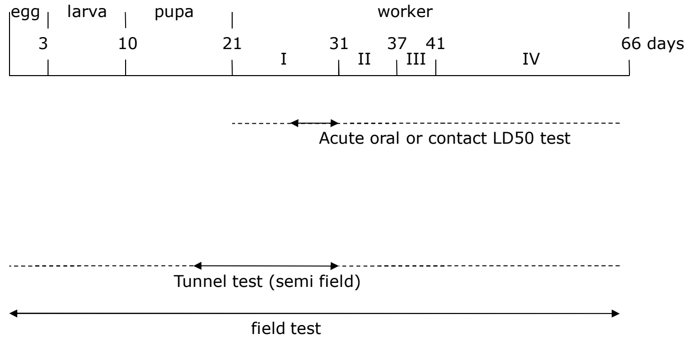
Life cycle



I = cleaning and feeding phase,
II = wax producing and cell construction phase,
III = guiding and ventilating phase, and
IV = forager phase

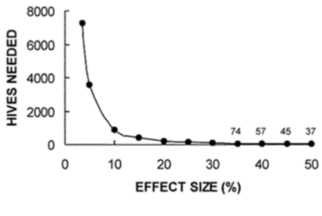
Toxicity tests available for risk assessment

What we have



Toxicity tests available for risk assessment

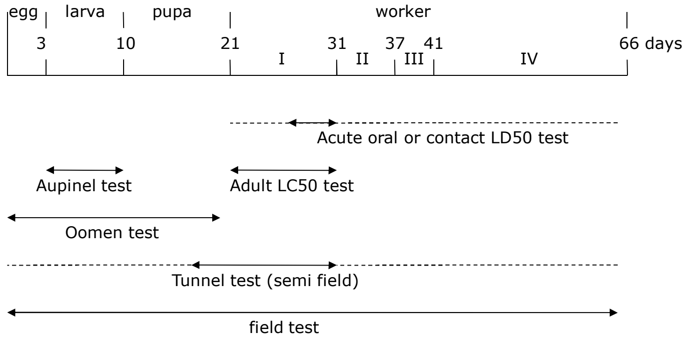
Field test problems



The number of honey bee hives needed to detect specified increases in mortality rate (percentage effect size) using dead bee traps.
A field-scale experiment using conventional bee traps would require 74 hives to detect an effect of 35% with a significance level of 0.05.

Toxicity tests available for risk assessment

What we are going to propose



Risk assessment scheme

Assess the toxicity of the product to worker honey bees by conducting contact and oral laboratory studies (LD50) and oral LC50 over 10 days (see Note 2).

Calculate the Hazard Quotient (HQ, see Note 3) between the application rate and the lower of the LD50 toxicity values (g ha-1 /LD50 in µg per bee).

Calculate the Exposure Toxicity Ratio (ETR_{adult}) between the amount of residues (see Note 4) that may be ingested by an adult bee in 1 day and the LC50 value.

Risk assessment scheme

Assess the toxicity (see Note 5) of the product to honeybee larvae with a chronic 7day larval test (e.g. Aupinel) and/or a bee brood feeding test if relevant (e.g. Oomen et al 1992).

Remark: If the LD50 for the adult bee is greater than 100 µg/bee and there is no evidence of cumulative toxicity in larvae in the chronic larval (Aupinel) then no further larval tests are required and the NOEL (chronic 7 day larva) is used below. In all other cases (including IGR) an Oomen et al (1992) type study is required to integrate brood care behaviour of the adult bees and the lower NOEL from the Aupinel and Oomen is used in the scheme.

Calculate the ETR_{larvae} between the amount of residues that may be ingested by a larva in 1 day and the no observed effect level (NOEL).

Asses whether there is evidence for cumulative toxicity according to Haber's Law in the toxicity tests with adult and larval honey bees (see note 6).

Thanks !