Neonicotinoid Proposed Interim Decisions

This effort reflects collaboration between RD, BEAD, EFED, HED and PRD, and chemical teams for all 4 neonics from each division. The interdivisional team met regularly to discuss assessment progress, methods and make sure that the assessments addressed PRD's needs.
The assessments conducted by EFED and BEAD were highly refined.

Outline

- Overview
- Risk Management Approach
- Bee Risks and Benefits
- Bee Risk Mitigation
- Other Ecological Risk Mitigation
- Human Health Mitigation
- Other Considerations
- Next Steps

Overview

Nitroguanidine-substituted neonicotinoids (includes: imidacloprid, clothianidin, thiamethoxam, and dinotefuran) are:

- A class of systemic insecticides registered for foliar (ground and air), soil, seed, and tree injection applications to a wide variety of agricultural crops
- Non-agricultural uses include turf, ornamentals, flea treatment for pets, wood preservative, poultry house, and other residential and commercial indoor/outdoor uses
- Most poundage applied as seed treatment for corn and soybean

Chemical	Est. annual usage (lbs/yr)	Major uses (lbs/year)
Clothianidin	1,500,000	**Corn** (seed treatment; 1,400,000)
Imidacloprid	1,120,000	**Soybean** (seed treatment, 430,000) **Cotton, Potato, Wheat** (all app. methods, 100,000 ea.)
Thiamethoxam	919,000	**Corn** (seed treatment; 300,000) **Cotton** (foliar, soil, seed; 160,000) **Soybean** (seed treatment; 300,000)
Dinotefuran	22,500	**Cantaloupes** (5,000) **Rice** (foliar; 4,000)

Overview

USEPA Regulatory history

- Registration review began in 2008 with imidacloprid, then others in 2011
- Public concern over pollinator issues related to incidents and honey bee losses (2008)
- Label revisions implemented – "Bee Box", pollinator restrictions for Ag and non-Ag products required by letter (2013)
- Hold placed on new uses to outdoor pollinator attractive crops (2015)
- 12 thiamethoxam/clothianidin voluntary product cancellations as a result of an ESA lawsuit (March 2019)

States

- States have passed legislation that address neonic issues
  - MD, VT, and CT; restricted homeowner use
  - OR banned use on certain trees
  - NJ required beekeeper notification
  - CDPR requires risk management plan by 2020
- Many states have implemented state-wide pollinator protection plans (MP3s); AAPCO maintains inventory

International

- EU – banned on all outdoor use (2018)
- Canada – seed licensing requirements (2015); proposed cancellation of all outdoor uses for aquatic risk (2018); prohibited foliar and soil application for certain uses (e.g., pome fruit, stone fruit, tree nuts, cucurbits) for pollinator risk (2019)

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Let's make sure our verbal intro to this slide hits hard on incidents and neonics in the media

Canada's seed licensing requirements: https://www.ontario.ca/page/neonicotinoid-regulations-seed-vendors

Overall Risk Management Approach

Risk Management Priorities

- Human Health Risks of Concern (residential and occupational)
- Ecological Risks of Concern
  - Pollinators (bees) – from multiple use sites
  - Birds and Mammals – from consuming treated seed
  - Aquatic Invertebrates – mainly from foliar application to multiple uses

Early Stakeholder Engagement

- Goals
  - To inform risk assessments and understanding of exposure to bees
  - To better understand benefits of uses preliminarily identified with risks of concern
- Stakeholders: Federal and state partners (USDA, OPMP; SFIREG, AAPCO, and NASDA; IR-4; Growers; Registrants; Other Stakeholders (American Hort, NALP, NPMA)

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In talking about risk management priorities, start out by letting the group know that these are the areas where the risk assessments indicated mitigation was needed, but that per our regs, we considered benefits extensively in our risk benefit calculus where appropriate, and this information is woven throughout our forthcoming discussion on mitigation

Discussed with registrants potential mitigation options

Bee Risk Management Approach

Declines in general honey bee colonies are due to multiple factors, however through our risk assessment we have identified certain neonicotinoid uses where risk estimates indicate adverse effects to hives are expected.

Goal: To preserve the plant protection benefits of neonicotinoids, while implementing targeted risk reductions, particularly to honey bees which provide a benefit to agriculture through pollination services.

- This can be achieved through: targeting specific uses with potentially lower benefits and higher risks, preserving current restrictions, Deliberative Process / Ex. 5 reduce off-site drift and runoff, promote positive stewardship efforts through education and outreach

Pollinator Protection Focus

- Focus on honey bees due to special economic benefits
  - 2017 USDA NASS Honey report estimates value of commercial pollination services at $435 million (increasing)
  - 2017 USDA Honey Report estimates value of honey production at $318 million (declining)
- Non-honey bees provide a significant contribution to pollination services
  - Some used for commercial pollination (bumble bees, leafcutter bees, blue orchard bees)
- Other pollinators expected to benefit from mitigation (i.e., rate reductions, spray drift reduction)

We propose addressing risk by:
Targeting certain uses with potentially lower benefits and higher risks during the critical pre-bloom exposure period
Preserving the current voluntary restrictions for application at-bloom to reduce the (acute risk) immediate impacts of exposure

Deliberative Process / Ex. 5

Reducing exposure off-site by reducing drift and runoff
Promoting voluntary stewardship efforts to encourage best practices, education, and outreach to applicators and beekeepers

Ecological Risk - Bees

Lines of evidence considered in making risk call

- Based on crops that are attractive to bees
- Based on agronomic practices (e.g., harvest time relative to bloom)
- Comparison of residues to adverse effects level for hives (residues above NOAEC and LOAEC)
  - Considered duration and frequency of exceedance
  - Considered magnitude of exceedance
    - Ratio of max residue value to NOAEC/LOAEC
    - % of diet from the treated field needed to reach the NOAEC/LOAEC
  - Considered usage and geographic scale/spatial distribution of exposure
- Major Categories of Incidents
  - Bee kills from dust-off from corn seeds treated with clothianidin
  - Bee kills from ornamental tree applications
  - Bee kills from drift of spray application to agricultural fields

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Risks of concern result primarily from foliar applications and some soil applications
Risks are estimated to extend >1,000 ft from the edge of the field (foliar spray)

Benefits Assessments

- BEAD evaluated the impacts of multiple mitigation options depending on the risks being considered by use site (multiple assessments)

Methodology

- BEAD identifies key pests and alternatives based on recent usage data and extension literature
- Impact of mitigation (restriction) is measured by increased cost/acre, reduced revenue/acre via yield and/or quality loss with use of alternatives

Conclusions

- In general, neonics' advantages are:
  - Fairly broad spectrum: control sap-sucking insects, many of which vector disease; Individual a.i.s control somewhat different pests
  - Systemic and contact activity
    - Systemic: residual control for an extended period of time
    - Contact: immediate control (stops-feeding activity) reduces disease vectoring
  - Often comparatively inexpensive and effective
- In general, alternatives include:
  - organophosphates, pyrethroids, and carbamates; acetamiprid

Potential Benefits by Application Timing Stage

	At-Plant/ Early Season	Pre-Bloom Benefit	At-Bloom Benefit	Post-Bloom Benefit	Important Actives
Berries (indeterminate bloomers)	N/A	Uncertain	**High**		Imidacloprid and Thiamethoxam; some clothi and dino use (target different pests)
Berries (discrete bloom period)	N/A	Uncertain	Low to None	**High**	
Grape	N/A	**High**	**High**	**High**	Imidacloprid
Cucurbit	High	Medium	Low		Imidacloprid, Thiamethoxam, and Dinotefuran
Fruiting Vegetables	High	**High**	**High**		Imidacloprid
Stone Fruit	N/A	Low	Low to None	**High**	Imidacloprid and Thiamethoxam
Pome Fruit	N/A	Medium*	Medium*	**High**	Thiamethoxam and Imidacloprid (target different pests)
Tree Nut	N/A	Low	Low	**High**	Imidacloprid
Cotton	**High**	**High**	Medium		Imidacloprid and Thiamethoxam
Citrus	N/A	**High**	**High**	**High**	Imidacloprid and Thiamethoxam
Ornamentals	**High**	**High**	N/A	**High**	Imidacloprid and Dinotefuran

**** Based on additional information received through grower feedback/discussions during PID preparation***
1. Uncertainty surrounding the benefits pre-bloom through post-bloom. Potentially high. Strawberry is an indeterminate bloomer and therefore there is no discrete difference between bloom and post-bloom.

Note that cucurbit and cotton are indeterminate bloom – not really a 'post-bloom' period. Also true of strawberry and some of the caneberries (denoted in table by the dots/different background).
Special Pest Issues generally defined as any pest that can potentially cause widespread and catastrophic reductions in yield or value of crops at harvest without full neonicotinoid (need for multiple neonics/multiple application methods) use (nationally or regionally).
Berries = SWD ex. blueberry maggot (crop rejection), whiteflies (disease vector)
Indeterminate bloomers include: strawberries, caneberries, potentially others within the group
Determinate bloomers (discrete bloom period) include: blueberries, cranberries, potentially others within the group
Grape = Sharpshooter
Pome = invasive brown marmorated stink bug (BMSB) ex. Pear psylla and plum curculio (thiamethoxam targets; very important for the pre-bloom and bloom time use); imi used to control aphids (full season control; pre-bloom alt is chlorpyrifos)
Cotton = indeterminate bloom; plant/stink bugs are bloom pests, combinations of OPs + pyrethroids are likely alternatives
Citrus = ACP (vectors HLB)
Ornamentals = emerald ash borer ; white flies ;

Summary of Risk Conclusions for Foliar Applications

Cell Key:
Red = higher risks
Green = lower risks
Gray = uses not registered

The strength of evidence for each risk call is identified in black text ("strongest" or "weakest").

Strongest evidence of risk for all A.I.s:
- Cotton
- Cucurbits
- Pre-bloom orchard, berries and small fruits
- Fruiting vegetables

Crop Group or Crop	Imidacloprid		Clothianidin		Thiamethoxam		Dinotefuran	
Cotton	Strongest		Strongest		Strongest		Strongest	
Cucurbit Vegetables			Strongest		Strongest		Strongest	
Citrus Fruits	Pre-Strongest	Post-Weakest			Pre-Strongest	Post-		
Pome Fruits	Pre-	Post-Weakest	Pre-	Post-	Pre-Strongest	Post-		
Stone Fruits	Pre-	Post-Weakest	Pre-	Post-	Pre-Strongest	Post-	Pre-Weakest	Post-
Tree Nuts	Pre-	Post-	Pre-	Post-	Pre-Strongest	Post-		
Tropical Fruits	Pre-Strongest	Post-Weakest	Pre-	Post-	Pre-Strongest	Post-		
Berries/Small Fruits	Pre-Strongest	Post-	Pre-Strongest	Post-	Pre-Strongest	Post-	Pre-Strongest	Post-
Root/Tubers Vegetables*	Weakest		Weakest		Weakest		Weakest	
Fruiting Vegetables*	Strongest				Strongest		Strongest	
Herbs/Spices	Weakest				Weakest			

The next few tables summarize the risk calls for agricultural crops. This table summarizes the risk conclusions for foliar applications. Red cells are risk, green cells are low risk, and gray cells are not registered. As with the low risk calls, for orchards and berries and small fruits, risk calls are distinguished for pre-bloom vs. post-bloom applications. Note that most of these calls were yellow in the preliminary assessments due to gaps in the residue database. Bridging really allowed us to make them all green or red. This table also identifies the strength of evidence for the risk call in black text. Cotton, cucurbits, pre-bloom orchard, pre-bloom berries and small fruits, and honey bee attractive fruiting vegetables are strongest evidence of risk for all chemicals.

Risk Management Decision Example Crop: Cotton

Risk Assessment Review:

- Risk: Foliar app. risk classified as strong evidence, soil app. risk (only applies to imidacloprid) as moderate evidence
  - Soil applications showed higher risk for lower percent organic matter soils (sandy soils)

Benefits Assessment Review:

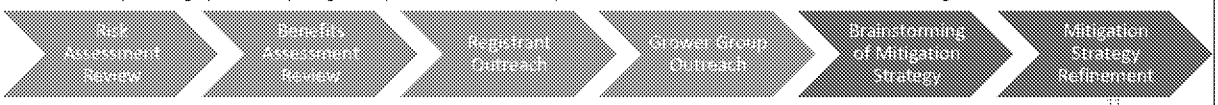
- Impacts: Identified significant benefits to cotton from neonicotinoid use
  - High benefits at-bloom, post-bloom, and for special pest issues
  - Indeterminant blooming for cotton makes crop stage restrictions challenging

Registrant Outreach:

- In initial discussion with registrants where EPA more noted risk exceedances and available benefits information, and invited registrants to provide additional information or potential mitigation suggestions

Grower Group Outreach:

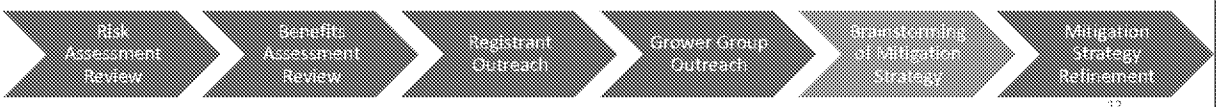
- EPA reached out to grower groups such as the National Cotton Council (NCC) to better inform the benefits assessment and refine a potential risk management approach
  - NCC provided feedback reiterating points from benefits assessments, that at-bloom usage is critical and expressed difficulty in providing specific crop stages for potential restrictions "pre-bloom" due to cotton's indeterminate blooming



Risk Management Decision Example Crop: Cotton [cont.]

Brainstorming of Mitigation Strategy:

- What potential mitigation strategies did we consider?
  - Cancellation – although risks from foliar use were strong, this was unfeasible with the strong benefits case
  - Crop stage restriction – due to indeterminate blooming, this option becomes complicated and potentially unclear to applicators, although could sufficiently reduce risk without a reduction in annual application rate
    - Considered potential crop stage restriction after emergence of 7th or 8th node
    - Although EFED provided a number of days for which this type of mitigation would be feasible (up to 11 days for imidacloprid), due to indeterminant blooming and high at-bloom benefits this was not feasible
  - Soil specific mitigation – applicable to imidacloprid only, considered reduction in max. app. rate in sandy soils
    - Based on EFED information this would be most impactful in < 0.75% organic matter or > 60% sand
    - Soil rate reductions would potentially impact growers for imidacloprid, as 64% of soil applications (before crop emergence) are at higher application rates (≥ 0.175 lb a.i./acre)
    - Cotton Council noted this would specifically impact growers in the southeast with sandy soil such as in Georgia
  - Rate reductions – this option seemed the most effective in reducing risk while minimizing impact to growers
    - Provides clear and enforceable mitigation when compared to crop stage restrictions, due to cotton's specific phenology
    - Provides a linear reduction in potential risk



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Imidacloprid used as an example only, this analysis was done for all four neonics.

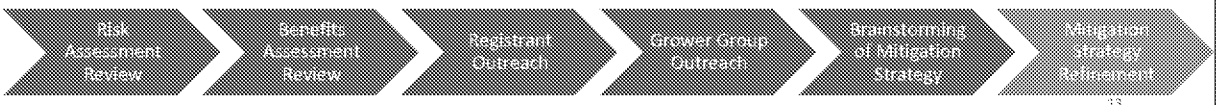
Risk Management Decision Example Crop: Cotton [cont.]

Mitigation Strategy Refinement:

- Rate reduction was determined to be best path forward
- Reduction of maximum annual and maximum single application rates only
  - reduces risk while retaining flexibility for growers
  - addresses neonic systemicity, reducing chronic exposure
- Although acute mitigation (*e.g.,* bee box) was triggered for other crops, was not applicable to non-food crops such as cotton
- Rates: BEAD provided detailed rate information [see table with imidacloprid as an example]. From this, PRD determined that a 25% reduction in the rate from 0.5 to 0.375 lbs a.i./A annually would reduce the overall risk while minimally impacting growers

BEAD Rate Analysis: Cotton

	Imidacloprid
Maximum Label Rate (lb a.i./Acre)	0.062 (F) 0.350 (S)
Maximum Annual Rate (lb a.i./Acre/year)	0.500
Average Application Rate (lb a.i./Acre)	0.103
Application Rate Distribution [% RR treated at or below rate]	16% ≥ 0.210 8% ≥ 0.280
Average Annual Rate (lb a.i./acre/year)	0.151
Annual Rate Distribution [% RR treated at or below rate]	13% ≥ 0.300 2% ≥ 0.400



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Imidacloprid used as an example only, this analysis was done for all four neonics.

Risk Mitigation Summary – Bees (agricultural use), slide 1 of 3

Highest Impact Uses: Uses where neonicotinoids play a critical role in pest management to the extent that certain risk mitigation measures targeted at reducing pollinator exposure would have significant impacts on the use (i.e., alternatives exist but are substantially more expensive) or existing alternatives pose potential increased risks to human health

Mitigation Measures

- Application Rate Reduction (annual) – Cotton, Pome Fruit, Stone Fruit
  - Rate reductions selected to have minimal impact on most applications – goal is to limit flexibility for highest rates that are rarely used
  - Cotton is indeterminate blooming, increasing impact of bloom restriction
  - Also reduces risks to aquatic invertebrates
  - Risk reductions extend off-field

- Pre-bloom Application Interval – Pome Fruit, Stone Fruit, and Tree Nuts (thiamethoxam and dinotefuran only)
  - Majority of benefit occurs post-bloom, other neonicotinoids already prohibit pre-bloom application
  - Use crop stage to designate when applications may no longer occur (i.e., "Do not apply after swollen bud until petal fall")

- No mitigation – Citrus, Grapes
  - Full use of neonicotinoids crucial to crops due to specific pest pressure (e.g., ACP, glassy-winged sharpshooter)

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Notes from BEAD
- Rate reductions could reduce efficacy, which could impact yield/quality or cause growers to make additional applications and/or use other AIs
- Note expected impacts in pome fruit from this mitigation

Risk Mitigation Summary – Bees (agricultural use), slide 2 of 3

Lower Impact Uses: Uses where neonicotinoids are an important tool for certain pests or at certain time periods

Mitigation Measures

- Application Rate Reduction (annual) – Berries (non-grape)
  - Some berries are indeterminate blooming, increasing impact of bloom restriction
- Pre-bloom Application Interval – Fruiting Vegetables, Cucurbits, Tropical and Sub-Tropical Fruit
  - Use crop stage to designate when applications may no longer occur ("Do not apply after appearance of flower bud until petal fall")
  - For Tropical and Sub-Tropical Fruit, would only apply to highest usage crops (e.g., avocado, pomegranate)
    - Note that benefits uncertain due to limited data; Agency will consider public comments on PID
- No mitigation – Root and Tuber, Herbs and Spices, Tropical and Sub-tropical fruits
  - Additional use characterization of acres grown and pollinator attractiveness limit extent of risks of concern

BEAD Notes that rate reductions could potentially reduce efficacy, which could impact yield/quality or cause growers to make additional applications and/or use other AIs

Risk Mitigation Summary – Bees (agricultural use), slide 3 of 3

Mitigation Measures

- For acute risk to bee (direct contact exposure during bloom)

Current Mitigation Measures

- At-bloom application restrictions/statement
  - Applies to all food crops that are pollinator attractive
  - For non-ag crops: do not apply while bees are foraging/plants are flowering etc.
  - Prohibiting application during bloom expected to reduce both acute and chronic risk
- Bee hazard advisory language ("bee box")
  - On all outdoor foliar/spray applications <u>except</u> for non-ag turf/lawns and perimeter sprays around structures.

PROTECTION OF POLLINATORS

APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.

Look for the bee hazard icon in the Directions for Use for each application site for specific use restrictions and instructions to protect bees and other insect pollinators.

This product can kill bees and other insect pollinators.

Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:

- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen when the pesticide is applied as a seed treatment, soil, tree injection, as well as foliar applications.

When Using This Product Take Steps To:

- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants around the application site.
- Minimize drift of this product on to beehives or to off-site pollinator attractive habitat. Drift of this product onto beehives or off-site to pollinator attractive habitat can result in bee kills.

Proposed Mitigation Changes

Deliberative Process / Ex. 5

Poultry Litter

Mitigation Measure – Limit number of whole house applications for imidacloprid, clothianidin, and thiamethoxam

Ex. 5 Deliberative Process (DP)

Risk Mitigation – Bees (Ornamental and Turf uses)

Risk

- Strongest evidence of risk for ornamentals and forestry (moderate evidence for turf)
- Incidents of bee kills recorded for imidacloprid, clothianidin, and dinotefuran
- Uncertainty considerations:
  - Very limited data set for a diverse set of plants
  - Residues exceeded colony-level endpoints through final measurements; EFED unable to derive a safe pre-bloom interval

Residential Ornamental Mitigation: **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Production/Commercial Ornamental Mitigation: **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Turf Mitigation: *E.g.* **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

BEAD notes:

Deliberative Process / Ex. 5

Risk Mitigation – Birds and Mammals

Seed Treatment

Risks

- For small-medium size birds and mammals, expected risk of concern with as little as 2-10% of diet
- Certain seeds are too big for small/medium sized passerine birds to ingest; some are pelleted
- Timing and duration of exposure to treated seeds at planting may limit the likelihood of exposure

Benefits

- Simple, effective control of soil pests and early-season above-ground pests
- Chlorpyrifos is likely other seed treatment but controls soil pests only
- Requiring (increased) pelleting would require machinery changes, could interfere with seed germination

Stakeholder Outreach

- Reached out to registrants and related stakeholders such as ASTA. EPA noted risk exceedances and available benefits information, and invited registrants to provide additional information or potential mitigation suggestions.

Brainstorming of Mitigation Strategy

Ex. 5 Deliberative Process (DP)

Proposed Risk Mitigation

Deliberative Process / Ex. 5

Ex. 5 Deliberative Process (DP)

Risk Mitigation – Aquatic Invertebrates

Risks

- RQs range up to 2,130
- Neonicotinoids are especially mobile and persistent in aquatic environments
- Large amount of registrant and open literature data to support toxic effects as well as monitoring data (imidacloprid) to support exposure estimates

Benefits

- PRD and BEAD conducted a screen of uses with few acres treated and/or high PCT vs risk; did not consider mitigating uses with lower risk/high benefit
- Targeted remaining uses based on feasibility of rate reductions (BEAD assessment provided rate information)

Stakeholder Outreach

- OPP reached out to the registrants in mid-2018 to discuss aquatic exceedances known at the time (prior to Guelph data) and invited the registrants to provide additional information or potential mitigation suggestions. Discussions focused on drift reduction.

Proposed Risk Mitigation

Deliberative Process / Ex. 5

Other considerations:
Based on representative test species, considering how these effects extend across aquatic communities + extent of risk concerns
Certain uses allow for high application rates
Risks dependent on rainfall/irrigation runoff

Risk Mitigation – Aquatic Invertebrates

Proposed Risk Mitigation (continued)

Deliberative Process / Ex. 5

Spray Drift Mitigation for all outdoor uses

Ex. 5 Deliberative Process (DP) r)

Runoff Mitigation for all outdoor agricultural uses

Ex. 5 Deliberative Process (DP)

Good labelling practices and label clarification

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

BEAD notes:

Ex. 5 Deliberative Process (DP)

Human Health Risk Summary

	Dietary Exposure	Residential Exposure	Aggregate Exposure	Occupational Exposure
Imidacloprid	none	Turf – post-application	Turf – post-application	Handler risks for multiple scenarios – seed treatment
Clothianidin	none	none	none	Handler risks for seed treatment and aerosol (commercial bedbug) uses
Thiamethoxam	none	none	none	Handler risks for multiple scenarios – seed treatment
Dinotefuran	none	none	none	none

Risk Mitigation – Human Health

Residential Risk – Imidacloprid Residential & Aggregate Risks of Concern

- Proposed Turf Mitigation: Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

- Previous risks of concern identified for pet collar uses
  - Comments and data received during comments to preliminary assessment changed the Agency's risk conclusions; no longer a risk of concern

Ex. 5 Deliberative Process (DP)

Risk Mitigation – Human Health

Seed Treatment (Occupational Risk)

- Additional PPE
- Ex. 5 Deliberative Process (DP)
-

Liquid Spray Application (Occupational Risk) – Additional PPE

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

BEAD Notes:

Ex. 5 Deliberative Process (DP)

Neonicotinoid Stewardship

US EPA Stewardship Efforts

- Describes education and outreach programs for the care of spilled or uncovered treated seed
- Describes certain best management practices (BMPs) and technologies available to reduce dust off from application of treated seed
- Describes importance of efforts directed at improving bee health, including planting habitat, IPM for common bee pests, along BMPs and Manager Pollinator Protection Plans (MP3) to reduce exposure to bees from pesticides

Registrant Stewardship Proposal

- EPA reached out to the neonic technical registrants to develop a voluntary neonic stewardship program. The registrants proposed a plan to work together to improve and expand existing stewardship efforts
- Includes registrant out-reach to growers to identify applicable BMPs; and,
- Promotes consistency and collaboration, and utilizing their wide network of partners to amplify their existing stewardship efforts.

Other Regulatory Considerations

Seed Dust-Off

- Incidents and some field measurements indicate potential for high risk to bees in certain scenarios (corn seed planting)

Ex. 5 Deliberative Process (DP)

Petitions

- Currently 2 petitions related to neonicotinoids pending outcome of these decisions
  - Clothianidin risk to pollinators
  - Seed Treatment; exemption for treated seed

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Ex. 5 Deliberative Process (DP)

New uses were accepted on a case by case basis by RD

Potential Section-18 Impact

The following are pending Section-18 requests that could be impacted by the registration review mitigation decisions:

- **Dinotefuran on Stone Fruit and Pome Fruit –**
  - IR-4 has generated residue data to support these uses but has not submitted a tolerance petition
    - EPA not considering new outdoor neonicotinoid uses while registration review is ongoing
  - EPA not currently taking any action for registered uses of dinotefuran and Section-18 uses while registration review ongoing
- **Dinotefuran on Kiwifruit –**
  - No tolerance petition pending with the Agency for a Section-3 registration for this use
- **Thiamethoxam on Rice –**
  - Syngenta has a Section-3 registration pending with the Agency for this use
- **Clothianidin on Citrus –**
  - Valent expects IR-4 to submit the tolerance petition to support Section-3 registration after registration review is completed

- **Pending Registration Actions**
- Clothianidin: New in-furrow new use on corn proposed. PRIA date of 9/13/2019
- Thiamethoxam: (1) Resubmission of various foliar uses for which EPA issued a not grant letter in 2014. (2) Increase requested on the rate for potato seed pieces. (3) New use on sugarcane
- Further submissions for outdoor uses on hold until PID, per EPA letter (4/2/2015) on the need to assess additional pollinator data and risks

Stakeholder Interest and Outreach

Stakeholder Interest

- **Registrants –** path forward for new uses as well as a level playing field
- **Growers –** continued availability of reasonably priced and safe tools for combating insect pest pressure
- **Non-Governmental Organizations/Public –** reduction in risk/exposure to bees
- **Beekeepers –** concerns with growers utilizing pesticides that are potentially impactful to bee populations
- **Federal Regulatory Partners –** targeted mitigation to reduce potential risk exceedances in accordance with current statutory requirements that does not unreasonably impact growers
- **State Regulatory Partners –** California will be looking closely into what mitigation EPA proposes which may effect the path forward they take in their own regulatory requirements, while other state department of Ag may be concerned with potential impact to prominent grower groups in their state.

Stakeholder Outreach

- PRD recently reached out to registrants and others (e.g., USDA, CDPR) to discuss initial scoping of mitigation
- PRD plans to continue outreach to stakeholders
  - Goals
    - Anticipate impacts of proposed mitigation [briefly described above]
    - Improve how implementable and enforceable mitigation may be
  - Stakeholders
    - USDA, OPMP and IR-4
    - Growers
    - Registrants
    - States (SFIREG, AAPCO, NASDA)
    - Beekeepers
    - The public
    - Other Stakeholders (American Hort, NALP, NPMA)

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Ex. 5 Deliberative Process (DP)

Next Steps and Timeline

Anticipated Timelines for Completion

Activity	Date
Brief to OPP	August 2019
Brief to OCSPP	September 2019
Draft Documents ready for DD review & signature	November 2019
Publication in FR and regulations.gov	Before the end of 2019

Planned Communications Materials for PID release:

- Higher level comms
- Desk statement
- OPP Update
- Website Update
- Q & A

Ex. 5 Deliberative Process (DP)

Questions?

Back Pocket Slides

Tiered Approach for Bee Assessments

- Tier 1 analysis
  - BeeREX for on-field default and refined exposures
  - AgDrift for off-field exposures

- Tier 2 analysis
  - Nectar equivalents method to combine residues in pollen and nectar (replaces "bee bread" method)
  - Residue bridging strategy to estimate exposure from untested crops
  - Strength of evidence based on evaluation of multiple lines of evidence

New Tier 2 Exposure Methodology – Residue Bridging Strategy

- Extremely broad neonicotinoid use pattern necessitated extrapolation of bee-relevant residue data to address gaps and limitations in data
- Relied on a data-driven bridging strategy from over 80 bee-relevant residue studies to extrapolate residues, when necessary, across:
  - Chemicals, application rates, crops, matrices, time, sites
- Improved consistency in how residue data are applied to bee risk assessment
- Incorporated residue data for non-agricultural uses
- Detailed residue bridging strategy documents provided as Attachments to the Final Bee RAs
  - 1 – soil and foliar applications; 2 – seed treatment applications; 3 – non-ag applications

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Moving on to the residues, the goals of the bridging strategy were to 1) develop methods to reduce uncertainties in the existing database due to lack of data or various data limitations; 2) improve how residues are applied to bee risk assessments by attempting to harmonize the methodology, where sufficient data were available, with those employed for other taxa or by other regulatory bodies; 3) and finally, to develop an approach for non-ag uses.

Distinct approaches were developed for seed treatments vs foliar/soil applications.

Residue Bridging Strategy Conclusions

- Residues from foliar applications > soil applications > seed treatments
- Faster decline after foliar application vs. soil application
- Pre-bloom applications result in residues that are generally much higher than post-bloom applications
- Data supported extrapolation of residues among neonics, but not among application methods
- Within an application method and crop group, residues extrapolated among crops
- In absence of data for a given crop group, considered all data within an application category (e.g., tree crops, herbaceous crops)

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Based on these analyses we saw some general trends in the data. At the 30,000 foot level, residues from foliar applications are greater than residues from soil applications, which are greater than residues from seed treatments. [Ranges presented here represent the max values normalized to 0.1 lb/a for foliar and soil applications and 1 mg/seed for seed treatments.] SPOILER ALERT: colony feeding study endpoints are in the 10s for IMI, CLOTHI, and THIA and 100-ish for DINO. I'll note that the range of residues presented for foliar applications is based on samples taken close to application (~2 weeks). After that the second bullet comes into play because residues from foliar applications tend to decline much more rapidly than residues from soil applications, with a steeper slope. Generally there is also a distinction between pre-bloom and post-bloom applications, with the former being greater.

Based on these general trends we decided to separated foliar and soil applications as well as pre-bloom and post-bloom applications. You'll see how this factors into the risk calls in a few slides.

Strength of Evidence

- Strong Evidence of Risk
  - Residues exceed colony-level endpoint(s) by a high magnitude, frequency, and/or duration
  - Chemical-specific or robust bridged residue data set available
  - Residues exceed across multiple locations
  - May be supported by modeled (*e.g.*, Monte Carlo) exposures or ecological incidents
- Moderate Evidence of Risk
  - Residues exceed colony-level endpoint(s) but magnitude, frequency, and/or duration are limited
  - Residues exceed across few locations
  - Maybe supported by limited ecological incident information
- Weak Evidence of Risk
  - Residues exceed colony-level endpoint(s) but there are uncertainties in the surrogacy in the bridged residue data set
  - Majority of residues below toxicity endpoint
  - Residues exceed at one location
  - Not supported by ecological incidents

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As part of the strength of evidence, we considered how the major assumptions of our assessment approach influence the risk call (e.g., 100% of the colony's diet comes from the treated field, a single exposure is enough to trigger the effect observed in the CFS). For a crop group with strong evidence of risk, maybe only 1% of the colony's diet would need to come from a treated field, measured and modeled residues across multiple geographic locations are above the colony level endpoint for several weeks, and these conclusions are supported by a robust set of chemical-specific or bridged residue data and potentially incidents as well. This suggest that no matter where the chemical is applied in the country, if a hive is in proximity to a treated field there is potential for a chance exposure to cause effects at the colony level. For a crop group with moderate evidence of risk, maybe a larger portion of the colony's diet would need to come from a treated field or residues across a few geographic locations are above the colony level endpoints for less than a week, and while there may be incident information, there is some recognized variability in the potential for exposure. For a crop group with weak evidence of risk, maybe there are uncertainties related to the surrogacy of the bridged residue data, or maybe a majority of the available residues are below the level of concern, suggesting uncertainties in the potential for exposure.

Since this weighing of the evidence is by nature a subjective process, the teams coordinated to ensure consistency in our calls.

Low Risk Calls

Foliar and Soil Applications

Crop Group or Crop	IMI		CLOTHI		THIA		DINO	
	Foliar	Soil	Foliar	Soil	Foliar	Soil	Foliar	Soil
Bulb Vegetables								
Leafy Vegetables								
Brassica Vegetables								
Legumes								
Cereal Grains								
Cucurbits								
Citrus Fruits	**	*	Post-	Post-	Post-	Post-		
Pome Fruits			Post-		Post-			
Stone Fruits			Post-		Post-		Post-	Pre-/Post-
Tree Nuts	Post-		Post-		Post-			
Tropical Fruits			Post-		Post-			
Berries/Small Fruits	Post-	Post-	Post-	Post-	Post-	Post-	Post-	Post-
Root/Tubers*								
Fruiting Veg*								

Seed Treatments

Crop Group or Crop	IMI	CLOTHI	THIA
Bulb Vegetables			
Leafy Vegetables			
Brassica Vegetables			
Legumes			
Cereal Grains			
Oilseed			
Cucurbit Vegetables			
Root/Tuber Vegetables*			

* Denotes call is for non-attractive crops
** Mandarin Orange Crop tented during bloom

This table summarizes the low risk calls for foliar and soil applications, represented by green cells. The gray cells indicate either the chemical is not registered for a particular use or there was a risk call (we'll get to those soon). For orchards and berries and small fruits, risk calls are distinguished for pre-bloom vs. post-bloom applications, which was a recommendation from the residue bridging strategy.

Crops/crop groups were considered low risk because they were harvested prior to bloom (e.g., bulb, leafy and brassica vegetables; artichoke and tobacco), not considered attractive to honey bees (i.e., certain crops within the root and tuber and fruiting vegetables crop groups), or had measured residues below the colony-level effects endpoints. The figure on the right is an example for foliar post-bloom applications to berry and small fruit crops where the residues are substantially lower than the imidacloprid colony level NOAEC and LOAEC.

A few things to note: the calls for root and tubers and fruiting vegetables are for non-attractive crops within the groups, and the call for IMI citrus is only for mandarin oranges, which are tented… all other citrus are high for both foliar and soil applications.

ADVANCE SLIDE: The table on the right summarizes the low risk calls for seed treatments, which accounts for the large majority of usage for imi, clothi, and thia. So things like soybean, corn, which are major uses for these chemicals, were identified as low risk (not accounting for dust-off)

Some of these crops were "uncertain" in the preliminary assessments, but the additional data generated for these 3 chemicals allowed us to make "low risk" calls.

[other green calls for thia include: artichoke, tobacco, peanuts, sod, christmas trees and other outdoor residential (eg crack and crevice)]

Summary of Risk Conclusions for Soil Applications

Crop Group or Crop	Imidacloprid		Clothianidin		Thiamethoxam		Dinotefuran	
Cotton	Moderate							
Cucurbit Vegetables	Strongest		Moderate		Moderate			
Citrus Fruits	Pre-Strongest	Post-Moderate	Pre-	Post-Moderate	Pre-Strongest	Post-Weakest		
Pome Fruits	Pre-	Post-Weakest						
Stone Fruits	Pre-	Post-Weakest					Pre-Weakest	Post-
Tree Nuts	Pre-	Post-Moderate						
Tropical Fruits	Pre-	Post-Weakest						
Berries/Small Fruits	Pre-Strongest	Post-	Pre-	Post-	Pre-Strongest	Post-	Pre-Moderate	Post-
Root/Tubers Vegetables*	Weakest		Weakest		Weakest		Weakest	
Fruiting Vegetables*	Strongest				Moderate		Weakest	
Herbs/Spices	Weakest							

* denotes call is for honeybee attractive crops within the crop group

Here is the table summarizing risk conclusions for soil applications. Where the foliar applications are mostly strong evidence of risk, the soil applications are more moderate and weak evidence. This is because, as you may recall from our previous discussion of the general trends in residue data, residues from soil applications tend to be lower than foliar applications but they may persist for much longer.

Summary of Risk Conclusions for Seed Treatments

Crop Group or Crop	Imidacloprid	Clothianidin	Thiamethoxam
Bulb Vegetables			
Leafy Vegetables			
Brassica Vegetables			
Legumes	[illegible]		
Cereal Grains			
Oilseed			
Cucurbit Vegetables			
Root/Tubers Vegetables*		[illegible]	

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* denotes call is for honeybee attractive crops within the crop group

Here is the table summarizing the risk conclusions for seed treatment uses. As you can see, most of the seed treatments are low risk, as we discussed previously, with the couple of exceptions noted here.

New Data Set – Guelph (Raby *et al.*) Aquatic Invert Toxicity Data

- Large acute and chronic datasets across all 4 neonics (and acetamiprid)
- Acute data published Jan 2018; chronic data published July 2018
- Allowed for apples-to-apples comparison of toxicity data across the 4 neonics, accounting for lab and study conduct variability
- 22 species tested for acute, including a range of species' sensitivities and 2 most sensitive acute species tested for chronic
- Tested species did not include the most sensitive species identified for imidacloprid

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We also received as part of the comment period data from Guelph, which has since been published. The Raby et al. study represents a large acute and chronic toxicity dataset across the four neonics (as well as acetamiprid) that allowed for an apples-to-apples comparison, accounting for lab and study conduct variability. There were 22 species included in the acute tests that included a range of species. The 2 most sensitive species from the acute test were then used in the chronic tests (the midge and a mayfly species). However, I'll note that the tested species did not include the most sensitive species identified for IMI.

Guelph Aquatic Invert Comparative Risk Conclusions

- Acute Toxicity
  - Imidacloprid similar to Clothianidin and Dinotefuran > Thiamethoxam
- Chronic Toxicity
  - Imidacloprid and Clothianidin > Dinotefuran > Thiamethoxam
- Acute and Chronic Risks
  - Comparison of risk incorporates varying chemical-specific application rates and aquatic modeling parameters
  - Imidacloprid, Clothianidin, and Dinotefuran have similar risk profiles (RQs within 10x)
  - Thiamethoxam presents lower risks

In response to receiving this data and to support potential mitigation options being considered by PRD, the team conducted two analyses: the first compared the acute and chronic toxicity of CLOTHI, THIA, and DINO to IMI and, since toxicity is only one part of the risk picture, the second analysis accounted for potential exposure to compare the acute and chronic risk of CLOTHI, THIA, and DINO to IM. The results of the toxicity comprison found that on an acute basis IMI is similar to CLOTHI and DINO and all three are more sensitive than THIA; on a chronic basis IMI is similar to CLOTHI and are more sensitive to DINO which is more sensitive than THIA. When this is translated into risk, IMI CLOTHI and DINO have similar risk profiles on an acute and chronic basis, while THIA presents a lower risk.