Re-evaluation Decision RVD2019-04

Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation

Final Decision

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a re-evaluation of all agricultural and ornamental uses for thiamethoxam and its associated end-use products, specifically to assess the risk to pollinators, such as honey bees, bumble bees, and solitary bees. This re-evaluation assessed the potential risk to pollinators in light of international updates to the pollinator risk assessment framework. Extensive information obtained from published literature, as well as data received from registrants, was considered. Health Canada applied internationally accepted risk assessment methods as well as current risk management approaches and policies. In addition to the pollinator risk assessment, the value of the active ingredient to the various use sectors was assessed.

Products containing thiamethoxam are sold as sprays to be applied to plants and to bare soil. Thiamethoxam is also used as a coating on crop seeds to prevent insects from eating the seeds when they are planted in the ground and to protect the plants grown from treated seeds. Some uses result in thiamethoxam being taken up by the plants from the soil or through their leaves, where it then moves into parts of the flower where nectar and pollen are produced. Because bees use nectar and pollen as their primary sources of food, bees may be exposed to thiamethoxam (and its breakdown products) when they visit certain flowers to collect pollen and nectar. Bees may also be accidentally sprayed or collect water containing thiamethoxam. Currently registered products containing thiamethoxam that are subject to this re-evaluation are listed in Appendix I.

This document presents the final regulatory decision[1] for the pollinator re-evaluation of thiamethoxam, including the required risk mitigation measures to protect bees. Most products containing thiamethoxam are subject to this regulatory decision. The proposed regulatory decision published in PRVD2017-24, *Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation*,[2] has undergone a 90-day consultation that ended on 19 March 2018.

Health Canada received comments mostly relating to the value and pollinator risk assessments. These comments are summarized in Appendix II along with the responses by Health Canada. The comments did not result in a change to the risk assessments. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2017-24. All of the data that were used as the basis for the proposed re-evaluation decision are published in PRVD2017-24. Further data used in the final re-evaluation decision, including data received during the consultation period, are listed in Appendix IV.

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

[2] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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Outcome of Science Evaluation

The risk assessment, conducted according to the *Guidance for Assessing Pesticide Risks to Bees*,[3] determined that there are varying degrees of effects on bees. Some current uses of thiamethoxam are not expected to affect bees. For some uses, mitigation measures (in other words, changes to the conditions of registration) are required to minimize potential exposure to bees. Mitigation measures include changes to the use pattern and label improvements. When thiamethoxam is used in accordance with these new risk reduction measures, the reduced environmental exposure is considered adequate and risks are acceptable. Label statements informing users of the potential for toxicity to pollinators are required on product labels. For other uses, risks to pollinators were not found to be acceptable; therefore, these uses are cancelled.

Regulatory Decision for Thiamethoxam

Health Canada has completed the pollinator re-evaluation of thiamethoxam. Under the authority of the *Pest Control Products Act*, Health Canada has determined that, with required amendments, continued registration of products containing thiamethoxam is acceptable; however, however, certain uses of thiamethoxam are cancelled to address potential risks of concern to pollinators. An evaluation of available scientific information found that some uses of thiamethoxam products meet current standards for protection of pollinators when used according to the conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix III, are required for all end-use products. No additional data are requested.

Risk Mitigation Measures to Protect Pollinators

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. As a result of this re-evaluation of thiamethoxam, further risk mitigation measures for product labels are required.

Certain crops are highly attractive to bees when their flowers are in bloom. Since large numbers of bees are attracted to these crops when they are in bloom and based on an assessment of the risks to bees, the application of pesticides containing thiamethoxam can lead to effects that may have an impact on the survival of bee colonies or solitary bee species.

In order to protect pollinators, **Health Canada is cancelling the following uses of thiamethoxam**:

- Foliar and soil application to ornamental crops that will result in pollinator exposure (in other words, are planted outdoors and are attractive to pollinators)
- Soil application to berry crops, cucurbit crops and fruiting vegetables, and
- Foliar application to orchard trees.

[3] United States Environmental Protection Agency (USEPA), Health Canada, California Department of Pesticide Regulation. USEPA Pollinator Risk Assessment Guidance webpage, https://www.epa.gov/pollinator-protection/pollinator -risk-assessment-guidance, accessed March 2019.

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Due to the attractiveness of some crops to bees and based on an assessment of the risks to bees, application of pesticides containing thiamethoxam before and during crop flowering can lead to effects that may have an impact on the survival of bee colonies or solitary bee species.

In order to protect pollinators, **Health Canada is changing the timing of application for the following uses of thiamethoxam**

The following crops cannot be sprayed before or during bloom:

- Foliar application to legume and outdoor fruiting vegetables, and
- Foliar application to berry crops (with renovation required for woody berries).

The following crops cannot be sprayed during bloom:

- Foliar application to sweet potato and potato

To minimize bee exposure to dust during planting of treated seed, **additional label statements are required for the following use**:

- Seed treatment of cereal and legume crops.

Thiamethoxam has value to crop production in Canada as an insecticide to control a variety of insect pests when applied as a foliar or soil application, as well as a seed treatment. An assessment of the registered products determined a lack of alternatives for the following pests and sites:

- Brown marmorated stink bug on apple, crab apple, pear, and oriental pear;
- Brown marmorated stink bug and obscure root weevil on bushberries;
- Black vine weevil, cranberry weevil and strawberry root weevil on low growing berries (except strawberry and lowbush blueberry); and
- Brown marmorated stink bug and black vine weevils on outdoor ornamentals.

The additional risk mitigation measures described above will be implemented over a 24-month period. The risks identified are not considered imminent because they are not expected to cause irreversible harm over this period. Potential effects include sublethal effects on colonies or solitary bees, but affected pollinator populations are expected to recover following implementation of the additional restrictions which will reduce exposure. Moreover, recovery is expected because risks to pollinators are geographically limited to areas where these products are applied and areas adjacent to application sites. The presence of unaffected solitary bees, bumble bees, and honey bees in areas where products are not being used will further facilitate recovery since unaffected bees in the environment can move back into areas where effects may have occurred. Overall, risk to pollinators is acceptable over the time period required to implement the mitigation measures.

As a result of this decision, growers will be required to change their pest management practices. Pesticides have extensive and precise instructions and often require specialized application and safety equipment and training. This transition period will allow for an orderly and safe

implementation of these new restrictions, and should reduce the risk of product misuse or the improper disposal of products as users switch to alternatives, where required. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses as a result of a re-evaluation (Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*) and with the practice of other international regulators.

A small subset of uses were found to lack alternatives for the management of certain serious pests (the invasive brown marmorated stink bug and certain weevils) on a very few crops present in limited geographical areas of Canada. As a result, the implementation of the re-evaluation decision for these uses will be delayed for an additional year to allow growers to find pest management solutions. During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing which will further reduce pollinator exposure. The risks to pollinators are therefore considered acceptable for an additional year for this small subset of uses.

Next Steps

To comply with this decision, taking into account Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing thiamethoxam that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[4] regarding this decision on thiamethoxam within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[4] As per subsection 35(1) of the *Pest Control Products Act*.

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Science Evaluation Update

1.0 Revised Environmental Risk Assessment

The initial pollinator risk assessment for thiamethoxam was provided in PRVD2017-24, *Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation*. Comments were received from the registrant, stakeholders and the general public on a range of issues including exposure, endpoint selection, risk assessment approach, incident reporting and risk mitigation. Detailed responses to the comments received on the pollinator assessment are provided in Appendix II.

The overall risk conclusions based on consideration of all information received during the consultation process remain consistent with those presented in PRVD2017-24.

1.1 Updates to the Environmental Risk Assessment

During the consultation period of PRVD2017-24, the registrant submitted additional residue data for foliar application to blueberries, and foliar and soil application to a variety of ornamental crops. These residues were used to refine the exposure in the risk assessment. An additional long-term colony feeding study for both thiamethoxam and clothianidin was submitted for consideration of colony level effects from sucrose dosing; and three field studies where red mason bees were exposed to fields grown from treated seed were also submitted. From the open literature, a study published by Bishop et al., 2018 was also considered in the risk assessment for blueberries.

The registrant also submitted alternative options for considering data, and proposed alternative mitigation; these comments and responses are found in Appendix II Response to Comments.

Some of the comments from Canadian Universities and public interest groups included additional open literature references for consideration in the risk assessment. A number of the open literature references were already considered in the pollinator risk assessment in PRVD2017-24. These studies included Iwasa et al., 2004; Alburaki et al., 2016 and 2017; Tsvetkov et al., 2017; and Woodcock et al., 2017. As such, the response for inclusion of these studies into the risk assessment and how these studies were used in the risk assessment is located in the response to comments. There were also open literature references submitted by commenters which were not incorporated in the pollinator risk assessment in PRVD2017-23 which are further discussed below.

A number of the open literature studies submitted by commenters were relevant for pollinator exposure to off-field plants following movement of neonicotinoid residues after planting of treated seed (Botias et al., 2015 and 2016; Krupke et al., 2017; Long and Krupke, 2016; and Steward et al., 2014). Although the off-field risk to pollinators was considered in PRVD2017-24, these additional reference endpoints are included in the Science Update and an additional risk assessment is conducted with the residues from these new studies and colony level endpoints. As well, additional information submitted by the registrant (PMRA 2842660), and from the open literature (Schaafsma et al., 2015) was also considered for off-field movement of thiamethoxam

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andclothianidin following the planting of treated seeds. The updated risk assessment conclusions are similar to those previously identified in the PRVD2017-24. There is an overall lack of colony level impacts expected for *Apis* and non-*Apis* bees when considering the residues in off-field plants.

A number of additional studies from the open literature which were not incorporated in the PRVD2017-24 were also submitted by commenters (Alford et al., 2017; Goulson, 2013; Hladik et al., 2017; Hladik et al., 2018; Krupke et al., 2017; Long et al., 2016; McCurdy et al., 2017). These studies are discussed in Appendix II Comments and Responses in Section 1.5 Risk assessment approach, Section 1.5.2 Risk Assessment outcome and additional literature.

1.1.1 Post-bloom orchard foliar applications

A large number of comments were received regarding foliar applications in orchard crops. The comments highlighted the importance of post-bloom foliar applications of thiamethoxam in orchard crops for pest and resistance management of key pests and requested that the PMRA re-assess the decision to remove post-bloom applications in orchard crops. Comments were also received from the registrant, requesting that Health Canada re-examine post-bloom residue data. The following outlines the method for the risk assessment and then the conclusions of this re-assessment.

Summary of the method for the Tier I refined risk assessment

As summarized in PRVD2017-24 the Tier I refined assessment compared laboratory endpoints to residues in orchard crops (in pollen and nectar). The assessment considered endpoints from thiamethoxam, and also clothianidin because thiamethoxam transforms to clothianidin which has a similar toxicity profile, and in some cases residues of clothianidin were high following application of thiamethoxam. These endpoints (for both adults and larvae) were then compared to residues of thiamethoxam and clothianidin, and included consideration of consumption values for various castes of bees. Please refer to PRVD2017-24 (page 8-9) for a summary.

Summary of the method for the Tier II refined – Colony feeding study assessment

As summarized in PRVD2017-24, the Tier II refined assessment compared colony feeding studies endpoints to residues in orchard crops (in pollen and nectar). The colony feeding study endpoints included dosing studies with *Apis* and non-*Apis* bees to either thiamethoxam and/or clothianidin in predominantly sucrose and/or pollen patties. This risk assessment also considers the results of the 2016 colony feeding studies submitted during the consultation period for both thiamethoxam and clothianidin (from dosing with sucrose solution). The following is a summary of all available colony feeding study endpoints, including the new studies.

Summary of colony level feeding study endpoints

Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
2014 Thiamethoxam colony feeding study (no overwintering results) Open **2586559**	Sugar solution 5 weeks	Honey bee Whole colony	NOAEC: **25.3 µg c.e./kg sucrose** LOAEC: **34 µg c.e./kg sucrose**	Number of adults, pupae, total brood, total live bees and pollen storage **Limitations** There was high overwintering mortality for control colonies. In CCAs (colony condition assessment) occurring post-exposure and pre-overwintering treatment, effects may have been masked when colonies declined in preparation for overwintering. There was a lack of dosing exposure from contaminated pollen/bee bread. Only nectar dosing was considered.
2016 Thiamethoxam colony feeding study (overwintering results) Open **2821253** **New study**	Sugar solution 5 weeks	Honey bee Whole colony	NOAEC: 34.8 µg c.e./kg sucrose LOAEC: 69.6 µg c.e. /kg sucrose	Brood, larval and pupae coverage, pollen storage in pre-overwintering CCAs (colony condition assessments). This study had low control mortality (before and after overwintering) and therefore provided useful overwintering information. **Limitations** Exposure is from nectar dosing. Hive detections from food sources other than thiamethoxam and its metabolite were detected during the exposure period and post-exposure period (although it is noted that the study was conducted in a low agricultural area to reduce foraging on other chemicals).
2014 Clothianidin colony feeding study (no overwintering results) Open **2610259**	Sugar solution 5 weeks	Honey bee Whole colony	NOAEC: **19 µg clothianidin/kg sucrose** LOAEC: **35.6 µg clothianidin/kg sucrose**	Number of adults, pupae, total brood, total live bees and pollen storage **Limitations** There was high overwintering mortality for control colonies. There was a lack of dosing exposure from contaminated pollen/bee bread. Only nectar dosing was considered.

Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
2016 Clothianidin colony feeding study (overwintering results) Open **2820119** **New study**	Sugar solution 5 weeks	Honey bee Whole colony	NOAEC: 19 µg clothianidin/kg sucrose LOAEC: 29 µg clothianidin/kg sucrose	Effects to pollen storage and brood were observed in a number of pre-overwintering CCAs (colony condition assessments). Colony survival was generally high across control and treatment groups with the exception of the 75 ppb treatment group where only 25% of colonies survived (highest treatment level tested). With respect to colony survival, the LOAEC for this study is reported as 75ppb and the NOAEC as 37 ppb. **Limitations** Exposure is from nectar dosing only. Other pesticides, including clothianidin detected in some pollen and uncapped nectar samples from untreated monitoring hives during the exposure period and post-exposure period (although it is noted that the study was conducted in a low agricultural area to reduce exposure to other chemicals). The source of clothianidin could be from outside sources or as a result from robbing within apiaries.
Thiamethoxam and clothianidin colony feeding study Open **Sandrock et al., 2014**	Pollen patties (40% sucrose and 55% pollen and 5% yeast) 6.5 weeks	Honey bee Colony	LOAEC: **6.6 µg c.e. /kg** (5.31 µg thiamethoxam /kg × 0.856 + 2.05 µg clothianidin/kg pollen patty)	Short-term effects (lower numbers of adult bees, brood and stored honey) Long-term effects (60% of queens in the treatment group were superseded within a year). No difference was observed in the fall observation, just prior to over wintering, indicating that the effects determined at CCA2 (second colony condition assessment) had recovered to the level of the control. However, after overwintering, 90% of control hives swarmed, whereas only 20% of treatment hives swarmed. **Limitations** Only one concentration was tested. No details were provided about the forage surrounding the test apiary location. The bees were stated to have come from an area characterized by intense agriculture yet there was no screen of potential pesticide exposure before feeding began.

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Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				Less pollen was collected by treated bees (as observed from the pollen traps), which may have led to some brood effects. It is noted that pollen traps were only in place during the exposure phase, and observations continued until after overwintering.
Thiamethoxam and clothianidin Open **Straub et al., 2016**	Pollen paste (10% honey and 30% powder sugar and 60% pollen) ~7.1 weeks	Honey bee queen and drone feeding study	LOAEC: **6.3 µg c.e./kg** (4.9 µg thiamethoxam /kg × 0.856 + 2.1 µg clothianidin/kg pollen patty	Declining drone survival/longevity for up to 14 days (the point of drone sexual maturity), an increase in median drone mortality, a decrease in sperm viability and the total amount of living sperm **Limitations** The amount of the pollen paste "patties" consumed was not quantified. There appeared to be large variation in the control data for the sperm assessments. Effects could be attributed to both queen and drone pollen paste exposure through exposed workers who facilitated the queen and drone brood feeding. Only one concentration was tested. The study authors did not measure thiamethoxam and clothianidin residues in bee matrices relevant to the queen (i.e., royal jelly).
Thiamethoxam and clothianidin colony feeding study Open **Williams et al., 2015**	Pollen patties (3:1 pollen: honey) 5.1 weeks	Honey bee One day old larvae were transplanted into queenless nuclei that had contaminated pollen patties.	LOAEC: **4.5 µg c.e./kg** (4.16 µg thiamethoxam /kg × 0.856 + 0.96 µg clothianidin/kg)	By 4 weeks after queens emergence 25% fewer neonicotinoid-exposed queens were alive compared to controls. Surviving queens had fewer eggs (34% less compared to controls), stored less spermatozoa (20%) and had lower proportion of stored living sperm (9%). Neonicotinoid-exposed queens also had significantly larger ovaries than controls by 6.8%. **Limitations** Only one concentration was tested. The amount of pollen patty consumed was not quantified and the authors noted that the bees never consumed the entire daily allotment. There was no mention if sucrose syrup was provided so the Agency review has assumed that nectar was provided via foraging. Pollen and honey used in the pollen patties were bee-collected from non-intensive agricultural areas in Switzerland. Dose

Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				verification was conducted on the pollen patties but residues from in-hive storage products (i.e., honey, bee bread) was not conducted. The study did not include long-term observations of the queen. It is unknown how these queen effects would relate to field colony observations.
Thiamethoxam Closed **Elston et al., 2013**	Sucrose solution and pollen 28 days	Bumble bees Colony	LOAEC: **8.56 µg c.e./kg pollen** (dose of 10 µg thiamethoxam /kg)	Reduced nest building activity, increased uncoordinated movement, and extensive grooming, and fewer eggs and no larvae produced
			LOAEC: **0.856 µg c.e./kg pollen** (dose of 1 µg thiamethoxam/kg)	Decreased honey water consumption. **Limitations** The results for the 1 µg/kg treatment for the number of eggs and larvae was not significant but with a value of p=0.051. Worker weights were measured but not stated in article. The mean consumption values for the controls were not stated. Bees had a limited alternate food source, therefore, exposure only to contaminated food.
Thiamethoxam and clothianidin Closed **Fauser-Misslin et al., 2014**	Sucrose solution and pollen patty 9 weeks	Bumble bees Colony (with parasite)	LOAEC: **4.9 µg c.e./kg** (4 ppb thiamethoxam + 1.5 ppb clothianidin)	Decreased worker production, shorter worker longevity, and decreased sucrose water and pollen collection (only during Weeks 6-9). Less gyne and male production, and queens had a decreased survival when also exposed to a parasite. **Limitations** Dose verification was not conducted. Bees were maintained in a nest attached to a foraging box for 63 days, which may have caused stress on the bees since the space available for flight was severely limited. Bees had a limited alternate food source, therefore, exposure only to contaminated food.
Thiamethoxam Closed **Stanley and Raine 2017**	Sucrose solution 27 days	Bumble bees Mature colony	NOAEC: **8.56 ppb c.e.** (10 ppb thiamethoxam) Study also dosed with 2.4 ppb thiamexthoxam	No effects on colony weight gain, number of males, workers or queens. Colonies exposed to 2.05 ppb c.e. produced larger males. **Limitations**

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Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
			(equivalent to 2.05 ppb c.e.)	The tests were started with relative larger colonies that were at a late stage in the colony development cycle, which may affect the ability of the colony to withstand more stress. Colony conditions were examined once at 13 days after the end of the exposure period, and brood effects were not examined during the study. Bees had a limited alternate food source since this was a closed feeding study.
Thiamethoxam Closed **Baron et al., 2017**	Sucrose solution 14 days	Bumble bees Queen (with parasitic infection and varying lengths of hibernation)	LOAEC: **2.05 ppb c.e.** (2.4 ppb thiamethoxam)	Lower colony initiation (26%) from treatment after hibernation. Hibernation duration alone also had an impact on egg laying, as did female weight. No effect on production of adult offspring. **Limitations** The study was conducted under laboratory conditions, including mating, hibernation, and pesticide exposure, which are different from field conditions. There are challenges with extrapolating endpoints from the laboratory feeding study to the field using mathematical models, and some of the assumptions of the model. It is unclear if bees were provided with fresh food daily. There were effects on hibernation from queen weight. Tested hibernation period in the study may be different to what may be seen in Canada.
Thiamethoxam Closed **Laycock et al., 2014**	Sucrose solution (multiple doses) 17 days	Bumble bees Individual adults	NOAEC: **13.4 µg c.e./kg** (15.7 µg thiamethoxam /kg) LOAEC**: 39 µg c.e./kg** (33.4 µg thiamethoxam /kg)	Impaired feeding on syrup and pollen and brood production. **Limitations** This study only considered the effects of dietary thiamethoxam in nectar and not in pollen. The exposure duration was only done for 17 days which may not be

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Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				realistic as bumblebees forage on mass-flowering crops throughout their bloom and this could extend for more than a month. Bees had a limited alternate food source since this was a closed feeding study.
Thiamethoxam Closed **Mommaerts et al., 2010**	Sucrose solution (multiple doses) Exposed after nest construction and larval production 11 weeks	Bumble bees Colony	NOAEC: **85.6 ppb c.e.** (100 ppb thiamethoxam)	Decreased drone production. **Limitations** It is not clear if bees were fed *ad libitum*, or a specific amount per week. Our review has presumed *ad libitum*. The results of the control fed mico-colonies were not discussed. There was a large amount of stress on these test organisms due to limited foraging over 11 weeks within a plastic box. The use of workers to test reproductive effects may not be representative of queen behaviour. The trial with foraging only tested one dose.
Thiamethoxam Closed **Stanley et al., 2015**	Sucrose solution (multiple doses) 4 weeks	Bumble bees Colony	LOAEC: **2.05 ppb c.e.** (2.4 ppb thiamethoxam)	Workers were slower to learn and showed impaired 3-hour memory after 3–4 weeks of chronic exposure at a level of 2.4 ppb. Minimal effects observed on learning and memory from acute exposure. **Limitations** The exposure scenario presented in this study is conservative since it only considered contaminated sugar exposure. Bumble bees were allowed to forage outside in an untreated apple orchard. Nothing was noted by the authors about the quality of the hives prior to the test.
Thiamethoxam Open **Stanley et al. 2015; Stanley et al., 2016**	Sucrose solution 9-10 days	Bumble bees Colony	LOAEC: **8.56 ppb c.e.** (10 ppb thiamethoxam)	Change in preference for flowers, increased pollen collection and faster foraging. **Limitations** The exact calendar dates of when the exposure period occurred were not clearly stated in the article. The data were collected in an outdoor flight arena in which bees had to fly less than 50 cm to access their first flower, representing a relatively simple environment with little need to navigate, locate forage resources

Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				or avoid predators. It was presumed by the authors and the Agency reviewers that the control bees had not yet fully learned how to forage to the best of their ability, and so may not yet have been 'accurate' foragers during their initial foraging bout. Nothing was noted by the authors about the quality of the hives prior to the test.
Thiamethoxam closed/open **Stanley et al., 2016**	Sucrose solution 6 weeks	Bumble bees Colony	LOAEC: **2.05 ppb c.e.** (2.4 ppb thiamethoxam)	Change in foraging patterns (longer foraging bouts and less pollen collection). Increased return to colonies. No effect on colony size. **Limitations** The volume of sugar solution was not reported. Large confidence intervals may have led to lower statistical power. The distance between the control and treated colonies was not reported. In some instances in the summary of results the study author indicated effects to certain parameters despite of lack of statistical significance, which led to contradictory statements (i.e., the number of dead bees). These would be considered as 'trends' by the Agency reviewer. The study assessed potential effects from oral consumption of sucrose solution only, not pollen. Bees were excluded from analysis if they had no prior foraging experience, if they drifted between colonies and if they took an excessively long time to return home. This resulted in fewer bees in the pesticide colonies for the 2 km homing experiment.
Thiamethoxam and clothiandin Closed **Sandrock et al., 2014**	Sucrose solution 4 months	Red mason bee Colony	LOAEC: **2.9 ppb c.e.** (2.87 ppb thiamethoxam plus 0.45 ppb clothianidin)	Significant reductions in brood cell number, offspring development (approximately 50% less hatched), and sex ratio (biased towards males). No significant effects for female body weight, longevity or offspring body weight in the treatment group compared to controls.

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Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				Limitations Two populations of the *Osmia bicornis* were tested; the experiment was not repeated. Exposure from pollen was not tested. It was unclear if the outliers in the study were excluded from analysis – exclusion may have changed results. The study indicated that female weight affected offspring production (including gender of offspring). It is unclear if smaller males also impacts reproduction. The offspring sex ratio was significant; however, it is unclear if 47% compared to 55% females would result in a significant effect in the field.
Thiamethoxam Open **Moffat et al., 2016**	Sucrose solution 5 weeks	Bumble bees Colony	LOAEC: **2.14 ppb c.e.** (2.5 ppb thiamethoxam) It is noted that there was no reduction in endpoints from exposure to another experiment from dosing with clothianidin alone at 2.5 ppb.	Reduced number of live bees present at the end of the 5-week exposure period by 38% compared to the control, and significantly reduced the number of brood cells at the end of the 5 week exposure period by 70% compared to the control. In addition, the change in nest mass was significantly lower in the thiamethoxam fed hives after a 5 week exposure period by 10% compared to the control; and the proportion of females was significantly lower in the thiamethoxam fed hives by 49% compared to the control at the end of the 5-week exposure period. **Limitations** The amount of sugar syrup provided to the hives and rate of replenishment was not stated (for the purpose of this review, we have presumed it was provided *ad libitum*). The size of each apiary location, the distance between them, the number of hives per location and the vegetation details within the foraging range were not provided by the authors. No other colony details for the field study (i.e., source of colonies, health parameters, etc.) were provided. Colonies were placed in fields from June – September and would have had access to very different forage based on the differences in timing. The authors stated that the estimates of colony performance

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Study Type & Reference (PMRA#)	Matrix which was dosed & length of exposure	Species and caste exposed to dose	Endpoint (clothianidin equivalents [c.e.])[1]	Endpoints affected & limitations
				are likely to be underestimates given the poor performance of the control colonies in 2015 which was attributed to cold weather. There were limited assessments during the study (only at end of exposure period).

[1] Converted as dose thiamethoxam × 0.856 + clothianidin if applicable.

Detailed Risk Assessment

The following assessment re-examines post-bloom application using available residue data and colony feeding study endpoints.

Exploring soil type

Tier I refined

Original Tier I refined assessment in PRVD2017-24: The residues in orchard crops were derived from application to cherry, peach, and plum after bloom (to leaves) and then residues were sampled the following spring (in pollen and/or nectar)(PMRA 2610249). In the PRVD2017-24, the highest maximum and mean residues (considering 3 different soil types) were considered for acute and chronic risk, respectively. In the original assessment, the highest residues (regardless of soil type) were considered, which in some cases resulted in pollen and nectar from different soils being considered in the risk assessment. Based on that assessment, there was a potential acute and chronic risk to individual bee castes (Table 1a). It is noted that the acute risk profile is similar for the thiamethoxam and clothianidin equivalents (c.e.) risk assessment because the acute endpoints are similar for both active ingredients. For the chronic risk profile, however, there is more risk estimated for the c.e. risk assessment owing to the more sensitive larval endpoints for clothianidin considered.

Table 1a Summary of original Tier I refined assessment [presented in PRVD2017-24]

Crop	Thiamethoxam acute risk	Thiamethoxam chronic risk	c.e. acute risk (considering clothianidin toxicity)*	c.e. chronic risk (considering clothianidin toxicity)*
Cherry year 1	No risk	No risk	No risk	Risk
Cherry year 2	Risk	No risk	Risk	Risk
Peach year 1	No risk	No risk	No risk	Risk
Peach year 2	Risk	No risk	Risk	Risk
Plum year 1	Risk	No risk	Risk	Risk
Plum year 2	No risk	No risk	No risk	No risk

* The c.e. risk assessment considered thiamethoxam residues converted to clothianidin (c.e.)(considering molar ratio of 0.856). When clothianidin residues were high and contributed to the total residues, the c.e thiamethoxam residues were added to the clothianidin residues.

Updated Tier I refined assessment for RVD: In the refined assessment presented here, the maximum and mean residues from each of the soils were considered separately for each crop to examine if that made a difference in the risk conclusions. There was acute risk identified in all three orchard crops considering thiamethoxam in at least one soil type and year of sampling (year 1 or 2) (Table 1 b and Appendix IV-Table 1a). There was acute and chronic risk in all three orchard crops considering clothianidin equivalents (in a number of soil types and years of sampling) (Table 1b). There was higher potential for chronic risk when considering c.e. owing to the more sensitive larval endpoints. Most of the risk came from sandy loam soils, and some from loamy sand.

Overall, the risk conclusions are consistent with the original assessment.

Table 1b Summary of Tier I refined assessment

Crop	Thiamethoxam acute risk			Thiamethoxam chronic risk			c.e. acute risk (considering clothianidin toxicity)			c.e. chronic risk (considering clothianidin toxicity)		
	Loamy sand	loam	Sandy loam	Loamy sand	loam	Sandy loam	Loamy sand	loam	Sandy loam	Loamy sand	loa m	Sandy loam
Cherry year 1	No	No	No	No	No	No	No	No	No	Yes	No	No
Cherry year 2	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	No	Yes
Peach year 1	No	No	No	No	No	No	No	No	no	Yes	Yes	Yes
Peach year 2	No	No	Yes	No	No	No	No	No	Yes	Yes	Yes	Yes
Plum year 1	No	No	Yes	No	No	No	No	No	Yes	No	No	Yes
Plum year 2	No	No	No	No	No	No	No	No	No	No	No	Yes

Tier II refined – Colony feeding study

Original PRVD2017-24 assessment: In the PRVD2017-24, the maximum mean residues (considering 3 different soil types) were compared to colony level endpoints. In the original assessment, the highest residues (regardless of soil type) was considered, which in some cases resulted in pollen and nectar from different soils being considered in the risk assessment. The residues in orchard crops were derived from application to cherry, peach, and plum after bloom (to leaves), and then residues were sampled the following spring (in pollen and/or nectar). Based on that assessment, there was a potential colony level risk to *Apis* and non-*Apis* bees from residues in pollen, but not nectar.

Refined assessment for RVD: In the refined assessment presented here, the mean residues from each of the three soils were considered separately for each crop to examine if that made a difference in the risk conclusions. There was potential colony level risk identified in all three orchard crops considering pollen residues in all three orchard crops in most soils (Figure 1a, and Appendix 1-Table 1b). In all three crops, the highest risk is for non-*Apis* bees in sandy loam soil and loamy sand. Higher residues were found in year 2 sampling for cherry and peach, and the

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opposite trend is found for plum (year 1 was higher). Similar to the original assessment, there was minimal risk identified from nectar residues (Figure 1b).

Overall, the risk conclusions are consistent with the original assessment.

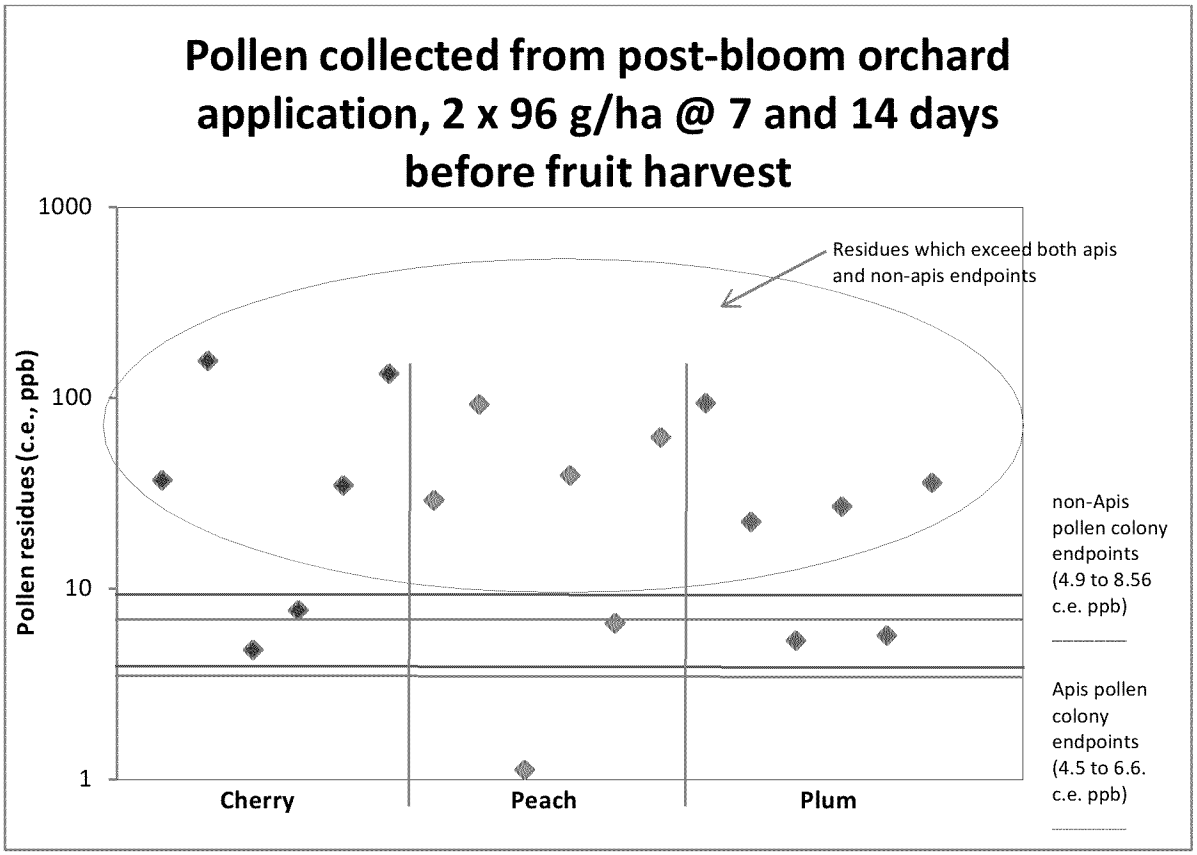

Figure 1a. Pollen residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Fauser-Misslin 2014 LOEC value of 4.9 ppb c.e.; and Elston 2013 LOEC value of 8.56 ppb c.e.). *Apis* endpoints included open literature studies (Sandrock 2014 LOEC of 6.6 ppb c.e.; Straub 2016 LOEC value of 6.33 ppb c.e.; and Williams 2015 LOEC value of 4.5 ppb c.e.). LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, queen effects, and decreased drone survival. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

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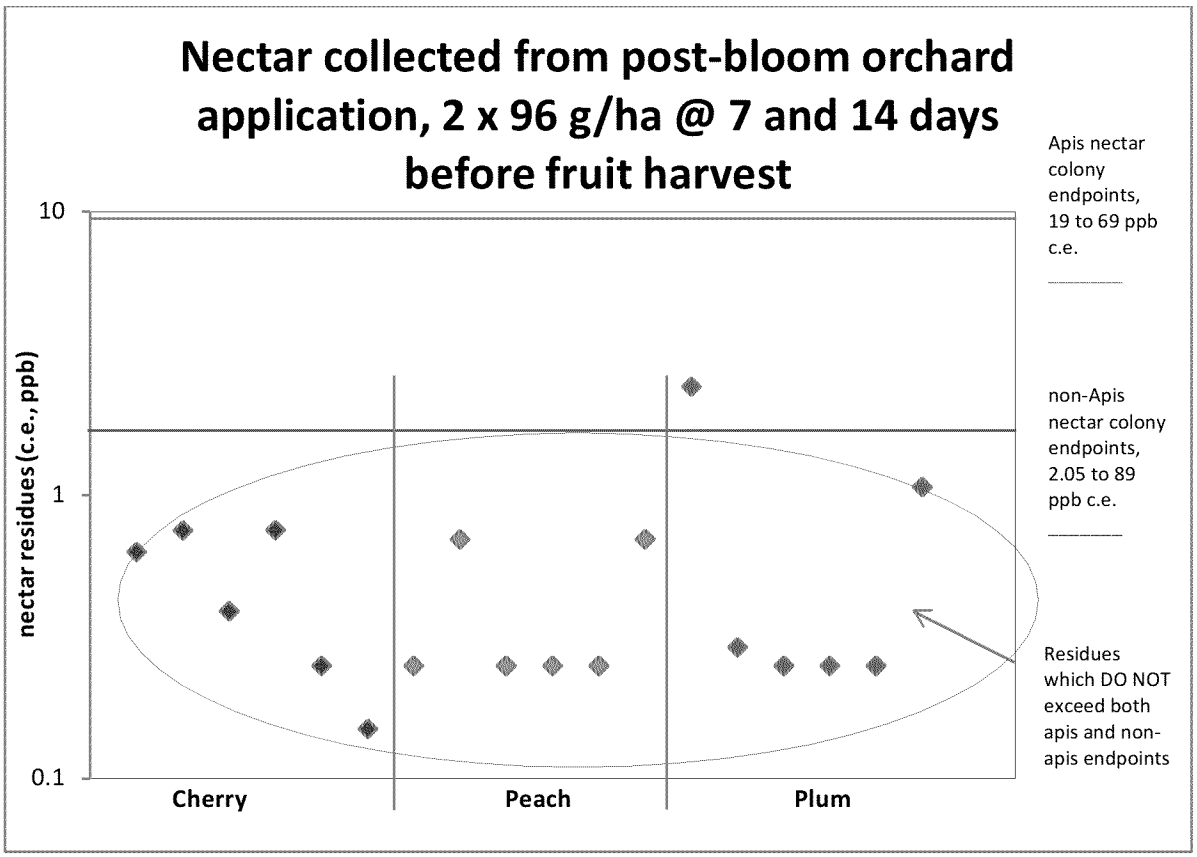

Figure 1b. Nectar residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Stanley and Raine 2017 NOEC value of 8.56 ppb c.e.; Stanley and Raine 2015 LOEC value of 8.56 ppb c.e.; Stanley 2015 & 2016 LOEC value of 2.05 ppb c.e.; Baron 2017 LOEC value of 2.05 ppb c.e.; Laycock 2014 NOEC value of 13.4 ppb c.e.; Mommaerts 2010 NOEC value of 85.6 ppb c.e.; Sandrock 2014 LOEC value of 2.9 ppb c.e.; and Moffat 2016 LOEC value of 2.14 ppb c.e.). *Apis* endpoints included registrant studies (2014 thiamethoxam CFS NOEC and LOEC values of 25.3 and 34 ppb c.e.; respectively; 2014 clothianidin CFS NOEC and LOEC values of 19 and 35.6 ppb c.e., respectively; 2016 thiamethoxam CFS NOEC and LOEC values of 34.8 and 69.6 ppb c.e.; respectively; 2016 clothianidin CFS NOEC and LOEC values of 19 and 29 ppb c.e.; respectively). Some studies had NOEC (no observable effects concentrations) at the highest dose tested. LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, and decreased worker production. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

1.1.2 Orchard Crops – foliar application

The registrant provided the following comment suggesting that it may not be reliable to consider the thiamethoxam pollen residues in the orchard studies, and additional data discussing the residue decline over time in residues. These comments were further examined, and the Health Canada response and update to the risk assessment follows.

Comment (Syngenta)

Residue data and residues in the control for peach, plum and cherry crops

The pollen/nectar residue study was conducted using applications that were made post-bloom the previous year (PMRA 2610249). Residues in nectar were found to be very low, however relatively high concentrations were found in pollen. The data suggest that the source of the residues found in pollen may not have been the result of foliar applications of thiamethoxam made the previous year. For one, pollen samples from control sites contained very similar levels of thiamethoxam as the treated sites. Also, the residue levels in pollen are much higher than those found in leaves, whole flowers and anthers. This is consistent with bees or other pollinators having spread pollen from treated trees located within the area. This information was summarized by the California Department of Pesticide Regulation (CDPR) and indicates an approximate mean of 25-30 ppb residues in the untreated control plants and approximately 40 ppb residues in the treated plants for cherry, plum and peach studies.

Residue decline: *No other pollen and nectar residue data are available for post-bloom applications of thiamethoxam on orchard crops. Data are available for other tree crops that demonstrate pollen concentrations degrade over time. For example, in the pome fruit study (PMRA 2769754; application made at 96 g a.i./ha 5 days prior to bloom to apple), residues show a decline in both pollen and nectar over a relatively short time frame (13-14 days after application; Figure 2).*

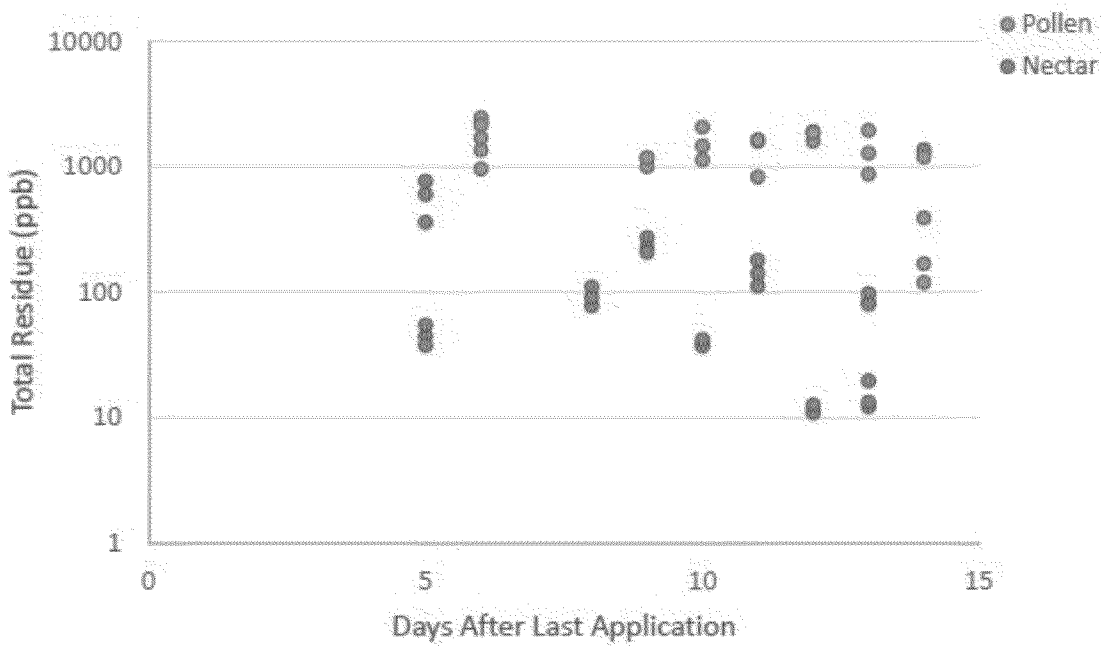

Figure 2. Total Residues (Thiamethoxam + CGA322704 (Clothianidin)) in Pollen andNectar after Pre-Bloom Foliar Application to Apple (1 × 96 g a.i./ha).

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Similar declines in residues over time were observed in a foliar citrus study. In this study, thiamethoxam was applied at 96.6 g a.i./ha under different application scenarios including pre-bloom applications 5 days prior to bloom and another scenario focusing on applications made the previous calendar year. Figure 3 shows that pollen residues decline at a steady rate with concentrations dropping below 10 ppb after approximately 90 days.

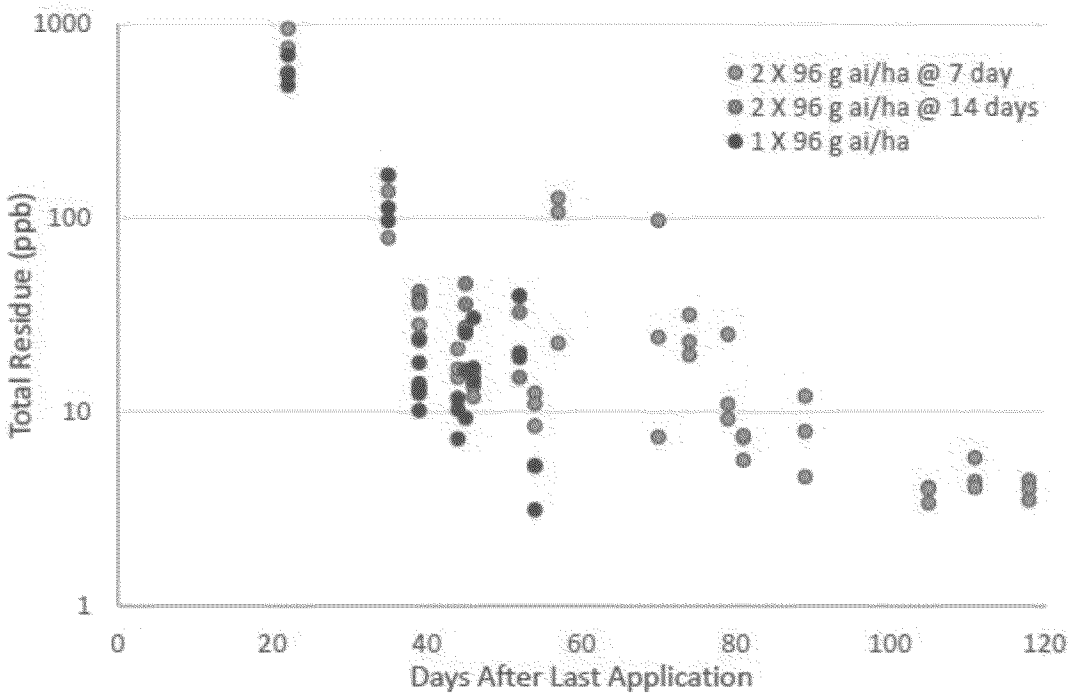

Figure 3. Total Residues (Thiamethoxam + CGA322704 (Clothianidin)) in Pollen after Foliar Applications to Citrus.

Overall, the proposal to eliminate all uses of thiamethoxam including post-bloom applications on orchard crops should be reconsidered based on a weight of evidence approach considering pollen data from other tree crops.

Health Canada Response

Residues in the control: PMRA 2610249 includes residue data for 3 stone fruit crops (cherry, peach and plum). Health Canada recognizes that mean nectar residues from post-bloom applications were low (0.88 ppb (year 2 residues (2 years following first application)) in cherry; 0.82 ppb (year 2) in peach, and 2.81 ppb (year 1 (the following spring)) for plum). In pollen, the registrant has indicated that residues in the control plots were almost as high as treatment plots. This data was presented as mean values in the comment, across all sites and all 3 stone fruit crops. Looking at the data in more depth, it is noted control pollen for plum ranged from 5 to 43 ppb, whereas the mean pollen residues in treated plants were as high as 110 ppb (range of 6.25 to 110 ppb). Even taking into account 43 ppb (in other words, subtracting control residues from the highest treatment residues), the residues would still exceed colony level endpoints. Control pollen for peach ranged from <LOQ to 34 ppb, whereas the mean pollen residues in treated

plants were as high as 108 ppb (range of 1.32 to 108 ppb). Similar to the plum data, taking into account the highest control residues and highest treatment residues would still result in residues that exceed colony level endpoints. Control pollen for cherry ranged from 5 to 53 ppb, whereas the mean pollen residues in treated plants were as high as 184 ppb (range of 5.59 to 184 ppb). Even taking into account the highest control (53 ppb) and highest treatment residues, colony level endpoints would still be exceeded.

Health Canada recognizes that pollen residues were higher than most other matrices sampled in the orchard residue studies. It is noted that this was also observed in some of the other studies (cranberry PMRA 2600069 and orange drench PMRA 2529334).

Cross foraging or wind pollination may result in residues being transferred from treated plants to control plants. This could also result in dilution of residues from treated plants, which would result in an underestimation of the risk. This is the only data available to assess the potential residues resulting from post-bloom application to orchard crops and, was considered in the risk assessment.

Residue decline: Based on an analysis of the individual sites of the apple residue study (PMRA 2769754), the highest mean nectar residue decline was from the Virginia (sandy loam site) from 568 ppb (early bloom) to 14 ppb (late bloom). There was some decline between early (226 ppb), mid (137 ppb) and late bloom (81.8 ppb) in the New York (loamy sand) site. The least amount of decline occurred in the Washington (loamy sand site); residues declined from 44.5 ppb at early bloom to 37.7 ppb at mid bloom and 11 ppb at late bloom. The nectar residues remained high enough to exceed colony level endpoints at late bloom in some cases (See Figure 4 below).

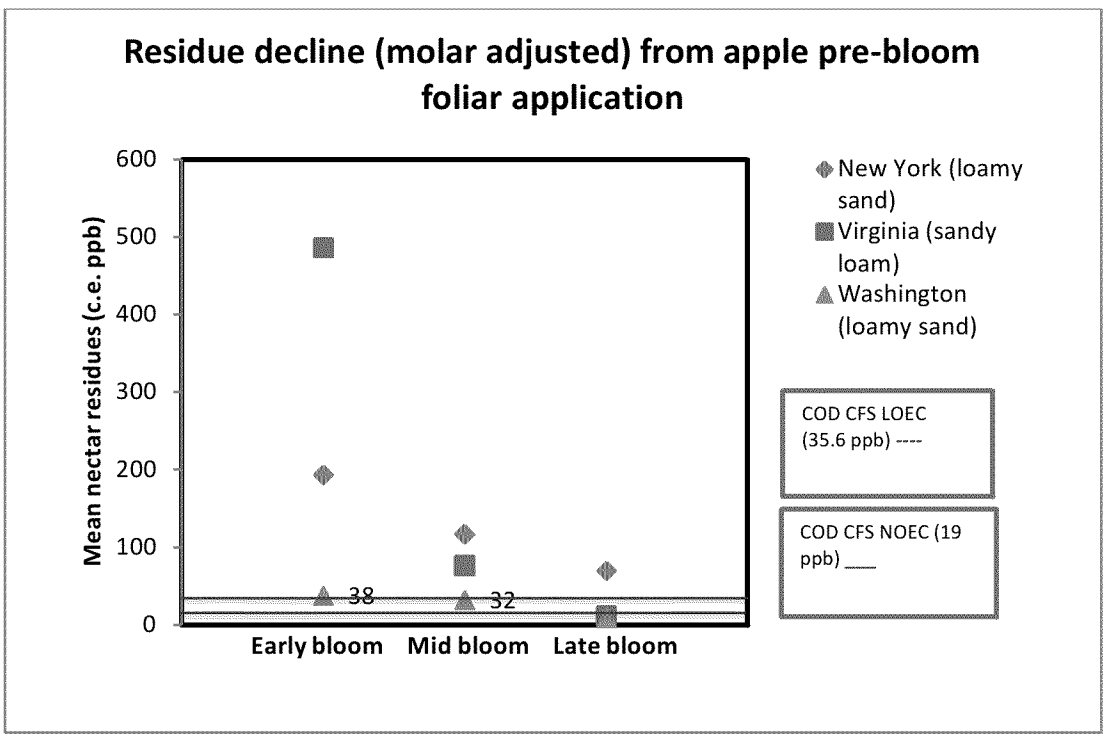

Figure 4. Mean clothianidin equivalents nectar residue levels (c.e. ppb) at early, mid and late bloom, from pre-bloom foliar applications to apple trees plotted with NOEC and LOEC values from the thiamethoxam (clothianidin equivalents) and clothianidin 2014 open nectar feeding studies (converted to ppb).

At the time of the review (PRVD2017-24), there was no citrus foliar application residue study available to review. Citrus is not a crop grown in Canada, and Health Canada had data available from crops (stone fruit, peaches and plums) which were considered more relevant to Canada. The application method (foliar) and application timing (post-bloom), as well as agronomics (stone fruit orchard crop) were similar to those expected in Canada. Therefore, the data that was considered in PRVD2017-24 (which identified potential risk) is still maintained.

1.1.3 Ornamental crops – foliar and soil

1.1.3.1 New residue data: foliar applications

In the original assessment presented in PRVD2017-24, there was no available residue data for ornamental crops. Therefore, the risk conclusions for the Tier I refined and Tier II refined assessments were based on surrogate crops including cucurbits, fruiting vegetables, cotton, strawberry, apple, peach, plum and cherry. Application timing for foliar application to ornamentals was pre-bloom and post-bloom. Following completion of the assessment for PRVD2017-24, residue studies were submitted for foliar application to ornamental plants (herbaceous stargazer lily, lilac and mock orange) (PMRA 2821249).

Tier I refined

Original PRVD2017-24 assessment: In the PRVD2017-24 assessment, considering some of the surrogate residues (fruiting vegetables, strawberry and orchard crops), there was a potential acute and chronic risk to individual bee castes.

Refined assessment for RVD: A refined assessment is presented here that incorporates the new residue data. The maximum and mean residues from all three plants (from different soils and sampling timing) were considered for acute and chronic risk, respectively. There was acute and chronic risk identified in all three ornamental crops considering thiamethoxam and also clothianidin equivalents (Appendix IV- Table 2a). Furthermore, there was risk identified at almost all sites [Oregon (sandy loam), Wisconsin (clay loam) and New York (loam)] at almost all sampling intervals (early, mid and late bloom).

Overall, the risk conclusions confirm the risk conclusions in the original assessment.

Table 2a Summary of Tier I refined assessment

Crop	Sample (bloom time)	Thiamethoxam acute risk			Thiamethoxam chronic risk			c.e. acute risk (considering clothianidin toxicity)			c.e. chronic risk (considering clothianidin toxicity)		
		NY	WI	OR	NY	WI	OR	NY	WI	OR	NY	WI	OR
Herbaceous stargazer lily	Early bloom	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Mid bloom	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Late bloom	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Lilac	Early bloom	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
	Mid bloom	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
	Late bloom	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Mock orange	Early bloom	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No
	Mid bloom	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
	Late bloom	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Tier II refined – Colony feeding study

Original PRVD2017-24 assessment: The Tier II refined assessment compared colony feeding study endpoints, to residues in surrogate crops (as listed above). Based on that assessment, there was a potential colony level risk to *Apis* and non-*Apis* bees from residues in nectar and pollen, depending on the surrogate crop considered.

Refined assessment for RVD: In the refined assessment presented here, the mean residues from all soil types and sampling timing (early, mid and late bloom) were considered for each ornamental crop in the risk assessment. There was potential colony level risk identified in all three ornamental crops considering pollen and nectar residues (Figures 5a and 5b, and Appendix IV, Table 2b). Lilac and Mock orange (woody shrubs) had the highest potential risk, and residues were highest in pollen and nectar at the New York (loam soil) site. There were lower residues in the Stargazer lily (perennial plant), although there was still risk for early, mid and late bloom at the New York site.

Overall, the risk conclusions are consistent with the original assessment.

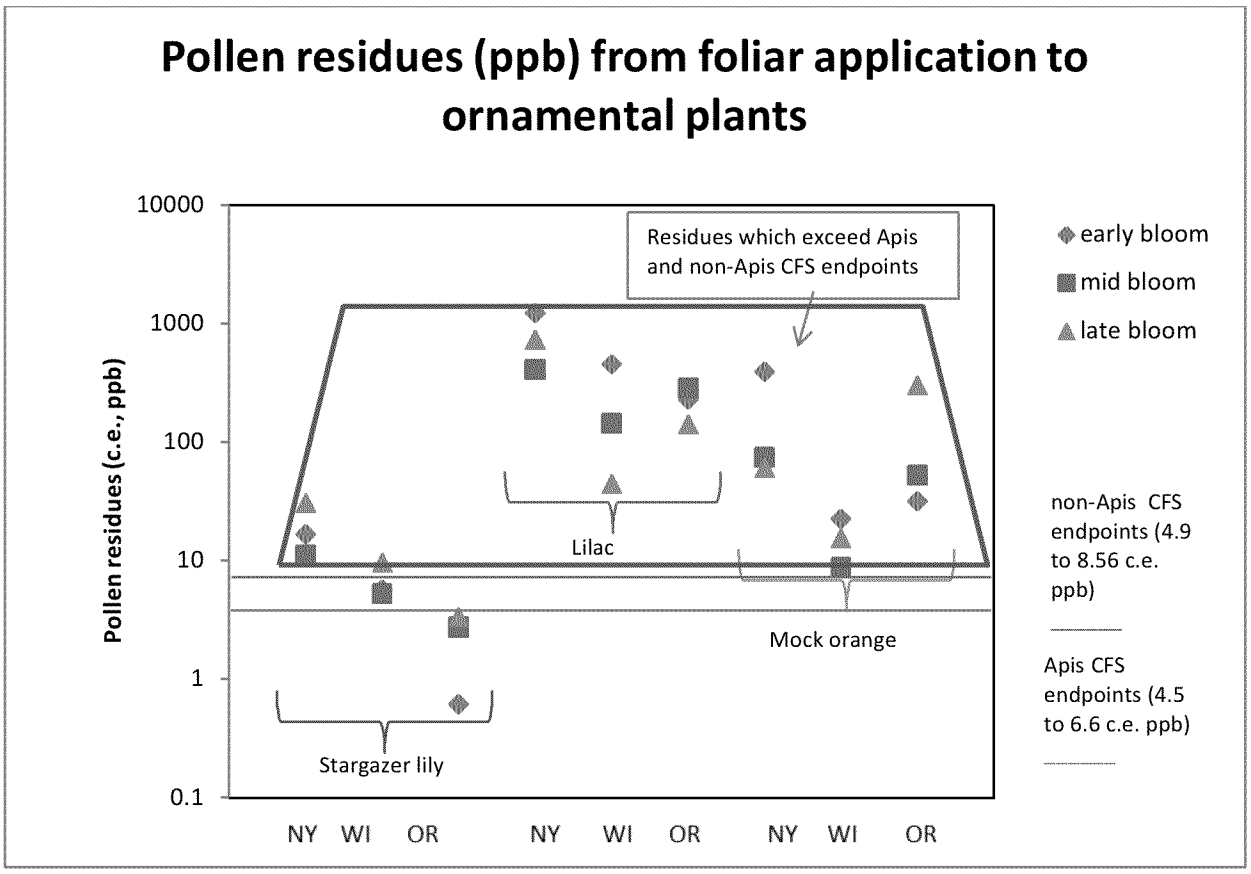

Figure 5a. Pollen residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Fauser-Misslin 2014 LOEC value of 4.9 ppb c.e.; and Elston 2013 LOEC value of 8.56 ppb c.e.). *Apis* endpoints included open literature studies (Sandrock 2014 LOEC of 6.6 ppb c.e.; Straub 2016 LOEC value of 6.33 ppb c.e.; and Williams 2015 LOEC value of 4.5 ppb c.e.). LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, queen effects, and decreased drone survival. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

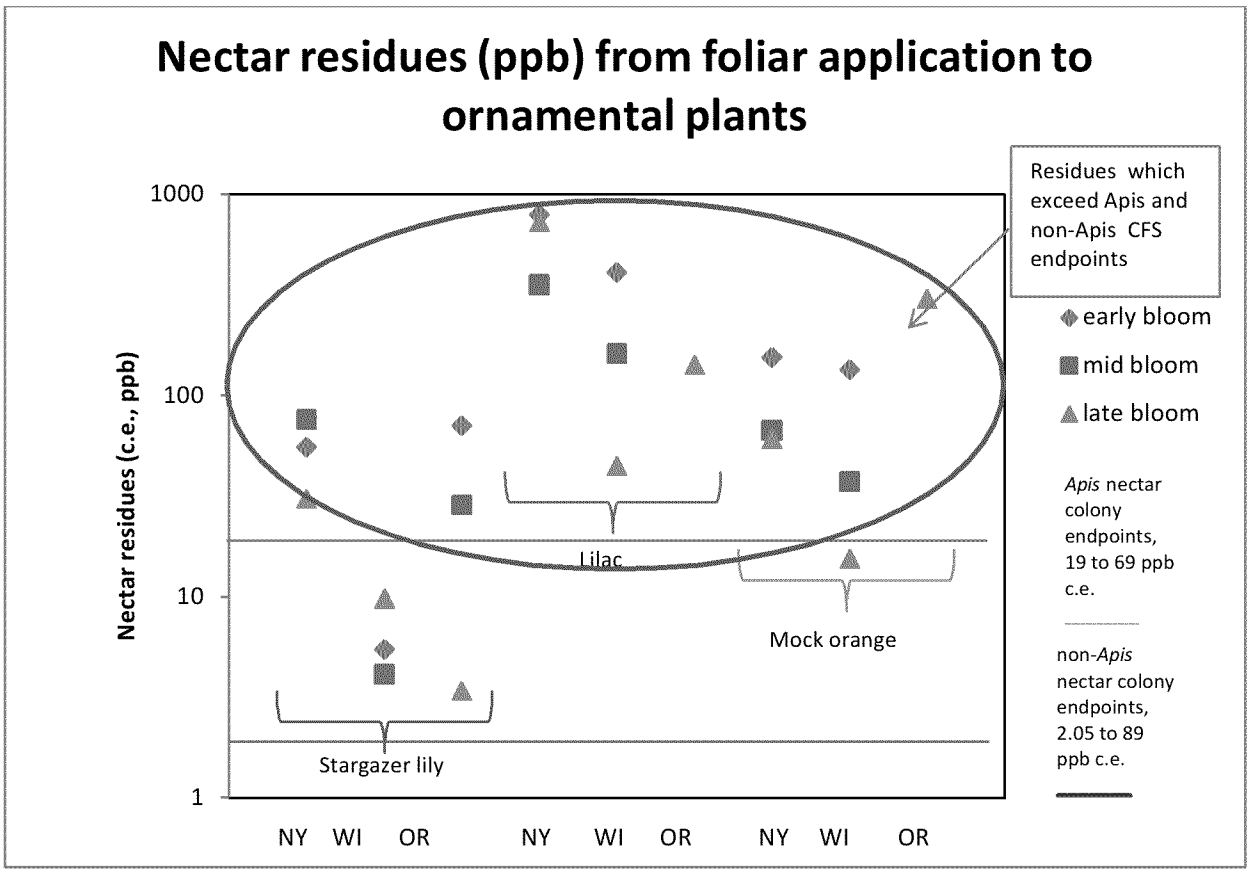

Figure 5b. Nectar residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Stanley and Raine 2017 NOEC value of 8.56 ppb c.e.; Stanley and Raine 2015 LOEC value of 8.56 ppb c.e.; Stanley 2015 & 2016 LOEC value of 2.05 ppb c.e.; Baron 2017 LOEC value of 2.05 ppb c.e.; Laycock 2014 NOEC value of 13.4 ppb c.e.; Mommaerts 2010 NOEC value of 85.6 ppb c.e.; Sandrock 2014 LOEC value of 2.9 ppb c.e.; and Moffat 2016 LOEC value of 2.14 ppb c.e.). *Apis* endpoints included registrant studies (2014 thiamethoxam CFS NOEC and LOEC values of 25.3 and 34 ppb c.e.; respectively; 2014 clothianidin CFS NOEC and LOEC values of 19 and 35.6 ppb c.e., respectively; 2016 thiamethoxam CFS NOEC and LOEC values of 34.8 and 69.6 ppb c.e.; respectively; 2016 clothianidin CFS NOEC and LOEC values of 19 and 29 ppb c.e.; respectively). Some studies had NOEC (no observable effects concentrations) at the highest dose tested. LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, and decreased worker production. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

1.1.3.2 New residue data: soil applications

In the original assessment presented in PRVD2017-24, there was no available residue data for ornamental crops. Therefore, the risk conclusions for the Tier I refined and Tier II refined assessments were based on surrogate crops including tomato, pepper, cucumber, pumpkin, melon, berries and orange trees.

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Tier I refined

Original PRVD2017-24 assessment: The Tier I refined assessment compared laboratory endpoints for thiamethoxam and also for clothianidin, to residues in surrogate crops. In the PRVD2017-24 assessment, considering some of the surrogate residues (cucurbits, berries and peppers), there was a potential acute and chronic risk to individual bee castes.

Refined assessment for RVD: Following completion of the assessment for PRVD2017-24, residue studies were submitted for soil application to ornamental plants (herbaceous stargazer lily, lilac, cotoneaster and crabapple) (PMRA 2821249). Therefore, in the refined assessment presented here, the maximum and mean residues from all three plants (from different soils and sampling timing) were considered for acute and chronic risk, respectively. There was acute risk from thiamethoxam and clothianidin equivalents for all four crops, with the highest risk from New York soils (Table 2b and Appendix IV - Table 2a). Except for the stargazer lily, there was also a chronic risk from both thiamethoxam and clothianidin equivalents. Again, the highest risk was from New York (loam soil), followed by Wisconsin (clay loam). There was very little risk identified in Oregon (sandy loam) soils. In crops grown in the New York soils, residues typically exceeded colony level endpoints at early, mid and late bloom. In some cases, for example, cotoneaster and lilac, the highest residues at the Wisconsin site were during late bloom, or mid and late bloom. Therefore, there was little trend with bloom time and residues.

Overall, the risk conclusions confirm the risk conclusions in the original assessment.

Table 2b. Summary of Tier I refined assessment

Crop	Sample (bloom time)	Thiamethoxam acute risk			Thiamethoxam chronic risk			c.e. acute risk (considering clothianidin toxicity)			c.e. chronic risk (considering clothianidin toxicity)		
		NY	WI	OR	NY	WI	OR	NY	WI	OR	NY	WI	OR
Herbaceous stargazer lily	Early bloom	Yes	No	No	No	No	No	Yes	No	No	Yes	No	No
	Mid bloom	No	No	No	No	No	No	No	No	No	Yes	Yes	No
	Late bloom	Yes	No	No	No	No	No	Yes	No	No	Yes	No	No
Lilac	Early bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No
	Mid bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No
	Late bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No
Cottoneaster	Early bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No
	Mid bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No

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Crop	Sample (bloom time)	Thiamethoxam acute risk			Thiamethoxam chronic risk			c.e. acute risk (considering clothianidin toxicity)			c.e. chronic risk (considering clothianidin toxicity)		
		NY	WI	OR	NY	WI	OR	NY	WI	OR	NY	WI	OR
	Late bloom	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes	No
Crabapple	Early bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	Yes
	Mid bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	Yes
	Late bloom	Yes	No	No	Yes	No	No	Yes	No	No	Yes	Yes	No

Tier II refined – Colony feeding study

Original PRVD2017-24 assessment: The Tier II refined assessment compared colony feeding study endpoints, to residues in surrogate crops (as listed above). Based on that assessment, there was a potential colony level risk to *Apis* and non-*Apis* bees from residues in nectar and pollen, depending on the surrogate crop considered.

Refined assessment for RVD: In the refined assessment presented here, the mean residues in crops grown from all soil types and sampling timing (early, mid and late bloom) were considered for each ornamental crop in the risk assessment. There was potential colony level risk identified in all three ornamental crops considering pollen and nectar residues (Figure 5c and 52d, and Appendix IV - Table 2b). Overall, the risk conclusions are consistent with the original assessment. Similar to foliar applications, residues from the New York (loam soil) site were the highest, and in most cases, Oregon (sandy loam) residues did not exceed colony level endpoints.

Stargazer lily: Pollen residues at the New York site exceeded colony level endpoints for *Apis* and non-*Apis* during early, mid and late bloom. Nectar residues were lower, and only some exceeded non-*Apis* endpoints (endpoints in the range of 2.05 to 2.9 ppb c.e.). Neither pollen nor nectar residues at the Wisconsin or Oregon sites exceeded endpoints.

Lilac: Pollen and nectar residues at the New York site exceeded colony level endpoints for *Apis* and non-*Apis*. Nectar residues exceeded endpoints during early, mid and late bloom, and pollen residues did not exceed late bloom. Neither pollen nor nectar residues at the Wisconsin site exceeded endpoints. At the Oregon site, there was no nectar sample collected. Considering pollen residues, only early bloom exceeded *Apis* and non-*Apis* endpoints.

Cotoneaster: Pollen and nectar residues were much higher in this crop (at the New York site) compared to the others, and residues exceeded *Apis* and non-*Apis* endpoints for early, mid and late bloom. At the Wisconsin site, both pollen and nectar residues increased with bloom time. As such, only late bloom pollen and nectar residues exceeded some of the *Apis* and non-*Apis* endpoints. Nectar residues were lower, and only some exceeded non-*Apis* endpoints (endpoints in the range of 2.05 to 2.9 ppb c.e.). At the Oregon site, only early bloom pollen residues (5.21 ppb) exceeded one *Apis* and non-*Apis* endpoint. Nectar residues were low.

Crabapple: Pollen and nectar residues at the New York site exceeded colony level endpoints for *Apis* and non-*Apis* for mid and late bloom, since residues were increasing with bloom time. Pollen residues at the Wisconsin site did not exceed any endpoints, and nectar residues were low and only exceeded endpoints at 2.05 c.e. ppb for non-*Apis* bees at early bloom. Neither pollen nor nectar residues exceeded endpoints at the Oregon site.

Overall Summary: Residues following soil applications were lower than from foliar applications at the same rate. Late bloom residues were sometimes higher than early and mid blooms, which may be the result of the time it takes for translocation from soil/roots into the flower (pollen/nectar), compared to foliar application before bloom and translocation from leaves into the flower (pollen/nectar). Overall, the New York site residues resulted in risk for all four crops (following soil application), and risk was generally identified at early, mid and late bloom. There was less risk at the Wisconsin and Oregon sites.

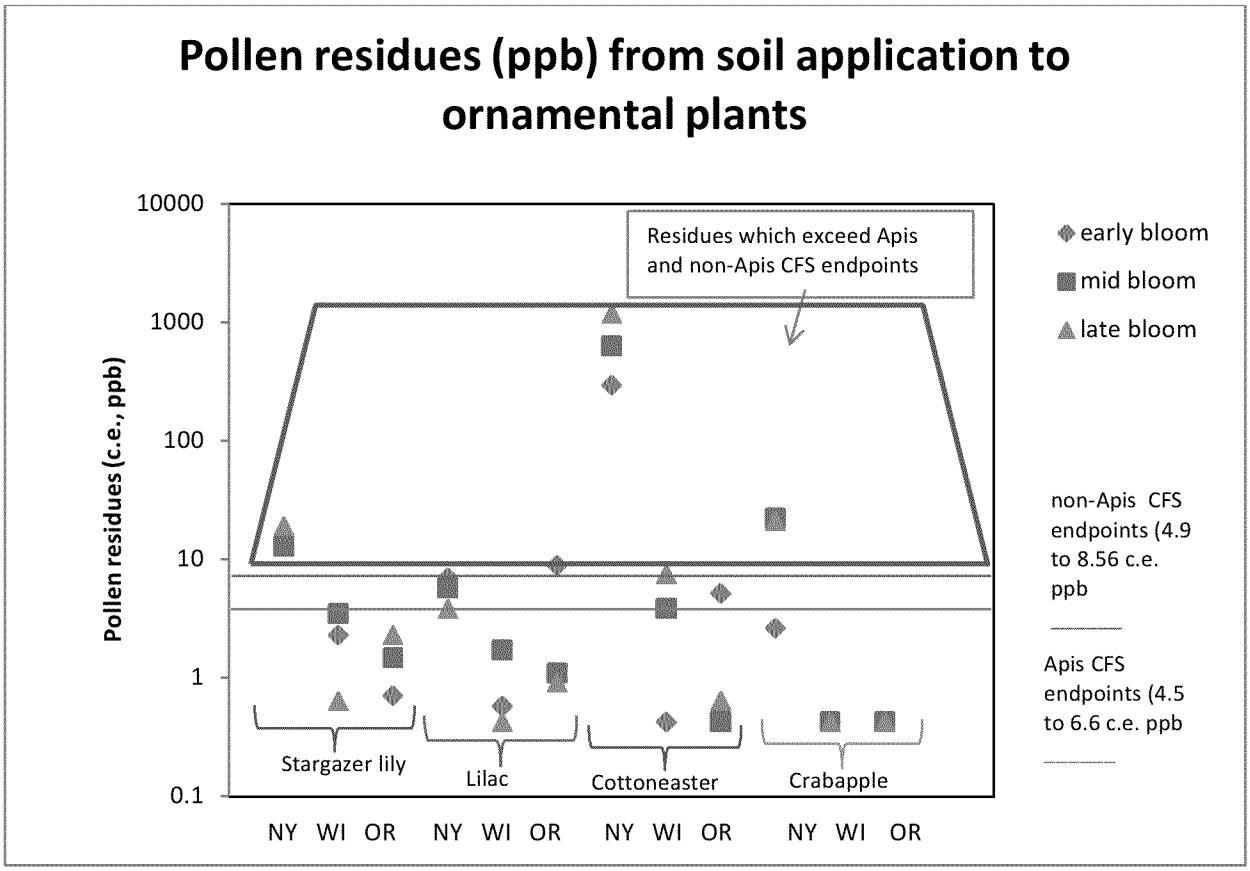

Figure 5c. Pollen residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Fauser-Misslin 2014 LOEC value of 4.9 ppb c.e.; and Elston 2013 LOEC value of 8.56 ppb c.e.). Apis endpoints included open literature studies (Sandrock 2014 LOEC of 6.6 ppb c.e.; Straub 2016 LOEC value of 6.33 ppb c.e.; and Williams 2015 LOEC value of 4.5 ppb c.e.). LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, queen effects, and decreased drone survival. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

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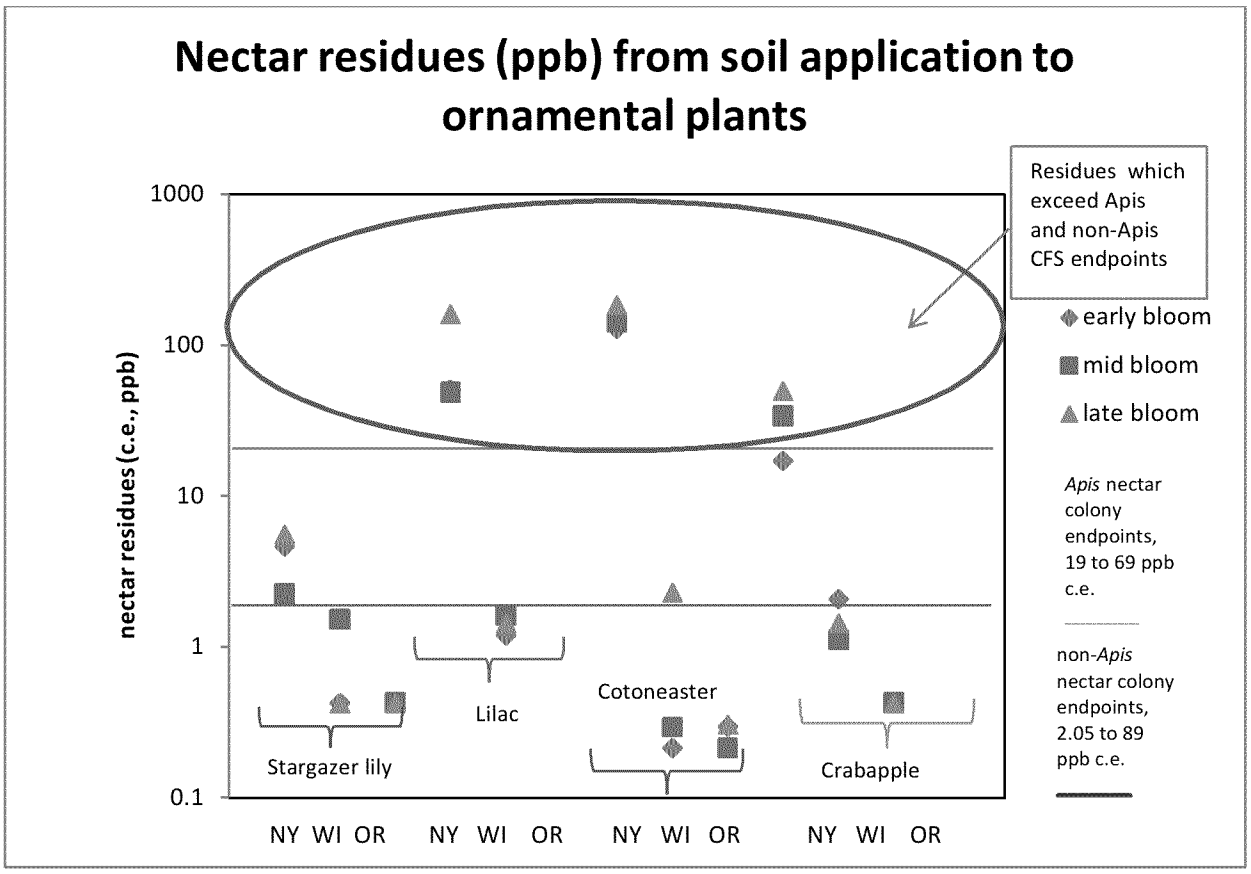

Figure 5d. Nectar residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Stanley and Raine 2017 NOEC value of 8.56 ppb c.e.; Stanley and Raine 2015 LOEC value of 8.56 ppb c.e.; Stanley 2015 & 2016 LOEC value of 2.05 ppb c.e.; Baron 2017 LOEC value of 2.05 ppb c.e.; Laycock 2014 NOEC value of 13.4 ppb c.e.; Mommaerts 2010 NOEC value of 85.6 ppb c.e.; Sandrock 2014 LOEC value of 2.9 ppb c.e.; and Moffat 2016 LOEC value of 2.14 ppb c.e.). *Apis* endpoints included registrant studies (2014 thiamethoxam CFS NOEC and LOEC values of 25.3 and 34 ppb c.e.; respectively; 2014 clothianidin CFS NOEC and LOEC values of 19 and 35.6 ppb c.e., respectively; 2016 thiamethoxam CFS NOEC and LOEC values of 34.8 and 69.6 ppb c.e.; respectively; 2016 clothianidin CFS NOEC and LOEC values of 19 and 29 ppb c.e.; respectively). Some studies had NOEC (no observable effects concentrations) at the highest dose tested. LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, and decreased worker production. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

Considerations in the risk assessment for ornamentals

Foliar applications:

Overall, there is a potential colony level risk to *Apis* and non-*Apis* bees from residues in ornamental crops following foliar applications. There is no change to the proposed risk mitigation proposed in PRVD2017-24.

The application rates in the residue studies (2 × 149 g a.i./ha) were higher than many of the labelled rates for ornamentals (see following table).

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PCP #	Product Name	Rates
30723	Flagship	2 × 70 g a.i./ha – outdoor ornamentals 1 × 70 g a.i./ha – outdoor nurseries
28408	Actara 25 WG	2 × 70 g a.i./ha – outdoor ornamentals 1 × 70 g a.i./ha – outdoor nurseries and landscapes
30901	Mainspring X Insecticide	150 g a.i./ha – outdoor ornamentals 300 g a.i./ha /crop cycle – greenhouse ornamentals

Despite the conservative rates in the residue studies, some of the pollen and nectar residues were very high and exceeded colony feeding endpoints by >100 times. This suggests that even if lower rates of application resulted in proportional decreases in residues, the residues would still far exceed colony level effects endpoints.

In addition, applications in the residue studies were made before bloom, whereas most of the labels (prior to the re-evaluation) included that application can be made during bloom. It is expected that applications during bloom would result in higher residues.

The risk assessment is conservative in that the bloom time of most ornamental plants are likely shorter (2-4 weeks) than the length of the colony feeding studies (>6 weeks), and therefore, the real world exposure from those treated crops may be less compared to the colony feeding studies.

Overall, there is still a potential colony level risk to *Apis* and non-*Apis* bees from residues in ornamental crops following foliar applications. There is no change to the proposed risk mitigation proposed in PRVD2017-24.

Soil applications:

There is one label (Mainspring X, registration 30901) with soil greenhouse application at 300 g a.i./ha. Therefore, the cumulative application rate in the studies (2 × 149 g a.i./ha applied at 5 and 12 days before bloom) are relevant for the Canadian label rates.

Applications in the residue studies were made before bloom, which would likely be relevant for the soil applications.

The risk assessment is conservative in that the bloom time of most ornamental plants are likely shorter (2-4 weeks) than the length of the colony feeding studies (>6 weeks), and therefore, the real world exposure from those treated crops may be less compared to the colony feeding studies.

Overall, there is still a potential colony level risk to *Apis* and non-*Apis* bees from residues in ornamental crops following soil applications. Health Canada recognizes that the highest risk is attributed to the New York site residues, with some degree of risk from Wisconsin residues. To

summarize, in the Tier I refined assessment acute and/or chronic risk during early, mid and late bloom was shown to be highest in New York and Wisconsin. In the Tier II assessment 14/33 nectar residues exceeded non-*Apis* colony level endpoints, of which 12/14 were from New York. Considering the lack of general trends between soil type and residues observed among all treatments, crops and soil types, the risk identified from residues in New York is considered relevant to support an overall conclusion of risk. There is no change to the proposed risk mitigation proposed in PRVD2017-24.

1.1.4 Blueberry foliar applications

Comments Received on Original PRVD2017-24 Assessment: The majority of comments regarding foliar applications to berries were value related. They highlighted the importance of foliar applications of thiamethoxam in cranberry and other berry crops for pest and resistance management of key pests and requested that Health Canada re-assess the decision to remove applications in berry crops. Comments were also received from the registrant, requesting that Health Canada examine new residue data for blueberries.

Exploring residue data
In the original assessment presented in PRVD2017-24, there was no available residue data specifically for blueberries, but there was residue information for other berry crops (cranberry and strawberry). Therefore, the risk conclusions for the Tier I refined and Tier II refined assessments were based on other berry crops.

Tier I refined

Original PRVD2017-24 assessment: The Tier I refined assessment compared laboratory endpoints for thiamethoxam and also for clothianidin, to residues following foliar application to strawberry and cranberries and soil application in strawberry fields. Based on these residues, there was a potential acute and chronic risk to individual bee castes.

Refined assessment for RVD: Following completion of the assessment for PRVD2017-24, residue studies were submitted for foliar application to blueberry plants (PMRA 2821245). Therefore, in the refined assessment presented here, the maximum and mean residues from different soils (California sand soil, Quebec loam soil, and Washington loamy sand) and sampling timing were also considered to see if there was a change in the acute and chronic risk conclusions specific to blueberry bushes. There was acute and chronic risk identified in all three sampling locations, and all three sampling times when considering thiamethoxam and also clothianidin equivalents (Table 3 and Table 3a in Appendix IV).

Overall, the risk conclusions confirm the risk conclusions in the original assessment.

Table 3. Summary of Tier I refined assessment

Soil/Location	Sample (bloom time)	Thiamethoxam acute risk	Thiamethoxam chronic risk	c.e. acute risk (considering clothianidin toxicity)	c.e. chronic risk (considering clothianidin toxicity)
Fresno California Sand soil	Early bloom	Yes	Yes	Yes	Yes
	Mid bloom	Yes	Yes	Yes	Yes
	Late bloom	Yes	Yes	Yes	Yes
Quebec Canada Loam soil	Early bloom	Yes	Yes	Yes	Yes
	Mid bloom	Yes	Yes	Yes	Yes
	Late bloom	Yes	Yes	Yes	Yes
Ephrata Washington Loamy sand	Early bloom	Yes	Yes	Yes	Yes
	Mid bloom	Yes	Yes	Yes	Yes
	Late bloom	No	No	Yes	Yes

Tier II refined – Colony feeding study

Original PRVD2017-24 assessment: The Tier II refined assessment compared colony feeding study endpoints, to residues in cranberry and strawberry for foliar applications and to strawberry for soil application. Based on that assessment, there was a potential colony level risk to *Apis* and non-*Apis* bees from residues in nectar and pollen.

Refined assessment for RVD: In the refined assessment presented here, the mean residues in blueberry pollen and nectar following application to plants growing in different soil types along with sampling timing (early, mid and late bloom) were considered in the risk assessment. There were potential colony level risk identified at all three sites considering pollen and nectar residues, with higher risk from pollen and higher risk from residues at the Canadian site (Quebec, loam soil), followed by the Washington (loamy sand) site (Figures 6a and 6b, and Appendix I, Table 3b).

Overall, the risk conclusions are consistent with the original assessment.

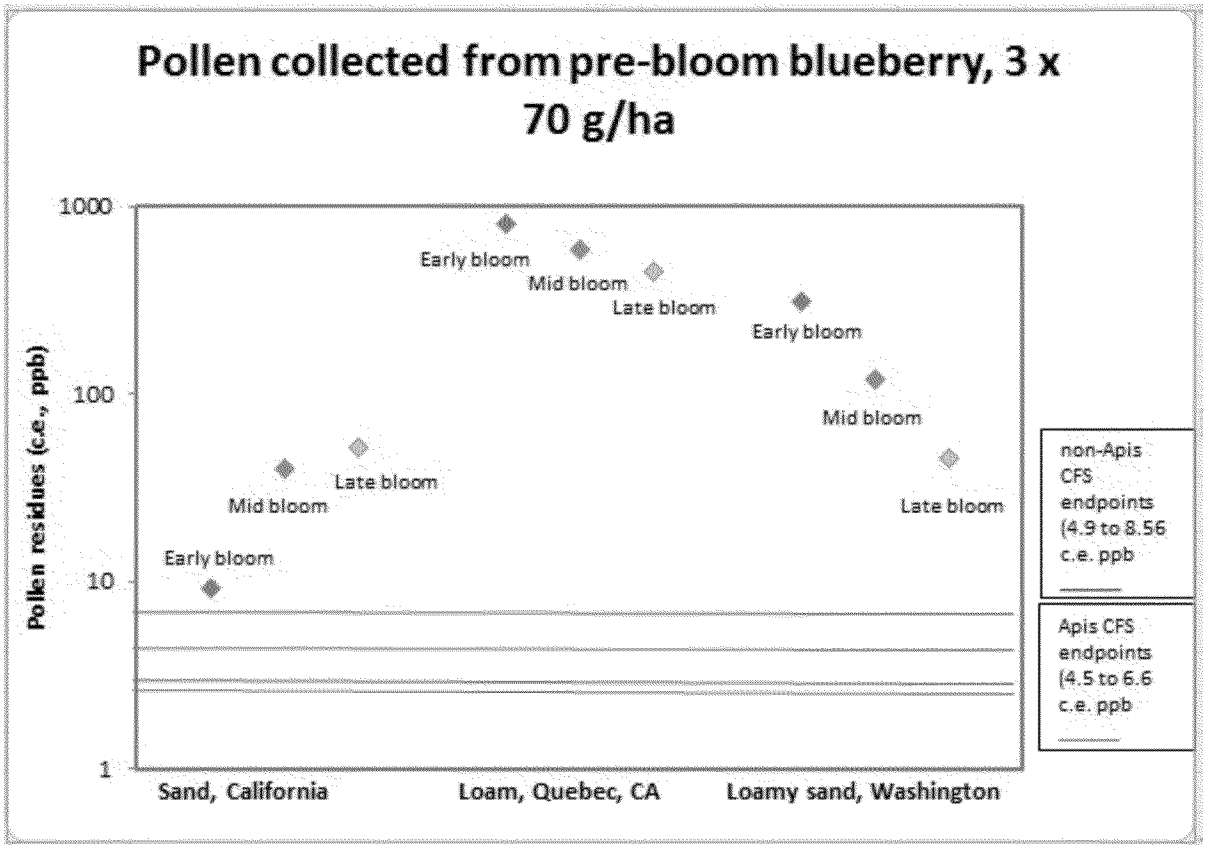

Figure 6a. Pollen residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Fauser-Misslin 2014 LOEC value of 4.9 ppb c.e.; and Elston 2013 LOEC value of 8.56 ppb c.e.). *Apis* endpoints included open literature studies (Sandrock 2014 LOEC of 6.6 ppb c.e.; Straub 2016 LOEC value of 6.33 ppb c.e.; and Williams 2015 LOEC value of 4.5 ppb c.e.). LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, queen effects, and decreased drone survival. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

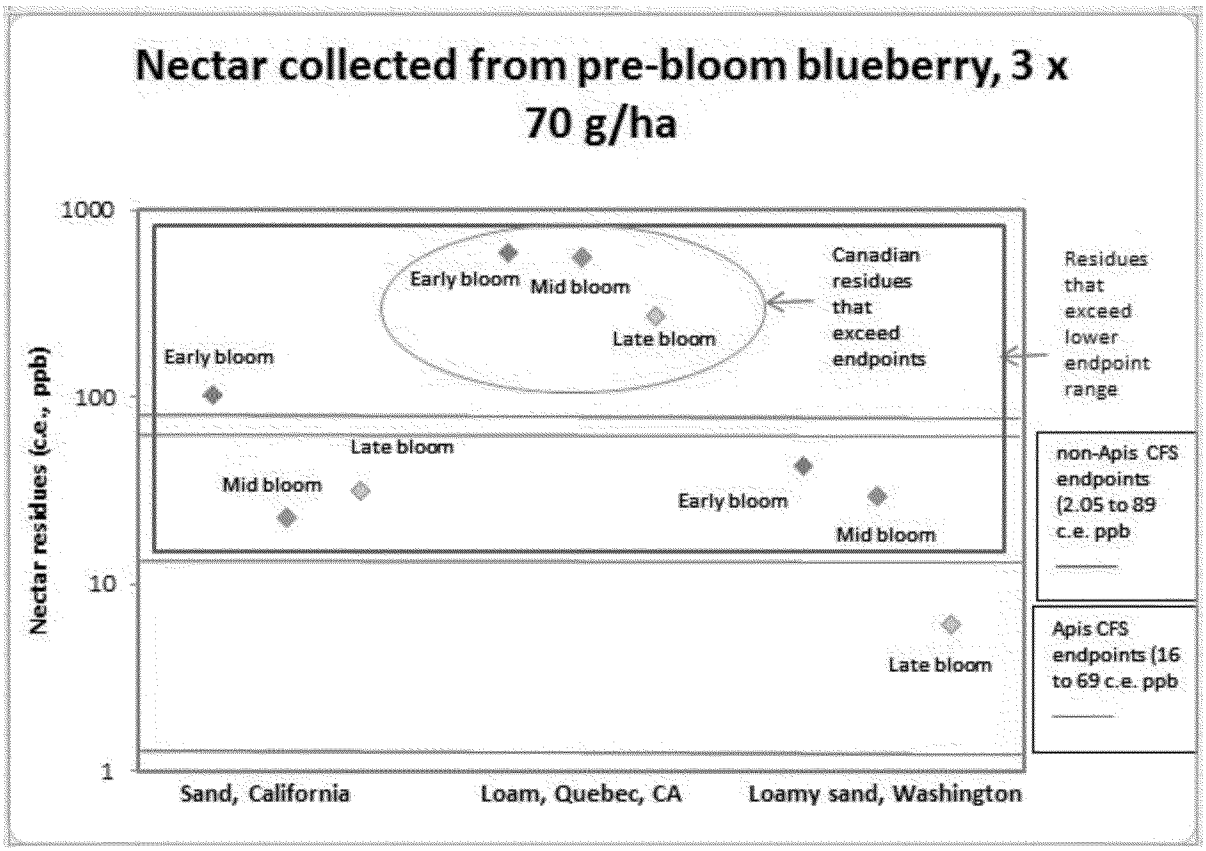

Figure 6b. Nectar residues from flowers (ppb c.e.) compared to *Apis* and non-*Apis* colony endpoints. Non-*Apis* endpoints included open literature studies (Stanley and Raine 2017 NOEC value of 8.56 ppb c.e.; Stanley and Raine 2015 LOEC value of 8.56 ppb c.e.; Stanley 2015 & 2016 LOEC value of 2.05 ppb c.e.; Baron 2017 LOEC value of 2.05 ppb c.e.; Laycock 2014 NOEC value of 13.4 ppb c.e.; Mommaerts 2010 NOEC value of 85.6 ppb c.e.; Sandrock 2014 LOEC value of 2.9 ppb c.e.; and Moffat 2016 LOEC value of 2.14 ppb c.e.). *Apis* endpoints included registrant studies (2014 thiamethoxam CFS NOEC and LOEC values of 25.3 and 34 ppb c.e.; respectively; 2014 clothianidin CFS NOEC and LOEC values of 19 and 35.6 ppb c.e., respectively; 2016 thiamethoxam CFS NOEC and LOEC values of 34.8 and 69.6 ppb c.e.; respectively; 2016 clothianidin CFS NOEC and LOEC values of 19 and 29 ppb c.e.; respectively). Some studies had NOEC (no observable effects concentrations) at the highest dose tested. LOEC (lowest observable effect concentrations) included colony level effects such as number of adults and brood, and decreased worker production. Each study had strengths and limitations and all data was considered in a weight of evidence approach.

Considerations in the risk assessment for blueberries

In the risk assessment in PRVD2017-24, a number of residues (including strawberry and cranberry pre-bloom applications) were considered to assess the potential risk from application to blueberry crops from both soil and foliar applications. The residues indicated a potential risk from application to blueberries, but that application could be made after bloom provided that renovation was implemented. In general, the new blueberry residue data for pollen and nectar supports the original conclusion of potential colony level risk. When compared to *Apis* (pollen: 4.5 to 6.6 ppb c.e.; nectar: 19 to 69 ppb c.e.) and non-*Apis* endpoints (pollen: 4.9 to 8.56 ppb c.e.; nectar: 2.05 to 89 ppb c.e.)), the residues are typically higher than the endpoints. All of the pollen

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residues exceed *Apis* and non-*Apis* endpoints, and the Canadian relevant nectar residues exceed both *Apis* and non-*Apis* endpoints at early, mid and late bloom.

There is one label (Actara 25 WG) with application on blueberries (bushberries) at a rate of 2 × 70 g a.i./ha for foliar application or 1 × 140 g a.i./ha for soil drench. The study rate was 3 × 70 g a.i./ha, which is conservative (higher) compared to the Canadian label rates.

Despite the conservative rates in the residue studies, some of the pollen and nectar residues were very high and exceeded colony feeding endpoints by >100 times. This suggests that even if lower rates of application resulted in proportional decreases in residues, the residues would still far exceed colony level effects endpoints, particularly at the Quebec site.

In addition, application in the residue studies were made before bloom, whereas most of the labels (prior to the re-evaluation) indicated applications can be made during bloom. It is expected that applications during bloom would result in higher residues.

Additional data being considered from open literature for exposure from blueberry use

A recent study by Bishop et al., 2018 examined pesticide exposure to hummingbirds and bees in British Columbia near blueberry fields. The study included sampling near conventionally sprayed fields and also organic blueberry farms. Exposure of hummingbirds was measured by residue analysis in fecal pellets and cloacal fluid (water passed directly through gut) of *Selesphorus rufus* and *Calypte anna*. The fecal pellets would primarily represent insects in the diet, while the cloacal fluid would represent exposure from nectar. Bumble bees (native to Canada), pollen collected from bumble bees, blueberry flowers and leaves were also analysed from blueberry fields sprayed with imidacloprid, and also from organic blueberry farms. The study was conducted over two years in 2015 and 2016.

Over the two years, the combined concentration of the neonicotinoid insecticides imidacloprid, thiamethoxam, and clothianidin detected in hummingbird cloacal fluid from sites near conventionally sprayed blueberry fields was 3.63 ng/mL (ppb)(0.197 ng/mL imidacloprid, 1.96 ng/mL clothianidin and 1.47 ng/mL thiamethoxam). Among the 18 compounds measured in fecal pellets, including one neonicotinoid (imidacloprid), only piperonyl butoxide was detected (1.47–5.96 ng/g). Piperonyl butoxide is a cytochrome P450 inhibitor applied with some insecticides to increase their efficacy. Only diazinon was detected in bumble bees (0.197 ng/g), whereas diazinon (1.54–1.7 ng/g) and imidacloprid (up to 18.4 ng/g) were detected in pollen collected from bumble bees including the bees from organic sites located near conventionally sprayed blueberry farms. Imidacloprid was also detected at 5.16 ng/g in blueberry flowers collected 1 year post spray from 1 of 6 conventionally sprayed blueberry farms.

This study is considered to provide monitoring information which indicates that bees and hummingbirds are exposed to varying pesticides (including neonicotinoids) in the field, including around blueberry fields where fields were sprayed with imidacloprid.

Residues from the study of 1.47 ppb thiamethoxam and combined clothianidin plus thiamethoxam (3.22 c.e. ppb) in cloacal fluid were compared to sucrose dosed colony level endpoints (*Apis* range of 19 to 35 ppb for clothianidin and 25 to 69 ppb for thiamethoxam (c.e);

and non-*Apis* range of 4.9 c.e ppb (combined dose of thiamethoxam and clothianidin), 8.56 c.e. (dosed with thiamethoxam) and 17 ppb (dosed with clothianidin). Overall, the residues did not exceed the colony level endpoints. There were no pollen residues to compare to pollen based colony feeding study endpoints.

When considering the results of this study in the context of the pollinator risk assessment, there is information lacking for the product applied and timing of application, and potential exposure in other blueberry growing regions of Canada. When comparing the residues with available endpoints, the Bishop et al., 2018 study also does not provide pollen residues or *Apis* exposure information. Nor were these likely the goal of the study design.

In comparison, the results of the residue study provided by the registrant (PMRA 2821245, summarized above) presents higher residues of thiamethoxam in pollen and nectar of blueberry plants from applications at Canadian relevant rates in a variety of different growing regions/soil types (of which Quebec resulted in the highest residues). The residue study also tracks the persistence of residues in pollen and nectar throughout the bloom period. Overall, these residues can more readily be compared to colony level endpoints for pollen and nectar exposure for both *Apis* and non-*Apis* bees.

1.1.5 Additional mason bee studies considered in risk assessment:

Three additional field and tunnel mason bee studies (PMRA 2766427 (conducted in Celle, Germany), PMRA 2667959 (conducted in Kraichtal, Germany) and PMRA 2667961 (conducted in Alsace, France) were submitted for consideration in the thiamethoxam pollinator risk assessment for the RVD. Two field and tunnel mason bee studies (PMRA 2694873 (conducted in Tubingen, Germany) and PMRA 2694872 (conducted in Niefern, Germany) were previously assessed in PRVD2017-24. The application rates and study design were similar in all of the studies.

The overall effects to mason bees in the 3 (three) new studies are similar to those already considered in PRVD2017-24. There appeared to be limited exposure to mason bees to thiamethoxam and its transformation product, clothianidin, based on residues < LOQ (0.0005 mg/kg nectar and 0.001 mg/kg (other samples, such as pollen and soil) in most samples. There was a low amount of oilseed rape collected by bees, and a large amount of pollen from oak trees at all sites. The protein content in the pollen was generally similar between treatment and control sites.

Overall, the three new mason bee studies did not change the risk conclusions presented in PRVD2017-24.

Below is a short summary of the new studies.

PMRA 2766427 (Celle, Germany): This tunnel and field study evaluated effects to red mason bees using the same methods as from PMRA 2694873 and 2694872 except the study was conducted in Celle, Germany. The field sizes (between 1.86 and 2.19 ha) and distance between treatment and control sites (9.7 km) were in a similar range to the other two studies in PMRA 2694873 and 2694872. Overall development and reproductive success parameters were similar

between the control and the treatment sites in this study (which is similar to the results in PMRA 2694873 and 2694872). In this study, there was a higher number of nesting females, higher flight activity and higher number of cocoons in the treatment field and tunnels (compared to control) despite similar hatching rates. Immature mortality in the cocoons (undeveloped larvae and bees) was higher in the treated field compared to the control field and the weight of hatched males and females was slightly lower in the control compared to the test item treatment field.

PMRA 2667959 (Kraichtal, Germany): This field study evaluated effects to red mason bees using the same methods as from PMRA 2694873 and 2694872 except the study was conducted in Kraichtal, Germany. The field sizes (approximately 2.3 ha) and distance between treatment and control sites (7 km) were in a similar range to the other two studies in PMRA 2694873 and 2694872. The number of bees in this study was higher (8 nesting units with 300 nest cavities, each) compared to other study locations. Also, this study did not have a tunnel component. Overall development and reproductive success parameters were similar between the control and the treatment sites in this study (which is similar to the results in PMRA 2694873 and 2694872). Additional observations noted in this study included variable foraging with slightly lower levels in the treatment hives, and higher parasitation in the treatment hives.

PMRA 2667961 (Alsace, France): This field study evaluated effects to red mason bees using the same methods as from PMRA 2694873 and 2694872 except the study was conducted in Alsace, France. The field sizes (2 to 2.2 ha) were similar, however, the distance between treatment and control sites (5 km) were slightly smaller than the other studies (>7 km apart). The number of bees in this study was also higher (8 nesting units with 300 nest cavities, each) compared to other study locations in PMRA 2694873 and 2694872. Also, this study did not have a tunnel component. Overall development and reproductive success parameters were similar between the control and the treatment sites in this study (which is similar to the results in PMRA 2694873 and 2694872). Additional observations noted in this study included higher parasitisation in the treatment hives compared to controls, and although foraging activity was lower in the treatment hives, flight activity was similar. As well, cell production was lower in the treatment compared to control.

1.1.6 Off-field exposure risk assessment

Off-field exposure to neonicotinoid residues was considered in the risk assessments presented in PRVD2017-23 and PRVD2017-24 for clothianidin and thiamethoxam, respectively. During the comment period there were new references submitted or identified that were relevant to the off-field exposure route for both clothianidin and thiamethoxam. Therefore, an update to the off-field exposure risk assessment is presented here and considers information for both clothianidin and thiamethoxam together.

Please also see Appendix II Comments and Responses, Section 1.2 Off-field Exposure and Section 1.4 Seed treatment for additional discussion on the off-field risk assessment.

There are multiple exposure pathways that can result in off-field neonicotinoid exposure. Residues can be present in the soil following soil treatments, foliar applications, or planting of treated seeds. These soil residues can move off the treated field through water movement and be taken up (or translocated) into plants in adjacent areas. As well, movement of residues off-field

can occur through spray-drift from foliar applications or through movement of dust generated during planting of certain seeds.

PRVD2017-23 and PRVD2017-24 assessed off-field exposure by considering residue levels in off-field plants and rotational crops (as a surrogate for off-field plants) and comparing them to Tier I and Tier II colony effects endpoints, as well as by considering a number of field effects studies that included off-field exposures. The off-field exposure scenario was also similarly considered in the imidacloprid pollinator assessment (PRVD2018-12, *Imidacloprid and its Associated End-use Products: Pollinator Re-evaluation*).

The studies and information relevant to off-field exposures, which were considered in PRVD2017-23 and PRVD2017-24, included the following:

- Field studies where bee colonies were placed in fields adjacent to seed treated crops. These field studies examined residue levels and effects to pollinators before, during and after planting of treated maize. These studies examined the potential risk from 1) dust (from observations taken during planting), 2) off-field plants (from observations after planting and prior to pollen shed) whereby pollen analysis showed that bees were foraging on non-crop plants, and 3) off-field plants and treated maize during pollen shed (from observations at pollen shed). Overall, these studies showed low overall colony effects at treated sites compared to control sites, low residues in pollen collected from bees, low residues (non-detectable up to 0.004 mg/kg) in soil in treated fields, low residues in corn pollen (non-detectable up to 0.003 mg/kg), and indication of foraging on off-field crops such as Hydrangea, *Trifolium* and *Heracleum*, and *Platnago* (thiamethoxam PRVD2017-24: PMRA 2365365, 2365373). There was also low risk when comparing these residue levels to colony level endpoints.

- Residue studies assessing residues in rotational crops/plants, which provide insight into the residues that persist in soil and translocate into untreated plants. Although the residues were measured from crops/plants growing the following season, these residues are expected to be similar to residues which may have moved off-site and translocated into non-target off-field plants (PRVD2017-23: PMRA Nos. 2355485, 2355486, 2355487, 2355488, 2355489, 2510484, 2510485, 2532797, 2630589; PRVD2017-24: PMRA Nos. 2365321, 2365330). Overall, residues in untreated plants (alfalfa, phacelia, oilseed rape, sunflower, maize, mustard, zucchini, and beans), soil, and nectar and pollen from bees were low, indicating low carry-over of residues, and low levels of residues getting into pollen and nectar. There was low risk when comparing these residues levels to colony level endpoints.

The studies discussed above which were used in PRVD2017-23 and PRVD2017-24 are summarized individually at the end of this section.

Additional (new) information considered and assessed in this section includes the following:

- Residue studies which examined concentrations of neonicotinoids in water and soil around treated maize fields during and after corn planting in southwestern Ontario (Schaafsma et al., 2015). The study concluded that residues of thiamethoxam and

clothianidin increased in water within maize fields during the first 5 weeks of planting, and then returned to pre-plant levels 7 weeks after planting. Concentrations in water sampled from outside the fields were similar throughout the sampling period. Soil samples from the top 5 cm of the soil profile were also collected in these fields before and immediately following planting, which showed some levels of neonicotinoids. With the exception of one sample, water samples tested had concentrations below those reported to have acute, chronic or sublethal effects to honey bees. Schaafsma et al., 2015 concluded residues of neonicotinoid insecticides after 3 to 4 years of repeated annual seed treatment use tend to plateau to a mean concentration of less than 6 ng/g in agricultural soils in southwestern Ontario. It was not determined the extent to which residues would translocate from soil into plants in off-field sites, and residues in off-field plants were not measured. While residue information from this study was not directly incorporated into the updated off-field risk assessment, it is noted that residue levels were lower than levels in soils where rotational crops were grown.

- A study designed to measure residues in soil and dust in adjacent fields, following Cruiser 5FS treated (thiamethoxam) corn seed with fluency agents and seeding equipment (PMRA 2842660) was submitted by the registrant. Overall, residues of thiamethoxam and clothianidin were lowest off-field in soil when using a deflector and a dust reducing lubricant at wind speeds of 3.2-17.7 km/hr. Residues in off-field plants were not measured, therefore results of this study were not incorporated into the updated off-field risk assessment. This study is further considered in discussion on seed treatments in Appendix II Comments and Responses, Section 1.4.3.

- In addition to the studies listed above, a number of open literature references with residues in wildflowers and off-field plants (following seed treatment) were submitted during the consultation period for consideration in the risk assessment. A refined risk assessment was conducted with these residues, as presented in Table 4, along with the study summary information. Overall, these updated results concluded a low overall potential for colony risk to bees from exposure through foraging on off-field areas, particularly fields adjacent to treated crops.

Table 4 Refined risk assessment with new off-field residue information for clothianidin and thiamethoxam

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
Botías, C., D. Arthur, J. Horwood, A. Abdul-Sada, E. Nicholls, E. Hill and D. Goulson (2015). Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees. Environmental Science & Technology 49: 12731-12740.	-Thiamethoxam (THE) treated winter oilseed rape (OSR) (4.2 g a.i/kg of seed or 0.02 mg a.i./seed) or clothianidin (COD) treated winter wheat (WW) (0.5 g a.i/kg of seed or 0.02 mg a.i./seed) in late August or late September 2012. - A total of 7 OSR fields and 5 WW fields were tested. -Pollen and nectar sampled from OSR flowers, from wildflowers at field margins of OSR or WW and from in-hive pollen traps placed on honey bee colonies (HB) that were placed near treated OSR fields during and after OSR bloom. -sampled ~250-365 DAP - LOQ: 0.36 ppb; LOD: 0.12 ppb in pollen for THE and COD - LOQ: 0.30 ppb; LOD: 0.10 ppb in nectar for THE - LOQ: 0.50 ppb; LOD: 0.17 ppb in nectar for COD -Other matrices sampled: soil -Field conditions, U.K.	pollen from OSR flower **THE** 3.26 (2.79) **COD** 2.27	nectar from OSR flower **THE** 3.20 (2.73) **COD** 2.18	pollen from OSR flower **THE** **NO** **COD** NO	nectar from OSR flower **THE** **YES** **COD** NO	-The tested application rates on aper seed and a per hectare basis is similar to the registered rates for oilseed rape but 5 times higher for wheat. -Study conducted in the UK where there may be different planting equipment, acreage of crop, and BMPs. - No description of the surrounding vegetation as potential forage, the size of the test fields or the distance between the test fields was provided. -It is unclear if residues in wildflowers are from other neonicotinoid applications (e.g. foliar applications to orchard crops).	**THE:** *Potential for risk indicated for non-*Apis* bees from pollen in treated OSR fields and for *Apis* and non-*Apis* bees from wildflower pollen in OSR field margins. Colony level pollen endpoints are 4.5-6.6 c.e. ppb for *Apis* bees and 4.9-8.6 c.e. ppb for non-*Apis* bees. No potential risk indicated for *Apis* bees from pollen collected directly from treated OSR fields or for *Apis* and non-*Apis* bees from pollen collected by honey bees that were placed near treated OSR fields during and after OSR bloom. No potential risk indicated from nectar exposure for *Apis* bees and non-*Apis* bees. Potential risk to non-*Apis* bees from nectar in treated OSR flowers for some lower end colony level endpoints. Colony
		pollen from wildflowers from OSR margins **THE** 14.8 (12.7) **COD** <LOQ	nectar from wildflowers from OSR margins **THE** 0.10 (0.09) **COD** <LOQ	pollen from wildflowers from OSR margins **THE** **YES*** **COD** NO	nectar from wildflowers from OSR margins **THE** NO **COD** NO		
		pollen from wildflowers from WW margins **THE** 0.14	nectar from wildflowers from WW margins **THE** <LOD	pollen from wildflowers from WW margins **THE** NO	nectar from wildflowers from WW margins **THE** NO		

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Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
		(0.12) **COD** <LOD	**COD** <LOD	**COD** NO	**COD** NO		level nectar endpoints are 2.05-85.6 c.e. ppb for non-*Apis* bees. **COD:** No potential risk indicated for *Apis* and non-*Apis* bees from nectar or pollen exposure from treated crops or wildflowers in field margins.
		pollen from in-hive traps during OSR bloom **THE** 0.20 (0.17) **COD** <LOD	not collected	pollen from in-hive traps during OSR bloom **THE** NO **COD** NO	n/a		
		pollen from in-hive traps after OSR bloom **THE** <LOD **COD** <LOD	not collected	pollen from in-hive traps after OSR bloom **THE** NO **COD** NO	n/a		
Botías, C., A. David, E. M. Hill and D. Goulson (2016). Contamination of wild plants near	-Thiamethoxam (THE) treated winter oilseed rape (OSR) (Cruiser® seed dressing: 280 g/l THE, 8 g/l fludioxonil and 32.2 g/l metalaxyl-M; ~ 33.6 g THE/ha; 4.2 g THE/kg of seed	pollen from OSR flower **THE**	not reported	pollen from OSR flower **THE**	n/a	-The tested application rates on a per seed and a per hectare basis is similar to the registered rates for oilseed rape.	**THE:** No potential risk for *Apis* or non- *Apis* bees

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
neonicotinoid seed-treated crops, and implications for non-target insects. Science of the Total Environment 566-567: 269-278.	or 0.02 mg THE/seed based on Botías et al., (2015)) in late August 2012. -A total of 5 OSR fields tested. -3 sites of 50 m^2 within each OSR field were sampled ~280 DAP for pollen. OSR sites were at least 100 m apart - LOQ: 0.36 ppb; LOD: 0.12 ppb in pollen for THE -other matrices sampled: foliage -Field conditions, U.K.	3.15 (2.70) **COD** 1.90		NO **COD** NO		-Previous crops in these fields had been treated with a range of pesticides, including use of clothianidin for at least the two previous years (wheat and barley crops in 2010 and 2011 in the studied fields were all seed-treated with Redigo Deter®, active substances: 50 g/l prothioconazole and 250 g/l clothianidin; application rate for clothianidin: ~ 100 g a.s./ha). -Study conducted in the UK where there may be different planting equipment, acreage of crop, BMP	from pollen collected directly from OSR flowers. **COD:** No potential risk for *Apis* or non- *Apis* bees from pollen collected directly from OSR flowers. NOTE: The OSR pollen samples for Botías et al., 2016 were analysed as part of Botías et al., 2015 study where 7 OSR fields were sampled. Thus, in this study, the data obtained from the 5 OSR fields where foliage samples were also collected in order to compare levels and mixtures of neonicotinoids present in different tissues (foliage and pollen) of a single plant species (*Brassica napus* L., oilseed rape). No new information is presented in this study for bee relevant matrices.

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Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
David, A., C. Botías, A. Abdul-Sada, E. Nicholls, E. L. Rotheray, E. M. Hill and D. Goulson (2016). Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. Environment International 88: 169-178.	-Thiamethoxam (THE) treated winter oilseed rape (OSR) (4.2 g a.i/kg of seed or 0.02 mg a.i./seed) or clothianidin (COD) treated winter wheat (WW) (0.5 g a.i/kg of seed or 0.02 mg a.i./seed) in late August or late September 2012. - A total of 7 OSR fields and 5 WW fields were tested. -Pollen and nectar sampled from OSR flowers, from wildflowers at field margins of OSR or WW and from in-hive pollen traps placed on honey bee colonies (HB) that were placed near treated OSR fields during and after OSR bloom. Pollen sampled from bumble bee (BB) pollen baskets and whole bees -sampled ~250-365 DAP - LOQ: 0.36 ppb; LOD: 0.12 ppb in pollen for THE and COD -other matrices sampled: soil -Field conditions, U.K.	pollen from OSR flower **THE** 5.7 (4.9) **COD** 3.6	not reported	pollen from OSR flower **THE** **YES*** **COD** NO	n/a	-The tested application rates on aper seed and a per hectare basis is similar to the registered rates for oilseed rape but 5 times higher for wheat. -The study looked at residues of neonicotinoid insecticides and other pesticides. Only residue detections of THE and COD are shown here. -study conducted in the UK where there may be different planting equipment, acreage of crop, and BMPs. –It is unclear if wildflower residues are the result of other applications of neonicotinoids (i.e. orchard spraying etc.). -residues in nectar not reported/ collected	**THE:** *Potential for risk indicated for *Apis* and non-*Apis* bees from pollen in treated OSR fields. Residues in bumble bee collected pollen from rural areas exceeded colony level endpoints for both *Apis* and non-*Apis* bees. Colony level pollen endpoints are 4.5-6.6 c.e. ppb for *Apis* bees and 4.9-8.6 c.e. ppb for non-*Apis* bees. No potential risk indicated for *Apis* and non-*Apis* bees from pollen collected from wildflowers next to treated OSR or WW fields or for *Apis* and non-*Apis* bees from pollen collected by honey bees that were placed near treated OSR fields during and after OSR bloom. **COD:** No potential risk indicated for *Apis* and non-*Apis* bees from pollen exposure from
		pollen from wildflowers from OSR margins **THE** 2.8 (2.4) **COD** <LOQ	not reported	pollen from wildflowers from OSR margins **THE** **NO** **COD** NO	n/a		
		pollen from wildflowers from WW margins **THE** 0.13 (0.11)	not reported	pollen from wildflowers from WW margins **THE** NO	n/a		

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
		COD 0.50		**COD** NO			treated crops or wildflowers in field margins or from pollen collected by either honey bees before or after OSR bloom or bumble bees in rural and/or urban areas.
		pollen from HB in-hive pollen traps after OSR bloom **THE** 0.15 (0.13) **COD** <2.2	not reported	pollen from HB in-hive pollen traps after OSR bloom **THE** NO **COD** NO	n/a		
		pollen from HB in-hive pollen traps after OSR bloom **THE** <LOQ **COD** <0.72	not reported	pollen from HB in-hive pollen traps after OSR bloom **THE** NO **COD** NO	n/a		

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
		BB collected pollen in rural areas **THE** 18 (15.4) **COD** <LOD	not reported	BB collected pollen in rural areas **THE** **YES*** **COD** NO	n/a		
		BB collected pollen in urban areas **THE** <LOD **COD** <LOD	not reported	BB collected pollen in urban areas **THE** NO **COD** NO	n/a		
Long, E. Y. and C. H. Krupke (2016). Non-cultivated plants present a season-long route of pesticide exposure for honey bees. Nature Communications	-Corn seed were treated with fungicides and clothianidin (166.8 mL/80 000 kernel). -Pollen collected by honey bees was collected from pollen traps, identified and screened for agricultural pesticides over a period of 16 weeks in 2011 in	pollen from in-hive traps in non-ag areas **THE** 0.12 (010) **COD**	not collected	pollen from in-hive traps in non-ag areas **THE** NO **COD**	n/a	- The study was initiated after all planting of treated seeds in the study was completed, to minimize dust from pneumatic planters as a direct source of pesticide residues. -Regardless of the location of honey bee	**THE:** No potential risk indicated for *Apis* and non-*Apis* bees from pollen exposure. **COD:** No potential risk

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Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
7: 11629.	Indiana, USA.	0.16		NO		colonies, pollen loads were dominated by the Fabaceae. The honey bees did not collect much pollen from maize (<1%) and soybean (7.9%). -A large number of insecticides, herbicides and fungicides were detected in pollen traps, at varying levels. -The study was conducted in the USA, and may have had different application rates, BMPs and planting equipment.	indicated for *Apis* and non-*Apis* bees from pollen exposure.
		pollen from in-hive traps in untreated corn area **THE** 0.23 (0.20) **COD** 0.20	not collected	pollen from in-hive traps in untreated corn area **THE** NO **COD** NO	n/a		
		pollen from in-hive traps in treated corn area **THE** 0.08 (0.07) **COD** 0.66	not collected	pollen from in-hive traps in treated corn area **THE** NO **COD** NO	n/a		

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
Stewart, S. D., G. M. Lorenz, A. L. Catchot, J. Gore, D. Cook, J. Skinner, T. C. Mueller, D. R. Johnson, J. Zawislak and J. Barber (2014). Potential exposure of pollinators to neonicotinoid insecticides from the use of insecticide seed treatments in the mid-southern United States. Environmental Science & Technology 48(16): 9762-9769.	-Thiamethoxam (THE) treated soybean (Cruiser 5SF 0.5 g a.i./kg seed), corn (Cruiser 5F; 0.25 or 0.5 mg a.i./seed) and cotton (Cruiser Avicta; 0.375 mg a.i./seed) or clothianidin (COD) treated soybean (NipsIt Inside; 0.5 g a.i/kg of seed), corn (Poncho 250; 0.25 or 0.5 mg a.i./seed) or imidacloprid (IMI) treated soybean (Gaucho 600; 0.78 g a.i./kg seed) and cotton (Aeris; 0.375 mg a.i./seed) in late August or late September 2012. A control group was also included for each crop. -Pollen sampled from corn and cotton plants, nectar from cotton, whole flowers from soybean, and whole flowers from wildflowers adjacent to recently planted fields, pollen carried by honey bee (HB) (*Apis mellifera* L.) foragers returning to hives. -sampled at various intervals after planting. - LOD: 1 ppb in pollen for THE and COD. -Other matrices sampled: soil (pre-planting and in-season), whole bees -Field conditions, Arkansas,	pollen from corn treated at: 1.25 mg a.i./seed: **COD** 5.9 0.5 mg a.i./seed: **THE** 0.4 (0.34) 0.25 mg a.i./seed: **COD** 2.5	not collected	pollen from corn treated at: 1.25 mg a.i./seed: **COD** **YES*** 0.5 mg a.i./seed: **THE** NO 0.25 mg a.i./seed: **COD** NO	n/a	-Studies conducted within the registered rate range for corn and soybean. Soybean seed treatment not a registered use for clothianidin in Canada. Cotton is not grown in Canada. -Other neonicotinoids were measured. Only residues detections of THE and COD are shown here. - Wildflowers were collected from cotton, corn or soybean fields that were planted the previous week (flowers may have been exposed to drift containing neonic-contaminated talc). -Residues from whole flowers were used as a surrogate for both pollen and nectar in the risk assessment. -The study was conducted in the USA, and may have had different application rates, crops, BMPs and planting equipment.	**THE:** Potential for risk indicated for *Apis* and non-*Apis* bees from residues in wildflowersadjacent to recently planted fields. Colony level pollen endpoints are 4.5-6.6 c.e. ppb for *Apis* bees and 4.9-8.6 c.e. ppb for non-*Apis* bees. Colony level nectar endpoints are 2.05-85.6 c.e. ppb for non-*Apis* bees. Residues in wildflowers were from whole flowers. Whole flowers are expected to represent a more conservative exposure matrix compared to pollen and/or nectar. No potential risk indicated from pollen/nectar exposure in treated crops or from bee collected pollen. **COD:** *Potential for risk from corn pollen at highest maximum application
		soybean whole flowers **THE** <LOD **COD**	soybean whole flowers **THE** <LOD **COD**	soybean whole flowers **THE** NO **COD**	soybean whole flowers **THE** NO **COD**		

Study Reference	Study Information	EEC [a] - highest mean residue value in ppb (c.e.) [d]		Potential risk from pollen or nectar?[b,c,d]		Considerations	Overall potential for risk?
		Pollen	Nectar	Pollen	Nectar		
	Mississippi, Tennessee, United States	<LOD	<LOD	NO	NO		rate. Maximum application rate not typically used by growers in Canada. No potential risk indicated following seed treatment applications at lower rates of clothianidin typically used on corn in Canada. No potential risk indicated from pollen/nectar exposure in other treated crops, wildflowers or from bee collected pollen.
		pollen from cotton **THE** <LOD **COD** <LOD	nectar from cotton **THE** <LOD **COD** <LOD	pollen from cotton **THE** NO **COD** NO	nectar from cotton **THE** NO **COD** NO		
		wildflowers **THE** 7.2 (6.2) **COD** 1.4	wildflowers **THE** 7.2 (6.2) **COD** 1.4	wildflowers **THE** **YES*** **COD** NO	wildflowers **THE** **YES*** **COD** NO		
		pollen collected by HB **THE** <LOD **COD** <LOD	not collected	pollen collected by HB **THE** NO **COD** NO	n/a		

CG = crop group, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, HB=honey bee, BB=bumble bee, COD=clothianidin, THE=thiamethoxam, c.e.=clothianidin equivalent

[a] EEC for pollen and nectar is the highest mean residue value measured among all scenarios within a study.

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[b] Clothianidin colony feeding study critical effect endpoint values for *Apis* bees include: nectar: 19 ppb (NOEC)-35.6 ppb (LOEC); pollen: 4.9 ppb (LOEC)-20 ppb (NOEC).
Clothianidin colony feeding study critical effect endpoint values for non- *Apis* bees include: nectar: 17 ppb (NOEC) to 39 ppb (LOEC); pollen: 4.9 c.e. ppb (LOEC).
Thiamethoxam colony feeding study critical effect endpoint values for *Apis* bees include: nectar: 26 c.e. ppb (NOEC) to 69 c.e. ppb (LOEC); pollen: 4.5-6.6 c.e. ppb (LOEC).
Thiamethoxam colony feeding study critical effect endpoint values for non-*Apis* bees include: nectar: 2.05 c.e. ppb (LOEC) to 85.6 c.e. ppb (NOEC); pollen: 4.9-8.6 c.e.ppb (LOEC).
[c] Highest mean clothianidin concentrations measured in pollen and nectar are compared with the colony feeding study critical effect endpoint values for pollen and nectar, respectively. "**Yes**" indicates the measured residue level is greater than the lower bound critical effect endpoint value and poses potential risk to *Apis* bees and/or non-*Apis* bees; "No" indicates that the measured residue level is less than the lower bound critical effect endpoint value and may not pose risk to *Apis* bees and/or non-*Apis* bees. "n/a" indicates residue information is not available. The overall potential for risk is considered as 'Yes' when either the pollen or nectar exposure route indicates a potential risk.
[d] Thiamethoxam residue values adjusted for molar ratio of thiamethoxam to clothianidin (0.856) and expressed as clothianidin equivalent (c.e.). NOTE: All endpoints in terms of ppb clothianidin or clothianidin equivalent (c.e.).

Summaries of studies previously used in PRVD2017-23 and PRVD2017-24:

Residue Studies: Carry-over from previous seed or soil treatment

Both assessments (PRVD2017-23 and PRVD2017-24) considered higher tier data where untreated crops/plants were planted in fields that were treated the previous year (with different uses, primarily seed treatments) (PRVD2017-23: PMRA Nos. 2355485, 2355486, 2355487, 2355488, 2355489, 2510484, 2510485, 2532797, 2630589; PRVD2017-24: PMRA Nos. 2365321, 2365330, 2365332, 2461577, 2365414, 2365090, 2365092, 2365094, 2365095, 2365412, 2365044, 2364945, 2364957, 2365020, 2365062, 2365067, 2580511). These carry-over studies measured residues in pollen and nectar that may have been taken up by soil and translocated into growing untreated crops/plants. The residue values in pollen and nectar were used in the Tier I and Tier II risk assessments which are presented in Appendix VII Pollinator Risk Assessment for Soil Applications of Clothianidin (PRVD2017-23) and Thiamethoxam (PRVD2017-24). Based on the available data, there was low colony risk to bees; residues in pollen and nectar were generally low and typically below the levels which were expected to result in colony level effects based on colony feeding study effects endpoints. While the residue information from the carry-over studies is presented in PRVD2017-23 and PRVD2017-24, a brief summary of each study is provided below to explain how it was used in the risk assessment. Maximum residues were used in the Tier I refined assessment, while the highest mean residues were used in the Tier II refined assessment which compared residue levels with colony effects endpoints.

PMRA 2365321 (THE) – Treated maize was sown in spring 2008, followed by treated winter barley in autumn 2008, and then followed by untreated alfalfa, Phacelia and oilseed rape in spring 2009:

Maximum residues in alfalfa plants, nectar and bee pollen were 0.005 and 0.0022 mg/kg but almost all were <0.005 (LOQ) and 0.001 (LOQ) mg/kg, respectively. Maximum residues in phacelia plants, nectar and bee pollen were <0.001 (LOQ), 0<0.005 (LOQ) and <0.001 (LOQ) mg/kg, respectively. Oilseed rape plants were not included. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees from thiamethoxam in alfalfa and phacelia.

PMRA 2365330 (THE) - Treated maize was sown in spring 2008, followed by treated winter barley in autumn 2008, and then followed by untreated alfalfa, Phacelia and oilseed rape in spring 2009:

Maximum residues in alfalfa plants, nectar and bee pollen were 0.005, <0.0005 (LOQ) and <0.001 (LOQ) mg/kg, respectively. Maximum residues in phacelia plants, nectar and bee pollen were 0.006, 0.014 and <0.001 (LOQ) mg/kg, respectively. Maximum residues in oilseed rape plants, nectar and bee pollen were 0.012, 0.0052, and 0.008 mg/kg, respectively. Therefore, residues were generally low from possible carry-over, and thus there was low exposure to the bees from thiamethoxam. Phacelia and oilseed rape residues were higher than alfalfa.

PMRA 2461577 (THE) – Treated canola seeds in the first year, followed untreated canola the following year:

Maximum residues in pollen and nectar collected from plants were <LOD (0.22 mg/kg). Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to thiamethoxam.

PMRA 2365414 (THE) – Treated sunflower seeds in the first year, followed untreated sunflower the following year:

Maximum residues in nectar collected from plants was <LOQ (1 mg/kg). Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to thiamethoxam.

PMRA 2365090, 2365092, 2365094, 2365095 (THE) – Treated barley seeds in the first year, followed untreated sunflower or corn the following year:

Maximum residues in pollen and nectar collected from plants were 1.5 and <LOQ (1) mg/kg, respectively. All corn pollen residues were below LOQ. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to thiamethoxam.

PMRA 2365412 (THE) – Treated corn seeds in the first year, followed untreated sunflower the following year:

Maximum residues in pollen collected from plants were 1.5 and <LOD (1) mg/kg, respectively. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to thiamethoxam.

PMRA 2365044 (THE) – Treated barley seeds in the first year, followed untreated oilseed rape the following year:

Maximum residues in pollen and nectar collected from bees were 6 and 4.1 mg/kg, respectively (highest mean 4.1 mg/kg pollen, 4 mg/kg nectar). Therefore, some residues were possible from possible carry-over, and thus there was some exposure to the bees to thiamethoxam.

PMRA 2364945, 2364957, 2365020, 2365062, 2365067 (THE) – Treated maize for two or three years with sampling at each year:

Maximum residues in pollen collected from bees or plants ranged from <LOQ (1 mg/kg) to 4 mg/kg for most studies. One study showed residues up to 12 mg/kg. Highest mean residues ranged from 1.0-8.3 mg/kg in pollen). Considering all of the data, residues were low from possible carry-over, and thus there was low exposure to the bees to thiamethoxam.

PMRA 2580511 (THE) – Treated in-furrow potato in the spring, followed by untreated canola the following year:

Maximum residues in pollen and nectar collected from plants were 45 and 3.4 mg/kg, respectively. Therefore, some residues were possible from carry-over, and thus there was some potential exposure to the bees to thiamethoxam.

PMRA 2355485 (COD) – Treated barley seeds and also soil application in year 1, followed by untreated winter rape in year 2, followed by sampling of winter rape in year 3:

Maximum residues in pollen and nectar collected from bees were 0.65 and 0.15 mg/kg, respectively. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to clothianidin.

PMRA 2355486 (COD) – Treated barley seeds and also soil application in year 1, followed by untreated winter rape in year 2, followed by sampling of winter rape in year 3:

Maximum residues in pollen and nectar collected from bees were 1 and 0.15 mg/kg, respectively. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to clothianidin.

PMRA 2355487 (COD) – Treated soil application followed by untreated summer rape:

Maximum residues in pollen and nectar collected from bees were 4 and 2.15 mg/kg, respectively. Therefore, residues were low from possible carry-over, and there was low exposure to the bees to clothianidin. Neither nectar nor pollen residues were expected to result in colony level effects.

PMRA 2355488 (COD) – Treated soil application followed by untreated corn:

Maximum residues in pollen collected from plants were 1.8 mg/kg. Therefore, residues were low from possible carry-over, and there was low exposure to the bees to clothianidin. Pollen residues were not expected to result in colony level effects.

PMRA 2355489 (COD) – Treated soil application followed by untreated corn:

Maximum residues in pollen collected from plants were 1.2 mg/kg. Therefore, residues were low from possible carry-over, and there was low exposure to the bees to clothianidin. Pollen residues were not expected to result in colony level effects.

PMRA 2510484 (COD) – Treated barley seed and soil application in year 1, followed by untreated corn, mustard or phacelia:

Maximum residues in pollen from bees and nectar collected from bees were 10 and 1 mg/kg, respectively (highest mean residues ranged from 1.0-9.1 mg/kg in pollen and 0.1- 0.77 mg/kg in nectar). Mustard had the highest residues. Other crops had lower residues. Residues in nectar were not expected to result in colony level effects. However, mustard pollen residues were above *Apis* and non-*Apis* colony level endpoints.

PMRA 2510485 (COD) – Treated barley seed and soil application in year 1, followed by untreated corn, mustard or phacelia:

Maximum residues in pollen from bees and nectar collected from bees were 11 and 6.9 mg/kg, respectively (highest mean residues ranged from 1.9-10 mg/kg in pollen and 2.6-6.2 mg/kg in nectar). Phacelia had the highest residues. Other crops had lower residues. Residues in nectar were not expected to result in colony level effects. However, phacelia pollen residues were above *Apis* and non-*Apis* colony level endpoints.

PMRA 2532797 (COD) – Three years of soil application followed by untreated sunflower:

Maximum residues in sunflower pollen, bee collected pollen and nectar from hives was 0.65 and 1 and 0.15 mg/kg, respectively. Therefore, residues were low from possible carry-over, and thus there was low exposure to the bees to clothianidin.

PMRA 2630589 (COD) – Treated soil application followed by untreated rapeseed, corn, mustard, zucchini, field beans and sunflower:

Maximum residues in pollen from hives and nectar collected from flowers were 11 and 3 mg/kg, respectively (highest mean residues ranged from 0.65-10 mg/kg in pollen and 0.15-2.67 mg/kg in nectar). Mustard had the highest pollen residues and rapeseed had the highest nectar residues. Other crops had lower residues. Residues in nectar were not expected to result in colony level effects. However, mustard pollen residues were above *Apis* and non-*Apis* colony level endpoints.

<u>Colony effects studies: Exposure to off-field crops</u>

A large number of studies which were already assessed in PRVD2017-24 and PRVD-23 concluded a low overall potential for colony risk to bees resulting from exposure to bees through foraging on fields <u>adjacent</u> to seed treated crops, and low residues in pollen and nectar. See below for details.

As already presented in PRVD2017-23 and PRVD2017-24:

PMRA 2365365 (THE) off crop field adjacent to treated maize.

Residue analysis indicated there were some residues of thiamethoxam in soil (up to 0.004 mg/kg) in the treatment field. There were also some residues in maize plants which ranged between 0.002 and 0.003 mg/kg in treated corn. However, there were no residues in pollen from plants or pollen collected from forager bees (<LOQ, 0.001 mg/kg). In addition there was a low percentage

of maize pollen collected for both treatment (up to 11%) and control hives (up to 18%) on most days. The one exception is that one treatment hive contained up to 64% pollen. Other sources of pollen included hydrangea, *Trifolium* and *Heracleum.*

Mortality was low and similar between treatment and control hives (11 to 16.9 dead bees/day) for the pre-drilling and post drilling phase. However, there was increased mortality around the time of maize emergence (up to 237 dead bees) in treatment hives which lasted for a few days; all the dead bee samples contained residues of thiamethoxam and metabolite CGA322704. Colony strength was similar between the treatment and control hives, and was variable throughout the study.

PMRA 2365370 (THE) off crop field adjacent to treated maize.

Mortality was higher (up to 75 dead bees) in the treatment hives compared to control after drilling on a number of days. Mortality was also higher in the treatment hives for a few days around the time of emergence (between 205 and 259 dead bees). Colony strength was similar between the treatment and control hives, and was variable throughout the study. Residue analysis indicated no residues of thiamethoxam or clothianidin in soil, or pollen samples from plants or forager bees at the treatment or control fields. However, there were some residues detected in maize plants (up to 0.003 mg/kg) at the treatment site.

PMRA 2365373 (THE) off crop field adjacent to treated maize.

Mortality and flight intensity was similar between control and treatment hives. Colony strength was similar between the treatment and control hives, and was variable throughout the study.

Residue analysis indicated there were no residues of thiamethoxam or clothianidin in soil, or pollen samples from maize plants or forager bees at the treatment fields. However, there were some residues detected in maize plants (up to 0.005 mg/kg) at the treatment site. There was also pollen from the control field plants which contained 0.261 mg/kg thiamethoxam and 0.036 mg/kg metabolite CGA322704. The percentage of pollen collected from maize ranged from 4 to 53% in the control and 3 to 71% in treatment hives. Other sources of pollen included *Trifolium repens* and *Platnago sp*.

1.1.7 Updated incident reports

Health Canada has continued to monitor pollinator incident reports following the assessment and publication of PRVD2017-24 (thiamethoxam) and PRVD2017-23 (clothiandin). Since 2016, Health Canada has continued to receive reports of effects in bee yards mainly in Ontario and Quebec. These included incidents reported throughout the season in 2017 and 2018 from 42 and 13 bee yards, respectively. Of these 55 bee yards, 22 were reported during the planting period and 14 during the post-plant period as potentially associated with exposure from treated seed dust. The symptoms reported for the yards in 2017 and 2018, were similar to those described in the Update on Canadian Bee Incident Reports 2012-2016. The number of incidents reported in 2017 and 2018 were similar to the number of reports received for 2014–2016, which were reduced by 70–90% compared to the number of reports in 2013.

2.0 Value Assessment

2.1 What is the Value of Thiamethoxam

Thiamethoxam has value to users as a broad spectrum insecticide when applied as a seed, soil or foliar treatment on a range of crops. For some uses, it is the only active ingredient registered to manage major pests and therefore has acceptable value to crop production in Canada.

During consultation, a number of stakeholders emphasized that for many of the registered uses of thiamethoxam there are few or no alternatives registered and indicated that in some cases where alternative products are registered, they may be more costly than, and/or not as effective as thiamethoxam. Health Canada acknowledges that there are no or limited alternative active ingredients registered for certain thiamethoxam uses or that certain alternatives may be more costly to apply than thiamethoxam. An assessment of the registered alternatives determined a lack of alternatives for the following pests and crops:

- Brown marmorated stink bug on apple, crab apple, pear, and oriental pear;
- Brown marmorated stink bug and obscure root weevil on bushberries;
- Black vine weevil, cranberry weevil and strawberry root weevil on low growing berries (except strawberry and lowbush blueberry); and
- Brown marmorated stink bug and black vine weevils on outdoor ornamentals.

3.0 Conclusion of Science Evaluation

Updates to the pollinator risk assessment included refinement for post-bloom foliar application to orchard crops considering all available pollen and nectar residue data and an update with new residue data for ornamentals (foliar and soil application) and blueberry crops (foliar). Updates also included additional residues for off-field exposure, and colony feeding study endpoints. These additional data and revisions to the risk assessment did not change the overall risk conclusions; therefore, Health Canada supports continued, but amended, registration of thiamethoxam for uses where risk is acceptable with mitigation as outlined below and in the label amendments listed in Appendix III.

In order to protect pollinators, Health Canada is cancelling the following uses of thiamethoxam:

- Foliar and soil application to ornamental crops that will result in pollinator exposure (in other words, are planted outdoors and are attractive to pollinators),
- Soil application to berry crops, cucurbit crops and fruiting vegetables, and
- Foliar application to orchard trees.

In order to protect pollinators, Health Canada is changing the timing of application for the following uses of thiamethoxam:

The following crops cannot be sprayed before or during bloom:

- Foliar application to legume and outdoor fruiting vegetables, and
- Foliar application to berry crops (with renovation required for woody berries).

The following crops cannot be sprayed during bloom:

- Foliar application to sweet potato and potato

To minimize bee exposure to dust during planting of treated seed, additional label statements are required for the following use:

- Seed treatment of cereal and legume crops.

Thiamethoxam has value to crop production in Canada as an insecticide to control a variety of insect pests when applied as a foliar or soil application, as well as a seed treatment, particularly for management of brown marmorated stink bug on a number of fruits and ornamentals and several weevils on some berries where there are no alternatives.

The additional risk mitigation measures described above will be implemented over a 24-month period. The risks identified are not considered imminent because they are not expected to cause irreversible harm over this period. Potential effects include sublethal effects on colonies or solitary bees, but affected pollinator populations are expected to recover following implementation of the additional restrictions which will reduce exposure. Moreover, recovery is expected because risks to pollinators are geographically limited to areas where these products are applied and areas adjacent to application sites. The presence of unaffected solitary bees, bumble bees, and honey bees in areas where products are not being used will further facilitate recovery since unaffected bees in the environment can move back into areas where effects may have occurred. Overall, risk to pollinators is acceptable over the time period required to implement the mitigation measures.

As a result of this decision, growers will be required to change their pest management practices. Pesticides have extensive and precise instructions and often require specialized application and safety equipment and training. This transition period will allow for an orderly and safe implementation of these new restrictions, and should reduce the risk of product misuse or the improper disposal of products as users switch to alternatives, where required. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses as a result of a re-evaluation (Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*) and with the practice of other international regulators.

A small subset of uses were found to lack alternatives for the management of certain serious pests (the invasive brown marmorated stink bug and certain weevils) on a very few crops present in limited geographical areas of Canada. As a result, the implementation of the re-evaluation decision for these uses will be delayed for an additional year to allow growers to find pest management solutions. During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing which will further reduce pollinator exposure. The risks to pollinators are therefore considered acceptable for an additional year for this small subset of uses.

List of Abbreviations

a.i.	active ingredient
BB	bumble bee
c.e	clothianidin equivalents
CFS	colony feeding study
CG	crop group
CLO	clothianidin
COD	clothianidin
DALA	days after last application
DAP	days after planting
EFSA	European Food Safety Authority
EEC	estimated environmental exposure concentration
EDD	estimated daily dose
g	grams
ha	hectare
IPM	Integrated pest managementkg kilogram
K_{oc}	organic-carbon partition coefficient
LD_{50}	Median lethal dose
LOAEC	Lowest observed adverse effect concentration
LOC	Level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOQ	limit of quantitation
mg	milligram
µg	microgram
ng	nanogram
NOEC	no observed effect concentration
NOED	No observed effect dose
OECD	Organization of Economic Co-operation and Development
OM	organic matter
PRVD	Proposed re-evaluation decision
ppb	parts per billion
RQ	Risk quotient
RVD	Re-evaluation Decision Document
TGAI	Technical grade active ingredient
THE	thiamethoxam
TMX	thiamethoxam
TU	toxic unit
USEPA	Environmental Protection Agency
Y	year

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Appendix I Registered Thiamethoxam Products in Canada Subject to This Re-evaluation[5]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
26665	Technical	Syngenta Canada Inc.	Thiamethoxam Technical	Dust or powder (solid)	99.1%
26637	Commercial	Syngenta Canada Inc.	Helix Liquid Seed Treatment	Suspension	Thiamethoxam 10.3%; metalaxyl-M and S isomer 0.39%; fludioxonil 0.13%; difenoconazole 1.24%
27045			Cruiser 5FS Seed Treatment		Thiamethoxam 47.6%
27986			Cruiser 350FS Seed Treatment Insecticide		Thiamethoxam 29.9%
28407			Actara 240SC Insecticide		Thiamethoxam 240 g/L
28408			Actara 25WG Insecticide	Wettable granules	Thiamethoxam 25.0%
28821			Cruiser Maxx Beans Seed Treatment	Suspension	Thiamethoxam 22.6%; metalaxyl-M and S isomer 1.70%; fludioxonil 1.12%
29127			Cruiser Maxx Cereals Commercial Seed Treatment		Thiamethoxam 2.8%; metalaxyl-M and S isomer 0. 56%; difenoconazole 3.36%
29192			Cruiser Maxx Cereals Seed Treatment		Thiamethoxam 2.8%; metalaxyl-M and S isomer 0. 56%; difenoconazole 3.36%
30388			A18046A Seed Treatment		Thiamethoxam 261 g/L; metalaxyl-M and S isomer 19.7 g/L; fludioxonil 12.9 g/L; azoxystrobin 10.4g/L
30404			Endigo Insecticide		Thiamethoxam 141 g/L; lambda-cyhalothrin 106 g/L
30436			Cruiser Maxx Vibrance Cereals Seed Treatment		Thiamethoxam 30.7 g/L; sedaxane 8.0 g/L; metalaxyl-M and S isomer 9.5 g/L; difenoconazole 36.9 g/L
30723			Flagship Insecticide	Wettable granules	Thiamethoxam 25%
30900			Minecto Duo 40WG	Wettable granules	Thiamethoxam 20%; cyantraniliprole 20%
30901			Mainspring X Insecticide		Thiamethoxam 20%; cyantraniliprole 20%

[5] As of 2 October 2018, excluding discontinued products and products with a submission to discontinue

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Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31024			Cruiser Maxx Potato Extreme	Suspension	Thiamethoxam 250 g/L; fludioxonil 62.5 g/L; difenoconazole 123 g/L
31453			Cruiser Vibrance Quattro		Thiamethoxam 61.5 g/L Difenoconazole 36.9 g/L Metalaxyl-M and S-Isomer 9.2 g/L Sedaxane 15.4 g/L Fludioxonil 7.7 g/L
31454			Helix Vibrance		Thiamethoxam 269 g/L Difenoconazole 16 g/L Metalaxyl-M and S-Isomer 5 g/L Sedaxane 3.4 g/L Fludioxonil 1.7 g/L

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Appendix II Comments and Responses

In response to the consultation for the thiamethoxam proposed pollinator re-evaluation decision, the following comments were received, in addition to the information already discussed in the main body of the document:

1.0 Comments and Responses Related to the Environment

Of the 13,900 comments received during the consultation period, a total of 49 substantive comments related to the environment were identified. Within these 49 comments, many contained multiple comments on different subject areas, for a total of approximately 70 substantive comments identified as relevant to the environmental risk assessment. The comments covered a wide range of subjects including endpoint selection, exposure, risk assessment approach, seed treatments, international context, and risk mitigation.

This appendix includes the comments and responses for both the clothianidin PRVD2017-23 and the thiamethoxam PRVD2017-24. This is because a majority of the comments applied to both the clothianidin and thiamethoxam environmental risk assessment, and only a small number of comments were relevant only to one of the PRVDs. Comments relevant only to one PRVD were typically related to the value of the products and specific to the clothianidin or thiamethoxam use pattern, such as comments regarding ornamentals (thiamethoxam only), turf (clothianidin only) or other use pattern specific comments applicable to only one of the pesticides. Because the majority of the comments are relevant or informative to both PRVDs, all comments and responses related to the environment for both PRVD2017-23 and PRVD2017-24 are included in this appendix.

Because many of the substantive comments contained multiple comments on different environmental subject areas, parts of comments submitted by the same commenter may be considered under different subject headings. Thus, only the relevant parts of some comments may be presented under a specific subject heading, and may not include all information that was provided in the comment.

1.1 Endpoint selection

1.1.1 Colony feeding studies

Concerns were raised regarding how the endpoints were selected for use in the risk assessment. There was concern that the lowest reported effect levels were used, and suggestions that probabilistic analysis and different weight of evidence approaches should be considered. There were also concerns regarding the use of published literature endpoints that may not have followed a validated test guideline.

1.1.1.1 Colony feeding studies - Bayer Crop Science

Comment (Bayer Crop Science)

When multiple toxicity studies are available, the Agency has tended to exclusively use endpoints from the study that reported the lowest effect level, rather than averaging across studies or choosing endpoints using a weight of evidence approach. Again, this practice tends to bias the assessment toward a conclusion

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of risk. Such practices are appropriate in screening risk assessments where the intent is to identify potential risks that need further assessment. However, regulatory decisions are better informed by assessments that have been refined using probabilistic analysis and weight of the evidence approaches.

Comment (Bayer Crop Science)

Perhaps our greatest concern with the PMRA pollinator assessments for Clothianidin and Thiamethoxam have to do with decisions to derive effects endpoints from published studies that have substantial weaknesses. Specifically, we'd like to make the following points: 1. Before accepting registrant-submitted studies, the Agency generally insists upon study methods being consistent with published test guidelines or otherwise in accordance with a study protocol submitted in advance to the Agency for review and comment. Published studies rarely if ever meet these criteria and have many weaknesses such as:

a. Not conducted in accordance with a validated test guideline or approved protocol

b. Endpoints not relevant to a regulatory risk assessment

c. Results inconsistent with other test results (are they reproducible?)

d. Limitations in experimental design (lack of enough replicates, test levels, etc.)

e. Inadequate analytical confirmation of test levels

f. Errors in methods or calculations

g. Underlying data to reproduce statistical analyses not available

h. Not conducted in accordance with Good Laboratory Practice requirements

Studies with the above limitations should be given less weight than studies conducted per Agency approved guidelines and protocols, including compliance with GLP regulations which ensures all raw data are available for Agency review. The practice of picking out and using the study with the lowest toxicity endpoint from all possible studies and using this endpoint exclusively in a risk assessment essentially gives maximum weight to such studies and minimum weight to all other studies. This may be done to comply with a policy objective to "err on the side of conservatism", i.e., to overestimate the level of risk rather than the other way around. However, the result may be bad science. A proper weight-of-evidence assessment considers the totality of available information and the relevance, strength, and reliability of each study (USEPA 2016). Studies that report low toxicity values but otherwise do not meet the criteria of high relevance, strength and reliability should be given little weight in an assessment.

Health Canada Response

The risk assessment took into consideration many lines of evidence including the potential for exposure, information on the toxicity of clothianidin and/or thiamethoxam on bees from laboratory tests, semi-field and field studies and information on the effects of clothianidin and/or thiamethoxam on the honey bee colony in the field including monitoring information and incident reporting. The risk assessment took into consideration all relevant data from the registrant and open literature.

All the reviewed studies had strengths and limitations. Selection of effect endpoints for use in the risk assessment was based on consideration of all available studies to date based on these strengths and limitations. At the Tier I level, for instance, all endpoints selected for use in the Tier I risk assessment were derived from registrant submitted studies but were considered

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alongside all available Tier I laboratory based studies from both the open literature and registrant. In many cases the laboratory derived endpoints reported from open literature studies were similar to the endpoints determined from registrant submitted studies. The most sensitive endpoints were selected for the risk assessment considering whether raw data were available to verify the toxic endpoints and consideration was given to whether the study was conducted in accordance with GLP and was scientifically sound.

Endpoints were also derived from Tier II colony feeding studies. The sucrose dosing colony feeding studies conducted by the registrant had many strengths, including high replication, hive residue, viral and effects information (including hive development before and after overwintering). However, in searching the open literature for additional studies, there were also a number of studies which dosed non-*Apis* bees, dosed bees with pollen /pollen patties, and/or dosed bees with a combination of thiamethoxam and clothianidin. In addition, open literature studies included various other endpoints which may also lead to colony level effects. Health Canada used all of the available information to assess potential colony effects to bees from exposure to thiamethoxam and/or clothianidin. For instance, the lowest pollen based effect endpoint used in the Tier II refined risk assessment was selected considering multiple open literature colony feeding studies with measurement endpoints that were different from registrant colony feeding studies. The open literature studies consistently demonstrated effects at lower exposure levels compared to registrant studies making it difficult to discount the results despite the study limitations.

1.1.1.2 Colony feeding studies - Valent

Comment (Valent)

Valent strongly support the PMRA's decision to derive effects endpoints for use in Tier II risk assessments from colony-level dietary exposure studies. However, there is no formal guidance to conduct these non-guideline studies. The available colony feeding studies (CFS) present differences in study designs and also variation of effects, in particular for the pollen studies. As reported by the PMRA, while some specific pollen-CFS effects were observed at doses ranging from 4.5 to 6.6 ppb, in others no-effects were detected at higher doses, i.e. 5-20 ppb. Given the results of all these studies, PMRA reports in different parts of the risk assessment two different critical endpoints for pollen and bee bread for clothianidin: a Lowest-Effect-Concentration (LOEC) of 4.9 ppb and a Non-Effect-Concentration (NOEC) of 20 ppb. These endpoints are in contradiction, and the PMRA's proposed decision for clothianidin was to simply select the lowest endpoint reported among open CFS studies, i.e. a LOEC of 4.9 ppb.

Comment (Valent)

The following comments are offered on several papers reviewed by the PMRA:

The Williams et al. (2015) study is not directly comparable to any of the other colony-feeding studies as it evaluated colonies set up for mass rearing of queens which involves very different colony management practices. The effect reported (queen failure) has not been found to occur in field studies (e.g., Cutler et al., 2014, Rundloff et al., 2015) of conventionally-managed colonies or by commercial beekeepers. The Williams study was also a small study (6 test colonies of which 3 received pesticide treatment) that employed pseudoreplication in the experimental design. It may therefore be dismissed as unsuitable for use in risk assessment.

The Sandrock et al. (2014) reported a small difference in colony strength endpoints immediately after the exposure period which disappeared by the time the colonies were getting prepared for winter. Then there was a dramatic difference between treatment and control colonies the following summer for which there is

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no explanation from a toxicological perspective. For example, it is not clear if the bees were even still being exposed at the time these colony failures occurred, or even at any time during their lives particularly given that no bee or pupae samples collected directly after treatment or hive samples collected 3 weeks after treatment contain detectable residues of either thiamethoxam or clothianidin (LOD of 0.1 ppb). A significant weakness of this study is that only a single exposure level was tested and it is not clear if the results would be reproduced along a dose-response gradient. The demonstration of a robust dose-response relationship is a significant strength of the registrant-submitted colony feeding studies.

In the Straub et al. (2016) study only one concentration was tested and the exposure scenario unclear. The authors conclude that significant effects were observed in longevity of drones and reduced sperm viability and living sperm quality. Interestingly, and conversely to other studies, in this study no significant effects were observed on teneral body mass of drones, longevity of female workers or quantity of drone sperm. Although the authors speculate about it, it is unknown whether the observed effects in this study will actually result in negative impacts to colony fitness in natural conditions, as this was not investigated. Also, it is worth noting the large variability in the sperm assessments in control groups in this study, which could have had impacted the results.

While the Williams, Straub and Sandrock studies were designed to reflect field exposure of honey bees to neonicotinoid treatments, we agree with PMRA that they cannot be used for the risk assessment specifically of clothianidin, as the treatments involved a mixture of both thiamethoxam and clothianidin i.e. any effects cannot be attributed to either one of them (particularly clothianidin as this was present at a significantly lower concentration).

In the Tsvetkov et al. (2017) study, honey bee colonies were chronically treated with artificial pollen containing clothianidin only. While in this study sub-lethal effects were observed at the highest dose of 4.9 ppb of clothianidin in worker bees (e.g. decline in hygienic behavior or reduction in age to last foraging flight) as well as increase of queenlessness, it is unknown whether these effects will actually result in negative impacts to colony fitness, as colony strength measurement or overwintering survival were not investigated. It is also noted that in this study there is lack of exposure confirmation in control groups, which is a clear deficiency that questions the reliability of the results. Additional conservatism in this study is the 12-week exposure period, compared to for example the 2-3 weeks of orchard bloom interval. Bees will also feed on a variety of alternative forage sources in natural conditions, both crop and non-crop in order to meet their nutritional needs.

Health Canada Response

Health Canada is currently working with international partners in order to develop guidance for colony feeding studies using dosing matrices of both sucrose solutions and pollen mixtures. No standard study guidelines for colony feeding studies were available at the time of the assessments, and the studies available for consideration (from registrants and literature) utilized various study designs and looked at a variety of measurement endpoints. When considering these studies, Health Canada considered the strengths and limitations of each study, consistency of effects among studies and reported effects, as well as whether or not effects measured in the studies would be likely to impact growth, reproduction, and/or survival of bee colonies.

Health Canada acknowledges that there were study limitations in the pollen based colony feeding studies that were considered in the risk assessments, and that the endpoint range selection used in the Tier II risk assessment to assess the pollen exposure route, may be somewhat unconventional. All of the studies provided some degree of strength and limitation in the context of the pollinator risk assessment, and thus a range of endpoints was considered. It is noted that even among the lower tier acute studies (registrant conducted or derived from the open literature) there was a large degree of variation in endpoints. It was not always the lowest endpoint which was used in the risk assessment, but rather the endpoint or endpoints thought to be the most valid. In the

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absence of more suitable studies from which to select endpoints, all available information was considered together (as a range of endpoints) in order to be able to assess the risk to bees from exposure to neonicotinoids through the pollen exposure route.

The following information is provided outlining the limitations we considered in the pollen based colony feeding studies for honey bees which were considered in the clothianidin and thiamethoxam risk assessments.

In the clothianidin pollen-based honey bee colony feeding study submitted by the registrant, there were no treatment related effects detected on mortality, foraging activity, comb production, honey storage, behaviour, or population growth (PMRA No. 1194878). However, there was no replication of control or treatment groups. Therefore, no measure of variability was possible, and no statistical analysis could be performed on the data. This limits the certainty of the results coming from this study.

In the pollen-based honey bee colony feeding studies from the open literature, effects were observed, but there were also a number of limitations in these studies. Tsvetkov et al., (2017) found that colonies fed an artificial pollen patty diet spiked with declining concentrations of clothianidin (4.9 declining to 2.0 ppb) over a period of 12 weeks demonstrated a decline in hygienic behavior (removal of dead capped brood), increased queenlessness, change in worker flight pattern (time, duration) and reduction in age to last foraging flight relative to controls. This study did not assess overwintering survival and other colony health related endpoints (as measured in some other studies), but did examine potential queen effects. However, as the experiment ended in August, it is uncertain whether treated hives would have gone on to rear replacement queens before the overwintering period. While supersedure tends to take place in late spring and summer, supersedure can occur anytime from early spring through to late fall. While the results of this study are difficult to relate to a single exposure concentration as the colonies were fed with a declining dose regimen over a 12 week period, this exposure regime may better represent what happens in the environment, with levels similar to ranges in some reported incidents.

Effects data from Sandrock et al., 2014, Straub et al., 2016 and Williams et al., 2015 (LOEC 4.5-6.6 µg c.e./kg) where bees were fed pollen patties containing both clothianidin and thiamethoxam, and effects are expressed as clothianidin equivalents, are comparable to the high end of the dose tested in the study by Tsvetkov et al., 2017 (4.9 ppb) where bees were fed pollen containing clothianidin only. In the Sandrock et al., 2014, Straub et al., 2016 and Williams et al., 2015 studies, only one dose was tested. Therefore, the level at which no effects are observed is unknown. There were some differences between the effects observed in the Sandrock et al., 2014 and Williams et al., 2015 studies (for example, varying degrees of queen observations). These differences may have been the result of varying exposure levels (pollen versus nectar ratios), study design, observed effects (for example, queen development was the focus of the Williams et al., 2015 study) or length of exposure (longer in the Sandrock et al., 2014 study), or length of observations (longer in the Sandrock et al., 2014 study and included overwintering). A lack of raw data precludes an analysis of the results.

In addition, there was a lack of replication, particularly in the Williams et al., 2015 study which may have affected the reliability of the statistical analysis. The Sandrock et al., 2014, Straub et al., 2016 and Williams et al., 2015 pollen feeding studies combined two neonicotinoid active

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ingredients: primarily thiamethoxam representing concentrations of parent, and to a lesser extent clothianidin representing concentrations as a metabolite of thiamethoxam. Multiple pesticide exposure in combination with differences in the exposure routes (pollen/pollen patties/pollen sucrose solution mixtures/sucrose solutions), study design (open versus closed feeding studies, differing methodology) and effect parameters measured, may account for the differences in endpoints compared to those from the registrant feeding studies. A comparison of individual and colony level endpoints used in the thiamethoxam risk assessment indicated that clothianidin and thiamethoxam have similar toxicity to bees; however, there may be some differences. Because these dosing studies represented exposure to thiamethoxam, incorporating a small amount of clothianidin to represent some breakdown of thiamethoxam to clothianidin, they were considered for the thiamethoxam risk assessment only.

While there are a number of uncertainties associated with the pollen based colony feeding studies, the NOEC derived from the registrant study (PMRA 1194878) (20 µg/kg) and the highest test dose used in the open literature study where bees were dosed with clothianidin only (Tsvetkov et al., 2017) (4.9 µg/kg) were considered together for comparison with pollen residue values for the clothianidin risk assessment.

1.1.2 Tiered process and endpoint selection

This comment raises questions around the validity of the tiered risk assessment process given the use of higher tier colony effects studies in the assessment that suggest effects may occur with low levels of pollen exposure.

Comment (Bayer Crop Science)

The tiered risk assessment process is "broken" if a conclusion of minimal risk is reached in Tier 1, but a conclusion of high risk is reached if one proceeds to Tier 2, or Tier 3, etc. The purpose of the lower Tiers is to screen out use scenarios that have minimal potential for risk. If such risks are screened out as minimal in a lower tier, but then are shown to be of concern in a higher tier, it means the methodology employed is flawed. According to the assumptions of the Tier 1 risk assessment, residue levels in pollen are of relatively small importance in producing effects in comparison to similar residue levels in nectar. Using the Agency's Tier 1 BeeREX model, it takes a residue level >10 times higher in pollen in comparison to nectar to reach a level of concern. Tier 2 studies that report effects from low pollen exposures are therefore surprising and should be met with some skepticism. Yet PMRA has accepted such studies and derived effects endpoints which in turn are the sole basis for some conclusions of risks being of concern.

To amplify on the above points, consider the decisions of the Agency to derive Tier II effects endpoints for honey bees exposed to residues in pollen. In Tier 1, PMRA (along with USEPA and California DPR) has established an exposure level equal or greater than 40% of the honey bee LD50 as an acute level of concern, and an exposure level equal to or greater than the no observed effect level (NOEL) of a chronic (10-day) dietary test with adult worker honey bees as a chronic level of concern. From these endpoints, one can calculate (see Table 1 below) residue levels in pollen that would need to be exceeded in order for the Agency's LOCs to be exceeded. The calculations are made for nurse bees (worker bees that care for the queen and larvae) because this caste consumes the most pollen. PMRA also routinely evaluates risk to larval honey bees, however, in tests with clothianidin and NNIs in general, larval bees have been shown to be less sensitive than adult workers.

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Table 1. Tier I Derivation of Residue Levels of Concern for Clothianidin in Pollen for Adult Honey Bees

Exposure Scenario	Applicable Test Endpoint	Measurement[1]	Nurse bee – maximum daily pollen intake	Threshold Residue Level of Concern – Pollen[2]
Acute	LD_{50}	0.0037 µg/bee	9.6 mg	154 ppb
Chronic	NOEL	0.00036 µg/bee/d	9.6 mg	38 ppb

[1]Measurement endpoints for honey bees that have been accepted by the US EPA and Health Canada PMRA.
[2]Acute Residue Level of Concern (ug chemical/kg pollen, or ppb) = LD50 (µg chemical/bee) x 0.4 / 9.6 mg/bee x 1,000,000 mg pollen/kg pollen; Chronic Residue Level of Concern (ug chemical/kg pollen, or ppb)= NOEL (µg chemical/bee/d) / 9.6 mg pollen/bee/d * 1,000,000 mg pollen/kg pollen. This is the residue level that would result in a bee's daily intake being equal to the toxicity endpoint.

From the above it can be concluded that residues in pollen less than 38 ppb are below both acute and chronic levels of concern, meaning that ingestion of such concentrations in pollen is expected to pose a minimum risk to individual honey bees. If the risk to individual bees is minimal, colony-level effects are not expected. It should therefore be surprising if a colony-level test were to be conducted that reported significant adverse effects for exposure levels in pollen that were lower than 38 ppb. Yet, this is the claim of the study of Tsvetkov et al., 2017, and also the studies of Sandrock et al. (2014) and Williams et al. (2015), although the latter two studies exposed bee colonies to pollen diets containing a mixture of thiamethoxam and clothianidin that was mostly the former compound, rather than clothianidin alone. These studies claim to have observed colony-level effects for concentrations in the range of 2 to 7 ppb. Given the Tier 1 assessment, such findings should be met with some skepticism and the results carefully evaluated before being accepted to establish an endpoint for use in a regulatory assessment.

Bayer believes that all three of these studies have substantial weaknesses in terms of relevance, strength and reliability that should preclude them from being used to establish effects endpoints used in a regulatory risk assessment. All three studies have low numbers of replicates (test colonies) and evaluated a single treatment level in addition to an untreated control, and therefore were unable to demonstrate a dose-response relationship. The Williams et al. study evaluated colonies set up for artificial queen rearing that have low relevance to honey bee colonies used for pollination services or honey production, or bee colonies in nature. The Tsvetkov et al. study is particularly of questionable reliability in that (1) the number of test colonies was too few (4 treatment and 5 untreated) to draw any meaningful conclusions about colony-level effects, (2) it reported rather obscure endpoints such as hygienic behavior (the removal of artificially-frozen pupae by nurse bees) and foraging flights of young bees after they were transplanted into a new colony, and (3) it did not report endpoints that are easily measured and more relevant to the question of impacts of chemical exposure on colony performance, such as changes in colony strength (adult bees, eggs, larvae, pupae, stored food) and weight, and longterm colony survival. In addition, the high rate of queen loss in the control colonies (80%) indicates the colonies used were unhealthy and unsuitable for use in a toxicology study.

In Table 3 of their pollinator assessment of clothianidin, PMRA pointed out many of the weaknesses in the Tsvetkov et al. study, and yet proceeded to use it to define a Tier II effects benchmark for use in their assessment. Bayer believes a proper response to the surprising findings of Tsvetkov et al. is skepticism, not acceptance. One might contemplate the requirement of a new colony-level pollen-diet feeding study to determine if the results of Tsvetkov et al. can be reproduced. Bayer has already begun working on performing such a study. A pilot study was conducted in 2017 which evaluated the response of colonies to exposure to pollen diets with nominal concentrations of 100, 400 and 1600 ppb. Clear effects were only observed in the colonies exposed to the highest concentration (1600 ppb). The 400 ppb concentration appeared to be close to the threshold for colony level effects. This is in line with expectations from results of previous studies in which the threshold for adverse effects was shown to be in the range of 30-40 ppb for colonies fed spiked artificial nectar. Since bees consume at least 10 times more nectar than pollen, one would logically expect the threshold for adverse effects for exposure via pollen to be at least 10 times

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higher, or at least 300 to 400 ppb. Again, this is because the concentration in pollen needs to be at least 10 times higher than for nectar to deliver the same dose to the most exposed caste of bees in the colony. The pilot study results are therefore in line with the Tier 1 assessment predictions that colony level responses should occur at substantially lower nectar concentrations than pollen concentrations.

Bayer plans to conduct a definitive test in 2018 to generate a robust dose-response relationship and effects endpoint for exposure of honey bees to concentrations of clothianidin in pollen. We believe these new data have the potential to significantly change the preliminary conclusions of both PMRA and USEPA about relative sensitivity of honey bee colonies to residue levels of neonicotinoids in pollen versus nectar. These new data should be welcomed by the Agencies because they not only will represent the best available data for use in refined risk assessments, but they will provide empirical evidence useful to an evaluation of the validity of the assumptions of the Tier 1 risk assessment model. If one accepts Tsvetkov et al., Sandrock et al., and Williams et al. as valid studies, then the tiered risk assessment process is clearly broken and needs to be scrapped. However, if the new Bayer study results come out as expected on the basis of pilot study results, the tiered risk assessment process will have been validated.

In the face of the above uncertainty, Bayer recommends PMRA not use the above referenced studies (i.e., Tsvetkov et al., Sandrock et al., and Williams et al.) to derive an effects endpoint for honey bees exposed through the pollen route of exposure, but rather wait for higher quality data to become available.

Health Canada Response

Health Canada followed the tiered pollinator risk assessment framework as outlined in the 2014 *North American Guidance for Assessing Pesticide Risks to Bees.* The Tier I risk assessment considers endpoints from laboratory based toxicity studies done with individual bees, whereas the Tier II refined assessment considers colony based endpoints from tests done in the field with controlled feeding of populations of bees (colony feeding studies). Typical endpoints from laboratory based toxicity tests include mortality whereas typical colony feeding study endpoints may include a wide range of endpoints including bee/hive mortality, over-wintering survival, colony strength, brood development, foraging activity, flight activity, behaviour and food storage. Considering the differences in measurement endpoints between the two types of studies, there may be cases where colony effects are observed at a lower exposure level than observed in laboratory based studies using individual bees. It is noted for the pollinator risk assessment for clothianidin and thiamethoxam that there were very few cases where the Tier I risk assessment resulted in no risk, followed by risk at the Tier II (and Tier II refined) risk assessment.

Health Canada considered all relevant data from the open literature and from the registrant in selecting endpoints for use in the Tier I and Tier II refined risk assessments. The endpoints derived from each study were considered together based on the strengths and limitations of each study. Health Canada agrees with Bayer CropScience that the available colony feeding studies from both the open literature and registrant where bees were exposed to clothianidin and/or thiamethoxam through pollen/pollen patties had substantial weaknesses. For instance, the lowest pollen based effect endpoint used in the Tier II refined risk assessment was selected considering multiple open literature colony feeding studies with measurement endpoints considered different from typical colony based measurement endpoints. The results from these studies were considered together and consistently demonstrated effects at lower exposure levels compared to an unreplicated registrant study that measured more typical endpoints. This made it difficult to discount the results from the open literature despite the many limitations of these studies. In the absence of higher quality studies and in order to consider this route of exposure, a range of colony based endpoints were used in the Tier II risk assessment.

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1.1.3 Study interpretation Baron et al., 2017

Comments were received regarding the study interpretation of:

Baron, G. L., V. A. A. Jansen, M. J. F. Brown and N. E. Raine (2017a). Pesticide reduces bumblebee colony establishment and increases probability of population extinction. Nature Ecology & Evolution 1: 1308-1316.

Baron, G. L., N. E. Raine and M. J. F. Brown (2017b). General and species-specific impacts of a neonicotinoid insecticide on the ovary development and feeding of wild bumblebee queens. Proceedings of the Royal Society B-Biological Sciences 284: 20170123.

> ***Comment (University of Guelph):*** *In text around "Major uncertainties" the report states "The species used in the study are not North American species, and may have differing sensitivities." Whilst it is true that these are UK species, not those found in North America, it is one of very few studies to directly compare sensitivity in endpoints across multiple bee species. The results highlight that even among relatively similar species (in this study four bumblebee species) the effects of directly comparable exposure scenarios can result in substantially different outcomes. This suggests that greater emphasis needs to be placed on variation in species level effects of exposure across a wider range of bee (and other pollinator) taxa in the risk assessment process.*
>
> ***Comment (University of Guelph):*** *Review comments state: "Although control queens had higher colony initiation (following the longer hibernation period) the study did not detect impacts of any experimental treatment on the ability of queens to produce adult offspring during the 14-week experimental period." This experiment was never intended to try and measure impacts on worker production, as this would effectively require rearing of all queens and their colonies throughout their summer cycle. This work was conducted by a PhD student as part of a thesis and it was logistically not feasible with the personnel to run this experiment full time for close to the year it would have taken to go from mating, through experimental hibernation to colony initiation to sexual production by colonies. The experiment as performed was both intensive in terms of data collection and sampling, and extensive in terms of total duration of the work. The document lists "Tested hibernation period in the study may be different to what may be seen in Canada" under UNCERTAINTIES. Clearly 6-12 weeks does not reflect the full duration of overwintering hibernation for bumblebee queens in either Canada or northern Europe. This duration was chosen due to concerns around potential high mortality effects of overwintering that might have left lower than ideal numbers of queens for the pesticide exposure part of the experiment (exposure occurred after emergence from hibernation). As such, the effects reported in this study are perhaps conservative compared to field scenarios in which hibernation duration might be 6 months or longer in Canada. Additionally, bumblebee queens in the field would likely be exposed to some pesticide residues between the time they eclose and go into hibernation (for example within their natal nest or when they forage alone outside their natal nest) and pesticide exposure would also occur via pollen ingestion (in this experiment neonicotinoid exposure was only via sugar water – artificial nectar).*

Health Canada Response

Health Canada reviewed the information from Baron et al., 2017a,b and considered the usefulness of these studies in the overall risk assessment for thiamethoxam based on their strengths and limitations and relevancy to the Canadian registered use pattern.

With respect to Baron et al., 2017a, an effect endpoint (LOEC 2.05 ppb clothianidin equivalents dosing through sucrose solution) was generated from this study which was used in the Tier II risk assessment for comparison with mean measured nectar residues. The endpoint was based on lower colony initiation (26%) from treatment after hibernation and impact of hibernation duration alone on egg laying and female weight. Health Canada recognizes that some of the

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effects observed in the study could show fewer effects compared to field scenarios in which hibernation duration might be 6 months or longer in Canada (as outlined in the uncertainties). While only a single treatment was tested in this study, the pollinator assessment aims to determine what doses result in effects (LOECs, lowest observable effect concentrations) as well as NOECs (no observable effect concentrations) and therefore studies with multiple doses and endpoints are helpful in determining this relationship. Health Canada interpreted the lack of detection of impacts on the ability of the queen to produce adult offspring, as a lack of effect in this particular study design.

With respect to Baron et al., 2017b, Health Canada is aware that there may be differing sensitivities among bee species to pesticides. The current pollinator risk assessment framework relies primarily on the use of honey bee data as a surrogate for non-*Apis* bees considering that it is not practical or possible to investigate how every single species will respond to a pesticide. When non-*Apis* bee data are available Health Canada considers this information together with *Apis* bee data in the overall risk description. Further discussion on this point can be found in Appendix II Section 1.5.7 Risk Assessment Approach: Pollinators other than bees and Section 1.5.8 Risk Assessment Approach: Non-*Apis* bees. It is noted that the highest dose level tested in Baron et al., 2017b (in other words, 4.55 ppb clothianidin equivalents, dosing through sucrose solution) where effects were seen in one of the test species of bumble bee falls within the range of endpoints used in the Tier II risk assessment for thiamethoxam. Therefore, the current pollinator risk assessment for thiamethoxam is expected to be protective of other bee species.

1.1.4 Study interpretation Stanley et al., 2015

The commenter had questions on the interpretation of the study Stanley et al., 2015

> ***Comment (University of Guelph):*** *Comments on this study (Stanley et al., 2015b) are shown on this page, and then there are further comments on page 196 of the same document. Does this reflect acute (p123) and chronic (p196) aspects of this study?*

Health Canada Response

Studies with multiple exposures or durations (such as acute and chronic effects studies) or multiple species (*Apis* and non-*Apis*) were typically summarized in separate sections of the document as relevant.

Data on page 123 of PRVD2017-24 considers the acute oral Tier I study design (with non-*Apis* bees).

Data on page 196 of PRVD2017-24 considers the higher Tier study design (closed feeding study with non-*Apis* bees).

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1.1.5 Statistical power of detection in effects studies

A comment questioned how low statistical power to detect impacts were considered when determining reliability of studies.

Comment (University of Guelph)

As noted in these PMRA documents, many of the studies reviewed (particularly those reporting data from field studies) have limited sample sizes due to practical and logistical constraints. Relatively low sample sizes can substantially affect the statistical power of those studies to detect effects – this makes non-significant differences between pesticide exposed and control colonies or sites harder to interpret (these limitations are explicitly reported in some studies, e.g. limitations to power to detect impacts on honeybee hives in Rundlöf et al., 2015). In the current PMRA documents it is unclear how low sample sizes (reduced statistical power to detect effects) is taken into account when considering the reliability of study findings.

Health Canada Response

The issue of low detection power has been identified by numerous researchers in higher tier studies conducted with many organisms, including bees. The detection power is largely limited by the feasibility of using a high number of replicates, particularly in field studies. In cases where studies had few replicates, Health Canada considered the information along with other studies in a weight of evidence approach taking into account the study's strengths (for example, realistic field conditions) and limitations (for example, low detection power).

1.2 Exposure

1.2.1 Exposure to multiple applications of neonicotinoids

A comment was received regarding concerns of cumulative exposure to the same or different neonicotinoids following application using different methods.

Comment (University of Guelph)

I was unable to find any sections in either document when the use of both treated seed and spray treatments were considered together. This could be an issue in crop rotations where a treated seed was used in year 1 (e.g. corn), followed by a crop using spray or soil drench application in year 2 (e.g. pumpkin/ squash). Such scenarios could increase rates of soil accumulation and movement of neonicotinioids in the environment. PMRA should consider such scenarios within revised versions of these re-evaluation documents. Could this result in recommendations restricting repeat applications of the same active ingredient in subsequent (or the same year)? Should this be extended to include both clothianidin and thiamethoxam given that the latter is converted into the former after application?

Health Canada Response

The pollinator risk assessments for both clothianidin and thiamethoxam considered exposure to carry-over of residues from a variety of scenarios. These included exposure to plants grown in soil where treated seeds were sown the previous year, exposure to plants grown in soil where soil treatment was applied the previous year, seed treated plants grown in soil where treated seeds were grown the previous two or three years, and also, seed treated plants grown in soil where soil treatment was applied the previous year (see summary below for more details).

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Collectively, these studies showed very low residues from translocation (of parent and transformation products). The residues did not result in effects to colonies, and were below colony level endpoints. The contribution of residues from the previous year's seed or soil treatment is expected to be minimal for application of either thiamethoxam or clothianidin. In addition, proposed phase out of foliar application before and during bloom, as well as soil application, for bee attractive crops (including cucurbits), are expected to further reduce exposure for pollinators.

Therefore, considering minimal residues from seed treatments and soil carrying over to the next year, as well as limited application for soil and foliar applications, the risk to bees is expected to be mitigated.

Additionally, to address the concern with clothianidin residues resulting from application of thiamethoxam, the studies showed very low residues of both actives. In almost all cases, the residues of clothianidin were below the limit of detection.

Clothianidin:

- Treated barley seeds and also soil application in year 1, followed by untreated winter rape in year 2, followed by sampling of winter rape in year 3 [PMRA 2355486]
- Treated soil application followed by untreated summer rape [PMRA 2355487]
- Treated soil application followed by untreated corn [PMRA 2355488]
- Treated soil application followed by untreated corn [PMRA 2355489]
- Treated barley seed and soil application in year 1, followed by untreated corn, mustard or phacelia the following spring [PMRA 2510484]
- Treated barley seed and soil application in year 1, followed by untreated corn, mustard or phacelia the following spring [PMRA 2510485]
- Three years of soil application followed by untreated sunflower [PMRA 2532797]
- Treated soil application followed by untreated rapeseed, corn, mustard, zucchini, field beans and sunflower the same season [PMRA 2630589]

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Thiamethoxam:

- Treated maize was sown in spring, followed by treated winter barley in autumn, and then followed by untreated alfalfa, Phacelia and oilseed rape the following spring [PMRA 2365330, 2365332, 2365321].
- Treated canola was sown in spring, followed by untreated canola the following spring [PMRA 2461577].
- Treated sunflower was sown in spring, followed by untreated sunflower the following spring [PMRA 2365414]
- Treated spring barley sown in spring, followed by untreated sunflower or corn planted later in the same growing season as a rotational crop [PMRA 2365090, 2365092, 2365094, 2365095]
- Treated corn sown in spring, followed by untreated sunflower the following spring [PMRA 2365412]
- Treated barley in the spring, followed by treated oilseed rape in the fall [PMRA 2365044]
- Treated maize for two or three years with sampling at each year [PMRA 2364945, 2364957, 2365020, 2365062, 2365067]
- Treated in-furrow potato in the spring, followed by untreated canola the following year [PMRA 2580511]

1.2.2 Accumulation in soil

Concerns were raised that the build-up of residues in soil from use in consecutive years was not considered.

> ***Comment (University of Guelph)***
>
> *PRVD2017-23 and PRVD2017-24 both appear to dismiss the importance of soil accumulation of neonicotinoids as a potential risk to pollinators regardless. This is surprising in light of both the wider documented issues with respect to movement of neonicotinoids into non-crop plants and also contact exposure with ground nesting solitary- and bumblebees (as outlined in the previous two sections). Accumulation has been demonstrated in trials using repeated year-on-year sowing of neonicotinoid treated seed (e.g. Anon 2006 cited in Goulson 2013, see Figure 2 therein). Interestingly these data are being cited in these documents as evidence that soil accumulation does not continue beyond 5 years although the studies (Anon 2006 cited in Goulson 2013) were terminated at 6 years.*

Health Canada Response

In the clothianidin and thiamethoxam PRVDs, Health Canada described issues relating to soil accumulation and the potential risk to pollinators. Clothianidin or thiamethoxam will come in contact with soil when it is applied directly on the ground, sprayed on foliage, or when clothianidin or thiamethoxam contained in the seed coating moves away from the seed into the surrounding soil. How long these chemicals will persist in soil depends on various factors

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including soil type. The properties of these chemical are such that they may persist long enough in soil to carryover from one growing season to the next. When these chemicals are used for many years, concentrations in soil have been shown to initially increase, and then stabilize after approximately 3-5 years. In the tiered risk assessment Health Canada used residue and effects information from various studies considered relevant to the Canadian use pattern to characterize the risk to bees in various crop systems, including studies examining carryover of neonicotinoid residues to successional growing crops that were also treated with neonicotinoids. Overall, the results of the residue portion of the carryover studies show that there are residues in soil (from previous years use) which translocate into successional growing crops. Comparing resulting residue levels in the pollen and nectar to respective effect endpoints, it was concluded that overall there is minimal risk to bees foraging in bee attractive crops planted in soil where crops directly treated with either clothianidin or thiamethoxam were grown the previous year. Overall, these studies indicate minimal risk to bees from soil accumulation.

1.2.3 Cumulative exposure: neonicotinoids

Multiple comments were received concerning the potential cumulative effects of neonicotinoids and their metabolites in the environment. Arguments were put forward that commonalities in persistence, mechanisms of action and breakdown products indicated that no neonicotinoid would be a good substitute for another.

Comment (Prevent Cancer Now)

Clothianidin and Thiamethoxam share metabolites. Although some major metabolites are tabulated, data on their toxicity is lacking, as is complete environmental breakdown information. Both insecticides are quite persistent in the environment, with thiamethoxam breaking down into clothianidin, with insecticidal activity lasting one season or longer. Although "half-life" generally refers to a parent compound, a large number of metabolites take years to break down and dissipate. Some metabolites are more toxic to mammals or other creatures than the parent compound; some break down into insecticidal metabolites. Commonalities in persistence, mechanisms of action and breakdown products argue that no neonicotinoid would be a good substitute for another.

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)

Because clothianidin is a metabolite of thiamethoxam, and multiple neonicotinoids are often used concurrently in pest management in Canada, cumulative exposure from these insecticides must be taken into account. While thiamethoxam is less persistent in the environment (half-life of 34 - 280 days in soil; residues can be detected in succeeding crops, and it is a potential groundwater contaminant), the PMRA acknowledges in PRVD2017-24 that thiamethoxam degrades into clothianidin, which is very persistent in soil (half-life ranges from 148 - 6931 days; residues can be found in soil 2 years after a treated seed was sown). In PRVD2017-23, the PMRA must take into account this additional exposure to clothianadin as a degradation product of thiamethoxam. Also, neonicotinoids have the same mechanism of toxicity, which means that their impacts may be additive (or worse) in field conditions in which multiple neonicotinoids are used. Without conducting an assessment on cumulative effects that appreciates the scale at which neonicotinoids are concurrently used in Canada, the Minister cannot conclude that the risks posed by these neonicotinoids are acceptable.

Comment (Fédération des apiculteurs du Québec)

Individual approvals do not take into account the synergy created between different pesticides and the effects on bees of the different combinations of neonicotinoids / fungicides to which they are exposed in the field (2)

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2. Hudson V. V. Tomé, Gabryele S. Ramos, Micaele F. Araújo, Weyder C. Santana, Gil R. Santos, Raul Narciso C. Guedes, Carlos D. Maciel, Philip L. Newland, and Eugênio E. Oliveira (2017).Agrochemical synergism imposes higher risk to Neotropical bees than to honeybees. NCBI DOI : 10.1098/rsos.160866

Health Canada Response

Regarding concurrent exposure to multiple neonicotinoids, it is important to note that the use of different neonicotinoids on the same crop in the same growing season is not supported in Canada, and only one application type (seed treatment, soil, or foliar) of neonicotinoids is permitted on the same crop in the same growing season, with only one exception for soybean. At the current time, the risk assessment considers each treated crop separately; however, considerations of exposures resulting from persistence in soil and uptake by rotational crops and non-crop plants were considered, as well as extended exposure periods which may occur when bees visit multiple treated fields throughout the season (refer to Appendix II, Section 1.2.1 Exposure to multiple applications of neonicotinoids and Appendix II, Section 1.3.2 Uptake by field-margin plants for further details). As is standard in the risk assessment process in Canada, major transformation products are considered in the risk assessment.

Health Canada believes that there is sufficient information to understand the persistence and toxicity of the major transformation products of the neonicotinoids. A fate assessment was conducted for thiamethoxam, clothianidin and relevant metabolites and a summary of the assessment is outlined in the respective PRVD documents. For PRVD2017-23 and PRVD2017-24 see Section 2.1 Fate and Behaviour in the Environment and Appendix III Summary of Fate in the Environment for further information. Toxicity information on clothianidin and thiamethoxam and relevant metabolites is presented in Appendix V of the respective documents.

Given that thiamethoxam converts to clothianidin, exposure to both thiamethoxam and clothianidin was considered when relevant. In particular, exposure to both thiamethoxam and clothianidin was considered in the context of residues in pollen and nectar, which is the main source of exposure for bees. When clothianidin was formed in plants as a result of application of thiamethoxam, the thiamethoxam residues were converted to clothianidin equivalents and summed with clothianidin residues to determine potential cumulative exposure when thiamethoxam is applied. As outlined in PRVD2017-24, the toxicity endpoint for both thiamethoxam and clothianidin were considered in the risk assessment.

In the clothianidin risk assessment, the parent clothianidin was considered to be the primary concern. Cumulative exposure from clothianidin as a transformation product of thiamethoxam application and direct clothianidin application was not considered given that application of multiple neonicotinoids to the same crop in the same growing season is not permitted in Canada, with one exception for soybean. The toxicity to honey bees of the two major clothianidin metabolites identified is orders of magnitude less than parent clothianidin (48-hour oral LD50s of 3.95 µg /bee and > 113 µg/bee, respectively, for TZNG and TZMU), compared to 0.00368 µg/bee for clothianidin. Additionally, residues of TZNG and TZMU detected in the vast majority of the residue studies were at much lower levels than parent clothianidin. Given the comparatively low toxicity and exposures of the metabolites relative to parent clothianidin, it is expected that any potential risk from the metabolites is taken into account by the risk assessment for the parent clothianidin.

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Multiple exposures could also occur from visiting multiple fields throughout the season, and while not explicitly assessed, the risk assessment takes this into account. Colony feeding studies considered toxicity resulting from extended exposure periods (between 5 and 16 weeks). Therefore effects resulting from extended exposure periods were compared against high residues expected in crops. In addition, other exposure scenarios such as non-crop plants and rotational crops were also considered in the risk assessment, although, these rotational crops and plants are expected to have lower exposures than treated crops, as demonstrated by measured residue levels in pollen and nectar.

Mammals are outside the scope of this risk assessment, which was focused on pollinators. However, it is noted that metabolites are always considered and taken into account in both human health and environmental risk assessments as relevant.

1.2.4 Cumulative exposure: mixtures of pesticides

Concerns were raised regarding exposure to mixtures in the environment, indicating that mixtures were not discussed or addressed in the risk assessment.

> ***Comment (Prevent Cancer Now)***
>
> *Multiple pesticides and metabolites are the reality in agriculture and today's foods. Despite knowledge that mixtures are risky, mixtures are not addressed here or in general. Substitution of similar chemicals will occur when limited restrictions are put in place. Thus there is a need to achieve pesticide exposures that are as low as reasonably achievable (ALARA).*
>
> ***Comment (Fédération des apiculteurs du Québec)***
>
> *Individual approvals do not take into account the synergy created between different pesticides and the effects on bees of the different combinations of neonicotinoids/ fungicides to which they are exposed in the field (2)]*
>
> *2. Hudson V. V. Tomé, Gabryele S. Ramos, Micaele F. Araújo, Weyder C. Santana, Gil R. Santos, Raul Narciso C. Guedes, Carlos D. Maciel, Philip L. Newland, and Eugênio E. Oliveira (2017).Agrochemical synergism imposes higher risk to Neotropical bees than to honeybees. NCBI DOI : 10.1098/rsos.160866*

Health Canada Response

Health Canada does not generally assess pesticide mixtures for environmental risk assessments of specific pesticides. The assessment of multiple pesticides and metabolites is complex. There is a lack of sufficient information for generalizing the level of exposure for multiple pesticides in the environment, as there is much variability in the amounts and combinations of pesticides to which bees could be exposed. For example, there may be variability in the composition of pesticides, the seasonal dynamics of pesticide composition and the concentrations of each pesticide in various matrices (including pollen and nectar of plants). As well, the toxicity information for various combinations of pesticides is limited. Therefore, in most cases, it is not possible to conduct a realistic risk assessment considering multiple active ingredients because it is not known which actives, how much, when and where multiple exposures would occur.

For the pollinator risk assessment, all three neonicotinoids were assessed individually along with their respective major transformation products (metabolites); however, there were some studies

that tested multiple pesticides, and the pollinator assessments did take this information into consideration for possible synergistic effects. In addition, many higher tier field studies with bee colonies were tested for effects from exposure to co-formulated products (such as seed treatments) that contain fungicides and insecticides. These studies were generally conducted with simple mixtures of two or more commercial chemicals. When there are data of co-occurrence of pesticides with a similar mode of action we will consider cumulative exposure if the data are sufficiently robust. For instance, there were a number of studies which exposed bees to both thiamethoxam and clothianidin and this information was considered together in the overall risk assessment as indicated in Section 1.2.3 of the response to comments (see above).

1.2.5 Higher application rates

A comment was received indicating that data from other regions using application rates different than those registered in Canada were important to consider. The commenter suggested that this data could be used to determine what might happened if the application rates were to increase in Canada.

> ***Comment (University of Guelph)***
>
> *Although application rate is clearly important in determining the exposure profile, data collected from other regions that might use non-Canadian application rates is still important to consider within re-evaluations. In regions where application rates are higher than allowed in Canada then this could, and arguably should, be considered as what might happen if usage patterns were to increase.*

Health Canada Response

Health Canada bases their environmental risk assessment and conclusions on what is currently registered or proposed for registration. If changes to the current use pattern of neonicotinoids are proposed in the future, including changes to the application rates, a new risk assessment would be conducted to account for the higher rates.

For the current pollinator risk assessment, Health Canada considered all available information in the risk assessment including studies which tested application rates higher than the current Canadian registered use pattern, such as pollen and nectar residue level studies, semi-field tunnel studies and field studies. This information was considered useful for confirming levels where no effects were observed. In cases where effects were observed at rates higher than Canadian rates, the data was still considered in the risk assessment, noting that the rate was higher than Canadian rates and therefore exposure may be overestimated.

For clothianidin, studies considered for the turf use were tested at rates higher than those registered in Canada. For all other foliar/soil uses of clothianidin available information was relevant to the Canadian use pattern. For seed treatment uses on oilseed crops there were multiple residue studies conducted at a rate higher than the Canadian registered rate, as well as residue studies conducted at Canadian relevant rates. While potential for risk to bees was indicated using residues from some of the studies at the higher rates, no potential for risk was indicated using residues from studies tested at Canadian relevant rates. Overall, for seed treatment uses on oilseed crops, Health Canada concluded that no risk for bees was expected at Canadian relevant rates.

For thiamethoxam, effects studies and/or residue studies with foliar and soil application to fruiting vegetables, berries and cucurbits were conducted at rates higher than Canadian registered rates as well as at Canadian relevant rates. There were a large number of seed treatment studies considered (mostly for corn and oilseed rape). Some of these studies were conducted at relevant rates, and others conducted at higher rates (sometimes more than twice the Canadian registered rate). While all information was considered in the risk assessment, conclusions were drawn based on the Canadian relevant rates where available.

1.2.6 Exposure estimates from residues

Comments were received regarding methods used to estimate the exposure of pollinators in the risk assessment, including use of maximum field residue measurements rather than the average or 90th percentile values.

Comment (Bayer Crop Science)

Bayer believes the general approach PMRA has used in the subject assessment is scientifically sound; however, from a design standpoint, it tends to overestimate the true level of risk. For example, defining point estimates for exposure as the maximum field residue measurement, rather than from the average or even a 90th percentile value of available measurements, biases the assessment toward a conclusion of finding a risk. Such an approach might conclude there is a risk of concern when the underlying data might indicate the risk is negligible except for on rare occasions.

Health Canada Response

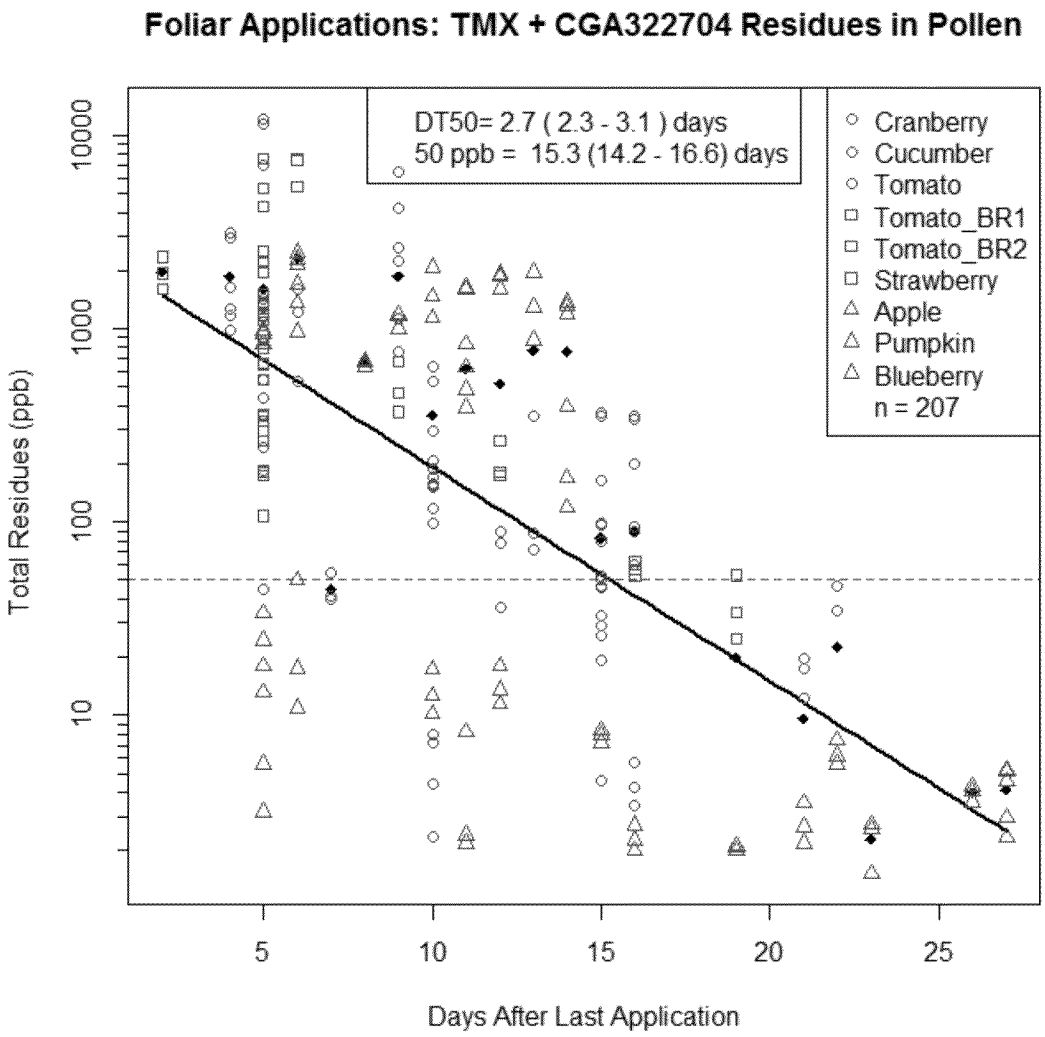
Due to the potential for variation in measured residues, the detected maximum and highest mean residue values were used in the lower tier bee risk assessment in order to identify any uses that may potentially cause risks to bees. While the 90th percentile and median value provide insight of the residue distribution in the available studies, the detected maximum and highest means were considered as a conservative exposure scenario for the Tier I refined risk assessment using laboratory based effect endpoints and Tier II risk assessment using endpoints from colony feeding studies. These conservative risk assessments using residue information may trigger higher tier studies, such as semi-field effect studies and Tier III field studies.

1.2.7 Residue decline

The commenter suggests that residues rapidly decline in pollen and nectar from pre-bloom applications, and risk can be mitigated with application timing restrictions.

Comment (Syngenta)

For foliar applications, potential risk to bees from foliar applications can be mitigated in many crops via timing of applications. Specific label restrictions for specific crops and chemicals can be made regarding timing of foliar applications necessary to manage risks to bees. Review of the pollen and nectar residue data from pre-bloom applications clearly indicate that residues decline rapidly after application with a DT50 of approximately 3 days for pollen and 4 days for nectar (Figure 1).


Foliar Applications: TMX + CGA322704 Residues in Pollen
DT50= 2.7 (2.3 - 3.1) days
50 ppb = 15.3 (14.2 - 16.6) days
Cranberry
Cucumber
Tomato
Tomato_BR1
Tomato_BR2
Strawberry
Apple
Pumpkin
Blueberry
n = 207
Total Residues (ppb)
10000
1000
100
10
5
10
15
20
25
Days After Last Application

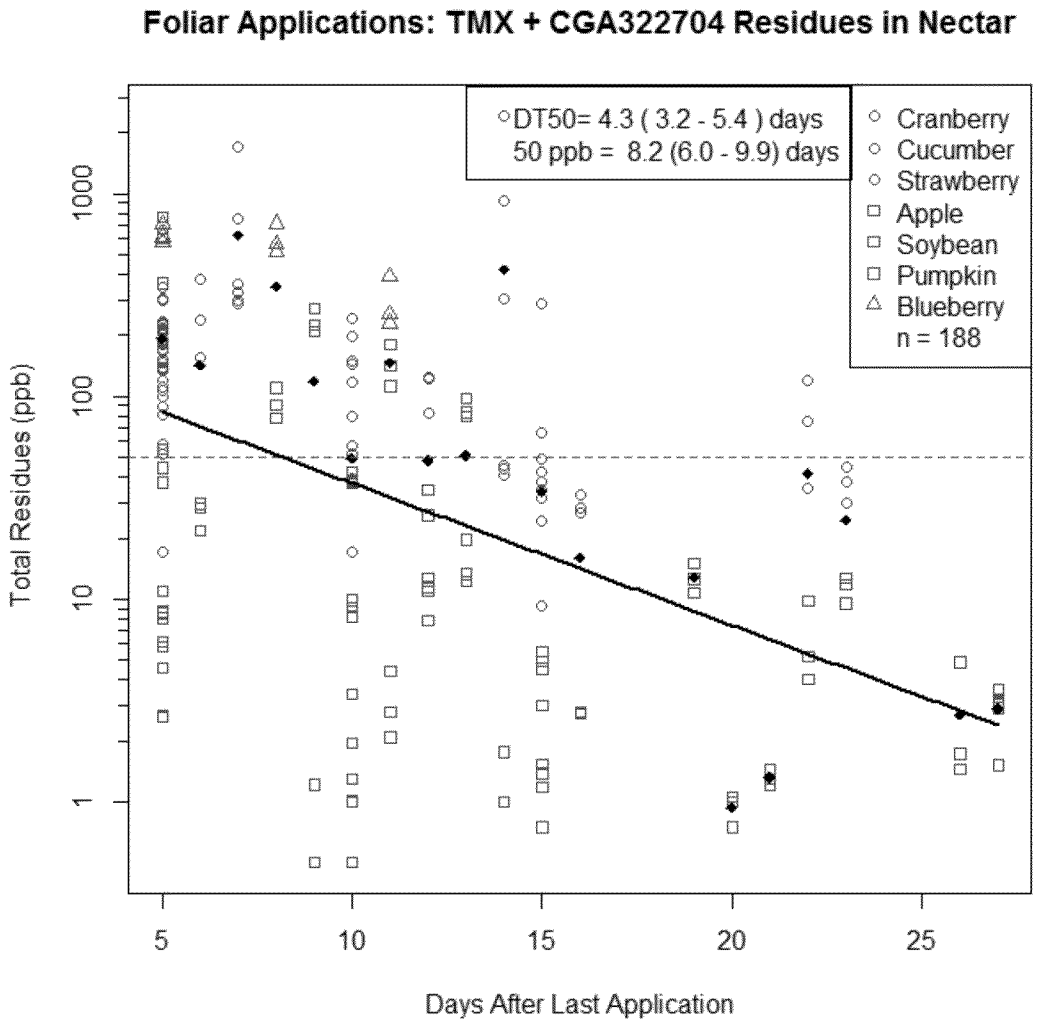


Figure 1. Aggregate data analysis of pollen and nectar residues from pre-bloom foliar applications (TMX = thiamethoxam; CGA322704 = clothianidin)

Health Canada Response

The data presented in the comment is an aggregate analysis with all pollen residues from 7 different crops and different application rates and timing.

Health Canada does not agree that it is appropriate to combine all of the crop residue data (collected from both plants and bees) with different application rates and timing to determine a general DT_{50} since many factors affect the degradation of the chemical in the plant (including the soil conditions, plant, application rate, etc.). Health Canada conducted a risk assessment specific to each use pattern, using relevant residue data as much as possible because the exposure to bees is very crop and application specific. In cases where Health Canada used surrogate data, the most relevant plant biology, rate and timing of application were considered for use as surrogates in the assessment.

The residue data does not support aggregation among all crops and timing. For example, apple and strawberry pollen residues from pre-bloom application were high and would have a much longer DT_{50} than 2.7 days. In fact, the residue decline data for strawberries from early, mid and late bloom indicated high residues throughout the bloom period, and in some plant residue data, residues were increasing over time.

For nectar residues, soybean residues were included in this aggregate data analysis, which appears to lower the overall DT_{50} value. These soybean residues were collected from honey bees and few residues were found, which may indicate a lack of foraging from honey bees and may under represent the actual residues found in nectar, and also underestimate the potential exposure to non-*Apis* bees.

1.2.8 Exposure via pollen or nectar route

Comments were received regarding methods used to estimate exposure of pollinators in the risk assessment, including comments related to whether the exposure route was through pollen or nectar. The commenter suggested that the majority of exposure to pollinators comes from ingestion of nectar not pollen, therefore, assumptions made in the risk assessment that bees are likely more sensitive to residues in pollen than nectar are uncertain.

Comment (Valent)

While the open literature CFS with clothianidin might be seen as showing that colonies provided spiked artificial pollen experience effects at relatively low concentrations, we believe that, based on dietary intake rates, a lower threshold concentration for adverse effects is expected if a honey bee colony is fed spiked sucrose solution in comparison to if it is fed spiked pollen. This assumption is consistent with the BeeREX model assumptions about the relative contributions of pollen and nectar to the total diet of a colony. In this model, it is clear that the vast majority of pesticide exposure to a honey bee colony comes from ingestion of nectar and not pollen Our assumption relies also on the results of the imidacloprid pilot study conducted by Bayer CropSciences with imidacloprid. These pilot studies demonstrated that nectar consumption was the driving factor in producing neonicotinoid effect at colony level compared to pollen. A decision was then taken between neonicotinoids registrants to feed test colonies of the definitive colony feeding studies spiking sucrose solution only. This decision was made in consultation with the all Agencies reviewers (PMRA, USEPA and CDPR). Agencies at the time approved the test protocols for these non-guideline studies, and for the definitive registrant-colony feeding studies with clothianidin, thiamethoxam and dinotefuran that also fed only spiked sucrose solution to the test colonies. Thus, it was assumed that as long as residues in pollen are of the same order of magnitude as residues in nectar, the response of colonies will be driven by the concentration in the nectar, and no specific assessment of risk to residues in pollen was likely needed except for instances in which the crop being treated is a significant source of pollen, but not nectar (e.g. corn).

The CFS by Dively et al. (2015) added additional support to this idea that the concentration causing effects is much higher when bees are exposed through residue in their pollen- based diet, in comparison to when exposed through sucrose-based diet. The Agencies determined for this study that the threshold effect level for bees fed artificial pollen patties spiked with imidacloprid was approximately 100 ppb, which is much higher than the 20-25 ppb no-effect level found in the various studies when colonies were fed spiked sucrose solution.

Although not submitted in time for review by the Agency in their pollinator risk assessment for clothianidin, Valent together with Bayer CropScience is conducting in 2018 a new CFS-pollen. The study design will be similar to the two registrant-submitted CFS-nectar. The two companies' aims with this new CFS at: 1) addressing the limitations and deficiencies identified in the open literature CFS-pollen, and 2) obtain a more reliable definitive clothianidin endpoint for pollen. A pilot study was conducted in 2017 which

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evaluated the response of colonies to exposure to pollen diets with nominal concentrations of 100, 400 and 1600 ppb. Clear effects were only observed in the colonies exposed to the highest concentration (1600 ppb). The 400 ppb concentration appeared to be close to the threshold for colony level effects. This is in line with expectations from results of previous studies in which the threshold for adverse effects was shown to be in the range of 30-40 ppb for colonies fed spiked artificial nectar. Since bees consume at least 10 times more nectar than pollen, one would logically expect the threshold for adverse effects for exposure via pollen to be at least 10 times higher, or at least 300 to 400 ppb. This is because the concentration in pollen needs to be at least 10 times higher than for nectar to deliver the same dose to the most exposed caste of bees in the colony. The pilot study results are therefore in line with the Tier 1 assessment predictions that colony level responses should occur at substantially lower nectar concentrations than pollen concentrations. We believe the final study in 2018 will have the potential to significantly change the preliminary conclusions of both PMRA and USEPA about relative sensitivity of honey bee colonies to residue levels of neonicotinoids in pollen versus nectar.

Health Canada Response

Health Canada approach and considerations for exposure through pollen or nectar routes

As described in PRVD2017-23 and PRVD2017-24 in Section 2.5.1, the Tier II risk assessment considered effect endpoints from *Apis* and non-*Apis* colony feeding studies compared to mean measured residues in pollen and nectar from specific crops. For comparison with nectar residue values, endpoints from colony feeding studies where bees were exposed through contaminated sucrose solution were used. For comparison with pollen residue values, endpoints from colony feeding studies where bees were exposed through contaminated pollen were used.

There is some uncertainty regarding how different exposure routes in colony feeding studies (nectar as simulated with sugar solution; pollen as simulated with collected pollen, pollen patties, mixtures of pollen and nectar) may affect the observed colony level treatment effects and relate to natural exposures.

In general, more nectar is consumed by the colony than pollen. Therefore, it is expected that higher residue concentrations in pollen are required to result in the same total amount of pesticide taken up by the hive. For example in Dively et al., 2015, it took five times the imidacloprid concentration in pollen (100 ppb) as in nectar (20 ppb) to result in the same total amount of imidacloprid being taken up by the hive (40 µg imidacloprid per week). It can be expected that pollen feeding studies conducted at similar concentrations as nectar feeding studies may demonstrate fewer effects as less total imidacloprid is likely taken up by the hive. However, as further discussed below, whether exposure is through pollen or nectar may result in other differences in exposure and effects.

In the same Dively et al., 2015 study discussed above, the exposure route affected distribution of residues throughout the hive, and the effects observed. With the same total amount taken up per week (40 µg imidacloprid per week), the pollen exposure route resulted in imidacloprid being detected in hive matrices at a higher level and at a higher frequency, and for longer durations than in the hives fed with the same total weekly amount of imidacloprid through spiked sugar solution. The hives exposed to imidacloprid through pollen also had 14–26% fewer frames of adult bees when compared to the hives exposed through sugar solution by the end of the exposure period, but this difference was not seen 6 weeks after the exposure period concluded. The study demonstrated that exposure route had an effect on where and at what levels residues were distributed in hive matrices, and on the effects observed. This is further discussed below.

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Various feeding studies showed that provision of residues in either pollen or nectar resulted in distribution of residues throughout hive food matrices (such as hive nectar, bee bread and royal jelly) at varying concentrations. This may be consistent with bee biology in that bees collect and process nectar and pollen into different hive foods. These hive foods contain varying amounts of pollen and nectar and associated residues, and are consumed in different amounts by different bee stages. The source of residues (pollen or nectar) is expected to affect how residues are distributed among hive foods, and therefore which bee stages are most highly exposed. This could affect the types of effects observed on the colony.

Another uncertainty with feeding studies is the extent to which colony behaviour is affected by the provision of pollen and/or nectar. If bees are provided with a supply of pollen and/or nectar in the hive, foraging for these food sources outside the hive may be reduced. If foraging behaviour is affected in this way, any endpoint related to foraging success such as quantity of pollen or nectar stores and hive development which depends on those stores is questionable. For instance, in cases where exposure to a pesticide affects foraging behaviour, the provision of pollen and nectar could mask the toxic effects and result in a lack of significant difference in endpoints related to foraging behaviour.

Since colony feeding exposure routes occur through experimentally supplied concentrations of pollen or nectar or both, there is uncertainty in how these relate to actual measured residue levels recovered in pollen and nectar. In the natural environment, there will be exposure to both pollen and nectar in varying ratios. Differences in experimental feeding concentrations and ratios could affect the distribution of neonicotinoids in food matrices, exposure of different bee stages, and types of effects induced.

Additional scientific studies may help to elucidate how exposures through pollen or nectar affect the distribution and levels of residues in hive matrices and bee foods and the type of effects observed.

1.2.9 Exposure through bee bread

Concerns were raised regarding the approach used by Health Canada for addressing the combined pollen and nectar routes of exposure in bee bread. Further considerations should be made before using this method in the regulatory context. Alternative approaches were suggested.

Comment (Valent)

Valent believes that the new approach for addressing the combined pollen and nectar routes of exposure in bee bread proposed by the Agency requires further consideration before it can be used in regulatory risk assessments. Reference is also made by PMRA to the uncertainties with regards to the estimation of bee bread exposure, and this is clearly significant. Thus, a number of assumptions have been made with regards to the residue levels measured in nectar and pollen and their use in the calculation of residue levels in bee bread. Residue levels for in-hive matrices are consistently lower than those found in the crop and from pollen and nectar samples collected by bees. In addition, it is assumed that there is no degradation of clothianidin in the bee bread, which is unrealistic. It would be more appropriate to use measured values in bee bread. This could either be at a general level, comparing measured values with those in nectar and pollen in order to calibrate the estimated values, or specifically in the case of clothianidin for direct use in the refined risk assessment.

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An alternative approach that is considered to be more realistic is the calculation of a total dietary concentration by dividing the concentration in pollen by a factor of 5 to give a value in nectar equivalents that can then be added to the nectar concentration. This can then be directly related to the endpoint from the CFS using sucrose dosing. This offers a more appropriate way to incorporate combined exposure to nectar pollen in the risk assessment until further information is available about the actual exposure of bees via bee bread.

Health Canada Response

Health Canada agrees that further consideration of how and when to use bee bread exposure estimations in the risk assessment is warranted. It is important to note that Health Canada did not make overall risk conclusions using estimated exposure concentrations in bee bread. Rather, Health Canada explored using exposure estimations in bee bread alongside exposure estimations using residues measured in pollen. It is noted that in most cases, the risk characterization using estimated bee bread exposure was similar to that from pollen exposure. The reason this was explored, in part, was because some colony feeding studies dosed colonies with pollen patties/mixtures of pollen and sucrose, and there was some uncertainty regarding how best to compare those effect doses with exposure to residues measured in the field. There was consideration as to whether this type of pollen patty/sucrose and pollen mixture dosing study was better compared to pollen residues or to estimated residues in bee bread (which is a mixture of both pollen and nectar).

For the colony feeding studies which dosed colonies with sucrose solution, the effect endpoints (based on sucrose dosing solution levels) were compared to nectar residue levels in crops. For colony feeding studies which dosed hives with pollen, pollen patties or some combination of both pollen and nectar, Health Canada compared these effect endpoints (based on the dosing matrix levels) to pollen residue levels measured in crops. In addition, for honey bees, Health Canada also compared these pollen /pollen patty/ sucrose and pollen mixture dosing effects endpoints to estimated concentrations in "bee bread," considering the contribution from both pollen and nectar residue levels. The pollen/pollen patty/pollen and sucrose mixture colony feeding study effects levels for honey bees were therefore compared with exposures based on both measured pollen residue levels alone and estimated "bee bread" residue levels which included contributions of residues from both pollen and nectar. Risk estimation results were similar for both comparisons.

In the honey bee colony feeding studies (both with sucrose solutions and with pollen patties/pollen mixtures), the measured residues in hive nectar and honey and hive bee bread were always lower than levels in the dosing matrices (sucrose solutions or pollen patties/pollen mixtures), but were not uniform or consistent, and varied with location and sampling time. These hive nectar, honey and bee bread measures were meant to demonstrate exposure was occurring in the feeding study; they were not meant to provide any robust measure of exposure to bees in the hive. The dynamics of bee exposures resulting from feeding source pollen and nectar and considering incorporation into hive bee bread and nectar/honey, along with degradation are not well defined at this time. Therefore, Health Canada used the source dosing matrix residue levels to represent the effect endpoints, and compared these effects endpoints with measured source residue levels in nectar and pollen from plants.

The proposed approach of dividing the concentration in pollen by a factor of 5 to give a value in nectar equivalents that can then be added to the nectar concentration, is not currently supported by Health Canada. Although this proposed approach does consider the effects endpoint observed for the sucrose solution dosing colony feeding study with honey bees against total dietary exposure from both nectar and pollen, it does not consider available effects data from dosing studies with pollen/pollen patties/pollen mixtures. It is noted that there were a number of open literature studies which dosed colonies via pollen/pollen patties/pollen and nectar mixtures, which had observed effects at levels different from the sucrose dosed colonies. There might be differences in effects observed in the colonies depending on the exposure routes, since different bee stages/castes can consume differing amounts of pollen and nectar. Colony effects dosing studies with sucrose solutions and with pollen/pollen patties/ pollen mixtures were available for both *Apis* and non-*Apis* bees, and were considered separately.

As further work continues and knowledge is gained, further consideration may be given to the appropriate matrices for dosing and defining effects levels in colony feeding studies, as well as appropriate estimates of exposure levels in the environment for comparison with the feeding study effects levels.

1.2.10 Long-term exposure

A comment was provided which expressed concern that limiting application frequency or application periods was not an adequate risk management strategy because neonicotinoids can produce toxic effects at any concentration if exposure is long enough (Rondeau et al., 2015 and Tennekes 2010).

An additional comment expressed concern that Health Canada did not consider exposure from ingestion of pollen, including from treated maize, and also long term/overwinter exposure of bee colonies to contaminated pollen (Codling et al., 2015).

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)

Recent findings in ecotoxicology suggest that some chemicals, including neonicotinoids, can produce toxic effects at any concentration provided a sufficiently long time of exposure (Rondeau et al., 2015 and Tennekes 2010) which means that limiting application frequencies or application periods is not an adequate risk management strategy. Because most neonicotinoid insecticides are persistent in soil and water, maintaining any neonicotinoid contamination in the environment is likely to potentially affect a broad range of biological organisms that provide ecosystem services, posing risks to ecosystem functioning and services.

Comment (Fédération des apiculteurs du Québec)

Exposure through the ingestion of pollen contaminated with thiamethoxam is raised in the list of different effects and / or situations of re-evaluation but no conclusion is drawn. Exposure to seed dust is taken into account but nothing is said about intoxication following the ingestion of contaminated pollen. Bees harvest maize pollen as a food source and this form of contamination should be considered important. (3) In addition, a study conducted in 2015 reveals a very high concentration of thiamethoxam in pollen samples taken from beehives in Saskatchewan (6)

An extended multi-year study should be conducted to document the effect of pesticides on colonies and overwintering. Consumption of pollen contaminated with thiamethoxam by bees during the winter could

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have negative effects on colony survival (6). According to this study, the daily consumption of pollen during the summer season would not be a major source of contamination for an adult bee. However, over a winter period of 150 days, the total consumption of pollen contaminated for this same bee would exceed the minimum threshold LD50 for several neonicotinoids.

3. Darclet Teresinha Malerbo-Souza (2010). The corn pollen as a food source for honeybees. Acta Scientiarum Agronomy DOI : 10.4025/actasciagron.v33i4.10533

6. Codling G, Naggar Y A, Giesy J P, Robertson A J. (2015). Concentrations of neonicotinoid insecticides in honey, pollen and honey bees (Apis mellifera L.) in central Saskatchewan, Canada. ScienceDirect https://doi.org/10.1016/j.chemosphere.2015.10.135

Health Canada Response

Health Canada considered a large number of studies with prolonged exposure to bees and bee colonies, including higher tier semi-field and field studies and colony dosing studies spanning multiple generations (Please refer to PRVD2017-24 and PRVD2017-23, Appendix V for a list of studies including duration of exposure).

Overall, for the longer-term colony feeding studies, these endpoints were compared to residues in pollen and/or nectar in crops treated with thiamethoxam and/or clothianidin. For many foliar and soil applications, this comparison resulted in potential risk. As such, Health Canada proposed mitigation to limit exposure to pollinators. There were also a large number of longer-term field studies in which bee colonies were placed in or adjacent to fields with treated seed. These studies resulted in a lack of colony level risk.

Two studies were referenced in the comment in relation to the statement that '*chemicals, including neonicotinoids, can produce toxic effects at any concentration provided a sufficiently long time of exposure'*. The Rondeau et al., 2015 study was related to imidacloprid, and essentially indicated (in a laboratory study) that LD50 values decrease with increasing exposure time. The study then extrapolated information into a model to suggest that certain levels of imidacloprid would be lethal to winter bees later in life cycle. Therefore, there was no field data to support this claim. The Tennekes 2010 article was also related to imidacloprid and is based on the Druckrey-Kupfmuller equation, which was based on effect of low concentrations of carcinogens to mammals. Therefore, this information is not directly applicable to pollinator exposure to neonicotinoids.

Ingestion of pollen:

Regarding pollen as a food source, ingestion of contaminated pollen was considered throughout the risk assessment (in PRVD2017-23 and PRVD2017-24). Ingestion of residues through both pollen and nectar are thought to be one of the primary exposure routes for bees, and were considered throughout the risk assessment for all crops, as well as for rotational crops and off-field plants.

Specifically for crops such as maize, which only produce pollen, pollen residues were considered as a route of exposure. Residues which translocated from treated maize seed were generally very low and did not exceed colony level effects endpoints for *Apis* and non-*Apis* bees from pollen (pollen patty) exposure (PRVD2017-24 and PRVD2017-23, Appendix VII, Table 3 and 4, respectively). Therefore, no risk was identified. In addition, a number of longer-term field

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studies were conducted with bee colonies, which were exposed to pollen shed from seed treated maize (PRVD2017-24 and PRVD2017-23, Appendix V, Table 4). Overall, these studies also concluded no colony level risk.

Overwinter exposure to pollen and/or nectar:

The additional reference provided by the commenter (Codling et al., 2016) detected thiamethoxam and clothianidin residues sampled from hives (hive pollen and nectar) during August in Saskatoon, Canada. The study authors then estimated levels that colonies could be exposed to during the winter months, assuming residue levels equivalent to those found in August, and used laboratory toxicity endpoints to estimate potential long-term effects.

Health Canada did consider long-term exposure of bee colonies to both contaminated pollen and/or nectar in the hive. However, the method of assessment was different from that of the Codling et al., 2016 study.

Health Canada uses a tiered pollinator risk assessment approach. At the Tier I level, we considered laboratory data to assess potential acute and chronic risk to individual bees, and default exposure based on maximum application rates. At the Tier I refined level, we considered laboratory data to assess potential acute and chronic risk to individual bees, and pollen and/or nectar residues from field studies. This Tier I refined assessment would be most similar to the Codling et al., 2016 study which compared residues to a laboratory endpoint. However, in contrast to the Codling et al., 2016 study, Health Canada assessment considered more laboratory endpoints (including acute and chronic exposure to larvae and adult bees).

To further assess potential colony level risks, Health Canada also conducted a Tier II refined assessment which compared colony feeding study endpoints to pollen and/or nectar residues from field studies. Colony feeding studies are field based studies which dose *Apis* or non-A*pis* colonies with pollen and/or nectar contaminated with thiamethoxam and/or clothianidin for 5 to 16 weeks, and the hives are observed until after overwintering. In many cases, there are still residues present in the hive after the dosing period, although these levels are declining and exposure is less than during dosing. However, the presence of these residues show field realistic residues in the hive before, during and after overwintering, following colony exposure to contaminated pollen and/or nectar.

Tier II semi-field and Tier III field study results were also considered. The higher Tier field studies place colonies in treated fields (primarily foliar and seed treatments) for multiple years (including overwintering) and monitor the hive for effects. Similar to the dosing study, hives in these studies would be exposed to contaminated pollen (and/or nectar) during the crop blooming period and potentially through the winter. Overall, no colony level effects were observed in field studies conducted with seed treatment applications.

In cases where colony level effects were observed, and/or residues in plants were expected to result in colony level exposure, Health Canada proposed mitigation to limit exposure (including cancellation of uses).

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1.2.11 Translocation mechanism in plant

The registrant highlighted a common misconception that for foliar application thiamethoxam enters the leaf tissue and moves systemically throughout the plant. They suggest that thiamethoxam found in pollen/nectar from pre-bloom and post-bloom applications is most likely from direct spraying of a developing flower bud or dormant bud tissue. A study provided (Daniels, 2008) demonstrated that thiamethoxam is not phloem mobile.

> ***Comment (Syngenta)***
>
> *A common misconception concerning foliar applications of thiamethoxam is that thiamethoxam enters leaf tissue and moves systemically throughout the plant. However, for foliar treatments, thiamethoxam is not phloem-mobile and foliar applications have a shorter pest control duration than soil applications or seed treatments. Thiamethoxam found in pollen/nectar from pre-bloom and post-bloom foliar applications most likely comes from the direct spraying of a developing flower bud or dormant bud tissue.*
>
> *A study by Daniels (2008) investigated the movement of several compounds in wheat after application of radio-labeled material to the leaf surface. As figure was provided which showed that radio-labeled sucrose, which is both xylem- and phloem-mobile, is detected not only in the leaf where the application was made (1st leaf) but also in the 2nd and 3rd leaf as well as the roots of the wheat plant. However, wheat treated with radio-labeled thiamethoxam is primarily only observed in the treated leaf with minimal detection in the 2nd and 3rd leaf and no detection in the roots. In addition, aphids, which are known to feed on phloem sap, were allowed to feed on the treated wheat plants and phloem samples were collected from their stylus. Both sucrose and glyphosate, which are phloem mobile, were detected in the phloem sap and showed increasing levels over time. However, thiamethoxam, pymetrozine and the control, which are not phloem mobile, were not detected in the phloem sap over time.*

Health Canada Response

Residue data from pre-bloom foliar application (similar to registered label timing of application in many cases) was considered in the risk assessment, and are thought to represent potential exposure in pollen and/or nectar. Pre-bloom foliar applications typically took place between 5 to 19 days before bloom, depending on the crop and number of applications. In addition, foliar applications after bloom have resulted in residues in pollen and/or nectar (and leaves) in the following spring. Flower buds may be present at the time of spraying both pre-bloom and post-bloom, though this may depend on the crop being sprayed and the timing of application. It is noted that buds on fruit trees, are formed in the summer, become dormant in the autumn, and develop further the next spring; therefore, buds could be present during post-bloom applications.

Residues in pollen and nectar resulting from pre-bloom applications exceeded colony level endpoints, therefore, Health Canada proposed no application before or during bloom, in order to minimize exposure to bees. As well, in some cases, post-bloom foliar applications resulted in residues in pollen or nectar collected the following season that exceeded colony level endpoints, and where this occurred, mitigation was proposed.

With respect to the characterization of thiamethoxam, Health Canada has reviewed the information presented with the comment, and agrees that residues from pre-bloom application of thiamethoxam may be the result of xylem mobility from spraying developing flower bud/tissue. However, this information does not affect the current risk assessment conclusions, as they included consideration of residues directly measured in pollen and nectar after pre-bloom and post-bloom applications.

1.3 Off-field exposure

A significant number of comments were received regarding potential exposure to off-target locations. The areas of concern included the movement of neonicotinoids off-field in water, spray drift, and dust, and subsequent uptake into pollen and nectar in plants off-field. The response to comments are included in Section 1.3.1 and 1.3.2.

The concerns raised included:

- Widespread occurrence of neonics in the environment (persistent in soil, detected in water across the country)
- Non-treated plants – both adjacent agriculture crops and other vegetation
    - may take up neonics as the chemicals move through the soil and water
    - may be contaminated with dust generated during the planting of treated seeds
    - may be exposed to neonicotinoids via spray drift
- Residues in these non-treated plants may be a significant source of exposure to pollinators if they are attractive to bees, given that these plants may be in bloom longer than the treated crop
- Pollen collected by honey bees in agricultural areas may include high percentages of non-crop plants (in other words, off-field plants), which may also contain neonicotinoid residues
- A commenter suggested that there were a number of studies not considered in the review documents that are relevant to the decision.

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)

Risks to pollinators from contamination of the broader environment.

*As is apparent from many of the foregoing comments, a significant limitation of both risk assessments is the failure to evaluate the potential for exposure to clothianidin and thiamethoxam beyond the treated field. There is clear evidence of widespread environmental contamination by neonics. Both clothianidin and thiamethoxam (as well as imidacloprid) are persistent in **soil** (for up to three years in the case of clothianidin) and have been detected in **water** samples across the country, likely as a result of agricultural runoff and leaching. It is reasonable to expect that plants in the vicinity of treated fields could also become contaminated. Non-treated plants – both adjacent agricultural crops and other vegetation – may take up neonics as the chemicals move through the soil and water, and also through **dust** (generated during the planting of treated seeds) and **spray drift**. Residues in the pollen and nectar of these plants could become a source of exposure, especially if they are attractive to bees.*

The PMRA proposes to reduce the maximum number of foliar applications of clothianidin to cucurbit vegetables to one per season, and proposes to eliminate spray of thiamethoxam as a foliar application to legume and outdoor fruiting vegetables, and foliar application to berry crops before and/or during bloom.

Limiting foliar application frequencies or application periods will not prevent environmental contamination. All foliar uses should be immediately deregistered.

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Comment (Ontario Beekeepers Association)- Struger et al., 2017 study

A recent study of surface waters in 15 agricultural areas in southwestern Ontario detected neonicotinoids in samples from more than half these sites, with seasonal maximums in spring and fall, especially in areas where row crops predominated.

John Struger, Josey Grabuski, Steve Cagampan, Ed Sverko, Daryl McGoldrick, Christopher H. Marvin, 2016. Factors influencing the occurrence and distribution of neonicotinoid insecticides in surface waters of southern Ontario, Canada, Chemosphere, Volume 169, 2017, Pages 516-523

https://doi.org/10.1016/j.chemosphere.2016.11.036.

Comment (City of Montréal) - water

In its re-evaluation, the PMRA has assumed that the route of pollinator exposure by water contaminated with pesticides is negligible. However, recent research in Quebec has shown that this route of exposure was underestimated by current risk assessment processes. The majority of puddle samples collected from neonicotinoid-treated crops in Quebec had residues of clothianidin (97% of samples) and thiamethoxam (86% of samples). This route of exposure should have been considered in the re-evaluation of the PMRA.

Comment (Ontario Beekeepers Association) - Tsvetkov et al., 2017 study

Another recently published study involving exposure to neonicotinoids from Canadian corn crops and crops of canola in Europe concluded:

The neonicotinoid contaminated pollen the honeybees collected did not belong to corn or soybean plants – the two primary crops grown from neonicotinoid treated seeds in Ontario and Québec. This indicates that neonicotinoids, which are water soluble, spill over from agricultural fields into the surrounding environment, where they are taken up by other plants that are very attractive to bees.
http://news.yorku.ca/2017/06/29/exposureto-neonics-results-in-early-death-for-honeybee-workers-and-queens-york-u-study/

Our study demonstrates that honey bees in corn-growing regions of Canada are exposed to toxicologically significant levels of NNIs for the majority of the active bee season despite the mandated use of dust-reducing seed lubricants during planting. Pollen from non-target plants represents the primary route of exposure to NNIs in our study.

https://www.apiservices.biz/documents/articles-en/chronic_exposure_neonicotinoids_reduces_honeybee_health_near_corn_crops.pdf

Comment (citizen): *While your Appendix lists certain important studies, it appears you did not consider any exposure of bees to thiamethoxam from non-target plants. You ignore the risk to bees when this persistent pesticide trans-locates via surface and ground water to neighboring flowering plants, bushes and trees. Concerns regarding the environmental fate and effects of thiamethoxam – including soil persistence, contamination of untreated areas, effects on managed and wild pollinator species, effects on other nontarget invertebrates, birds, bats, have been described in research paper after research paper.The scientific evidence continues to accumulate. You appear to disregard any of the literature describing the environmental fate and alternative routes of exposure for pollinators which have repeatedly highlighted the pitfalls associated with the widespread use of these systemic pesticides. There is no safe application for a highly mobile systemic insecticide*

Comment (City of Montréal) - off-field exposure

Exposure to clothianidin or thiamethoxam by surrounding plants is not considered in the draft decisions (eg bees foraging the grasses surrounding neonicotinoid-treated fields are a source of exposure real). Thus, even if a crop is considered "non-attractive" to bees and there would be no exposure, pollinators

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could still be exposed via the surrounding plants that would have absorbed one or the other of these molecules which, moreover, are easily leached into the soil. We therefore consider the notion of "attractiveness" of plant species to be a poor parameter that leads the PMRA to erroneous conclusions.

Comment (Fédération des apiculteurs du Québec) - PRVD2017-24

No importance is given to contamination by puddles in the field. Recent research shows that the risk associated with this source of contamination is underestimated and distorts the calculation of risk (4)

4.Samson-Robert O, Labrie G, Chagnon M, Fournier V (2014)Neonicotinoid-Contaminated Puddles of Water Represent a Risk of Intoxication for Honey Bees. PloS One 9(12): e108443. http://doi.org/10.1371/journal.pone.0108443

Comment (Fédération des apiculteurs du Québec) - PRVD2017-23

Contamination by puddles

One of the important forms of intoxication is not considered in risk mitigation measures. In the PRVD2017-23 re-evaluation, it is stated that 'Health Canada has also assessed the risks to bees posed by water sources in which pollinators may collect water in areas where clothianidin is applied and concluded that water sources do not pose a worrying risk to bees. 'This is without taking into account observations in the field made by beekeepers who find that bees drink regularly in puddles near the hives. These observations are echoed in a recent study which shows that bees prefer standing puddles that contain organic matter and minerals, and that these puddles are very abundant in fields treated with seeds coated with neonicotinoids. (1) Still according to the same study, 78% @ 96% of the neonicotinoids used in coating would not be used by the plant but would rather be lost by leaching into the soil. Combined with a half-life of 148-1155 days, the concentration of clothianidin in the soil would increase and this concentration would play an important role in the contamination of the puddles in which the bees drink. (1) To add to problem, if we give the choice to the bees, they will prefer to drink to sweet solutions containing neonicotinoids (imidacloprid, thiamethoxam and clothianidin) rather than to sweet solutions without neonicotinoids (6) To conclude that puddles do not are not a possible source of intoxication for bees no longer a possibility for the PMRA and must be reconsidered in the draft decision on clothianidin.

1. Samson-Robert O, Labrie G, Chagnon M., Fournier V (2014) Neonicotinoid-Contaminated Puddles of Water Represent a Risk of Intoxication for Honey Bees. PloS One 9 (12): e108443. http://doi.org/10.1371/journal.pone.0108443

6. Kessler S, Tiedeken EJ, Simcock KL, Derveau S, Mitchell J, Softley S, Stout JC, Wright GA. (2015). Bees prefer foods containing neonicotinoid pesticides. Nature May 7; 521(7550):74-76. doi: 10.1038/nature14414.Epub 2015 Apr 22

Comment (Univeristy of Guelph)

Recent evidence suggests that the potential for both managed honeybees, wild bees (and also likely other pollinator taxa) to be exposed to neonicotinoids in the nectar and pollen from the flowers of non-crop plants they visit is appreciable. In some cases these studies indicate that the period of exposure to these pesticides via non-crop plants is substantially longer than the bloom period of treated crops, and may therefore represent a major/significant route of dietary exposure to these systemic pesticides. The PMRA documents for review seem to have overlooked a number of relevant studies that need to be included in any re-evaluation decision related to pollinators and neonicotinoids. Published studies that must also be considered include: Long & Krupke (2016); Krupke et al. (2017); David et al. (2016); Botías et al. (2015, 2016); Stewart et al. (2014). Without a wider consideration of this route of exposure, then dietary exposure for an evaluation (based only on the residues found in the nectar and pollen of bee-attractive crops in bloom) could be substantially under-estimated. These studies revealing measurable, and non-trivial, levels of exposure in non-crop plants also underline that protecting pollinators is not simply about considering the bee attractive crops on which these pesticides are used, it is also about the wider environment on farms

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where these pesticides are used, and potentially beyond due to the environmental movement of these compounds as dust, blown soil or through water movement. PMRA are certainly aware of measurable neonicotinoid residues in Canadian water courses as this was highlighted in recent proposals to phase out the use of imidacloprid.

Botías, C., D. Arthur, J. Horwood, A. Abdul-Sada, E. Nicholls, E. Hill and D. Goulson (2015). Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees. Environmental Science & Technology 49: 12731-12740.

Botías, C., A. David, E. M. Hill and D. Goulson (2016). Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects. Science of the Total Environment 566-567: 269-278.

David, A., C. Botías, A. Abdul-Sada, E. Nicholls, E. L. Rotheray, E. M. Hill and D. Goulson (2016). Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. Environment International 88: 169-178.

Krupke, C. H., J. D. Holland, E. Y. Long and B. D. Eitzer (2017). Planting of neonicotinoid treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. Journal of Applied Ecology 54: 1449-1458.

Long, E. Y. and C. H. Krupke (2016). Non-cultivated plants present a season-long route of pesticide exposure for honey bees. Nature Communications 7: 11629.

Stewart, S. D., G. M. Lorenz, A. L. Catchot, J. Gore, D. Cook, J. Skinner, T. C. Mueller, D. R. Johnson, J. Zawislak and J. Barber (2014). Potential exposure of pollinators to neonicotinoid insecticides from the use of insecticide seed treatments in the mid-southern United States. Environmental Science & Technology 48(16): 9762-9769.

1.3.1 Water – direct consumption

Multiple comments indicated that exposure through water should be considered. It is noted that water sources considered in the Health Canada risk assessment included both off-field and on-field water sources.

Health Canada Response

The PRVD2017-23 and PRVD2017-24 considered potential risk from direct consumption of water sources used by bees that may contain residues of neonicotinoids. The water consumption risk assessment considered water sources of guttation droplets as well as surface waters that may be relevant for bees, such as puddles near agricultural fields and other shallow water sources. The water assessment can be found in each document in Sections "2.5.3 Water assessment", with details in "Appendix IX Risk assessment for bees via water exposure route" of each document.

Regarding the water concentrations for surface waters used in the pollinator risk assessments, only surface waters thought to be relevant to bees were considered. Health Canada is aware of the levels of neonicotinoids in surface waters throughout Canada, and has considered this information extensively in the aquatic risk assessments for the neonicotinoids. Health Canada has published proposed decisions for all three neonicotinoids relating to effects in aquatic organisms (PRVD2016-20 *Imidacloprid Proposed Re-evaluation Decision*; PSRD2018-01 *Special Review of Clothianidin Risk to Aquatic Invertebrates: Proposed Decision for Consultation*; PSRD2018-02 *Special Review of Thiamethoxam Risk to Aquatic Invertebrates:*

Proposed Decision for Consultation). These three proposed decisions considered water monitoring data from across Canada. The study from Struger et al. (PMRA 2703534) referenced in one of the comments was considered in these assessments. Residues from the Struger et al. study were not included in the pollinator risk assessments in PRVD2017-23 and PRVD2017-24 because the water sources were unlikely to be potential drinking water sources for bees.

The water sources considered relevant for bees focused mainly on puddles near corn fields, and shallower sources of water that were likely to be used by bees, and/or which were specifically located near bee hives. The Samson-Robert et al., 2014 (PMRA 2526146) residues were considered in PRVD2017-24 and PRVD2017-23, Appendix IX, among other sources of available information, in the risk assessment. The maximum concentrations of clothianidin and thiamethoxam in potential sources of drinking water for bees were 55.7 µg/L and 63.4 µg/L, respectively, from puddles located in Quebec corn fields sampled during planting (Samson-Robert et al., 2014 (PMRA# 2526146)), and they noted that neonicotinoid concentrations in puddles located in corn fields were higher during corn planting (from drifting and deposition of dust) compared to after planting, which is consistent with Health Canada's evaluation of the bee mortality incidents (Health Canada, *Update on Neonicotinoid Pesticides and Bee Health, 2014*). Considering these residues from puddles in agricultural areas, among others, there is expected to be negligible acute or chronic risks to adult or larval bees from neonicotinoids found in bee relevant water sources. Therefore, the overall risk conclusions, based on consideration of all information received during the consultation process, have not changed.

The PRVD2017-23 and PRVD2017-24 also considered movement of residues in soil via water, such as run-off from agricultural fields into off-field areas, where residues could be taken up by non-target plants and expressed in the pollen and nectar. Consideration of exposure to off-field plants is further discussed in the responses below.

1.3.2 Uptake by field-margin plants

Multiple comments raised concerns regarding the uptake of neonicotinoids in plants in field margins that may be attractive to pollinators. It was suggested that, given the water solubility of these chemicals, they are moving off-field and are available for uptake by off-field plants. Mention was also made of off-field movement of spray drift and of dust during planting of treated seed, both of which can also land on soils making residues available for uptake by off-field plants, or land on flowering non-target plants directly contaminating pollen and nectar.

Health Canada Response

Health Canada agrees that off-field plants are an important consideration, and Health Canada did consider this exposure route in the risk assessment, including all potential sources of off-field exposure as mentioned by commenters.

In PRVD2017-23 and PRVD2017-24, the risk assessment was organized by application type: foliar application; soil application; seed treatment. Within each of these, both on field and off-field exposures were considered using available data. Residues of both on-field crop plants and off-field plants and rotational crops were compared to Tier I and Tier II colony level effects endpoints. As well, higher tier field and tunnel studies considering both on-field and off-field exposures were considered.

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Health Canada agrees that bees often forage off-field, and residue levels in off-field plants are important to consider in the risk assessment. Based on residue information available, the residues from off-field plants are typically much lower than residues of on-field crop plants. While residues are lower, it is possible that a succession of off-field flowering plants could result in longer bloom periods and exposures from off-field plants compared to crop plants. Different bee species may collect different amounts of pollen and nectar from crop plants and off-field plants, depending on the attractiveness and availability of pollen and nectar to various bee species. The findings that the majority of pollen in some agricultural areas does not originate from crop plants is consistent with the studies and information considered by Health Canada, including for corn and soybean agricultural areas, such as mentioned in Tsvetkov et al., 2017.

As mentioned, residue data available from off-field plants and rotational crops were considered in the risk assessment for comparison with Tier I laboratory and Tier II colony feeding study effects endpoints. Residues in pollen and nectar were available from rotational crops grown in fields where soils contained residues of neonicotinoids, and thus were also used to support estimates of residues expected in off-field plants. The Tier II colony feeding study effects endpoints considered were for both *Apis* and non-*Apis* bees, where colonies were dosed for longer periods of time (ranging from 4 to 16 weeks of exposure). Therefore, the effects endpoints considered included effects resulting from longer exposure periods, such as those that may occur with off-field plants. When comparing these effects endpoints to off-field plant residues, there was negligible risk identified.

It is noted that the specific colony effects endpoints considered in the risk assessments, including the risk assessments for off-field plants, are presented in PRVD2017-23 andPRVD2017-24 in Table 3 Summary of Endpoints Selected from Colony Feeding Studies for the Tier II Refined Risk Assessments for clothianidin and thiamethoxam, respectively. One of the colony level effects studies that was considered in the clothianidin risk assessment was the clothianidin pollen patty feeding study from Tsvetkov et al., 2017, as mentioned by a commenter. The residues in off-field plants and rotational crops were frequently below the selected colony level effects endpoints, including the effects level considered from the Tsvetkov et al., 2017 colony feeding study (Refer to the refined risk assessment tables in Appendix VI, VII and VIII of PRVD2017-23 and PRVD2017-24 for further details).

In addition, some higher tier field studies included exposure to non-target off-field crops, and were considered in the off-field risk assessment. There were seed treatment field studies with treated corn adjacent to fields with pollinator attractive crops, where hives were exposed during, and after planting. Other studies (PMRA Nos. 2365365, 2364957, 2365373, Alburaki et al., 2015) examining effects from exposure to corn during pollen-shed which was grown from treated seed, analyzed pollen samples from bees and determined high levels of other types of forage, such as *Trifolium repens, Sedum spp., Centaruea jacea* etc., indicating bees were foraging on non-target plants as well. The majority of these studies indicated limited colony level effects, although in some cases there were short-term/transient effects (typically around planting only). Overall, these studies where bees were foraging both on and off-field demonstrated a lack of colony level effects.

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A commenter provided a number of additional references relevant for off-field exposures to flowering plants. When considering these additional field and/or monitoring studies with pollen and nectar residue information relevant for off-field exposure, most residues were below *Apis* and non-*Apis* colony level effects endpoints. Only some pollen residues in off-field plants exceeded some of the lower-end non-*Apis* endpoints.

Please refer to the update to the off-field risk assessment considering the new information in the Science Evaluation Update Section.

Also, it is noted that responses to other comments may also be relevant to this question. Please see Section 1.4 Seed treatment, in particular Section 1.4.3 Evaluation of the effectiveness of dust-reducing mitigation.

1.4 Seed treatment

1.4.1 Seed treatment: proposed decision

A commenter indicated that they disagreed with the decision to maintain seed treatment uses, and that these seed treatment uses should also be phased out.

> ***Comment (citizen)***
>
> *The Pest Management Regulatory Agency should reconsider the proposed re-evaluation and registration decisions addressing pollinator risks from the neonicotinoids clothianidin and thiamethoxam. Seed treatments represent the most widespread use of neonics in Canada and have been identified as a major ecological threat.*
>
> *Half measures aren't enough. Neonicotinoids are toxic to bees. A credible approach to pollinator protection must include phasing out the major use of these chemicals - seed treatments - as well as other applications.*

Health Canada Response

Health Canada agrees that neonicotinoids are toxic to bees; however, the risk assessment process for bees considers not only the toxicity (effects) of a pesticide to bees, but also the potential for pollinator exposure considering multiple exposure routes. The risk assessment for clothianidin and thiamethoxam compared various effects endpoints for bees to the expected exposure, which differs with application rates and methods. Some current uses of clothianidin and thiamethoxam are not expected to result in exposures which affect bees while some uses result in exposures that 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. The mitigation measures proposed for clothianidin and thiamethoxam include cancellation of some uses, changes to the use pattern and label improvements for other uses. When clothianidin and thiamethoxam are used in accordance with these new proposed risk reduction measures, the environmental exposure is reduced to levels where risks to bees are considered to be acceptable. Where negligible risk was identified, no mitigation is required; however, label improvements to further reduce exposure for some uses are still proposed.

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Negligible risk to pollinators was identified for all seed treatment uses of clothianidin and thiamethoxam based on the potential for pollinator exposure through translocation of residues into pollen and nectar of treated seed. Carrots, bulb vegetables, leafy vegetables, brassica leafy vegetables and sugar beets are all crops that are harvested before bloom and are not typically grown for seed production in Canada, and therefore no pollinator exposure is expected in these crops following seed treatment application with either clothianidin or thiamethoxam. For the other seed treated crops including potato, legume vegetables, fruiting vegetables, cucurbit vegetables, cereals, oilseeds and rotational crops, the risk from translocation of residues into pollen and nectar of treated crops to bees was determined to be negligible based on the results of the risk assessment using Canadian relevant information.

Incident reporting information, including potential exposure from dust generated during planting of treated seed, was also considered in the risk assessment. In determining the potential risk from dust, there was consideration of the planting equipment used for different types of seeds, and the dustiness of different types of treated seed based on how the seed coating adheres. Exposure to dust has been identified as a concern primarily for crops that may utilize vacuum (negative pressure) seeders. Other than corn and soybean, other crops do not typically use vacuum seeders. Some cereal and legume seeds have been identified as being typically dustier, but do not use vacuum planters for planting; therefore relevant additional best management practices were added to labels of these seeds.

Health Canada agrees that seed treatments represent the most widespread use of neonicotinoids in Canada. In addition to Health Canada completing a thorough risk assessment for seed treatment uses of clothianidin and thiamethoxam which determined negligible risk to pollinators, many growers use integrated pest management (IPM) which further reduces exposure to pollinators. Health Canada supports various stakeholders in the development of sustainable pest management strategies, including the development and promotion of IPM. These strategies allow each user to be more involved in their pest management by having increased access to the best reduced risk practices available.

Specifically for seed treatment use of neonicotinoids, Health Canada 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.

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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-pollinisateurs/treated_seed-semences_traitees-eng.pdf

1.4.2 Seed Treatment: Exposure routes

A comment was received indicating the seed treatment risk assessment for corn, winter wheat and soy is not accurate and should also consider exposure from guttation droplets, and not just effects associated from exposure during sowing.

> ***Comment (citizen)***
>
> *In your re-evaluation of thiamethoxam, you claim negligible risk to honeybees and other pollinators from seed treated with thiamethoxam. The current risk to bees and pollinators from seed application of thiamethoxam on soy (and corn and winter wheat) is NOT ACCEPTABLE. Acute toxicity sources for bees associated with the use of seed-coating insecticides have already been identified, specifically via guttation droplets. It is not just direct exposure during sowing of treated seeds.*

Health Canada Response

As outlined in PRVD2017-24 and PRVD2017-23, acute toxicity effects were considered in the risk assessment, as well as chronic (longer-term) toxicity to bees and colonies. Multiple exposure routes were considered in the seed treatment risk assessments, as outlined below:

Residues in pollen and nectar of crops: Exposure to pollen and/or nectar resulting from the systemic movement of the pesticides in corn, soy and wheat, as well as all other seed treatments, was assessed. When crops are planted using neonicotinoid treated seeds, the pesticide from the treated seed can be taken up by the growing plant, and be distributed throughout the plant including pollen and nectar. There was low risk identified through this pollen and nectar exposure route for treated seeds because residues in pollen and nectar of these plants were very low (in other words, at levels below effect endpoints/levels). Additionally, in some cases, the plants are not attractive to bees (for example, wheat).

Residues from dust generated during sowing of treated seed: During planting of treated seeds, dust from certain seeds can drift to adjacent crops and become a source of contaminated pollen and/or nectar. In addition, dust on soils following seed treatment (as well as the planted treated seeds) can result in residues in the soil moving off the treated field with water and taken up (or translocated) into plants in adjacent fields. A number of studies were considered which looked at the effects of exposure from planting of treated seed on bee colonies. These studies considered exposure to dust during planting, as well as exposure later in the season to pollen and nectar from the treated crop and from non-target plants off-field. Overall, these studies indicated an overall lack of colony level effects. Please refer to Section 1.3.2 Off-field exposure- Uptake by field-margin plants of this RVD for an additional summary of these studies. In addition, the reduction in reported incidents during planting of treated corn and soy seed following implementation of requirements for mandatory fluency agents and BMPs was also considered. However, further analysis of the incidents in corn and soybean areas is still ongoing, particularly the later season incident reports. This is further discussed in the response below (Section 1.4.3 Seed treatment- Evaluation of the effectiveness of dust reducing mitigation).

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Residues in guttation droplets: The risk assessment considered guttation droplets, as found in the water assessment in PRVD2017-24 and PRVD2017-23 in Sections 2.5.3 of the Science Evaluation, and further detailed in Appendix IX of both documents. There were high residues in guttation droplets on treated crops; however, as demonstrated in higher tier field studies, bees were not often observed visiting droplets, and limited colony level effects were observed through exposure to guttation droplets. Therefore, there was limited risk associated to bees from guttation droplets. The overall risk conclusions, based on consideration of all information received during the consultation process, have not changed.

1.4.3 Evaluation of the effectiveness of dust reducing mitigation

One commenter supported the proposed mitigation strategies that had previously been implemented for corn and soybean (mandatory use of dust-reducing fluency agent and BMPs), and further supported the additional mitigation strategies to limit fugitive dust during the planting of other types of treated seed.

Four commenters did not support the dust-reduction measures as an effective mitigation strategy, and were concerned that they did not address concerns with neonicotinoids.

- Comments indicated that Health Canada has not evaluated the effectiveness of BMPs (Best Management Practices) and mandatory use of dust-reducing fluency agents (as implemented in 2014) to reduce exposure of pollinators to dust during planting of treated seed.

- There was also concern that the incident reports do not capture sub-lethal effects and/or effects from chronic exposure.

- Comments also state that even with a reduction in dust during planting, neonicotinoids are a source of exposure from off-site movement and translocation into plants, and large scale use in Canada.

- Comments also indicated that certain science conclusions from the open literature and EFSA review were not considered in the Health Canada assessment.

Comment (CropLife Canada): *CropLife is supportive of the proposed mitigation strategies to further limit the potential for bees to be exposed to fugitive dust released during the planting of treated seed. We are proud of the collaborative work that the extended agricultural value chain conducted to develop and implement a successful mitigation strategy in a very short period of time and we commend the PMRA for the integral role they played in this process.*

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association):

In the absence of evidence, it cannot be assumed that best management practices for dust control have reduced pollinator exposure to neonicotinoids from dust to acceptable levels. Furthermore, the assessment must consider risks to pollinators from widespread contamination of the broader environment (including pollen and nectar of non-target plants). In light of evidence that bees continue to be exposed to neonicotinoids at levels that show mortality and sublethal impacts, the PMRA should conclude that the use of clothianidin and thiamethoxam as seed treatments poses unacceptable risks to pollinators and cancel these uses. Dust mitigation measures are insufficient to prevent environment contamination and protect pollinators.

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Use of incident reports and assessment of dust reduction measures:

Studies have documented extensive dust drift to adjacent farms during treated seed sowing (Krupke et al., 2017). The proposed re-evaluation decisions, PRVD2017-23 and PRVD2017-24, appear to dismiss this risk noting the introduction in 2014 of new best management practices and requirements for fluency agents designed to reduce dust during the sowing of neonicotinoid treated seeds. However, the proposed re-evaluations offer no assessment of the effectiveness of these measures apart from fewer reports of bee mortality incidents.

Honeybee incident report trends are an insufficient basis for dismissing risks to pollinators from treated seeds. In particular, the honeybee incident reporting mechanism is poorly suited to provide information about native bee exposure or known sublethal effects such as hygienic behaviour, and the abilities of colonies to sustain a laying queen over time.

It is reasonable to assume that the new best management practices and requirements for dust-reducing fluency agents, where they have been applied, may have reduced (not eliminated) dust generated during the planting of treated seeds. But the risk assessments offer no information about compliance rates or evaluation of pollinator exposure to residual levels of dust, nor the extent to which the proposed label statements for treated seeds can be expected to improve compliance.

Furthermore, even if dust generated during planting is minimized, the use of neonicotinoid treated seeds will continue to be a source of exposure of neonicotinoids to pollinators through both the crop and contamination of the surrounding area.

Studies in the literature PMRA should consider:

A study conducted in a typical Canadian corn-growing setting after PMRA mandated dust suppression techniques and equipment nevertheless detected clothianadin in pollen at levels found, in laboratory experiments, to have significant effects on bee mortality, hygienic behaviour, and the abilities of colonies to sustain a laying queen overtime (Tsvetkov et al., 2017). The study concluded that, "honeybees in corn-growing regions of Canada are exposed to toxicologically significant levels of NNIs [neonicotinoids] for the majority of the active bee season despite the mandated use of dust-reducing seed lubricants during planting." This study also found honeybees near fields sown with neonic-treated corn seeds were exposed via pollen from non-target plants. These findings suggest the best management practices designed to reduce dust (label statements specifying best management practices and mandatory use of dust-reducing fluency agents in certain types of planters) have not been as effective as PMRA assumes in the current assessments and/or that non-target plants are contaminated through other routes that the PMRA has also not considered in the assessment. The proposed re-evaluation decision does not reference this study, except for its inclusion in an appendix where some uncertainties are noted. None of the uncertainties are so fatal as to indicate the findings of the study are flawed. The PMRA provides no explanations or reasons for ignoring this study that found strong evidence of harm from clothianidin treated seeds, even with use of the new mandated planting procedures.

Other studies confirm the relevance of pollinator exposure via non-target plants. In a multicounty experiment on rapeseed in Europe, Woodcock and colleagues found that neonicotinoid exposure from several non-target sources reduces overwintering success and colony reproduction in both honeybees and wild bees (Woodcock et al., 2017). Another recent study found that clothianidin treated seed pose a substantial risk to wild bees and suggested that the contribution of pesticides to the global decline of wild bees is underestimated (Rundolf et al., 2015) although this study was dismissed by the PMRA because the application rates were higher than permitted in Canada.

Neonicotinoid treated seeds are a major source of environmental contamination, as seed treatments represent the most widespread use of neonics in the US and likely in Canada and worldwide. In addition to the thirteen thiamethoxam and ten clothianidin registered seed treatments listed in Appendix 1 of each respective pollinator risk evaluation consultation document, seeds treated in other countries may be imported and planted in Canada under the Seeds Act. As of 2013, virtually all field corn planted in Canada

was treated with either thiamethoxam or clothianidin and greater than half the soybean seeds planted in Canada were treated with thiamethoxam. This translates into nearly 2.5 million hectares planted with thiamethoxam and clothianidin-treated corn and soybean seed alone; neonics are commonly used as seed treatments on a number of other cereal crops as well. Sources of exposure beyond treated fields, as a result of contamination of the broader environment, must be taken into account in the risk assessments.

Comment (Ontario Beekeepers Association)

PMRA continues to blame crop dust at planting and reduced number of reported incidents as evidence that risks to bees from neonicotinoids is acceptable:

(S)ubsequent investigation and analysis of pesticide residues suggested that exposure to neonicotinoids in dust generated during the planting of treated corn or soybean seed with vacuum planters contributed to the mortalities observed. And that a dust-reducing lubricant has solved the problem and that the number of incidents reported between 2014 and 2017 during the planting period were between 70 and 92% lower, compared to 2013.

These conclusions are faulty and are refuted in several recently published studies. Containing dust at planting may reduce some acute exposures but does not solve the problem of chronic exposure as bees are exposed to these highly toxic pesticides from a variety of sources. After reviewing 1500 studies, EFSA concluded that exposure is not confined to crop dust:

Bees can be exposed to neonicotinoids in multiple ways, depending on the use of the pesticide. The assessments indicated that in many cases bees foraging on the treated crop in the field as well as in its vicinity are likely to be exposed to harmful levels of the neonicotinoid pesticides. This is because pollen and nectar of the treated crop contain pesticide residues, and plants in the vicinity can also be contaminated by dust drifting away from the field.

https://www.efsa.europa.eu/en/press/news/180228

Comment (Suzuki form letter – citizen): *New methods to control dust while planting treated seeds do not reduce the total volume of neonicotinoids entering the environment. While acute risks to honey bees may be lower, chronic risks to pollinators because of widespread environmental contamination remain a concern for pollinator health. Reducing acute risks without addressing overall environmental loading is a flawed and short-sighted strategy.*

Comment (City of Montréal)

The mitigation measures put in place (such as the dust deflector or the addition of a talc to the seed drill to limit the spread of seed treatment dust) have, according to the PMRA, been successful. The number of reported incidents of bee mortality is decreasing. This number is very likely underestimated and yet the PMRA is satisfied with this parameter alone to evaluate the effectiveness of its mitigation measure. This argument is weak from a scientific point of view. It is difficult to believe that it is on the basis of this single parameter that the agency has judged this measure effective. A warning has been added to the labels of the affected products, but there is a lack of reliable information as to whether this is effective.

Health Canada Response

Health Canada agrees that there are many exposure routes of neonicotinoids that must be considered in the risk assessment. As well, Health Canada agrees that a reduction in incident reports cannot be the only indication of acceptable risk, and incident reports are only one consideration among many other lines of evidence that must be taken into account. Health Canada considered multiple routes of exposure and many lines of evidence in the risk assessments presented in PRVD2017-23 and PRVD2017-24.

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The pollinator risk assessment for clothianidin (PRVD2017-23) and thiamethoxam (PRVD2017-24) considered multiple exposure pathways:

- Exposures were considered according to application types: foliar, soil applications, seed treatments.
- Foliar, Soil, and Seed treatments: Dietary exposure through pollen/nectar in plants (including crop plants; off-field non-target plants; rotational crops). Note that residues in soil from all application types may also move to off-field areas via water / run-off from the field, and then be translocated to pollen and nectar of off-field plants. Foliar applications may also result in exposure to off-field plants through spray drift.
- Foliar: Contact exposure through foliar spray and spray drift
- Seed treatments: Contact and dietary exposure through dust generated during planting of treated seed. Note that dust could result in direct contact exposure, dietary exposure when dust is directly deposited on flowering plants and pollen and nectar is contaminated; and exposure through pollen and nectar when dust is deposited on soil, taken up by plants and translocated to pollen and nectar of crop plants, off-field non-target plants, or rotational crops. This last exposure route is also considered under the dietary exposure route discussed in 2.
- Foliar, Soil, and Seed treatments: Dietary exposure through water sources that might be used by bees (guttation droplets and relevant surface waters, including puddles).

Based on the results of the risk assessment, Health Canada proposed mitigation measures to reduce pollinator exposure, including removal of uses, changes to the use pattern, and label improvements for some uses. In reaching the risk conclusion Health Canada considered many lines of evidence including the results of the Tier I and Tier I refined risk assessment (based on laboratory data for adults and larvae from acute and chronic exposure, and on residues in pollen and nectar from field trials examining exposure), Tier II risk assessment (based on colony feeding studies with whole colonies of both *Apis* and non-*Apis* bees, as well as residues in pollen and nectar 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).

In addition to all the Tier I, Tier II and Tier III information, Health Canada did also consider incident reports as a line of evidence in the risk assessments for pollinators. Incident reports can be an important post-registration indicator of potential concerns with use of a pesticide. Incident reports were the primary indicator that there was a potential risk to bees from dust generated during planting of neonicotinoid treated corn and soybean seed. Following the 2012 and 2013 incidents reported in Canada, Health Canada concluded that neonicotinoids present in fugitive dust at the time of planting corn and soybean seed contributed to the observed mortality. As a result, at the start of the 2014 growing season, Health Canada required the use of dust-reducing fluency agents and also provided guidance on Best Management Practices (BMPs) to reduce exposure of pollinators from dust produced during the planting of treated corn and soybean seeds, with certain BMPs being mandatory. A strong stewardship campaign involving multiple stakeholders was initiated along with these requirements in 2014. Data were collected in 2014

that demonstrated a very high percentage of growers were aware of and using both the dust-reducing fluency agent and the BMPs, particularly in Ontario, which has the largest number of corn and soy related incident reports. Starting in 2014 and continuing in subsequent years, there has been a large reduction in incidents reported during planting of corn and soybean seed. Please also see Incident Report Update in the Science Evaluation Update (Section 1.1.7 for thiamethoxam and Section 1.1.3 for clothianidin) for further discussion of incident reports.

For the purposes of re-evaluations in PRVD2017-23 and PRVD2017-24, the analysis of risk from exposure to dust generated during planting of seed (exposure route 4 above) was based on all information available, and did not rely only on a reduction of incidents related to planting of corn and soybean. The assessment also included consideration of higher tier studies examining exposure from treated seed, including exposures both during planting as well as later in the season when off-field plants and the treated crop are blooming and exposure can occur through movement into pollen and nectar. The higher tier studies considered included colony feeding study effects endpoints compared to pollen and nectar residue information from crops grown from treated seeds. Higher tier studies also included field studies; a number of the field studies considered in relation to seed treatments are discussed further below.

Health Canada discussion of the references related to seed treatments cited by the commenter:

As described above, the pollinator risk assessment considered multiple exposure routes. For evaluating the exposure route of treated seed and dust generated during planting of treated seed (see exposure route 1 and 4 above), Health Canada considered not only incident reports, but also the Tier 1 refined, Tier II, and Tier III assessments. The higher tier information considered included residues in pollen and nectar from seed treatments compared to colony feeding study effect levels, tunnel studies, and field studies examining seed treatments. Field studies examined multiple exposure routes, including: exposure to dust generated during planting (where dust has landed directly on bees or on pollen/nectar of other flowering plants where bees are foraging); translocation of residues to pollen and nectar of the crop grown from treated seed; translocation of residues to pollen and nectar of non-crop plants resulting from residue movement in soils (via dust or treated seed).

A number of specific studies were mentioned by the commenter. As well, some new studies relevant to the seed treatment assessment were submitted during the PRVD comment period. These studies are further discussed below.

<u>The following two studies are new studies that were not considered in the PRVD2017-23 and PRVD2017-24.</u>

These two new studies are consistent with data already considered in the Health Canada risk assessment and do not change the conclusions presented in PRVD2017-23 and PRVD2017-24.

Krupke et al., 2017: This study was published after Health Canada reviews were completed. The study presents information on the estimated risk of contact exposure to neonicotinoid residues from dust drift during maize sowing, using honey bee foragers as a model. Exposure estimates were based on residue data collected in 2012 and 2013, which overlaps with some of the data already considered by Health Canada from Krupke et al., 2012. Krupke et al., 2017

indicate that "*Mortality survey showed that colonies located in a corn-dominated area had daily mortality counts 3.51 times those of colonies from corn crop-free sites. Chemical analyses revealed that honey bees were exposed to various agricultural pesticides during the corn planting season, but were primarily subjected to neonicotinoid compounds (54% of analysed samples contained clothianidin, and 31% contained both clothianidin and thiamethoxam). Performance development simulations performed on hive populations' show that increased mortality during the corn planting season sets back colony development and bears contributions to collapse risk but, most of all, reduces the effectiveness and value of colonies for pollination services.*" Looking more in depth at the study, the author states that the neonicotinoid clothianidin was the only compound whose acute RQ value exceeded the acceptable limit and is therefore an identified source of concern. The study also considers a low percent acute mortality in a model in order to estimate potential populations; however, the model results may not necessarily reflect real effects in the field. This study considers acute mortality and not long-term colony effects. Monitoring colonies over winter for effects to the hive would have provided long term colony effects.

Overall, the results of this study support the current Health Canada Tier I risk conclusions, which indicate that there is a potential acute risk to adult bees following contact exposure to residues in dust. In addition, following the 2012 and 2013 incidents reported in Canada, Health Canada concluded that neonicotinoids present in fugitive dust at the time of planting corn and soybean seed contributed to the observed mortality. As a result, at the start of the 2014 growing season, Health Canada required the use of dust-reducing fluency agents and also provided guidance on Best Management Practices (BMPs) to reduce exposure of pollinators from dust produced during the planting of treated corn and soybean seeds, with certain BMPs being mandatory. Thus, the Krupke et al., 2017 study supports the acute risk identified by Health Canada.

Health Canada also considered higher tier long-term field effects data and residue (exposure) data in the risk assessment. This information considered exposure to off-field residues from translocation/dust into off-field plants, as well as on-field exposure to residues in pollen and nectar in the treated crops. Overall these studies indicated a lack of colony level effects.

PMRA 2842658 (new study submitted during comment periods): This study investigated the formation and movement of seed treatment dust generated during planting of Cruiser 5FS treated corn seed using a low pressure pneumatic planter. Petri dishes and adhesive-coated cards were placed at 3, 5, 10, 20 and 30 metre distance from planting (1 hectare sized cropped area) to collect dust. Soil samples were also collected. The study compared dust from the following planting scenarios: no deflector and standard lubricant (e.g, talc or graphite), with low and high wind speed (either 3.2-17.7 km/h or 24.1-40.2 km/h); no deflector and dust-reducing fluency agent as the lubricant, with low and high wind speed; with deflector and dust-reducing fluency agent as the lubricant, with low or high wind speed. Overall, the lowest average residues of thiamethoxam and clothianidin residues in dust (collected from petri-dishes and cards) were found in trials, conducted using both a deflector and dust-reducing fluency agent as the lubricant at wind speeds of 2-11 mph (the lower wind speeds). In this scenario, maximum residues reached 0.123 µg/dish. The highest average residues of thiamethoxam and clothianidin at the furthest distance from planting were found using no deflector and standard lubricant at wind speeds of 15-25 mph (high wind speeds). In this scenario, maximum residues reached 1.856 µg/dish. Residues of thiamethoxam were generally lower for the Petri-dishes placed further out from the

zero line (30 m), whereas, location of the Petri-dishes in relation to the zero line did not appear to have much of an effect on the clothianidin residues. Overall, the study concludes that dust is most reduced when seeds are planted with equipment using a deflector and dust-reducing fluency agent lubricant.

The following studies are those that are relevant to seed treatment that were already considered by Health Canada in the PRVDs.

The below studies referenced by the commenter were already considered by Health Canada in the pollinator risk assessment for clothianidin and/or thiamethoxam (PRVD2017-23 and PRVD2017-24). How Health Canada used and considered these studies in the risk assessment is discussed in the summaries below. There were also many more higher tier studies relevant to seed treatments that were also considered in the PRVDs. Below is a response for each individual study referenced by the commenters regarding seed treatments. As noted in Health Canada's pollinator assessments and during the technical briefing, all studies are considered in a weight of evidence approach, along with strengths and limitations in the studies, in relation to the risk assessment.

Tsvetkov et al., 2017: This study was considered in Health Canada pollinator assessments. As summarized in Appendix V of PRVD2017-23 and PRVD2017-24, there were two components to the study, as well as a third hive monitoring component that was used to determine exposure levels in the field.

The first part of the study design was to examine the laboratory effects of dosing bees with various chemicals. The LD_{50} estimated for clothianidin and thiamethoxam was within the range found in the literature (clothianidin 1.24-6.76 ng/bee and thiamethoxam 1.99-9.0 ng/bee). The endpoints considered in the Health Canada Tier I and Tier I refined assessments were more conservative than the endpoints in this study.

The second part of the study involved feeding colonies an artificial pollen diet containing declining concentrations of clothianidin (4.9 declining to 2.0 ppb) over a 12 week period. The colony effect parameters measured in the study included queen mortality, hygienic behaviour, flight duration and number of flights, worker age at last flight. The study demonstrated a decline in hygienic behavior (removal of dead capped brood) and increased queenlessness over time relative to controls. As well, workers that were exposed to clothianidin as larva had a 23% reduction in age to last foraging flight relative to controls and exhibited a different flight pattern (time, duration) relative to controls. The results suggest that exposure to clothianidin in pollen at field exposure levels adversely effects worker behavior and colony health.

There were a number of uncertainties outlined in the second part of the study, including that treatment and control hives were in the same apiary and residue analysis of in-hive matrices were not conducted to determine whether control hives were exposed to clothianidin. The study authors assume that the cessation of foraging flights corresponds with forager mortality; however bee mortality was not directly observed. Colony strength measurements such as number of adults and brood and colony overwintering survival were not investigated in this study, and therefore it is not possible to establish whether the adverse effects on worker behaviour and colony health observed in this study would have had long-term impacts on colony survival.

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The endpoints in the colony effects study were considered in the Tier II risk assessment for clothianidin (colony feeding study endpoints compared to residues in the field) as found in PRVD2017-23. While this study was considered in the thiamethoxam assessment, it was not selected as a colony feeding study endpoint for use in the Tier II risk assessment because the study was conducted by dosing only with clothianidin, not thiamethoxam. [For use of this study in the clothianidin PRVD2017-23, please see Section "2.3.3 Tier II refined assessment" and "Table 3 Summary of Endpoints Selected from Colony Feeding Studies for the Tier II Refined Clothianidin Risk Assessment"; as well, see Appendix V of both PRVD2017-23 and PRVD2017-24 for more detailed study summaries].

Woodcock et al., 2017: This study was referenced and was considered in the Health Canada pollinator assessment (please refer to PRVD2017-23 and PRVD2017-24 Appendix V for study review details; also see page 29 of PRVD2017-24). This study examined residues and effects to honey bees, bumble bees and *Osmia bicornis* which were exposed to flowering winter sown oilseed rape treated with either clothianidin, thiamethoxam or a control, in three different locations (Hungary, United Kingdom and Germany). The study found **both negative and positive effects** on honey bee colonies during crop flowering following exposure to neonicotinoids. Residues collected by bees (honey bees, bumble bees and *O. bicornis*) for some control sites had residues of either thiamethoxam and/or clothianidin and/or imidacloprid. In addition, treated sites contained other actives, not applied at those sites. Analysis was done to assess relationships between residues and effects for honey bees, bumble bees, and *O. bicornis*.

While this study was considered in the risk assessment, no conclusions were made regarding effects levels of concern since both negative and positive effects on colonies were demonstrated in relation to exposure to neonicotinoid residues.

Rundlöf et al., 2015: Rundlöf et al., 2015, was considered in the Health Canada pollinator assessment for clothianidin, as this field study looked at exposures to clothianidin but not thiamethoxam treated seed (please refer to PRVD2017-23 Appendix V; see also page 25 of PRVD2017-23). This field study examined effects to bees from planted oilseed rape seed coated with clothianidin (400 g/L) and B-cyfluthrin (180 g/L), and a fungicide (thiram, 7.5 to 7.7 kg/ha)). This study concluded that effects were not seen in honey bee colony strength during the exposure period; however, in bumble bee colonies there were significant effects with treatment including lower weight gain and fewer cocoons of all castes; and in the *Osmia bicornis* solitary bee nests, significantly lower numbers of nesting tubes were observed. Some of the uncertainties in the study included that the control fields contained just the fungicide while the treated fields contained both a neonicotinoid and a pyrethroid along with a fungicide. Exposure through pollen to *O. bicornis* cannot be confirmed since none were found nesting in the treated fields (therefore there was no pollen to collect from provisions). Overall, the study suggested that non-*Apis* bees may be more sensitive than *Apis* bees; however, endpoint measurements were not the same between the species. Synergistic effects from neonicotinoids and fungicides were also considered in the Tier I assessment quantitatively.

Consideration of the Rundlöf et al, 2015 study in the clothianidin risk assessment was discussed on page 25 of PRVD2017-23, under the non-Apis Tier III field studies summary:

> *A total of nine Tier III field and hive monitoring studies were reviewed and considered in the risk assessment. The studies examined individual and colony level effects following exposure of non-Apis bees*

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to bee attractive crops grown from clothianidin treated seed including oilseed rape and corn. No or negligible short- or long-term colony level effects were observed for non-Apis bees in available Tier III field studies conducted at Canadian-relevant rates, which is similar to the findings for Apis bees. Significant effects were seen in one seed treatment field study conducted on spring oilseed rape (Rundlöf et al., 2015), including significantly lower weight gain, fewer queens, male bees (drones) and worker cocoons in bumble bee colonies and a complete halt to red mason bee nesting; however, in addition to other limitations, this study was conducted at a rate 2.5 times higher than the rate registered in Canada. Therefore, this study is not considered relevant to the Canadian use pattern for seed treatment uses. In another seed treatment field study conducted on corn (Cutler and Dupree, 2014), clothianidin seed treatment had no effect on any bumble bee hive endpoints measured, except the number of workers where significantly fewer workers were removed from hives placed next to conventional fields compared to organic fields. In terms of the most important parameter for bumble bees, queen production (both number and weight), was unaffected by clothianidin treated seed and was actually higher (by >25%) compared to organic. Therefore, it was concluded that exposure during pollen shed from corn grown with treated seed poses low risk to bumble bee colonies.

1.5 Risk assessment approach

1.5.1 Non-standard aspects of the pollinator risk assessment

A comment was received requesting guidance from Health Canada on how the exposure to surface water, bee bread and assessment to non-*Apis* bees are considered in the risk assessment given that these are deviations from the Pollinator Risk Assessment Guidance.

Comment (CropLife Canada)

We request that assessment framework include a robust and transparent mechanism to integrate new information which will, in turn, ensure that the best science is used to inform regulatory decision making. We note that the pollinator risk assessments described in PRVD2017-23 and PRVD2017-24 include exposure scenarios not directly addressed in the Pollinator Risk Assessment Guidance (e.g., exposure to surface water, exposure via bee bread, non-Apis bees). We commend PMRA for proactively assessing, for example, the impact of surface water to pollinators; however, we note that these are deviations and respectfully request guidance from the PMRA if they foresee these officially being integrated into the pollinator risk assessment paradigm. We also request that the PMRA harmonize their approach with the USEPA, where possible.

Health Canada Response

The *North American Guidance for Assessing Pesticide Risks to Bees* was developed jointly by Health Canada, the USEPA and the California Department of Pesticide Regulation, and thus is a harmonized risk assessment framework for the United States and Canada. As indicated by the commenter, at this time the Guidance does not include a standard method for assessing the potential risk of pesticides to non-*Apis* bees or for assessing the potential risk to bees from exposure through water or bee bread. As indicated in the guidance, the water exposure route is not considered to be a primary exposure route for bees. However, as some Canadian beekeepers and researchers have raised potential concerns around exposure to neonicotinoids through water sources used by honey bees, the exposure route was explored in PRVD2017-23 and PRVD2017-24. While the guidance also does not discuss “bee bread”, this was explored in PRVD2017-23 and PRVD2017-24 as a way to consider exposure through the contribution of both pollen and nectar mixed into “bee bread”, and was used for comparison with effects studies from honey bee colony feeding studies dosing with pollen patties (mixtures of pollen and nectar). This was considered an exploratory method, and was considered along with exposure estimates based on

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pollen residues alone. Risk conclusions were similar whether using pollen or "bee bread" as the exposure estimate. Please see Section 1.2.8 Exposure- Exposure through bee bread for further discussion regarding bee bread.

The assessments in PRVD2017-23 and PRVD2017-24 were specific to the neonicotinoids, and Health Canada does not intend to routinely integrate assessments on water and bee bread exposure scenarios at this time. For non-*Apis* bees, the pollinator risk assessment framework relies primarily on the use of honey bee data as a surrogate for non-*Apis* bees. However, when non-*Apis* bee data are available Health Canada considers this information together with *Apis* bee data in the overall risk description. As the science of non-*Apis* effects testing improves, and further information is developed regarding exposure estimations for non-*Apis* bees, Health Canada expects that improvements in conducting non-*Apis* risk assessments will be developed.

1.5.2 Risk Assessment outcome and additional literature

A comment was submitted which disagreed with the Health Canada proposed regulatory decision, and which cited a number of references.

Comment (citizen)

Your decision does not uphold what you are supposed to stand for, but rather an attempt to mask the influence the pesticide industry has in Canada. Your decision is in favor of pesticide manufacturers, you are supposed to be the regulatory body for our environment. What is happening in the environment from the prophylactic use of these systemic insecticides needed action years ago. People really need to be worried. Your decision goes against overwhelming scientific evidence showing acute and chronic effects on bees. Hundreds of independent scientific studies have linked neonicotinoids to pollinator declines in Europe, Canada and North America. It is no longer an area of debate.

We have great challenges as our ecosystems continue to decline in a tailspin that is disturbing to any biologist. You cannot keep ignoring the science. People should not have to fight our own government to save the environment. Rachel Carson author of Silent Spring predicted the vanishing of the bees back in 1962. E.O. Wilson said if all mankind were to disappear, the world would regenerate back to the rich state of equilibrium that existed ten thousand years ago. If insects were to vanish, the environment would collapse into chaos. This is happening right before our eyes and there will be no rationalization to the destruction of our planet.

References

Health Canada needs to do something to correct these mistakes. We need you to make the decision to ban thiamethoxam and the other neonicotinoid insecticides.

Alford, A., Krupke C. March 2017. Translocation of the neonicotinoid seed treatment clothianidin in maize. PLOS ONE. DOI:10.1371

Goulson, D. 2013. An overview of the environmental risks posed by neonicotinoid insecticides. Journal of Applied Ecology. DOI:10.111

Hladik, M. et al., 2017. Neonicotinoid insecticide removal by prairie strips in row-cropped watersheds with historical seed coating use. Agriculture, Ecosystems and Environment. DOI:10.1016

Hladik, M. et al., 2018. Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA. Environmental Pollution. DOI:10.1016

Krupke C. et al., 2017. Planting of neonicotinoids-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. Journal of Applied Ecology. DOI:10.1111

Long, E., Krupke C., June 2015. Non-cultivated plants present a season-long route of pesticide exposure for honey bees. Nature Communications. DOI:10.1038

McCurdy J. et al., March 2017. Dew from warm-season turfgrasses as a possible route for pollinator exposure to lawn-applied imidacloprid. Crop Forage Turfgrass Manage. DOI:10.2134

OBA. February 2018. Good News for the Environment and Canada's Bees and Beekeepers – Martineau v Bayer Class Action Lawsuit Against Pesticide Manufacturers Now Authorized in Québec. Ontario Beekeepers Association Website

Tsvetkov, N. et al., June 2017. Chronic exposure to neonicotinoids reduces honey bee health near corn crops. Science Magazine. DOI:10.1126

Health Canada Response

Health Canada's PMRA is responsible for the regulation of pest control products in Canada under the authority of the *Pest Control Products Act*. The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. The health or environmental risks of a product are considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration. To determine if risks are acceptable, pest control products undergo a thorough science-based risk assessment and meet strict health and environmental standards before being approved for registration. In addition, every 15 years pest control products undergo a re-evaluation to ensure that they continue to meet current scientific standards.

The risk assessment for bees is conducted according to the 2014 *Guidance for Assessing Pesticide Risks to Bees* which was developed jointly with the USEPA, Health Canada and California's Department of Pesticide Regulation. The risk assessment framework for bees uses a tiered approach and considers multiple exposure routes (primarily through contact with the pesticide and from dietary exposure through pollen and nectar). The risk assessment moves from a conservative laboratory based risk assessment at Tier I using individual bees and modeled exposure estimates to a higher tier risk assessment using whole colonies and more realistic field based exposure scenarios. When a potential risk to bees is identified at lower tiers, we move to higher tier assessments to refine risks or we determine whether the risk can be reduced to acceptable levels using risk management options. Overall, the risk assessment uses a weight of evidence approach and considers multiple lines of evidence (including studies from the registrant and open literature if available) to characterize the risks to bees.

The clothianidin and thiamethoxam pollinator risk assessments outlined in PRVD2017-23 and PRVD2017-24, respectively, followed the 2014 risk assessment framework described above to characterize the potential risk to bees. Health Canada considered a large body of scientific information determined to be relevant to the pollinator risk assessment for clothianidin and thiamethoxam, including studies from the open public literature and registrants. Health Canada did a thorough review of each study and considered its usefulness in the risk assessment based on its strengths and limitations and relevancy to the Canadian use pattern (for instance, whether the

application rate and timing in the studies were applicable to the product as used in Canada). Some of the open literature/public studies played an integral role in assessing exposure to *Apis* and non-*Apis* bees and exposure from pollen.

Health Canada considers the scientific integrity of studies in the risk assessments, and their ability to answer science based questions, regardless of whether the source is from the registrant, public literature, or other sources (for example, unpublished data from researchers or governments). The risk assessments identified risk to pollinators through a number of application scenarios, and as such, a large number of uses that posed risk to bees/pollinators are proposed for removal. The uses that Health Canada continued to support in PRVD2017-23 and PRVD2017-24, were those that did not pose risks to bees.

The commenter provided a number of references to support their point. Some of the referenced studies were not considered in PRVD2017-23 and PRVD2017-24, and are thus summarized below. A few of the studies were already considered in the pollinator assessments, but are re-summarized below.

The following are summaries and responses for each study cited in the comment which was not previously considered in the PRVD2017-23 and/or PRVD2017-24 pollinator assessments. The new references do not change the overall risk conclusion.

Alford, A., Krupke C. March 2017. Translocation of the neonicotinoid seed treatment clothianidin in maize. PLOS ONE. DOI:10.1371

This study concluded that 'the proportion of the neonicotinoid seed treatment clothianidin translocated into plant tissues throughout the growing season is low overall and this observation may provide a mechanism to explain reports of inconsistent efficacy of this pest management approach and increasing detections of environmental neonicotinoids.'

It is noted, that low residues in pollen and/or nectar are consistent with Health Canada's knowledge of residue translocation in plants (from seed treatment). These low residues result in low pollinator exposure to blooming crops following seed treatments.

Goulson, D. 2013. An overview of the environmental risks posed by neonicotinoid insecticides. Journal of Applied Ecology. DOI:10.111

This paper looked at available literature for neonicotinoids up to 2013. The paper concludes that neonicotinoids are persistent and toxic (considering mostly laboratory endpoints), that there may be sub-lethal effects and there are still (at the time of publication) a number of data gaps.

It is noted that Health Canada considered the studies reported in the paper, and also considered data that was generated between 2013 and 2017.

Hladik, M. et al., 2017. Neonicotinoid insecticide removal by prairie strips in row-cropped watersheds with historical seed coating use. Agriculture, Ecosystems and Environment. DOI:10.1016

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This study assessed neonicotinoid residues in groundwater, surface runoff water, soil, and native plants adjacent to corn and soybean crop fields with a history of being planted with neonicotinoid-treated seeds from 2008 to 2013. Residues in plants (flowers) were either non-detectable or not sampled. Three of the six neonicotinoids analyzed were detected in at least one environmental matrix (soil, surface water or groundwater), and residues were variable. There were no detections (limit of detection: 1 ng/g) of neonicotinoids in the foliage or roots of plants comprising prairie strips, indicating a low likelihood of exposure to pollinators and other insects visiting these plants following the cessation of seed coating use. Offsite transport of neonicotinoids to aquatic systems through the groundwater and surface water were furthermore reduced with prairie strips. This study demonstrates the potential for prairie strips comprising 10% of an agricultural catchment to mitigate the non-target impacts of neonicotinoids.

Health Canada conducted a risk assessment for bees from exposure to water sources relevant to bees as presented in PRVD2017-23 and PRVD2017-24 (in both documents, see Section 2.5.3 Water assessment, and Appendix IX Risk assessment for bees via water exposure route). Regarding measurements of neonicotinoids in various matrices (plants, soils, etc), overall, with respect to the pollinator assessment, this study suggests low exposure to pollinators off-field.

Health Canada also considered this study in the special review for aquatic invertebrates, PSRD2018-01 (for clothianidin) and PSRD2018-02 (for thiamethoxam). Since the monitoring was specific to the United States, it was not used in the aquatic risk assessment which focused specifically on Canadian data; the effectiveness of prairie strips (vegetative filter strips) as mitigation to protect aquatic organisms was considered in PSRD2018-01 and PSRD2018-02.

Hladik, M. et al., 2018. Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA. Environmental Pollution. DOI:10.1016

This study characterized neonicotinoid residues (October 2015-September 2016) from 10 major tributaries flowing into the Great Lakes from the United States. At least one neonicotinoid was detected in 74% of the monthly samples with up to three neonicotinoids detected in an individual sample (10% of all samples). The most frequently detected neonicotinoid was imidacloprid (53%), followed by clothianidin (44%), thiamethoxam (22%), acetamiprid (2%), and dinotefuran (1%). Thiacloprid was not detected in any samples. This study primarily pertains to residues in water.

As noted already, Health Canada conducted a risk assessment for bees from exposure to water sources relevant to bees as presented in PRVD2017-23 and PRVD2017-24 (in both documents, see Section 2.5.3 Water assessment, and Appendix IX Risk assessment for bees via water exposure route). It is noted that the data in this study is from the United States and the crops and use rates may not be the same as Canada. Owing to the date of publication, this study was not considered in the special review for aquatic invertebrates, PSRD2018-01 (for clothianidin) and PSRD2018-02 (for thiamethoxam). However, it may be considered prior to the final decision for the special reviews on risk to aquatic invertebrates, noting that this is United States data and may not be relevant, since the focus in the PSRDs is Canadian monitoring data.

Krupke C. et al., 2017. Planting of neonicotinoids-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. Journal of Applied Ecology. DOI:10.1111

This study was published after the Health Canada reviews were completed. The study presents information on the estimated risk of contact exposure to neonicotinoid residues from dust drift during maize sowing, using honey bee foragers as a model. Exposure estimates were based on residue data collected in 2012 and 2013, which overlaps with some of the data already considered by Health Canada from Krupke et al., 2012. Krupke et al., 2017 indicate that "*Mortality survey showed that colonies located in a corn-dominated area had daily mortality counts 3.51 times those of colonies from corn crop-free sites. Chemical analyses revealed that honey bees were exposed to various agricultural pesticides during the corn planting season, but were primarily subjected to neonicotinoid compounds (54% of analysed samples contained clothianidin, and 31% contained both clothianidin and thiamethoxam). Performance development simulations performed on hive populations' show that increased mortality during the corn planting season sets back colony development and bears contributions to collapse risk but, most of all, reduces the effectiveness and value of colonies for pollination services.*" Looking more in depth at the study, the author states that the neonicotinoid clothianidin was the only compound whose acute RQ value exceeded the acceptable limit and is therefore an identified source of concern. The study also considers a low percent acute mortality in a model in order to estimate potential populations; however, the model results may not necessarily reflect real effects in the field. This study considers acute mortality and not long-term colony effects. Monitoring colonies over winter for effects to the hive would have provided long-term colony effects.

Overall, the results of this study support the current Health Canada Tier I risk conclusions, which indicate that there is a potential acute risk to adult bees following contact exposure to residues in dust. In addition, following the 2012 and 2013 incidents reported in Canada, Health Canada concluded that neonicotinoids present in fugitive dust at the time of planting corn and soybean seed contributed to the observed mortality. As a result, at the start of the 2014 growing season, Health Canada required the use of dust-reducing fluency agents and also provided guidance on Best Management Practices (BMPs) to reduce exposure of pollinators from dust produced during the planting of treated corn and soybean seeds, with certain BMPs being mandatory. Thus, the Krupke et al., 2017 study supports the acute risk identified by Health Canada.

Health Canada also considered higher tier long-term field effects data and residue (exposure) data in the risk assessment. This information considered exposure to off-field residues from translocation/dust into off-field plants, as well as on-field exposure to residues in pollen and nectar in the treated crops. Overall these studies indicated a lack of colony level effects.

Long, E., Krupke C. June 2016. Non-cultivated plants present a season-long route of pesticide exposure for honey bees. Nature Communications. DOI:10.1038

This study was not considered in the pollinator risk assessment for clothianidin and thiamethoxam. In May 2011, honey bee colonies were placed near agricultural sites (fungicide + clothianidin seed treated or untreated maize) or non-agricultural sites near maize and soybean dominated agricultural landscapes in Indiana and pollen samples were collected from pollen traps over a 16 week period. Pollen from crop plants represented only a tiny fraction of the total diversity of pollen resources used by honey bees in these landscapes, with the principle sources of pollen originating from non-cultivated plants. Pollen collected by honey bee foragers was shown to be contaminated throughout the growing season with multiple agricultural pesticides with fungicides and herbicides being the most frequently detected pesticides. The most

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frequently detected neonicotinoid was thiamethoxam (33%) in untreated maize, followed by acetamiprid (28.1%) and clothianidin (21.88%) in treated maize. Neonicotinoids were infrequently detected in non-agricultural sites (<10%). The mean, median and range of thiamethoxam concentrations in bee collected pollen was 0.12, 0.0, 1.52-1.69 ppb in non-agricultural areas, 0.23, 0.0 and 0.18-1.82 ppb in untreated maize and 0.08, 0.0 and 0.07-0.95 ppb in treated maize. For clothianidin the mean, median and range of concentrations in pollen was 0.16, 0.0, 4.66-4.66 ppb in non-agricultural areas, 0.20, 0.0 and 0.70-1.79 ppb in untreated maize and 0.66, 0.0 and 0.64-9.37 ppb in treated maize.

While the majority of pollen collected by bees was from non-crop plants, as the residue analysis was not species specific, it is not possible to say whether pesticide residues were coming from crop or non-crop plant pollen. Overall, it is noted that the reported mean measured concentrations of thiamethoxam and clothianidin detected in bee collected pollen did not exceed the colony level effect endpoints selected for *Apis* and non-*Apis* bees.

McCurdy J. et al., March 2017. Dew from warm-season turfgrasses as a possible route for pollinator exposure to lawn-applied imidacloprid. Crop Forage Turfgrass Manage. DOI:10.2134

In addition to exposure through pollen and nectar, bees may be exposed to neonicotinoids through contaminated water sources such as surface water, puddles, dew droplet formation on leaves and guttation fluids following foliar, soil and seed treatment applications. At this time the *North American Guidance for Assessing Pesticide Risks to Bees* does not include a method for assessing the potential risk to bees from exposure through water, as it is not thought to be a primary exposure route. However, as some Canadian beekeepers and researchers raised potential concerns around exposure to neonicotinoids through water sources used by honey bees, the exposure route was nonetheless explored by Health Canada considering available monitoring data in surface water, effects and residue data in guttation fluid. As outlined in Appendix IX Risk assessment for bees via water exposure route in PRVD2017-23 and PRVD2017-24, negligible risk is expected for bees exposed to surface water or plant guttation liquid in areas that are treated with neonicotinoids by foliar, soil or seed treatment application. McCurdy et al., 2017 observed imidacloprid concentrations in dew water containing guttation fluid following foliar applications to turf grass at levels similar to those reported in creeping bentgrass guttation droplets but at lower levels than those typically found in agronomic crops grown from treated seed. Therefore the information provided does not change the risk conclusions for this exposure route.

OBA. February 2018. Good News for the Environment and Canada's Bees and Beekeepers – Martineau v Bayer Class Action Lawsuit Against Pesticide Manufacturers Now Authorized in Québec. Ontario Beekeepers Association Website

This reference was not considered relevant for the risk assessment because there are no endpoints or data presented. This reference is related to a campaign on behalf of Canadian beekeepers and beekeeping operations to bring litigation against Bayer CropScience regarding claims of harm to hives from pesticides.

The following study was previously considered in the pollinator assessments (PRVD2017-23 and PRVD2017-24):

Tsvetkov, N. et al., June 2017. Chronic exposure to neonicotinoids reduces honey bee health near corn crops. Science Magazine. DOI:10.1126

This study was considered in the Health Canada pollinator assessments. As summarized in Appendix V of PRVD2017-23 and PRVD2017-24, there were two components to the study, as well as a third hive monitoring component used to determine exposure levels in the field.

The first part of the study design was to examine the laboratory effects of dosing bees with various chemicals. The LD50 estimated for clothianidin and thiamethoxam was within the range found in the literature (clothianidin 1.24-6.76 ng/bee and thiamethoxam 1.99-9.0 ng/bee). The endpoints considered in the Health Canada Tier I and Tier I refined assessments were more conservative than the endpoints in this study.

The second part of the study involved feeding colonies an artificial pollen diet containing declining concentrations of clothianidin (4.9 declining to 2.0 ppb) over a 12 week period. The colony effect parameters measured in the study included queen mortality, hygienic behaviour, flight duration and number of flights, worker age at last flight. The study demonstrated a decline in hygienic behavior (removal of dead capped brood) and increased queenlessness over time relative to controls. As well, workers that were exposed to clothianidin as larva had a 23% reduction in age to last foraging flight relative to controls and exhibited a different flight pattern (time, duration) relative to controls. The results suggest that exposure to clothianidin in pollen at field exposure levels adversely affects worker behavior and colony health.

There were a number of uncertainties outlined in the second part of the study, including that treatment and control hives were in the same apiary and residue analysis of in-hive matrices were not conducted to determine whether control hives were exposed to clothianidin, The study authors assume that the cessation of foraging flights corresponds with forager mortality; however bee mortality was not directly observed. Colony strength measurements such as number of adults and brood and colony overwintering survival were not investigated in this study, and therefore it is not possible to establish whether the adverse effects on worker behaviour and colony health observed in this study would have had long-term impacts on colony survival.

The endpoints in the colony effects study were considered in the Tier II risk assessment for clothianidin (colony feeding study endpoints compared to residues in the field) as found in PRVD2017-23. While this study was considered in the thiamethoxam assessment, it was not selected as a colony feeding study endpoint for use in the Tier II risk assessment because the study was conducted by dosing only with clothianidin, not thiamethoxam. [For use of this study in the clothianidin PRVD2017-23, please see Section "2.3.3 Tier II refined assessment" and "Table 3 Summary of Endpoints Selected from Colony Feeding Studies for the Tier II Refined Clothianidin Risk Assessment"; as well, see Appendix V of both PRVD2017-23 and PRVD2017-24 for more detailed study summaries].

1.5.3 Public literature considered

A comment was received suggesting that Health Canada did not consider all available data for the risk assessment.

> ***Comment (David Suzuki Foundation/Équiterre/EnvironmentalDefence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)***
>
> *Both PRVD2017-23 and PRVD2017-24 rely upon mostly unpublished or non-peer reviewed data and studies submitted by registrants in support of these assessments. In the case of the risk assessment on clothianidin, 74% of 234 studies cited are unpublished and non-peer reviewed, while 61% of 218 studies cited for thiamethoxam are unpublished and non-peer reviewed. The total number of studies is less than 400, as many studies were considered in both assessments.*
>
> *We question whether the PMRA may have missed or overlooked a large number of relevant studies in the re-evaluation of thiamethoxam and clothianidin. Over 200 peer-reviewed papers can be retrieved from some of the largest scientific journal databases with search terms that pair "neonic" with "pollinator OR bee".*
>
> *Reliance on unpublished and non-peer reviewed data primarily from the registrants, without also fully considering the peer reviewed independent literature, is concerning because of the potential appearance of conflicts of interest, the limited transparency in the studies submitted by the registrants and the difficulty in obtaining access to, or having sufficient time to review content available in, the Reading Room.*
>
> *For the EU risk assessments of clothianidin, thiamethoxam and imidacloprid, EFSA identified 680 potentially relevant sources (from an initial list of 1599) and ultimately, after full-text screening, critically appraised and extracted data from 588 studies. It is not clear whether the PRVD2017-23 and PRVD2017-24 reference lists reflect all potentially relevant studies considered in the assessment, or the subset of those from which data was ultimately extracted. Either way, it appears the PMRA considered significantly fewer studies than did the EFSA – perhaps only half. Some of the missing studies will have been considered in the PMRA's forthcoming pollinator risk assessment for imidacloprid but this may not account for the entire difference.*

Health Canada Response

Health Canada considered a large number of studies referenced in the EFSA review which were considered relevant to the pollinator risk assessment. Health Canada included additional studies, not used in the EFSA assessment from the open literature and registrant, including a number of colony feeding studies. The initial open literature search (including neonicotinoids, bees, and loading) in 2014 resulted in approximately 1,356 potential articles of relevancy. Between 2014 and 2016 another open literature search was completed which resulted in an additional 484 potential articles of relevancy. Relevant articles were reviewed and used in the risk assessments. For review articles, the primary articles upon which the reviews relied were reviewed for the Health Canada risk assessment. Overall, Health Canada completed an extensive literature search and selected studies that were considered relevant to the pollinator risk assessment, considering the Canadian use pattern.

Health Canada does not consider the source of the data in its scientific reviews, but rather the scientific integrity of the study, and its ability to answer science based questions in the review. Each study has strengths and limitations and was considered in a weight of evidence approach in the risk assessment. Importantly, some of the open literature studies provided key endpoints considered in the risk conclusions, particularly for colony feeding study endpoints and endpoints for non-*Apis* bees. It is noted that some of the registrant studies are also published in peer reviewed journal articles.

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1.5.4 Mathematical modeling to consider colony-level effects

The comment questions why modeling was not considered in the risk assessment for determining colony-level effects over longer periods of time, including multiple years.

> ***Comment (University of British Columbia)***
>
> *My concern is that none of the pesticide consultation studies appear to include any mathematical modelling work on the effect of pollinator sublethal pesticide exposure. Mathematical modelling is a critical approach for understanding the colony-level effects of sublethal pesticide exposure over a longer period, say, multiple years. This sort of effect generally does not show up in traditional studies of pesticide content and bee behaviour in response to exposure. What the mathematics can do, is show how small changes in behaviour which seem insignificant (say, only 10% or 5% of the bees exhibiting some loss of foraging efficiency) can actually have disastrous effects at the level of the entire colony. Also, the effects of these pesticides have to be considered in combination with the other stressors that honey bees are dealing with, especially varroa and the increased incidence of disease. Under the combined effects of all of these stressors, a very small detrimental effect of pesticide exposure can be enough to cause the colony to collapse.*
>
> *1. Bull Math Biol. 2017 Jun;79(6):1218-1253. doi: 10.1007/s11538-017-0281-6*
>
> *2. Myerscough, Mary R.; Khoury, David S.; Ronzani, Sean; et al. Why Do Hives Die? Using Mathematics to Solve the Problem of Honey Bee Colony Collapse Edited by: Anderssen, B; Broadbridge, P; Fukumoto, Y; etal.Conference: Forum on Math-for-Industry - Role and Importance of Mathematics in Innovation Location: KyushuUniv, Ito Campus, Inst Math Ind, Fukuoka, JAPAN Date: OCT 26-30, 2015 ROLE AND IMPORTANCE OFMATHEMATICS*

Health Canada Response

Models represent a useful tool that can be used to integrate exposure and effects data with the complexities of the social structure and biology of a honey bee colony. The *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) Scientific Advisory Panel (SAP) supported the use of colony simulation models for assessing effects of pesticides on honey bees; however, currently there are no models available for regulatory use. A collaborative effort is currently underway between the USEPA and the United States Department of Agriculture (USDA) to develop a model for regulatory use building on an existing USDA model. Health Canada will further consider the use of models in the pollinator risk assessment as the science supporting such efforts evolves.

1.5.5 Relation of risk assessment to real world effects

The commenter made a number of specific comments on the risk assessment approach. Comments suggested that there was a lack of real world data indicating exposure and effects are occurring, considering in-hive residue levels from monitoring studies and incident data. Additionally, comments questioned the method used to consider clothianidin residues and clothianidin toxicity endpoints as part of the thiamethoxam risk assessment.

> ***Comment (Syngenta):*** *The PMRA's pollinator risk assessment is based not only on field-derived measures of exposure from crop-specific pollen/nectar residue studies but also on effects studies, including colony feeding studies, that may not be indicative of actual field exposures. Measured residues in pollen/nectar represent residue levels that are worst-case for individual bee exposure rather than colony-level exposure.*

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While PMRA does characterize crop attractiveness in the risk assessment in determining exposure (high versus moderate to low exposure), the risk assessment process does not quantitatively account for attractiveness of the crop to honey bees in estimating colony level exposure. Therefore, risk conclusions from this assessment represent "potential risks" to bees as noted in the Proposed Re-evaluation Decision and not actual adverse impacts that are occurring from use of thiamethoxam under actual field conditions.

Data available in the literature that include ***in-hive residue*** *levels demonstrate a lack of widespread exposure to thiamethoxam at concentrations expected to result in colony level effects. In addition, available field and/or* ***incident data*** *show little evidence of colony-level effects from the foliar and soil use of neonicotinoids including thiamethoxam. Potential risk to bees from foliar applications can be mitigated in many crops via timing of applications. For soil applications, potential risk to bees can be managed by adjusting application timing, planting density and possibly by varying application rate based on soil type. Specific label restrictions regarding timing of foliar and soil applications necessary to manage potential risk to bees will likely vary among crops and chemicals.*

PMRA converted all thiamethoxam bee toxicity endpoints and residue concentrations in pollen and nectar to ***clothianidin equivalents*** *based on the assumption that the toxicity of clothianidin and thiamethoxam are similar for bees. However, the standard toxicity studies with both terrestrial (i.e., bees) and aquatic invertebrates indicate a clear difference in chronic toxicity between clothianidin and thiamethoxam. In addition, recent laboratory chronic toxicity data show significant differences in adult bee sensitivity to thiamethoxam versus clothianidin. Considering the chronic toxicity of clothianidin to bees is not similar to thiamethoxam, the use of clothianidin equivalents is not appropriate.*

Health Canada Response

In-hive residues: Bee-collected pollen and nectar as well as residues in pollen and/or nectar from plants were considered as exposure values in the risk assessment. Pollen and nectar residues collected from plants are preferred in most cases, since it represents potential exposure for all bee species (not just honey bee collected sources of food). For both bee-collected and in-hive residues, honey bees were the primary source of information, though bumble bee collected pollen was available for some crops. In-hive residues were typically not considered for exposure values, unless no other information was available. Residues found in-hive tend to be highly variable within the hive, and are affected by multiple factors such as timing relative to exposure, sampling matrix, different locations in the hive. For example, considering colony feeding studies, where bees were provided sucrose solution with known neonicotinoid concentrations, the distribution of residues throughout the hive matrices varied depending on sampling location, did not always represent the dose, and the residue levels were typically much lower than the dosing solution. Therefore, it was not feasible to translate the sucrose solution concentration to an in-hive residue exposure level. However, it is believed to be more relevant to compare the sources of residues (in other words, compare source dosing solution or pollen patty in effects studies with source plant pollen and nectar residue exposure levels). When comparing the source dosing residue levels in the effects studies (from the source dosing sucrose solution or pollen patty) with the source residues in pollen and nectar for exposure, in both cases the variability in incorporation of residues into the hive and resulting in-hive concentrations does not have to be considered.

When considering monitoring information, for most in-hive residue sampling from hive-monitoring studies, there was limited information available regarding use of neonicotinoids in the vicinity of the hives. Therefore no relationship could be determined between exposure to neonicotinoids and residues in the hive. Because of this, the in-hive residues from monitoring studies were not relied upon for the risk assessment.

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Incident data: Health Canada recognizes that there were a limited number of incident reports for soil and foliar applications. However, some of the available field data did show some effects from both soil and foliar uses, as considered in PRVD2017-24. Incident reports for pesticides typically are made for acute effects (in other words, bee mortality) rather than longer-term sub-lethal effects that may be occurring over time.

Semi-field and field studies: The risk assessment considered effects from semi-field tunnel studies, field studies and incident reports in addition to the colony feeding study endpoints for *Apis* and non-*Apis* bees. The endpoints in colony feeding studies are different than effects that might be observed in incident reports (which are typically acute mortality). As such, a direct comparison is difficult to make. Typical endpoints from colony feeding studies include number of adults and brood, number of gynes or drones and other reproductive endpoints, foraging behaviour and nest construction. These observations usually take place before, during and after a dosing period, and are compared to control hive performance. These type of effects noted in the colony feeding studies, while expected to affect *Apis* and non-*Apis* bees, may not be readily observed, and may not result in incident reports.

Toxicity of thiamethoxam and clothianidin: Specifically for pollinators, Health Canada recognizes that clothianidin appears more toxic to larval bees than thiamethoxam. However, the adult toxicity of thiamethoxam is considered similar to clothianidin, although thiamethoxam appears slightly less toxic to adults from chronic exposure. Considering the sucrose colony feeding study with honey bees, thiamethoxam resulted in less sensitive endpoints compared to clothianidin. Some of the open literature colony feeding studies conducted with thiamethoxam and clothianidin had even lower endpoints, depending on dosing matrix and species.

The Health Canada assessment considered both thiamethoxam and clothianidin endpoints. Health Canada conducted the refined Tier I risk assessment with both thiamethoxam residues (compared to thiamethoxam toxicity endpoints), and also with residues converted to clothianidin equivalents (which were compared to clothianidin toxicity endpoints), and the overall conclusion of risk was similar with either method of assessment. Health Canada does recognize that, depending on the magnitude of the residues, in some cases there is more risk identified for clothianidin; particularly for larvae since the clothianidin endpoint is lower. In the higher Tier II refined assessment, thiamethoxam colony feeding study endpoints (for honey bees dosed with sucrose) were compared to thiamethoxam residues. These results were also compared to clothianidin endpoints and residues converted to clothianidin equivalents. The overall conclusion of risk was consistent between both approaches. There were also a number of colony feeding studies which dosed bees with both thiamethoxam and clothianidin. These toxicity endpoints were therefore converted to clothianidin equivalents and compared to residues represented as clothianidin equivalents.

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1.5.6 Crops harvested before bloom but grown for seed production

The commenter indicated that crops harvested before bloom could also be grown for seed production, and if they are, then risk should be evaluated.

> ***Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association):***
>
> *The PMRA should determine whether any of the crops typically harvested before bloom are or could be grown for seed production in Canada. In this case, a complete risk assessment should be conducted for all registered uses of clothianadin and thiamethoxam on these crops.*
>
> *The risk assessments conclude that use of clothianidin and thiamethoxam on crops harvested before bloom poses negligible risk to pollinators because these crops are not attractive to pollinators since there is no nectar or pollen source available. No new risk mitigation measures are proposed (other than changes to label statements in some cases). Potential risks to bees when the same crops are grown for seed production - and therefore harvested later, post-bloom - are overlooked in the assessment. According to the Canadian Seed Growers' Association, 1.2 million acres of seed crops were planted in Canada in 2012 – mainly cereals, oilseeds and pulses, but also including 1,200 acres of "minor crops".*

Health Canada Response

The Health Canada pollinator assessment considered current agricultural practices to determine which crops are harvested before bloom, and whether any of these are grown for seed production in Canada. When crops are harvested before bloom, there is no pollen and nectar available for bee forage. However, when crops were harvested before bloom, Health Canada also considered whether or not these crops were grown for seed in Canada, as when they are grown for seed, the crops are allowed to flower, and pollen and nectar would be available for bee forage. Based on agricultural practices in Canada, the crops typically harvested before bloom (Crop Group 1-root and tuber vegetables; Crop Group 3- bulb vegetables; Crop Group 4- leafy vegetables; Crop group 5-brassica leafy vegetables) are not typically grown for seed in Canada. This information was noted in Appendix X of PRVD2017-23 and PRVD2017-24 where these crop groups are discussed. In Appendix X, information for these crop groups states in the Pollinator Exposure Potential column that these crops are "*Typically harvested before bloom except when grown for seed. Generally not grown for seed in Canada.*" As well, Appendix IV of both documents outlines the Pollinator risk assessment framework, and indicates the criteria for the pollinator exposure characterization, which includes consideration of whether a crop is grown for seed production. In Appendix IV, as indicated under the criteria for "Seed Production", it is considered whether or not a crop is grown for seed production, and "*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.*" As outlined in Appendix IV, the other pollinator exposure characteristics considered include: Crop attractiveness to *Apis* and non-*Apis* bees; Pollination services and whether they are required for crop production; and Crop acreage. In summary, Health Canada took into consideration whether or not crops that are harvested before bloom were grown for seed production in Canada.

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1.5.7 Pollinators other than bees

There were various comments received indicating concern regarding a lack of consideration of other pollination species in the risk assessments. The commenters discussed the importance of considering different pollinators including beneficial insects, non-*Apis* bees, humming birds, etc.

Points raised by the commenters included:

- All of the data presented and used in the risk assessment were on bees with the majority for honey bees.
- The assessment did not consider the majority of the pollinating species in Canada
- Species other than honey bees are not actively maintained
- Wild pollinators include: native bees, flies, butterflies, wasps, moths, beetles and vertebrates like bats, squirrels, birds and primates
- Some crops and plants are pollinated by unique pollinators
- Pollinators in general are instrumental to a healthy ecosystem and biodiversity

Comment (Prevent Cancer Now)

Although assessments are ostensibly considering "pollinators" in fact the focus is entirely on bees, and almost entirely on honey-bees. As well, only two chemically related neonicotinoid insecticides of six total marketed in Canada are considered.

The assessments do not consider the majority of pollinating species in Canada.

Ssymank et al., report that at all Canadian latitudes more Diptera (flies) than Hymenoptera (bees) are responsible for pollination. Species and roles of flies in pollination and impacts of insecticides represent large data gaps in Canada. In the PRVDs, "Diptera" and "flies" only refer to pest species, indicating that the Pest Management Regulatory Agency did not consider impacts on these species. Although beneficial roles such as eating aphids, are well known, the "value" of insecticides does not include assessment of losses of natural bio-control species. A research study demonstrated that soy yields were decreased with neonicotinoid applications because the insecticide residues in the slugs killed predatory beetles (Douglas et al., 2015). This observation was generalized to arthropod predators and parasitoids in a 2016 meta-analysis of over 1000 observations of abundance of natural enemies associated with and without neonicotinoid seed coats, or pyrethroid insecticides (Douglas et al., 2016). Agriculture Canada and the Canadian Wildlife Federation are currently cooperating on research on pollinators other than bees.

Ssymank, A., Kearns, C. A., Pape, T. & Thompson, F. C. Pollinating Flies (Diptera): A major contribution to plant diversity and agricultural production. Biodiversity 9, 86–89 (2008).

Douglas, M. R., Rohr, J. R. & Tooker, J. F. Neonicotinoid insecticide travels through a soil food chain, disrupting biological control of non-target pests and decreasing soya bean yield. J. Appl. Ecol. 52, 250–260 (2015).

Douglas, M. R. & Tooker, J. F. Meta-analysis reveals that seed-applied neonicotinoids and pyrethroids have similar negative effects on abundance of arthropod natural enemies. PeerJ 4, (2016).

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)

The PMRA should more accurately present PRVD2017-23 and PRVD2017-24 as re-evaluations of risks to bees (not all pollinators), and clearly acknowledge uncertainties in the assessment of risks to non-Apis species, for which data is limited. Even though the assessments were limited in that they did not consider impacts on all pollinators, the evidence on impacts on bees (apis and non-apis) should be significant enough to deregister these pesticides immediately. PRVD2017-23 and PRVD2017-24 do not evaluate risks to all pollinators, despite known risks, and do not acknowledge this limitation.

Number of species considered in the risk assessment: While the thiamethoxam risk assessment evaluates the impacts on Apis bees (honey bees) and on one non-apis bee, specifically the bumble bee, the clothianidin risk assessment evaluates risk to Apis bees (honey bees) and non-apis bees including bumble bees and solitary bees. The assessments therefore fail to consider impacts on all types of bees beyond honey bees, bumble bees and solitary bees, without acknowledging this limitation or acknowledging that these species may be being used as proxies for whole groups. The assessments also fail to consider impacts on all other pollinators that are known to experience risks from exposure to neonicotinoids.

Consideration of other pollinators: Whereas honey bees populations are actively maintained by the honey industry, other pollinator populations are not similarly managed. For example, honey bee queens are produced or imported by beekeepers whereas no comparable intervention occurs for threatened wild pollinators to maintain healthy populations. Wild pollinators include: native bees, flies, butterflies, wasps, moths, beetles, and vertebrates, like bats, squirrels, birds and some primates.

Beyond providing valuable ecosystem services, wild pollinators play a critical role within foodwebs. A loss of pollinating species has been shown to impair ecosystem functioning as a whole. According to the Worldwide Integrated Assessment of the Impact of Systemic Pesticides on Biodiversity and Ecosystems, "adverse impacts of wide-scale insect pollinator and predator loss can lead to cascade effects in biotic communities that can ultimately affect human populations."

Some particular crops and plants are pollinated by unique pollinators, and the survival of certain host plants is directly linked to the survival of their pollinating species. Kearns and Inouye and Ollerton et al., explain how hundreds of plant species are often dependent on a distinct and unique wasp species for pollination, and that those plant species often provide staple food or habitat for many vertebrates. The loss of the wasps in these cases as a keystone species has the potential to shift the whole structure of the biotic community. The PMRA has failed to identify if any of these kinds of unique pollinator-host plant species exist in Canada; they would merit a more in-depth risk assessment.

In sum, pollinators in general -- not just managed apis populations and some non-apis bees -- are instrumental in increasing the genetic diversity in plant species, and thus are not only important for healthy ecosystems and biodiversity but also for human diets, the resilience of our global food system, and the Canadian economy.

Health Canada Response

While additional data that may be available on other bee species can be included in the tiered risk assessment process as an additional line of evidence, the primary process relies on honey bee data as a surrogate for both *Apis* and non-*Apis* bees, as well as other insect pollinators. Additional data available for non-*Apis* bees including bumble bees and solitary bees was considered in the risk assessments for both clothianidin and thiamethoxam in PRVD2017-23 and PRVD2017-24, and included higher tier studies on non-*Apis* bees. As well, special consideration was given for unique crop-pollinator relationships, where exposure may be increased. This included special consideration of squash bees (a non-*Apis* solitary bee) which rely solely on

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cucurbits crops for forage and breeding. The surrogate approach is consistent with the approach taken for other pesticide risk assessments globally.

Honey bees are chosen as a surrogate species for *Apis* bees, non-*Apis* bees and other insect pollinators including flies due to a variety of reasons. Measures of effect are based primarily on honey bees because they are readily available, are relatively easy to work with under laboratory conditions and their husbandry needs are well documented both at the level of the individual bee as well as the colony. In addition, compared to most pollinator species (for example hummingbirds or bats, or other insects), bees are expected to have higher exposure to pesticides. This is because both adult bees and brood (young bees) can consume both contaminated pollen and nectar. In addition, there is potential for direct contact from pesticides while adult bees are foraging and nesting. Bees may live in habitats close to, or in areas of treatment, and in many cases, bees are used for pollination services which results in high exposure. In addition, with over 855 bee species in Canada, bees are the most common pollinators.

Comparatively, other pollinators typically have a more varied diet (and consume protein sources outside of pollen), thereby diluting exposure to pesticides in blooming crops. A number of other pollinator species can also be migratory, and therefore correlating exposure from a treated crop and effects to some pollinators may prove challenging.

In addition to conducting a pollinator risk assessment, Health Canada also conducts a beneficial arthropod risk assessment which focuses on risks to insect predators and parasitoids. While pollinating insects are considered beneficial, they are considered separately from beneficial insects. The risk to other beneficial arthropods such as predators and parasitoids is currently being assessed under the general re-evaluation for neonicotinoids. Typically, Health Canada would conduct a risk assessment on all aquatic and terrestrial organisms in the same review. In developing the work plan for neonicotinoids, Health Canada has taken a risk-based approach to prioritize re-evaluations and special reviews where potential risk issues have been identified.

1.5.8 Non-*Apis* bees

Multiple comments were received describing concerns about how non-*Apis* bees were considered in Health Canada's risk assessment.

- Diversity of pollinators is important
- Solitary bees and bumble bees nest in the ground and could be exposed to neonicotinoids through soil manipulation and contact
- Impacts of comparable levels and duration of exposure to solitary bees and bumble bees could be substantially different
- Interspecies differences or uncertainty surrounding them due to paucity of non-*Apis* data, should be explicitly explained in the re-evaluation documents
- Health Canada documents assume that bumble bees respond to thiamethoxam and clothianidin in the same manner as honey bees. There is a concern that this is not sufficiently protective of the diversity of bees along with non-bee pollinators.

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- Concerns were raised regarding the assumption that bees do not come into contact with neonicotinoids if these chemicals are in the soil.

- The number of native bee species in Canada was underestimated in the documents

Comment (University of Guelph)

As a researcher focusing on wild pollinators (rather than managed honeybees, Apis mellifera) I would encourage Health Canada/ PMRA to take a broader perspective when considering pollinator protection. The diversity of pollinators is important and substantial – these essential ecosystem service providers are highly variable in many aspects of their behaviour, ecology and life-history likely to affect both extent and duration of exposure to pesticides in the environment, and also potentially susceptibility to impacts of these chemicals. Honeybees live in large, perennial colonies that contain many thousands of workers laboring to support their mother queen. The other 854 bee species in Canada are either solitary throughout their lives (810/855 or 95%) or have a substantial period in their lifecycle supported by a solitary queen (i.e. the 44 species of bumblebees in Canada). Pesticide exposure for these wild bees could be substantially different to that experienced by managed honeybee hives (for example most solitary bee species and bumblebees nest in the ground, and could be exposed to neonicotinoids through soil manipulation and contact), and/or the impacts of comparable levels and duration of exposure could be substantially different. These interspecific differences, or uncertainty surrounding them due to paucity of non-Apis data, should be explicitly included and explained in these reevaluation documents.

Comment (University of Guelph)

The reality we face is that the majority of information we have on potential impacts of neonicotinoids on pollinators comes from a single, and highly atypical, species – the managed honeybee (Apis mellifera). Recently more research effort has been invested into impacts on bumblebees, with only a handful of studies on solitary bees or other (non-bee) pollinators. However, despite the diversity of pollinator species (either among the 855 bee species in Canada, or the wider Canadian pollinator community) there remains in these documents a very limited acknowledgement around the risk that ecotoxicological data from honeybees alone might not be sufficiently protective to avoid risk of harm to pollinators more generally. In these documents the general assumption is that bumblebees respond to thiamethoxam and clothianidin the same as honeybees (from limited studies) and then this is scaling of this to all non-Apis bee species. All of the calculations based on tier 1 assessments of mortality including RQ (risk quotients of different crops) are scaled up from just three studies on bumblebees for clothianidin (1 oral and 2 contact) and 2 for thiamethoxam (one contact and one oral) or from values found in honeybees. Where risk assessments for non-apis have not been conducted it is assumed that they are the same as honeybees. I have concerns that this approach is not sufficiently protective to deal with lethal and sublethal impacts on measurable endpoints on the diversity of bee and non-bee pollinators these re-evaluations are aimed at protecting.

Comment (University of Guelph)

A common theme throughout all assessments is the assumption that bees do not come into contact with neonicotinoids if they are in soil, on non-flowering crops or if applied after blooming. This is concerning when we know that a high proportion of Canadian bee species are ground nesting bees (including most bumblebee species and most solitary bee species), many of which nest in and around farmed fields, and that the diversity and abundance of these wild bees are critical for the pollination of many economically and culturally important crops in Canada (e.g. Garibaldi et al., 2013; Pindar et al., 2017). Both PRVD2017-23 and PRVD2017-24 appear to overlook the role exposure in the soil could represent for ground nesting bees (and potentially other pollinator taxa too). For example, ground nesting solitary bees (including the squash bee, Peponapis pruinosa for which a special PMRA review is underway) dig into the ground as adults, and complete their development in the soil. As such, almost their entire life is spent in contact with soil.

Comment (University of Guelph)

The text states on Page 1 in both PRVD2017-23 & PRVD2017-24: "With over 700 native species in Canada, bees are the most common pollinators." This is a substantial underestimate of the number of bee species in Canada, at last count there were 855 bee species recorded in Canada (Pindar et al., 2017).

Comment (City of Montréal)

The City also has reservations about maintaining the use of clothianidin and thiamethoxam in seed treatments and ground applications that will still be allowed in Canada. Indeed, in its risk reassessment, the PMRA did not consider the pathway for pollinator exposure by soil. The Agency assumes that this route of exposure is negligible. Although it is true that the honeybee may be less exposed by this route, native pollinators are mainly soil breeders and may therefore be exposed to clothianidin or thiamethoxam in the soil during a good part of their life cycle. Knowing that this neonicotinoid can easily run off, can accumulate in the soil and is found in the soil again one year after application, it is very likely that pollinators will be exposed to it when applied to soil or by seed treatment.

The honeybee would not be the ideal model organism to assess the risks of pesticides to pollinators, particularly because the use of this species does not reflect all possible pathways of exposure. In January 2017, following a tripartite effort among regulators, universities and the agrochemical industry, an international workshop was held in Washington DC from January 10 to 12, 2017. Forty researchers and risk assessors from ten different countries came together to discuss the current state of science on pesticide exposure of bees (other than Apis), and to determine the extent to which estimates of bee exposure used by different Regulators can protect native pollinator species. There was general agreement that the current paradigm for assessing honey bee exposure is very conservative. However, several data gaps prevented a complete analysis of the different routes of exposure between Apis and non-Apis bees, particularly when non-Apis bees may be exposed by nesting materials such as soil (eg for example, Osmia spp., Nomia spp.), leaves (eg, megachids), or a combination of soil and leaves (eg, Meliponini bees). Experts suggest turning to another, more representative pollinator species for pesticide risk assessments on these groups of organisms.

Comment (Fédération des apiculteurs du Québec)

In a context where biodiversity is more important than ever, the revisions do not include wild pollinators. Differences in size, food and nesting should be investigated to ensure that known sublethal doses for honey bees should not be downgraded to accommodate smaller pollinators. (5)

5. Lundin O, Rundlöf M, Smith H G, Fries I, Bommarco R, (2015). Neonicotinoid Insecticides and Their Impacts on Bees: A Systematic Review of Research Approaches and Identification of Knowledge Gaps. PloS One: http://doi.org/10.1371/journal.pone.0136928

Health Canada Response

Health Canada considered all available information on non-*Apis* bees and incorporated the information into the risk assessment for clothianidin and thiamethoxam. It is noted that the majority of available information on non-*Apis* bees is from the open literature. The studies evaluated the effect of exposure to a variety of non-*Apis* bees including bumble bees, solitary red mason bee (*Osmia bicornis*), stingless bee (*Nannotrigona perilampoides)* and squash bees. Many of the colony feeding studies were conducted with non-*Apis* bees, and then compared to field residues in pollen and/or nectar in the Health Canada Tier II refined assessment.

Ground dwelling bees are not typically expected to be found within agricultural fields of treated crops. Most ground dwelling bees would likely be in other areas, such as off-field areas, or areas farther from the fields. Further work on development of non-*Apis* bee risk assessment methods, and how to consider other exposure routes (such as through soil) is ongoing internationally. It is

currently thought that the exposure through pollen and nectar is the greatest exposure route for bees.

Special consideration was given for bee species with unique crop-pollinator relationships, where exposure may be increased. This included special consideration of squash bees (a non-*Apis* solitary bee) which rely solely on cucurbits crops for forage and breeding, and may be exposed through pollen, nectar, and soil in cucurbit crop areas.

The risk assessment process described in the pollinator risk assessment framework identifies a tiered approach using honey bee data as a surrogate for all bees. While additional data may be available for non-*Apis* bee species and may be included in the tiered risk assessment process as an additional line of evidence, the primary process relies on honey bee data as a surrogate for both *Apis* and non-*Apis* bees. The risk assessment framework indicates that as the science evolves, methods and studies using non-*Apis* bees may be considered and incorporated into the risk assessment framework.

Health Canada was on the organizing committee and participated in the Non-*Apis* Bee Exposure Workshop in January 2017, which brought together international experts from regulatory authorities, academia, and the agrochemical industry to discuss non-*Apis* bees exposure routes as related to the assessment of risk to bees from pesticides. The results of this workshop have now been published in Environmental Entomology in December of 2018 (https://academic.oup.com/ee/advance-articles). Ongoing international work on assessing risk to non-*Apis* bees continues, and as methods evolve and there are improvements in assessing exposure routes to non-*Apis* bees, these considerations can be better incorporated into bee risk assessments.

It is agreed that a more precise number of bee species in Canada is 855 species, as provided in the recent reference (Pindar et al., 2017).

1.5.9 Synergism: neonicotinoids and fungicides

Multiple comments were received raising the concern around synergistic effects when pollinators are exposed to neonicotinoids and other pesticides, specifically fungicides.

> ***Comment (Ontario beekeepers association)***
>
> *It appears PMRA has not considered the dangerous synergistic effects of fungicides commonly applied as a seed treatment on the same seeds treated with neonicotinoids.*
>
> *The effect of neonicotinoids on honey bees quickly turns from bad to worse when you add a common fungicide Boscalid to the mix. Field realistic levels of Boscalid can make neonicotinoids twice as toxic to honeybees. http://science.sciencemag.org/content/356/6345/1395*
>
> ***Comment (General public)***
>
> *We are beginning to understand better how their effect cannot be assessed independently (as most studies do) but as part of an interactive spectrum of factors that impact pollinators. For example, there is now evidence that, used in conjunction with certain common fungicides, the effect of some neonicitinoids is more dramatic. The peril facing pollinators is too great to go on allowing even restricted use of these chemicals. We cannot state that we have conclusive and comprehensive evidence of their safety, while there is mounting scientific and experiential evidence that they are likely a contributor to increased honeybee mortality.*

Comment (David Suzuki Foundation/Équiterre/EnvironmentalDefence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)

Fungicides and synergistic effects:

Synergistic effects of neonicotinoids were not considered thoroughly in the assessments, despite assertions like "Some of the open literature suggested that combination of thiamethoxam with fungicides increased toxicity." According to the PMRA's response to the webinar Q&A about PRVD2017-23 and PRVD2017-24, the proposed removal of certain foliar and soil uses would reduce the concurrent pollinator exposure of neonicotinoids and fungicides which are commonly used in hives -- but this does not go far enough. Honey bees are also regularly exposed to miticides in hives, and all other pollinators are regularly exposed to multiple insecticides. Iwasa et al., 2004 provide evidence of additivity and synergisms of toxic mechanisms of action between neonicotinoids and other pesticide active ingredients.

Comment (Fédération des apiculteurs du Québec)

Individual approvals do not take into account the synergy created between different pesticides and the effects on bees of the different combinations of neonicotinoids/ fungicides to which they are exposed in the field (2)

2. Hudson V. V. Tomé, Gabryele S. Ramos, Micaele F. Araújo, Weyder C. Santana, Gil R. Santos, Raul Narciso C. Guedes, Carlos D. Maciel, Philip L. Newland, and Eugênio E. Oliveira (2017).Agrochemical synergism imposes higher risk to Neotropical bees than to honeybees. NCBI DOI : 10.1098/rsos.160866

Health Canada Response

Where data were available, Health Canada considered the potential effects of fungicides and neonicotinoids. There were some lower tier laboratory studies available which examined effects of fungicides and neonicotinoids. As well, some of the higher tier seed treatment studies used formulations with fungicides in them. Overall, the laboratory data demonstrated that the toxicity for the formulations with fungicides was within the range of the toxicity for the single neonicotinoids. It was determined that the conservative endpoints used in the risk assessment for the technical grade active ingredients are expected to be protective of potential effects for fungicides and neonicotinoids.

The Tsvetkov et al., 2017 paper included a number of different study designs, with both laboratory and field components, including laboratory acute studies looking at effects with fungicides, clothianidin colony feeding study with dosing through pollen, and a hive monitoring study to look at exposures in the field and determine field realistic exposure levels for the colony feeding study. The results of the acute laboratory and colony feeding study endpoints were considered in the pollinator risk assessments. As referenced on page 81 of PRVD2017-23 for clothianidin and page 102 of PRVD2017-24 for thiamethoxam, the increased toxicity of boscalid with clothianidin and/or thiamethoxam was also considered in the reviews. Overall, the median oral LD_{50} (from the Tsvetkov et al., 2017 study) for boscalid plus clothianidin or thiamethoxam was 0.0275 to 0.003 µg/bee. The Health Canada clothianidin risk assessment considered an oral LD_{50} range of 0.00125 to 0.017 µg/bee, and the thiamethoxam risk assessment considered an oral LD_{50} range of 0.0039 to 0.014 µg/bee. Therefore, an analysis using the endpoint value range from the Tsvetkov et al., 2017 study would not change the results of the Tier I risk assessment for acute oral exposure.

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Health Canada also considered higher tier studies in which the active ingredients were co-formulated with fungicides in seed treatment applications. Overall, these studies showed a lack of colony level impacts (Cutler and Dupree, 2014; Elston et al., 2013, McArt et al., 2017, Woodcock et al., 2017, Botias et al., 2017, Thompson et al., 2014, PMRA 2365330, 2365332, 2365321, 2365336, 2365365, 2365370, 2365373, 2364945, 2364957, 2364952, 2694873, 1694872).

The study referenced in the comment (Iwasa et al., 2004), was also considered in the Health Canada assessments (please refer to PRVD2017-24, page 91 for thiamethoxam and PRVD2017-23, page 70 for clothianidin). It is noted that this particular study looked at the contact toxicity of thiamethoxam or clothianidin (without fungicides). The resulting LD_{50} value of 0.0229 µg/bee for thiamethoxam and 0.0218 µg/bee for clothianidin was in the same range of endpoints considered in the risk assessment for thiamethoxam (contact LD_{50} values ranged from 0.014 to 0.50 µg/bee) and clothianidin (contact LD_{50} values ranged from 0.014 to 0.0439 µg/bee). Therefore, an analysis using the endpoint from the Iwasa et al., 2004 study would not change the results of the Tier I risk assessment for acute contact exposure. The study looked at effects from combination of fungicides with imidacloprid, thiacloprid and acetamiprid, and relevant information was considered in the imidacloprid pollinator assessment.

1.5.10 Synergism: neonicotinoids and disease susceptibility

A comment was received indicating concerns that exposure to neonicotinoids can result in increased disease levels, which may then also result in increased use of miticides in-hive, further increasing pesticide exposure to bees.

> ***Comment (David Suzuki Foundation/Équiterre/EnvironmentalDefence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association)***
>
> *(Alburaki et al., 2015 & 2017): There is also evidence that exposure to neonicotinoids can increase disease and pests that impact bees. A study in Quebec found honeybee colonies located in neonic-treated corn fields with significantly higher burdens of viruses and biomarkers of physiological stress than those in untreated fields suggesting an indirect weakening of honeybee health via induction of stress and increased pathogen loads. A second year of study on these hives found similar results. With increased risk of disease in hives, there is likely an increased need for the use of miticides and other insecticides thus adding to the cumulative pesticide burden.*

Health Canada Response

The studies referenced in the comment (Alburaki et al., 2015 and 2016 [NOTE: error in publication date, it is actually 2016, not 2017 as referenced in comment]) were considered in the Health Canada assessment (please refer to PRVD2017-24 and PRVD2017-23).

The Alburaki et al., 2015 study is summarized in PRVD2017-24, and is further detailed here. This study monitored hives placed near treatment (thiamethoxam treated corn) and control (organic corn) agricultural fields including during corn tasselling period in July 2012 and were monitored over four sampling dates periods (July, August, October, January). Hives were kept over nine months through to April 2013, with indoor overwintering, with surviving hives further studied in 2013 as described below from the paper Alburaki et al., 2016. Effects in treatments were observed for AChE gene expression (when including only hives where corn pollen was collected; no effects were noted when considering all treatment and all control hives), black

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queen cell virus infection (in August and October) and *Varroa* mite levels. No effects were observed for deformed wing virus (levels similar in treatment and controls) or Israeli acute paralysis virus (none detected in any hives). No treatment effects were noted on colony weight or brood production. Links between effects and exposure to thiamethoxam in the field were considered weak due to the low level of confirmed thiamethoxam exposure (no detections of neonicotinoids in honey, adult bee, pollen; clothianidin detected at low levels in one corn flower sample; no thiamethoxam detections), and because corn pollen was found only in five of 32 hives (approximately 1% of total pollen from corn).

The Alburaki et al., 2016 study is summarized in both PRVD2017-23 and PRVD2017-24. Similar to the previous study, hives surviving from 2012 were placed near control (untreated corn) and treatment (clothianidin or thiamethoxam treated corn) fields including during corn tasselling and were sampled three times (July, August, September). Higher levels of *Varroa* mites were seen in the treated hives compared to the untreated hives. This observation was most prominent in the corn flowering period around 15 August 2013. No significant difference in colony weight or brood production was seen over time, although there was a noticeable trend in the treated hives where colony weight increased in May and June and then rapidly decreased from August to September when compared to the control hives. In corn pollen collected by foragers, clothianidin was detected in one treated and one untreated apiary sample, and thiamethoxam was detected in one treated apiary sample. No detections of thiamethoxam or clothianidin were found in forager bees. However, low concentrations of other pesticides were detected in both trapped pollen and forager bee samples. Corn pollen was found in a total of 19.6% of the total pollen collected, from 10 of 22 hives. By the end of the observation period in September 2013, four treated colonies and one untreated colony died. The low levels of neonicotinoid residues detected, along with detections in control areas, make it difficult to link the higher levels of *Varroa* mites from treated areas to neonicotinoid exposure.

A number of other higher tier studies that were considered in the pollinator assessments also monitored for *Varroa* and disease as part of the study design. In particular, colony feeding studies which dosed colonies with contaminated sucrose solution (PMRA 2610259 and 2820119 for clothianidin, and PMRA 2586559 and 2821253 for thiamethoxam) assessed colony endpoints such as number of adults, presence of queens, larvae, pupae, hive weight, and food stores, in addition to presence of *Varroa* and *Nosema*. In these studies, the levels of *Varroa* and *Nosema* were similar between control and treatment groups, and there did not appear to be a link between high doses and *Varroa* and/or *Nosema* levels.

Other higher tier field studies with results for *Varroa* are also summarized in PRVD2017-23 and PRVD2017-24 for clothianidin and thiamethoxam, respectively. Overall, there was a lack of colony level effects following exposure to crops grown from treated seed, and in some studies *Varroa* levels were also examined. Similar to the colony feeding study results, *Varroa* levels were typically detected at the same levels in both the control and treated hives (clothianidin: PMRA 2142805, 2355497, 2510486, 2535904, 2355498, 2510477, 2535882, and Woodcock et al., 2017; thiamethoxam: PMRA 2365365, 2365370, 2365373, 2364945, 2364957, 2364952, and Woodcock et al., 2017).

There was not a clear correlation that could be confirmed between neonicotinoid levels and *Varroa* infestation or other diseases in the available field studies. However, it is expected that if hives are weakened, or aspects of disease defenses are affected (such as hygienic behaviour) that

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hives could be more susceptible to disease. The colony feeding study effects endpoints considered in the risk assessment included consideration of disease levels and hygienic behaviours (as well as other effects on the colonies) when choosing the effects endpoint, and therefore were accounted for in the Health Canada risk assessment. The overall risk conclusions, based on consideration of all information received during the consultation process, have not changed.

1.6 International context - risk assessment comparisons

1.6.1 Risk assessment approaches and data considered

A number of comments were received which were concerned that Health Canada did not consider the same data, and did not have the same risk conclusions, as those presented in the EU, EFSA and Task Force reviews. Commenters requested an explanation for differences in conclusions of Health Canada compared to the EFSA and Task Force reviews.

Comment (Ontario Beekeepers Association)

The evidence of the harmful effects of neonicotinoids on honey bees and wild bees is overwhelming:

The Task Force on Systemic Pesticides – a team of independent scientists brought together by the International Union for Conservation of Nature – has been assessing peer-reviewed science on neonics for several years. After two rounds of comprehensive reviews, they report:

"Overall, a compelling body of evidence has accumulated that clearly demonstrates that the wide-scale use of these persistent, water-soluble chemicals is having widespread, chronic impacts upon global biodiversity and is likely to be having major negative effects on ecosystem services such as pollination that are vital to food security and sustainable development" (https://link.springer.com/article/10.1007/s11356-014-3220-1)

In February of this year, the European Food Safety Authority (EFSA) released its report on the three most widely used neonicotinoid pesticides. After reviewing 1500 studies, EFSA concluded:

"The conclusions on risk varied according to factors such as the bee species, the intended use of the pesticide and the route of exposure (residues in bee pollen and nectar; dust drift during the sowing/application of the treated seeds; and water consumption). However, taken as a whole the conclusions confirm that neonicotinoids pose a risk to bees." https://www.efsa.europa.eu/sites/default/files/news/180228-QA-Neonics.pdf

The result of the EFSA review has led to proposals for further restrictions – and potentially a total ban – on neonicotinoids used on outdoor crops in the European Union. Health Canada, however, continues to permit the use of these pesticides on field crops.

Despite overwhelming evidence from beekeepers, provincial governments and scientists of the damage to insect pollinators by the use of neonicotinoids on field crops, Health Canada is proposing that these products be granted a three-year registration.

"Scientific evidence shows that with the proposed restrictions applied, the use of clothianidin and thiamethoxam does not present an unacceptable risk to bees," said Margherita Conti, an official with Health Canada's pest management regulatory agency. http://www.cbc.ca/news/politics/bees-environment-pesticides-1.4456011

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Comment (Ontario Beekeepers Association)

Health Canada's Pesticide Management Regulatory Agency pollinator re-evaluation of neonicotinoid pesticides Chlothianidin, Thiamethoxam and Imidicloprid is seriously flawed. PMRA's conclusions fly in the face of scientific authorities and hundreds of published, peer-review studies. Beekeepers in Québec and Ontario continue to experience the negative impacts of the widespread use of neonicotinoid pesticides used on field crops.

Given the importance of insect pollinators to Canada's food security, there is more than enough evidence to invoke the precautionary principle and revoke the registration of these pesticides.

We are very concerned that the PMRA did not adequately consider the rapidly expanding science that demonstrates the destructive impact of neonicotinoids on beneficial insect populations. New systemic pesticides, that we fear will have similar effects on bees and other pollinators, are being introduced at a rapid rate. This makes us gravely concerned for the future of beekeeping and for the health of the natural environment.

We request an immediate, independent review of PMRA's decision-making process, methods and policies for pesticide approvals.

Comment (Prevent Cancer Now)

Scientific assessments are only as strong as the methods used to assemble and assess the data, and can be no stronger than the data availability and reliability. Health Canada, and the PMRA in particular, should carry out international best practices in systematic scientific review, so that the present claims of "weight of evidence" are transparently supported with the scientific evidence systematically presented along with meta-analyses when appropriate, grading of said evidence, and final weighing. The current assessments are largely limited to confidential data that could only be accessed by the public after the final decision, hampering comments directly on the assessment. Subsequent use of the Reading Room with no means to access or manipulate data electronically is of very limited usefulness.

The conclusions reached during scientific assessments can be no more applicable to pressing concerns in the real world than the questions posed during reviews. Insects are impacted by all neonics, and all of the neonics have all been detected in Canadian honey.

Mitchell, E. a. D. et al. A worldwide survey of neonicotinoids in honey. Science 358, 109–111 (2017).

Rooney, A. A., Boyles, A. L., Wolfe, M. S., Bucher, J. R. & Thayer, K. A. Systematic Review and Evidence Integration for Literature-Based Environmental Health Science Assessments. Environ. Health Perspect. 122, 711–718 (2014).

Comment (University of Guelph)

On page 3-4 both PRVD2017-23 & PRVD2017-24 documents acknowledge that European Food Safety Authority (EFSA) has conducted a pollinator risk assessment for clothianidin and thiamethoxam. These documents are now finalised and available – as such, the EFSA findings and conclusions should be compared (and contrasted) with the PMRA evidence review in these documents. Careful justifications and explanations should be included in the revised versions of PRVD2017-23 & PRVD2017-24 where evidence assessments and/or conclusions diverge between PMRA and this latest EFSA opinion.

Comment (Friends of the Earth)

Friends of the Earth call for an explanation of the dramatic difference between PMRA's findings documented in its consultation reports and the EFSA findings supported by pesticides experts in EU Member States.

European Food Safety Authority (EFSA) https://www.efsa.europa.eu/en/press/news/180228

Comment (citizen)

The European Food Safety Authority has concluded that neonicotinoids pose a serious danger to bees. EU member countries are expected to approve a proposal to ban neonicotinoids in a vote later this month. France already passed a law to phase out all neonicotinoids, starting in September 2018. Parallel comprehensive action is needed in Canada to protect pollinators, ecosystems and food security.

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association

With respect to other applications of clothianidin and thiamethoxam proposed for continued use in Canada, we are concerned that the re-evaluation takes an unrealistically narrow view of, and therefore underestimates, some exposure risks. We are also concerned that proposed mitigation measures are inadequate to reduce identified risks to pollinators to "acceptable" levels.

The proposed re-evaluation decisions generally mirror the approach the European Union adopted in 2013, to protect honey bees, although the PMRA's proposal is considerably more limited in scope. EU Regulation No 485/2013 prohibits all uses of clothianidin, imidacloprid and thiamethoxam in bee-attractive crops with the exception of uses in greenhouses, on winter cereals, and on some crops after bloom. The measure was based on the European Food Safety Authority's (EFSA) 2012 pollinator risk assessments.

A half-decade ago, when the EU introduced Regulation No 485/2013, it was an appropriately precautionary response to the global pollinator crisis, based on the information available at the time. However, subsequently EFSA has updated its pollinator risk assessments for neonics in light of new evidence of harm.

EU member states are expected to approve a proposal to extend the moratorium to prohibit all outdoor uses of the three main neonics. We find it concerning that the PMRA is proposing to largely replicate the EU's partial restrictions, just as the EU itself is set to update its policy to be more comprehensive.

In our view, the approach used by EFSA in its updated assessments to address variability in the level of risk is preferable. While identifying some lower risk use/exposure scenarios, EFSA concludes that overall the risk to bees – both honey bees and wild bees - is confirmed. In most of the cases where some low risks were identified for a particular use, high risks were also identified for the same use. EU-members states are considering a proposal to ban virtually all outdoor uses of neonics. This approach is a more reliable way to reduce overall risks to pollinators, and such a comprehensive approach also helps to avoid regrettable ecosystemic trade-offs.

Health Canada Response

The pollinator risk assessment conducted by Health Canada considered hundreds of studies on acute and chronic exposure to bees in the laboratory and field. Following conservative Tier I and Tier I refined assessments, higher tier semi-field and field studies (including residue and colony dosing studies) were considered in the risk assessment based on a weight of evidence approach. The weight of evidence approach involves consideration of multiple sources of information (from other regulatory bodies, international organizations, scientific literature and models), and lines of evidence to support the risk assessment conclusion. The strength of using multiple lines of evidence is that it can reduce uncertainties identified in one line of evidence by considering additional sources of information. Health Canada also applies conservative assumptions to address uncertainties when scientific evidence for a more realistic assumption is lacking. If during the course of a re-evaluation Health Canada has reasonable grounds to believe that cancellation or amendments to the product's registration are necessary to deal with a situation that endangers human health or the environment, Health Canada can immediately take action to address the danger while additional scientific evidence is generated and/or reviewed to either

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support or refute the need for these interim measures. The weight of evidence approach, the use of conservative risk assessments and, where appropriate, the application of precautionary measures are all approaches to address uncertainty in risk assessments; thus all three concepts are considered together in decision-making.

Overall, the Health Canada assessment considered exposure to *Apis* and non-*Apis* bees from exposure to thiamethoxam and clothianidin from foliar application, soil application and seed treatment application to various crops throughout the season (before, during and after bloom). For seed treatment applications, Health Canada considered exposure from residues translocated through the seed into pollen and nectar, and also from residues generated from dust during planting (in other words, residues in off-field plants from movement of the pesticide away from the treated field/crop). The Health Canada assessment also considered incident reporting information from beekeepers as well as results available to date from an investigation of the incidents. Health Canada also assessed potential risk to bees resulting from water exposure (including guttation droplets and bee relevant surface water sources such as contaminated puddles). Based on the risk assessment, when a potential risk was identified, Health Canada proposed mitigation. Similarly, Health Canada had enough information and data to conclude when no risk was identified. In those latter cases, no mitigation was proposed.

With respect to international regulation of neonicotinoids, Health Canada did review and consider the EFSA and Task Force reviews as part of its assessment, as well as reviews from United States EPA (Environmental Protection Agency) and California Department of Pesticide Regulation. Health Canada reviewed the underlying studies that were considered in the reviews, and incorporated the information into the Health Canada risk assessment.

Some of the key differences in the assessments which lead to the differences in risk conclusions between Health Canada and EFSA include the following:

- A different pollinator risk assessment framework in North America than the EU, with incorporation of a Tier II risk assessment that compares colony effects endpoints to pollen and nectar residues in the field from various application scenarios;

- Consideration of the Canadian use pattern and agricultural practices, which are not the same as agricultural practices in Europe. There are different crops and rates of application in Canada compared to the EU.

- For certain aspects of the risk assessment the EFSA assessment relied on modeled or default exposure values to estimate exposure to pollinators whereas the Canadian assessment used measured values, including measured values in water and rotational crops, to estimate exposure to pollinators.

It is noted that the most up to date EU assessments still have a number of continued data gaps identified that would need to be addressed in order to fully assess the acute and the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees, and therefore many conclusions of risk are based on a conservative lower tiered risk assessment.

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1.6.2 Integration of multiple exposures

The commenter questioned why Health Canada assessed some of the exposure routes separately (such as water) rather than integrating all potential exposures together (in other words, pollen, nectar, water, other routes) as was done in the EFSA review.

Comment (Friends of the Earth)

We ask PMRA and the Minister of Health to explain why the PMRA assessment does not integrate the three exposure routes as per the EFSA assessment rather hiving off water/aquatic effects as a separate consideration. As with the previous (EFSA) assessments, exposure of bees to the substances was assessed via three routes: residues in bee pollen and nectar; dust drift during the sowing/application of the treated seeds; and water consumption."

Health Canada Response

The pollinator risk assessment of clothianidin (PRVD2017-23) and thiamethoxam (PRVD2017-24) considered three exposure pathways: exposure through pollen/nectar, dust and water via direct contact or diet following foliar, soil or seed treatment applications. While the exposure pathways were assessed separately in the lower tier assessments, some of the higher tier full-field studies assessed multiple exposure pathways which were considered together under the method of application (in other words, seed treatment studies where bees were exposed to dust, guttation water and residues in pollen and nectar). Integrating exposure pathways in the risk assessment presents some challenges as exposure to pesticides may occur over a wide time scale (for example, at planting, during plant growth and flowering in the same or next season) and involve exposure to various bee developmental stages. Incorporating simulation models may represent a potentially useful tool for integrating exposure and effects data with the complexities of the social structure and biology of a honey bee colony (see response for Mathematical Modelling). Health Canada will further consider the use of models in the pollinator risk assessment as the science supporting such efforts evolves. Therefore, the overall risk conclusions, based on consideration of all information received during the consultation process, have not changed.

1.6.3 Task Force on Systemic Pesticides conclusions for all organisms

The commenter indicated that The Task Force on Systemic Pesticides has concluded neonicotinoids harm not only honey bees, but also many other species, such as aquatic insects, earthworms, and birds.

Comment (Friends of the Earth)

Another important player, The Task Force on Systemic Pesticides – a team of independent scientists brought together by the International Union for Conservation of Nature – has been assessing peer-reviewed science on neonics for several years. After two rounds of comprehensive reviews, they say that neonics harm honeybees and many other species, including aquatic insects at the base of the food chain, earthworms and common birds. The Task Force's earlier work identified neonicotinoids as powerful neurotoxins, up to 10,000 times more lethal to bees than DDT.

The Task Force on Systemic Pesticides http://www.tfsp.info/findings/harm/

Comment (Prevent Cancer Now)

Extensive international efforts by independent scientists on the Task Force for Systemic Insecticides conclude that neonics should be replaced with other approaches.

Lexmond, M. B. van, Bonmatin, J.-M., Goulson, D. & Noome, D. A. Worldwide integrated assessment on systemic pesticides. Environ. Sci. Pollut. Res. 22, 1–4 (2015).

Giorio, C. et al. An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 1: new molecules, metabolism, fate, and transport. Environ. Sci. Pollut. Res. 1–33 (2017). doi:10.1007/s11356-017-0394-3

Furlan, L. et al. An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 3: alternatives to systemic insecticides. Environ. Sci. Pollut. Res. 1–23 (2018). doi:10.1007/s11356-017-1052-5

Health Canada Response

Health Canada is aware of the Task Force on Systemic Pesticides and has reviewed the documents produced by this group. The pollinator relevant studies referenced in the Task Force documents were considered in the current pollinator risk assessment. The relevant references in the Task Force documents related to aquatic invertebrates were considered in the recent proposed decision for the special reviews of clothianidin (PSRD2018-01) and thiamethoxam (PSRD2018-02). The remaining information presented in the Task Force documents related to birds and other species will be considered in the cyclical re-evaluation for clothianidin and thiamethoxam.

Health Canada agrees with the Task Force that neonicotinoids are potentially harmful to pollinators; however, the potential for risk is dependent on the use pattern. Some current uses of clothianidin and thiamethoxam are not expected to harm pollinators, whereas some uses may pose a risk of concern. Where a potential for risk was identified in the pollinator assessment, risk mitigation measures are proposed to minimize potential exposure to bees where necessary. The mitigation measures proposed for clothianidin and thiamethoxam include cancellation of some uses, changes to the use pattern and label improvements for other uses. When clothianidin and thiamethoxam are used in accordance with these new proposed risk reduction measures, the reduced environmental exposure is sufficient to determine that the risks to bees are acceptable. Where negligible risk was identified, no proposed mitigation is required; however, label improvements for some uses are proposed.

1.7 Importation of Queen bees

A concern was raised regarding the potentially disastrous practice of importing queen bees into Canada.

Comment (Prevent Cancer Now)

The Parliamentary Standing Committee on Agriculture and Agri-Food held a hearing in March 2017 regarding another neonicotinoid, the most prevalent – imidacloprid. It was stated by Pierre Giovenazzo, Professor, Sciences apicoles, Centre de recherche en sciences animales de Deschambault, Université Laval, that Canada has not been self-sufficient in bees since 2011. Packets containing queen bees must be imported annually. This potentially disastrous trend merits strong, prompt actions, particularly when the persistence

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of the implicated pesticides renders environmental and pollinator recovery a long-term proposition. To many Canadians, this fact, along with extensive research linking pollinator decline to persistent systemic insecticides should be sufficient to spur strong actions.

Lexmond, M. B. van, Bonmatin, J.-M., Goulson, D. & Noome, D. A. Worldwide integrated assessment on systemic pesticides. Environ. Sci. Pollut. Res. 22, 1–4 (2015).

Simon-Delso, N. et al. Systemic insecticides (neonicotinoids and fipronil): trends, uses, mode of action and metabolites. Environ. Sci. Pollut. Res. Int. 22, 5–34 (2015).

Sluijs, J. P. van der et al. Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning. Environ. Sci. Pollut. Res. 22, 148–154 (2015).

Health Canada Response

In order for beekeepers to import live honey bees (including queens) beekeepers must first obtain a permit from the Canadian Food Inspection Agency (CFIA). There are many concerns with importing live bees to the Canadian honey bee industry including the importation of pests and diseases and Africanized bee traits; as such, the importation of queens is regulated. The CFIA closely monitors conditions in other countries and will prevent importation from countries where disease issues have been identified. Due to the Canadian climate, domestic queens are not always available in early spring when beekeepers are trying to rebuild colonies lost during the winter months in Canada. A clear link between overwintering losses and neonicotinoid exposure has not been established. There are many factors that affect the overwintering success of a colony including cold temperatures, poor queens entering the winter months and diseases.

Health Canada has considered, and continues to consider, incident reports from beekeepers in its assessment of the neonicotinoids. In addition to incident reports, Health Canada has assessed hundreds of studies (including laboratory and field data) in order to assess potential risks to honey bees (*Apis*) as well as non-*Apis* bees. The risk assessment evaluated potential acute and chronic risks to various castes of bees in the hive from various application methods (foliar, soil, tree injection and seed treatment, including exposure in pollen and nectar from systemic translocation in plants). Health Canada also assessed potential risk from water, dust, and carry-over. Health Canada has proposed mitigation, including cancellation of uses, in order to reduce exposure (and risk) to bees from use patterns that resulted in unacceptable risk.

1.8 Incident reporting bias

A concern was raised regarding the potential reporting bias for pollinator mortality reports, specifically in Ontario. The commenter indicated that given that Health Canada will no longer take samples for analytical analysis that beekeepers no longer want to report effects observed in their yards.

Comment (Ontario Beekeepers Association)

PMRA ignores reporting bias when it cites the sharp reduction in reported incidents as proof that their mitigation of crop dust has solved the problem of neonicotinoid exposure from field crops. Bee mortality continues at unacceptably high levels while beekeepers in corn and soy growing provinces continue to suffer acute bee kills, chronic poisoning and queen failures. What PMRA fails to note is that the highest number of reported incidents occurred when PMRA took physical samples of bees, comb and pollen and providing reports of pesticide residues to the affected beekeepers. Without follow up to a reported incident there is little

or no incentive for beekeepers, some of whom may experience up to 12 incidents a year, to report bee kills. It is not clear why PMRA neglects to note this reporting bias.

Health Canada Response

Since 2007, the Pest Control Products Incident Reporting Regulations require registrants to report incidents of which they are made aware and Health Canada has actively encouraged the voluntary reporting of incident reports by the general public. In 2012, following the reporting of a large number of bee incidents, Health Canada has actively encouraged beekeepers to report effects observed in their yards through appropriate channels, which typically includes contacting the provincial apiculturists, who then contact Health Canada if the incident is thought to be related to pesticides. Promotion of incident reporting and how to report incidents has been done using various means such as trade shows, provincial apicultural organizations, provincial governments, presentations with the beekeeper community and on the Pesticides Section of the Canada.ca website. Feedback on 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 the Pesticides Section of the Canada.ca website.

Health Canada uses the information it receives under the Incident Reporting Program, along with current knowledge of the active ingredient to assess the potential relationship between the pesticide and the effects reported. The assessment is generally completed without the pesticide residue information unless it is provided to Health Canada in the report. Given the large number of reports in 2012, Health Canada, along with its compliance staff in the provinces, established a special program to investigate the situation. After the collection of four years of residue information, Health Canada determined that sufficient information was available. This program went above and beyond the mandate of the PMRA's Incident Reporting Program.

The reduction in reported incidents started before intensive collection of samples was stopped. A sharp decrease in reported incidents during the planting period started in 2014, following the implementation of the dust-reducing fluency agent requirement. In 2014, Health Canada continued to complete intensive sampling with over 450 samples collected during the year. In 2015, a more focused approach was taken in incident investigation and there was a reduction in the number of samples collected; however, more than 130 samples were still collected in this year. Limited sampling occurred in 2016, where the focus was placed on incidents which were identified as different from the previously reported incidents.

If beekeepers are not reporting adverse effects in their yards because they are in turn not receiving analytical results from samples collected, Health Canada cannot track and evaluate the suspected adverse effects. Health Canada can only evaluate what is reported and, as mentioned above, Health Canada does assess environmental incidents without the presence of analytical results. If beekeepers believe that pesticides are affecting their colonies, they are encouraged to continue to report the effects through the appropriate channel in their provinces. A list of contacts within the provinces are located at the following link: https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/pollinator-protection.html

1.9 Mitigation

1.9.1 Foliar and soil applications

1.9.1.1 Multiple crops - Clothianidin specific

Clothianidin specific comments were received regarding the mitigation proposed for multiple foliar and soil uses.

Comment (Saskatchewan Ministry of Agriculture) – clothianidin specific

The Saskatchewan Ministry of Agriculture is concerned about restrictions to foliar application of clothianidin-containing products where effective alternatives are limited or not available at this time.

ORCHARD CROPS: Clothianidin (IRAC Class 4) represents one of only two modes of action approved for brown marmorated stink bug. This is an invasive species that is likely to become established in Southern Saskatchewan and is a serious pest of a large number of important crops. Clothianidin controls brown marmorated stink bug when applied as a foliar spray and is essential for insecticide resistance management in pome fruit. Clothianidin-containing products are currently registered for post-bloom applications only. No chronic dietary risk to adult forager bees or bee larvae, or acute dietary risk to adult bees or bee larvae was indicated with high label rate (210 g a.i./ha) applied post-bloom.

STRAWBERRIES: Foliar application of clothianidin is an important component of Integrated Pest Management and resistance management strategies for Lygus bug control in strawberries. According to PMRA's evaluation, risk to pollinators associated with pre-bloom application depends on timing, and evaluation was based on very limited information. Exposure was characterised as low to moderate. The only reported incidents associated with clothianidin on strawberries were due to outside-label timing (during bloom) applications.

PROPOSED MITIGATION: Our Ministry believes that risks associated with pre-bloom foliar applications of clothianidin products can be mitigated with label statements. We request that the PMRA consider minor uses in Saskatchewan and include labeling requirements to mitigate risk to pollinators, rather than removing the specific foliar applications of clothianidin listed.

ENVIRONMENTAL LOADING: As part of this consultation response we also request PMRA consider that elimination of uses in this proposed decision will result in the reduction of total neonicotinoids into the environment (including water bodies). So, while making a proposed/final decision on the impact of neonicotinoids on aquatic insects, the PMRA should account for this reduction when calculating total load of neonicotinoids released into the environment.

Health Canada Response - Clothianidin specific

Health Canada acknowledges the growers' need for pest control products; however, in accordance with the *Pest Control Products Act*, Health Canada must demonstrate that the use of a product will pose acceptable risks to human health and the environment.

ORCHARD CROPS: Health Canada acknowledges the limited alternatives approved for control of brown marmorated stink bug in orchard crops. In light of the comments received and proposed changes to the use pattern by the registrant and other commenters, Health Canada has re-examined the available post-bloom application residue information to determine whether further refinements can be made to the risk assessment (see Section 1.1 Updates to the Environmental Risk Assessment). No additional residue or effects information was submitted for consideration.

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Based on the reassessment of available information, it was concluded that the risk to bees following post-bloom applications in orchard crops cannot be ruled out.

STRAWBERRIES: Health Canada acknowledges that the incident reports for strawberries were from applications made during bloom which would be considered an off-label use for this crop. Clothianidin is currently registered for only pre-bloom applications in strawberry for control of *Lygus* bugs. In reaching the risk conclusion for strawberry, Health Canada considered effects endpoints in relation to clothianidin residue levels in pollen and nectar following pre-bloom applications in other crops (grape and cucumber) in addition to residue levels of thiamethoxam in pollen and nectar following pre-bloom applications in strawberry. Pre-bloom foliar applications of thiamethoxam to strawberry resulted in high residues that pose a risk to both *Apis* and non-*Apis* bees for both pollen and nectar exposure. No higher tier semi-field tunnel or full field studies were available for consideration. While pollinator exposure in strawberry was classified as low to moderate and most varieties do not require insect pollination, some varieties do, and pollination services may be used to enhance crop production. In addition some cultivars of strawberry are indeterminate bloomers, and therefore exposure may extend during the bloom season (although residues are expected to decline with time). Therefore in order to reduce the risk to pollinators in strawberries, Health Canada proposed to remove pre-bloom foliar applications in this crop.

PROPOSED MITIGATION: Health Canada has used as much data as possible to determine potential risk from each individual use pattern (foliar, soil and seed treatment) and crop group, and proposed risk mitigation measures in cases where the risk to bees was not considered acceptable.

ENVIRONMENTAL LOADING: When uses are removed from a label there is a phase out period; as such, Health Canada proceeded with the aquatic risk assessment with all currently registered uses. With the removal of uses, Health Canada cannot predict the effect on loading. The aquatic risk assessment relied on real-world concentrations from surface water monitoring to assess the risk. The impact on these concentrations cannot be realized until after the uses are phased out and additional monitoring is conducted.

1.9.1.2 Multiple crops - Thiamethoxam specific

Thiamethoxam specific comments were received regarding the mitigation proposed for multiple foliar and soil uses.

> ***Comment (Saskatchewan Ministry of Agriculture) - thiamethoxam specific***
>
> *The Saskatchewan Ministry of Agriculture supports Heath Canada's PMRA assessment of thiamethoxam-containing products: "the products have value and do not present an unacceptable risk to human health or the environment." We support the assessment that the use of thiamethoxam-containing seed treatments requires no further mitigation for oral systemic exposure. We do not object to the incorporation of additional label statements regarding best management practices for cereal and legume crop seed treatments. We also support PMRA's assessment that soil applications of thiamethoxam-containing products require no mitigation for crops harvested before bloom and rotational crops.*
>
> ***Comment (Saskatchewan Ministry of Agriculture):*** *The Saskatchewan Ministry of Agriculture is concerned about restrictions on the use patterns for thiamethoxam-containing products where effective alternatives are limited or not available at this time.*

ORCHARD CROPS: *Thiamethoxam (IRAC Class 4) represents one of only two modes of action approved for brown marmorated stink bug. This is an invasive species that is likely to become established in Southern Saskatchewan and is a serious pest of a large number of important crop species. Thiamethoxam effectively suppresses brown marmorated stink bug when applied as a foliar spray and is essential for insecticide resistance management in pome fruit in particular. No T3 effects on honey bee exposed to apple treated with 100-200 g a.i./ha 7 days before bloom was reported. Pome fruit is registered for pre-bloom application at one application of 40-79 g a.i./ha. PMRA stated "It is the degree of realism that increases with higher tier studies."*

BERRIES: *The loss of thiamethoxam for cane berries, bush berries and most low growing berries will reduce ability to control several pests including root weevils. Since only one other mode of action is registered for root weevils on these crops, thiamethoxam is essential for resistance management. According to PMRA's evaluation, no incident has been reported for foliar application of thiamethoxam in strawberry. Since the CFS exposure duration was more than double the 2-3 week bloom time normally seen for small fruit and berry, the risk was assessed as possibly being overestimated.*

CUCURBITS: *Cucurbit crops, particularly pumpkin, are also a small but important component of Saskatchewan's agricultural portfolio and can be attacked early-season by cucumber beetles. Although there are several products registered for control of this insect, only the neonicotinoids have systemic activity and protect plants from larval feeding. No effect (T3) on honey bees was detected at soil-applied rates up to 200 g a.i./ha. Cucurbit crops are currently registered at 1 × 88 - 150 g a.i./ha, in-furrow before bloom. PMRA stated "It is the degree of realism that increases with higher tier studies."*

FOLIAR APPLICATION TIMING*: Our Ministry agrees that foliar applications of any insecticide during bloom constitute risk to pollinators but believe that risks associate with pre-bloom foliar and soil applications can be mitigated with label statements.*

PROPOSED MITIGATION: *We request that the PMRA consider all uses of thiamethoxam-containing products in Saskatchewan and include labeling requirements to mitigate risk to pollinators, rather than removing the specific foliar and soil applications of thiamethoxam listed.*

ENVIRONMENTAL LOADING: *As part of this consultation response we also request PMRA consider that elimination of uses in this proposed decision will result in the reduction of total neonicotinoids into the environment (including water bodies). So, while making a proposed/final decision on the impact of neonicotinoids on aquatic insects, the PMRA should account for this reduction when calculating total load of neonicotinoids released into the environment.*

Health Canada Response - Thiamethoxam specific

Health Canada acknowledges the growers' need for pest control products; however, in accordance with the *Pest Control Products Act,* Health Canada must demonstrate that the use of a product will pose acceptable risks to human health and the environment.

ORCHARD CROPS: The Tier 3 field effects study examining pre-bloom application to pome fruit was considered in the risk assessment. Health Canada agrees that limited effects to bees from pre-bloom application were observed; however, only 15 to 33% apple pollen was collected by bees, which suggested they may not have been sufficiently exposed in this study. In addition, there was close proximity between the control and field plots which may have resulted in dilution of residues brought to the hive (because bees could have been foraging on uncontaminated pollen/nectar). In addition to this study, residue studies were also considered. Residues in pollen and nectar were collected during bloom following pre-bloom application to apple trees. The resultant residues between early to late bloom were very high (in both pollen (up

to 1712 c.e. ppb) and nectar (up to 486 c.e. ppb) and exceeded colony level endpoints considered in the risk assessment for both *Apis* and non-*Apis* bees.

Additionally, in light of the comments received and proposed changes to the use pattern to consider allowing post-bloom application to orchard crops, Health Canada has re-examined the available post-bloom application residue information to determine whether further refinements can be made to the risk assessment (see Section 1.1 Updates to the Environmental Risk Assessment). Based on the reassessment of available information, it was concluded that the risk to bees following post-bloom applications in orchard crops cannot be ruled out.

BERRIES: Health Canada acknowledges the lack of incident reports for berry use. There were incidents associated with application of clothianidin during bloom to strawberry plants (PRVD2017-23). Health Canada considered residue data in strawberry and cranberry in the risk assessment. Residues in pollen and nectar of these berry crops were very high (following pre-bloom application). Residues in strawberry and cranberry pollen reached levels of 5749 and 1366 c.e. ppb, respectively. Corresponding nectar residues reached 326 and 1156 c.e. ppb. Information on blueberry residues were submitted to Health Canada for consideration in the risk assessment as a result of this proposed risk assessment. Similar to the other berry crops, residues in blueberry pollen and nectar reached to 809 and 592 c.e. ppb (in Quebec, Canada). Collectively, these berry crop residue levels exceeded colony level endpoints considered in the risk assessment for both *Apis* and non-*Apis* bees. Please see Section 1.1 Updates to the Environmental Risk Assessment, on blueberry foliar applications of the thiamethoxam RVD for the new risk assessment.

CUCURBITS: The Tier 3 field effects study on cucurbits was considered in the risk assessment. Health Canada agrees that there were limited effects to bees from application to melon up to 200 g a.i./ha; however, there was between 0 and 15% melon pollen in the treatment hives, which suggested that the bees may not have been exposed in this study. A number of cucurbit residue studies were also considered in the risk assessment (cucumber, pumpkin, summer squash, muskmelon and melon). Among all of the crops, there was range in residues. However, collectively, the residues in pollen (up to 57 c.e. ppb) and nectar (up to 27 c.e. ppb) exceeded some of the colony level endpoints (mostly for pollen residues and non-*Apis* endpoints). Consideration was also given to squash bees, which live and reproduce using cucurbit crops and are therefore highly exposed to residues in these crops.

PROPOSED MITIGATION: Health Canada has used as much data as possible to determine potential risk from each individual use pattern (foliar, soil and seed treatment) and crop group, and propose mitigation in cases where acceptable risk cannot be demonstrated.

ENVIRONMENTAL LOADING: When uses are removed from a label there is a phase out period; as such, Health Canada proceeded with the aquatic risk assessment with all currently registered uses. With the removal of uses, Health Canada cannot predict the effect on loading. The aquatic risk assessment relied on real-world concentrations from surface water monitoring to assess the risk. The impact on these concentrations cannot be realized until after the uses are phased out and additional monitoring is conducted.

Soybean Foliar Applications - Thiamethoxam specific

The following comment was received requesting consideration of refinements to the risk assessment, and alternate mitigation. This information was considered by Health Canada.

Comment (Syngenta):

Consideration of refinements and alternate mitigation: *The following risk assessment refinements are proposed for the following crops along with alternative mitigation measure to be considered by the PMRA. The focus will be on those crops where uses of thiamethoxam are proposed to be eliminated or restricted to post-bloom applications only and for which the data supports alternative mitigation options. For foliar applications, this includes data in support of pre-bloom applications on soybean (legumes) and post-bloom applications on orchard trees (e.g., stone and pome fruits).*

Attractiveness of crop: *Soybeans are moderately attractive to bees, and have a high crop acreage. Soybeans do not require pollination by bees and do not use managed bees.*

PMRA determined that pre-bloom applications pose potential risk to bees. However, looking at the pollen and nectar residue data over time suggests that the risk from pre-bloom application is acceptable for honey bees and can be mitigated for non-Apis bees with a labelled pre-bloom interval (PMRA 2769753). Figure 2 shows that the nectar concentrations are all below 10 ppb and that the anther (pollen could not be collected in this study) residues drop appreciably over time.

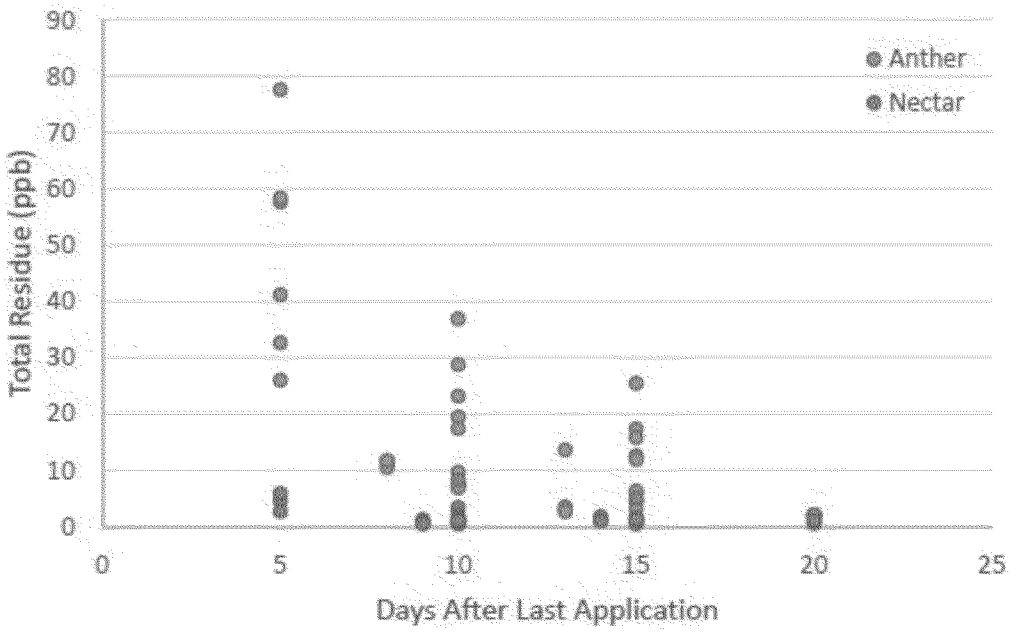

Figure 2. Total Residues (Thiamethoxam + CGA322704) in Anther and Nectar after Pre-Bloom Foliar Applications on Soybean (2 × 71 g a.i./ha with 7 day interval)

Risk assessment approach and residues: *The data were then converted using the Toxic Unit approach but using the following endpoints and modifications. For honey bees, the NOAEC for clothianidin and thiamethoxam used was 20 ppb and 50 ppb, respectively. The pollen (anther) data were also converted to "nectar equivalents" by dividing the residue values by 5 as proposed by the Neonicotinoid Consortium.*

For non-Apis bees, the NOAEC value of 10 ppb was used for both pollen and nectar as the LOAEC from colony feeding studies in the open literature were generally above this value although there is a great deal

of uncertainty in these endpoints based on closed type study designs, use of micro-colonies and other concerns related to representing field relevant conditions. Results presented in Figure 3 indicate acceptable risk to honey bees with a pre-bloom application at least 5-days prior to bloom (TU < 1). For non-Apis bees, the pre-bloom application interval can be extended to 14 days. It should be noted that the current maximum application rate for soybeans in Canada is 25.4 g a.i./ha which is less than half the rate used in the study. Therefore a 10-14 day pre-bloom application interval is a conservative mitigation option for soybeans and Syngenta requests the PMRA's consideration of this option.

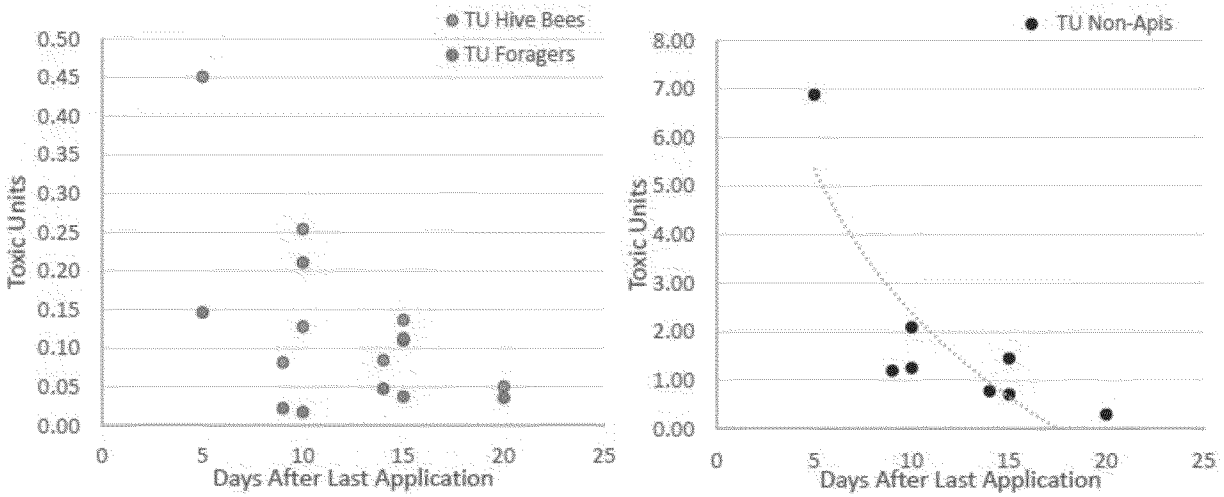

Figure 3. Toxic Units for Hive Bees, Foragers, and Non-Apis Bees using Mean Residue Data (per sample event) for Anther and Nectar after Pre-Bloom Foliar Applications on Soybean (2 × 71 g a.i./ha with 7 day interval)

Health Canada Response

Toxic Unit approach: The proposed Toxic Unit (TU) approach of converting pollen data into nectar equivalents and using only the *Apis* colony feeding study with dosed sucrose solution, as submitted from the registrant, is not currently supported by Health Canada. Although this proposed approach does consider the endpoints for both the clothianidin and thiamethoxam colony feeding studies, it does not consider effects from dosing studies with pollen, and also does not consider non-*Apis* effects data. The proposed TU (toxic unit) approach uses honey bee data (with a safety factor) to represent potential endpoints for non-*Apis* bees.

Health Canada considered non-*Apis* data (bumble bees and solitary bees) from the open literature in the risk assessment, in addition to *Apis* data.

In this particular TU approach, it considers the percentage of nectar and pollen in the bee diet. It considers 90% consumption of nectar and 10% consumption of pollen for hive workers and 100% consumption nectar and 0% consumption of pollen for nectar foragers. It is unclear if these percentages would also represent larval bees and queen consumption in the hive, which may consume more pollen. Since pollen residues are typically higher than nectar residues, there may be an underestimation of exposure.

This proposed TU approach appears to be more representative of a Tier I refined assessment, where consumption is calculated and a benchmark of '1' is used to represent potential risk. At

the current time, Health Canada is not doing the risk assessment using a TU approach. Health Canada has followed the tiered risk assessment approach as outlined in the *North American Guidance for Assessing Pesticide Risks to Bee*.

Risk assessment approach and residues: Health Canada did consider the soybean residue data referenced in the comment (PMRA 2769753). In this residue study the nectar (from honey stomachs) was collected from honey bees in tunnels and thus, represents the amount of nectar from *Apis* (but not necessarily free foraging non-*Apis* bees). As mentioned in the comment, soybean may not be attractive to honey bees. As such, the nectar residue levels may not represent what is typically found in soybean flowers; especially given that the whole flower contained up to 459 ppb. Pollen sampling from bees was unsuccessful and therefore anthers were considered instead. Although in most cases, nectar residues decline below 10 ppb (as outlined in the comment), and this is below the sucrose based *Apis* endpoints, there were some non-*Apis* sucrose endpoints considered in the risk assessment which were below 10 ppb. As such, there is still a potential risk to non-*Apis* bees. There would also be a potential risk if whole flower residues were considered in the risk assessment, considering different sites (Iowa, Louisiana and North Carolina) and residue decline (between days 5 to 20).

1.9.1.3 Fruiting vegetables soil applications - thiamethoxam specific

The following comment was received requesting consideration of refinements to the risk assessment, and alternate mitigation. This information was considered by Health Canada.

Comment (Syngenta)

Consideration of refinements and alternate mitigation:

For soil applications, potential risk to bees can be managed by adjusting application timing, planting density and by varying application rate based on soil type. Specific label restrictions regarding timing of soil applications necessary to manage potential risk to bees, although less flexible given that applications are typically made during transplant, can be made.

In general, pollen and nectar residues from crops treated with soil applications are highly variable within each crop group. For example, cucumber and pumpkin have relatively low residues versus muskmelon within the current crop group (PMRA 2770410). In addition, many factors can influence pollen and nectar concentrations including application type (drench versus drip), application rate and timing, soil type (coarse versus fine soils) and planting density (plants per hectare). Mitigations based on soil type, application rate or planting density (i.e., application rate per plant) should be considered as opposed to eliminating soil uses for a crop or crop group entirely, particularly for crops that have no other or limited plant protection options or concerns about pest resistance.

Fruiting Vegetables (soil applications)

Fruiting vegetables including tomato, pepper and eggplant are not attractive to honey bees but can be attractive to non-Apis bees, mainly bumble bees. Bumble bees are effective "buzz pollinators" in tomatoes and are often used to pollinate tomatoes in greenhouses. Tomatoes grown outdoors are self-fertile and can be pollinated via shaking of the plant by wind which frees the pollen, although bumble bees and other bees that are effective buzz pollinators can aid in cross pollination of tomato and other fruiting vegetables.

With few exceptions, fruiting vegetables only provide pollen, as nectar is not produced by the plants. An important consideration for exposure to bumble bees is that fruiting vegetables do not bloom during spring in Canada. Because bumble bees start their colonies early in the spring, they need abundant early-

flowering plants to supply their queens with pollen and nectar. Fruiting vegetables would, therefore, not be a source of pollen for queens coming out of hibernation. By the time that fruiting vegetables are blooming, bumble bee colonies should be relatively large with an ample supply of workers able to forage for the colony.

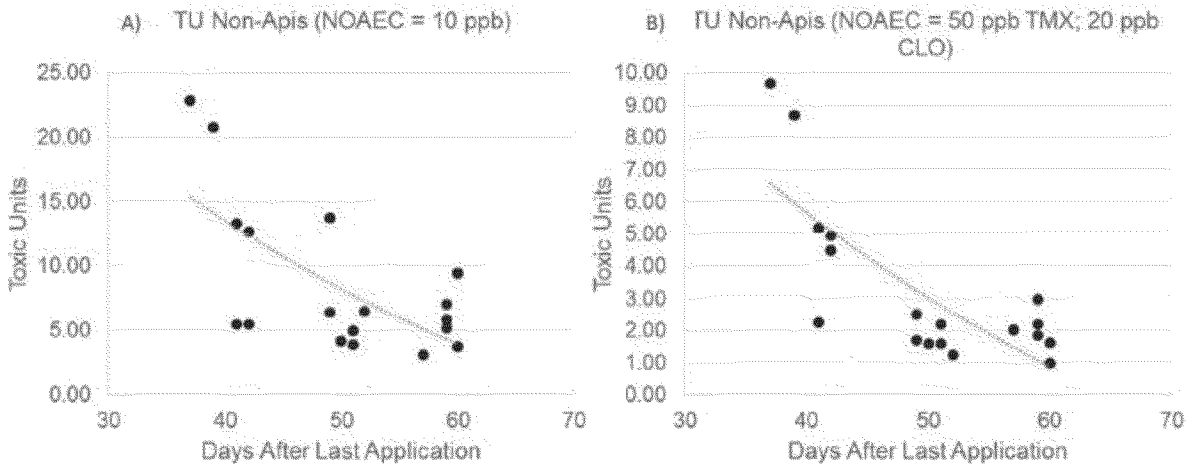

Figure 4. Toxic Units for Non-Apis Bees using Mean Residue Data (per sample event) for Pollen after Soil Applications on Tomato (140 or 193 g a.i./ha). Graph "A" represents non-Apis CFS NOAEC of 10 ppb and "B" represents a larger non-Apis CFS NOAEC equivalent to honey bees NOAEC of 50 ppb for thiamethoxam (TMX) and 20 ppb for clothianidin (CLO).

Risk assessment approach and residues: *The above scenario (Figure 4) represents potential sub-lethal effects on whole colonies when fed spiked nectar and/or pollen.*

Higher tier study results: *Out of the three Syngenta submitted studies which exposed small bumble bee hives to tomatoes treated by drip irrigation at rates ranging from 150 to 200 g ai./ha (PMRA 2365420, 2364898 and 2364997), only one showed effects on mortality and pupae at 200 g ai./ha when applications were made close to hive introductions. PMRA also cites two relevant studies from the open literature. Alarcon et al. (2005) and Sechser et al. (2003) exposed Bombus terrestris to tomato plants at rates ranging from 150 to 166 g a.i./ha. Alarcon et al. (2005) (2 applications × 100 g a.i./ha) concluded that there were no significant effects on mortality and, based on fruit set of the tomato plants, pollination rates were not affected regardless of treatment applied. Sechser et al. (2003) concluded possible effects on mortality of adults and larvae and food storage when exposed to 1 application of 161 g a.i./ha or 1 application of 150 g a.i./ha when applications were made close to hive introductions. These studies demonstrate that observable effects on bumble bee colonies are likely to occur only if soil applications are made prior to bloom and applications during transplanting, if given sufficient time prior to bloom.*

Health Canada Response

Attractiveness of crop: Since some of the crops bloom indeterminately (in other words, bloom all season), exposure can occur throughout the season. Health Canada has considered the potential exposure to different fruiting vegetables (including pepper which has both pollen and nectar) and also to potential dietary requirements throughout the season for all types of bees, including honey bees, bumble bees, and solitary bees.

Degradation of residues:
As can be observed in the following figure (Figure 5), residue decline for tomato pollen (and other crops) following soil application were considered in the risk assessment. Residues of clothianidin were high in the case of tomato pollen, and these were considered in the risk assessment (in addition to thiamethoxam residues). The highest and lowest pollen residues, considering early to late bloom, exceeded the pollen level colony endpoints that were considered in the Health Canada assessment. In addition, residues in pollen resulting from different application rates and methods exceeded the pollen level colony endpoints that were considered in the Health Canada assessment. Therefore, the overall conclusion of risk is maintained.

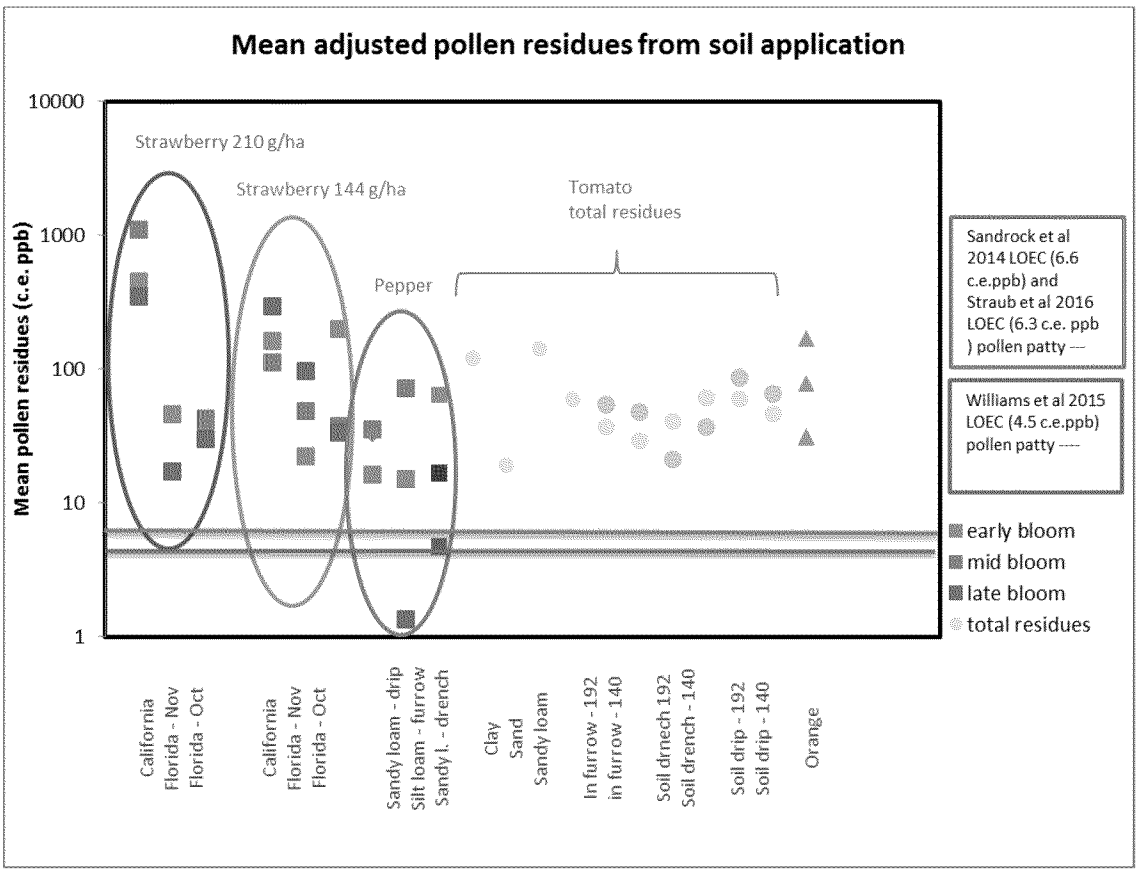

Figure 5. Mean clothianidin equivalents pollen residue levels (ppb) from soil applications to berries, fruiting vegetables and orange, plotted with endpoints from Straub et al., 2016, Sandrock et al., 2014 open literature colony study and Williams et al., 2015 queen open literature study. All scenarios produced residues that exceeded the effects endpoints.

<u>Risk assessment approach and residues:</u> Residues of clothianidin were high in both the pepper (PMRA 2600071) and tomato (PMRA 2769751 and 2365435) residue studies. Therefore, total residues were considered for both crops. Mean residues in the pepper study ranged from 76.2 to 237 ppb in pollen and 36.6 ppb in nectar; and pollen residues in the tomato study, ranged from 53 to 220 ppb. Overall, pollen and nectar residues in the pepper study, and pollen residues in the tomato study, exceeded all colony level endpoints for *Apis* and non-*Apis* bees.

At the current time, Health Canada has not incorporated a TU approach into the risk assessment (as explained above). The PMRA has followed the tiered risk assessment approach as outlined in the *North American Guidance for Assessing Pesticide Risks to Bee,* and compared residues to colony level endpoints.

Higher tier study results: Health Canada recognizes that there were limited effects from some of the Tier II semi-field studies, as noted in the summary. However, many of the studies also had limitations that led to difficulty in interpretation. A short summary of some of the limitations was presented in the Appendix of the PRVD2017-24. These uncertainties in the individual studies were considered in a weight of evidence approach in the overall risk assessment. Therefore, a lack of risk could not be concluded owing to study design limitations, and the results of the higher tier studies were in contrast to the Tier II refined assessments which determined potential risk, considering residues in plants and colony level endpoints for *Apis* and non-*Apis* bees. It is noted that the application rates in the residue studies ranged from 140 to 192 g a.i./ha, which overlaps with the study rates in the tunnel studies. In the tunnel studies, exposure to bees was not measured (in other words residues in pollen), which is another limitation in comparing the results of the tunnel study with the Tier II refined assessment.

In **PMRA 2365420**, tomato plants were treated at 148 to 168 g a.i./ha by soil application. Despite a lack of statistically significant effects, the control also had high mortality and thus a comparison was difficult to make. Despite the lack of statistical significance, when colonies were introduced 1 day in the tunnels after application, there were less pupae and larvae. Mortality was still high when hives were introduced 8 days after application.

In **PMRA 2364898**, tomato plants were treated with 150 g a.i./ha prior to colonies being introduced. There was high mortality in all hives including the control, and no eggs or larvae were present at study termination, which could have been the result of confinement. Therefore, it was difficult to compare to the control.

In **PMRA 2364997**, tomato plants were treated with 2 applications of 100 g a.i./ha. Hives were introduced at various time periods after application (2, 9, 14 or 21 days). No effects were observed on sugar consumption, mortality or brood development. Pollination activity was lower (for one day only) in the tunnel where bees were introduced close to the application (2 and 9 days after application).

Some uncertainties with the interpretation of the studies include that colonies in some studies were treated differently for the different assays (for example, some colonies were fed pollen before the test which may have diluted exposure); there were inconsistent approaches for brood observations, and in some instances the control hive performed poorly, which may indicate issues with the test design. The longer study length could have led to stress from confinement. Typically, replicates were low and exposure levels (residues in pollen and/or nectar) were not confirmed. Residues in studies conducted in the field may also be different from studies conducted under semi-field conditions.

Alarcon et al., (2005) exposed *Bombus terrestris* in a tunnel to tomato plants which were treated with thiamethoxam via drip irrigation in Spain (either 2 × 100 g a.i./ha or 1 × 200 g a.i./ha). No significant mortality effects were noted. Based on fruit set of the tomato plants, pollination rates were not affected regardless of treatment applied. No significant differences in sugar water

consumption was observed in the hives that were exposed to two drip applications of 100 g a.i./ha and inconsistent results were seen in the hives that were exposed to one drip application of 200 g a.i./ha. After 6 weeks of exposure, no significant effects were seen in any of the parameters tested; however numerically, effects were noted in both treatments which resulted in lower counts in the treated hives compared to the control. More pronounced effects were seen in the hives exposed to one drip application of 200 g a.i./ha compared to the two drip applications of 100 g a.i./ha each.

Some of the uncertainties included that the second hive introduction was carried out in the third month of the crop and therefore it was more difficult to differentiate between the effect of the treatments and the normal decline of hive activity. The pollination activity was very irregular due to a reduction in the flower set, and therefore the results are not as conclusive as for the first hive introductions. In the second introduction, the control hives performed worse than the reference toxicant imidacloprid hives.

Sechser et al., (2003) exposed *Bombus terrestris* in a tunnel to tomato plants which were treated with Actara 25WG via drip irrigation in Switzerland. Hives were exposed to one of three treatments; 2 applications of 161 g a.i./ha in a 450 m^2 greenhouse, 1 application of 150 g a.i./ha in a 2300 m^2 tunnel, or an untreated control (1800 m^2 tunnel). The results from the trial conducted in a greenhouse suggest that effects on adults, dead larvae and food storage and consumption in bumble bee hives exposed to drip irrigation could not be ruled out. Results from the tunnel trials suggest that effects on larvae and food consumption in bumble bee hives exposed to drip irrigation could also, not be ruled out. However, both of these trials had no replication and in the tunnels, there was evidence that the large hives out competed the small hives which affected the results. Some other uncertainties include that only 1 small and 1 large hive/treatment was tested in the tunnel with no replication. The control and treated tunnels were different sizes. Residue analysis on the pollen was not conducted to confirm the amount of active ingredient present after drip irrigation.

1.9.1.5 Curcurbit Soil Application-Thiamethoxam specific

The following comment was received requesting consideration of refinements to the risk assessment, and alternate mitigation. This information was considered by Health Canada.

Comment (Syngenta)

Consideration of refinements and alternate mitigation:

<u>Pollinator Exposure Potential:</u>

Cucurbits are pollinator attractive plants that require insect pollination to produce fruit. Pollen and nectar residue data from soil applications are highly variable with some crops, such as pumpkin and squash, expressing relatively low residue concentrations in pollen and nectar while others, such as muskmelon, express higher residue concentrations. If data for a specific crop indicate low relative exposure to bees, then these data should be considered for determining risk mitigation for that crop rather than selecting the worst-case crop (e.g., muskmelon) to represent the whole cucurbit crop group. For example, the majority of pumpkin pollen and nectar residues are less than 10 ppb particularly for the 140 g a.i./ha rate (Figure 6) which is relevant to the application rate for Canada.

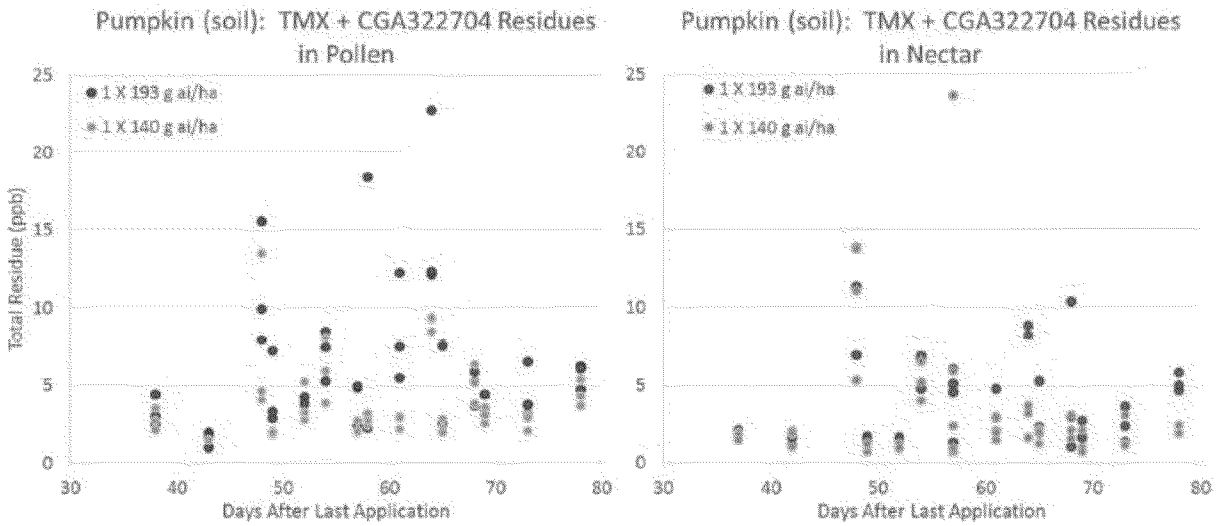

Figure 6. Total residues (thiamethoxam + CGA322704 (clothianidin)) in pollen and nectar after soil application to pumpkin.

Risk assessment approach and residues: *The data were then converted to Toxic Units using the honey bee NOAEC for clothianidin and thiamethoxam (20 ppb and 50 ppb, respectively). The pollen data were also converted to "nectar equivalents" by dividing the residue values by 5 as proposed by the Neonicotinoid Consortium. For non-Apis bees, the effect value of 10 ppb for both pollen and nectar was used. Results presented in Figure 7 indicate acceptable risk to honey bees with soil application to pumpkin (TU < 1).*

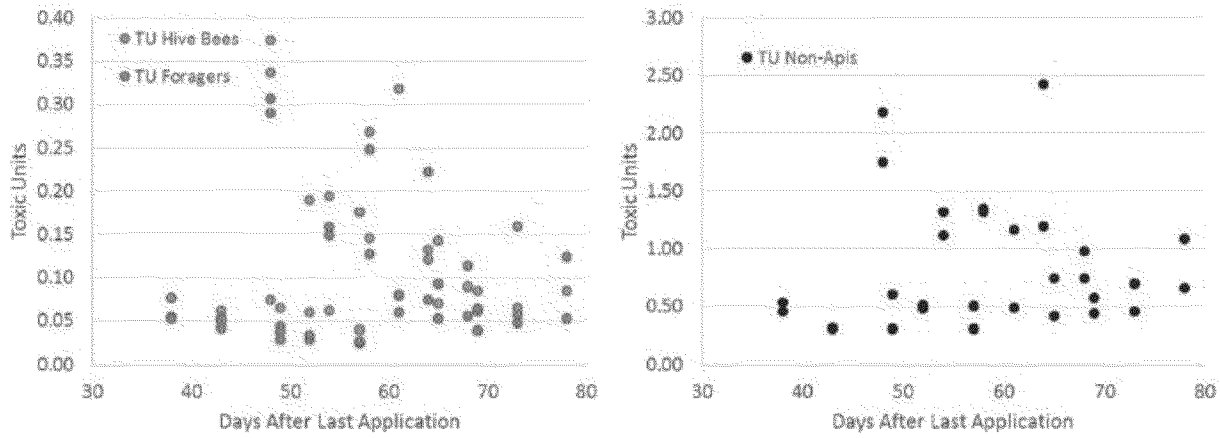

Figure 7. Toxic Units for Non-Apis Bees using Mean Residue Data (per sample event) for Pollen and Nectar after Soil Applications on Pumpkin (140 or 193 g a.i./ha)

Similar results were also observed for squash. Results presented in Figure 8 indicate acceptable risk to honey bees with soil application to squash (TU < 1).

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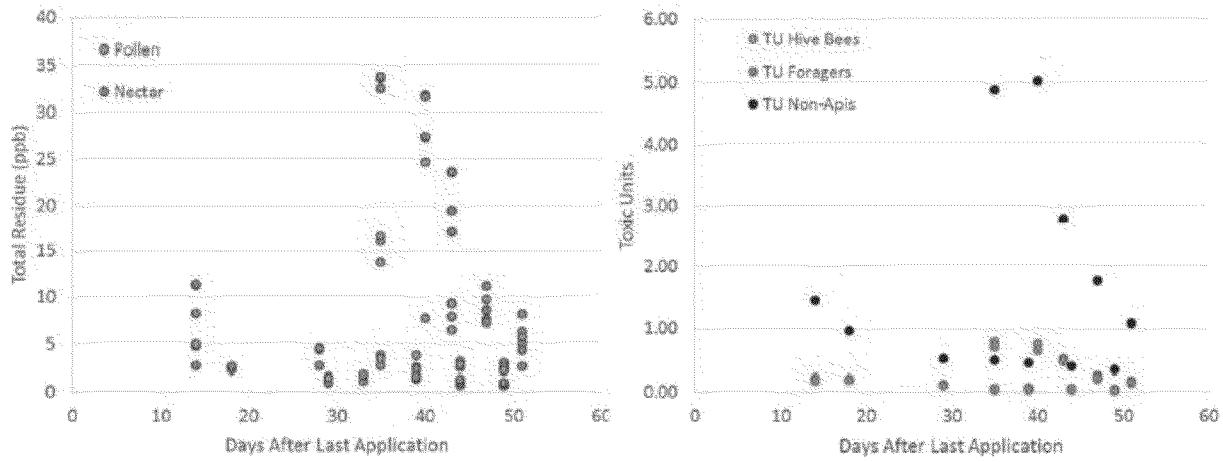

Figure 8. Total Residues (Thiamethoxam + CGA322704 (Clothianidin)) in Pollen and Nectar after Soil Application (193 g a.i./ha) to Squash and Converted to Toxic Units for Apis (Hive and Foragers) and Non-Apis Bees using Mean Residue Data (per sample event)

Health Canada Response

Risk assessment approach and residues: Health Canada recognizes that the data from soil application to cucurbits are variable. However, considering all of the data, and the potential for increased exposure to squash bees, all of the data was taken into consideration. Many of the pollen and nectar residues did exceed colony level endpoints as outlined in PRVD2017-24.

The following summaries are in response to studies in the registrant comment with additional details that were considered in the risk assessment:

Cucumber (PMRA 2459449): The highest mean pollen and nectar residues from pre bloom in-furrow application to cucumber were 4.84 and 7.70 c.e. ppb respectively. The lowest corresponding residues were 2.94 and 1.16 c.e. ppb, respectively.

Pumpkin (Dively and Kamel 2012): The highest mean pollen and nectar residues from pre bloom transplant water and drip irrigation application to pumpkin were 49.2 and 9.16 c.e. ppb respectively. The lowest corresponding residues were 21.2 and 8.13 c.e. ppb, respectively. It was noted that residues of thiamethoxam in 2009 were almost twice as high as 2010.

Pumpkin (PMRA 2770410): This pumpkin study was conducted at different rates and sampled at different times during bloom. The highest mean total (THE and COD) pollen and nectar residues from pre bloom drip irrigation application to pumpkin were 10 and 9.6 c.e. ppb respectively. These residues declined to 3.4 and 1.9 ppb, respectively, 21 days later. In the sand soil, there was less clothianidin formed; the highest mean pollen and nectar residues were 8.56 and 5.68 c.e. ppb, which did not occur on the first day of sampling. In this case, residues actually increased and then decreased again.

Melon (PMRA 2364975): The highest mean anther (no pollen available) and nectar residues from pre bloom granule application to melon were 2.57 and 3.19 c.e. ppb respectively. The lowest corresponding residues were 2.57 and 0.55 c.e. ppb, respectively. Residues declined between 35 and 51 days after application. It was noted that the lower application rate resulted in

the higher residues, and it is unclear how granule soil application relates to other types of soil applications such as in-furrow.

Summer squash (PMRA 2770410): This squash study was conducted at different sites and sampled at different times during bloom. The highest mean pollen and nectar residues from pre bloom drip irrigation were 16 and 27.3 c.e. ppb, respectively in the loamy sand soil. These residues did not occur on the first sampling date for pollen, but did for nectar. On the final sampling time, residues declined below 3.5 c.e. ppb. The lowest corresponding residues were 2.0 and 2.48 c.e. ppb, respectively, in the clay loam soil. Again, the pollen residues increased between the first and second sample, and then decreased over time.

Muskmelon (PMRA 2770410): This muskmelon study was conducted at different sites and sampled at different times during bloom. The highest mean pollen and nectar residues (THE and COD) from pre bloom drip irrigation were 310 and 29 c.e. ppb, respectively in the loamy sand soil. The highest residues of thiamethoxam and clothianidin both occurred at later sampling days. The lowest corresponding residues were 4.2 and 4.7 c.e. ppb, respectively, in the clay loam soil.

1.9.2 Post-bloom foliar applications-vegetables and fruits

A commenter agreed with removal of uses for foliar use on orchard trees, berries and ornamentals, but did not think that removal of pre-bloom and during-bloom applications only to some fruit and vegetable crops was an adequate mitigation measure.

> ***Comment (citizen)***
>
> *I applaud your approach to protect our pollinators by phase out of the following uses of thiamethoxam:*
>
> *• Foliar application to orchard trees, cane berries, bush berries and low growing berries*
>
> *• Foliar application to outdoor ornamentals*
>
> *Removing foliar applications to fruit or vegetables pre-bloom is not an aggressive enough risk mitigation. Being that thiamethoxam is a highly persistent and mobile chemical, applications post bloom will still result in routes of exposure to our managed and wild pollinators.*

Health Canada Response

The potential risk from post-bloom application was assessed for bee-attractive perennial crops, such as orchard crops and some berry crops. For those crops which are seasonal and the whole plant is harvested, the post-bloom assessment is not considered relevant as exposure to pollinators from foraging on the crop is not expected.

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. Following post-bloom applications, data also show that residues are present in the pollen and nectar of developing flowers the following season. Health Canada has proposed mitigation, including removal of uses, in cases where acceptable risk cannot be demonstrated.

The persistence and movement of the pesticide to result in other routes of exposure (off-field plants, water, etc.) was also considered. See discussion under Section 1.3.2 Off-field exposure: Uptake by field-margin plants.

1.9.3 Post-bloom foliar applications - orchard crops

The majority of public comments regarding foliar applications in orchard crops were value related. They highlighted the importance of post-bloom foliar applications of clothianidin and thiamethoxam in orchard crops for pest and resistance management of key pests and requested that Health Canada re-assess the decision to remove post-bloom applications in orchard crops. Several commenters proposed alternative mitigation, including reducing the number of post-bloom applications from 2 to 1 or maintaining 2 post-bloom applications and changing the application timing to early post-bloom.

Comment (British Columbia Ministry of Agriculture)

The data that was presented in the proposed re-evaluation document states that in a number of trials where the application were made post bloom, the hives were placed back into the orchard prior to the application. This is very unlikely to happen in an orchard as the growers rely on the pollinators to pollinate the crop so they will ensure that all hives are removed from the orchard prior to applications. All applications will only occur after petal fall as per label as the pollinators are out of the orchard at that time. It also states in the Risk Conclusion Summary that for trials on stone fruit and pome fruit that "Risk may be overstated". These statements are also in bold in the document that would indicate it should be considered and that the application made after petal fall is unlikely to be as harmful to the pollinators as these trials may indicate.

Clothianidin and thiamethoxam are 2 of only 3 chemistries that are registered for suppression of Brown Marmorated Stinkbug, an invasive species that has just been identified in the Okanagan Valley and the Lower Mainland of British Columbia. If clothianidin and thiamethoxam are not available to the growers in British Columbia these pests could cost millions of dollars to the agriculture industry in BC.

We believe that the application of Clothianidin should be allowed in pome fruit and stone fruit as a post petal fall application. For concerns with other pollinator attractants in the pathways between the trees a mitigation label statement could be added that states "ensure pathways have been mowed prior to application to remove any pollinator attractants, ie flowering plants".

Comment (Valent)

"Valent agrees with the PMRA conclusion in pages 296 and 297 of the PRVD2017-23, in that the potential for risk post-bloom via pollen exposure depends on application timing. Assuming that residues in pollen are from residues in soil remaining after a foliar application from the previous year, and in the light of available residue data, we also believe that increasing the time between the application and dormancy and reducing the maximum single application rate, will reduce systemic clothianidin residues in pollen the following year. Regrowth of, for example, new apple flower buds for the following year typically occurs in early August, depending on the region and variety. These buds will be the flower for the following year and their development does not stop during winter dormancy but continues through spring until bud breaks. Apple tree dormancy when leaf buds, shoots and flower buds stop growing, in some regions may start in December.

On this basis, we have re-evaluated our residue studies and conclude that there is sufficient data supporting that earlier post-bloom application timing (e.g. in June) in pome and stone fruits reduces the risks.

In the pome fruit (apple) residue study (PMRA #2571751) conducted by Valent in 2015 and 2016, one single post-bloom foliar application of 210 g a.i./ha (maximum annual application rate approved in

Canada) was made in late August and September, at 7 days before harvest (BBCH 85-89). About 219-248 days after the last application, resulted in a maximum average of 31.2 ppb (year 1), which is higher than the LOEC proposed by PMRA (i.e. <4.9 ppb) for pollen and bee bread. However, in the stone fruit (peach) residue study (PMRA #2571752) two post-bloom applications (10-14 days interval) of 112 g a.i./ha were made, in 2015 and 2016, in June and July, 21-40 days before harvest (first application BBCH 72-77, second application BBCH 74-81). While the July application, 248-250 days after the last application, resulted in a maximum average of clothianidin of 5.52 ppb (year 1), the June application, 277-281 days after last application, resulted in a maximum average of 2.05 ppb (year 2). This last value is lower than the LOEC proposed by PMRA (i.e. <4.9 ppb) for pollen and bee bread.

The timing of these growth stages is very weather dependent, and also variety dependent. We are estimating that an early post-bloom application at BBCH 71-76 will occur in Canada beginning to end of June. This application timing can be between 40 to ~90 days before harvest, depending on the variety. It could even be even longer for later varieties. The typical harvest dates for most of the apple varieties in Ontario will start from early-September to October (http://www.onapples.com/applevarieties.php).

On this basis, Valent Canada respectfully requests that further consideration is given to the PMRA proposal of phasing out the use of clothianidin in orchards, and propose changing the current use pattern for foliar uses on pome and stone fruits as follows:

• 2 × 105 g a.i./ha at 10-14 days intervals (respecting the current maximum season rate 210 g a.i./ha), in early post-bloom foliar applications (BBCH 71-76)."

Health Canada Response

In the case of the risk assessment for post-bloom applications in orchard crops, the exposure estimates were focussed on maximum and highest mean 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 apple, peach and almond for clothianidin and peach, plum and cherry for thiamethoxam. 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, queen production and 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.

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

In light of the comments and proposed changes to application timing, Health Canada has re-examined the available post-bloom application residue information to determine whether further

refinements can be made to the risk assessment. Updates to the environmental risk assessment for post-bloom foliar applications in orchard crops is presented in Section 1.1 of the Science Evaluation Updates for clothianidin and thiamethoxam.

1.9.4 Ornamental crops - Thiamethoxam specific

1.9.4.1 Comment 1

A commenter thought that mitigation to remove ornamental uses was too stringent, and that post-bloom application should be allowed.

> ***Comment (Canadian Nursery Landscape Association)- thiamethoxam specific***
>
> *Where pollinators could be at risk, the re-evaluation document makes reference to implementation of risk mitigation measures. It is unclear why these same measures could not be applied to ornamental horticultural crops. We recognize the potential risk to pollinators in some cases and would suggest that PMRA improve the label directions to limit to only post bloom timings for those impacted flowering plants. Effective timing for root weevils is in late summer/early fall when eggs have hatched and larvae are present. These kinds of mitigation strategies could then allow continued use of this product on pollinator attractive plants.*

Health Canada Response - Thiamethoxam specific

It should be noted that application in greenhouses to cut flowers (in other words, not planted outside after application), and plants that are non-attractive to pollinators such as coniferous evergreens and grasses, do not pose a risk to bees.

The label for "ornamentals" is not descriptive, and can therefore include woody perennials such as lilacs or flowering apple. There are both soil and foliar applications permitted on the label. Since some of the data on post-bloom foliar application to orchard crops (trees) results in potential risk from residues translocating into the next year's flowers, there may also be a potential risk for other types of flowering shrubs/trees, including ornamentals.

Considering new data submitted during the comment period, a potential for colony level risk to bees was identified based on high residues in pollen and/or nectar from soil application and pre-bloom foliar applications. Please see Section 1.1 Updates to the Environmental Risk Assessment, section on ornamentals of the thiamethoxam RVD for the updated risk assessment on ornamentals.

1.9.4.2 Comment 2

A commenter thought that mitigation for ornamentals in nurseries and sold in garden centers was too stringent because these plants are not typically pollinator attractive.

> ***Comment (Canadian Nursery Landscape Association) - thiamethoxam specific***
>
> *Most ornamental plants produced in nurseries and sold in garden centers are not attractive to flower visiting pollinators. In these situations there is no risk to pollinators with the use of this product. While this type of data is hard to find, a recent (2017) study from England showed that most flowering plants sold in garden centre are not attractive to flower visiting pollinators (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5344017/.*

Health Canada Response - Specific to thiamethoxam

Health Canada does consider attractiveness of plants/crops in the risk assessment, and considered crop attractiveness information specific to ornamentals found in Canada. There are many types of flowering ornamental plants that are sold in nurseries to which thiamethoxam could be applied (with both soil and foliar application), which have varying degrees of attractiveness to pollinators. Ornamentals that are not attractive to pollinators, such as coniferous evergreens and ornamental grasses, were excluded from the restrictions.

During the comment period, Health Canada also received thiamethoxam residue information for pollen and/or nectar from foliar and soil application of thiamethoxam to bee-attractive ornamental plants. These residues were compared to colony level endpoints for both honey bees and non-*Apis* bees. Please refer to Section 1.1 Updates to the Environmental Risk Assessment of the thiamethoxam RVD for this refined risk assessment for ornamental crops. This risk assessment showed that the residue levels in these plants reached levels that could potentially harm bee colonies.

1.9.5 Turf uses - Clothianidin specific

1.9.5.1 Removal of certain turf uses

A commenter disagreed with the proposed removal of clothianidin use on turf grass, and indicated that mitigation of mowing prior to foliar application would adequately reduce exposure and risk to bees while maintaining this turf use.

> ***Comment (Valent)- specific to clothianidin***
>
> *Larson et al. (2013)[6] exposed colonies of the bumble bee Bombus impatiens to turf with blooming white clover that had been treated with clothianidin at label rate and then lightly irrigated. Nectar from clover blooms directly contaminated by spray residues contained high levels of clothianidin residues. However, bee colonies confined on the treated turf after it had been mown to remove clover blooms present at the time of treatment, and new blooms had formed were not adversely impacted. This was confirmed in a second study (Larson, Redmond & Potter (2014)[7] in which the transference of imidacloprid or clothianidin into nectar of flowering lawn weeds (white clover) or grass guttation droplets was tested. Following application, clover blooms that were directly sprayed during application or that formed after the first mowing were analyzed for residues.*
>
> *These studies concluded that the hazard to non-target insects via nectar of flowering weeds in treated lawns can be mitigated by adhering to label precautions and mowing to remove blooms if they are inadvertently sprayed. Therefore, likewise for turf grown for sod and golf courses, negligible risk to bees is also expected for municipal, industrial and residential turf if sites are previously mowed. Therefore, Valent Canada respectfully requests that further consideration is given to the PMRA proposal of phasing out this use of clothianidin in turf, and propose changing the current conditions as follows:*
>
> *• Mow flowering plants prior to the foliar application of clothianidin.*

[6] Larson, J.L., C.T. Redmond, and D.A. Potter. 2013. Assessing Insecticide Hazard to Bumble Bees Foraging on Flowering Weeds in Treated Lawns. PLoS ONE, 8(6): e66375.

[7] Larson, J.L., C.T. Redmond, D.A. Potter (2015) Mowing mitigates bioactivity of neonicotinoid insecticides in nectar of flowering lawn weeds and turfgrass guttation. Environmental Toxicology and Chemistry, online publication 15 October 2014

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Health Canada Response – Specific to clothianidin

Health Canada considered the references cited by Valent in addition to other higher tier information in the risk assessment for turf. The information was considered insufficient to determine whether the proposed mitigation to mow flowering plants in turf prior to treatment will result in negligible risk to bees foraging on subsequent developing blooms. Larson, Redmond and Potter (2013) demonstrated that bumble bee colonies showed significantly reduced numbers of foragers, increased worker and brood mortality, fewer honey pots, slower growth and did not produce any new queens following one and two week exposure periods to treated turf containing flowering clover. In this case bumble bee colonies were placed in turf up to 2 days after treatment. In this study clothianidin residues on nectar from clover blooms were measured 6 days after application and resulted in residues of 171 ± 44 ppb. In contrast, there were no adverse colony level effects when bumble bee colonies were placed on turf one week after mowing of turf that had been treated 2 weeks prior to mowing (thus colonies were placed in turf three weeks after the initial treatment). Residue levels of clothianidin were not measured in this treatment scenario. In Larson Redmond and Potter (2015), mowing was shown to reduce clothianidin residues in nectar from clover blooms sampled at about 2 weeks after mowing. Nectar from directly sprayed clover contained 6041ng/g imidacloprid (range: 3281 to 7817) or 2937 ng/g clothianidin (range: 1883 to 4475) sampled immediately after application. The residues of both insecticides were reduced by more than 99.4% to less than 20 ng/g on average in nectar of clover blooms that formed 10-13 days after the turf was treated, irrigated and mowed; however, clothianidin residues in the clover nectar were still at a level that would indicate a potential effect to bees when compared to effect endpoints derived from sucrose based colony feeding studies. It is noted that residue levels of clothianidin in clover pollen were not investigated in either study for comparison with effect endpoints derived from pollen based colony feeding studies.

Considering the studies together, there is a time period up to 3 weeks after mowing where residue levels in subsequent blooms may result in a potential risk to bees. After mowing, clover can start to re-bloom almost immediately, resulting in exposure to bees. In the effects study, hives were placed in turf to forage on clover blooms one week after mowing without the need for supplemental feeding since blooms were abundant. Based on consideration of all study and residue information together, there is a potential risk to bees for a time period after treatment and mowing, and a proposal was made to remove the use of clothianidin in municipal, industrial and residential turf sites where clover or other flowering plants that are attractive to bees are present. No use restrictions were proposed for use of clothianidin in turf grown for sod and golf course as these sites are actively managed to remove flowering plants and therefore negligible risk to bees is expected in these turf sites.

1.9.5.2 Maintenance of certain turf uses

A commenter disagreed with the proposed maintenance of clothianidin use on golf courses and sod farms.

> ***Comment (City of Montréal):***
>
> *However, the City has some reservations about what uses will still be allowed in Canada, including foliar applications of clothianidin on golf courses. Indeed, it seems incoherent to prohibit foliar applications of clothianidin on all types of lawns except golf courses and sod farms.*

In its consultation document PRVD2017-23, the PMRA concludes that all foliar uses of clothianidin, as well as spray drift resulting from foliar uses, pose a risk to adult bees and larval bees following exposure, acute or chronic, to attractive crops for bees, namely potato, strawberry, cucurbits, grapes, orchard crops and some grassed areas. For turfgrass-only areas (sod farms and golf courses), the PMRA assumes that the risks to bees should be negligible and that bees would not be exposed to clothianidin due to regular maintenance. (mowing, chemical control) to remove weeds that bloom on golf courses. This assumption seems simplistic and does not take into account the diversity of ground cover on golf courses. Some parts of the land are composed mainly of grasses and are mowed regularly, but more grassy areas with flowers rub shoulders with them. Bees and pollinators may therefore be exposed to drift during foliar spraying of clothianidin. In addition, the assumption of the PMRA is based on the premise that weed management on golf courses is primarily based on chemical control. However, good IPM practices are more likely to use other control methods. As a result, golf courses applying best integrated pest management practices are likely to have greater biodiversity (both plant and animal) and the risk of pollinator exposure to these pesticides would be underestimated.

Health Canada Response – Specific to clothianidin

In the consultation document PRVD2017-23, Health Canada concluded that foliar uses of clothianidin on bee attractive crops including strawberry, cucurbit vegetables, orchard crops and certain turf sites pose a potential risk to bees. This risk conclusion was based on Tier I screening, Tier I refined, Tier II refined assessments with Canadian-relevant residue information and/or Tier II tunnel data and considering potential for high pollinator exposure in these crops. In addition based on a Tier I screening assessment, Health Canada concluded that spray drift from all foliar uses of clothianidin pose a risk to bees foraging off-site of treated crops. As a result of the risk assessment for foliar uses of clothianidin, Health Canada proposed mitigation measures to minimize potential exposure to bees, where necessary. Mitigation measures for foliar uses of clothianidin included reducing the number of pre-bloom applications to cucurbit vegetables, cancellation of pre-bloom applications to strawberry and cancellation of all foliar applications to orchard crops and municipal, residential and industrial turf grass sites. Current label mitigation to minimize potential exposure to bees from spray drift in habitats close to the application site is expected to minimize risk to bees off-field.

For turf sites containing grass species only (in other words, sod farms and golf courses), Health Canada understands that these sites receive routine maintenance such as regular mowing and/or chemical control to remove flowering plants and therefore negligible risk to bees is expected from foliar application of clothianidin in these sites. Health Canada also understands that some golf courses may use integrated pest management (IPM) to control pests in turf grass including cultural, chemical and biological control and that this may include the maintenance of adjacent habitat that is species rich in both plants and animals including beneficial arthropods such as predators and parasitoids of turf pests. Overall, Health Canada expects that all golf courses, including those that use IPM, will receive routine maintenance to remove flowering weeds, and the label mitigation to minimize spray drift in habitats next to the application site is expected to minimize risk from spray drift. Therefore, the overall risk conclusions, based on consideration of all information received during the consultation process, have not changed.

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1.9.6 Effectiveness of label statements

Commenters indicated concerns that label statements are not an effective mitigation strategy as the responsibility is on the end user to follow label directions.

Comment (David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment/Canadian Environmental Law Association):

The risk mitigation strategies proposed in PRVD2017-23 and PRVD2017-24, apart from the few uses that would be cancelled, rely on label statements to indicate restrictions on use. However, there is an important information gap in this approach. A recent literature review of studies published worldwide found critical gaps in knowledge regarding the efficacy of labelling for mitigating risks. While this review mainly included studies from developing countries and of migrant workers, it identified the lack of adequate data in the EU and elsewhere to assess efficacy of labelling.

Given our overriding concern that these pesticides should be removed from such widespread use in light of the serious environmental risks discussed herein, we are not confident that the PMRA has the capacity to either ensure compliance with proposed label changes or assess their effectiveness.

In the absence of our preferred approach of a full ban on these pesticides, we urge a robust, independent evaluation of the effectiveness of precautionary label statements on neonic pesticides within a Canadian context. Beyond these immediate concerns with the risks associated with neonics, such studies are more broadly necessary to ascertain with a high degree of confidence whether those applying pesticides and pesticide-treated seeds in Canada read, understand and follow label requirements aimed at reducing risk.

Comment (Fédération des apiculteurs du Québec) PRVD2017-24

Labeling statements are welcome, but they relieve the PMRA of its responsibility for tracking uses. These statements, by the PMRA's own admission, describe best management practices by users. In practice, labels are often applied to pallets containing several bags of treated seed but rarely on each of the bags. The labels do not follow the bags individually.

Comment (Fédération des apiculteurs du Québec) PRVD2017-23

Insufficient protection measures

The additional measures proposed by the PMRA, namely the addition of new label statements regarding its use, are clearly inadequate. By relying solely on labeling, the PMRA gives the impression of placing the burden of environmental protection on users.

Health Canada Response

The pesticide label contains legally-binding conditions of use, including mitigation measures that must be followed. It is the responsibility of the user to comply with label directions.

As stated in the *Pest Control Products Act*:

No person shall handle, store, transport, use or dispose of a pest control product in a way that is inconsistent with

a) The regulations; or

b) If the product is registered, the directions on the label recorded in the Register, subject to the regulations.

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As such, it is an offence under the *Pest Control Products Act* not to follow the label directions when using the product.

The PRVD2017-23 and PRVD2017-24 each outline in Appendix X Health Canada's risk assessment outcome and mitigation requirements (in other words conditions of registration), including label statements. The table in Appendix X in both documents is organized by crop group, and includes a detailed summary of the required label mitigation for the crop group, which may differ for some specific crops within the crop group. The required mitigation and label statements were based on the risk assessment conclusions for each use. Each type of use (foliar, soil application, seed treatments) has different exposure scenarios, which may result in different risks. Rates and timing of application affect the potential for risk. As well, the crops on which the product is used also have an effect on the potential for risk, as there are differences in pollinator exposure depending on attractiveness and agronomic practices associated with the crop. Based on the risk characterization, appropriate mitigation to reduce the potential for risk to pollinators was proposed for each crop group as outlined in Appendix X of the PRVD.

The required label mitigation is also outlined in Appendix III Label Amendments for End-Use Products Containing either Clothianidin or Thiamethoxam of the RVDs.

2.0 Comments Related to the Value Assessment

Comments related to value were received from: growers, grower groups, provincial governments, members of the public, non-profit organizations and registrants, including:

Apple Growers of Ontario, Association des Producteurs de Fraises et Framboises du Québec, British Columbia Ministry of Agriculture, Canadian Canola Growers Association, Canadian Nursery Landscape Association, Canadian Horticultural Council, Christian Farmers Federation of Ontario, The Cranberry Institute, Grain Growers of Canada, Les Producteurs de Pomme du Québec, Nova Scotia Fruit Growers, Ontario Tender Fruit Growers, Ontario Ministry of Agriculture, Food & Rural Affairs, Saskatchewan Ministry of Agriculture, David Suzuki Foundation/ Équiterre/ Environmental Defence/ Canadian Association of Physicians for the Environment (CAPE)/Canadian Environmental Law Association (CELA), Syngenta, and Union des Producteurs Agricoles.

2.1 Comment: Limited or no alternatives to thiamethoxam.

A number of stakeholders emphasized that for many of the registered uses of thiamethoxam there are few or no alternatives registered. In some cases where alternative products are registered, they may be more costly than, and/or not as effective as thiamethoxam. Where there are limited alternative chemistries available, the loss of thiamethoxam could present increased challenges with managing pest resistance, and negatively affect integrated pest management leading to major crop losses.

Health Canada Response

Health Canada acknowledges that there are no or limited alternative active ingredients registered for certain thiamethoxam uses or that certain alternatives may be more costly to apply than thiamethoxam. Health Canada also acknowledges the challenges in finding replacement products

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to thiamethoxam where there are limited or no alternatives. Health Canada encourages grower groups to contact the registrants of potential alternative products, Agriculture and AgriFood Canada (AAFC), and their provincial minor use coordinator to discuss the possibility of pursuing new registrations to address their crop-specific needs.

2.2 Comment: Loss of thiamethoxam will negatively affect the domestic and international competitiveness of Canadian producers.

In order to remain competitive growers need access to innovative and effective tools to manage weed, insect and disease problems that can threaten crops. Canadian farmers will become less competitive, and pay the price for the loss of these innovations.

Health Canada Response

Health Canada acknowledges the importance of producers being competitive in the domestic and international marketplace and recognizes the need for pest control products that are effective.

2.3 Comment: Value of uses that are proposed for cancellation.

The reviews of thiamethoxam and clothianidin have carefully considered the potential impact of exposure risks to pollinators from the various crops, application methods, and other secondary exposure risks these may create for pollinators. However, what have not been as carefully considered are the value of these extensive and various uses of thiamethoxam and clothianidin for all the different crops where they are currently used. It is not possible to weigh the value of clothianidin and thiamethoxam against the risk when the full value of these active ingredients has not been considered, especially where the most stringent restriction, removal of use, has been proposed.

Health Canada Response

Health Canada acknowledges the value of thiamethoxam to agricultural users. However, the primary mandate of Health Canada's PMRA is to prevent unacceptable risk to individuals and the environment from the use of pest control products. Health Canada does not weigh risk versus benefit. The *Pest Control Products Act* requires that the risks of the pesticides are acceptable in order to stay in the market. Health Canada encourages grower groups to contact the registrants of potential alternative products, AAFC, and their provincial minor use coordinator to discuss the possibility of pursuing new registrations to address their crop-specific needs.

2.4 Comment: The value of thiamethoxam is limited.

PRVD2017-23 and PRVD2017-24 refer to the value assessment of the use of neonicotinoid corn and soybean seed treatments, which Health Canada published for consultation in 2016. The published document, REV2016-03, *Value Assessment of Corn and Soybean Seed Treatment Use of Clothianidin, Imidacloprid and Thiamethoxam*, concludes that neonicotinoids add limited value to corn and soybean production in Canada. REV2016-03 also refers to the need to seek additional information to finalize the value assessment for both corn and soybean seed treatment. It appears the PMRA has not collected such information for either corn or soybeans or any of the

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many other crops for which seed treatments would be allowed under the proposed registration decisions in PRD2017-17 and PRD2017-18.

Research from around the world found that insect pest resistance to neonicotinoids is increasing, that economic benefits of seed treatments are limited or absent because, in many cases, pest populations are below levels that would cause significant damage, and that neonicotinoids cause adverse collateral effects on beneficial species, which undermines their overall value to agriculture. This research supports the fact that the systemic use of treated seeds in Canada can no longer be defended in value and risk assessments. The PMRA must revisit its value assessment for clothianidin and thiamethoxam seed treatments in light of the latest findings from the Task Force on Systemic Pesticides.

Health Canada Response

Comments submitted to Health Canada during the consultation period for REV2016-03 were reviewed and responses were published in PRVD2017-24 and PRVD2017-23. The comments provided through the consultation process did not change the conclusions in REV2016-03 that clothianidin and thiamethoxam seed treatments contribute to insect pest management in agriculture in Canada and complement current crop production practices such as use of reduced tillage or no-till for soybean and corn and earlier planting for corn and soybean.

Clothianidin and Thiamethoxam are effective in managing a wide variety of insect pests on many different crops. They can be applied by several application methods including soil, foliar and seed treatments to target the destructive life stage of the insect pest. For some uses, it is the only active ingredient registered to manage major pests.

3.0 Other Comments

3.1 Comments related to International Activities

- A comment was received from David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment (CAPE)/Canadian Environmental Law Association (CELA) that the PMRA should present a more complete overview of regulatory restrictions in other countries in PRVD2017-23 and PRVD2017-24 and Canada should match the leading standards for pollinator protection.

- Many comments were received regarding the international status of neonicotinoids; specifically, the European Union's decision to ban outdoor uses of three neonicotinoids.

Health Canada Response

Health Canada continues to monitor regulatory activities in other OECD countries related to pollinators and neonicotinoids. Health Canada assessments are based on internationally accepted risk assessment methods as well as current risk management approaches and policies. While Canada and other international regulators can be closely aligned in terms of the science assessment, differences in the final regulatory outcome (for example, cancellation of uses or type of restriction) can occur because of a variety of reasons, that can include differences in the assessed data, registered use patterns, timing of the evaluations, as well as any legislative and

policy requirements. The purpose of Health Canada's proposed re-evaluation decision documents is to outline the risk assessment and associated risk management of a pesticide, as it relates to the Canadian use pattern and regulatory framework. An overview of the international regulatory context is included in the document for information purposes only, and is as accurate as possible, acknowledging that international regulatory action can happen at any moment.

3.2 Comments relating to an immediate ban of neonicotinoids

- A comment was received from David Suzuki Foundation/Équiterre/Environmental Defence/Canadian Association of Physicians for the Environment (CAPE)/Canadian Environmental Law Association (CELA), in addition to many received from individuals, that the PMRA should immediately ban clothianidin and thiamethoxam uses/products without any further delay, as well as expressing an overall concern for pollinator health.

Health Canada Response

Health Canada acknowledges the comments requesting an immediate ban or cancellation of neonicotinoids, and also shares in the concern for pollinator health and agrees with the importance of pollinators to food production.

For the pollinator re-evaluation of clothianidin and thiamethoxam, Health Canada has concluded that continued registration of products containing these active ingredients is acceptable with required amendments; however, certain uses of clothianidin and thiamethoxam are cancelled to address potential risk of concern to pollinators. The overall exposure to pollinators will be significantly reduced through both removal of many uses that pose a risk to bees and through implementation of additional restrictions in application timing that will further reduce pollinator exposure. As stated earlier, a two year period to allow for the implementation of the additional risk mitigation measures required to protect pollinators is considered acceptable. The risks identified are not considered imminent because they are not expected to cause irreversible harm over the phase-out period.

The risks to pollinators are also acceptable for one additional year for uses having critical pest management needs (for example, the invasive brown marmorated stink bug, and certain weevils). During this period, the overall exposure to pollinators will be significantly reduced through both removal of uses to control other pests on these crops and other crops that pose a risk to bees, as well as through implementation of additional restrictions in application timing thereby further reducing pollinator exposure.

3.3 Comments relating to compliance

A comment was received from David Suzuki Foundation/Équiterre/Environmental Defence/ Canadian Association of Physicians for the Environment (CAPE)/Canadian Environmental Law Association (CELA).

- *The use of label modifications makes risk mitigation the responsibility of end users while the risk of non-compliance has far-reaching consequences. We appreciate that the PMRA has recently begun to report annually on its compliance and enforcement activities. While such efforts, and reporting on them, are laudable, the 2015-16 and 2016-17 Compliance and Enforcement Reports indicate how limited such inspection and enforcement efforts are at the farm level across a country as vast as Canada. Both the 2015-*

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16 and 2016-17 reports note that uses contrary to the label were among the most common areas of non-compliance. Both reports also note that compliance and enforcement activities have focused in areas of particularly high risk. While such an approach makes the best use of scarce resources, the consequence is an inspection capacity that is woefully inadequate to monitor compliance with label restrictions.

Given our overriding concern that these pesticides should be removed from such widespread use in light of the serious environmental risks discussed herein, we are not confident that the PMRA has the capacity to either ensure compliance with proposed label changes or assess their effectiveness.

Health Canada Response

Compliance with the *Pest Control Products Act* and its Regulations is monitored by Health Canada through its National Pesticide Compliance Program (NPCP). Health Canada inspectors verify the manufacture, possession, storage, handling, import, distribution and use of pest control products (pesticides). Annual compliance promotion and inspection priorities are determined by Health Canada after consultations with Provincial and Territorial partners to identify major compliance issues across the country. Previous inspection results, stakeholder concerns and changes in product registration status or use patterns are also considered. As inspections are risk-based, in some instances, when non-compliance is known or suspected, a targeted approach may be used. In other situations, random inspections are preferred.

As part of the verification of pesticide use, inspectors verify that approved pest control products are used according to label instructions. The labels of approved pest control products contain detailed information, including directions of use. Use outside of the instructions on the label is an offence under the *Pest Control Products Act*.

Inspections have found, as reported in the Compliance and Enforcement Annual Report (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports.html), some instances of use of registered pesticides contrary to label instructions. This is an area of concern, and when identified, the user is notified of the contravention under the *Pest Control Products Act* and the corrective action requested to be compliant. When non-compliance is identified, Health Canada applies an enforcement response, using a risk management approach that is consistent with the nature and severity of the contravention. Health Canada may also conduct a follow up surveillance inspection to determine if the user returns to compliance. The return to compliance rate under surveillance for all inspections over the past 4 years has been 79%.

Appendix III Label Amendments for Products Containing Thiamethoxam

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

I) The following changes must be made to the labels as identified in the tables.

Table 1 Label amendments for thaimethoxam products that contain applications made using foliar sprays

Crop **(Foliar applications)**	**CG1 Root and Tuber Vegetables:** **CG1B and C**	**CG4 Leafy Vegetables**	**From CG6: Legume Vegetables:** **Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)**	**CG8: Fruiting Vegetables** **and** **Greenhouse grown pepper**	**From CG11: Pome fruit:** **Apple, crabapple, pear, Oriental pear**	**From CG12: Stone fruit: Cherry**	**GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry**	**Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)**
Current Registered Label Statements and Restrictions for pollinators	**CG1: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 28407 28408 **Current Label Statements:** 28408, 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in*	**CG4: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 28408 **Current Label Statements:** 28408: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering*	**CG6: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 30404 **Current Label Statements:** 30404: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the*	**CG8: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 28408 30723 **Current Label Statements:** 28408, 30723: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and*	**CG11: Apple: Pre and post bloom; Pear: Post bloom. Not during bloom. Not when bees are visiting treatment area.** **Products:** 28408 **Current Label Statements:** 28408: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in*	**Cherry: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 28408 **Current Label Statements:** 28408: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering*	**CG13A,B,G: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 28408 **Current Label Statements:** 28408: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the*	**Ornamentals: No timing restrictions. Not when bees are visiting treatment area.** **Products:** 30901 30723 28408 **Current Label Statements:** 30901: Environmental Precautions: *Toxic to bees. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* ***DO NOT apply***

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site 28408, 28407: Use Directions-crop specific (potato): *This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply Actara 25WG Insecticide/Actara 240SC Insecticide or allow it to drift onto blooming crops or weeds if bees are visiting treated areas. After an Actara 25WG Insecticide application, wait at least 5 days before*	*crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site* 28408: Use Directions-crop specific (Leafy Vegetables CG4): *This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply Actara 25WG Insecticide or allow it to drift onto blooming crops or weeds if bees are foraging in/or adjacent to the treatment area. If bees are foraging in the ground cover and it contains any blooming plants or weeds, always remove flowers before making an application. This may be*	*treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.*	*weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site* 30723: Environmental Precautions: *Greenhouse uses: Toxic to bees and other beneficial insects. Avoid application when bees or other beneficial insects are actively visiting the treatment area. Residues in/on plants or soil may harm bees and other beneficial insects used in greenhouse production.* 28408: Use Directions-crop specific (Fruiting vegetable CG8; field pepper): *This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply Actara 25WG Insecticide or*	*leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site* 28408: Use Directions-crop specific (Apple, crabapple, pear, oriental pear): *Remarks: DO NOT apply Actara 25WG Insecticide During Bloom* *Pollinator Precautions: This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. [*Apple, crabapple*: Do not apply ACTARA 25WG Insecticide after pre-bloom (early pink growth stage) or before post bloom (petal fall*	*crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site* 28408: Use Directions-crop specific (Cherries, sweet and sour): *Pollinator Precautions: This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply Actara 25WG Insecticide or allow it to drift onto blooming crops or weeds if bees are foraging in/or adjacent to the treatment area. If bees are foraging in the orchard ground cover and it contains any blooming plants or weeds, always*	*treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site*	***this product during bloom or when bees are present.*** *Greenhouse Use: Toxic to bees and other beneficial insects. Avoid foliar application when bees or other beneficial insects are actively visiting the treatment area. This product is systemic and residues from soil may be transported through plants into leaves, pollen, and nectar. Residues in/on plants or soil may harm bees and other beneficial insects used in greenhouse production.* 30723, 28408: Environmental Hazards: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT*

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	placing the beehives in the treated field. 28408: Use Directions-crop specific (Root Vegetables CG1B and 1C; Celeriac): *This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply Actara 25WG Insecticide or allow it to drift onto blooming crops or weeds if bees are foraging in/or adjacent to the treatment area. If bees are foraging in the ground cover and it contains any blooming plants or weeds, always remove flowers before making an application. This may be accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. After an Actara 25WG Insecticide application, wait at least 5 days before*	*accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. After an Actara 25WG Insecticide application, wait at least 5 days before placing the beehives in the treated field.*		*allow it to drift onto blooming crops or weeds if bees are foraging in/or adjacent to the treatment area. If bees are foraging in the ground cover and it contains any blooming plants or weeds, always remove flowers before making an application. This may be accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. After an Actara 25WG Insecticide application, wait at least 5 days before placing the beehives in the treated field.*	*growth stage)] [Pear, Oriental pear: Do not apply ACTARA 25WG Insecticide before postbloom (petal fall).] Do not apply Actara 25WG Insecticide or allow it to drift onto blooming crops or weeds if bees are visiting the treated area. This is especially critical if there are adjacent orchards that are blooming (Refer to Recommendations to Avoid Spray Drift for additional information). If bees are foraging in the orchard ground cover and it contains any blooming plants or weeds, always remove flowers before making an application. This may be accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. This restriction does not apply to blooming crops (such as potatoes) that are not attractive to bees.*	*remove flowers before making an application. This may be accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. This restriction does not apply to blooming crops (such as potatoes) that are not attractive to bees. After an Actara 25WG Insecticide application, wait at least 5 days before placing the beehives in the treated field.*		*apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 30723: Environmental Hazards: *Greenhouse uses: Toxic to bees and other beneficial insects. Avoid foliar application when bees or other beneficial insects are actively visiting the treatment area. Residues in/on plants or soil may harm bees and other beneficial insects used in greenhouse production.* 30723, 28408: Use directions- crop specific (ornamentals: outdoor ornamentals; outdoor nurseries and landscape; viburnum in outdoor nurseries and landscape (30723 only)): *Pollinator Precautions: This product is highly toxic to bees exposed to direct treatment or to residues on blooming crops and weeds. Do not apply [FLAGSHIP]*

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	placing the beehives in the treated field.				*After an Actara 25WG Insecticide application, wait at least 5 days before placing the beehives in the treated field.*			*[ACTARA 25WG] Insecticide or allow it to drift onto blooming crops or weeds if bees are foraging in/or adjacent to the treatment area. If bees are foraging in the ground cover and it contains any blooming plants or weeds, always remove flowers before making an application. This may be accomplished by mowing, disking, mulching, flailing, or applying a labeled herbicide. After a [FLAGSHIP] [ACTARA 25WG] Insecticide application, wait at least 5 days before placing the beehives in the treated field.*
Risk Management & Label Amendments	**CG1 excluding Potato and Sweet Potato:** **Maintain use considering negligible exposure as harvested before bloom.** **No additional risk management.** **Label update:** **Add to the bee**	**Maintain use considering negligible exposure as harvested before bloom.** **No additional risk management.** **Label update:** **Add to the bee toxicity section under:** Environmental Hazards/	**Remove during-bloom and pre-bloom use based on potential for risk. Maintain post-bloom use as negligible risk.** **Add to the bee toxicity section under:** Environmental Hazards/ Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete*	**Outdoor fruiting vegetables: Remove during-bloom and pre-bloom use based on potential for risk. Maintain post-bloom use as negligible risk.** **Greenhouse grown pepper: No change** **Add to the bee toxicity section under:**	**Cancel use based on potential for risk.**	**Cancel use based on potential for risk.**	**Remove during-bloom and pre-bloom use based on potential for risk. Maintain post-bloom use based on low risk.** **For strawberry: Maintain post-bloom use based on low/moderate exposure.** **For woody berry plants: Maintain post-bloom use with renovation (cutting back old growth) after harvest, which will**	**Remove some uses based on potential for risk.** **Potential risk identified for greenhouse ornamentals that will be planted outdoors and are attractive to pollinators.** **Uses without pollinator exposure as identified below may**

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	toxicity section under: Environmental Hazards/ Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators). Follow crop specific directions for application timing.* **CG1 Potato and Sweet Potato only:** **Remove during-bloom use based on potential for risk. Maintain pre-bloom use considering low pollinator exposure. Maintain post-bloom use as negligible risk.**	Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators). Follow crop specific directions for application timing.*	*guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.gc.c a/ pollinators). Follow crop specific directions for application timing.* **Under:** Use Directions- crop specific (SOYBEANS; DRIED SHELLED BEANS (*Phaseolus* spp., *Lupinus* spp., *Vigna* spp., dry fava beans, dry lablab beans and chickpeas): **Add** (allows only post-bloom application): *Do not apply pre-bloom or during bloom (Do not apply until petal fall). Do not apply when bees are present.*	Environmental Hazards/ Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.g c.ca/pollinators). Follow crop specific directions for application timing.* **For outdoor uses on CG8 Fruiting Vegetables:** **Under:** Use Directions- crop specific (CG8: Fruiting Vegetables; field pepper): **Add** (allows only post-bloom application): *Do not apply pre-bloom or during bloom (Do not apply until petal fall). Do not apply when bees are present.* **For greenhouse uses on CG8 Fruiting**			**reduce exposure.** **Add to the bee toxicity section under:** Environmental Hazards/ Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/ pollinators). Follow crop specific directions for application timing.* **Under:** Use Directions- crop specific (Caneberries- Crop Sub Group 13-07A; Bushberries - Crop Group 13-07B; Low Growing Berries - Crop Group 13-07G): **Add**: *Do not apply pre-bloom or during bloom (Do not apply until petal fall). Do not apply when bees are present.* *When applying after petal fall, renovation of woody plants (cutting back old growth) must occur after harvest and before the next season's bloom.*	**be maintained.** Removal of use **does not include** the following ornamentals, as they would not result in pollinator exposure. **Coniferous evergreens – greenhouse or outdoor** (pine, fir, juniper, spruce, arborvitae, hemlock, cypress, yew,). (as they are not attractive to pollinators). **Greenhouse Uses: Cut flowers** (as they are not planted outside) **Ornamental grasses – greenhouse or outdoor** (as they are not attractive to pollinators) **Indoor potted plants**: Plants grown in greenhouses for indoor use only (e.g., potted plants maintained indoors) (as there would be no pollinator exposure since they are not planted outside).

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	Under: Use Directions- crop specific (potato and sweet potato): **Add** (allows pre-bloom and post-bloom application only): *Do not apply treatment between 50% row closure and petal fall. Do not make more than one application per year prior to 50% row closure.* **Add to the bee toxicity section under:** Environmental Hazards/ Environmental Precautions: *To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying- Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators*			**Vegetables (Greenhouse peppers): No change in timing of application** **Under:** Use Directions- crop specific (CG8: Fruiting Vegetables; Greenhouse peppers): **Add** (the same directions as under Environmental Hazards/ Environmental Precautions): *Greenhouse uses: Toxic to bees and other beneficial insects. Avoid application when bees or other beneficial insects are actively visiting the treatment area. Residues in/on plants or soil may harm bees and other beneficial insects used in greenhouse production.*				

Crop (Foliar applications)	CG1 Root and Tuber Vegetables: CG1B and C	CG4 Leafy Vegetables	From CG6: Legume Vegetables: Soybeans; Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans, chickpeas)	CG8: Fruiting Vegetables and Greenhouse grown pepper	From CG11: Pome fruit: Apple, crabapple, pear, Oriental pear	From CG12: Stone fruit: Cherry	GG13 Small fruit and berry: Subgroups A,B,G: caneberry, bushberry, , low growing berry	Ornamentals: (outdoor ornamentals; outdoor nurseries and landscapes; viburnum; greenhouse ornamentals)
	). Follow crop specific directions for application timing.							

Table 2 Label amendments for thaimethoxam products that contain applications made to the soil

Crop (Soil application)	CG1 Root and Tuber Vegetables: Potato only	CG4 Leafy Vegetables	CG5: Brassica Vegetables:	CG8: Fruiting Vegetables	CG9: Cucurbit Vegetables	GG13 Small fruit and berry: Subgroup G: low growing berry	Ornamentals: (greenhouse ornamentals)
Current Registered Label Statements and Restrictions for pollinators	**CG1 (potato only): Soil application at seeding, in-furrow.** **Products:** 28407 (potato) 30900 **Current Label Statements:** No specific use directions for potato soil treatment. 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To*	**CG4: Soil application at seeding or transplant.** **Products:** 28407 30900 **Current Label Statements:** 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT*	**CG5: Soil application at seeding or transplant.** **Products:** 28407 30900 **Current Label Statements:** 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT*	**CG8: Soil application at seeding or transplant.** **Products:** 28407 28408 30900 **Current Label Statements:** 28408, 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to*	**CG9: Soil application at seeding or transplant.** **Products:** 28407 30900 **Current Label Statements:** 28407: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT*	**CG13 G: Soil drench post renovation only (note: typically applied in spring, pre-bloom).** **Products:** 28408 **Current Label Statements:** 28408: Environmental Precautions: *Toxic to bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar*	**Greenhouse Ornamentals: Drench application indoor use only (no timing restriction)** **Products:** 30901 **Current Label Statements:** 30901: Environmental Precautions: *Toxic to bees. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. DO NOT apply this*

Crop (Soil application)	CG1 Root and Tuber Vegetables: Potato only	CG4 Leafy Vegetables	CG5: Brassica Vegetables:	CG8: Fruiting Vegetables	CG9: Cucurbit Vegetables	GG13 Small fruit and berry: Subgroup G: low growing berry	Ornamentals: (greenhouse ornamentals)
	minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site 30900: Environmental Precautions: *Toxic to bees. This product is systemic and bees can be exposed to product residues in flower, leaves, pollen and/or nectar resulting from soil applications.*	*apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 30900: Environmental Precautions: *Toxic to bees. This product is systemic and bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from soil applications.*	*apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 30900: Environmental Precautions: *Toxic to bees. This product is systemic and bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from soil applications.*	*bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 30900: Environmental Precautions: *Toxic to bees. This product is systemic and bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from soil applications.*	*apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 30900: Environmental Precautions: *Toxic to bees. This product is systemic and bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from soil applications.*	*application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.* 28408: Additional Use Direction- crop specific (low growing berry) for soil drench only: *Apply as a soil drench post renovation only.*	*product during bloom or when bees are present.* *Greenhouse Use: Toxic to bees and other beneficial insects. Avoid foliar application when bees or other beneficial insects are actively visiting the treatment area. This product is systemic and residues from soil may be transported through plants into leaves, pollen, and nectar. Residues in/on plants or soil may harm bees and other beneficial insects used in greenhouse production.*
Risk Management & Label Amendments	**Maintain use considering low pollinator exposure.** **No additional risk management.**	**Maintain use considering negligible pollinator exposure as harvested before bloom.** **No additional risk management.**	**Maintain use considering negligible pollinator exposure as harvested before bloom.** **No additional risk management.**	**Cancel use based on potential for risk.**	**Cancel use based on potential for risk.**	**Cancel use based on potential for risk.**	**Remove some uses based on potential for risk.** **Potential risk identified for greenhouse ornamentals that will be planted outdoors and are attractive to pollinators.** **Uses without pollinator exposure as identified below may be maintained.** **Coniferous evergreens** (pine, fir, juniper, spruce, arborvitae, hemlock,

Crop (Soil application)	CG1 Root and Tuber Vegetables: Potato only	CG4 Leafy Vegetables	CG5: Brassica Vegetables:	CG8: Fruiting Vegetables	CG9: Cucurbit Vegetables	GG13 Small fruit and berry: Subgroup G: low growing berry	Ornamentals: (greenhouse ornamentals)
							cypress, yew, live Christmas trees). (as they are not attractive to pollinators) **Cut flowers** (as they are not planted outside). **Ornamental grasses** (as they are not attractive to pollinators) **Indoor potted plants**: Plants grown in greenhouses for indoor use only (e.g., potted plants maintained indoors) (as there would be no pollinator exposure since they are not planted outside).

Table 3 Label amendments for thaimethoxam products that contain seed treatments

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
Current Registered Products; Label Statements and Restrictions for pollinators	**CG1 (potato only): Planting treated seed pieces.** **Products:** 28407 31024 **Current Label Statements:** 28407: Environmental Precautions: *Toxic to*	**CG1 (sugarbeet only): Planting treated seed.** **Products:** 27045 **Current Label Statements:** 27045 (label includes corn and soybean, therefore more extensive):	**CG6 Legume vegetables: Planting treated seed.** **Products:** 27045 27986 28821 30388 **Current Label Statements:**	**CG9 Cucurbit vegetables: Planting treated seed.** **Products:** 27045 **Current Label Statements:** 27045 (label includes corn and soybean, therefore more extensive): Environmental Precautions:	**CG15 Cereals grains: Planting treated seed.** **Products:** 27045 27986 29127 29192 30436 31453 **Current Label Statements:**	**CG20 Oilseeds (canola, rapeseed, mustard, sunflower only): Planting treated seed.** **Products:** 26637 27045 31454 **Current Label Statements:** 26637, 31454 Environmental Precautions: *Toxic to bees. Bees*

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
	bees. This product is systemic and residues from soil may be transported through plants into leaves, pollen and nectar. Bees may be exposed directly, through spray drift, or to residues on/in leaves, pollen and nectar in flowering crops and weeds. To minimize exposure to bees from foliar application, DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site 31024: Environmental Hazards: *Toxic to bees, beneficial arthropods and aquatic organisms. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.*	Environmental Precautions: *Thiamethoxam is toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid*	27045; 27986; 28821; 30388 (label includes corn and soybean, therefore more extensive): Environmental Precautions: *Thiamethoxam is toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed - Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting*	*Thiamethoxam is toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* Use Restrictions: *Additionally, all treated corn and soybean seed for sale or use in Canada must*	29127, 29192, 30436, 31453 (small grained cereals: barley, winter wheat, spring wheat, oats, rye, triticale, buckwheat, millet, sorghum): Environmental Precautions: *Toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* 27045, 27986 (label includes corn and soybean, therefore more extensive) (small grained cereals: wheat, barley, corn, rye, triticale, buckwheat, millet, sorghum): Environmental Precautions: *Thiamethoxam is toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use*	*can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* 27045 (label includes corn and soybean, therefore more extensive): Environmental Precautions: *Thiamethoxam is toxic to bees. Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* Use Restrictions: *Additionally, all treated corn and soybean*

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
		engaging the system where emitted dust may contact honey bee colonies. Use Restrictions: *Additionally, all treated corn and soybean seed for sale or use in Canada must be labeled with the following information: Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed - Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may*	*equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* Use Restrictions: *Additionally, all treated corn and soybean seed for sale or use in Canada must be labeled with the following information: Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed - Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean*	*be labeled with the following information: Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.*	*directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* Use Restrictions: *Additionally, all treated corn and soybean seed for sale or use in Canada must be labeled with the following information: Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators. To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators. When using a seed flow lubricant with this treated seed, only a dust reducing fluency agent is permitted. Talc and graphite are not permitted to be used as a seed flow lubricant for corn or soybean seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering*	*seed for sale or use in Canada must be labeled with the following information:* (similar to above)

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
		be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.	*seed treated with this insecticide. Carefully follow use directions for the seed flow lubricant. Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.*		*crops or weeds. When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.*	
Risk Management & Label Amendments	**Maintain use considering low pollinator exposure.** **No additional risk management.** **Label update:** May update label language to include the following[1]: Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to product residues in flowers, leaves, pollen*	**Maintain use considering negligible pollinator exposure as harvested before bloom.** **No additional risk management.** **Label update:** May update label language to include the following[1]: Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to*	**Maintain use based on risk characterization of low risk from pollen and nectar exposure route.** **Additional mitigation to reduce the potential for exposure to dust during planting of treated legume seeds.** **Additional label mitigation for legume seeds:** As some legume seeds may be dusty, propose addition of label statements to all containers of treated legume seeds instructing user to follow best management practices for planting of treated seed. Use restrictions:	**Maintain use based on risk characterization of low risk.** **No additional risk management.** **Label update:** May update label language to include the following[1]: Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.*	**Maintain use based on risk characterization of low risk from pollen and nectar exposure route.** **Additional mitigation to reduce the potential for exposure to dust during planting of treated cereal seeds.** **Additional label mitigation for cereal seeds:** As cereal seeds can be dusty, propose addition of label statements to all containers of treated cereal seeds instructing user to follow best management practices for planting of treated seed. Use restrictions: **Add:** Use restrictions (corn): No additions; Label statements are acceptable for	**Maintain use based on risk characterization of low risk.** **No additional risk management.** **Label update:** May update label language to include the following[1]: Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* ***When used according to label directions minimal exposure or risk is***

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
	and/or nectar resulting from seed treatment applications. ***When used according to label directions minimal exposure or risk is expected.***	*product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* ***When used according to label directions minimal exposure or risk is expected.***	**Add:** Use restrictions (soybean): No additions; Label statements are acceptable for soybean. Use restrictions (all other CG6 legume seeds excluding soybean): *Additionally, all treated CG 6 legume seed (excluding soybean) for sale or use in Canada must be labeled with the following information:* *Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators.* *To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed - Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators.* *Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops*	***When used according to label directions minimal exposure or risk is expected.***	corn. Use restrictions (all other CG15 cereal seeds excluding corn): *Additionally, all treated CG 15 cereal seed (excluding corn) for sale or use in Canada must be labeled with the following information:* *Thiamethoxam is toxic to bees. Dust generated during planting of treated seed may be harmful to bees and other pollinators.* *To help minimize the dust generated during planting, refer to the "Pollinator Protection and Responsible Use of Treated Seed- Best Management Practices" on the Health Canada webpage on pollinator protection at www.healthcanada.gc.ca/pollinators.* *Do not load or clean planting equipment near bee colonies, and avoid places where bees may be foraging, such as flowering crops or weeds.* *When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* *Spilled or exposed seeds and dust must be incorporated into the soil or cleaned up from the soil surface.* **Additionally, Label update:** May update label language to include the following[1]:	***expected.***

Crop	SEED TREATMENT From CG1 Root and Tuber Vegetables: Potato	SEED TREATMENT From CG1 Root and Tuber Vegetables: Sugar beet	SEED TREATMENT CG6 Legume vegetables	SEED TREATMENT CG9: Cucurbit Vegetables	SEED TREATMENT From CG15: Cereal grains: Barley, buckwheat, corn, millet, oat, rye, sorghum, triticale, wheat	SEED TREATMENT From CG20: Oilseeds: canola, rapeseed, mustard; importation of treated sunflower seeds
			or weeds. *When turning on the planter, avoid engaging the system where emitted dust may contact honey bee colonies.* *Spilled or exposed seeds and dust must be incorporated into the soil or cleaned up from the soil surface.* **Additionally, Label update:** May update label language to include the following[1]: Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* ***When used according to label directions minimal exposure or risk is expected.***		Environmental Precautions: **Add:** *When used according to label directions minimal exposure or risk is expected.* Example: Where states the following, the additional sentence may be added: *Bees can be exposed to product residues in flowers, leaves, pollen and/or nectar resulting from seed treatment applications.* ***When used according to label directions minimal exposure or risk is expected.***	

II) In order to allow for an additional year for uses that do not have alternatives, the following tables must be added to the front page of thiamethoxam labels for the specific end use products.

1. Reg. No. 28408, Actara 25 WG Insecticide

Crop	Pest	Last Date of Use
Apple, pear, crabapple, oriental pear	Brown marmorated stink bug	[date of decision + 3 years]
Bushberries (Crop Group 13-07B)	Brown marmorated stink bug, obscure root weevil	[date of decision + 3 years]
Low growing berries (Crop Group 13-07G) except lowbush blueberry and strawberry	Black vine weevil, cranberry weevil, strawberry root weevil	[date of decision + 3 years]
Outdoor nurseries and landscapes	Brown marmorated stink bug	[date of decision + 3 years]

2. Reg. No. 30723, Flagship Insecticide

Crop	Pest	Last Date of Use
Outdoor ornamentals	Black vine weevil	[date of decision + 3 years]
Outdoor nurseries and landscapes	Brown marmorated stink bug	[date of decision + 3 years]

3. Reg. No. 30901, Mainspring X Insecticide

Crop	Pest	Last Date of Use
Outdoor ornamentals	Black vine weevil	[date of decision + 3 years]

III) For all thiamethoxam end-use products listed in Appendix I, the following label amendments must be made:

- On all thiamethoxam labels, replace 'guarantee' with 'active ingredient.'
- On all thiamethoxam labels, replace 'control of certain insect pests' with 'control of listed insect pests.'
- As per Section 3.10 of Regulatory Directive DIR2016-02, *Notifications/Non-notifications*, remove any vague or non-specific claims that the product can be tank mixed with another pesticide (fungicide, insecticide or herbicide).
- As per Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site / Mode of Action*, verify that the resistance management statement on each end use product label is updated to reflect the wording in there.
- All locations where website of www.healthcanada.gc.ca/pollinators is found should be updated to www.canada.ca/pollinators.

Appendix IV Revised Environmental Assessment

Post-bloom orchard applications

Table 1a Foliar Application: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Thiamethoxam (ppb) and also clothianidin equivalents (c.e.) – separated by soil type and incorporating new data submitted following PRVD2017-24 [new risk assessment]

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Orchard crops											
Cherry Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 324, 304 and 314 DALA Y2: 321, 306 and 315 DALA Cherry is a registered crop. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only). Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate.	**Original risk assessment from PRVD2017-24**										**CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can apply anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 12: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* **CG 12: Pome fruit (apple and crabapple) (for post bloom)** *Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also*
	Thiamethoxam										
	Y1: 77.4 **Loamy sand** pollen from flowers Y2: 382 **Sandy loam** pollen from flowers	Y1: 1.54 **Loamy sand** nectar from flowers Y2: 2.03 **Loam** nectar from flowers	Y1: No (0.10) Y2: No (0.14)	Y1: No (0.22) **Y2: Yes (0.90)**	Y1: No (0.00) Y2: No (0.00)	Y1: 43.3 **Loamy sand** pollen from flowers Y2: 184 **Sandy loam** pollen from flowers	Y1: 0.74 **Loamy sand** nectar from flowers Y2: 0.88 **Loam** nectar from flowers	Y1: No (0.09) Y2: No (0.11)	Y1: No (0.21) Y2: No (0.77)	Y1: No (0.02) Y2: No 0.05)	
	Clothianidin equivalents										
	Y1: 66.3 pollen from flowers Y2: 327 pollen from	Y1: 1.32 nectar from flowers Y2: 1.74 nectar from	Y1: No (0.11) Y2: No (0.14)	Y1: No (0.22) **Y2: Yes (0.92)**	Y1: No (0.22) **Y2: Yes (0.77)**	Y1: 37.1 pollen from flowers Y2: 157 pollen from	Y1: 0.63 nectar from flowers Y2: 0.75	Y1: No (0.50) Y2: No (0.61)	**Y1: Yes (1.21)** **Y2: Yes (4.38)**	Y1: No (0.23) Y2: No (0.73)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Pre-bloom application timing scenario not represented for apple or cherry.	flowers	flowers				flowers	nectar from flowers				*registered for pre-bloom application at one application of 40-79 g a.i./ha.*
	Refined risk assessment for RVD (considering all soil types)										
	Thiamethoxam – Loam										
	Y1: 5.69 Y2: 14.25	Y1: 1.01 Y2: 2.03	Y1: No (0.07) Y2: No (0.13)	Y1: No (0.04) Y2: No (0.10)	Y1: No (0.00) Y2: No (0.00)	Y1: 5.59 Y2: 9.01	Y1: 0.46 Y2: 0.88	Y1: No (0.03) Y2: No (0.06)	Y1: No (0.03) Y2: No (0.05)	Y1: No (0.00) Y2: No (0.00)	
	Thiamethoxam – Sandy loam										
	Y1: 40.8 Y2: 382	Y1: <LOD Y2: <LOD	Y1: No (0.02) Y2: No (0.01)	Y1: No (0.10) **Y2: Yes (0.84)**	Y1: No (0.00) Y2: No (0.00)	Y1: 40.8 Y2: 184	Y1: <LOD Y2: <LOD	Y1: No (0.02) Y2: No (0.01)	Y1: No (0.10) Y2: No (0.72)	Y1: No (0.00) Y2: No (0.04)	
	Thiamethoxam – Loamy sand										
	Y1: 77.4 Y2: 329	Y1: 1.54 Y2: 0.27	Y1: No (0.10) Y2: No (0.02)	Y1: No (0.22) **Y2: Yes (0.73)**	Y1: No (0.00) Y2: No (0.00)	Y1: 43.3 Y2: 158	Y1: 0.74 Y2: 0.17	Y1: No (0.09) Y2: No (0.02)	Y1: No (0.21) Y2: No (0.35)	Y1: No (0.02) Y2: No (0.00)	
	Clothianidin equivalents – Loam										
	Y1: 4.87 Y2: 12.2	Y1: 0.86 Y2: 1.74	Y1: No (0.07) Y2: No (0.14)	Y1: No (0.05) Y2: No (0.10)	Y1: No (0.07) Y2: No (0.14)	Y1: 4.79 Y2: 7.71	Y1: 0.39 Y2: 0.75	Y1: No (0.31) Y2: No (0.60)	Y1: No (0.27) Y2: No (0.60)	Y1: No (0.07) Y2: No (0.13)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Clothianidin equivalents – Sandy loam										
	Y1: 34.9 Y2: 326	Y1: <LOD Y2: <LOD	Y1: No (0.02) Y2: No (0.00)	Y1: No (0.10) **Y2: Yes (0.85)**	Y1: No (0.09) **Y2: Yes (0.65)**	Y1: 34.9 Y2: 157.5	Y1: <LOD Y2: <LOD	Y1: No (0.04) Y2: No (0.00)	Y1: No (0.93) **Y2: Yes (4.11)**	Y1: No (0.15) Y2: No (0.63)	
	Clothianidin equivalents – Loamy sand										
	Y1: 66.3 Y2: 282	Y1: 1.32 Y2: 0.23	Y1 No (0.11) Y2: No (0.02)	Y1 No (0.22) **Y2: Yes (0.74)**	Y1 No (0.22) **Y2: Yes (0.58)**	Y1: 37.1 Y2: 135	Y1: 0.63 Y2: 0.15	Y1: No (0.50) Y2: No (0.13)	**Y1: Yes (1.21)** **Y2: Yes (3.58)**	Y1: No (0.23) Y2: No (0.56)	
Peach Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 297, 300 and 168 DALA Y2: 266, 284 and 249 DALA Other stone fruits (cherry) are registered. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only).	**Original risk assessment from PRVD2017-24**										**Potentially Relevant for Other Stone fruit labelled Crop(s):** **CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can apply anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 11: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)*
	Thiamethoxam										
	Y1: 58 **Sandy loam** pollen from flowers Y2: 167 **Sandy loam** pollen from flowers	Y1: <LOQ **Sandy loam** nectar from flowers Y2: 1.77 **Loam** nectar from flowers	Y1: No (0.03) Y2: No (0.12)	Y1: No (0.14) **Y2: Yes (0.42)**	Y1: No (0.00) Y2: No (0.00)	Y1: 34 **Sandy loam** pollen from flowers Y2: 108 **Sandy loam** pollen from flowers	Y1: <LOQ **Sandy loam** nectar from flowers Y2: 0.82 **Loam** nectar from flowers	Y1: No (0.0) Y2: No (0.10)	Y1: No (0.13) Y2: No (0.47)	Y1: No 0.01) Y2: No (0.03)	
	Clothianidin equivalents										
	Y1: 49.6 **Sandy loam** pollen from flowers	Y1: <LOQ **Sandy loam** nectar from flowers	Y1: No (0.04)	Y1: No (0.16)	Y1: No (0.13)	Y1: 29.1 **Sandy loam** pollen from flowers	Y1: <LOQ **Sandy loam** nectar from flowers	Y1: No (0.80)	**Y1: Yes (1.14)**	Y1: No (0.25)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate. Pre-bloom application timing scenario not represented for apple or cherry.	Y2: 143 **Sandy loam** pollen from flowers	Y2: 1.52 **Loam** nectar from flowers	Y2: No (0.16)	**Y2:** **Yes** **(0.43)**	Y2: No (0.39)	Y2: 92.5 **Sandy loam** pollen from flowers	Y2: 0.70 **Loam** nectar from flowers	Y2: No (0.57)	**Y2:** **Yes** **(2.68)**	Y2: No (0.46)	**CG 12: Pome fruit (apple and crabapple) (for post bloom)** *Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also registered for pre-bloom application at one application of 40-79 g a.i./ha.* **Outdoor Ornamentals** *Registered at 2 × 75 g a.i./ha, at 14 day intervals (maximum seasonal rate of 150 g a.i./ha)*
	Refined risk assessment for RVD (considering all soil types)										
	Thiamethoxam – Clay loam										
	Y1: 1.96 Y2: 64.5	Y1: <LOQ Y2: <LOD	Y1: No (0.02) Y2: No (0.02)	Y1: No (0.01) Y2: No (0.15)	Y1: No (0.00) Y2: No (0.00)	Y1: 1.32 Y2: 46.2	Y1: <LOD Y2: <LOD	Y1: No (0.03) Y2: No (0.03)	Y1: No (0.02) Y2: No (0.20)	Y1: No (0.00) Y2: No (0.01)	
	Thiamethoxam – Loam										
	Y1: 20 Y2: 90	Y1: <LOD Y2: 1.77	Y1: No (0.02) Y2: No (0.02)	Y1: No (0.05) Y2: No (0.20)	Y1: No (0.00) Y2: No (0.00)	Y1: 7.7 Y2: 72.5	Y1: <LOD Y2: 0.82	Y1: No (0.03) Y2: No (0.10)	Y1: No (0.04) Y2: No (0.33)	Y1: No (0.00) Y2: No (0.02)	
	Thiamethoxam – Sandy loam										
	Y1: 58 pollen from flowers Y2: 167 pollen from flowers	Y1: <LOQ nectar from flowers Y2: 1.11 nectar from flowers	Y1: No (0.03) Y2: No (0.08)	Y1: No (0.14) **Y2:** **Yes** **(0.40)**	Y1: No (0.00) Y2: No (0.00)	Y1: 34 pollen from flowers Y2: 108 pollen from flowers	Y1: <LOQ nectar from flowers Y2: 0.5 nectar from flowers	Y1: No (0.0) Y2: No (0.14)	Y1: No (0.13) Y2: No (0.72)	Y1: No 0.01) Y2: No (0.05)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Clothianidin equivalents – Clay loam										
	Y1: 1.68 Y2: 55.2	Y1: <LOQ Y2: <LOD	Y1: No (0.02) Y2: No (0.02)	Y1: No (0.01) Y2: No (0.15)	Y1: No (0.02) Y2: No (0.13)	Y1: 1.13 Y2: 39.5	Y1: <LOD Y2: <LOD	Y1: No (0.20 Y2: No (0.20)	Y1: No (0.12) **Y2: Yes (1.13)**	Y1: No (0.04) Y2: No (0.19)	
	Clothianidin equivalents – Loam										
	Y1: 17.2 Y2: 77	Y1: <LOD Y2: 1.52	Y1: No (0.02) Y2: No (0.12)	Y1: No (0.05) Y2: No (0.26)	Y1: No (0.05) Y2: No (0.26)	Y1: 6.59 Y2: 62.1	Y1: <LOD Y2: 0.70	Y1: No (0.20) Y2: No (0.56)	Y1: No (0.27) **Y2: Yes (1.89)**	Y1: No (0.06) Y2: No (0.34)	
	Clothianidin equivalents – Sandy loam										
	Y1: 49.6 pollen from flowers Y2: 143 pollen from flowers	Y1: <LOQ nectar from flowers Y2: 0.95 nectar from flowers	Y1: No (0.04) Y2: No (0.08)	Y1: No (0.16) **Y2: Yes (0.41)**	Y1: No (0.13) Y2: No (0.35)	Y1: 29.1 pollen from flowers Y2: 92.5 pollen from flowers	Y1: <LOQ nectar from flowers Y2: 0.43 nectar from flowers	Y1: No (0.80) Y2: No (0.35)	**Y1: Yes (1.14)** **Y2: Yes (2.58)**	Y1: No (0.25) Y2: No (0.43)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Plum Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 268, 287 and 286/195 DALA Y2: 234 and 231 DALA Other stone fruits (cherry) are registered. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only). Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate. Pre-bloom application timing scenario not represented for apple or cherry.	**Original risk assessment from PRVD2017-24**										**Potentially Relevant for Other Stone fruit labelled Crop(s):** **CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can be applied anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 12: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* **CG 12: Pome fruit (apple and crabapple) (for post bloom)** *Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also registered for pre-bloom application at one application of 40-79 g a.i./ha.*
	Thiamethoxam										
	Y1: **Sandy loam** 182 pollen from flowers Y2: **Clay loam** 45.7 pollen from flowers	Y1: **Sandy loam** 6.31 nectar from flowers Y2: **Clay loam** 0.5 nectar from flowers	**Y1:** **Yes** **(0.42)** Y2: No (0.03)	**Y1:** **Yes** **(0.60)** Y2: No (0.12)	Y1: No (0.00) Y2: No (0.00)	Y1: **Sandy loam** 110 pollen from flowers Y2: **Clay loam** 26.2 pollen from flowers	Y1: **Sandy loam** 2.81 nectar from flowers Y2: **Clay loam** 0.34 nectar from flowers	Y1: No (0.34) Y2: No (0.04)	Y1: No (0.59) Y2: No (0.12)	Y1: No (0.05) Y2: No (0.01)	
	Clothianidin equivalents										
	Y1: 156 **Sandy loam** pollen from flowers Y2: 39.1 **Clay loam** pollen from flowers	Y1: 5.40 **Sandy loam** nectar from flowers Y2: 0.428 **Clay loam** nectar from flowers	**Y1:** **Yes** **(0.43)** Y2: No (0.10)	**Y1:** **Yes** **(0.61)** Y2: No (0.12)	**Y1:** **Yes** **(0.67)** Y2: No (0.11)	Y1: 94.2 **Sandy loam** pollen from flowers Y2: 22.4 **Clay loam** pollen from flowers	Y1: 2.41 **Sandy loam** nectar from flowers Y2: 0.29 **Clay loam** nectar from flowers	**Y1:** **Yes** **(1.92)** Y2: No (0.23)	**Y1:** **Yes** **(3.37)** Y2: No (0.69)	Y1: No (0.70) Y2: No (0.13)	
	Refined risk assessment for RVD (considering all soil types)										
	Thiamethoxam – Clay loam										
	Y1: 11.6 Y2: 45.7 pollen from flowers	Y1: <LOD Y2: 0.428 nectar from flowers	Y1: No (0.02) Y2: No (0.10)	Y1: No (0.03) Y2: No (0.12)	Y1: No (0.00) Y2: No (0.11)	Y1: 6.25 Y2: 22.4 pollen from flowers	Y1: <LOD Y2: 0.29 nectar from flowers	Y1: No (0.03) Y2: No (0.23)	Y1: No (0.04) Y2: No (0.69)	Y1: No (0.00) Y2: No (0.13)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Thiamethoxam – Loam										
	Y1: 51.6 Y2: 9.9	Y1: <LOD Y2: <LOD	Y1: No (0.02) Y2: No (0.02)	Y1: No (0.12) Y2: No (0.03)	Y1: No (0.00) Y2: No (0.00)	Y1: 31.4 Y2: 6.68	Y1: <LOD Y2: <LOD	Y1: No (0.03) Y2: No (0.03)	Y1: No (0.14) Y2: No (0.04)	Y1: No (0.00) Y2: No (0.00)	
	Thiamethoxam – Sandy loam										
	Y1: 182 pollen from flowers	Y1: 6.31 nectar from flowers	**Y1: Yes (0.42)**	**Y1: Yes (0.60)**	Y1: No (0.00)	Y1: 110 pollen from flowers	Y1: 2.81 nectar from flowers	Y1: No (0.34)	Y1: No (0.59)	Y1: No (0.05)	
	Updated from PMRA 2821252 **Sandy loam** Y2: 59.31	Updated from PMRA 2821252 **Sandy loam** Y2: 2.38	Y2: No (0.02)	Y2: No (0.03)	Y2: No (0.00)	Updated from PMRA 2821252 **Sandy loam** Y2: 42.1	Updated from PMRA 2821252 **Sandy loam** Y2: 1.25	Y2: No (0.15)	Y2: No (0.24)	Y2: No (0.02)	
	Clothianidin equivalents – Clay loam										
	Y1: 9.9 Y2: 39.1 pollen from flowers	Y1: <LOD Y2: 0.428 nectar from flowers	Y1: No (0.02) Y2: No (0.10)	Y1: No (0.04) Y2: No (0.12)	Y1: No (0.04) Y2: No (0.11)	Y1: 5.35 Y2: 22.4 pollen from flowers	Y1: <LOD Y2: 0.29 nectar from flowers	Y1: No (0.20) Y2: No (0.23)	Y1: No (0.23) Y2: No (0.69)	Y1: No (0.05) Y2: No (0.13)	
	Clothianidin equivalents – Loam										
	Y1: 44.2	Y1: <LOD	Y1: No (0.02)	Y1: No (0.12)	Y1: No (0.11)	Y1: 26.9	Y1: <LOD	Y1: No (0.20)	Y1: No (0.80)	Y1: No (0.14)	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Y2: 8.47	Y2: <LOD	Y2: No (0.02)	Y2: No (0.03)	Y2: No (0.03)	Y2: 5.72	Y2: <LOD	Y2 : No (0.20)	Y2 : No (0.24)	Y2 : No (0.06)	
	Clothianidin equivalents – Sandy loam										
	Y1: 156 pollen from flowers	Y1: 5.40 nectar from flowers	**Y1: Yes (0.43)**	**Y1: Yes (0.61)**	**Y1: Yes (0.67)**	Y1: 94.2 pollen from flowers	Y1: 2.41 nectar from flowers	**Y1: Yes (1.92)**	**Y1: Yes (3.37)**	Y1: No (0.70)	
	Updated from PMRA 2821252 Y2: 50.8	Updated from PMRA 2821252 Y2: 2.04	Y2: No (0.16)	Y2: No (0.21)	Y2: No (0.24)	Updated from PMRA 2821252 Y2: 36	Updated from PMRA 2821252 Y2: 1.07	Y2: No (0.85	**Y2: Yes (1.35)**	Y2: No (0.29)	

CG = crop group, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, Y = year
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)
Bold values indicate that acute LOC (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
Blue shaded boxes indicate newly submitted trial results.
[1] Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0 × 106]
[2] Chronic RQ = Chronic estimated daily dose (EDD)/chronic toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total
Note, for thiamethoxam RA: adult acute oral **LD50 = 0.0044 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = 0.78 µg a.i./larva/day for TGAI**
Note, for thiamethoxam RA: adult chronic oral **NOED = 0.00245 µg a.i./bee for TGAI;** bee larvae chronic **22-day NOED = 0.0157 µg a.i./larva/day for TGAI**
Note, for clothianidin equivalents RA: adult acute oral **LD50 = 0.00368 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = >0.0018 µg a.i./larva/day**
Note, for clothianidin equivalents RA: adult chronic **NOED = 0.000368 µg a.i./bee/day;** bee larvae chronic **NOED = 0.0009 µg a.i./larva/day**
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856), and added to clothianidin in cases whereby clothianidin residues are high enough to contribute to the risk profile.
[2] Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ

Table 1b Foliar Application: Colony Level Risk to Apis and non-Apis bees Based on Mean Residues of clothianidin equivalents (c.e.) – separated by soil type and incorporating new data submitted following PRVD2017-24

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)			Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Considerations	Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Bee bread*	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)		
Orchard crops											
Cherry Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 324, 304 and 314 DALA Y2: 321, 306 and 315 DALA	Y1: 37.1 **Loamy sand** Y2: 157 **Sandy loam** **Sandy loam** Y1: 34.9 Y2: 157.5 **Loamy sand** Y1: 37.1 Y2: 135 **Loam** Y1: 4.79	Y1: 0.63 **Loamy sand** Y2: 0.75 **Loam** **Sandy loam** Y1: <LOD Y2: <LOD **Loamy sand** Y1: 0.63 Y2: 0.15 **Loam** Y1: 0.39	Range (Y1) 18.1 (Y2) 71.6	**Sandrock 2014⁺** **LOEC** **(6.6)** **Straub 2016⁺** **LOEC** **(6.3 ppb)** **Williams 2015⁺** **LOEC** **(4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	**Sandrock 2014** **LOEC** **(6.6)** **Straub 2016** **LOEC** **(6.3 ppb)** **Williams 2015** **LOEC** **(4.5)**	**Fauser-Misslin 2014⁺** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6)	**Fauser-Misslin 2014** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	Cherry is a registered crop. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only). Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate. Pre-bloom application timing scenario not represented for apple or cherry.	**CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can apply anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 12: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* **CG 12: Pome fruit (apple and crabapple) (for post bloom)** *Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also registered for pre-bloom application at one application of 40-79 g a.i./ha.*

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)			Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Considerations	Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Bee bread*	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)		
	Y2: 7.71	Y2: 0.75						Sandrock 2014+ LOEC (2.9) Moffat 2016 LOEC (2.14)			
Peach Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 297, 300 and 168 DALA Y2: 266, 284 and 249 DALA	Y1: 29.1 **Sandy loam** Y2: 92.5 **Sandy loam** **Clay loam** Y1: 1.13 Y2: 39.5 **Loam** Y1: 6.59 Y2: 62.1	Y1: <LOQ **Sandy loam** Y2: 0.70 **Loam** **Clay loam** Y1: <LOD Y2: <LOD **Loam** Y1: <LOD Y2: 0.70	Range (Y1) 13.6 (Y2) 42.8	**Sandrock 2014+ LOEC (6.6)** **Straub 2016+ LOEC (6.3 ppb)** **Williams 2015+ LOEC (4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	**Sandrock 2014 LOEC (6.6)** **Straub 2016 LOEC (6.3 ppb)** **Williams 2015 LOEC (4.5)**	**Fauser-Misslin 2014+ LOEC (4.9)** **Elston 2013 LOEC (8.56)**	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39)	**Fauser-Misslin 2014 LOEC (4.9)** **Elston 2013 LOEC (8.56)**	Peach is not a registered crop, however stone fruits are registered. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only). Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate. Pre-bloom application timing scenario not represented for apple or cherry.	**Potentially Relevant for Other Stone fruit labelled Crop(s):** **CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can apply anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 11: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* **CG 12: Pome fruit (apple and crabapple) (for post bloom)** *Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also*

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)			Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Considerations	Residue Data is Related to Registered Crop Group
	Pollen	**Nectar**	**Bee bread***	**Pollen (ppb)**	**Nectar (ppb)**	**Bee bread (ppb)**	**Pollen (ppb)**	**Nectar (ppb)**	**Bee bread (ppb)**		
	Sandy loam Y1: 29.1 Y2: 92.5	**Sandy loam** Y1: <LOQ Y2: 0.43						Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016 LOEC (2.14)			*registered for pre-bloom application at one application of 40-79 g a.i./ha.* **Outdoor Ornamentals** *Registered at 2 × 75 g a.i./ha, at 14 day intervals (maximum seasonal rate of 150 g a.i./ha)*
Plum Applied at 2 × 96 g a.i./ha, post-bloom 7 and 14 days before fruit harvest, Year 1 (Y1). Y1: 268, 287 and 286/195 DALA Y2: 234 and 231 DALA	Y1: 94.2 **Sandy loam** Y2: 22.4 **Clay loam**	Y1: 2.41 **Sandy loam** Y2: 0.29 **Clay loam**	Range (Y1) 45.3 (Y2) 11.7	**Sandrock 2014+** **LOEC** **(6.6)** **Straub 2016+** **LOEC** **(6.3 ppb)** **Williams 2015+** **LOEC** **(4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	**Sandrock 2014** **LOEC** **(6.6)** **Straub 2016** **LOEC** **(6.3 ppb)** **Williams 2015** **LOEC** **(4.5)**	**Fauser-Misslin 2014+** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** Laycock 2014	**Fauser-Misslin 2014** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	Plum is not a registered crop, however stonefruits are registered. Post bloom study application is consistent with application timing for pear and apple and cherry (for post bloom only). Single study rate is consistent with maximum post bloom pear and apple rate. Single study rate is higher than cherry rate. Pre-bloom application timing scenario not represented for apple or cherry.	**Potentially Relevant for Other Stone fruit labelled Crop(s):** **CG 12: Cherry (Stone fruit)(for post bloom)** *Registered at 2 × 40 g a.i./ha, at 7 day intervals (maximum seasonal rate 80 g a.i./ha) (can be applied anytime)* **Potentially Relevant for Other Labelled Crop(s):** **CG 12: Pome fruit (pear and oriental pear)** *Registered at 2 × 79-96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* **CG 12: Pome fruit (apple and**
	Clay loam Y1: 5.35 Y2: 22.4	**Clay loam** Y1: <LOD Y2: 0.29									
	Loam Y1: 26.9	**Loam** Y1: <LOD									

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)			Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.			Considerations	Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Bee bread*	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)	Pollen (ppb)	Nectar (ppb)	Bee bread (ppb)		
	Y2: 5.72	Y2: <LOD						NOEC (13.4) LOEC (39)			**crabapple) (for post bloom)**
	Sandy loam Y1: 94.2	**Sandy loam** Y1: 2.41						Mommaerts 2010 NOEC (85.6)			*Registered at 2 × 96 g a.i./ha, at 10 day intervals (maximum seasonal rate 192 g a.i./ha) (post-bloom)* *NOTE: pome fruit is also registered for pre-bloom application at one application of 40-79 g a.i./ha.*
								Sandrock 2014+ LOEC (2.9)			
								Moffat 2016 LOEC (2.14)			

CFS = colony feeding study, CG = crop group, CLO = clothianidin, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, TMX = thiamethoxam, Y = year

Bold values indicate that acute LOC (RQ ≥1.0) is exceeded.

NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)

NOTE: for thiamethoxam CFS from registrant, endpoints were also compared to thiamethoxam residues (see mean residues from Tier I refined level assessment)

***Bee bread is calculated based on molar adjusted thiamethoxam pollen and nectar. Not calculated for new residues.**

[2]Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ

+ These studies were conducted with both thiamethoxam and clothianidin

Foliar and soil ornamental applications

Table 2a Foliar and Soil Application: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Thiamethoxam (ppb) and also clothianidin equivalents (c.e.)

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Ornamental Foliar applications											
Herbaceous stargazer lily Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (5 DALA), mid bloom (10 DALA) and late bloom (15 DALA) – during BBCH 60-69 No control residues LOQ=0.5	NY **Early bloom** THE: 29.2 COD: 1.83 **Mid bloom** THE: 11.4 COD: 1.40 **Late bloom** THE: 45.1 COD: 4	NY **Early bloom** THE: 66.5 COD: 19 **Mid bloom** THE: 21.5 COD: 6.26 **Late bloom** THE: 93.5 COD: 26.7	**Early bloom** THE: **Yes** **4.41** **Mid bloom** THE: **Yes** **1.43** **Late bloom** THE: **Yes** **6.21**	**Early bloom** THE: **Yes** **2.18** **Mid bloom** THE: **Yes** **0.71** **Late bloom** THE: **Yes** **3.07**	**Early bloom** THE: No 0.01 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.01	NY **Early bloom** THE: 18 COD: 1.39 **Mid bloom** THE: 11.4 COD: 1.40 **Late bloom** THE: 32.6 COD: 2.9	NY **Early bloom** THE: 51 COD: 11.9 **Mid bloom** THE: 21.5 COD: 6.26 **Late bloom** THE: 70.6 COD: 15.6	**Early bloom** THE: **Yes** **6.08** **Mid bloom** THE: **Yes** **2.56** **Late bloom** THE: **Yes** **8.41**	**Early bloom** THE: **Yes** **2.98** **Mid bloom** THE: **Yes** **1.27** **Late bloom** THE: **Yes** **4.16**	**Early bloom** THE: No 0.39 **Mid bloom** THE: No 0.17 **Late bloom** THE: No 0.55	
	c.e. **Early bloom** THE: 25 Combined residues 26.8 **Mid bloom** THE: 9.76	c.e. **Early bloom** THE: 56.9 Combined residues 75.9 **Mid bloom** THE: 18.4	c.e. **Early bloom** Combined residues **Yes** **6.02** **Mid bloom** Combined residues **Yes** **1.96**	c.e. **Early bloom** Combined residues **Yes** **2.96** **Mid bloom** Combined residues **Yes** **0.97**	c.e. **Early bloom** Combined residues **Yes** **5.11** **Mid bloom** Combined residues **Yes** **1.67**	c.e. **Early bloom** THE: 15.4 Combined residues 16.8 **Mid bloom** THE: 9.76	c.e. **Early bloom** THE: 43.7 Combined residues 55.6 **Mid bloom** THE: 18.4	c.e. **Early bloom** Combined residues **Yes** **44.1** **Mid bloom** Combined residues **Yes** **19.6**	c.e. **Early bloom** Combined residues **Yes** **21.6** **Mid bloom** Combined residues **Yes** **9.69**	c.e. **Early bloom** Combined residues **Yes** **7.48** **Mid bloom** Combined residues **Yes** **3.34**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Combined residues 11.2 **Late bloom** THE: 38.6 Combined residues 42.6	Combined residues 24.7 **Late bloom** THE: 80 Combined residues 107	**Late bloom** Combined residues **Yes** **8.49**	**Late bloom** Combined residues **Yes** **4.18**	**Late bloom** Combined residues **Yes** **7.22**	Combined residues 11.1 **Late bloom** THE: 27.9 Combined residues 30.8	Combined residues 24.7 **Late bloom** THE: 60.4 Combined residues 76	**Late bloom** Combined residues **Yes** **60.3**	**Late bloom** Combined residues **Yes** **29.7**	**Late bloom** Combined residues **Yes** **10.3**	
	WI **Early bloom** THE: 7.06 COD: 1.22 **Mid bloom** THE: 9.68 COD: 1.03 **Late bloom** THE: 14 COD: 2.3	WI **Early bloom** THE: 8.27 COD: 1.08 **Mid bloom** THE: 6.67 COD: 2.0 **Late bloom** THE: 6.53 COD: 2.29	**Early bloom** THE: **Yes** **0.55** **Mid bloom** THE: **Yes** **0.44** **Late bloom** THE: **Yes** **0.43**	**Early bloom** THE: No 0.28 **Mid bloom** THE: No 0.23 **Late bloom** THE: No 0.24	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	WI **Early bloom** THE: 5.64 COD: 0.862 **Mid bloom** THE: 5.39 COD: 0.678 **Late bloom** THE: 9.9 COD: 1.35	WI **Early bloom** THE: 5.27 COD: 0.96 **Mid bloom** THE: 3.58 COD: 1.4 **Late bloom** THE: 3.44 COD: 1.18	**Early bloom** THE: No 0.63 **Mid bloom** THE: No 0.43 **Late bloom** THE: No 0.41	**Early bloom** THE: No 0.32 **Mid bloom** THE: No 0.23 **Late bloom** THE: No 0.24	**Early bloom** THE: No 0.04 **Mid bloom** THE: No 0.03 **Late bloom** THE: No 0.03	
	c.e. **Early bloom** THE: 6.04 Combined residues 7.26	c.e. **Early bloom** THE: 7.08 Combined residues 8.16	c.e. **Early bloom** Combined residues **Yes** **0.65** **Mid bloom** Combined	c.e. **Early bloom** Combined residues No 0.33 **Mid bloom** Combined	c.e. **Early bloom** Combined residues **Yes** **0.56** **Mid bloom** Combined	c.e. **Early bloom** THE: 4.83 Combined residues 5.69	c.e. **Early bloom** THE: 4.51 Combined residues	c.e. **Early bloom** Combined residues **Yes** **4.34** **Mid bloom** Combined	c.e. **Early bloom** Combined residues **Yes** **2.23** **Mid bloom** Combined	c.e. **Early bloom** Combined residues No 0.75 **Mid bloom** Combined	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Mid bloom THE: 8.29 Combined residues 9.32 **Late bloom** THE: 11.9 Combined residues 14.3	**Mid bloom** THE: 5.71 Combined residues 7.71 **Late bloom** THE: 5.59 Combined residues 7.88	residues **Yes** **0.61** **Late bloom** Combined residues **Yes** **0.63**	residues No 0.32 **Late bloom** Combined residues No 0.34	residues **Yes** **0.53** **Late bloom** Combined residues **Yes** **0.55**	**Mid bloom** THE: 4.61 Combined residues 5.29 **Late bloom** THE: 8.47 Combined residues 9.8	5.47 **Mid bloom** THE: 3.06 Combined residues 4.46 **Late bloom** THE: 2.94 Combined residues 4.12	residues **Yes** **3.54** **Late bloom** Combined residues **Yes** **3.27**	residues **Yes** **1.83** **Late bloom** Combined residues **Yes** **1.82**	residues No 0.62 **Late bloom** Combined residues No 0.59	
	OR **Early bloom** THE: 1.17 COD: LOQ (0.5) **Mid bloom** THE: 3.40 COD: LOQ (0.5) **Late bloom** THE: 5.21 COD: LOQ (0.5) c.e. **Early bloom**	OR **Early bloom** THE: 108 COD: 10.6 **Mid bloom** THE: 90 COD: 6.15 **Late bloom** THE: 34.2 COD: 6.19 c.e.	**Early bloom** THE: **Yes** **7.17** **Mid bloom** THE: **Yes** **5.97** **Late bloom** THE: **Yes** **2.27** c.e. **Early bloom**	**Early bloom** THE: **Yes** **3.44** **Mid bloom** THE: **Yes** **2.87** **Late bloom** THE: **Yes** **1.10** c.e. **Early bloom**	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.01 c.e. **Early bloom**	OR **Early bloom** THE: 0.723 COD: LOQ (0.5) **Mid bloom** THE: 3.23 COD: LOQ (0.5) **Late bloom** THE: 3.98 COD: LOQ (0.5) c.e.	OR **Early bloom** THE: 73.3 COD: 8.61 **Mid bloom** THE: 47.6 COD: 5.5 **Late bloom** THE: 27.4 COD: 5.17 c.e.	**Early bloom** THE: **Yes** **8.74** **Mid bloom** THE: **Yes** **5.67** **Late bloom** THE: **Yes** **3.27** c.e. **Early bloom**	**Early bloom** THE: **Yes** **4.19** **Mid bloom** THE: **Yes** **2.73** **Late bloom** THE: **Yes** **1.58** c.e. **Early bloom**	**Early bloom** THE: No 0.56 **Mid bloom** THE: No 0.36 **Late bloom** THE: No 0.21 c.e. **Early bloom**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	THE: 1.0 **Mid bloom** THE: 2.9 **Late bloom** THE: 4.46	**Early bloom** THE: 92.4 Combined residues 103 **Mid bloom** THE: 77 Combined residues 83.2 **Late bloom** THE: 29.3 Combined residues 35.5	Combined residues **Yes** **8.17** **Mid bloom** Combined residues **Yes** **6.60** **Late bloom** Combined residues **Yes** **2.82**	Combined residues **Yes** **3.92** **Mid bloom** Combined residues **Yes** **3.17** **Late bloom** Combined residues **Yes** **01.36**	Combined residues **Yes** **6.87** **Mid bloom** Combined residues **Yes** **5.55** **Late bloom** Combined residues **Yes** **2.38**	**Early bloom** THE: 0.619 **Mid bloom** THE: 2.76 **Late bloom** THE: 3.41	**Early bloom** THE: 62.7 Combined residues 71.4 **Mid bloom** THE: 40.7 Combined residues 46.2 **Late bloom** THE: 23.5 Combined residues 28.6	Combined residues **Yes** **56.7** **Mid bloom** Combined residues **Yes** **38.7** **Late bloom** Combined residues **Yes** **22.7**	Combined residues **Yes** **27.2** **Mid bloom** Combined residues **Yes** **17.7** **Late bloom** Combined residues **Yes** **10.9**	Combined residues **Yes** **9.5** **Mid bloom** Combined residues **Yes** **6.2** **Late bloom** Combined residues **Yes** **3.83**	
Lilac Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Oregon trial 3 did not have pollen samples Samples collected	NY **Early bloom** THE: 3391 COD: 225 **Mid bloom** THE: 709 COD: 86.3 **Late bloom** THE:	NY **Early bloom** THE: 1257 COD: 116 **Mid bloom** THE: 822 COD: 62.6 **Late bloom** THE:	**Early bloom** THE: **Yes** **83.5** **Mid bloom** THE: **Yes** **54.6** **Late bloom** THE: **Yes** **30.2**	**Early bloom** THE: **Yes** **47.4** **Mid bloom** THE: **Yes** **27.7** **Late bloom** THE: **Yes** **19.2**	**Early bloom** THE: No 0.21 **Mid bloom** THE: No 0.13 **Late bloom** THE: No 0.08	NY **Early bloom** THE: 1341 COD: 90.4 **Mid bloom** THE: 425 COD: 45.9 **Late bloom** THE:	NY **Early bloom** THE: 863 COD: 57.8 **Mid bloom** THE: 528 COD: 35.3 **Late bloom** THE: 380	**Early bloom** THE: **Yes** **103** **Mid bloom** THE: **Yes** **62.9** **Late bloom** THE: **Yes** **45.3**	**Early bloom** THE: **Yes** **54.5** **Mid bloom** THE: **Yes** **31.8** **Late bloom** THE: **Yes** **24.8**	**Early bloom** THE: **Yes** **6.9** **Mid bloom** THE: **Yes** **4.13** **Late bloom** THE: **Yes** **3.08**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
early bloom (F5), mid bloom (F6) and late bloom (F7) – during BBCH 60-69	2147 COD: 177 c.e. **Early bloom** THE: 2903 Combined residues 3127 **Mid bloom** THE: 607 Combined residues 693 **Late bloom** THE: 1838 Combined residues 2014	455 COD: 45 c.e. **Early bloom** THE: 1076 Combined residues 1192 **Mid bloom** THE: 704 Combined residues 766 **Late bloom** THE: 389 Combined residues 434	c.e. **Early bloom** Combined residues **Yes 94.6** **Mid bloom** Combined residues **Yes 60.8** **Late bloom** Combined residues **Yes 34.46**	c.e. **Early bloom** Combined residues **Yes 53.5** **Mid bloom** Combined residues **Yes 30.95** **Late bloom** Combined residues **Yes 21.8**	c.e. **Early bloom** Combined residues **Yes 85.7** **Mid bloom** Combined residues **Yes 52.5** **Late bloom** Combined residues **Yes 32.9**	776 COD: 68.9 c.e. **Early bloom** THE: 1148 Combined residues 1238 **Mid bloom** THE: 364 Combined residues 410 **Late bloom** THE: 664 Combined residues 733	COD: 31.1 c.e. **Early bloom** THE: 739 Combined residues 796 **Mid bloom** THE: 452 Combined residues 487 **Late bloom** THE: 325 Combined residues 356	c.e. **Early bloom** Combined residues **Yes 632** **Mid bloom** Combined residues **Yes 386** **Late bloom** Combined residues **Yes 283**	c.e. **Early bloom** Combined residues **Yes 335** **Mid bloom** Combined residues **Yes 196** **Late bloom** Combined residues **Yes 155**	c.e. **Early bloom** Combined residues **Yes 111** **Mid bloom** Combined residues **Yes 66.6** **Late bloom** Combined residues **Yes 50.4**	
	WI **Early bloom** THE: 765 COD: 57.5 **Mid bloom** THE: 251 COD:	WI **Early bloom** THE: 649 COD: 27.4 **Mid bloom** THE: 334 COD:	**Early bloom** THE: **Yes 43.1** **Mid bloom** THE: **Yes 22.2** **Late bloom**	**Early bloom** THE: **Yes 22.3** **Mid bloom** THE: **Yes 11.2** **Late bloom**	**Early bloom** THE: No 0.10 **Mid bloom** THE: No 0.05 **Late bloom**	WI **Early bloom** THE: 493 COD: 35.5 **Mid bloom** THE: 142 COD:	WI **Early bloom** THE: 449 COD: 24.4 **Mid bloom** THE: 290 COD: 17.3	**Early bloom** THE: **Yes 53.5** **Mid bloom** THE: **Yes 34.6** **Late bloom**	**Early bloom** THE: **Yes 27.6** **Mid bloom** THE: **Yes 17.1** **Late bloom**	**Early bloom** THE: **Yes 3.54** **Mid bloom** THE: **Yes 2.25** **Late bloom**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	36.2 **Late bloom** THE: 43.4 COD: 14.8	28 **Late bloom** THE: 221 COD: 9.83	THE: **Yes** **2.88**	THE: **Yes** **1.86**	THE: No 0.01	23.2 **Late bloom** THE: 37.8 COD: 12.6	**Late bloom** THE: 180 COD: 8.21	THE: **Yes** **21.5**	THE: **Yes** **10.4**	THE: **Yes** **1.38**	
	c.e. **Early bloom** THE: 655 Combined residues 712 **Mid bloom** THE: 215 Combined residues 251 **Late bloom** THE: 37.2 Combined residues 51.9	c.e. **Early bloom** THE: 555 Combined residues 583 **Mid bloom** THE: 286 Combined residues 314 **Late bloom** THE: 182 Combined residues 199	c.e. **Early bloom** Combined residues **Yes** **56.5** **Mid bloom** Combined residues **Yes** **24.9** **Late bloom** Combined residues **Yes** **15.8**	c.e. **Early bloom** Combined residues **Yes** **28.6** **Mid bloom** Combined residues **Yes** **12.6** **Late bloom** Combined residues **Yes** **7.71**	c.e. **Early bloom** Combined residues **Yes** **48.6** **Mid bloom** Combined residues **Yes** **21.4** **Late bloom** Combined residues **Yes** **13.4**	c.e. **Early bloom** THE: 422 Combined residues 458 **Mid bloom** THE: 122 Combined residues 145 **Late bloom** THE: 32.4 Combined residues 44.9	c.e. **Early bloom** THE: 384 Combined residues 409 **Mid bloom** THE: 248 Combined residues 264 **Late bloom** THE: 154 Combined residues 162	c.e. **Early bloom** Combined residues **Yes** **325** **Mid bloom** Combined residues **Yes** **209** **Late bloom** Combined residues **Yes** **129**	c.e. **Early bloom** Combined residues **Yes** **168** **Mid bloom** Combined residues **Yes** **104** **Late bloom** Combined residues **Yes** **62.8**	c.e. **Early bloom** Combined residues **Yes** **56.4** **Mid bloom** Combined residues **Yes** **35.8** **Late bloom** Combined residues **Yes** **21.8**	
	OR **Early bloom** THE: 189 *COD:* *79.1*	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.00	**Early bloom** No nectar input in calculation THE: **Yes** **0.41**	**Early bloom** No nectar input in calculation THE: No 0.00	OR **Early bloom** THE: 184 *COD:* *72.6*	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.00	**Early bloom** No nectar input in calculation THE: No 0.72	**Early bloom** No nectar input in calculation THE: No 0.04	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Mid bloom THE: 313 *COD:* *109* **Late bloom** THE: 115 *COD:* *112*		**Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	**Mid bloom** THE: **Yes** **0.68** **Late bloom** THE: No 0.25	**Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	**Mid bloom** THE: 225 *COD:* *94* **Late bloom** THE: 81 *COD:* *74.1*		**Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	**Mid bloom** THE: No 0.88 **Late bloom** THE: No 0.32	**Mid bloom** THE: No 0.05 **Late bloom** THE: No 0.02	
	c.e. **Early bloom** THE: 162 Combined residues *241* **Mid bloom** THE: 268 Combined residues *377* **Late bloom** THE: 98.4 Combined residues *210*		No nectar input in calculation c.e. **Early bloom** Combined residues No 0.00 **Mid bloom** Combined residues No 0.00 **Late bloom** Combined residues No 0.00	No nectar input in calculation c.e. **Early bloom** Combined residues **Yes** **0.63** **Mid bloom** Combined residues **Yes** **0.98** **Late bloom** Combined residues **Yes** **0.55**	No nectar input in calculation c.e. **Early bloom** Combined residues **Yes** **0.48** **Mid bloom** Combined residues **Yes** **0.75** **Late bloom** Combined residues **Yes** **0.42**	c.e. **Early bloom** THE: 157 Combined residues *230* **Mid bloom** THE: 193 Combined residues *287* **Late bloom** THE: 69 Combined residues *143*		No nectar input in calculation c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.03 **Late bloom** Combined residues No 0.02	No nectar input in calculation c.e. **Early bloom** Combined residues **Yes** **6.0** **Mid bloom** Combined residues **Yes** **7.49** **Late bloom** Combined residues **Yes** **3.73**	No nectar input in calculation c.e. **Early bloom** Combined residues No 0.92 **Mid bloom** Combined residues **Yes** **1.15** **Late bloom** Combined residues No 0.57	
Mock orange Pollen and nectar from plants	NY **Early bloom** THE: 550	NY **Early bloom** THE: 315	**Early bloom** THE: **Yes** **20.9**	**Early bloom** THE: **Yes** **11.2**	**Early bloom** THE: No 0.05	NY **Early bloom** THE: 443	NY **Early bloom** THE: 148	**Early bloom** THE: **Yes** **17.7**	**Early bloom** THE: **Yes** **10.2**	**Early bloom** THE: **Yes** **1.23**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (F5), mid bloom (F6) and late bloom (F7) – during BBCH 60-69	COD: 26.4 **Mid bloom** THE: 97.7 COD: 11.6 **Late bloom** THE: 109 COD: 12.7	COD: 44 **Mid bloom** THE: 59.5 *COD: 29* **Late bloom** THE: 87.6 COD: 37.5	**Mid bloom** THE: **Yes 3.95** **Late bloom** THE: **Yes 5.81**	**Mid bloom** THE: **Yes 2.11** **Late bloom** THE: **Yes 3.03**	**Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.01	COD: 16.9 **Mid bloom** THE: 77.1 COD: 8.57 **Late bloom** THE: 62.3 COD: 7.82	COD: 28.6 **Mid bloom** THE: 53.2 COD: 26.8 **Late bloom** THE: 49.6 COD: 24.8	**Mid bloom** THE: **Yes 6.34** **Late bloom** THE: **Yes 5.91**	**Mid bloom** THE: **Yes 3.34** **Late bloom** THE: **Yes 3.08**	**Mid bloom** THE: No 0.42 **Late bloom** THE: No 0.42	
	c.e. **Early bloom** THE: 471 Combined residues 497 **Mid bloom** THE: 83.6 Combined residues 95.2 **Late bloom** THE: 93.3 Combined residues 106	c.e. **Early bloom** THE: 269 Combined residues 314 **Mid bloom** THE: 50.9 Combined residues *79.9* **Late bloom** THE: 75 Combined residues 112	c.e. **Early bloom** Combined residues **Yes 24.9** **Mid bloom** Combined residues **Yes 6.34** **Late bloom** Combined residues **Yes 8.89**	c.e. **Early bloom** Combined residues **Yes 13.2** **Mid bloom** Combined residues **Yes 3.29** **Late bloom** Combined residues **Yes 4.54**	c.e. **Early bloom** Combined residues **Yes 21.9** **Mid bloom** Combined residues **Yes 5.52** **Late bloom** Combined residues **Yes 7.68**	c.e. **Early bloom** THE: 379 Combined residues 396 **Mid bloom** THE: 66 Combined residues 74.6 **Late bloom** THE: 53.3 Combined residues 61.1	c.e. **Early bloom** THE: 127 Combined residues 155 **Mid bloom** THE: 45.5 Combined residues 48.3 **Late bloom** THE: 42.5 Combined residues 67.3	c.e. **Early bloom** Combined residues **Yes 123** **Mid bloom** Combined residues **Yes 38.3** **Late bloom** Combined residues **Yes 53.4**	c.e. **Early bloom** Combined residues **Yes 69** **Mid bloom** Combined residues **Yes 20.3** **Late bloom** Combined residues **Yes 27.2**	c.e. **Early bloom** Combined residues **Yes 22.3** **Mid bloom** Combined residues **Yes 6.74** **Late bloom** Combined residues **Yes 9.22**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	WI **Early bloom** THE: 15.1 *COD:* *16.3* **Mid bloom** THE: 3.10 *COD:* *11.9* **Late bloom** THE: 8.15 COD: 12.7	WI **Early bloom** THE: 215 COD: 39 **Mid bloom** THE: 18.3 *COD:* *24.1* **Late bloom** THE: 26.6 *COD:* *26.1*	**Early bloom** THE: **Yes** **14.3** **Mid bloom** THE: No 0.21 **Late bloom** THE: **Yes** **1.77**	**Early bloom** THE: **Yes** **6.87** **Mid bloom** THE: No 0.14 **Late bloom** THE: **Yes** **0.86**	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	WI **Early bloom** THE: 11 *COD:* *13.1* **Mid bloom** THE: 2.51 *COD:* *6.68* **Late bloom** THE: 5.41 COD: 11	WI **Early bloom** THE: 119 COD: 32.7 **Mid bloom** THE: 16.3 *COD:* *18.9* **Late bloom** THE: 18 *COD:* *22.1*	**Early bloom** THE: **Yes** **14.2** **Mid bloom** THE: **Yes** **1.94** **Late bloom** THE: **Yes** **2.15**	**Early bloom** THE: **Yes** **6.84** **Mid bloom** THE: No 0.14 **Late bloom** THE: **Yes** **1.05**	**Early bloom** THE: No 0.91 **Mid bloom** THE: No 0.13 **Late bloom** THE: No 0.14	
	c.e. **Early bloom** THE: 12.9 Combined residues *29.2* **Mid bloom** THE: 2.65 Combined residues *14.6* **Late bloom** THE: 6.98 Combined	c.e. **Early bloom** THE: 184 Combined residues 223 **Mid bloom** THE: 15.7 Combined residues *39.8* **Late bloom** THE: 22.8 Combined	c.e. **Early bloom** Combined residues **Yes** **17.7** **Mid bloom** Combined residues **Yes** **3.16** **Late bloom** Combined residues **Yes** **3.88**	c.e. **Early bloom** Combined residues **Yes** **8.56** **Mid bloom** Combined residues **Yes** **1.55** **Late bloom** Combined residues **Yes** **1.91**	c.e. **Early bloom** Combined residues **Yes** **14.9** **Mid bloom** Combined residues **Yes** **2.68** **Late bloom** Combined residues **Yes** **3.3**	c.e. **Early bloom** THE: 9.42 Combined residues *22.5* **Mid bloom** THE: 2.15 Combined residues *8.83* **Late bloom** THE: 4.63 Combined	c.e. **Early bloom** THE: 102 Combined residues 135 **Mid bloom** THE: 13.9 Combined residues *32.8* **Late bloom** THE: 15.4 Combined	**Early bloom** THE: **Yes** **107** **Mid bloom** THE: **Yes** **26** **Late bloom** THE: **Yes** **30.6**	**Early bloom** THE: **Yes** **52.0** **Mid bloom** THE: **Yes** **12.7** **Late bloom** THE: **Yes** **15**	**Early bloom** THE: **Yes** **18.1** **Mid bloom** THE: **Yes** **4.41** **Late bloom** THE: **Yes** **5.2**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	residues 19.7	residues *48.9*				residues 15.6	residues *37.5*				
	OR **Early bloom** THE: 6.51 *COD:* *31.9* **Mid bloom** THE: 4.42 *COD:* *62.1* **Late bloom** THE: 11.1 *COD:* *556* c.e. **Early bloom** THE: 5.57 Combined residues *37.5* **Mid bloom** THE: 3.78 Combined residues *65.9*	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.0 **Mid bloom** THE: No 0.0 **Late bloom** THE: No 0.0 COD: No 0.01 No nectar input in calculation c.e. **Early bloom** Combined residues No 0.00 **Mid bloom** Combined residues No	**Early bloom** No nectar input in calculation THE: No 0.01 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.02 COD: **Yes** **1.21** No nectar input in calculation c.e. **Early bloom** Combined residues No 0.10 **Mid bloom** Combined residues No	**Early bloom** No nectar input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00 COD: No 0.00 No nectar input in calculation c.e. **Early bloom** Combined residues No 0.08 **Mid bloom** Combined residues No	OR **Early bloom** THE: 3.77 *COD:* *29* **Mid bloom** THE: 3.46 *COD:* *50.2* **Late bloom** THE: 8.54 *COD:* *297* c.e. **Early bloom** THE: 3.23 Combined residues *32.2* **Mid bloom**	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.0 COD: No 0.0 **Mid bloom** THE: No 0.0 COD: No 0.0 **Late bloom** THE: No 0.0 COD: No 0.00 No nectar input in calculation c.e. **Early bloom** Combined residues No 0.00	**Early bloom** No nectar input in calculation THE: No 0.01 COD: No 0.11 **Mid bloom** THE: No 0.01 COD: No 0.20 **Late bloom** THE: No 0.03 COD: **Yes** **1.16** No nectar input in calculation c.e. **Early bloom** Combined residues No 0.84	**Early bloom** No nectar input in calculation THE: No 0.00 COD: No 0.0 **Mid bloom** THE: No 0.00 COD: No 0.01 **Late bloom** THE: No 0.00 COD: No 0.07 No nectar input in calculation c.e. **Early bloom** Combined residues No 0.13	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Late bloom THE: 9.5 Combined residues *565*		0.00 **Late bloom** Combined residues No 0.01	0.17 **Late bloom** Combined residues **Yes** **1.47**	0.13 **Late bloom** Combined residues **Yes** **1.13**	THE: 2.96 Combined residues *53.2* **Late bloom** THE: 7.31 Combined residues *304*		**Mid bloom** Combined residues No 0.01 **Late bloom** Combined residues No 0.03	**Mid bloom** Combined residues **Yes** **1.39** **Late bloom** Combined residues **Yes** **7.93**	**Mid bloom** Combined residues No 0.21 **Late bloom** Combined residues **Yes** **1.22**	
Ornamental Soil applications											
Stargazer lily Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7) – during BBCH 60-69	NY **Early bloom** THE: 18 COD: 15.9 **Mid bloom** THE: 10.2 COD: 7.52 **Late bloom** THE: 23.8 COD: 18.6 c.e. **Early bloom** THE: 15.4	NY **Early bloom** THE: 6.63 COD: 1.57 **Mid bloom** THE: 3.02 COD: LOQ (0.5) **Late bloom** THE: 10.8 COD: 1.92 c.e. **Early bloom** THE: 5.67	**Early bloom** THE: **Yes** **0.44** **Mid bloom** THE: No 0.20 **Late bloom** THE: **Yes** **0.72** c.e. **Early bloom** Combined residues **Yes**	**Early bloom** THE: No 0.25 **Mid bloom** THE: No 0.12 **Late bloom** THE: No 0.40 c.e. **Early bloom** Combined residues No	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00 c.e. **Early bloom** Combined residues **Yes**	NY **Early bloom** THE: 10 COD: 7.2 **Mid bloom** THE: 8.10 COD: 6.17 **Late bloom** THE: 12.8 COD: 8.11 c.e. **Early bloom** THE: 8.56	NY **Early bloom** No 0.25 COD: 0.857 **Mid bloom** THE: 2.63 COD: LOQ (0.5) **Late bloom** THE: 5.41 COD: 0.973 c.e. **Early bloom** THE: 3.77	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.31 **Late bloom** THE: No 0.64 c.e. **Early bloom** Combined residues **Yes**	**Early bloom** THE: No 0.05 **Mid bloom** THE: No 0.18 **Late bloom** THE: No 0.36 c.e. **Early bloom** Combined residues **Yes**	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.02 **Late bloom** THE: No 0.04 c.e. **Early bloom** Combined residues No	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Combined residues 31.3 **Mid bloom** THE: 8.73 Combined residues 16.3 **Late bloom** THE: 20.4 Combined residues 38.9	Combined residues 7.24 **Mid bloom** THE: 2.58 **Late bloom** THE: 9.24 Combined residues 11.2	**0.57** **Mid bloom** Combined residues No 0.20 **Late bloom** Combined residues **Yes** **0.89**	0.36 **Mid bloom** Combined residues No 0.14 **Late bloom** Combined residues **Yes** **0.53**	**0.55** **Mid bloom** Combined residues No 0.20 **Late bloom** Combined residues **Yes** **0.82**	Combined residues 15.8 **Mid bloom** THE: 6.93 Combined residues 13 **Late bloom** THE: 10.9 Combined residues 19.1	Combined residues 4.63 **Mid bloom** THE: 2.25 **Late bloom** THE: 4.63 Combined residues 5.6	**3.68** **Mid bloom** Combined residues **Yes** **1.79** **Late bloom** Combined residues **Yes** **4.45**	**2.17** **Mid bloom** Combined residues **Yes** **1.20** **Late bloom** Combined residues **Yes** **2.63**	0.68 **Mid bloom** Combined residues No 0.35 **Late bloom** Combined residues No 0.82	
	WI **Early bloom** THE: LOQ (0.25) COD: 4.24 **Mid bloom** THE: 5.69 COD: 3.65 **Late bloom** THE: 1.78	WI **Early bloom** THE: LOQ (0.50) COD: LOQ (0.50) **Mid bloom** THE: 4.40 COD: LOQ (0.50) **Late bloom** THE: LOQ (0.50)	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.29 **Late bloom** THE: No 0.03	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.15 **Late bloom** THE: No 0.02	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	WI **Early bloom** THE: LOQ (0.25) COD: 2.11 **Mid bloom** THE: 2.06 COD: 1.71 **Late bloom** THE: 0.76	WI **Early bloom** THE: LOQ (0.50) COD: LOQ (0.50) **Mid bloom** THE: 1.80 COD: LOQ (0.50) **Late bloom** THE: LOQ (0.50)	**Early bloom** THE: No 0.06 **Mid bloom** THE: No 0.21 **Late bloom** THE: No 0.06	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.11 **Late bloom** THE: No 0.03	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.00	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	**Nectar**	**Nectar forager**	**Nurse bees**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bees**	**Bee larvae**	
	COD: LOQ (0.25) c.e. **Early bloom** THE: LOQ (0.214) Combined residues 4.45 **Mid bloom** THE: 4.87 Combined residues 8.52 **Late bloom** THE: 1.52	COD: LOQ (0.50) c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: 3.77 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.03 **Late bloom** Combined residues No 0.03	c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.04 **Late bloom** Combined residues No 0.02	c.e. **Early bloom** Combined residues No 0.04 **Mid bloom** Combined residues No 0.05 **Late bloom** Combined residues No 0.03	COD: LOQ (0.25) c.e. **Early bloom** THE: LOQ 0.214 Combined residues 2.32 **Mid bloom** THE: 1.76 Combined residues 3.5 **Late bloom** THE: 0.65	COD: LOQ (0.50) c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: 1.54 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** Combined residues No 0.34 **Mid bloom** Combined residues **Yes** **1.22** **Late bloom** Combined residues No 0.34	c.e. **Early bloom** Combined residues No 0.22 **Mid bloom** Combined residues No 0.68 **Late bloom** Combined residues No 0.18	c.e. **Early bloom** Combined residues No 0.07 **Mid bloom** Combined residues No 0.22 **Late bloom** Combined residues No 0.06	
	OR **Early bloom** THE: 1.21 COD: LOQ (0.25) **Mid bloom** THE: 1.36 COD: 0.892	OR **Early bloom** THE: LOQ (0.50) COD: LOQ (0.50) **Mid bloom** THE: LOQ (0.50) COD: LOQ	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.03 **Late bloom** THE: No 0.03	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.02 **Late bloom** THE: No 0.03	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	OR **Early bloom** THE: 0.84 COD: LOQ (0.25) **Mid bloom** THE: 0.957 COD: 0.676	OR **Early bloom** THE: LOQ (0.50) COD: LOQ (0.50) **Mid bloom** THE: LOQ (0.50) COD: LOQ	**Early bloom** THE: No 0.06 **Mid bloom** THE: No 0.06 **Late bloom** THE: No 0.06	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.03 **Late bloom** THE: No 0.04	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Late bloom THE: 5.02 COD: 1.06	(0.50) **Late bloom** THE: LOQ (0.50) COD: LOQ (0.50)				**Late bloom** THE: 2.03 COD: 0.604	(0.50) **Late bloom** THE: LOQ (0.50) COD: LOQ (0.50)				
	c.e. **Early bloom** THE: 1.04 Combined residues 1.29 **Mid bloom** THE: 1.16 Combined residues 2.06 **Late bloom** THE: 4.30 Combined residues 5.36	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.03 **Late bloom** Combined residues No 0.03	c.e. **Early bloom** Combined residues No 0.02 **Mid bloom** Combined residues No 0.02 **Late bloom** Combined residues No 0.03	c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.03 **Late bloom** Combined residues No 0.04	c.e. **Early bloom** THE: 0.72 **Mid bloom** THE: 0.819 Combined residues 1.49 **Late bloom** THE: 1.74 Combined residues 2.34	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** Combined residues No 0.34 **Mid bloom** Combined residues No 0.34 **Late bloom** Combined residues No 0.34	c.e. **Early bloom** Combined residues No 0.18 **Mid bloom** Combined residues No 0.20 **Late bloom** Combined residues No 0.22	c.e. **Early bloom** Combined residues No 0.06 **Mid bloom** Combined residues No 0.06 **Late bloom** Combined residues No 0.07	
Lilac Pollen and nectar from plants	NY **Early bloom** THE: 20	NY **Early bloom** THE: 81.4	**Early bloom** THE: **Yes** **5.4**	**Early bloom** THE: **Yes** **2.63**	**Early bloom** THE: No 0.01	NY **Early bloom** THE: 8.21	NY **Early bloom** THE: 50.9	**Early bloom** THE: **Yes** **6.07**	**Early bloom** THE: **Yes** **2.94**	**Early bloom** THE: No 0.39	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7) – during BBCH 60-69	COD: LOQ (0.50) **Mid bloom** THE: 7.57 COD: 1.47 **Late bloom** THE: 6.11 COD: 1.31	COD: 14.9 **Mid bloom** THE: 78.4 COD: 16 **Late bloom** THE: 245 COD: 126	**Mid bloom** THE: **Yes** **5.2** **Late bloom** THE: **Yes** **16.3**	**Mid bloom** THE: **Yes** **2.51** **Late bloom** THE: **Yes** **7.81**	**Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.04	COD: LOQ (0.50) **Mid bloom** THE: 5.72 COD: 0.822 **Late bloom** THE: 3.35 COD: 1.01	COD: 7.89 **Mid bloom** THE: 45.4 COD: 9.92 **Late bloom** THE: 127 COD: 52	**Mid bloom** THE: **Yes** **5.41** **Late bloom** THE: **Yes** **15.1**	**Mid bloom** THE: **Yes** **2.62** **Late bloom** THE: **Yes** **7.27**	**Mid bloom** THE: No 0.35 **Late bloom** THE: No 0.97	
	c.e. **Early bloom** THE: 17.1 Combined residues 17.6 **Mid bloom** THE: 6.5 Combined residues 7.95 **Late bloom** THE: 5.23 Combined residues 6.54	c.e. **Early bloom** THE: 69.7 Combined residues 84.6 **Mid bloom** THE: 67.1 Combined residues 83 **Late bloom** THE: 210 Combined residues 335	c.e. **Early bloom** Combined residues **Yes** **6.71** **Mid bloom** Combined residues **Yes** **6.59** **Late bloom** Combined residues **Yes** **26.6**	c.e. **Early bloom** Combined residues **Yes** **3.26** **Mid bloom** Combined residues **Yes** **3.18** **Late bloom** Combined residues **Yes** **12.8**	c.e. **Early bloom** Combined residues **Yes** **5.68** **Mid bloom** Combined residues **Yes** **5.55** **Late bloom** Combined residues **Yes** **22.3**	c.e. **Early bloom** THE: 7.03 **Mid bloom** THE: 4.90 Combined residues 5.72 **Late bloom** THE: 2.87 Combined residues 3.88	c.e. **Early bloom** THE: 43.6 Combined residues 51.4 **Mid bloom** THE: 38.9 Combined residues 48.8 **Late bloom** THE: 109 Combined residues 161	c.e. **Early bloom** Combined residues **Yes** **40.8** **Mid bloom** Combined residues **Yes** **38.7** **Late bloom** Combined residues **Yes** **128**	c.e. **Early bloom** Combined residues **Yes** **19.7** **Mid bloom** Combined residues **Yes** **18.7** **Late bloom** Combined residues **Yes** **62.4**	c.e. **Early bloom** Combined residues **Yes** **6.9** **Mid bloom** Combined residues **Yes** **6.53** **Late bloom** Combined residues **Yes** **21.5**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	WI **Early bloom** THE: 1.02 COD: LOQ (0.5) **Mid bloom** THE: 2.35 COD: 0.537 **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	WI **Early bloom** THE: 2.49 COD: LOQ (0.25) **Mid bloom** THE: 2.58 COD: LOQ (0.25) **Late bloom** THE: 2.16 COD: LOQ (0.25)	**Early bloom** THE: No 0.17 **Mid bloom** THE: No 0.17 **Late bloom** THE: No 0.14	**Early bloom** THE: No 0.08 **Mid bloom** THE: No 0.09 **Late bloom** THE: No 0.07	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	WI **Early bloom** THE: 0.674 COD: LOQ (0.5) **Mid bloom** THE: 1.42 COD: 0.518 **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	WI **Early bloom** THE: 1.40 COD: LOQ (0.25) **Mid bloom** THE: 1.89 COD: LOQ (0.25) **Late bloom** THE: 1.69 COD: LOQ (0.25)	**Early bloom** THE: No 0.17 **Mid bloom** THE: No 0.23 **Late bloom** THE: No 0.20	**Early bloom** THE: No 0.08 **Mid bloom** THE: No 0.11 **Late bloom** THE: No 0.10	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.01	
	c.e. **Early bloom** THE: 0.87 Combined residues 1.37 **Mid bloom** THE: 2.01 Combined residues 2.55	c.e. **Early bloom** THE: 2.13 **Mid bloom** THE: 2.21	c.e. **Early bloom** Combined residues No 0.17 **Mid bloom** Combined residues No 0.18 **Late bloom** Combined residues No 0.15	c.e. **Early bloom** Combined residues No 0.17 **Mid bloom** Combined residues No 0.09 **Late bloom** Combined residues No 0.07	c.e. **Early bloom** Combined residues No 0.17 **Mid bloom** Combined residues No 0.15 **Late bloom** Combined residues No 0.12	c.e. **Early bloom** THE: 0.577 **Mid bloom** THE: 1.22 Combined residues 1.73 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** THE: 1.20 **Mid bloom** THE: 1.62 **Late bloom** THE: 1.45	c.e. **Early bloom** Combined residues No 0.95 **Mid bloom** Combined residues **Yes** **1.29** **Late bloom** Combined residues **Yes** **1.15**	c.e. **Early bloom** Combined residues No 0.47 **Mid bloom** Combined residues No 0.66 **Late bloom** Combined residues No	c.e. **Early bloom** Combined residues No 0.16 **Mid bloom** Combined residues No 0.22 **Late bloom** Combined residues No	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Late bloom THE: 0.428	**Late bloom** THE: 1.85							0.56	0.20	
	OR **Early bloom** THE: 9.92 *COD:* *14.8* **Mid bloom** THE: 2.87 COD: LOQ (0.5) **Late bloom** THE: 1.15 COD: LOQ (0.5)	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	**Early bloom** No nectar input in calculation THE: No 0.02 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.00	**Early bloom** No nectar input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	OR **Early bloom** THE: 4.37 *COD:* *5.27* **Mid bloom** THE: 1.29 COD: LOQ (0.5) **Late bloom** THE: 1.08 COD: LOQ (0.5)	OR No sample collected	**Early bloom** No nectar input in calculation THE: No 0.00 **Mid bloom** THE: No 0 **Late bloom** THE: No 0.00	**Early bloom** No nectar input in calculation THE: No 0.02 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.00	**Early bloom** No nectar input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	
	c.e. **Early bloom** THE: 8.49 Combined residues *23.3* **Mid bloom** THE: 2.46		No nectar input in calculation c.e. **Early bloom** Combined residues No 0.00 **Mid bloom** Combined	No nectar input in calculation c.e. **Early bloom** Combined residues No 0.06 **Mid bloom** Combined	No nectar input in calculation c.e. **Early bloom** Combined residues No 0.05 **Mid bloom** Combined	c.e. **Early bloom** THE: 3.74 Combined residues *9.01* **Mid bloom** THE: 1.10		No nectar input in calculation c.e. **Early bloom** Combined residues No 0.00 **Mid bloom** Combined	No nectar input in calculation c.e. **Early bloom** Combined residues No 0.24 **Mid bloom** Combined	No nectar input in calculation c.e. **Early bloom** Combined residues No 0.04 **Mid bloom** Combined	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Late bloom THE: 0.98		residues No 0.00 **Late bloom** Combined residues No 0.00	residues No 0.01 **Late bloom** Combined residues No 0.00	residues No 0.00 **Late bloom** Combined residues No 0.00	**Late bloom** THE: 0.924		residues No 0.00 **Late bloom** Combined residues No 0.00	residues No 0.03 **Late bloom** Combined residues No 0.02	residues No 0.00 **Late bloom** Combined residues No 0.00	
Cotoneaster Nectar from plants. No pollen collected. Flowers collected. Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (5 DALA), mid bloom (10 DALA) and late bloom (15 DALA) LOQ=0.5 ppb flowers and 0.25 ppb nectar Note: WI early bloom for flowers was -1 DALA	NY Whole flower **Early bloom** THE: 451 COD: 1.33 **Mid bloom** THE: 844 COD: 369 **Late bloom** THE: 1278 COD: 547	NY **Early bloom** THE: 123 COD: 43.3 **Mid bloom** THE: 180 COD: 28.9 **Late bloom** THE: 198 COD: 53.3	**Early bloom** THE: **Yes** **8.17** **Mid bloom** THE: **Yes** **11.9** **Late bloom** THE: **Yes** **13.2**	**Early bloom** THE: **Yes** **4.9** **Mid bloom** THE: **Yes** **7.57** **Late bloom** THE: **Yes** **9.09**	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.03 **Late bloom** THE: No 0.04	NY Whole flower **Early bloom** THE: 345 COD: 0.988 **Mid bloom** THE: 582 COD: 138 **Late bloom** THE: 911 COD: 419	NY **Early bloom** THE: 119 COD: 28.6 **Mid bloom** THE: 136 COD: 25.1 **Late bloom** THE: 162 COD: 47.3	**Early bloom** THE: **Yes** **14.19** **Mid bloom** THE: **Yes** **16.2** **Late bloom** THE: **Yes** **19.3**	**Early bloom** THE: **Yes** **8.15** **Mid bloom** THE: **Yes** **10.1** **Late bloom** THE: **Yes** **12.8**	**Early bloom** THE: No 0.99 **Mid bloom** THE: **Yes** **1.17** **Late bloom** THE: **Yes** **1.45**	
	c.e. Whole flower **Early bloom** THE: 386 Combined residues 387 **Mid bloom** THE:	c.e. **Early bloom** THE: 105 Combined residues 149 **Mid bloom** THE:	c.e. **Early bloom** Combined residues **Yes** **11.8** **Mid bloom** Combined residues **Yes** **14.5**	c.e. **Early bloom** Combined residues **Yes** **6.68** **Mid bloom** Combined residues **Yes** **9.81**	c.e. **Early bloom** Combined residues **Yes** **10.7** **Mid bloom** Combined residues **Yes** **14.4**	c.e. **Early bloom** THE: 295 **Mid bloom** THE: 498	c.e. **Early bloom** THE: 102 Combined residues 130 **Mid bloom** THE: 116	c.e. **Early bloom** Combined residues **Yes** **103** **Mid bloom** Combined residues **Yes** **113**	c.e. **Early bloom** Combined residues **Yes** **57.2** **Mid bloom** Combined residues **Yes** **70.6**	c.e. **Early bloom** Combined residues **Yes** **18.5** **Mid bloom** Combined residues **Yes** **21.5**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	722 Combined residues 1091 **Late bloom** THE: 1093 Combined residues 1641	154 Combined residues 183 **Late bloom** THE: 169 Combined residues 222	**Late bloom** Combined residues **Yes** **17.6**	**Late bloom** Combined residues **Yes** **12.7**	**Late bloom** Combined residues **Yes** **18.1**	Combined residues 636 **Late bloom** THE: 779 Combined residues 1199	Combined residues 142 **Late bloom** THE: 139 Combined residues 186	**Late bloom** Combined residues **Yes** **148**	**Late bloom** Combined residues **Yes** **102**	**Late bloom** Combined residues **Yes** **29.6**	
	WI Whole flower **Early bloom+** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: 2.29 COD: 3.08 **Late bloom** THE: 6.86 COD: 4.12	WI **Early bloom** THE: LOQ (0.250) COD: LOQ (0.250) **Mid bloom** THE: 0.532 COD: LOQ (0.250) **Late bloom** THE: 3.35 COD: 0.9	**Early bloom** Whole flower input in calculation THE: No 0.03 **Mid bloom** THE: No 0.15 **Late bloom** THE: **Yes** **0.46**	**Early bloom** Whole flower input in calculation THE: No 0.02 **Mid bloom** THE: No 0.08 **Late bloom** THE: No 0.23	**Early bloom** Whole flower input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	WI Whole flower **Early bloom+** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: 1.91 COD: 2.25 **Late bloom** THE: 5.0 COD: 3.27	WI **Early bloom** THE: LOQ (0.250) COD: LOQ (0.250) **Mid bloom** THE: 0.344 COD: LOQ (0.250) **Late bloom** THE: 2.13 COD: 0.467	**Early bloom** Whole flower input in calculation THE: No 0.06 **Mid bloom** THE: No 0.23 **Late bloom** THE: No 0.60	**Early bloom** Whole flower input in calculation THE: No 0.03 **Mid bloom** THE: No 0.12 **Late bloom** THE: No 0.31	**Early bloom** Whole flower input in calculation THE: No 0.00 **Mid bloom** THE: No 0.02 **Late bloom** THE: No 0.04	
	c.e. Whole flower **Early bloom** THE: LOQ	c.e. **Early bloom** THE: LOQ	c.e. **Early bloom** Combined residues No	c.e. **Early bloom** Combined residues No	c.e. **Early bloom** Combined residues No	c.e. **Early bloom** THE: LOQ 0.428	c.e. **Early bloom** THE: LOQ 0.214	c.e. **Early bloom** Combined residues No	c.e. **Early bloom** Combined residues No	c.e. **Early bloom** Combined residues No	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	**Nectar**	**Nectar forager**	**Nurse bees**	**Bee larvae**	**Pollen**	**Nectar**	**Nectar forager**	**Nurse bees**	**Bee larvae**	
	0.428 **Mid bloom** THE: 1.96 Combined residues 5.04 **Late bloom** THE: 5.87 Combined residues 9.99	0.214 **Mid bloom** THE: 0.455 **Late bloom** THE: 2.87 Combined residues 3.77	0.16 **Mid bloom** Combined residues No 0.40 **Late bloom** Combined residues **Yes** **0.79**	0.08 **Mid bloom** Combined residues No 0.19 **Late bloom** Combined residues No 0.39	0.13 **Mid bloom** Combined residues No 0.34 **Late bloom** Combined residues **Yes** **0.67**	**Mid bloom** THE: 1.63 Combined residues 3.88 **Late bloom** THE: 4.28 Combined residues 7.55	**Mid bloom** THE: 0.294 **Late bloom** THE: 1.82 Combined residues 2.29	0.17 **Mid bloom** Combined residues No 0.23 **Late bloom** Combined residues **Yes** **1.82**	0.09 **Mid bloom** Combined residues No 0.21 **Late bloom** Combined residues **Yes** **1.07**	0.03 **Mid bloom** Combined residues No 0.05 **Late bloom** Combined residues No 0.34	
	OR Whole flower **Early bloom** THE: 1.72 COD: 4.64 **Mid bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Late bloom** THE: 1.28 COD:	OR **Early bloom** THE: 0.546 COD: LOQ (0.250) **Mid bloom** THE: LOQ (0.250) COD: LOQ (0.250) **Late bloom** THE: 0.581 COD:	**Early bloom** THE: No 0.04 **Mid bloom** THE: No 0.02 **Late bloom** THE: No 0.04	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.02	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	OR Whole flower **Early bloom** THE: 1.57 COD: 3.87 **Mid bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Late bloom** THE: 0.760 COD: LOQ	OR **Early bloom** THE: 0.349 COD: LOQ (0.250) **Mid bloom** THE: LOQ (0.250) COD: LOQ (0.250) **Late bloom** THE: 0.360 COD: 0.523	**Early bloom** THE: No 0.04 **Mid bloom** THE: No 0.03 **Late bloom** THE: No 0.04	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.02 **Late bloom** THE: No 0.02	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	LOQ (0.5) c.e. Whole flower **Early bloom** THE: 1.47 Combined residues 6.11 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: 1.09	1.07 c.e. **Early bloom** THE: 0.467 **Mid bloom** THE: LOQ 0.214 **Late bloom** THE: 0.497 Combined residues 1.57	c.e. **Early bloom** Combined residues No 0.04 **Mid bloom** Combined residues No 0.02 **Late bloom** Combined residues No 0.12	c.e. **Early bloom** Combined residues No 0.03 **Mid bloom** Combined residues No 0.01 **Late bloom** Combined residues No 0.06	c.e. **Early bloom** Combined residues No 0.04 **Mid bloom** Combined residues No 0.02 **Late bloom** Combined residues No 0.11	(0.5) c.e. **Early bloom** THE: 1.34 Combined residues 5.21 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: 0.65	c.e. **Early bloom** THE: 0.299 **Mid bloom** THE: LOQ 0.214 **Late bloom** THE: 0.308	c.e. **Early bloom** Combined residues No 0.24 **Mid bloom** Combined residues No 0.17 **Late bloom** Combined residues No 0.24	c.e. **Early bloom** Combined residues No 0.25 **Mid bloom** Combined residues No 0.09 **Late bloom** Combined residues No 0.13	c.e. **Early bloom** Combined residues No 0.06 **Mid bloom** Combined residues No 0.03 **Late bloom** Combined residues No 0.04	
Sargent Crabapple Pollen from plants and whole flowers. No nectar. Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom. Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7)	NY **Early bloom** THE: 1.17 COD: 3.30 **Mid bloom** THE: 41.1 COD: 15.3 **Late bloom** THE:	NY Whole flowers **Early bloom** THE: 20.5 COD: 5.96 **Mid bloom** THE: 69.1 COD: 4.49 **Late bloom** THE:	**Early bloom** Whole flower input in calculation THE: **Yes** **1.36** **Mid bloom** THE: **Yes** **4.59** **Late bloom** THE:	**Early bloom** Whole flower input in calculation THE: **Yes** **0.70** **Mid bloom** THE: **Yes** **2.35** **Late bloom** THE:	**Early bloom** Whole flower input in calculation THE: No 0.00 **Mid bloom** THE: No 0.01 **Late bloom** THE:	NY **Early bloom** THE: 0.723 COD: 2.03 **Mid bloom** THE: 15.9 COD: 8.82 **Late bloom** THE:	NY Whole flowers **Early bloom** THE: 16.1 COD: 3.52 **Mid bloom** THE: 36.1 COD: 3.20 **Late bloom** THE:	**Early bloom** Whole flower input in calculation THE: **Yes** **1.92** **Mid bloom** THE: **Yes** **4.30** **Late bloom** THE: **Yes**	**Early bloom** Whole flower input in calculation THE: No 0.98 **Mid bloom** THE: **Yes** **2.20** **Late bloom** THE: **Yes**	**Early bloom** Whole flower input in calculation THE: No 0.13 **Mid bloom** THE: No 0.28 **Late bloom** THE: No	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	35.2 COD: 6.62	98.5 COD: 10.9	**Yes** **6.54**	**Yes** **3.35**	No 0.02	18.5 COD: 5.56	52 COD: 5.6	**6.20**	**3.18**	0.41	
	c.e. **Early bloom** THE: 1.0 Combined residues 4.3 **Mid bloom** THE: 35.2 Combined residues 50.5 **Late bloom** THE: 30.1 Combined residues 36.7	c.e. Whole flowers **Early bloom** THE: 17.5 Combined residues 23.5 **Mid bloom** THE: 59.1 Combined residues 63.6 **Late bloom** THE: 84.3 Combined residues 95.2	c.e. **Early bloom** Combined residues **Yes** **1.86** **Mid bloom** Combined residues **Yes** **5.05** **Late bloom** Combined residues **Yes** **7.55**	c.e. **Early bloom** Combined residues **Yes** **0.91** **Mid bloom** Combined residues **Yes** **2.55** **Late bloom** Combined residues **Yes** **3.72**	c.e. **Early bloom** Combined residues **Yes** **1.58** **Mid bloom** Combined residues **Yes** **4.34** **Late bloom** Combined residues **Yes** **6.42**	c.e. **Early bloom** THE: 0.619 Combined residues 2.65 **Mid bloom** THE: 13.6 Combined residues 22.4 **Late bloom** THE: 15.8 Combined residues 21.4	c.e **Early bloom** THE: 13.8 Combined residues 17.3 **Mid bloom** THE: 30.9 Combined residues 34 **Late bloom** THE: 44.5 Combined residues 50.1	c.e. **Early bloom** Combined residues **Yes** **13.7** **Mid bloom** Combined residues **Yes** **26.9** **Late bloom** Combined residues **Yes** **39.8**	c.e. **Early bloom** Combined residues **Yes** **6.65** **Mid bloom** Combined residues **Yes** **13.5** **Late bloom** Combined residues **Yes** **19.6**	c.e. **Early bloom** Combined residues **Yes** **2.32** **Mid bloom** Combined residues **Yes** **4.62** **Late bloom** Combined residues **Yes** **6.77**	
	WI **Early bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: LOQ	WI Whole flowers **Early bloom** THE: LOQ (0.5) COD: 1.65 **Mid bloom** THE: LOQ	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.03 **Late bloom** THE: No	**Early bloom** THE: No 0.02 **Mid bloom** THE: No 0.02 **Late bloom** THE: No	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No	WI **Early bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: LOQ	WI Whole flowers **Early bloom** THE: LOQ (0.5) COD: 1.65 **Mid bloom** THE: LOQ	**Early bloom** THE: No 0.06 **Mid bloom** THE: No 0.06 **Late bloom** THE: No	**Early bloom** THE: No 0.03 **Mid bloom** THE: No 0.03 **Late bloom** THE: No	**Early bloom** THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	(0.5) COD: LOQ (0.5) **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	(0.5) COD: 1.08 **Late bloom** THE: LOQ (0.5) COD: 2.06	0.03	0.02	0.00	(0.5) COD: LOQ (0.5) **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	(0.5) COD: 0.692 **Late bloom** THE: LOQ (0.5) COD: 1.02	0.06	0.03	0.00	
	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** THE: LOQ 0.428 Combined residues 2.1 **Mid bloom** THE: LOQ 0.428 Combined residues 1.5 **Late bloom** THE: LOQ 0.428 Combined residues 2.49	c.e. **Early bloom** Combined residues No 0.17 **Mid bloom** Combined residues No 0.12 **Late bloom** Combined residues No 0.20	c.e. **Early bloom** Combined residues No 0.08 **Mid bloom** Combined residues No 0.06 **Late bloom** Combined residues No 0.10	c.e. **Early bloom** Combined residues No 0.14 **Mid bloom** Combined residues No 0.10 **Late bloom** Combined residues No 0.17	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428 **Late bloom** THE: LOQ 0.428	c.e. **Early bloom** THE: LOQ 0.428 Combined residues 2.08 **Mid bloom** THE: LOQ 0.428 Combined residues 1.12 **Late bloom** THE: LOQ 0.428 Combined residues 1.45	c.e. **Early bloom** Combined residues **Yes** **1.65** **Mid bloom** Combined residues No 0.89 **Late bloom** Combined residues **Yes** **1.15**	c.e. **Early bloom** Combined residues No 0.80 **Mid bloom** Combined residues No 0.44 **Late bloom** Combined residues No 0.56	c.e. **Early bloom** Combined residues No 0.28 **Mid bloom** Combined residues No 0.15 **Late bloom** Combined residues No 0.20	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	OR **Early bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	OR Whole flowers **Early bloom** THE: 1.01 COD: 1.65 **Mid bloom** THE: 1.18 COD: 2.48 **Late bloom** THE: LOQ (0.5) COD: 1.11	**Early bloom** Whole flower input in calculation THE: No 0.07 **Mid bloom** THE: No 0.08 **Late bloom** THE: No 0.03	**Early bloom** Whole flower input in calculation THE: No 0.03 **Mid bloom** THE: No 0.04 **Late bloom** THE: No 0.02	**Early bloom** Whole flower input in calculation THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	OR **Early bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Mid bloom** THE: LOQ (0.5) COD: LOQ (0.5) **Late bloom** THE: LOQ (0.5) COD: LOQ (0.5)	OR Whole flowers **Early bloom** THE: 1.01 COD: 1.65 **Mid bloom** THE: 0.727 COD: 1.55 **Late bloom** THE: LOQ (0.5) COD: 0.702	**Early bloom** Whole flower input in calculation THE: No 0.12 **Mid bloom** THE: No 0.09 **Late bloom** THE: No 0.06	**Early bloom** Whole flower input in calculation THE: No 0.06 **Mid bloom** THE: No 0.04 **Late bloom** THE: No 0.032	**Early bloom** Whole flower input in calculation THE: No 0.01 **Mid bloom** THE: No 0.01 **Late bloom** THE: No 0.00	
	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428	c.e **Early bloom** THE: 0.865 Combined residues 2.51 **Mid bloom** THE: 1.01 Combined	c.e. **Early bloom** Combined residues No 0.20 **Mid bloom** Combined residues No 0.28	c.e. **Early bloom** Combined residues No 0.10 **Mid bloom** Combined residues No 0.13	c.e. **Early bloom** Combined residues No 0.17 **Mid bloom** Combined residues No 0.23	c.e. **Early bloom** THE: LOQ 0.428 **Mid bloom** THE: LOQ 0.428	c.e. **Early bloom** THE: 0.865 Combined residues 2.51 **Mid bloom** THE: 0.622 Combined residues	c.e. **Early bloom** Combined residues **Yes** **1.99** **Mid bloom** Combined residues **Yes** **1.72**	c.e. **Early bloom** Combined residues No 0.97 **Mid bloom** Combined residues No 0.84	c.e. **Early bloom** Combined residues No 0.34 **Mid bloom** Combined residues No 0.29	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Late bloom THE: LOQ 0.428	residues 3.49 **Late bloom** THE: LOQ 0.428 Combined residues 1.54	**Late bloom** Combined residues No 0.12	**Late bloom** Combined residues No 0.06	**Late bloom** Combined residues No 0.10	**Late bloom** THE: LOQ 0.428	2.17 **Late bloom** THE: LOQ 0.428 Combined residues 1.13	**Late bloom** Combined residues No 0.90	**Late bloom** Combined residues No 0.44	**Late bloom** Combined residues No 0.15	

Notes: North Rose NY (New York) (Trial 1) was loam soil; Racine WI (Wisconsin) (Trial 2) was clay loam soil; Oregon city OR (Oregon) (Trial 3) was sandy loam.
Treated plots were divided into 3 replicate sub-plots.
Each site had a control plot, located 100 ft from treated plots (upwind and upslope). Mesh netting was placed over the crops to prevent pollinator activity and cross contamination.
+ -1 DALA

CG = crop group, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, Y = year , CLO = clothianidin, THE = thiamethoxam
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)
Bold values indicate that acute LOC (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
1 Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0 × 106]
2 Chronic RQ = Chronic estimated daily dose (EDD)/chronic toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total

Note, for thiamethoxam RA: adult acute oral **LD50 = 0.0044 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = 0.78 µg a.i./larva/day for TGAI**
Note, for thiamethoxam RA: adult chronic oral **NOED = 0.00245 µg a.i./bee for TGAI;** bee larvae chronic **22-day NOED = 0.0157 µg a.i./larva/day for TGAI**
Note, for clothianidin equivalents RA: adult acute oral **LD50 = 0.00368 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = >0.0018 µg a.i./larva/day**
Note, for clothianidin equivalents RA: adult chronic **NOED = 0.000368 µg a.i./bee/day;** bee larvae chronic **NOED = 0.0009 µg a.i./larva/day**
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856), and added to clothianidin for c.e. calculations.
2 Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ

Table 2b Foliar and Soil Application: Colony Level Risk to Apis and non-Apis bees Based on Mean Residues of clothianidin equivalents (c.e.)

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
Foliar applications							
Herbaceous stargazer lily Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (5 DALA), mid bloom (10 DALA) and late bloom (15 DALA) – during BBCH 60-69 No control THE residues. Two COD control contamination (13.5 ppb and 3.11 ppb COD in nectar at NY) LOQ=0.5	NY **Early bloom** 16.8 **Mid bloom** 11.1 **Late bloom** 30.8	NY **Early bloom** 55.6 **Mid bloom** 24.7 **Late bloom** 76	**Sandrock 2014⁺** **LOEC** **(6.6)** **Straub 2016⁺** **LOEC** **(6.3 ppb)** **Williams 2015⁺** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC** **(34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)**	**Fauser-Misslin 2014⁺** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** Mommaerts 2010 NOEC (85.6) **Sandrock** **2014⁺** **LOEC**	**Product:** *MainspringX [registration 30901]* **Application timing:** On the label, it states 'Do not apply this product during bloom or when bees are present.' Therefore, the timing of application (before bloom) would be applicable to the use pattern. There is no timing restriction on the label for application before bloom. **Application rate:** GH: Application rate for greenhouse ornamentals is 300 g a.i./ha/crop cycle. Therefore, 2 × 149 g a.i./ha would be similar to the rate per crop cycle. Outdoor: Application rate for outdoor ornamentals is 150 g a.i./ha. Therefore, 2 × 149 g a.i./ha would be conservative. **Plant relevancy:** Outdoor and greenhouse ornamentals – no plants specified on label. Therefore, all tested crops are applicable. **Product:** *Flagship [registration 30723]* **Application timing:** No restriction on the label. It states 'Do not apply this product to flowering crops or weeds if bees are visiting the treatment area.' Therefore, the timing of application (before bloom) would be applicable to the use pattern. **Application rate:** Application rate for outdoor ornamentals is 2 × 70 g a.i./ha (total of 140 g a.i./ha). Therefore, 2 × 149 g a.i./ha would be conservative (double the rate) compared to the rate per crop cycle. Application rate for outdoor nurseries and landscapes and viburnum is 1 × 70 g a.i./ha. Therefore, the 2 × 149 g a.i./ha would be conservative (4 x the rate) compared to the rate per crop cycle.

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						(2.9) **Moffat 2016 LOEC (2.14)**	The label indicates to wait at least 5 days before placing beehives in treated field. **Plant relevancy:** The label indicates outdoor ornamentals. Therefore, all tested crops are applicable.
	WI **Early bloom** 5.69 **Mid bloom** 5.29 **Late bloom** 9.8	WI **Early bloom** 5.47 **Mid bloom** 4.46 **Late bloom** 4.12	**Sandrock 2014⁺ LOEC (6.6)** **Straub 2016⁺ LOEC (6.3 ppb)** **Williams 2015⁺ LOEC (4.5)** **Only late bloom exceeds**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	**Fauser-Misslin 2014⁺ LOEC (4.9)** **Elston 2013 LOEC (8.56)** **Only late bloom exceeds**	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) **Stanley 2015 & 2016 LOEC (2.05)** **Baron 2017 LOEC (2.05)** Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) **Sandrock 2014⁺**	For viburnum, woody perennials such as lilac and mockorange may be considered most relevant. **Product:** *Actara 25 WG [registration 28408]* **Application timing:** No restriction on the label. It states 'Do not apply this product to flowering crops or weeds if bees are visiting the treatment area.' Therefore, the timing of application (before bloom) would be applicable to the use pattern. **Application rate:** Application rate for outdoor ornamentals is 2 × 70 g a.i./ha (total of 140 g a.i./ha). Therefore, 2 × 149 g a.i./ha would be conservative (double the rate) compared to the rate per crop cycle. Application rate for outdoor nurseries and landscapes is 1 × 70 g a.i./ha. Therefore, the 2 × 149 g a.i./ha would be conservative (4 x the rate) compared to the rate per crop cycle. The label indicates to wait at least 5 days before placing beehives in treated field. **Plant relevancy:** The label indicates outdoor ornamentals and for nurseries and landscapes. Therefore, all tested crops are applicable. Stargazer lilies bloom 1-3 weeks in summer. Lilacs bloom 2 weeks in spring. Mock oranges bloom 2-3 weeks in summer.

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						LOEC (2.9) **Moffat 2016 LOEC (2.14)**	
	OR **Early bloom** 0.619 **Mid bloom** 2.76 **Late bloom** 3.41	OR **Early bloom** 71.4 **Mid bloom** 46.2 **Late bloom** 28.6	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb) Williams 2015+ LOEC (4.5)	**2014 TMX CFS LOEC (34) NOEC (25.3)** **2016 TMX CFS LOEC (69.6) NOEC (34.8)** **2014 CLO CFS LOEC (35.6) NOEC (19)** **2016 CLO CFS LOEC (29) NOEC (19)** **Late bloom does not exceed some endpoints**	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013 LOEC (8.56)	**Stanley and Raine 2017 NOEC (8.56)** **Stanley and Raine 2015 LOEC (8.56)** **Stanley 2015 & 2016 LOEC (2.05)** **Baron 2017 LOEC (2.05)** **Laycock 2014 NOEC (13.4) LOEC (39)** **Mommaerts 2010 NOEC (85.6)** **Sandrock**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						2014[+] **LOEC** **(2.9)** **Moffat** **2016** **LOEC** **(2.14)**	
Lilac Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Oregon trial 3 did not have pollen samples Samples collected early bloom (F5), mid bloom (F6) and late bloom (F7) – during BBCH 60-69 Minimal control residues (maximum of 0.86 ppb THE in nectar at NY site; and 1.13 ppb THE in pollen at NY site. 2.58 ppb COD in pollen at NY site.) LOQ=0.5	NY **Early bloom** 1238 **Mid bloom** 410 **Late bloom** 733	NY **Early bloom** 796 **Mid bloom** 487 **Late bloom** 356	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC** **(34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)**	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts** **2010** **NOEC** **(85.6)**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						Sandrock 2014[+] LOEC (2.9) **Moffat 2016 LOEC (2.14)**	
	WI **Early bloom** 458 **Mid bloom** 145 **Late bloom** 44.9	WI **Early bloom** 409 **Mid bloom** 264 **Late bloom** 162	**Sandrock 2014[+] LOEC (6.6)** **Straub 2016[+] LOEC (6.3 ppb)** **Williams 2015[+] LOEC (4.5)**	**2014 TMX CFS LOEC (34) NOEC (25.3)** **2016 TMX CFS LOEC (69.6) NOEC (34.8)** **2014 CLO CFS LOEC (35.6) NOEC (19)** **2016 CLO CFS LOEC (29) NOEC (19)**	**Fauser-Misslin 2014[+] LOEC (4.9)** **Elston 2013 LOEC (8.56)**	**Stanley and Raine 2017 NOEC (8.56)** **Stanley and Raine 2015 LOEC (8.56)** **Stanley 2015 & 2016 LOEC (2.05)** **Baron 2017 LOEC (2.05)** **Laycock 2014 NOEC (13.4) LOEC (39)** **Mommaerts 2010 NOEC (85.6)**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						Sandrock 2014[+] LOEC (2.9) **Moffat 2016 LOEC (2.14)**	
	OR **Early bloom** *230* **Mid bloom** *287* **Late bloom** *143*	OR No sample collected	**Sandrock 2014[+] LOEC (6.6)** **Straub 2016[+] LOEC (6.3 ppb)** **Williams 2015[+] LOEC (4.5)**	No residues for comparison	**Fauser-Misslin 2014[+] LOEC (4.9)** **Elston 2013 LOEC (8.56)**	No residues for comparison	
Mock orange Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (F5), mid bloom (F6) and late bloom (F7) – during BBCH 60-69	NY **Early bloom** 396 **Mid bloom** 74.6 **Late bloom** 61.1	NY **Early bloom** 155 **Mid bloom** 48.3 **Late bloom** 67.3	**Sandrock 2014[+] LOEC (6.6)** **Straub 2016[+] LOEC (6.3 ppb)** **Williams 2015[+] LOEC (4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19)	**Fauser-Misslin 2014[+] LOEC (4.9)** **Elston 2013 LOEC (8.56)**	**Stanley and Raine 2017 NOEC (8.56)** **Stanley and Raine 2015 LOEC (8.56)** **Stanley 2015 & 2016 LOEC (2.05)** **Baron 2017 LOEC**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
A number of control sample residues. Range of 0.29 to 13.7 ppb THE in pollen at across all sites. Range of 0.315 to 3.07 ppb COD in pollen across all sites. LOQ=0.5				2016 CLO CFS LOEC (29) NOEC (19)		**(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** Mommaerts 2010 NOEC (85.6) **Sandrock 2014⁺** **LOEC** **(2.9)** **Moffat 2016** **LOEC** **(2.14)**	
	WI **Early bloom** *22.5* **Mid bloom** *8.83* **Late bloom** 15.6	WI **Early bloom** 135 **Mid bloom** *32.8* **Late bloom** *37.5*	**Sandrock 2014⁺** **LOEC** **(6.6)** **Straub 2016⁺** **LOEC** **(6.3 ppb)** **Williams 2015⁺** **LOEC** **(4.5)**	**2014 TMX CFS LOEC (34)** **NOEC** **(25.3)** 2016 TMX CFS LOEC (69.6) **NOEC** **(34.8)** **2014 CLO CFS LOEC (35.6)** NOEC (19)	**Fauser-Misslin 2014⁺** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine 2017** **NOEC** **(8.56)** **Stanley and Raine 2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
				2016 CLO CFS LOEC (29) NOEC (19)		**LOEC (2.05)** **Laycock 2014 NOEC (13.4) LOEC (39)** Mommaerts 2010 NOEC (85.6) **Sandrock 2014[+] LOEC (2.9)** **Moffat 2016 LOEC (2.14)**	
	OR **Early bloom** *32.2* **Mid bloom** *53.2* **Late bloom** *304*	OR No sample collected	**Sandrock 2014[+] LOEC (6.6)** **Straub 2016[+] LOEC (6.3 ppb)** **Williams 2015[+] LOEC (4.5)**	No residues for comparison	**Fauser-Misslin 2014[+] LOEC (4.9)** **Elston 2013 LOEC (8.56)**	No residues for comparison	
Soil applications							

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
Stargazer lily Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7) – during BBCH 60-69 No control residues. LOQ=0.5	NY **Early bloom** 15.8 **Mid bloom** 13 **Late bloom** 19.1	NY **Early bloom** 4.63 **Mid bloom** 2.25 **Late bloom** 5.6	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) **Sandrock 2014[+]** **LOEC** **(2.9)** **Moffat 2016** **LOEC**	One product, Mainspring X [registration 30901] **Application timing:** On the label, it states 'Do not apply this product during bloom or when bees are present.' Therefore, the timing of application (before bloom) would be applicable to the use pattern. **Application rate:** GH: Application rate for greenhouse ornamentals is 300 g a.i./ha/crop cycle. Therefore, 2 × 149 g a.i./ha would be similar to the rate per crop cycle. **Plant relevancy:** Greenhouse ornamentals – no plants specified on label. Therefore, all tested crops are applicable. Stargazer lilies bloom 1-3 weeks in summer. Lilacs bloom 2 weeks in spring. Cotoneaster bloom 2-3 weeks in spring to summer. Crabapples bloom about 2 weeks in spring.

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						(2.14)	
	WI **Early bloom** 2.32 **Mid bloom** 3.5 **Late bloom** 0.65	WI **Early bloom** LOQ 0.428 **Mid bloom** 1.54 **Late bloom** LOQ 0.428	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb) Williams 2015+ LOEC (4.5)	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						LOEC (2.14)	
	OR **Early bloom** 0.72 **Mid bloom** 1.49 **Late bloom** 2.34	OR **Early bloom** LOQ 0.428 **Mid bloom** LOQ 0.428 **Late bloom** LOQ 0.428	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb) Williams 2015+ LOEC (4.5)	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						LOEC (2.14)	
Lilac Pollen and nectar from plants Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7) – during BBCH 60-69 No control residues. LOQ=0.5	NY **Early bloom** 7.03 **Mid bloom** 5.72 **Late bloom** 3.88	NY **Early bloom** 51.4 **Mid bloom** 48.8 **Late bloom** 161	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)** **Late bloom does not exceed**	**2014** **TMX CFS LOEC (34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)**	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)** **Late bloom does not exceed**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts** **2010** **NOEC** **(85.6)** **(note, only exceeds late bloom)** **Sandrock** **2014[+]** **LOEC** **(2.9)**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						Moffat 2016 LOEC (2.14)	
	WI **Early bloom** 0.577 **Mid bloom** 1.73 **Late bloom** LOQ 0.428	WI **Early bloom** 1.20 **Mid bloom** 1.62 **Late bloom** 1.45	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb) Williams 2015+ LOEC (4.5)	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						(2.9) Moffat 2016 LOEC (2.14)	
	OR **Early bloom** *9.01* **Mid bloom** 1.10 **Late bloom** 0.924	OR No sample collected	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)** **Only early bloom exceeds**	No residues for comparison	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)** **Only early bloom exceeds**	No residues for comparison	
Cotoneaster Nectar from plants. No pollen collected. Flowers collected. Applied at 2 × 149 g a.i./ha, first application made 12 days before bloom and second application made 5 days before bloom Samples collected early bloom (5 DALA), mid bloom (10 DALA) and late bloom (15	NY **Early bloom** 295 **Mid bloom** 636 **Late bloom** 1199	NY **Early bloom** 130 **Mid bloom** 142 **Late bloom** 186	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC (34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS**	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
DALA) LOQ=0.5 ppb flowers and 0.25 ppb nectar Note: WI early bloom for flowers was -1 DALA Some control residues. Only one sample – 0.65 ppb THE in nectar from NY. Eight samples - 0.699 to 4.86 ppb COD in whole flower and nectar across all sites. LOQ=0.5				**LOEC (29)** **NOEC** **(19)**		**Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts 2010** **NOEC** **(85.6)** **Sandrock 2014**[+] **LOEC** **(2.9)** **Moffat 2016** **LOEC** **(2.14)**	
	WI **Early bloom** LOQ 0.428 **Mid bloom** 3.88 **Late bloom** 7.55	WI **Early bloom** LOQ 0.214 **Mid bloom** 0.294 **Late bloom** 2.29	**Sandrock 2014**[+] **LOEC** **(6.6)** **Straub 2016**[+] **LOEC** **(6.3 ppb)** **Williams 2015**[+] **LOEC** **(4.5)** **Only late bloom exceeds**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC	**Fauser-Misslin 2014**[+] **LOEC** **(4.9)** **(Only late bloom exceeds)** Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
				(29) NOEC (19)		**(2.05)** Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016 **LOEC** **(2.14)** **Only late bloom exceeds (residues close to endpoint)**	
	OR **Early bloom** 5.21 **Mid bloom** LOQ 0.428 **Late bloom** 0.65	OR **Early bloom** 0.299 **Mid bloom** LOQ 0.214 **Late bloom** 0.308	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb) **Williams 2015+** **LOEC** **(4.5)**	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6)	**Fauser-Misslin 2014+** **LOEC** **(4.9)** **Only early bloom exceeds** Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
			Only early bloom exceeds	NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)		(2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014[+] LOEC (2.9) Moffat 2016 LOEC (2.14)	
Sargent Crabapple Pollen from plants and whole flowers. No nectar. Drip irrigation. Applied at 2 × 149 g a.i./ha, first application made 12 days before	NY **Early bloom** 2.65 **Mid bloom** 22.4 **Late bloom** 21.4	NY Whole flowers **Early bloom** 17.3 **Mid bloom** 34 **Late**	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC (34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)**	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)** **Exceeds mid and late bloom**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
bloom and second application made 5 days before bloom. Samples collected early bloom (S5), mid bloom (S6) and late bloom (S7) Minimal control residues. Two samples – 1.52 and 2.11 ppb THE in pollen from NY. LOQ=0.5		**bloom** 50.1	**Exceeds mid and late bloom**	**2014 CLO CFS LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS LOEC (29)** **NOEC** **(19)** **Exceeds mid and late bloom**		**LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** Mommaerts 2010 NOEC (85.6) **Sandrock** **2014+** **LOEC** **(2.9)** **Moffat** **2016** **LOEC** **(2.14)** **Exceeds mid and late bloom**	
	WI **Early bloom** LOQ 0.428 **Mid bloom** LOQ 0.428	WI Whole flowers **Early bloom** 2.08 **Mid**	Sandrock 2014+ LOEC (6.6) Straub 2016+ LOEC (6.3 ppb)	2014 TMX CFS LOEC (34) NOEC (25.3) 2016 TMX CFS LOEC (69.6) NOEC	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013 LOEC (8.56)	Stanley and Raine 2017 NOEC (8.56) Stanley and Raine 2015 LOEC	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	**Nectar**	**Pollen (ppb)**	**Nectar (ppb)**	**Pollen (ppb)**	**Nectar (ppb)**	
	Late bloom LOQ 0.428	**bloom** 1.12 **Late bloom** 1.45	Williams 2015+ LOEC (4.5)	(34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)		(8.56) **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Only exceeds early bloom (residues close to endpoint)** Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016 LOEC (2.14)	
	OR **Early**	OR Whole flowers **Early bloom**	Sandrock 2014+ LOEC (6.6) Straub 2016+	2014 TMX CFS LOEC (34) NOEC (25.3)	Fauser-Misslin 2014+ LOEC (4.9) Elston 2013	Stanley and Raine 2017 NOEC (8.56)	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
	bloom LOQ 0.428 **Mid bloom** LOQ 0.428 **Late bloom** LOQ 0.428	LOQ 0.428 **Mid bloom** LOQ 0.428 **Late bloom** LOQ 0.428	LOEC (6.3 ppb) Williams 2015+ LOEC (4.5)	2016 TMX CFS LOEC (69.6) NOEC (34.8) 2014 CLO CFS LOEC (35.6) NOEC (19) 2016 CLO CFS LOEC (29) NOEC (19)	LOEC (8.56)	Stanley and Raine 2015 LOEC (8.56) Stanley 2015 & 2016 LOEC (2.05) Baron 2017 LOEC (2.05) Laycock 2014 NOEC (13.4) LOEC (39) Mommaerts 2010 NOEC (85.6) Sandrock 2014+ LOEC (2.9) Moffat 2016 LOEC (2.14)	

CFS = colony feeding study, CG = crop group, CLO = clothianidin, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, TMX = thiamethoxam, Y = year
Bold values indicate that acute LOC (RQ ≥1.0) is exceeded.
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)
NOTE: for thiamethoxam CFS from registrant, endpoints were also compared to thiamethoxam residues (see mean residues from Tier I refined level assessment)

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
[2]Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ + These studies were conducted with both thiamethoxam and clothianidin							

Blueberry foliar application

Table 3a Foliar Application: Acute and Chronic Dietary Risk to Different Bee Castes Based on Maximum and Mean Residues of Thiamethoxam (ppb) and also clothianidin equivalents (c.e.)

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Blueberry Three treatments; control, 3 applications before bloom (19, 12 and 5 days before bloom) and 1 application before bloom @ 15 days before bloom. Application rate: 70 g a.i./ha per application. Flowers were sampled at early, mid and late bloom. Sandy soil was in Fresno, California Loam soil was in Quebec, Canada	sand **Early bloom** THE: 21.6 COD: 2.16 **Mid bloom** THE: 44.6 COD: 15.8 **Late bloom** THE: 60.6 COD: 14.9	sand **Early bloom** THE: 92.3 COD: 38.6 **Mid bloom** THE: 10.9 COD: 17 **Late bloom** THE: 10.3 COD: 30.8	**Early bloom** THE: **Yes** **6.13** **Mid bloom** THE: **Yes** **0.72** **Late bloom** THE: **Yes** **0.68**	**Early bloom** THE: **Yes** **2.98** **Mid bloom** THE: **Yes** **0.44** **Late bloom** THE: **Yes** **0.46**	**Early bloom** THE: No 0.01 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00	sand **Early bloom** THE: 9.62 COD: 1.0 **Mid bloom** THE: 33 COD: 11.8 **Late bloom** THE: 44.8 COD: 13.7	sand **Early bloom** THE: 65.3 COD: 47.4 **Mid bloom** THE: 9.25 COD: 14.8 **Late bloom** THE: 8.85 COD: 24	**Early bloom** THE: **Yes** **3.77** **Mid bloom** THE: **Yes** **1.10** **Late bloom** THE: **Yes** **1.06**	**Early bloom** THE: **Yes** **7.78** **Mid bloom** THE: No 0.66 **Late bloom** THE: No 0.68	**Early bloom** THE: No 0.50 **Mid bloom** THE: No 0.08 **Late bloom** THE: No 0.08	*Blueberries* *Registered* for *foliar application at 2 × 70 g a.i./ha (total of 140 g a.i./ha) per season. Also registered for soil drench at140 g a.i./ha, renovation is applicable to lowbush blueberries after one or two years of harvest.*

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
Loamy sand soil was in Ephrata, Washington LOQ: 1 ppb for pollen and 0.5 ppb for nectar	c.e. **Early bloom** THE: 18.5 Combined residues 20.6 **Mid bloom** THE: 38.2 Combined residues 54 **Late bloom** THE: 51.9 Combined residues 66.8	c.e. **Early bloom** THE: 79 Combined residues 118 **Mid bloom** THE: 9.3 Combined residues 26 **Late bloom** THE: 8.8 Combined residues 39.6	c.e. **Early bloom** Combined residues **Yes** **9.36** **Mid bloom** Combined residues **Yes** **2.06** **Late bloom** Combined residues **Yes** **3.14**	c.e. **Early bloom** Combined residues **Yes** **4.54** **Mid bloom** Combined residues **Yes** **1.13** **Late bloom** Combined residues **Yes** **1.68**	c.e. **Early bloom** Combined residues **Yes** **7.91** **Mid bloom** Combined residues **Yes** **1.84** **Late bloom** Combined residues **Yes** **2.77**	c.e. **Early bloom** THE: 8.23 Combined residues 9.23 **Mid bloom** THE: 28.2 Combined residues 40 **Late bloom** THE: 38.3 Combined residues 52	c.e. **Early bloom** THE: 55.9 Combined residues 103 **Mid bloom** THE: 7.9 Combined residues 22.7 **Late bloom** THE: 7.58 Combined residues 31.6	c.e. **Early bloom** Combined residues **Yes** **81.7** **Mid bloom** Combined residues **Yes** **18** **Late bloom** Combined residues **Yes** **25.1**	c.e. **Early bloom** Combined residues **Yes** **39.4** **Mid bloom** Combined residues **Yes** **9.68** **Late bloom** Combined residues **Yes** **13.4**	c.e. **Early bloom** Combined residues **Yes** **13.8** **Mid bloom** Combined residues **Yes** **3.19** **Late bloom** Combined residues **Yes** **4.42**	
	loam **Early bloom** THE: 828 COD: 168 **Mid bloom** THE: 546 COD:	loam **Early bloom** THE: 431 COD: 421 **Mid bloom** THE: 459 COD:	**Early bloom** THE: **Yes** **28.6** **Mid bloom** THE: **Yes** **30.5** **Late bloom** THE:	**Early bloom** THE: **Yes** **15.5** **Mid bloom** THE: **Yes** **15.8** **Late bloom** THE:	**Early bloom** THE: No 0.07 **Mid bloom** THE: No 0.07 **Late bloom** THE:	loam **Early bloom** THE: 788 COD: 135 **Mid bloom** THE: 518 COD:	loam **Early bloom** THE: 275 COD: 357 **Mid bloom** THE: 282	**Early bloom** THE: **Yes** **32.8** **Mid bloom** THE: **Yes** **33.6** **Late bloom** THE:	**Early bloom** THE: **Yes** **18.8** **Mid bloom** THE: **Yes** **18.1** **Late bloom** THE:	**Early bloom** THE: **Yes** **2.28** **Mid bloom** THE: **Yes** **2.27** **Late bloom** THE:	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	174 **Late bloom** THE: 462 COD: 173 c.e. **Early bloom** THE: 709 Combined residues 877 **Mid bloom** THE: 467 Combined residues 641 **Late bloom** THE: 395 Combined residues 568	381 **Late bloom** THE: 267 COD: 184 c.e. **Early bloom** THE: 369 Combined residues 790 **Mid bloom** THE: 392 Combined residues 773 **Late bloom** THE: 228 Combined residues 413	**Yes** **17.7** c.e. **Early bloom** Combined residues **Yes** **62.7** **Mid bloom** Combined residues **Yes** **61.3** **Late bloom** Combined residues **Yes** **32.8**	**Yes** **9.5** c.e. **Early bloom** Combined residues **Yes** **32.3** **Mid bloom** Combined residues **Yes** **31.1** **Late bloom** Combined residues **Yes** **17.2**	No 0.04 c.e. **Early bloom** Combined residues **Yes** **54.4** **Mid bloom** Combined residues **Yes** **52.8** **Late bloom** Combined residues **Yes** **28.7**	146 **Late bloom** THE: 378 COD: 126 c.e. **Early bloom** THE: 675 Combined residues 809 **Mid bloom** THE: 443 Combined residues 589 **Late bloom** THE: 323 Combined residues 450	COD: 317 **Late bloom** THE: 143 COD: 149 c.e. **Early bloom** THE: 235 Combined residues 592 **Mid bloom** THE: 241 Combined residues 558 **Late bloom** THE: 122 Combined residues 271	**Yes** **17.1** c.e. **Early bloom** Combined residues **Yes** **470** **Mid bloom** Combined residues **Yes** **443** **Late bloom** Combined residues **Yes** **215**	**Yes** **9.65** c.e. **Early bloom** Combined residues **Yes** **246** **Mid bloom** Combined residues **Yes** **228** **Late bloom** Combined residues **Yes** **115**	**Yes** **1.18** c.e. **Early bloom** Combined residues **Yes** **82.2** **Mid bloom** Combined residues **Yes** **76.8** **Late bloom** Combined residues **Yes** **37.9**	
	Loamy sand **Early bloom**	Loamy sand **Early bloom**	**Early bloom**	**Early bloom**	**Early bloom**	Loamy sand **Early bloom**	Loamy sand	**Early bloom**	**Early bloom**	**Early bloom**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	THE: 379 COD: 55.4 **Mid bloom** THE: 164 COD: 49.4 **Late bloom** THE: 52.2 COD: 7.76 c.e. **Early bloom** THE: 324 Combined residues 380 **Mid bloom** THE: 140 Combined residues 189 **Late bloom** THE: 44.7	THE: 16 COD: 39.6 **Mid bloom** THE: 14.9 COD: 29.7 **Late bloom** THE: 2.05 COD: 6.07 c.e. **Early bloom** THE: 13.7 Combined residues 53.3 **Mid bloom** THE: 12.8 Combined residues 42.5 **Late bloom** THE: 1.8	THE: **Yes** **1.07** **Mid bloom** THE: **Yes** **0.99** **Late bloom** THE: No 0.14 c.e. **Early bloom** Combined residues **Yes** **4.23** **Mid bloom** Combined residues **Yes** **3.37** **Late bloom** Combined residues **Yes** **0.62**	THE: **Yes** **1.34** **Mid bloom** THE: **Yes** **0.83** **Late bloom** THE: No 0.18 c.e. **Early bloom** Combined residues **Yes** **3.02** **Mid bloom** Combined residues **Yes** **2.11** **Late bloom** Combined residues	THE: No 0.00 **Mid bloom** THE: No 0.00 **Late bloom** THE: No 0.00 c.e. **Early bloom** Combined residues **Yes** **4.31** **Mid bloom** Combined residues **Yes** **3.21** **Late bloom** Combined residues **Yes** **0.62**	THE: 314 COD: 43.7 **Mid bloom** THE: 96 COD: 38.1 **Late bloom** THE: 46.6 COD: 5.62 c.e. **Early bloom** THE: 269 Combined residues 312 **Mid bloom** THE: 82 Combined residues 120 **Late bloom** THE: 40	**Early bloom** THE: 13.4 COD: 31.5 **Mid bloom** THE: 9.85 COD: 21.2 **Late bloom** THE: 1.6 COD: 4.74 c.e. **Early bloom** THE: 11.5 Combined residues 42.9 **Mid bloom** THE: 8.43 Combined residues 29.6	THE: **Yes** **1.6** **Mid bloom** THE: **Yes** **1.18** **Late bloom** THE: No 0.19 c.e. **Early bloom** Combined residues **Yes** **34.1** **Mid bloom** Combined residues **Yes** **23.5** **Late bloom** Combined residues	THE: **Yes** **2.0** **Mid bloom** THE: No 0.94 **Late bloom** THE: No 0.24 c.e. **Early bloom** Combined residues **Yes** **24.5** **Mid bloom** Combined residues **Yes** **14.4** **Late bloom** Combined residues **Yes** **3.51**	THE: No 0.17 **Mid bloom** THE: No 0.10 **Late bloom** THE: No 0.02 c.e. **Early bloom** Combined residues **Yes** **6.97** **Mid bloom** Combined residues **Yes** **4.43** **Late bloom** Combined residues **Yes** **1.0**	

Sampled Crop & Considerations	EEC - Maximum residue value in ppb / Maximum residue value in c.e. ppb		Did the Acute RQ[1] exceed LOC (0.4)? (RQ)			EEC - Mean residue value in ppb / Mean residue value in c.e. ppb		Did the Chronic RQ[2] exceed LOC (1.0)? (RQ)			Residue Data is Related to Registered Crop Group
	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	Pollen	Nectar	Nectar forager	Nurse bees	Bee larvae	
	Combined residues 52.4	Combined residues 7.8		**Yes 0.43**		Combined residues 45.5	**Late bloom** THE: 1.37 Combined residues 6.1	**Yes 4.85**			

CG = crop group, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, Y = year
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)
Bold values indicate that acute LOC (RQ ≥0.4 acute and 1.0 chronic) is exceeded.
1 Acute RQ = Acute estimated daily dose (EDD)/acute toxicity endpoint
Acute EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose [pollen consumption rate (mg/day) × maximum pollen residue (µg/kg)/1.0 × 106]
2 Chronic RQ = Chronic estimated daily dose (EDD)/chronic toxicity endpoint
Chronic EDD = nectar dose [nectar consumption rate (mg/day) × maximum nectar residue (µg/kg)/ 1.0 × 106] + pollen dose
Daily consumption rate used for adult worker bees foraging for nectar: 292 mg/day nectar; 0.041 mg/day pollen; 292 mg/day total
Daily consumption rate used for adult nurse bees: 140 mg/day nectar; 9.6 mg/day pollen; 149.6 mg/day total
Daily consumption rate used for bee larvae: 120 mg/day nectar; 3.6 mg/day pollen; 124 mg/day total

Note, for thiamethoxam RA: adult acute oral **LD50 = 0.0044 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = 0.78 µg a.i./larva/day for TGAI**
Note, for thiamethoxam RA: adult chronic oral **NOED = 0.00245 µg a.i./bee for TGAI;** bee larvae chronic **22-day NOED = 0.0157 µg a.i./larva/day for TGAI**
Note, for clothianidin equivalents RA: adult acute oral **LD50 = 0.00368 µg a.i./bee for TGAI;** bee larvae acute **7-day LD_{50} = >0.0018 µg a.i./larva/day**
Note, for clothianidin equivalents RA: adult chronic **NOED = 0.000368 µg a.i./bee/day;** bee larvae chronic **NOED = 0.0009 µg a.i./larva/day**
NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856), and added to clothianidin for c.e. calculations.
2 Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ

Table 3b Foliar Application: Colony Level Risk to Apis and non-Apis bees Based on Mean Residues of clothianidin equivalents (c.e.)

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
Blueberry Three treatments; control, 3	sand **Early bloom**	sand **Early bloom**	**Sandrock 2014[+] LOEC (6.6)**	**2014 TMX CFS LOEC (34)**	**Fauser-Misslin 2014[+] LOEC (4.9)**	**Stanley and Raine 2017 NOEC**	**Product:** *Actara 25 WG [registration 28408]- Lowbush blueberry*

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
applications before bloom (19, 12 and 5 days before bloom) and 1 application before bloom @ 15 days before bloom. Application rate: 70 g a.i./ha per application. Flowers were sampled at early, mid and late bloom. Sand soil was in Fresno, California Loam soil was in Quebec, Canada Loamy sand soil was in Ephrata, Washington LOQ: 1 ppb for pollen and 0.5 ppb for nectar	9.23 **Mid bloom** 40 **Late bloom** 52	103 **Mid bloom** 22.7 **Late bloom** 31.6	**Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)** **Considering early bloom**	**Elston 2013** **LOEC** **(8.56)**	**(8.56)** **Stanley and Raine 2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts 2010** **NOEC** **(85.6)** **Sandrock 2014[+]** **LOEC** **(2.9)** **Moffat 2016** **LOEC** **(2.14)** **Considering early bloom**	**Application timing:** No restriction on the label. It states 'Do not apply this product to flowering crops or weeds if bees are visiting the treatment area.' Therefore, the timing of application (before bloom) would be applicable to the use pattern. <u>However, it would **not** be conservative for during bloom application</u>. Wait at least 5 days before placing beehives in treated field. **Application rate:** Application rate for foliar application is 2 × 70 g a.i./ha (total of 140 g a.i./ha). Application rate for soil drench is 140 g a.i./ha, renovation is applicable to lowbush blueberries after one or two years of harvest. Therefore, the application in the study at 3 × 70 g a.i./ha is conservative. **Plant relevancy:** The label indicates blueberries, lowbush. Therefore, tested crop is applicable. The method of application in the study is most relevant for the foliar application registration. Residues from the Quebec growing region may be most applicable to Canada.

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
	loam **Early bloom** 809 **Mid bloom** 589 **Late bloom** 450	loam **Early bloom** 592 **Mid bloom** 558 **Late bloom** 271	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC** **(34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)**	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts** **2010** **NOEC** **(85.6)** **Sandrock** **2014[+]** **LOEC** **(2.9)** **Moffat** **2016** **LOEC**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						(2.14)	
	Loamy sand **Early bloom** 312 **Mid bloom** 120 **Late bloom** 45.5	Loamy sand **Early bloom** 42.9 **Mid bloom** 29.6 **Late bloom** 6.1	**Sandrock 2014[+]** **LOEC** **(6.6)** **Straub 2016[+]** **LOEC** **(6.3 ppb)** **Williams 2015[+]** **LOEC** **(4.5)**	**2014** **TMX CFS LOEC** **(34)** **NOEC** **(25.3)** **2016 TMX CFS** **LOEC** **(69.6)** **NOEC** **(34.8)** **2014 CLO CFS** **LOEC (35.6)** **NOEC** **(19)** **2016 CLO CFS** **LOEC (29)** **NOEC** **(19)** Late bloom does not exceed endpoints	**Fauser-Misslin 2014[+]** **LOEC** **(4.9)** **Elston 2013** **LOEC** **(8.56)**	**Stanley and Raine** **2017** **NOEC** **(8.56)** **Stanley and Raine** **2015** **LOEC** **(8.56)** **Stanley 2015 & 2016** **LOEC** **(2.05)** **Baron 2017** **LOEC** **(2.05)** **Laycock 2014** **NOEC** **(13.4)** **LOEC** **(39)** **Mommaerts** **2010** **NOEC** **(85.6)** **Sandrock** **2014[+]** **LOEC** **(2.9)** **Moffat** **2016**	

Sampled Crop	EEC - mean molar adjusted residue value in ppb (c.e.)		Potential risk to *Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Potential risk to non-*Apis* bees from pollen, bee bread or nectar? All endpoints in terms of c.e. ppb. Bolded values exceed residues.		Considerations and relevancy of residues to registered use pattern
	Pollen	Nectar	Pollen (ppb)	Nectar (ppb)	Pollen (ppb)	Nectar (ppb)	
						LOEC (2.14) Late bloom does not exceed some endpoints	

CFS = colony feeding study, CG = crop group, CLO = clothianidin, DALA = days after last application, DAP = days after planting, EEC = estimated environmental concentration, RQ = risk quotient, TMX = thiamethoxam, Y = year

Bold values indicate that acute LOC (RQ ≥1.0) is exceeded.

NOTE: residues are adjusted for molar ratio of thiamethoxam to clothianidin (0.856)

NOTE: for thiamethoxam CFS from registrant, endpoints were also compared to thiamethoxam residues (see mean residues from Tier I refined level assessment)

[2]Standardized maximum value either ½ LOD or ½ LOQ or ½ LOD +LOQ

+ These studies were conducted with both thiamethoxam and clothianidin

List of References

A. Registrant Submitted Studies/Information

A.1 Environmental Assessment

A.1.1 Environmental Fate and Effects Assessment

PMRA Document Number	Reference
2842660	2016, Thiamethoxam 5 FS (A9765N) – Investigating the use of vacuum planter exhaust deflectors and a polyethylene wax lubricant (BFA) in mitigating dust released from pneumatic planting equipment during corn planting in North America in 2014 – Final report. DACO: 8.5.
2821253	2017, Thiamethoxam Technical - Honey bee brood and colony level effects following thiamethoxam intake via treated sucrose solution in a field study in North Carolina - USA 2016 - Final report. DACO: 9.9
2820119	2017, Colony feeding study evaluating the chronic effects of clothianidin-fortified sugar diet on honey bee (Apis mellifera) colony performance under free foraging conditions, DACO: 9.2.4.6
2821252	2017, Thiamethoxam 25WG (A9584C) Magnitude of residues in Pollen, Nectar, Flowers, and Leaves of Stone Fruit After Foliar Application with Actara 25WG in California Final Report Amendment 2. DACO 8.5
2821249	2017, Thiamethoxam 75WG (A9584C) Residues in Leaves, Flowers, Pollen, and Nectar of Ornamental Plants After Foliar or Soil Applications in the USA Final Report. DACO: 8.5
2821245	2017, Thiamethoxam 75WG (A9584C) Determination of Residues in Leaves, Flowers, Pollen, and Nectar of Blueberry After Foliar Application Final Report
2766427	2016, Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) – A field Study to Evaluate Side Effects on Red Mason Bees (*Osmia bicornis L*) in Winter Oil Seed Rape in Germany (Celle), Final report.
2667959	2015, Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) – A field Study to Evaluate Side Effects on Red Mason Bees (*Osmia bicornis L*) in Winter Oil Seed Rape in Germany (Kraichtal), Final report.
2667961	2015, Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) – A field Study to Evaluate Side Effects on Red Mason Bees (*Osmia bicornis L*) in Winter Oil Seed Rape in France (Alcase), Final report.

Additional Information Considered

B.1 Published Information

B.1.0 Environmental Assessment

B.1.1 Environmental Fate and Effects Assessment

Reference
Alford, A., Krupke C. March 2017. Translocation of the neonicotinoid seed treatment clothianidin in maize. PLOS ONE. DOI:10.1371
Bishop CA, Moran AJ, Toshack MC, Elle E, Maisonneuve and JE Elliott. 2018. Hummingbirds and bumble bees exposed to neonicotinoid and organophosphate insecticides in the Fraser Valley, British Columbia, Canada. Environmental Toxicology and Chemistry. 37(8): 2143-2152. DACO 9.2.4.6
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Botías, C., A. David, E. M. Hill and D. Goulson (2016). Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects. Science of the Total Environment 566-567: 269-278.
David, A., C. Botías, A. Abdul-Sada, E. Nicholls, E. L. Rotheray, E. M. Hill and D. Goulson (2016). Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. Environment International 88: 169-178.
Goulson, D. 2013. An overview of the environmental risks posed by neonicotinoid insecticides. Journal of Applied Ecology. DOI:10.111
Hladik, M. et al., 2017. Neonicotinoid insecticide removal by prairie strips in row-cropped watersheds with historical seed coating use. Agriculture, Ecosystems and Environment. DOI:10.1016
Hladik, M. et al., 2018. Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA. Environmental Pollution. DOI:10.1016
Krupke, C. H., J. D. Holland, E. Y. Long and B. D. Eitzer (2017). Planting of neonicotinoid treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. Journal of Applied Ecology 54: 1449-1458.
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McCurdy J. et al., March 2017. Dew from warm-season turfgrasses as a possible route for pollinator exposure to lawn-applied imidacloprid. Crop Forage Turfgrass Manage. DOI:10.2134
Stewart, S. D., G. M. Lorenz, A. L. Catchot, J. Gore, D. Cook, J. Skinner, T. C. Mueller, D. R. Johnson, J. Zawislak and J. Barber (2014). Potential exposure of pollinators to neonicotinoid insecticides from the use of insecticide seed treatments in the mid-southern United States. Environmental Science & Technology 48(16): 9762-9769.
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Schaafsma, A., Limay-Rios V., and Forero L. (2018). The role of field dust in pesticide drift when pesticide-treated maize seeds are planted with vacuum-type planters. Pest Management

Science. 74(2): 323-331
Rondeau, Gary, Francisco Sánchez-Bayo, Henk A. Tennekes, Axel Decourtye, Ricardo Ramírez-Romero, and Nicolas Desneux (2015). "Delayed and Time-Cumulative Toxicity of Imidacloprid in Bees, Ants and Termites." Scientific Reports 4, no. 1. https://doi.org/10.1038/srep05566.
Tennekes H.A. "The Significance of the Druckrey-Küpfmüller (2010) Equation for Risk Assessment - The Toxicity of Neonicotinoid Insecticides to Arthropods Is Reinforced by Exposure Time." Toxicology 276, no. 1: 1–4. https://doi.org/10.1016/j.tox.2010.07.005.