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 – advisory "Bee Box", pollinator restrictions for Ag and non-Ag products (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

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

Pollinator Risk Mitigation Approach Table

	High Benefit	Medium/Low Benefit
Higher Risk	Deliberative Process / Ex. 5	
Lower Risk	No mitigation	No mitigation

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

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Risk Mitigation – Bees (agricultural use)

Highest Impact to 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 though are substantially more expensive or existing alternatives pose potential increased risks to human health)

Mitigation Measures

- 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 – Bees (agricultural use)

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

Mitigation Measures

- 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

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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 – Bees (agricultural use)

Other Mitigation Measures

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

Current Mitigation Measures

- Continuation of at-bloom application restrictions and pollinator advisory "bee box"
  - At-bloom restriction statement, applies to all food crops that are pollinator attractive
  - Prohibiting application during bloom expected to reduce both acute and chronic risk
- Bee hazard advisory language, also in "bee box"

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.

Poultry Litter

Mitigation Measure

- Limit number of whole house applications for imidacloprid, clothianidin, and thiamethoxam

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 IMI, CLOTHI, and DINO
- Uncertainty considerations:
  - Very limited data set for a diverse set of plants
  - Unable to refine exceedances based on time

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

Deliberative Process / Ex. 5

Production/Commercial Ornamental Mitigation: Reduce maximum application rates

Ex. 5 Deliberative Process (DP)

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

Ex. 5 Deliberative Process (DP)

Deliberative Process / Ex. 5

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

Current Risk Mitigation

- Consistency with seed stewardship and label statements advising users to clean up spills, dispose of excess seed to avoid contamination of water bodies
  - Will also be included on seed bag tags

Talking Point: Stewardship efforts will also attempt to address issues from dust-off.

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
- Large amount of monitoring data (imid) 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)

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

Ex. 5 Deliberative Process (DP)

Runoff Mitigation

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

Deliberative Process / Ex. 5

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)

Other Regulatory Considerations

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)

Pending Registration Actions

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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Deliberative Process / Ex. 5

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)

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	October 2019
Publication in FR and regulations.gov	Before the end of 2019

Planned Communications Materials for PID release:

- Desk statement
- OPP Update
- Website Update
- Q & A

Coms are what we're envisioning but will have to talk to Rick about what he thinks moving forward. Also mention that we plan on reaching out to registrants again in a brief thirty minute conference call to update them more generally on developments. We will not be going into detail regarding mitigation.

Questions?