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EPA Neonicotinoid Ecological Risk Summary

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APRIL 24, 2023

Morgan Griffith

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Neonic Ecological Risk Summary

EPA PROPOSED INTERIM REGISTRATION REVIEW DECISION

Timeline for EPA Review of Neonics

- Updated pollinator risk assessment and a proposed interim decision released in January 2020
- Draft listed species biological evaluation issued in August 2021
- Final listed species biological evaluation issued in June 2022
- Registration review amended proposed interim decision anticipated in early 2023
- Registration review interim decision anticipated in 2024

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Neonic Ecological Risk Summary

EPA PROPOSED INTERIM REGISTRATION REVIEW DECISION

References

U.S. Environmental Protection Agency. (2020, January). Imidacloprid Proposed Interim Registration Review Decision. Case Number 7605, EPA-HQ-OPP-2008-0844.

U.S. Environmental Protection Agency. (2020, January). Clothianidin and Thiamethoxam Proposed Interim Registration Review Decision. Case Numbers 7620 and 7614, EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581.

Wagman, M., Peck, C., Mroz, R., Koper, C., Garber, K. (2020). Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. U.S. Environmental Protection Agency, EPA-HQ-OPP-2011-0865-1164.

Sappington, K., Niesen, M., Yingling, H., & Ruhman, M. (2020). Final Bee Risk Assessment to Support the Registration Review of Imidacloprid. U.S. Environmental Protection Agency, EPA-HQ-OPP-2008-0844-1611.

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Neonic Ecological Risk Summary

EPA PROPOSED INTERIM REGISTRATION REVIEW DECISION

The largest agricultural use of imidacloprid, clothianidin and thiamethoxam in terms of pounds active ingredient applied has been in the form of seed treatments.

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Neonic Ecological Risk Summary

EPA PROPOSED INTERIM REGISTRATION REVIEW DECISION

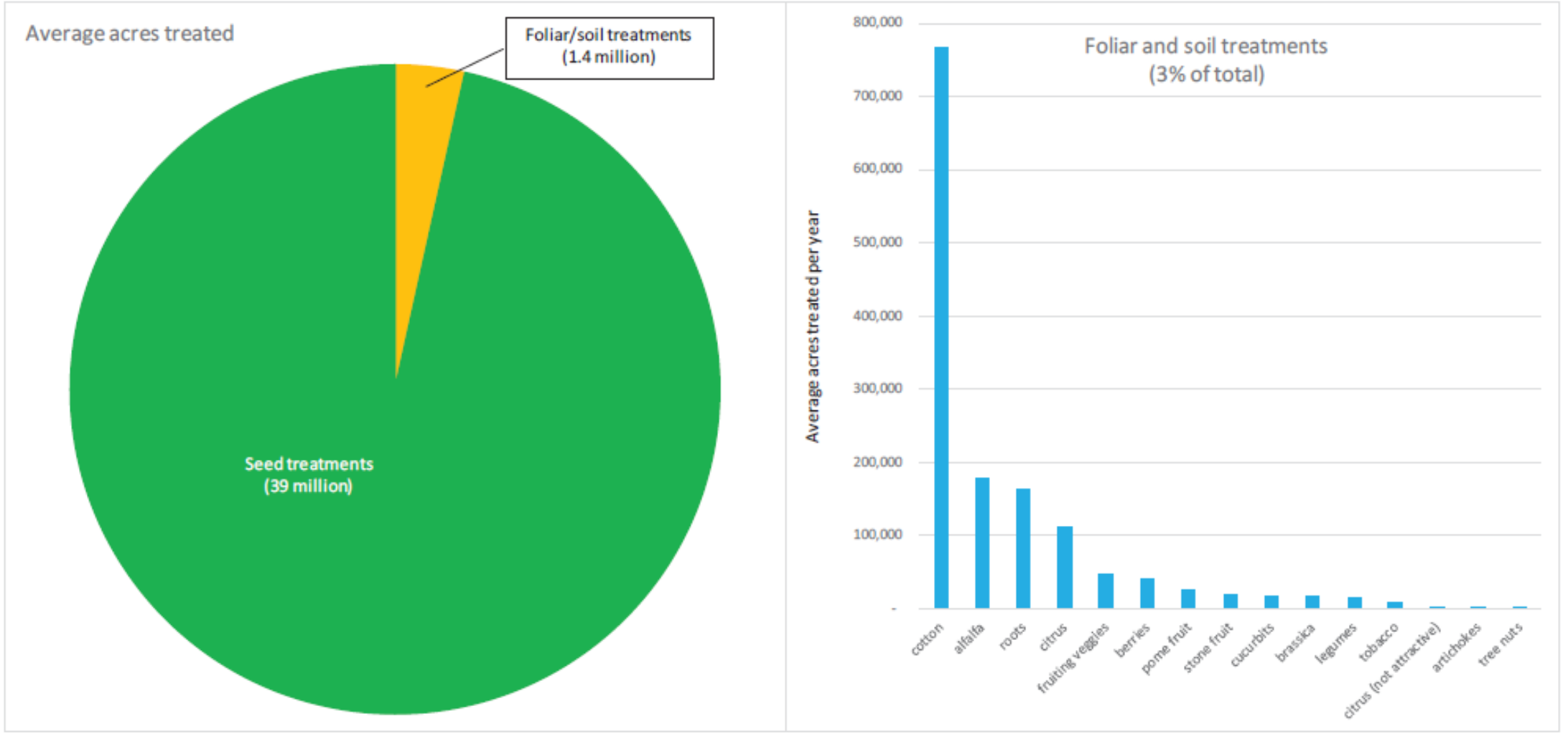

Figure 2.1. Average acres treated of thiamethoxam in the US per year.

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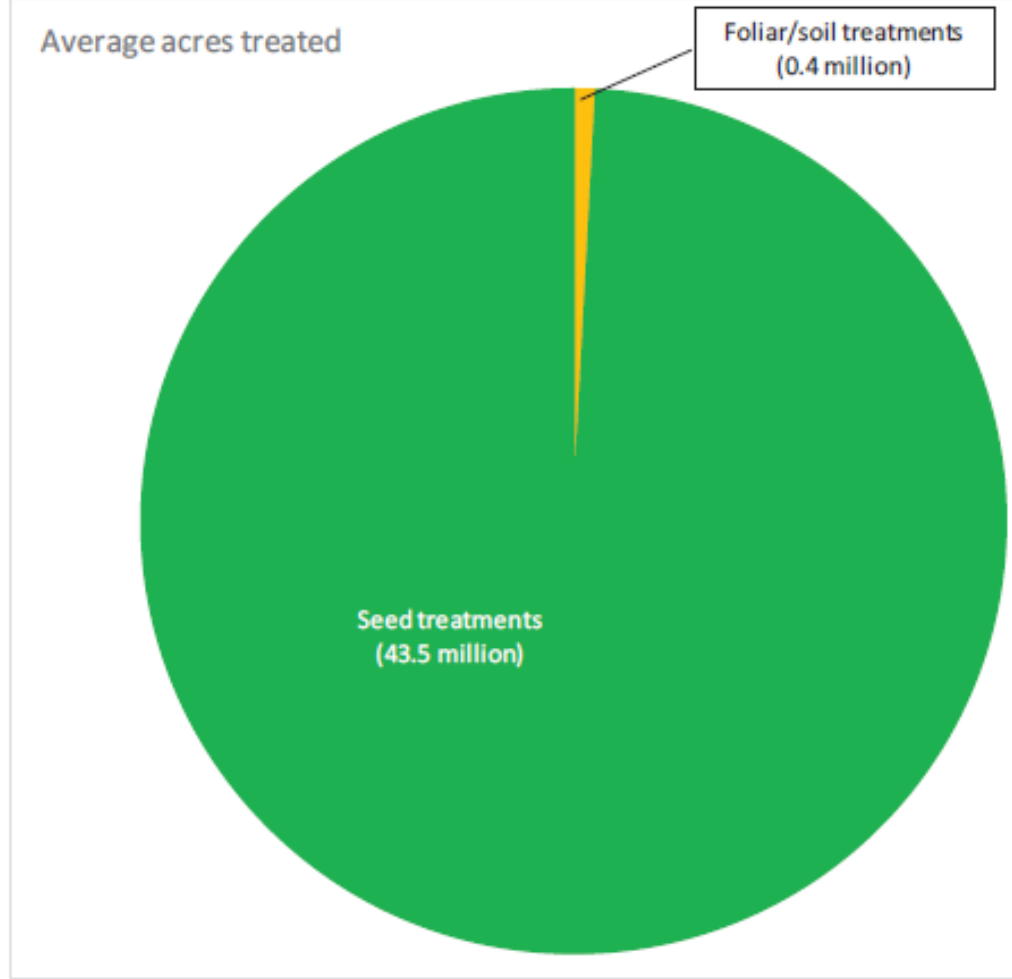
Neonic Ecological Risk Summary

EPA PROPOSED INTERIM REGISTRATION REVIEW DECISION



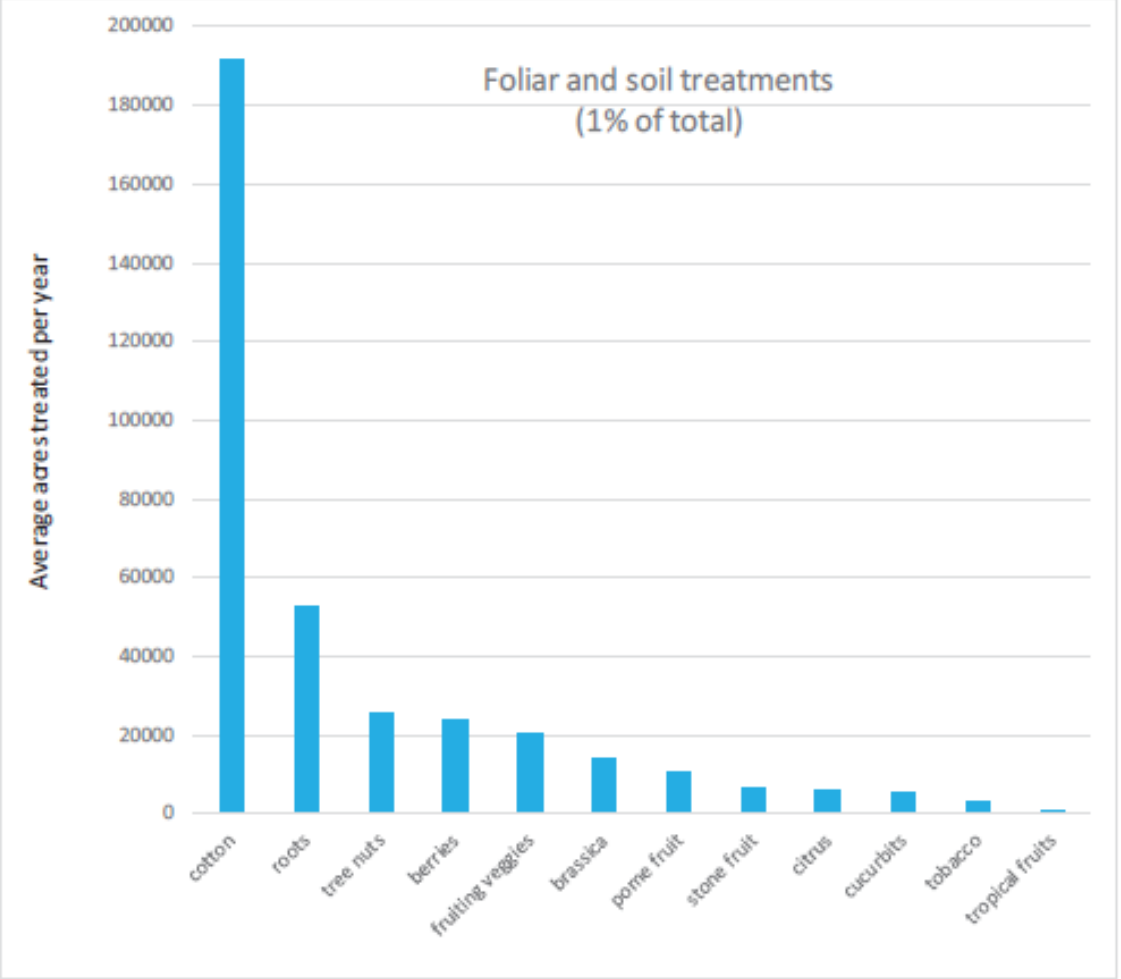


Figure 2.2. Average acres treated of clothianidin in the US per year.

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Neonic Ecological Risk Summary

Terrestrial Exposures

- Avian and mammalian species – ingestion of residues on treated seed
- Terrestrial invertebrates – contact with spray droplets, ingestion via pollen and nectar, exposure to seed treatment dust
- Terrestrial plants – exposure from ground/foliar applications to turf and/or ornamentals

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Neonic Ecological Risk Summary

TERRESTRIAL EXPOSURES

Terrestrial Exposures

- Exposures from treated seeds results in the highest acute and chronic risks to terrestrial organisms, but risks vary considerably.
  - Small seeds (lettuce, sugar beets) have higher concentration a.i. and easier to eat by smaller birds or mammals
  - Larger seeds (corn, soybean) have lower concentrations of a.i. and too big for the smaller birds/mammals to eat.

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Neonic Ecological Risk Summary

MAMMAL RISK ASSESSMENT

- Potential acute risks of concern, but more likely risk of concern is from chronic consumption of treated seed
- Variables impacting exposure to mammals from seed treatment:
  - How far apart and number of seeds available
  - Amount of cover in the field (newly planted have less cover than no till fields so less attractive to smaller mammals)
  - Whether seeds are incorporated into soil (depth) or on surface
  - Life stage and size of mammal

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Neonic Ecological Risk Summary

MAMMAL RISK ASSESSMENT

Imidacloprid

- Chronic Level of Concern (LOC) exceeded for all sizes of mammals consuming each of assessed treated seed (corn, soybean, cotton, wheat, sorghum)

Clothianidin

- Chronic LOC was exceeded for all size classes of mammals consuming any of the assessed treated seed (corn, soybean, cotton, sugar beet, lettuce)

Thiamethoxam

- Chronic risk exceedances for corn, cotton, and sugar beet
- No chronic LOC exceedances for soybean

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Neonic Ecological Risk Summary

BIRD RISK ASSESSMENT

Risk Assessment for Birds, Reptiles, Terrestrial-Phase Amphibians

- Imidacloprid classified as highly toxic to birds (acute oral exposure), slightly toxic (subacute dietary)
- Clothianidin classified as moderately toxic (acute oral), practically nontoxic (subacute dietary)
- Thiamethoxam classified as slightly toxic (acute oral), practically nontoxic (subacute dietary)

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Neonic Ecological Risk Summary

BIRD RISK ASSESSMENT

Imidacloprid

- In order to exceed acute LOC, % treated seed in diet (depending on bird size) must be:
  - 3% field corn (large bird only)
  - 12% soybean (large bird only)
  - 1-4% cotton seed
  - 1-3% sorghum/wheat seed

Clothianidin

- Expected risks are highest for small birds and decrease with increased body weight
- Acute LOC exceedance when <10% of diet is treated lettuce or sugar beet
- Chronic LOC exceedance for birds eating any of assessed seeds

Thiamethoxam

- Acute dose-based exceedances for all seeds except soybean
- Chronic exceedances for all modeled crops and size classes

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Neonic Ecological Risk Summary

BIRD RISK ASSESSMENT

- Size of the seed and size of the bird dictate the size of the risk
  - Large birds foraging in corn fields would have to have approximately 99% of diet be treated corn seed in order to reach the acute LOC
  - May only be likely in instances of treated seed spillage than in normal foraging behavior

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Neonic Ecological Risk Summary

TERRESTRIAL INVERTEBRATES RISK ASSESSMENT

- Imidacloprid, clothianidin & Thiamethoxam classified as highly toxic to honeybees
- Primary routes of exposure considered are direct contact with foliar spray and oral ingestion (i.e. consumption of contaminated nectar or pollen)
  - May also be exposed via contaminated surface water, plant guttation fluids, honey dew, soil and leaves, but high uncertainty and lack of information to quantify these routes
- EPA also lacks method to reliably quantify exposures of bees via dust from treated seeds
- Imidacloprid risk assessment considered year-to-year accumulation in soils that lead to higher residues in pollen and nectar

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Neonic Ecological Risk Summary

TERRESTRIAL INVERTEBRATES RISK ASSESSMENT

- Imidacloprid risk assessment considered year-to-year accumulation in soils that lead to higher residues in pollen and nectar
  - Models and data suggest possible accumulation in soils, but residue data in pollen and nectar do not show carryover in treated crops
  - Imidacloprid residues in succeeding crops (e.g. white clover following treated corn seed) are low when detected so that risk to honeybees is not expected

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Neonic Ecological Risk Summary

TERRESTRIAL INVERTEBRATES RISK ASSESSMENT

Imidacloprid

- Foliar and soil applications to honeybee attractive crops not harvested before bloom result in potential for colony-level risks of concern
- Full field colony level studies on effects of seed treatment uses generally did not indicate treatment related effect
- Seed treatment associated with relatively low residue levels in pollen and nectar (field residue studies)

Clothianidin

- Foliar and soil applications to honeybee attractive crops not harvested before bloom result in potential for colony-level risks of concern
- Residues from seed treatment were all below NOAEC for honeybee colony effects, so low risk on colony level
- Multiple bee kill incidents associated with planting of treated corn seed (dust drift)

Thiamethoxam

- Foliar and soil applications to honeybee attractive crops not harvested before bloom result in potential for colony-level risks of concern
- Residues from seed treatment were all below NOAEC for honeybee colony effects, so low risk on colony level
- Multiple bee kill incidents associated with planting of treated corn seed (dust drift)

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Neonic Ecological Risk Summary

TERRESTRIAL INVERTEBRATES RISK ASSESSMENT

Clothianidin Field Studies Evaluating Effects of Seed Treatments to Honeybees/Bumble bees/Mason bees/Wild bees

- Honeybee colonies placed in or adjacent to fields planted with either treated corn or treated canola seeds. No significant difference between treated and control sites for colony development or health
- Colonies located in treated corn fields had a transient increase in amount of brood compared to control
- Seed treated oilseed rape study found no significant differences in number of adult honeybees between control and treated fields
- Bumble bee colonies placed adjacent to oilseed rape seed fields treated with clothianidin had significant decrease in mean number of queen and worker/male cocoons per colony and a decreasing rate of growth
- Study on impact on wild bees and mason bees adjacent to oilseed rape fields with clothianidin treated seed found wild solitary bees per flower was reduced in treated field and field borders. Mason bee colonies placed adjacent to the treated seed field had reduced median number of brood tubes (6/8 females in control and 0/8 females in treated group started to build brood cells)

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Neonic Ecological Risk Summary

TERRESTRIAL INVERTEBRATES RISK ASSESSMENT

Thiamethoxam Field Studies Evaluating Effects of Seed Treatments to Honeybees/Bumble bees

- 5 studies evaluated exposure after treatment of sunflower seed reported transient effects on honeybee mortality, no treatment related effects on brood number or adult bee foraging activity
- Study with thiamethoxam treated oilseed rape seeds observed increased honeybee mortality
- Another oilseed rape treated seed study shoed no clear treatment related trends for measured endpoints (lifespan, foraging, homing activity
- Study examining sowing operations of thiamethoxam treated corn seeds observed similar mortality in the control hives and the treatment hives the day of planting, but transient increases in honeybee mortality immediately after sowing in the treatment group. Except for the day of sowing the control hives had higher mortality on all other days compared to treatment hives
- Bumble bee colonies placed adjacent to clothianidin and/or thiamethoxam treated conventional corn fields or adjacent to reported organic corn fields. Number of workers was significantly reduced (down 25%) in the neonic treated fields compared to orgranic. Worker and drone weights were reduced >25% in colonies adjacent to treated fields (but not significant $p>0.05$)
- Bumble bees exposed to flowering rape grown from thiamethoxam treated seed and no significant effects were observed in the treatment group compared to control
- Study evaluated development of bumble bee colonies that foraged on flowering oilseed rape (from thiamethoxam treated seed) for 5 weeks: increase in colony mass and foraging activity, higher number queens, workers, eggs, larvae. But lower number of drones compared to control

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Neonic Ecological Risk Summary

SALTWATER INVERTEBRATES RISK ASSESSMENT

Imidacloprid

- No acute risks identified
- Chronic risks identified for all application methods
  - Combined uses > foliar > soil > seed treatment

Clothianidin

- No acute or chronic LOC exceedances for seed treatment use except for on rice

Thiamethoxam

- No acute or chronic LOC exceedances for foliar, soil or seed treatment use

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Neonic Ecological Risk Summary

FISH AND AQUATIC-PHASE AMPHIBIANS RISK ASSESSMENT

- No direct risks of concern for fish or aquatic-phase amphibians for any ag or non-ag imidacloprid use assessed
  - Risk of indirect risks through reduction of their invertebrate food source
- Clothianidin and thiamethoxam classified as practically non-toxic to fish on acute exposure basis
  - Both chemicals had minor effects on fish growth after chronic exposure, but overall no risks of concern

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Neonic Ecological Risk Summary

TERRESTRIAL AND AQUATIC PLANT RISK ASSESSMENT

Imidacloprid

- Not toxic to terrestrial plants
- Aquatic plants were not assessed because data show toxicity endpoints several orders of magnitude above highest estimated exposure concentrations in surface waters

Clothianidin

- No risks of concern to terrestrial or aquatic plants

Thiamethoxam

- No risks of concern to terrestrial or aquatic plants

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Ecological Incidents

TERRESTRIAL NON-POLLINATOR

- Imidacloprid: 1 seed treatment incident reported 1995-2017
  - Large number of birds dying allegedly due to ingestion of imidacloprid treated wheat seeds. Residue analysis did not detect imidacloprid in the birds
- Clothianidin and Thiamethoxam: handful of incidents reporting crop damage and 1 incident involving birds, but these were also associated with other chemicals

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Ecological Incidents

POLLINATOR

Imidacloprid

- 10 of 19 incidents originated from agricultural use
- 5 of 10 were seed treatment applications
- Clear association between individual bee or colony losses from imidacloprid not indicated (lack of confirmatory residue analysis)
  - Hive monitoring studies (US & EUR) of imidacloprid residues in pollen, nectar, bee, & wax samples
    - Frequency of detection <10%, mean values marginally above limits of quantitation

Clothianidin

- 54 incidents affecting bees in the US associated with clothianidin use reported to EPA 2010-2018
- 27 incidents affecting entire honeybee colonies were associated with corn, insufficient evidence to correlate to specific chemical
  - 23 of these 27 incidents occurred before 2015

Thiamethoxam

- 22 incidents reported in US for honeybees in association with agricultural uses of thiamethoxam
- 7 of those incidents with certainties of “highly probable” or “possible” have been reported in association with corn planting in Indiana, Minnesota and Illinois
  - Observations included hundreds to thousands of dead bees and bees with behavioral impacts

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Proposed Mitigation Measures

SEED TREATMENT RELATED

- Because of identified risk to birds and small mammals ingesting treated seed, EPA proposed additional seed bag label language:

"Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)."

"Dispose of all excess treated seed by burying seed away from bodies of water."

"Do not contaminate bodies of water when disposing of planting equipment wash water."

- EPA stated "These risk mitigation measures were considered with the understanding of the high benefits associated with seed treatment uses, which through their use, have the potential to reduce overall neonicotinoid exposure and offer a lower overall ecological risk compared to foliar uses."

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Imidacloprid Ecological Risk Summary

Sappington, K., Niesen, M., Yingling, H., & Ruhman, M. (2020). Final Bee Risk Assessment to Support the Registration Review of Imidacloprid. U.S. Environmental Protection Agency, EPA-HQ-OPP-2008-0844-1611.

U.S. Environmental Protection Agency. (2020, January). Imidacloprid Proposed Interim Registration Review Decision. Case Number 7605, EPA-HQ-OPP-2008-0844.

The largest agricultural use for imidacloprid, in terms of pounds active ingredient applied, has been in the form of seed treatments.

Ecological Risks

Terrestrial Exposures

Risk to terrestrial wildlife was modeled for potential dietary exposure based on consumption of residues on food following spray applications as well as from ingestion of residues on treated seed. Different seed sizes and planting rates of treated seeds could result in a range of exposures.

Acute risk to avian and mammalian species from foliar and soil treatments are low. Exposures from treated seeds results in the highest acute and chronic risks to terrestrial organisms, but the risks vary considerably. For example, a low number of small treated seeds (e.g. lettuce and sugar beets) are needed to reach levels of concern for smaller birds and mammals because the surface of these seeds have higher concentrations of imidacloprid applied. Also these small seeds are easier for small birds and mammals to consume. However, larger seeds (e.g. corn and soybean) have far lower risks to birds and mammals because lower concentrations of active ingredient are applied to the seed surface and the larger seed size prevents consumption by smaller birds and mammals.

The primary routes of exposure for terrestrial invertebrates include contact of bees with spray droplets, oral ingestion via pollen and nectar, or exposure from seed treatment dust.

Terrestrial plants are not sensitive to imidacloprid.

Mammals

Imidacloprid is classified as moderately toxic to mammals on an acute oral exposure basis. Chronic mammalian risk quotients were calculated for corn, soybean, cotton, wheat, sorghum, and potato when assessing risk to mammals from imidacloprid treated seed. The acute LOC was exceeded for four of the six scenarios modeling the range of application rate to seed size ratios. The highest acute exceedances were for use on cotton. The chronic LOC was exceeded for all size classes of mammals consuming each of the assessed seed with the exception of potato, indicating potential chronic risk. The highest chronic exceedances for treated seed was for cotton.

Variables impacting exposure to mammals from seed treatment include: how far apart and how many seeds are available at a given time; the amount of cover provided by field conditions (newly planted are more open and have less cover than no till fields so less attractive to smaller mammals); whether seeds are incorporated in soil or remain on surface; life stage of mammal (uncertain if effects seen in lab-based

reproduction studies happen at specific sensitive life stage or are from exposure over the entire exposure period).

The percent of a mammal's diet (depending on mammal size) that would need to be imidacloprid treated seed in order to exceed the acute level of concern is: 34-78% for sorghum/wheat seed; 37-82% for corn seed; 160-331% for soybean seed; 47-96% for cotton seed; and 2200-3688% for potato seed

Although EPA risk estimates indicate the potential for acute risks of concern, especially for smaller sized mammals, the risk of concern is more likely from chronic consumption of treated seed.

Birds, Reptiles and Terrestrial-phase Amphibians

Imidacloprid is classified as highly toxic to birds on a acute exposure basis and slightly toxic on subacute dietary exposure basis. Japanese quail has the most sensitive acute toxicity endpoint and mallard duck has the most sensitive chronic toxicity endpoint. Potential risks to birds from imidacloprid treated seeds are highest for small birds.

The percent of a bird's diet (depending on bird size) that would need to be imidacloprid treated seed in order to exceed acute levels of concern is: 3% for field corn seed (risk only to large birds); 12% soybean seed (risk only to large birds); 1-4% cotton seed; and 1-3% sorghum/wheat seed. Given the availability of other seed sources (i.e. remaining waste grain or seeds from weed species), eating diets made up entirely of a specific seed type is unlikely but may be more likely in instances of treated seed spillage.

Terrestrial Invertebrates

Imidacloprid is classified as very highly toxic to adult honeybees. The primary routes of exposure considered in EPA's risk assessment are direct contact with foliar spray of imidacloprid and oral ingestion (e.g. consumption of contaminated pollen or nectar). They may also be exposed via contaminated surface water, plant guttation fluids, honey dew, soil (for ground-nesting bees) and leaves. But there is high uncertainty regarding the importance of these other exposure routes and the EPA lacks information to quantify risks from these other routes. The EPA also does not have a method to reliably quantify exposures of bees via dust from treated seeds and therefore their risk assessment focuses on quantitative estimates of exposure via contact and ingestion of pollen and/or nectar. The EPA is working with different stakeholders to identify best management practices and promote technology-based solutions that reduce the potential exposure via dust from treated seeds. The EPA's risk assessment of imidacloprid on bees does consider the potential exposure route of year to year accumulation of imidacloprid in soils that lead to higher residues in pollen and nectar. While model results and some empirical data from multi-year applications in soil suggest possible year-to-year accumulation in soils, available residue data in pollen and nectar are not indicative of imidacloprid carryover in treated crops. Furthermore, imidacloprid residues in succeeding crops (e.g. white clover following seed treatment applications to corn) are low when detected, such that risk to honey bees is not expected.

There are robust data sets of pollen and nectar residue data available for foliar and/or soil applications to bee-attractive crops. The imidacloprid risk assessment found that foliar and soil applications to honeybee attractive crops that are not harvested prior to bloom result in the potential for colony-level risks of concern.

For chronic oral toxicity to adult bees, a 10-day study indicated a No Observed Adverse Effect Concentration (NOAEC) at 0.0011 ug a.i/bee/day. The Lowest Observed Adverse Effect Concentration (LOAEC) was 0.0018 ug a.i/bee/day. A 21-day chronic toxicity test did not show significant effects up to and including the highest concentration tested (0.00183 ug a.i/bee). The highest chronic risk exceedances noted were from uses on citrus, pome fruit, ornamentals and turf.

Data of exposure from imidacloprid seed treatments was not mentioned in the characterization of the risk to terrestrial invertebrates. There was only one mention that the strength of evidence is considered weakest in indicating a colony-level risk to honeybees for the registered use of seed treatments on beans (soybeans were found to be low risk, only beans with seed treatment had risk with weakest evidence) and peanuts.

The EPA's Final Bee Risk Assessment to Support the Registration Review of Imidacloprid states that multiple full field colony level studies were available from the registrant and open literature that examined the effects of various seed treatment, soil and foliar uses of imidacloprid on honey bee colonies. The colony level studies involving seed treatment uses generally did not indicate a treatment related effect, which is consistent with this application method being associated with relatively low residues in pollen and nectar reported from field residue studies.

Freshwater Invertebrates

EPA modeled potential exposure based on likelihood of imidacloprid residues reaching waterbodies, the major routes being runoff and spray drift. The chemical properties of imidacloprid indicate that it is readily soluble in water and that volatilization and bioaccumulation in aquatic organisms are negligible. It is persistent in aquatic environments except in conditions that are favorable for photolysis.

Based on review of data, risks of concern were identified to freshwater invertebrates on both acute and chronic basis. On an acute basis LC50 values for clothianidin were 2.4 times higher than those for imidacloprid and dinotefuran, suggesting clothianidin may be somewhat less toxic on an acute basis. Thiamethoxam LC50 values were 5.6 times higher than those of imidacloprid across all tested species, suggesting that thiamethoxam is potentially the least toxic on an acute basis. On a chronic basis clothianidin and imidacloprid have similar toxicity, and dinotefuran and thiamethoxam being less sensitive.

Estuarine/Marine Invertebrates

Acute risks were not identified for saltwater invertebrates. Chronic risks were identified for all application methods: the highest exceedances being identified from combined uses followed by foliar, soil, then seed treatment.

Fish and Aquatic-Phase Amphibians

The risk assessment noted no direct risks of concern for fish or aquatic phased amphibians from any of the agricultural or non-agricultural uses assessed. The limited number of aquatic incidents reported for imidacloprid indicate a lack of direct adverse impacts on fish. Also, available monitoring data detect concentrations of imidacloprid several orders of magnitude below levels shown to cause adverse effects in fish and aquatic-phase amphibians. However, there is a risk for indirect risks to fish and aquatic-phase amphibians through reduction in their invertebrate food source.

Terrestrial Plants

Imidacloprid was not found to be toxic to terrestrial plants when tested up to its maximum single application rate.

Aquatic Vascular and Non-Vascular Plants

Potential imidacloprid risk to aquatic plants is expected to be low. Aquatic plants were not assessed as available data for vascular and non-vascular aquatic plants indicate toxicity endpoints that are several orders of magnitude above the highest estimated exposure concentrations in surface waters.

Ecological Incidents

Terrestrial Non-Pollinator Incidents

Reviewed the Environmental Information Incident System incident database and there were 16 reported terrestrial organism incidents from 1995-2017. For incidents from foliar applications, the reports primarily concern plant damage to agricultural crops (with "unlikely" or "possible" certainty). For soil and ground applied related incidents, 3 of the 7 involved deaths of birds. There was one reported incident associated with seed treatment application of a large number of birds reported as allegedly dying due to ingestion of imidacloprid-treated wheat seeds. However, a residue analysis did not detect imidacloprid in the birds, so the incident was categorized as "possible".

Pollinator Incidents

Pollinator incidents are reported through the Environmental Information Incident System as well as registrant reports required under FIFRA, local, state, national and international government reports, news reports, and correspondence made to the EPA from homeowners and beekeepers. 10 of 19 incidents originated from agricultural use while others were mainly from residential and commercial use on ornamentals. Of the 10 incidents from agricultural use, half were from soil applications and half were from seed treatment applications.

Based on the reported ecological incidents for bees, a clear association between individual bee or colony losses to imidacloprid was often not indicated, generally due to a lack of a confirmatory residue analysis. Hive monitoring studies across the US and Europe investigated imidacloprid residues in pollen, nectar, bee and wax samples. In these studies Imidacloprid was detected in various matrices, but the frequency of detection was generally below 10%, and where frequency exceeded 10%, the mean values were marginally above the limits of quantitation. Overall, these studies suggest that despite widespread use of imidacloprid on crops through multiple application methods, the magnitude and frequency of detection in hive matrices is relatively low. One explanation for low detection is dilution from non-contaminated sources of pollen and nectar.

Proposed Risk Mitigation Measures

Appendix A: Summary of Proposed Actions for Imidacloprid

Registration Review Case#: 7605
PC Code: 129099
Chemical Type: Insecticide
Chemical Family: Neonicotinoids
Mode of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Crop stage restrictions • General other use restrictions • Spray drift reduction
Occupational Handlers	Aerial and ground application	Dermal and inhalation	Short and intermediate term	Portal of entry effects	• Require additional PPE (e.g., double layer clothing, gloves) • Precautionary statements • Prohibition of on-farm seed treatments for canola, millet, and wheat
Residential post-application (adults and children)	Ground application	Dermal and inhalation	Short and intermediate term	Portal of entry effects	• Use deletion for residential spray applications to turf
Aquatic Invertebrates	Runoff from treated sites	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Spray drift and runoff reduction • Vegetative filter strips • Use deletion for bulb vegetables • Reduce perimeter treatment applications
Birds and Mammals	Residues on ingested seeds	Dietary and ingestion	Acute and chronic	Acute and chronic toxicity	• Clean up spills of treated seeds

One proposed mitigation measure directly related to treated seed addresses an identified human health risk to occupational handlers. Because of the risk, despite maximum PPE, EPA has proposed to prohibiting on-farm imidacloprid seed treatments of canola, millet, and wheat, requiring that treatment be conducted in commercial seed treatment facilities only.

The proposed mitigation measure reducing the maximum allowable annual application rates are for foliar and soil applications of imidacloprid products.

Because risks of concern were identified to birds and small mammals associated with imidacloprid treated seed, the EPA proposed additional label language encouraging the promotion of Best Management Practices (BMPs) and education programs to help inform users about the importance of picking up spilled seed in order to reduce exposure to birds and mammals. The EPA proposed adding the following statements to seed bag tag labels to clean up spills, dispose of excess seed to avoid contamination of water bodies:
"Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)."
"Dispose of all excess treated seed by burying seed away from bodies of water."
"Do not contaminate bodies of water when disposing of planting equipment wash water."

These risk mitigation measures were considered with the understanding of the high benefits associated with seed treatment uses, which through their use, have the potential to reduce overall neonicotinoid exposure and offer a lower overall ecological risk compared to foliar uses.

All supporting documents can be found on the Imidacloprid Registration Review Docket: Regulations.gov

Clothianidin and Thiamethoxam Ecological Risk Summary

U.S. Environmental Protection Agency. (2020, January). Clothianidin and Thiamethoxam Proposed Interim Registration Review Decision. Case Numbers 7620 and 7614, EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581.

Wagman, M., Peck, C., Mroz, R., Koper, C., Garber, K. (2020). Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. U.S. Environmental Protection Agency, EPA-HQ-OPP-2011-0865-1164.

The largest agricultural use for clothianidin and thiamethoxam, in terms of pounds active ingredient applied, has been in the form of seed treatments. Of all the average acres treated with thiamethoxam in the US in a year, 3% of those acres are treated with soil or foliar applications and the remaining 97% acres that receive thiamethoxam do so though seed treatments. This is similar with clothianidin where 1% of the average acres treated with clothianidin per year receive soil and/or foliar applications, and the remaining 99% of the acres have clothianidin seed treatments.

Ecological Risks

Terrestrial Exposures

Both clothianidin and thiamethoxam are water soluble compounds that are unlikely to volatilize in field conditions and are unlikely to bioaccumulate. Thiamethoxam can be applied through aerial and ground methods including sprayers, chemigation, soil drenching, and seed treatments. Clothianidin can be applied with the same methods, but also can be applied as basal bark treatments and spot treatments. For terrestrial wildlife the EPA modeled potential dietary exposure based on consumption of clothianidin and thiamethoxam residues on food items following foliar or soil applications and from possible ingestion of residues on treated seeds. For treated seeds different seed sizes and planting rates could result in a range of exposures.

Overall, acute risks to avian and mammalian species from foliar and soil treatments appear to be low. Exposures from treated seeds result in the highest acute and chronic risks to terrestrial organisms, but these risks vary considerably. For example, a low number of small treated seeds (e.g. lettuce and sugar beets) are required to reach levels of concern for smaller birds and mammals because the surface of these seeds have higher concentrations of active ingredient applied and the smaller seeds are easier to eat. Larger seeds (e.g. corn and soybean) pose far lower risks to birds and mammals because lower concentrations of active ingredient are applied to the seed surface and the seeds are too big for smaller birds and mammals to eat.

For terrestrial invertebrates the primary routes of exposure assessed include contact of bees with spray droplets and ingestion via pollen and nectar. Exposure can also occur from seed treatment dust.

Terrestrial and semi-aquatic (wetland) plant exposure estimates were modeled from a maximum single ground application to turf and/or ornamentals since aerial applications are not prevalent in clothianidin and thiamethoxam use patterns for turf and ornamentals. Risks of clothianidin and thiamethoxam are considered low for terrestrial and semi-aquatic plants.

Mammals

For clothianidin there are no acute risks of concern via foliar applications for mammals of any weight class. Also for foliar applications, there are no chronic mammalian level of concern exceedances on a chronic dietary basis for all application rates, but there were some exceedances for small and medium sized mammals consuming short grass and/or broadleaf plants. For soil applications, acute levels of concern were exceeded for small mammals only at highest application rates which represent residues in fields following soil amendment applications of manure from clothianidin-treated poultry houses. For treated seed applications, risks were modeled for six crops (corn, soybean, cotton, sugar beet, and lettuce). For all sizes of mammals the acute level of concern was exceeded for dose-based exposures to any of the seeds other than soybeans and acute exceedances occur when less than 10% of the mammal's diet consists of lettuce or sugar beet seeds. The chronic level of concern was exceeded for all size classes of mammals consuming any of the assessed treated seed (the highest exceedances for treated lettuce seed).

For thiamethoxam there are no acute or chronic risks of concern identified for mammals from any foliar or soil applications. There are potential acute risks of concern for mammals from certain thiamethoxam seed treatments, with sugar beet being the only crop assessed where there was an acute level of concern exceedance. There were chronic risk exceedances for corn, cotton, and sugar beet. There were no chronic level of concern exceedances for soybean.

Although there are potential acute risks of concern for clothianidin (all seeds evaluated except soybean) and thiamethoxam (sugar beet) treated seeds, the uncertainties and variables impacting potential risks to mammals (e.g. how far apart and number of seeds available, amount of cover provided by field conditions, depth seeds are incorporated into soil, life stage of mammal consuming seed, and size of the mammal) limit the likelihood that an animal will eat acutely toxic levels of treated seed. Overall, for clothianidin and thiamethoxam, potential risk is associated with chronic consumption of treated seeds, where the estimated number of seeds required for chronic effects is low.

Birds, Reptiles and Terrestrial-Phase Amphibians

Clothianidin is characterized as moderately toxic to birds on an acute oral exposure basis and practically nontoxic on a subacute dietary exposure basis. Thiamethoxam is characterized as slightly toxic to birds on an acute oral exposure basis and practically nontoxic on a subacute dietary exposure basis. Birds are used as surrogates for potential risks to terrestrial-phase amphibians and reptiles.

For clothianidin seed treatment exposures expected risks are highest for small birds and decrease with increase body weight. For small and medium birds there are acute dose-based species level of concern exceedances for all crops assessed. For large birds there are acute dose-based species level of concern exceedances for birds feeding on corn, sugar beets and lettuce. Acute exceedances occur when less than 10% of the animal's diet consists of treated lettuce or sugar beet seeds. There is chronic level of concern exceedance for birds consuming any of the assessed treated seeds.

For thiamethoxam treated seed potential exposures there were acute dose-based exceedances for all crops except soybean, and chronic exceedances for all modeled crops and size classes.

The same uncertainties and variables explained with mammalian exposure risk apply for birds. The size of the seed and size of the bird dictate the size of the risk. For example, large birds can consume a wider range of treated seeds, but would need to consume a greater number of seeds to experience negative

health effects. Large birds foraging in corn fields would have to have 99% of their diet be treated seed in order to reach the acute level of concern. Given the availability of other seed sources, this may only be likely in instances of treated seed spillage than through normal foraging behavior.

Terrestrial Invertebrates

In general the extensive literature and data review over multiple years conducted by the EPA found that foliar and/or soil applications of clothianidin and thiamethoxam to honeybee attractive crops which are not harvested prior to bloom result in a potential for colony-level risk and risks of neonicotinoid seed treatments to honeybee colonies are considered low. Residues from seed treatment were all below the NOAEC for honeybee colony effects, indicating a low risk on a colony level.

Potential off-field dietary risks to individual bees exposed to foliar spray drift extend over 1,000 feet from the edge of the treated field. Soil applications are assumed to have a low off-field risk because of low potential to drift. There is potential exposure from off-site movement of abraded seed dust during planting of treated seeds. This concern is supported by multiple bee kill incidents for both clothianidin and thiamethoxam that are associated with the planting of treated seed, in particular corn.

The majority of the available valid full field studies for clothianidin and thiamethoxam evaluated effects to honeybees from seed treatments of various crops. There are uncertainties and limitations to these studies including: uncertainty in exposure and the origin of the pollen and nectar brought back to the hives; high variability in the data collected (including in control hives); and lack of replication. Therefore these studies were considered supplemental or qualitative because of these limitations. As studies move from individual bee effects to colony effects, all the factors influencing declines in bee health (pesticides; pests [varroa/hive beetles]; disease [viral, fungal, bacteria]; nutrition [suitably diverse sources of pollen/nectar]; bee management practices; weather; queen condition) become more relevant. In some of the studies factors like weather and nutritional deficits were likely more dominant and were reflected in the control data.

For clothianidin, there were several registrant-submitted studies in which honeybee colonies were placed in or adjacent to fields that were planted with either treated corn or treated canola seeds. No significant differences between the treated and control sites were reported for colony development or health. Another study (Pohorecka, 2013) showed that colonies located in seed treated corn fields had a transient increase in the amount of brood compared to control (which is not necessarily an adverse effect). In a study with seed treated oilseed rape (Rundolf et al, 2014) there were no significant differences in the number of adult bees between the treated and control fields.

For thiamethoxam, there were five studies that evaluated exposure after treatment of sunflower seed which reported transient effects on honeybee mortality (mostly after application), with no treatment related effects on brood number or adult bee foraging activity. In a study conducted using treated oilseed rape seeds increased honeybee mortality was observed. In another treated oilseed rape seeds, no clear treatment-related trends were observed for the measured endpoints (i.e. lifespan, foraging homing activity) from the treated seed (Thompson et al, 2016). A study that examined sowing operations with treated corn seeds (0.0065 lb a.i./A) observed mortality in the control hives and the treatment hives were similar the day of planting, but transient increases in bee mortality occurred immediately after sowing in the thiamethoxam treatment group. However, except for the day of

sowing, the control hives had higher mortality on all other days compared to treatment hives (Tremolada et al, 2010).

For bumble bee colony studies for seed treatments, one study (Cutler and Scott-Dupree, 2014) placed colonies adjacent to clothianidin and/or thiamethoxam seed treated conventional fields or adjacent to reported organic corn fields. The number of workers was significantly reduced (down 25%) in the neonicotinoid treated fields compared to the organic fields. Worker and drone weights were also reduced by more than 25% in the colonies adjacent to the conventional fields, but these results were not significant ($p>0.05$). Another study observed that bumble bee colonies placed adjacent to oilseed rape seed fields (seed treated with clothianidin) had a significant decrease in the mean number of queen and worker/male cocoons per colony and a decreasing rate of growth (Rundolf et al, 2014). In a study where bumble bees were exposed to flowering rape grown from thiamethoxam treated seed, no significant effects were observed in the treatment group compared to the control. A 2015 study examined development of bumble bee colonies where bees had foraged for 5 weeks on flowering winter oilseed rape grown from thiamethoxam treated seed. They reported an increase in colony mass and foraging activity as well as a higher number of queens, workers, eggs, larvae, but a lower number of drones compared to control.

One study looked at effects on wild bees and mason bees adjacent to oilseed rape fields with clothianidin treated seed. During flowering the number of wild solitary bees per flower was reduced in treated field and field borders. Mason bee colonies placed adjacent to the oilseed rape fields had reduced median number of brood tubes (6/8 females in control and 0/8 females in treated group started to build brood cells) (Rundolf et al, 2014).

The strongest evidence for supporting colony-level risk resulting from application was for foliar and/or soil applications in crops like cotton, cucurbits, orchard crops, and ornamentals. Moderate evidence of colony-level risk to honey bees was identified for the registered uses of clothianidin and thiamethoxam including foliar and/or soil applications to residential lawns, ornamental, and honey bee attractive fruiting vegetables. The only seed treatment use that had evidence (weakest) for colony-level risk to honey bees was clothianidin seed treatment on turmeric.

Terrestrial Plants

No risks of concern to terrestrial plants are identified for either clothianidin or thiamethoxam.

Freshwater Fish, Estuarine/Marine Fish and Aquatic-Phase Amphibians

On an acute basis, clothianidin is characterized as practically non-toxic to freshwater fish and no more than slightly toxic to estuarine/marine fish. Thiamethoxam is classified as practically non-toxic to fish on an acute exposure basis. Both chemicals had minor effects on fish growth after chronic exposure, but overall no risks of concern to fish or aquatic-phase amphibians.

Freshwater Invertebrates

Risks of concern were identified for all four neonicotinoid insecticides (clothianidin, thiamethoxam, imidacloprid, and dinotefuran) to freshwater invertebrates on both an acute and chronic basis.

On an acute basis across all tested species, LC50 values for dinotefuran were similar, but slightly higher than imidacloprid. On average, LC50 values for clothianidin were 2.4 times higher than those of

imidacloprid and dinotefuran, suggesting that clothianidin may be relatively less acutely toxic than imidacloprid and dinotefuran. Thiamethoxam's LC50 values were 5.6 times higher than those of imidacloprid across all tested species, which suggests that thiamethoxam is potentially the least acutely toxic.

On a chronic basis clothianidin and imidacloprid have similar toxicities, where as based on midge data (generally more sensitive than mayflies), dinotefuran and thiamethoxam are relatively less toxic than imidacloprid and clothianidin. Overall, thiamethoxam was found to have lower exceedances to aquatic invertebrates than the other three nitroguanidine neonicotinoids.

Estuarine/Marine Invertebrates

For clothianidin seed treatments there are no acute level of concern exceedances except for use on rice, and no chronic level of concern exceedances except for use on rice. None of the saltwater invertebrate acute or chronic levels of concern were exceeded for thiamethoxam uses with foliar, soil or seed treatments.

Aquatic Vascular and Non-Vascular Plants

There are no risks of concern to aquatic plants from either clothianidin or thiamethoxam.

Ecological Incidents

Pollinator Incidents

There were 54 ecological incidents affecting bees in the US associated with the use of clothianidin that were reported to the EPA between 2010 and 2018. The legality of the use was not determined in 34 of the reported incidents, and a single case was considered a misuse. There were 27 incidents where entire honey bee colonies were affected that were associated with corn, however there was insufficient evidence to correlate clothianidin or the other neonicotinoids to these incidents. All but 4 of these 27 incidents occurred prior to 2015.

From 2002 – 2018, there were 22 incidents reported in the US for honeybees in association with agricultural uses of thiamethoxam. Seven of the incidents with certainties of highly probable or possible have been reported in association with corn planting in Indiana, Minnesota, and Illinois. Observations included hundreds to thousands of dead bees and bees with behavioral impacts.

Aquatic and Non-Pollinator Terrestrial Incidents

There were a handful of incidents reporting plant crop damage for clothianidin or thiamethoxam, and one incident involving birds. However, these incidents were also associated with other chemicals. Although there were limited or no incident reports received by the agency for clothianidin or thiamethoxam related to terrestrial wildlife and/or plants, the absence of reported incidents should not be construed as the absence of incidents. Incident reports for non-target organisms typically provide information only on mortality events and plant damage incidents. Except for phytotoxic effects in terrestrial plants, sublethal effects, such as reduced growth or impaired reproduction, are rarely reported.

Proposed Risk Mitigation Measures

Table 1: Summary of Proposed Actions for Clothianidin

Registration Review Case#: 7620
PC Code: 044309
Chemical Type: insecticide
Chemical Family: nitroguanidine-substituted neonicotinoid
[Mode or Mechanism (for herbicides)] of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Occupational Handlers	Aerial and ground application, treated seeds	Dermal and inhalation	Short and intermediate term	Systemic effects	• Require additional PPE (*e.g.*, gloves and respirators) • Precautionary statements • Use Restrictions
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Crop stage restrictions • Use deletions • Use restrictions • Buffers • Spray drift reduction
Aquatic Invertebrates	Runoff from treated sites	Contact and ingestion	Acute and chronic	Acute and chronic toxicity	• Spray drift reduction • Prevent runoff • Vegetative filter strips • Reduce perimeter treatment applications
Birds and Mammals	Residues on ingested seeds	Dietary and ingestion	Acute and chronic	Acute and chronic toxicity	• Clean up spills of treated seeds

Table 2: Summary of Proposed Actions for Thiamethoxam

Registration Review Case#: 7614
PC Code: 060109
Chemical Type: insecticide
Chemical Family: nitroguanidine-substituted neonicotinoid
[Mode or Mechanism (for herbicides)] of Action: Nicotinic acetylcholine receptor (NACHR) competitive modulators

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Occupational Handlers	Aerial and ground application	Dermal and inhalation	Short and intermediate term	Systemic effects	• Require additional PPE (gloves and respirators) • Precautionary statements • Require closed loading for seed treatment • Cancel equipment/application uses
Pollinators	Residues on treated site	Ingestion and contact	Acute and chronic	Acute and chronic toxicity	• Reduce application rates • Bloom restrictions • Use deletions • Use restrictions • Buffers • Spray drift reduction
Aquatic Invertebrates	Runoff from treated sites	Contact and ingestion	Acute and chronic	Acute and chronic toxicity	• Spray drift reduction • Prevent runoff • Vegetative filter strips • Reduce perimeter treatment applications
Birds and Mammals	Residues on ingested seeds	Dietary and ingestion	Acute and chronic	Acute and chronic toxicity	• Clean up spills of treated seeds

One clothianidin seed treatment identified human health risk of concern was to occupational handlers performing several activities (e.g. loading, applying, sewing, bagging, etc). Therefore EPA proposed the use of a respirator and updated glove statements for all handlers of clothianidin treated corn seed.

Another proposed mitigation measure addresses the identified human health risk of concern to occupational handlers from the use of thiamethoxam for corn seed treatments in commercial facilities even with maximum PPE. Therefore to protect the health of workers involved in commercial seed treatments of corn with thiamethoxam, the EPA proposed that a closed loading system be required for all thiamethoxam corn seed treatments in commercial facilities. EPA identified no risks of concern for corn seed treatment uses of thiamethoxam in the case of on-farm seed treatments.

Because risks of concern were identified to birds and small mammals associated with clothianidin and/or thiamethoxam treated seed, the EPA proposed additional label language encouraging the promotion of Best Management Practices (BMPs) and education programs to help inform users about the importance of picking up spilled seed in order to reduce exposure to birds and mammals. The EPA proposed adding the following statements to seed bag tag labels to clean up spills, dispose of excess seed to avoid contamination of water bodies:
"Cover or collect treated seeds spilled during loading and planting in areas (such as in row ends)."
"Dispose of all excess treated seed by burying seed away from bodies of water."
"Do not contaminate bodies of water when disposing of planting equipment wash water."
Although these advisory statements were developed with the primary intention of reducing the exposure of birds and mammals to neonicotinoid-treated seed, adding these statements to labels is also expected to benefit aquatic organisms by reducing neonicotinoid loading in aquatic systems.

These risk mitigation measures were considered with the understanding of the high benefits associated with seed treatment uses, which through their use, have the potential to reduce overall neonicotinoid exposure and offer a lower overall ecological risk compared to foliar uses.

In addition to establishing both advisory and compulsory language for product labels, EPA's registration review provides an opportunity to inform stakeholders and the general public about opportunities to minimize potential ecological risks and promote pollinator health more generally. Since treated seed is most likely to become available to birds and mammals through accidental spills, excess unplanted seed on the edges of the field, shallow planted seed, and the improper disposal of treated seed, an effective method to reduce exposure would be encouraging growers to take additional care when planting treated seed to ensure any exposed seed is retrieved. The American Seed Trade Organization has published a guide to help educate applicators on practices to help reduce potential risks to the environment from seed treatments.

All supporting documents can be found on the Thiamethoxam Registration Review Docket: Regulations.gov and the Clothianidin Registration Review Docket: Regulations.gov