Neonicotinoid Registration Review and Pollinator Risk Assessment

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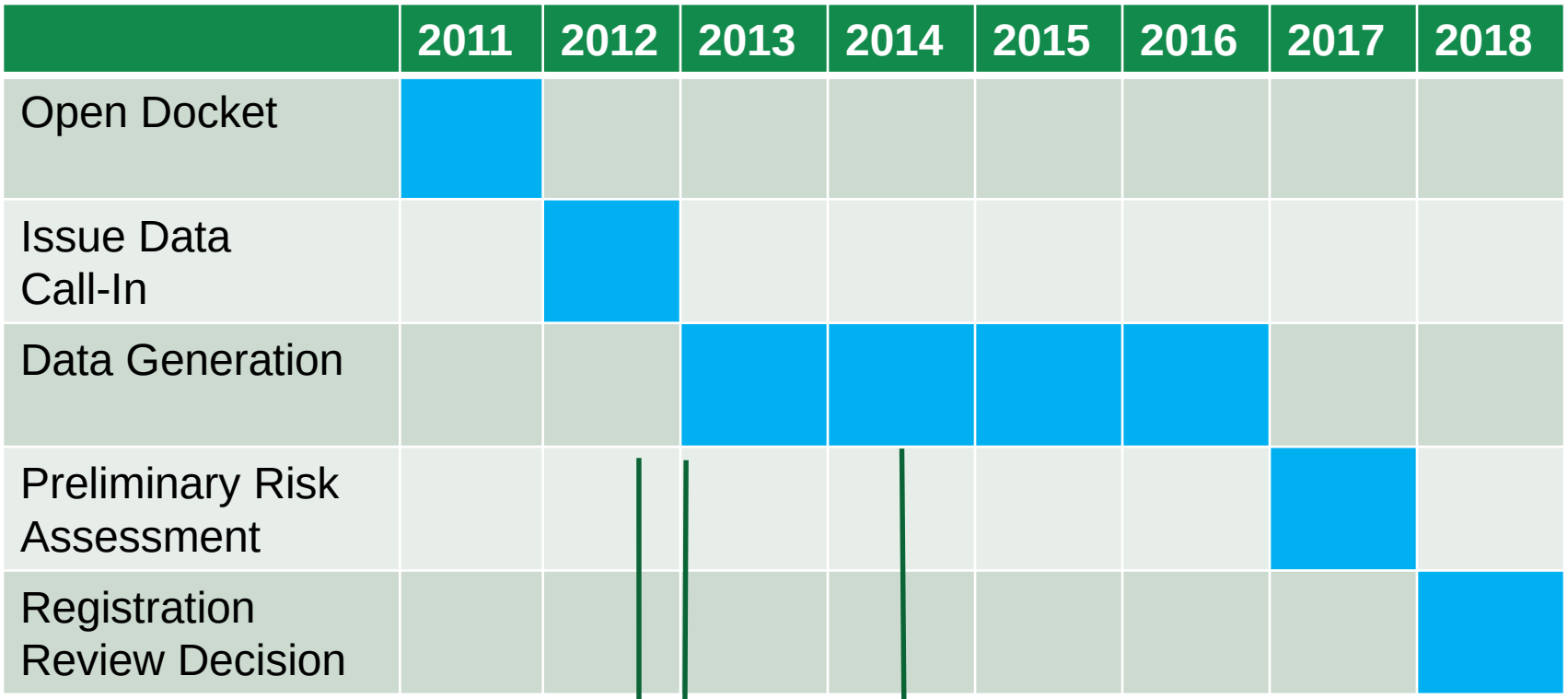
Topics

- Registration Review Process and Timelines
- Development and Implementation of Pollinator Risk Assessment Scheme
- Challenges for the Assessment of Risk to Pollinators following Use of Neonicotinoids to Control Pests in Ornamental Plants and Suburban Landscape

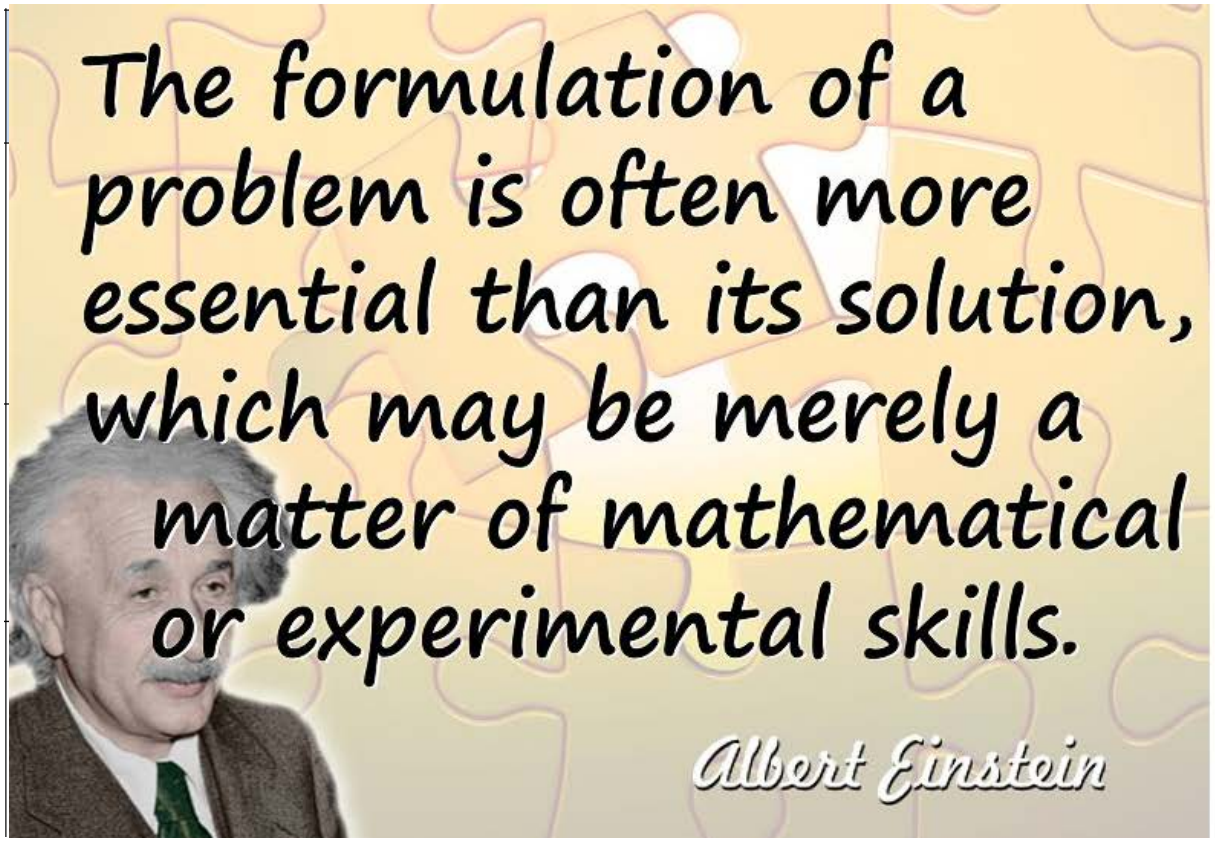
EPA's Registration Review Process

- 15 year cycle to ensure each registered pesticide meets the current FIFRA standard for registration
  - Human Health
  - Environment
- Scope and depth of review tailored to circumstances
- Imidacloprid registration review started in FY2008 (first registered in 1994)
- EPA accelerated the registration review timeline for other neonicotinoids to begin in FY2012

Neonicotinoid Registration Review and Pollinators – Clothianidin Example



PROBLEM FORMULATION



RISK HYPOTHESIS

- Stressor-initiated
  - *Based on the physico-chemical properties of neonicotinoid insecticides, the compounds can be translocated from soil to pollen and nectar systemic resulting in adverse impact on honeybee colonies*

Specific
Measurable

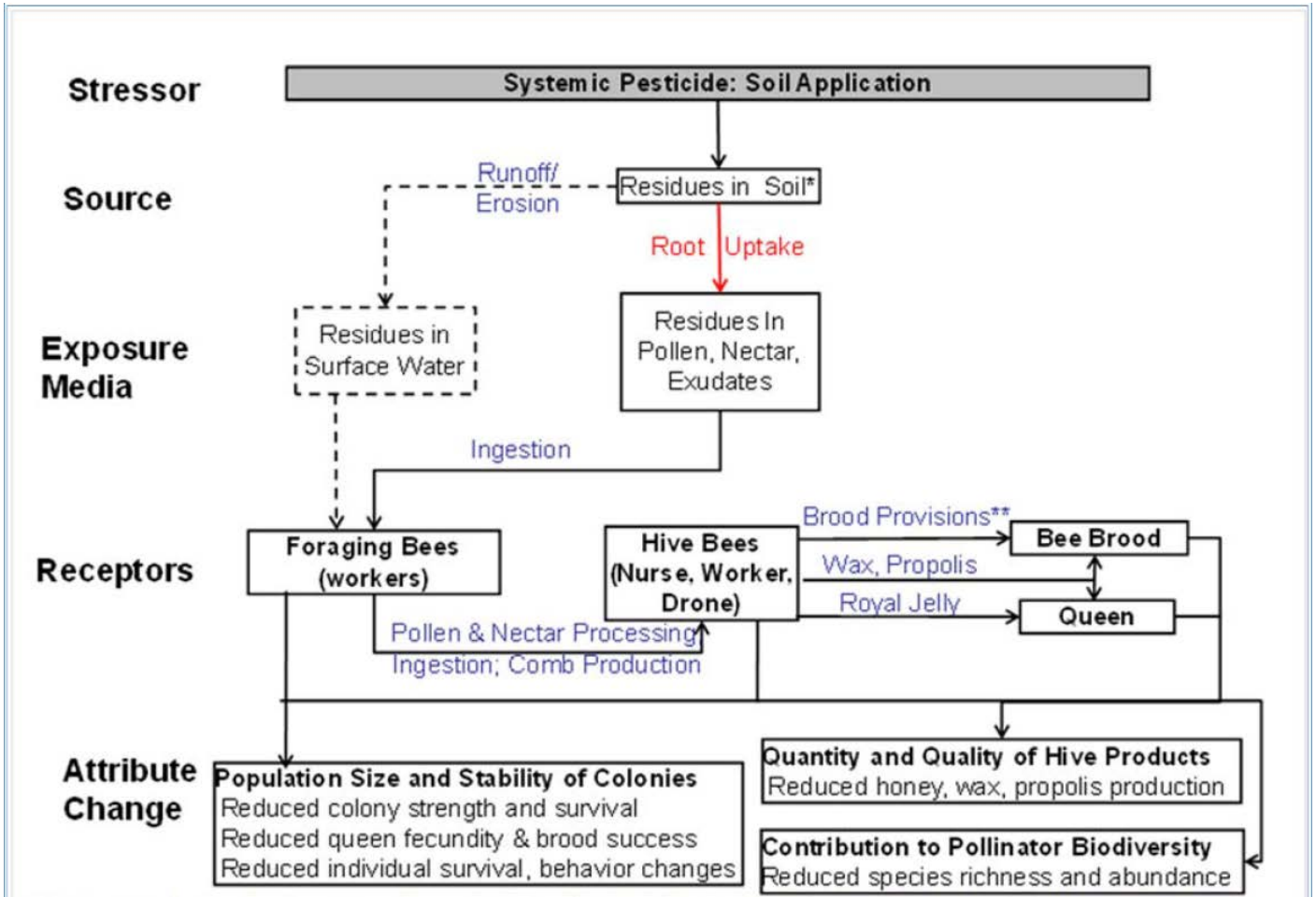
- Effect-initiated
  - *Honeybee colonies are adversely impacted when foraging adults are exposed to dust generated during the planting of corn seed treated with neonicotinoid insecticides*

Specific
Measurable

- Value initiated
  - *Declines in colony health are related to the widespread use of neonicotinoid insecticides*

Vague
Not easily measured

CONCEPTUAL MODEL



RISK QUOTIENTS AND LEVELS OF CONERN

Risk Quotient = $\frac{\text{Point Estimates of Exposure}}{\text{Point Estimates of Effect}}$

Level of Concern to which the Risk Quotient is compared is:

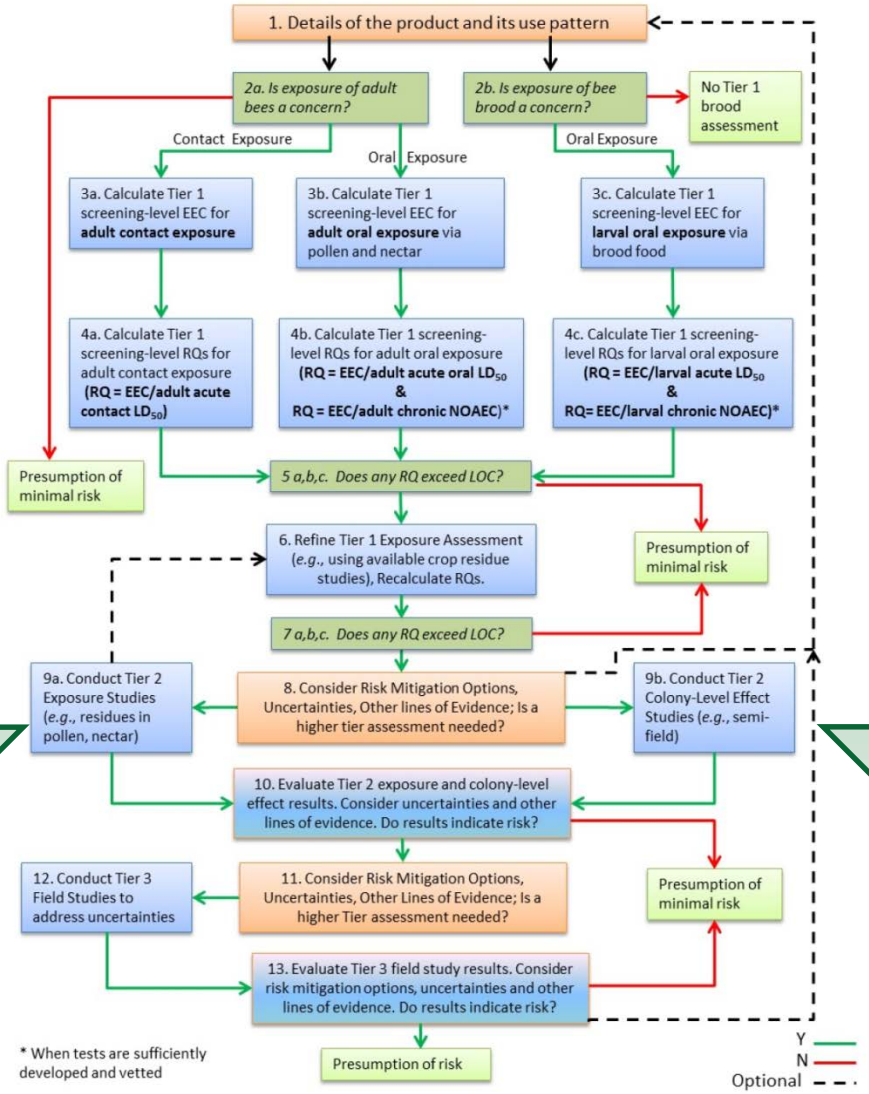
- 0.4 for acute risk (based on historic dose response relationships for bees & 10% mortality level)
- 1.0 for chronic risk

Pollinator Risk Assessment – Tiered Process

EXPOSURE
Tier 1
Conservative estimates (models)

Tier 2
Pollen & nectar residues

Tier 3
Field Studies



EFFECTS
Tier 1
Acute & Chronic Studies

Tier 2
Semi Field Scale Studies

Tier 3
Field Studies

Pollinator Risk Assessment - Analysis Phase

Exposure – Tier 1

- Foliar Applications
  - Assessment based on empirical measurements
  - Contact Exposure (µg/bee) = 2.7 x App. Rate (lb ai/A)

Koch & Weisser (1997)

Clothianidin: 0.27 µg/bee

  - Oral Exposure (µg/bee) = 110 x 0.292 x App. Rate (lb ai/A)

[µg/g]
Residue in tall grass – based on Hoerger & Kenaga(1972)

[g]
Daily consumption of nectar by foraging bees – EPA (2012)

Clothianidin: 3.2 µg/bee

Pollinator Risk Assessment - Analysis Phase

Exposure – Tier 1

- Soil Applications
  - Assessment based on empirical model (after Briggs *et al*., 1982)
  - Oral Exposure (µg/bee):

Equation 1. $C_{stem} = \left[10^{(0.95*LogKow-2.05)} + 0.82\right] * TSCF * \left[\frac{\rho}{\theta+\rho*Koc*foc}\right] * C_{soil}$

Where: C_{stem} = concentration in stems (μg a.i./g plant)
C_{soil} = concentration in soil (μg a.i./g soil)
f_{oc} = fraction of organic carbon in soil
θ = soil-water content by volume (cm^3/cm^3)
ρ = soil bulk density (g-dw/cm^3)
K_{oc} = soil organic carbon-water partitioning coefficient (cm^3/g-oc or L/kg-oc)
TSCF =Transpiration Stream Concentration Factor

Equation 2. $TSCF = -0.0648 * (Log\ Kow)^2 + 0.241 * LogKow + 0.5822$

Pollinator Risk Assessment - Analysis Phase

Exposure – Tier 1

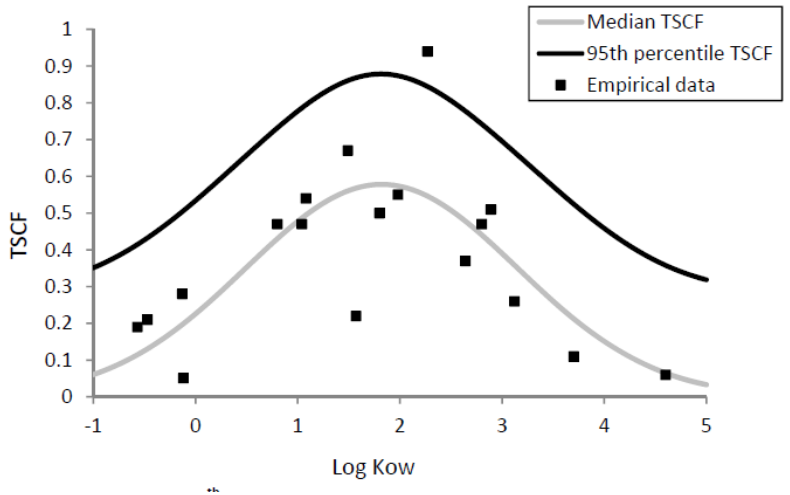
- Soil Applications
  - Assessment based on empirical model (after Briggs *et al*., 1982)
  - Oral Exposure (µg/bee):

Clothianidin: 0.0083 µg/bee

Low Koc
Low OC
High Rate

Concentration in Soil Water

High Koc
High OC
Low rate



Transpiration Stream Concentration Factor

Pollinator Risk Assessment - Analysis Phase

Exposure – Tier 1

- Tree Trunk Applications
  - Simple Math
  - Oral Exposure (µg/bee) = $\frac{\text{Amount applied (µg)}}{\text{Mass of foilage (g)}}$ x 0.292

Pollinator Risk Assessment - Analysis Phase

Effects Characterization – Tier 1

- Acute Contact Exposure (Adults) – (LD50) - µg/bee
- Acute Oral Exposure (Adults) – (LD50) - µg/bee
- Toxicity of Residues on Foliage (RT25) – days
- 10 Day Adult Feeding Study (LC50 & NOAEC) - µg/g
- Repeat Dose Larval Toxicity (NOAEC) - µg/g

Photographs from www.eurofins.com

Pollinator Risk Assessment - Analysis Phase

Risk Characterization – Tier 1

Endpoint	Effect	Application Method	Exposure	RQ	LOC	What next?
Oral Toxicity to adult foragers	LD50: 0.0037 µg/bee	Foliar (0.1 lb ai/A)	3.2 µg/bee	865	0.4	Label mitigation
		Soil (0.2 lb ai/A)	0.0083 µg/bee	2.4	0.4	Tier 2 measurements of pollen/nectar residues. Tier 2 Semi field effect studies
Dietary toxicity to larvae	NOAEC: 0.68 µg/g diet	Soil (0.2 lb ai/A)	0.028 µg/g	0.04	1	No direct impact on brood development expected.

Pollinator Risk Assessment - Analysis Phase

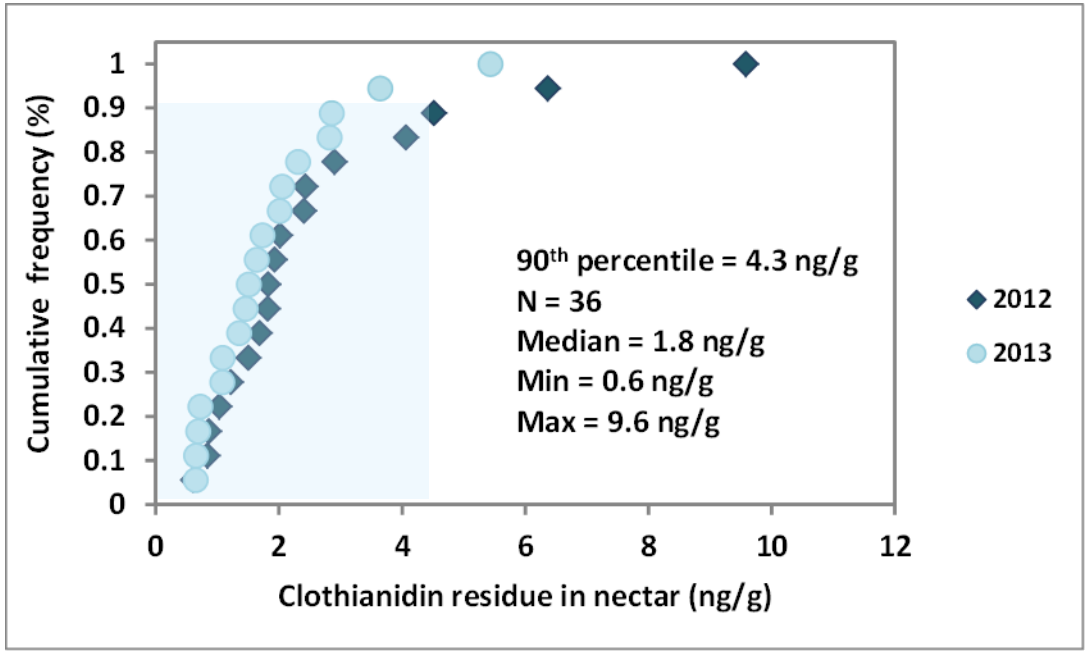
Exposure – Tier 2

- Field studies to characterize residues in nectar and pollen following application under actual use conditions
- Key variables:
  - Soil type
  - Climate/ weather
  - Irrigation practices
  - Application type
  - Timing between application and bloom

Pollinator Risk Assessment - Analysis Phase

Exposure – Tier 2

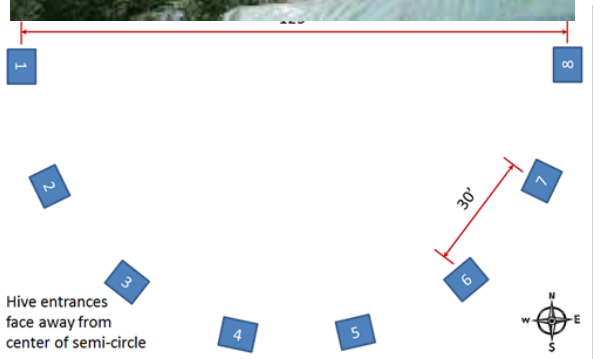
- Field studies to characterize residues in nectar and pollen following application under actual use conditions



Pollinator Risk Assessment - Analysis Phase

Colony Effects – Tier 2

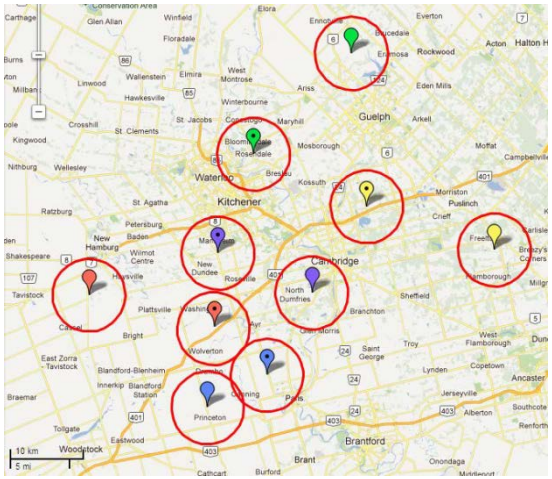
- Tunnel tests
  - Assess acute hazard
  - Surrogate crop which provides large amounts of bee forage
  - Target crop can be used if attractive to bees – e.g. canola seed treatment
  - Limited extrapolation possible
- Colony Feeding Studies
  - Exposure via sucrose solution placed inside hives
  - Honey bees are free foraging - not stressed by being constrained
  - Chronic NOAEC can be compared to a wide range of exposure scenarios with different crops and use patterns



Pollinator Risk Assessment – Analysis Phase

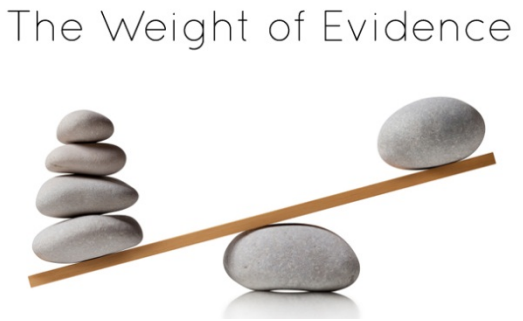
Full Field Studies – Tier 3

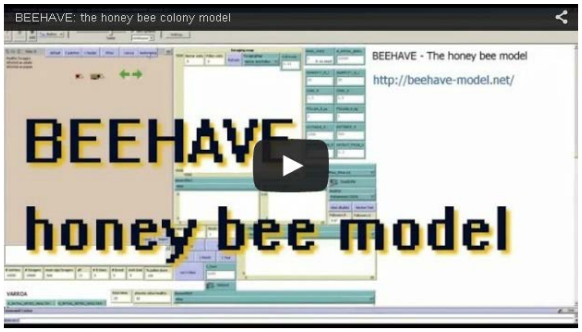
- Reserved to resolve risk associated with a particular use pattern to address specific uncertainties remaining from lower tier risk assessments
- Resource intensive
- Need to minimize impact of other stressors or variables over a large geographical area
- Are monitoring studies with a focus of hive health and levels of exposure or product use a viable alternative?

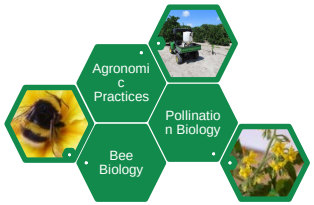


Risk Characterization

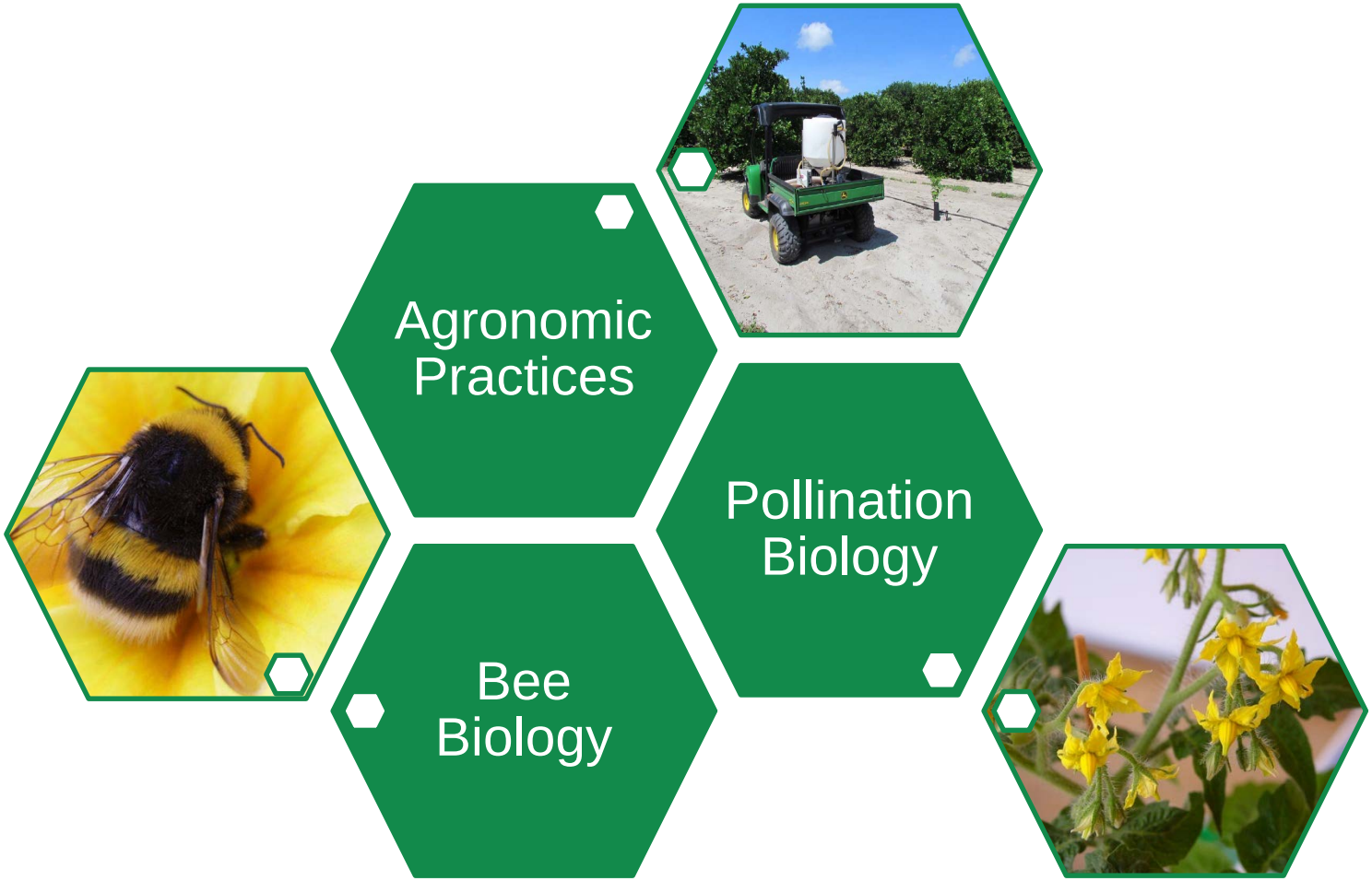
- Risk Quotients
- Lines of evidence
  - Regulatory studies
  - Incident data
  - Peer reviewed literature
- Weight of evidence
  - Robustness
  - Consistent
  - Plausible
- Use of simulation models
- Describing uncertainties
- Filling data gaps







Addressing Uncertainties



Challenges of Applying Pollinator Risk Assessment Process to Ornamental and Landscape Use Patterns

- Environmental risk assessment becomes more complex the greater the heterogeneity of the landscape under consideration.

- Tools, supporting data, processes are already developed to assess risk of plant protection products in agriculture.

- Diversity of use areas, application techniques, behavior of receptors in use areas all add to the complexity of the challenge.

But Remember… FIFRA is a risk/benefit statute