Risk Assessment Schemes

an overview

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Outline

- Routes of exposure
- Core data requirements
- Screening step
- First tier risk assessment
- Higher tier

- ***NB Focus will be on honey bees and the risk from spray applications***

Routes of exposure considered

- **Exposure via contact –** either from spray deposits (i.e. overspray or spray drift) or from dust particles when bees are either foraging the treated crop, weeds in the field, plants in field margin and the adjacent crop
- **Consumption of pollen –** from the treated crop, weeds in the field, plants in field margin, the adjacent crop or succeeding crop/permanent crop the following year
- **Consumption of nectar –** from the treated crop, weeds in the field, plants in field margin, the adjacent crop or succeeding crop/permanent crop the following year
- **Consumption of water** – guttation fluid, surface water and puddles
- **Risk from metabolites present in pollen and nectar**

Core dataset

- Acute oral toxicity to adults
- Acute contact toxicity to adults
- Chronic oral toxicity to adults
- Assessment of the effects on the hypopharyngeal glands
- Toxicity to larvae
- Consideration of potential accumulative effects

Risk Assessment Schemes

- Schemes for honey bees, bumble bees and solitary bees
- For each type of bee there are schemes for applications via spray and applications of solid formulations
- The latter is divided in to two, depending on how the application is made
- Each scheme is split in to screening and Tier 1

Risk assessment for applications applied as sprays for honey bees

Screening step

- Negligible exposure/risk is defined
- Need to calculate the following:
  - **HQcontact**
  - **ETRacute adult oral**
  - **ETRchronic adult oral**
  - **ETRlarvae**
  - **Assessment of accumulative toxicity**
  - **ETRhpg**

Risk assessment for applications applied as sprays for honey bees – Screening Step

- In addition need to:
  - Assess the risk from water consumption
  - Assess the risk from metabolites
- Separate standalone schemes – risk always needs to be considered

Risk assessment for applications applied as sprays for honey bees – Screening Step

HQcontact = AR/LD50 contact

Where:

AR = application rate in g a.s./ha

LD50 contact is expressed in µg a.s./bee

ETRacute adult oral = AR * SV/LD50oral

Where:

AR = application rate in kg/ha

SV = 7.55 for an application made via a downwards spraying or 10.6 for an application made via an upwards and/or sideward spray (µg a.s./bee)

LD50oral is expressed in µg a.s./bee

Risk assessment for applications applied as sprays for honey bees – Screening Step

Trigger values

- The resulting **HQ** or **ETR** is compared to a trigger value

- **HQcontact** has been revised – now **42** for downward sprays and **85** for an upward/sideways spray **NOT 50!**

- **All other trigger values are new**

Risk assessment for applications applied as sprays for honey bees

Tier 1

- If trigger values at the Screening Step are breached, then need to progress to Tier 1

- Trigger values stay the same, exposure is refined

Risk assessment for applications applied as sprays for honey bees – Tier 1

- If **HQcontact** trigger value is breached it ***may*** be possible to refine the exposure:

$$HQ = fdep * AR/LD50$$

Where:

AR = application rate in g a.s./ha

fdep = fraction of the dose deposited on foragers visiting plants in the field margin or an adjacent crop

LD50 contact is expressed in µg a.s./bee

Risk assessment for applications applied as sprays for honey bees – Tier 1

Refined risk assessment for exposure via pollen and nectar. It is necessary to consider the following:

- risk from foraging on the treated crop
- risk from foraging on weeds in the treated field
- risk from foraging in the field margin
- risk from foraging on an adjacent crop
- risk from foraging the following year on a permanent crop or on a succeeding crop for annual crops

Risk assessment for applications applied as sprays for honey bees – Tier 1

ETRacute adult oral = AR * Ef * SV/LD50 oral

Where:

AR = application rate in kg/ha

SV = shortcut value (µg a.s./bee) taken from Tables J4–J7 of Appendix J

Ef = exposure factor taken from Appendix X

Risk assessment for applications applied as sprays for honey bees – Tier 1

Need to also assess:

- **ETRchronic adult oral**
- **ETRlarvae**
- **Assessment of accumulative toxicity**
- **ETRhpg**

Higher tier assessment

NO STRUCTURED APPROACH FOR HIGHER TEIR ASSESSMENT

WHY?

Higher tier assessment

- Screening step and first tier can result in many different outcomes
- Risk mitigation measures may be sufficient to reduce the risk to an acceptable level and still maintain the usefulness of the product
- It may be sufficient to replace one of the default exposure values with a ‘real’ figure that is relevant to the active substance/product
- It may not be necessary to carry out a higher tier study for every use or crop combination as it may be possible to read across from existing studies

Higher tier assessment

Possible approaches:

- Risk mitigation – see Chapter 11
- Refinement of exposure – see Chapter 7
- Refinement of effects – see Chapter 8

Field studies

- If field studies are conducted then the following key issues need to be considered:
    - appropriate exposure
    - appropriate design/replication so that it can be determined that the specific protection goal is met

Field effects studies

Contact exposure:

- Residues in bees in the field should be determined
- Alive and foraging the treated crop
- Dead bees as well
- Two datasets should be kept separate, merged and then compared to what was measured in the field exposure study

Field effects studies

Oral exposure:

Determine residues in plants or bees foraging the treated crop but only sample those bees returning to the colony and not those leaving the colony.

Worst case landscape, i.e. no bee attractive crop within two kilometres of the treated crop and no flowering hedges or flowering trees within two kilometres of the colonies. No flowering weeds in the treated field and no flowering plants in field margins of the treated crop and adjacent crops.

Final step of risk assessment…

- It is essential to consider the uncertainty in the assessment
- Should be a key step of every assessment

Risk assessment for applications made as solid formulations for honey bees

- All new!
- Takes a similar approach to the spray scheme
- Split in to two schemes –
  - seed treatment or granules applied at drilling or incorporated into the soil
  - granules that are broadcast

Seed treatment or granules applied at drilling or incorporated into the soil

Screening Step

HQcontact = *fdep* * AR/LD50

Where:

AR = application rate in g a.s./ha

fdep = fraction of the dose deposited on the type of plants that foragers visit

LD50 contact is expressed in µg a.s./bee

- Note the different trigger value

Seed treatment or granules applied at drilling or incorporated into the soil

Screening Step – two steps

ETRacute adult oral = AR * Ef * SV/LD50 oral

Where:

AR = application rate in kg a.s./ha

SV = 7.55 µg a.s./bee

Ef = 0.3

Seed treatment or granules applied at drilling or incorporated into the soil

Screening Step – ETRacute adult oral (cont'd)

If the application is a seed treatment

ETRacute adult oral = AR * SV/LD50 oral

Where:

AR = application rate in mg a.s./seed

SV = 0.78 µg a.s./bee (see Table J3 in Appendix J.)

Seed treatment or granules applied at drilling or incorporated into the soil

- In addition to the adult acute oral, need also to assess:
  - **ETRchronic adult oral**
  - **ETRlarvae**
  - **Assessment of accumulative toxicity**
  - **ETRhpg**

Seed treatment or granules applied at drilling or incorporated into the soil – Tier 1

Pollen and nectar following drilling of treated seeds need to consider the following:

- the risk to bees from foraging the treated crop
- the risk to bees from foraging the succeeding crop
- the risk to bees from foraging in the field margin
- the risk to bees from foraging on an adjacent crop

Seed treatment or granules applied at drilling or incorporated into the soil – Tier 1

Application of granules at the time of drilling incorporated in to the soil (including in-furrow application):

- the risk to bees from foraging the treated crop
- the risk to bees from foraging weeds in the treated field
- the risk to bees from foraging in the field margin
- the risk to bees from foraging on an adjacent crop
- the risk to bees from foraging the succeeding crop

Seed treatment or granules applied at drilling or incorporated into the soil – Tier 1

ETRacute adult oral = AR * Ef * SV/LD50 oral

Where:

AR = application rate in kg/ha and/or mg/seed

SV = shortcut value taken from Tables J4, J6 and J7 of Appendix J (expressed in µg a.s./bee)

Ef = exposure factor taken from Appendix X

Summary

- New risk assessment schemes
- Covers range of routes of exposure and toxicological endpoints
- All routes and toxicological endpoints need to be considered
- Screening step and first tier use defaults
- No higher tier framework provided, possible refinements include:
  - Risk mitigation
  - Exposure estimates
  - Effects studies

Thank you for your attention

Any questions?