



# Current Thinking for Implementing New Bee Exposure and Effects Testing and Schedule for Neonicotinoid Risk Assessments

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Office of Pesticide Programs

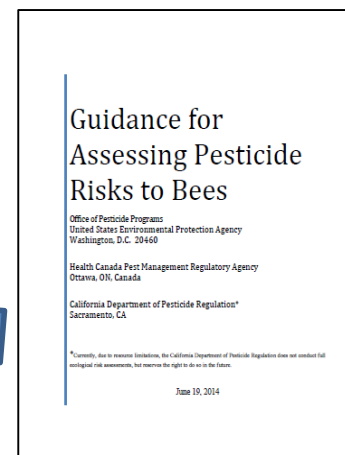
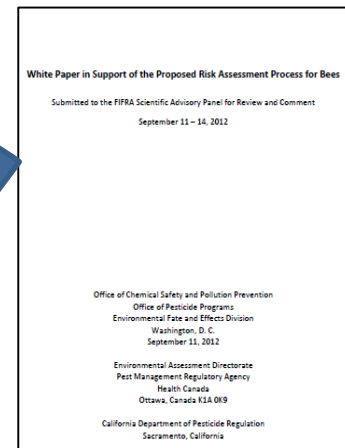
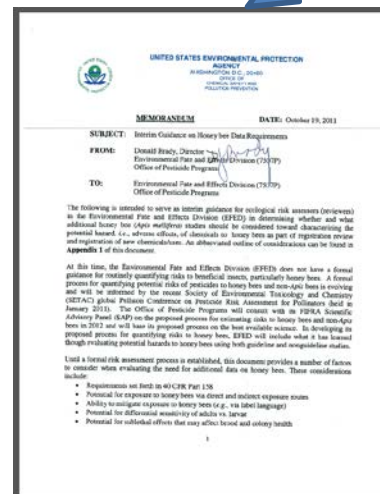
May 18, 2016





# Guidance Documents

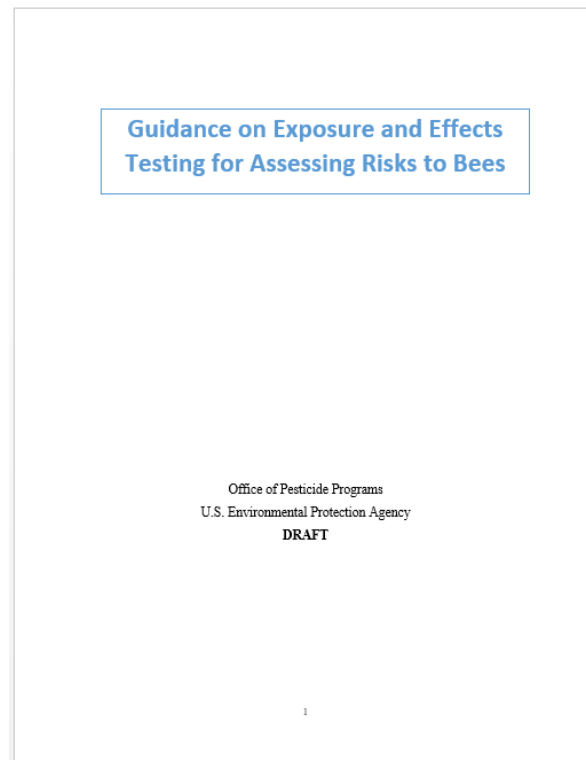
- **2011 Interim Guidance on Honey Bee Data Needs**
- **2012: Pollinator Risk Assessment Framework White Paper**
- **2014: Final EPA Guidance on Risk Assessments for Pollinating Bees**





# Guidance Documents

- **2016 Guidance on Exposure and Effects Testing for Assessing Risks to Bees (drafted)**
  - Statutory/Regulatory Provisions
  - Conventional Pesticides: Current Data Requirements
  - Conventional Pesticides: Additional Bee Testing Guidance
    - Tier 1 (Screening-level) Toxicity Studies
    - Tier 2 Toxicity Testing
    - Tier 3 Toxicity Testing





# Pollinator Exposure and Effect Data

- Currently requiring new bee data as “special studies,” depending on use.
- Applicable to all pesticides where significant exposure is expected (not just insecticides).
- Revising Part 158 data requirements; rule making effort currently underway (<http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201510&RIN=2070-AK10>).
- Proposed SubPart H (pollinator data requirements)
- Tentative completion date January 2017
- EPA continuing to work with regulatory counterparts and researchers to develop suitable tests with non-*Apis* bees.

Guideline Number	Data Requirement	Terrestrial Use Patterns	Aquatic Use Patterns	Forestry Use Patterns	Residential Outdoor Use Patterns	Greenhouse Use Patterns	Test Substance
<b>Tier I</b>							
<b>Acute Testing</b>							
850.3020	Honey bee adult acute contact toxicity	R	CR	R	R	CR	TGAI, TEP
None	Honey bee adult acute oral toxicity	R	CR	R	R	CR	TGAI, TEP
None	Honey bee larvae acute oral toxicity	R	CR	R	R	CR	TGAI, TEP
<b>Chronic Testing</b>							
None	Honey bee adult chronic oral toxicity	R	CR	R	R	CR	TGAI, TEP
None	Honey bee larvae chronic oral toxicity	R	CR	R	R	CR	TGAI, TEP
<b>Tier II</b>							
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	CR	TEP
None	Residues in pollen and nectar	CR	CR	CR	CR	CR	TEP
None	Semi-field testing for pollinators	CR	CR	CR	CR	CR	TGAI or TEP
<b>Tier III</b>							
850.3040	Field testing for pollinators	CR	CR	CR	CR	NR	TEP

\* R = “required”; CR = conditionally “required.” New bee data shown in **red**



# Registration

- Codification of new data requirements in 40 CFR Part 158 is underway
- Registrants Beginning Already to Develop/Submit Tier 1 Data Based on the 2014 Risk Evaluation Methods
- Data for New Chemicals (and First Outdoor Uses) to be Requested in Pre-Submission Meetings
- Risk Management Determinations Informed By:
  - Risk Calculations for Pollinators
  - Proposed Use Pattern(s)
  - Potential Benefits of Use
  - Alternatives Analysis
  - Feasibility/Utility of Potential Mitigations
- Conditional Registration considered on a case-by-case basis



# Conventional Pesticides in Registration Review

- There are 459 conventional pesticide cases subject to Registration Review
  - Registration Review DCI issued **before** January 1, 2015
    - ~250 cases subject to subsequent DCI that will require the suite of pollinator studies
  - Registration Review DCI issued **after** January 1, 2015
    - ~130 cases have or will require the suite of pollinator studies as part of the initial registration review DCI
  - 70 cases have either been cancelled since the beginning of registration review or registered use patterns do not result in exposure to bees



# Follow-Up DCI to Require Suite of Pollinator Studies

- ~250 Registration Review conventional cases
- New active ingredients registered between 2008 and today also should be subject to new data requirements
  - 43 cases
- Concerns about registrant/CRO lab capacity to handle testing requirements for 298 pesticide cases
  - Priority scheme developed that will be used to identify the top cases for priority testing
    - ⌚ The toxicity of the pesticide to bees and/or related taxa;
    - ⌚ The mode of action of the pesticide (*i.e.*, some pesticides are not acutely toxic to adult bees but may be chronically toxic to larval bees based on their mode of action);
    - ⌚ Information regarding bee kill incidents for the pesticide;
    - ⌚ Information indicating the pesticide has been detected in honey bee colonies (*e.g.*, Mullin *et al.* 2010, Stoner and Eitzer 2012 and USDA 2012);
    - ⌚ Pesticide use patterns with a high potential for contact exposure of bees (*e.g.*, applications at bloom of bee-attractive crops identified through the USDA list);
    - ⌚ Pesticide use patterns that lead to a high potential for oral exposure of bees (*e.g.*, applications at or prior to bloom for systemic pesticides); and
    - ⌚ Pesticide uses on crops that require commercial pollination with managed bees



# Schedule for Imidacloprid

## **January 2016 - Preliminary Pollinator Assessment**

- Agricultural uses only
- Public comment period January 15 – April 15, 2016
- 2000+ comments received

## **December 2016 – Draft Ecological and Human Health Risk Assessments**

- Ecological assessment will include update to pollinator assessment with non-ag uses assessed and new data/information, in addition to assessments for other taxa (plants, mammals, birds, aquatic organisms)
- 60-Day comment period

## **December 2017 – Update to Pollinator Assessment**

- Incorporation of registrant full field (Tier III) studies for cotton and pumpkin
  - Potential to bridge with residue data of other neonicotinoids (*i.e.* clothianidin, thiamethoxam, and dinotefuran)
  - Incorporation of any additional relevant registrant submitted/open literature studies





# Schedule for Clothianidin, Thiamethoxam, and Dinotefuran

## **December 2016 – Preliminary Pollinator Assessment**

- Pollinator only (honey bee focus)
- Agricultural and non-agricultural uses
- 60-Day public comment period

## **December 2017 – Draft Ecological and Human Health Risk Assessments**

- Ecological assessment will include update to pollinator assessment with new pollen/nectar residue data and other relevant registrant submitted/open literature studies, in addition to assessments for other taxa (plants, mammals, birds, aquatic organisms)
- 60-Day comment period

- Questions?

