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An official website of the United States government.

The President has signed a continuing resolution, and EPA will be open on Monday January 28th.

We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

EPA United States
Environmental Protection
Agency

How We Assess Risks to Pollinators

Related Information

- EPA Released Neonicotinoid Risk Assessments
- Pollinator Risk Assessment Guidance
- Background FIFRA Peer Review of the Risk Assessment Process
- Background: Global SETAC Workshop

EPA has improved how it evaluates the risks to bees resulting from the use of pesticides. This Web page provides an overview of the process.

On this page:

- Overview of EPA's pesticide risk assessment process for bees
  - Initial assessment (Tier I)
  - More refined assessments (Tier II and III)
- Data for informing EPA's pesticide risk assessment process for bees
- More information

Overview of EPA's Pesticide Risk Assessment Process for Bees

Historically, EPA's pesticide risk assessment process for bees has been qualitative (i.e., not measured). The process relied primarily on developing an understanding of the types of effects that might be caused by the pesticide (hazard characterization), based on toxicity studies.

In 2011, EPA began expanding the risk assessment process for bees to quantify or measure exposures and relate them to effects at the individual and colony level. This involved identifying additional data that would be needed to inform that process. These data are summarized in the table below.

In November 2012, EPA, in collaboration with Health Canada's Pest Management Regulatory Agency and the California Department of Pesticide Regulation, presented a quantitative risk assessment process for bees and other insect pollinators to the FIFRA Scientific Advisory Panel.

EPA has begun to employ its new risk assessment framework for bees as part of its regulatory decision-making process for all pesticide chemistries. The new framework:

- Relies on a tiered process.
  ◦ The lowest tier (Tier I) is intended to serve as a screening tool. It employs conservative assumptions regarding exposure (i.e., assumptions that are likely to overestimate exposure) and uses the most sensitive toxicity estimates from laboratory studies of individual bees to calculate risk estimates.
  ◦ Higher tiers (Tiers II and III) rely on characterization of risk based on measured exposure values and colony-level effects studies and so are more realistic.
- Focuses on the major routes of exposure, including contact exposure (e.g., from overspray or direct contact with the pesticide on the plant surface) and dietary exposure (e.g., from consumption of contaminated pollen or nectar).
- Distinguishes different types of pesticide treatments, such as compounds applied to plant leaves or seed/soil-applied (systemic) compounds.

Initial Assessment (Tier I)

The new process begins as a screen, i.e., Tier I, which is designed to quickly determine which pesticides are expected to pose minimal risk, indicating pesticides for which further risk analysis is not needed. Tier I risk assessments are designed to be conservative, relying upon high-end estimates of exposure and laboratory-based toxicity data from studies conducted with individual bees.

If we identify a potential risk of concern at the Tier I level, EPA and/or the pesticide registrant can propose information with which to refine exposure estimates. Additional information that can be used to refine a Tier I risk estimate includes information on the intended use of the product or possible mitigation options. With this additional information and/or data, risk estimates may be revised.

More Refined Assessments (Tier II and Tier III)

For compounds where potential risks of concern persist, higher tier assessments may be conducted:

- Tier II (semi-field studies) and
- Tier III (full-field studies).

When graduating to a higher tier analysis, EPA may require studies designed to more closely reflect real world exposures and effects on the whole colony. Tier II data may include:

- Feeding studies, which examine effects on colonies following exposures to known concentrations of a pesticide in a food source fed to a bee colony.
- Semi-field studies, which examine effects on colonies contained within enclosures.
- Residue studies intended to quantify pesticide concentrations in pollen and nectar of crops treated according to the labels.

Tier II studies can be used to characterize risk at the colony level. Because the information at this level, i.e., both exposure and effects information, is more specific to the actual use of the pesticide under review, it can also be used to identify risk mitigation options. EPA can then begin to determine whether sufficient information is available to support the regulatory decision process or whether additional information is needed to understand the potential risk.

If refined exposure and/or effect data or risk mitigation options at the Tier II level do not indicate acceptable risk or substantial uncertainties remain, then EPA may require a Tier III evaluation to resolve uncertainties. A Tier III assessment may include a full-field (free-foraging bees) study. A Tier III assessment is intended to:

- address specific questions regarding the potential effects of the pesticide compound at the colony level where the compound is applied in accordance with label conditions;
- take into account the broad dynamics of a whole colony in a free-foraging scenario; and,
- consider long-term effects on the colony, such as over-wintering success.

Information from Tier III is intended to be used with the information gathered through Tier I and Tier II, as well as other lines of evidence available to the Agency (e.g., bee kill incident information or open literature studies that meet EPA guidelines). With the information from all the studies in hand, EPA can determine whether mitigation options exist protect bees from pesticide exposure.

Data for Informing EPA's Pesticide Risk Assessment Process for Bees

Test Title	Tier	Test Objective
Honey bee adult acute contact toxicity	I	Laboratory test that identifies the dose that is lethal to half of the test population (LD_{50}) by dermal contact.
Honey bee adult acute oral toxicity	I	Laboratory test that identifies the oral dose that is lethal to half of the test population (LD_{50}) by oral ingestion.
Honey bee larvae acute oral toxicity	I	Laboratory test that identifies the dose that is lethal to half of the larval test population (LD_{50}).
Honey bee adult chronic oral toxicity	I	Laboratory test that identifies effects following repeat exposures (*e.g.*, 10-day) to the test compound.

Test Title	Tier	Test Objective
Honey bee larvae chronic oral toxicity	I	Laboratory test that identifies effects on larvae following repeat exposure to the test compound.
Honey bee toxicity of residues on foliage	I	Provides information on the amount of time during which contact exposure to weathered residues of the test compound remains toxic to >25% of the adult bees.
Semi-field testing for pollinators	II	Field-level test, where exposure to bee colonies is conducted within enclosures; study provides information on exposure as well as effects on a whole colony.
Field feeding study	II	Field-level test where bee colonies are located in an open field setting, but exposure is delivered at predetermined concentrations in either sucrose solution or a pollen supplement. Field feeding studies can provide information on long-term effects.
Measure of residues in pollen and nectar	II	Provides exposure information (from the pollen and nectar) following application of the product at label rates.
Field testing for pollinators	III	Field-level test that typically looks at long-term effects under environmentally realistic exposure conditions.

More Information

- Pollinator Risk Assessment Guidance
- EPA's White Paper on Risk Assessment Process
- Scientific Peer Review of Proposed Risk Assessment Process

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