

Health Canada Technical Brief - Consultations on the Neonicotinoid Pesticides - Clothianidin and Thiamethoxam: Proposed Pollinator Decisions

Presentation - January 23, 2018

Webinar - Questions and Answers

The following questions were received during the webinar via the chat function – in addition several questions were sent via email either prior to, during, or following the webinar.

Fruit/Orchard Crop Questions

Question 1

There has been a longstanding use of insecticides post bloom in orchards without an issue if used correctly. I see NO evidence to support the elimination of these actives for post bloom uses in orchards.

The fruiting vegetable uses are important too. It could become even more critical that thiamethoxam be allowed on transplant tomatoes if we indeed lose the protection afforded currently by imidacloprid for Colorado potato beetle control with a planting water or in furrow treatment at planting time. So much hinges on the outcome for imidacloprid. Note that just like for potatoes, tomatoes are NOT favoured by bees either.

PMRA Response:

In the case of the risk assessment for orchard crops and post-bloom applications, the exposure estimates were focussed on measured residues in pollen and nectar of flowers present in the spring after application the previous fall. These residues came from application post-bloom to cherry, plum, peach, apple and almond for the two actives. Although the majority of residues in nectar were at low levels the next season in spring blooms, pollen residues were higher. And they were at levels higher than potential effects from colony feeding studies. So that is to say, if honey bees and bumble bees were feeding on these levels of residues, there may be colony level effects. For thiamethoxam and clothianidin, some of the colony level effects expected for honey bees include: decreased number of adult bees and effects to queens (at 6.6 ppb dosing in pollen); decreased drone survival and sperm viability (at 6.3 ppb dosing in pollen); reduced queen emergence and egg production (at 4.5 ppb dosing in pollen); change in flight pattern and reduction in age to last foraging flight (at 4.9 ppb dosing in

pollen). For non-*Apis* bees, there was also decreased worker production and longevity, decreased gyne and male production, and decreased queen survival at 4.9 ppb dosing in pollen. However, it is noted that acute mortality effects are not expected, and therefore it is unlikely growers would have directly observed the types of effects identified in the colony feeding studies.

There were no available field studies examining whether or not there were colony effects in orchards during the spring blooming period as a result of post-bloom application the previous season. Rather, the risk assessment was based on higher tier studies comparing measured field residues in pollen and nectar from post-bloom application to effect endpoints from colony feeding studies for *Apis* and non-*Apis* bees.

If additional scientific information is available that would affect the risk assessment for orchard crops, this may be submitted during the comment period.

In the case of fruiting vegetables, again, the risk assessment indicated high residues in the pollen of tomato plants from soil application (up to about 200 ppb) which is higher than the level that led to colony effects for both honey bees and non-*Apis* bees. In addition, the PMRA had some higher tier data indicating effects from soil application to tomato plants. Therefore, the risk assessment was based on available higher tier data.

With respect to crop attractiveness, from the information available to PMRA, it is recognized that tomatoes are not as attractive as other crops, such as orchard crops or berries, and they do only provide a source of pollen and not nectar. While honeybees do not typically utilize tomatoes and other fruiting vegetables, other non-*Apis* bees will forage on these crops, both of which are currently considered more attractive than crops such as potatoes.

Question 2

It was indicated they found neonicotinoids in pollen the next year. Was there actual field data that also precluded its use on orchard crops pre-bloom that year? That use is currently labelled. In fact what tree species was involved since both almond and orange were listed. I can tell you that pollinators are Not in APPPC crops after bloom. Since fruit bud formation for the next year's crop would not occur yet at our use time I cannot believe the assumption made.

Please get a definitive science study to verify?

PMRA Response:

As the question appears focused on foliar applications in orchard crops, the response is specific to this crop grouping.

Thiamethoxam and clothianidin are both currently registered for foliar application to pome fruit and stone fruit crops. Residue information specific to the registered use pattern for orchard crops was used in the risk assessment for both clothianidin and thiamethoxam where available (e.g., field studies which determined the measured residues in both pollen and nectar from various pome fruit and stone fruit crops, with either pre-bloom or post-bloom application timing). Thiamethoxam and clothianidin are systemic, and when applied as a foliar spray, residues can be taken up by the plant and move throughout the plant into pollen in nectar. Some residue studies examined pre-bloom application timing where pollen and nectar residues were measured in flowers blooming the same season as the pre-bloom application. Other residue studies examined post-bloom application timing where pollen and nectar residues were measured in the flowers blooming the following spring. Where crop specific residue information was not available, residue information from other crops was used based on how similar the crop type, application rate and application timing in the study design were in comparison to the registered use pattern.

Specifically for clothianidin:

Clothianidin is currently registered for post-bloom applications in pome fruit and pre- and post-bloom applications in stone fruit. Measured field residues of clothianidin in pollen and nectar following post-bloom foliar applications in apple trees and peach trees were available and used in the risk assessment to characterize risk to bees from post-bloom foliar applications in pome fruit and stone fruit. In addition, residue information from post-bloom applications in almond were also considered in a weight-of-evidence approach in the risk assessment even though this crop is not specific to the registered use pattern; almond was considered relevant to provide surrogate information based on the crop type, application rate and timing in the study design. While no crop specific residue information was available to assess pre-bloom foliar applications on stone fruit, residue information from pre-bloom applications on grape and cotton were available and used in the risk assessment, considering the relevance of the application timing in the study to the registered use pattern for stone fruit.

Based on the clothianidin risk assessment, considering all relevant residue information and effect endpoints, it was concluded that residues from pre- and post-bloom applications in orchard crops pose a potential risk to bees. For pre- and post-bloom applications, the risk to bees is not at the time of application, but rather, results from exposure to residues that have moved into the tree after application and are subsequently translocated to the flower and pollen/nectar at the time of blooming. Because residues remain in the tree for a significant period of time, exposure to bees can occur if the pesticide is applied pre-bloom and can also occur if the pesticide is applied post bloom.

Specifically for thiamethoxam:

Thiamethoxam is currently registered for pre-bloom applications for apples and cherry; during bloom applications for cherry, and post-bloom applications for apples, cherries and pears. It is noted that provincial regulations (such as the *Bees Act* of Ontario) may further restrict application timing, such as not allowing application during bloom for orchard crops. Measured field residues of thiamethoxam (and clothianidin as a transformation product) in pollen and nectar following post-bloom applications in cherry trees, peach trees, and plum trees were available and used in the risk assessment to characterize risk to bees from post-bloom foliar applications in pome fruit and stone fruit. There were also pre-bloom residue data available for apples, which were also considered in the risk assessment.

Based on the thiamethoxam risk assessment considering all relevant residue information and effect endpoints, it was concluded that residues from pre- and post-bloom applications (and during bloom applications) in orchard crops pose a potential risk to bees. As described above for clothianidin, for pre- and post-bloom applications, the risk to bees is not at the time of application, but rather, results from exposure to thiamethoxam residues that move into the tree and are subsequently translocated to the pollen and/or nectar when the crop is blooming and when bees are expected to be foraging. Because residues remain in the tree for a significant period of time, exposure to bees can occur if the pesticide is applied pre-bloom and can also occur if the pesticide is applied post bloom.

Question 3

Do you have specific studies that outline what bees are found in given crops, AND at what time of the growing season? It seems obvious that while residues may be found, if bees are not found there, what is the risk?

PMRA Response:

We considered crop specific pollinator exposure potential in the risk assessment for each crop or crop grouping recognizing that the main exposure period for bees is when plants are flowering. Therefore for applications to crops that are harvested before bloom or do not produce blooms that are attractive to bees, no pollinator exposure is expected, as bees are not expected to be found there. For other crops, the PMRA used a number of sources for the crop categorization. We considered:

- The EFSA 2013 document, Guidance on the risk assessment of plant protection products on bees (*Apis*, *Bombus* and solitary bees) which looked at the attractiveness of pollen and/or nectar for HB, BB and solitary bees by using data for visitation on those crops.

- Data compiled from Dr. Peter Kevan from the University of Guelph (CANPOLIN) which looked at Canadian crop plants and their pollination requirements, managed and non-managed pollinator crops in Canada, pesticide management in Canada and their effects on pollinators, and honey and pollen production of plants including if they provide a major or minor source of pollen or nectar to *Apis* and non-*Apis* bees.
- The United States Department of Agriculture (USDA) 2017 document, *Attractiveness of Agricultural crops to pollinating bees for collection of nectar and/or pollen*, which also looks at the degree of visitation of honey bees, bumble bees and solitary bees for pollen and nectar on a large number of crops. The document also reports, for each crop, if bees are required for pollination, or if the crop uses managed pollinators.
- We also considered Canadian-relevant information for crop acreage.
- All of these documents considered whether crops are harvested before bloom, or if the crop is used for seed production.

PMRA has further work underway to develop Canadian-specific information on pollinator crop attractiveness and agricultural practices affecting pollinator exposure in crops. We also welcome any additional information that stakeholders may like to submit that could affect our classification of pollinator exposure potential for specific crops.

Additionally, it is reiterated that thiamethoxam and clothianidin are systemic, and when applied as a foliar spray, residues can be taken up by the plant and move throughout the plant into pollen and nectar. This can happen even when application occurs when no blooms are present. If a product is not applied during bloom, but is applied either pre-bloom or post-bloom, residues can be taken up by the plant, remain in the plant, and then when blooms are formed, residues may move into pollen and nectar. Typically, the closer to the blooming period that the product is applied, the greater the residues levels in pollen and nectar. For example, pre-bloom application close to bloom time (e.g., 1 – 2 weeks pre-bloom) may result in fairly high residues in pollen and nectar. Post-bloom application to perennial crops (such as orchard crops) may result in residues persisting in the plant and moving through the plant into pollen and nectar of flowers forming the following spring; these residues would typically be lower than residues resulting from a pre-bloom application closer to bloom time. The PMRA relied on actual measured residues in pollen and nectar following various application timings, rates, and in various crops.

Therefore the potential exposure to bees is only considered during bloom time when the bees are in the crop; but exposure to residues in blooms can result from application when bees are not there due to the systemic nature and persistence of these pesticides.

Question 4

Of course bees are attracted when in bloom, but how does post-bloom application affect bees if they are not there?

PMRA Response:

Consideration of post-bloom application and potential effect on bees is relevant for bee-attractive perennial crops, such as orchard crops and some berry crops, and is not relevant to seasonal crops where the whole plant is harvested at the end of the season. For post-bloom applications to perennial crops such as pome fruit, data show that there is systemic uptake of the active ingredient in the plant and movement through the plant. Data also show that residues are present in the pollen and nectar of developing flowers the following season as a result of post-bloom applications the previous season.

In other words, applications made post-bloom to perennial crops are not expected to affect bees until the following season, when bees foraging on blooms may be exposed to the residues that have moved into pollen and nectar of developing flowers.

Question 5

There needs to be a separation of effects - the purported residues the next year could have been from legal uses pre-bloom that year.

PMRA Response:

Field-measured residues of clothianidin and thiamethoxam in both pollen and nectar were available from studies designed specifically to investigate post-bloom application scenarios in perennial crops. The studies were designed so that no additional applications with neonicotinoids were applied to the test site. The residue information from these studies were used to specifically address the potential risk to bees following post-bloom foliar applications in pome fruit and stone fruit by comparing measured residues in pollen and nectar to exposure levels where individual and colony level effects are expected to occur. Other residue information was considered to assess the risk from pre-bloom applications. Overall, there is a risk to bees from both pre-bloom and post-bloom applications of clothianidin and thiamethoxam in perennial crops that are attractive to bees. The risk to bees is expected to be greater from pre-bloom applications because pre-bloom applications are made closer to bloom time, and residues are higher because there is less time for them to dissipate as compared to post-bloom application.

Question 6

Do you actually have proof that these residues are due to use the previous year?

PMRA Response:

Residue studies were designed to test specific application scenarios. To ensure that the residues detected in samples are from the test substance under the specific application scenario, a variety of measures may be taken in designing the study. These measures may include, for example:

- selecting test sites where the application history is known and the use of the test item in the past has been limited. For instance, selecting sites where the test item has not been used at the test site for at least two years prior to the study.

- analysing soil samples before the test item has been applied to ensure that no residues are detected

- using a control site and taking samples from various matrices (soil, leaves, flowers, bees) to look for contamination from other sources.

Question 7

Bee exposure studies were done on orchard trees pre-bloom... were there any complimentary studies done post-bloom, when bees were no longer foraging?

PMRA Response:

To further clarify, the risk to bees from post-bloom applications in orchard crops is from exposure to residues in pollen from blossoms that are produced the following spring. We reviewed a number of residue studies which specifically tested this application scenario where applications were made post-bloom and residues were measured in the pollen and nectar of orchard blossoms the following season. Based on a comparison of the highest mean measured residues in pollen and nectar derived from these studies, with colony level effects endpoints derived from colony feeding studies, it was determined that the residue levels in pollen were above the level of concern for colony level effects to bees. No risk to bees from post-bloom applications was identified based on residue levels in nectar for clothianidin and thiamethoxam. For both chemicals, no higher tier semi-field (tunnel) or field studies were available for characterizing effects to bees following post-bloom applications based on exposure of bees to residues in pollen and nectar the following season. Further information on the effects of post-bloom applications in orchard crops may be submitted during the comment period, if available.

Question 8

Tree Fruit Growers have many questions regarding the risk identified for post-bloom application to orchard trees. Questions have been received such as the following: "I would still like clarification on how exactly the residues last in a tree for over 6 months

and are then mobilized into pollen, which is not vascularized (clothianadin is xylem mobile) to such an extent that it is toxic to bees when the residual activity of the a.i. is 10 days for target insects. This is really bothering me. And it is VERY important because the tree fruit growers are requesting post bloom applications but PMRA is suggesting that the residues carry over to toxic levels in pollen the following year, and that even post bloom applications are detrimental.

Maybe I'm over thinking this, but I would really like to understand what is going on from a biological point of view.”

PMRA Response:

When clothianidin or thiamethoxam are applied to orchard crops by foliar application methods, the insecticide is readily taken up by the leaves of treated plants and moved upwards inside the plant through the xylem to provide control against chewing and sucking insect pests at target sites. Once inside the plant, clothianidin and thiamethoxam also move into non-target sites including the pollen and nectar of developing flowers, as demonstrated through many residue studies across multiple plant types. Some of the residue studies considered for the pollinator risk assessment measured clothianidin or thiamethoxam concentrations in pollen and nectar in flowers following pre-bloom or post-bloom applications in a variety of orchard crops or other crops considered relevant to orchard use. Concentrations in pollen and nectar following pre-bloom applications were generally higher than concentrations following post-bloom applications, indicating that there may be some degradation between the time of application and bloom. Although there was evidence of degradation over time, the measured concentrations in pollen/nectar under both pre-bloom and post-bloom application scenarios were determined to be at a level that is a potential risk to pollinators. The risk characterization for orchard crops was based on a comparison of mean measured residue levels in pollen or nectar compared with colony level effect endpoints derived from colony feeding studies where bees were fed contaminated pollen/nectar. For pre-bloom applications, a risk to bees was indicated based on residue levels in both pollen and nectar whereas for post-bloom applications, a risk to bees was indicated based on residues in pollen only. No risk was indicated based on residue levels in nectar following post-bloom applications. Additional higher tier field studies were also considered in the risk assessment for thiamethoxam.

Overall, the detection of residues in pollen and nectar following post-bloom applications in studies specifically designed to test this application scenario confirms that clothianidin and thiamethoxam do carry over in the plant from one growing season to the next. While the mechanism for this process was not the focus of this risk assessment, considering that the residue studies controlled for contamination from other sources, the

pesticide is likely being stored in plant tissue over winter and then moves into the developing flowers the next growing season.

General comment from PMRA regarding the Tree Fruit risk assessment: The PMRA will re-examine the post-bloom application residue data for tree-fruit for the neonicotinoids and determine whether further refinements can be made to the risk assessment. Any additional available scientific data relevant to the risk assessment or risk mitigation for orchard trees, including exposure, toxicity, or value information, should be provided to the PMRA during the comment period.

Question 9

Could you clarify the proposed mitigation for foliar application of thiamethoxam in cranberries?

PMRA Response:

The PMRA is proposing to remove pre-bloom and during bloom foliar application to cranberries.

Question 10

Actara is the only insecticide registered to control cranberry weevils in cranberry which is a major pest in Quebec. In one of the research on cranberry you considered in your evaluation, Actara was applied three times right before bloom. Then pollen and nectar samples were taken 5, 10 and 15 days after the last application. The concentration of thiamethoxam was relatively high. By decreasing the number of possible application to one and by insuring a period of time of 2 weeks between the application and bloom, could it become an acceptable mitigation?

PMRA Response:

The PMRA considered the data that was available to the Agency. There was a risk from foliar use of cranberry based on the Tier I, Tier I refined and also the Tier II colony feeding study assessment. From pre-bloom applications, the residues were as high as 2227 ppb in pollen and 2353 ppb in nectar. These residues far exceed colony level endpoints for thiamethoxam for species such as honey bees and bumble bees. In addition, in cranberries there were high residues of both thiamethoxam and clothianidin, from the transformation of thiamethoxam to clothianidin. If additional residue information from different timing and numbers of application (etc.) were available, PMRA would consider that data in the final assessment.

Questions Related to Incident Reporting

Question 11

What has PMRA done to promote the reporting of incidents or to provide feedback to beekeepers who report incidents?

PMRA Response:

In 2006, the Incident Reporting Regulations were brought into force, which requires registrants to report incidents that they are made aware of. In addition, since that time the PMRA has actively encouraged the voluntary reporting of incident reports by the general public. In 2012, following the reporting of the first bee incident reports, the PMRA has actively encouraged beekeepers to report effects observed in their yards through appropriate channels, which typically includes contacting the provincial apiculturists, who then contact PMRA if the incident is thought to be related to pesticides. Promotion of incident reporting and how to report incidents have been done using various means such as trade shows, provincial apicultural organizations, provincial governments, presentations with the beekeeper community and on our website. Feedback on the bee incidents to the beekeepers has occurred in various ways which included open communication with beekeepers who reported incidents, annually providing the analytical results of samples collected from their bee yards, presentations to the beekeeping community as well as published documents that are available on our website.

Question 12

Will you correct your faulty conclusions based on incidents to note that you are not measuring incidents but in fact you are measuring reported incidents?

PMRA Response:

PMRA refers to 'incident reports' in our reviews and presentations. The PMRA can only evaluate what is reported. In accordance with the [Pest Control Products Incident Reporting Regulations](#), pesticide registrants and applicants are required to report all incidents associated with their products to the PMRA that they are aware of. In addition, anyone can also submit a voluntary pesticide incident the PMRA.

Question 13

Many issues such as queen failures that threaten the viability of the colony would not be termed incidents and therefore may be considered not reportable.

PMRA Response:

The current guidance in the Incident Reporting Regulations for honey bees includes death or abnormal behavioural effects. Queen failure can be reported to the PMRA if it is suspected of being the result of pesticide exposure. The PMRA has received this type of information in reported bee incidents.

Question 14

Therefore would you agree that your metric of incidents is faulty data and not in any way a reliable indicator leading to false conclusions relating to the safety of neonicotinoids on treated seeds?

PMRA Response:

The PMRA considers incident reports as a line of evidence in our conclusions for the potential risk to pollinators. In addition, we have considered many other lines of evidence including the results of the Tier I assessment (laboratory data for adults and larvae from acute and chronic exposure), Tier II assessment (colony feeding studies with whole colonies of both *Apis* and non-*Apis* bees, as well as residues from field trials examining exposure), Tier II tunnel studies and also Tier III field studies (which both examine bee colonies following exposure to pesticides from label applications).

For dust-exposure during planting of treated seed, incident reports were the primary indicator that there was a potential risk to bees from dust generated during planting of treated corn and soybean seed. However, in addition to extensive evaluation of the incidents, additional information, such as research on effects on bees resulting from dust-exposure during planting of treated corn seed, was also considered, and supported the incident evaluations.

Incident reports are an important post-registration activity to identify potential concerns with use of a pesticide. For example, incident reports could identify a need for additional mitigation, or improved label precautions or restrictions. As with all incident reports, however, only those incident reports received by the PMRA can be evaluated. Reporting of incidents is strongly encouraged by the PMRA, including reporting of bee mortality incidents.

Additional information may be found in the responses above.

Question 15

In Slide 29 and 31 it appears that residues from Soy are above the acceptable threshold. Why is no action being taken to restrict the use of neonicotinoids as a seed treatment for Soy?

PMRA Response:

On slides 29 and 31, the residues from pre-bloom FOLIAR application exceed colony level endpoints for pollen and nectar. Considering potential exposure to other legume vegetables, there was a risk identified, and the PMRA is proposing that foliar uses are restricted (not allowed) before and during bloom. Soybean residues from TREATED SEED were much lower (maximum of 2.34 ppb in nectar and 1.71 ppb in anther).

Other Questions

Question 16

Please bring us up to date on PMRA's evaluation of neonicotinoid impact on aquatic invertebrates. The first evaluation recommended the phase out of the use of imidacloprid? What is the status of this proposed recommendation and when will recommendations be forthcoming for both Clothianidin and Thiamethoxam?

PMRA Response:

PMRA is currently conducting special reviews for clothianidin and thiamethoxam focussing on aquatic insects. This includes reviewing a large amount of data, including data that has been submitted to the Agency over the past growing season with respect to environmental concentrations in water across the country. In addition, as part of the imidacloprid comment period, additional monitoring information from aquatic environments across Canada has been submitted and is under review. The PMRA expects to publish proposed decisions for clothianidin and thiamethoxam special reviews in July 2018 and a final decision for imidacloprid by the end of 2018. These reports will consider all the available information that has been submitted to the PMRA.

Question 17

Recent studies e.g. "Chronic exposure to neonicotinoids reduces honey bee health near corn crops", N. Tsvetkov, O. Samson-Robert, K. Sood, H. S. Patel, D. A. Malena, P. H. Gajiwala, P. Maciukiewicz, V. Fournier and A. Zayed concluded that pollen from nontarget plants represents the primary route of exposure to neonicotinoids. However, PMRA appears to be measuring risk based on potential contact of pollinators with treated target crops. Did PMRA's evaluation measure exposure from non-target crops in proximity to neonicotinoid applications? If so where is this methodology described and what was the nature of the exposure and results from pollen sampling?

Did your evaluation measure exposure from translocation to non-target crops outside of the immediate field area?

PMRA Response:

Some higher tier studies did include exposure to non-target off field crops. There were seed treatment field studies with treated corn adjacent to fields with pollinator attractive crops, whereby hives were exposed during, and after planting. Other studies (examining effects from seed treated corn) analyzed pollen samples from bees and determined high levels of other types of forage, such as *trifolium repens*, *sedum*, *centaruea jacea* etc., indicating bees were foraging on non-target plants as well. Overall, these studies resulted in a lack of colony level effects.

It is noted that the recent Tsvetkov study was considered in the risk assessment.

Please see Appendix 5 from the respective PRVDs for further details.

Question 18

Did your study evaluate possible synergistic effects of fungicides commonly mixed or applied together with neonicotinoids as reported in other studies?

PMRA Response:

When the data was available, the PMRA did look at the potential effects of fungicides. There was some lower tier study information available examining effects of fungicides and neonicotinoids. In the case of seed treatments, some of the higher tier studies used formulations with fungicides in them.

It is noted that the proposed removal of certain foliar and soil uses for both clothianidin and thiamethoxam would reduce the concurrent pollinator exposure of neonicotinoids and fungicides.

Question 19

Were your field studies limited only to treated Canola seeds?

PMRA Response:

No. Specifically for seed treatment applications, we had effects field studies (Tier III studies) with treated corn, treated rape, treated canola, and treated sunflowers. Some of the studies were conducted in Europe at rates higher than those registered in Canada, which would result in conservatism in the risk assessment. For effects field studies (Tier III studies) for foliar applications, we had studies with phacelia, orchard crops, cucumber, and melon.

Question 20

Has PMRA reviewed Ontario sampling data showing the broad extent of exposure of pollinators to neonicotinoids throughout Ontario as well as PMRA own data on the ubiquity of neonicotinoids in aquatic environments and therefore evaluated the impact of this amount of neonicotinoids applied in consecutive years and the ensuing risks to pollinators and our environment?

PMRA Response:

Water sampling data relevant to pollinators (such as puddles in agricultural fields, and other water sources that may be used by bees) were considered in the pollinator assessment. The majority of data regarding the levels of neonicotinoids in the aquatic environment from surface waters, however, do not play into the pollinator risk assessment. All of the information available for levels in the aquatic environment (included those in Ontario) will be considered in the aquatic risk assessments for the neonicotinoids.

Question 21

Any recommendation to reduce the widespread prophylactic use of neonics?

PMRA Response:

Sustainable pest management is a key goal of the PMRA. Beyond its mandate to prevent unacceptable risks to people and the environment from the use of pesticide products, the PMRA supports various stakeholders in the development of sustainable pest management strategies, including the development and promotion of Integrated Pest Management (IPM). These strategies allow each user to be more involved in their pest management future by having increased access to the best reduced risk practices available.

Specifically for seed treatment use of neonicotinoids, the PMRA has published the Pollinator Protection and Responsible Use of Treated Seed - Best Management Practices. This document further promotes the practice of IPM when choosing seed treatments as outlined in the following excerpt from the BMP document:

Practicing integrated pest management (IPM) is essential for sustainable pest control. This approach can include cultural practices to discourage pests (for example, crop rotation), correct identification of the pest problem and risk factors.

- As part of an IPM program, evaluate fields and determine if soil pests are present at threshold levels or if fields have a high pest risk before making

a decision to use treated seed. (Under Related Information see provincial websites for soil pest information.)

- Use insecticide treated seed only where necessary.
- If insecticide treatment is required, use the lowest effective seed treatment rate.
- Most seed companies can accommodate orders for non-insecticide treated seed. Talk to your seed dealer about timing and options.

Refer to the following link for further information:

https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/cps-spc/alt_formats/pdf/pubs/pest/fact-fiche/pollinator-protection-pollinistateurs/treated_seed-semences_traitees-eng.pdf

Question 22

Page 18: "If a crop harvested before bloom is grown for seed production in Canada, then consideration of the above pollinator exposure characteristics should be used to determine pollinator exposure when grown for seed." Please use example of a crop grown for seed, but harvested before bloom?

PMRA Response:

There are quite a few crops that are harvested before bloom in Canada. Crops in Crop Group 1: Root Vegetables (e.g., beets, carrots and other root crops except potatoes and sweet potatoes), 3: Bulb Vegetables (e.g., onions), 4: Leafy Vegetables (e.g., lettuce, spinach, celery) and 5: Brassica Leafy Vegetables (e.g., broccoli) are all harvested before bloom in Canada. If these crops were grown for seed production then they would be left to bloom and there are varying degrees of attractiveness to bees depending on the crop. However, crops in these crop groups are not typically grown for seed production in Canada.

Question 23

PMRA proposed some uses being removed, is there an evaluation in progress for the alternatives that may be used by crop growers?

Also, could you send us the name and title of the presenters?

PMRA Response:

PMRA generally does the assessment of alternatives for the final decision, therefore the alternatives assessment will be the next piece that PMRA will be assessing prior to

making the final decision. This information will help us determine the phase out schedule for uses that are being proposed for removal. We do ask for any feedback on the availability of alternatives during the public consultation period.

The presenters for this webinar are:

Scott Kirby, M.Sc. Director General, Environmental Assessment Directorate

Connie Hart, PhD. Senior Science Advisor, Environmental Assessment Directorate

Barbara Martinovic Barrett, M.Sc. Senior Evaluation Officer, Environmental Assessment Directorate

Nicole Lauro, M.Sc. Senior Evaluation Officer, Environmental Assessment Directorate

Mélanie Whiteside, M.Sc. A/Section Head, Environmental Assessment Directorate

Tina Singal, Re-evaluation Co-ordinator, Value Assessment and Re-evaluation Management Directorate

Question 24

Please define rotational crops?

PMRA Response:

Rotational crops are crops that are grown in succession in the same field and are typically different from the crop grown the preceding season (for instance a field plot planted with potato one year is rotated with a legume crop the next year).

We had a number of rotational crops that were used in the studies that tended to be bee attractive crops including clover, corn, mustard, rapeseed, Phacelia zucchini, field beans and sunflower. The idea behind the rotational crop studies is that they were planting bee attractive crops after other treated crops had been planted in the soil.

Question 25

Given PMRA is eliminating some uses of these neonics, how are you going to weigh this when estimating load into environment while estimating risk to aquatic insects?

PMRA Response:

At this time the removal of uses of these neonicotinoids is not a final decision. In addition, when uses are removed from a label there is a phase out period; as such, the PMRA will be proceeding with the aquatic risk assessment with all currently registered uses.

Question 26

What does an acceptable risk to bees mean? Can you further explain the amount of risk that is acceptable?

PMRA Response:

Acceptable risk to bees means that no population level harm will result from exposure to or use of the product taking into account current and proposed conditions of registration. As indicated in the presentation, the risk assessment for clothianidin and thiamethoxam determined that there are varying degrees of exposure and effects on bees depending on the use. Some current uses of clothianidin and thiamethoxam are not expected to affect bees while some uses may pose a risk of concern to bees. Where a potential for risk was identified, risk mitigation measures are proposed to minimize potential exposure to bees, as necessary. When clothianidin and thiamethoxam are used in accordance with these new proposed risk reduction measures, the reduced environmental exposure is deemed adequate and risks to bees are considered to be acceptable.

Question 27

What is the level of acceptable risk? Can you provide any more context onto what this means, such as the probability of colony recovery?

PMRA Response:

The determination of acceptability of risk for each use followed the tiered pollinator risk assessment framework. In the case of clothianidin and thiamethoxam this was based on the available data we had, including individual effect endpoints derived from laboratory studies and colony level effect endpoints derived from colony feeding studies compared to measured residues in pollen and nectar under various application scenarios. In addition higher tier tunnel and field studies were also considered where available. The effects considered, particularly for higher tier colony level studies, are those that were considered likely to affect the survival, growth or reproduction of Apis and non-Apis bees. Some of these studies included exposure of bees to either thiamethoxam and/or clothianidin followed by long observation periods (which followed potential recovery of the hives (i.e. number of adults, pupae, larvae, eggs, honey storage etc.) after exposure). Some of these studies included an overwintering component to see how colonies were doing the following spring.

Question 28

Did the study look into long term accumulation of the pesticides in the soil? If so, what are the risks from accumulation of the pesticides in the soil from seed treatments?

PMRA Response:

We had fate data looking at the long term accumulation of pesticides in the soil, and therefore we do have an idea of what levels the pesticide builds up to in the soil. As well, we had a number of studies on rotational crops. In the rotational crop studies, untreated crops were planted in soils where in the previous growing season a seed treated crop had been planted. This allowed us to look at the residues that remained in the soil that were then taken up by untreated plants and transferred to the pollen and nectar of developing flowers. From these studies it was determined that the residue levels in the pollen and nectar of untreated rotational crops are typically below the levels that are expected to cause effects in bees.

Question 29

What evidence is available to demonstrate the effectiveness of label information as a risk management measure?

PMRA Response:

It is a contravention of the *Pest Control Products Act* (PCPA) to use a pest control product contrary to the registered label. Health Canada inspectors monitor and enforce compliance with the PCPA, including inspections of pesticide users and other regulated parties. Additionally, provincial and territorial pesticide legislation requires certain users to complete certification programs to use pest control products. Please consult the provincial or territorial pesticide regulatory department for details on their certification requirements.

With respect to the effectiveness of implemented mitigation measures, there are data to support that certain mitigation measures reduce exposure. Some higher tier studies are conducted with varying mitigation, which can demonstrate effectiveness of the proposed label mitigation. As an example, where pre-bloom application is proposed, systemic chemicals may be applied before bloom in tunnels according to label direction, and then hives are placed in the tunnels during bloom. With no other forage available, the bees are forced to feed on the treated crop. Depending on the study design, if there are no effects observed in these studies, there may be limited exposure and limited potential risk demonstrated from application before bloom. As another example, effectiveness of mitigation which allows application only in the evening can be examined through studies. Studies conducted either in the field or in tunnels according to label direction (to apply in the evening when most bees are not foraging) may be conducted in order to establish a lack of colony effects following evening application.

In addition, the incident reporting program can provide information on effectiveness of label information, in some cases. For example, if use of a product results in incident

reports, the risk can be further evaluated and additional mitigation may need to be implemented. Any available incident reports are also considered in the PMRAs risk assessments.

Question 30

Did studies look at the maximum residues that occur on pollen and nectar and their impacts on pollinators? The mean may not capture the full impact of exposure.

PMRA Response:

The PMRA considers the maximum pollen and/or nectar residue value for the acute risk assessment as there was considerable spatial and temporal variability in the available residue data, and considers the highest daily mean residue values in pollen and nectar for the chronic risk assessment as bees in the Tier I chronic studies are typically exposed to chemicals over a prolonged period of time (3-4 days for larvae and 10 days for adults). An example of the highest daily mean would be if you had 5 days of sampling with 5 sampling events on each day – we would take the highest value on each day and take the mean of those values. Therefore, it is still considered a conservative estimate of exposure in the risk assessment.

Question 31

Do these proposed mitigation measures apply to greenhouses that supply bedding plants to consumers?

PMRA Response:

Yes. The mitigation measures apply to greenhouse plants that are treated in the greenhouse and then planted outside.

Question 32

What are the crops included in "rotational crops"?

PMRA Response:

We had a number of rotational crops that were used in the studies that tended to be bee attractive crops including clover, corn, mustard, rapeseed, Phacelia zucchini, field beans and sunflower. So the idea behind the rotational crop studies is that they were planting bee attractive crops after other treated crops had been planted in the soil.

Question 33

What relevant data will be considered for the squash bee risk assessment?

PMRA Response:

The PMRA will consider data that was used in the current pollinator risk assessment, as well as any additional relevant information that may become available (prior to completion of the assessment).

Question 34

The pollen colony level effect endpoints would pass under the Tier 1 assessment. Does this invalidate the pollen component of the Tier 1 assessment? In other words crops that only produce pollen may pass Tier 1 but would fail at Tier 2.

PMRA Response:

The pollen colony level effects endpoints are considered in the Tier II colony level assessment, and the potential risk would depend on the residues found in pollen, and also the colony level endpoint. We do recognize that there is consumption of only pollen for some plants, which can reduce the overall consumption of chemicals compared to plants that produce both pollen and nectar, again, depending on the level of residues.

In the case of thiamethoxam, the Tier I refined acute and chronic level of concern were both exceeded for tomato, based on nurse bees (which consume more pollen) and larvae. The Tier II colony level assessment, which considered the pollen colony level effect endpoint, also resulted in potential risk (i.e. tomato pollen residues were higher than colony endpoints).

Question 35

Why can you not force the companies to make information submitted for supporting registration open to the public? How can the process be transparent if the public cannot see what they are claiming in their supporting studies? Specifically: what is the half life of thiamethoxam and clothianidin in the soils of PEI?

PMRA Response:

All data submitted by the registrant are available for viewing by the public in the reading room. In addition all endpoints relevant to the risk assessment are published in our consultation documents. With respect to the specific question about the half-lives of thiamethoxam and clothianidin in the soils of PEI, the half-lives determined are not specific to provinces, and are meant to be representative of soils in Canada.

Question 36

When you say that Tier 3 studies are the most important, and now have a new Tier 3 study, done right here in Ontario and Quebec that shows synergistic effects from neonicotinoids and fungicides, an effect which is NOT included in your looked at criteria, but obviously of high importance to the pollinators (especially since it is on label use to even mix the insecticide with a fungicide in the case of potatoes anyway with which I am most familiar) why are you not re-evaluating in the light of this?

PMRA Response:

All of the studies provide important information. It is the degree of realism that increases with higher tier studies, meaning that in Tier III studies, bees are placed in, or near fields under actual use conditions in accordance with label directions. As with all studies, there are strengths and limitations to Tier III studies as well.

With respect to fungicides, some of the higher tier studies for seed treatments included fungicides in the formulation, and few colony effects were observed in these studies. In some cases, the rates of application for the seed treatments were 4 x higher than Canadian registered rates, and thus considered conservative. All of the available studies are considered in a weight of evidence approach, and not the results of only one study. We also considered laboratory data which examined the potential effects of neonicotinoids in combination with fungicides.

When available, the PMRA will review data on the potential toxicity of exposure to both fungicides and insecticides, and will mitigate as required. The PMRA also reviews potential toxicity of end-use product formulations.

It is noted that the proposed removal of certain foliar and soil uses for both clothianidin and thiamethoxam would reduce the concurrent pollinator exposure of neonicotinoids and fungicides.

With respect to pollinator exposure from application to potatoes, the current risk assessment identifies potato as a low exposure crop. If there is a specific study (conducted in Ontario/Quebec) you think was not included or accurately represented in the PRVD, you are encouraged to submit it for review and consideration for the final assessment. If you are unsure whether it was in fact considered in the review, please consult Appendix 5 of the PRVD for study summaries.