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Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D Ottawa, Ontario K1A 0K9
Email: PMRA.publications@hc-sc.gc.ca

To Whom It May Concern:

Re: Response to Proposed Registrations and Pollinator Re-evaluations of Clothianidin and Thiamethoxam

These are the joint comments of Équiterre, Environmental Defence, the Canadian Association of Physicians for the Environment (CAPE), Canadian Environmental Law Association and the David Suzuki Foundation on PRD2017-17[1] and PRVD2017-23[2] as well as PRD2017-18[3] and PRVD2017-24,[4] the pollinator re-evaluations and proposed registration decisions of clothianidin and thiamethoxam and their end use products. Our organizations have a long standing interest in pesticide regulation and protecting pollinators.

The value of pollination services is unquestioned. Of 124 major commodity crops directly used for human consumption, 70% are dependent on pollination for enhanced production.[5,6] What is more, crop pollination as an ecosystem service is increasing in relative importance

[1] Health Canada, Pest Management Regulatory Agency, Clothianidin - Proposed Registration Decision. PRD 2017-17, 19 December 2017. Hereinafter PRD 2017-17.
[2] Health Canada, Pest Management Regulatory Agency, Clothianidin and Its Associated End-use Products: Pollinator Evaluation. Proposed Re-evaluation Decision, PRVD 2017-23, December 2017. Hereinafter PRVD 2017-23.
[3] Health Canada, Pest Management Regulatory Agency, Thiamethoxam - Proposed Registration Decision. PRD 2017-18, 19 December 2017. Hereinafter PRD 2017-18.
[4] Health Canada, Pest Management Regulatory Agency, Thiamethoxam and Its Associated End-use Products: Pollinator Evaluation. Proposed Re-evaluation Decision, PRVD 2017-24, December 2017. Hereinafter PRVD 2017-24.
[5] Chagnon, Madeleine, David Kreutzweiser, Edward A.D. Mitchell, Christy A. Morrissey, Dominique A. Noome, and Jeroen P. Van der Sluijs. "Risks of Large-Scale Use of Systemic Insecticides to Ecosystem Functioning and Services." *Environmental Science and Pollution Research* 22, no. 1 (January 2015): 119–34. https://doi.org/10.1007/s11356-014-3277-x.
[6] Klein, A.-M., B. E Vaissiere, J. H Cane, I. Steffan-Dewenter, S. A Cunningham, C. Kremen, and T. Tscharntke. "Importance of Pollinators in Changing Landscapes for World Crops." *Proceedings of the Royal Society B: Biological Sciences* 274, no. 1608 (February 7, 2007): 303–13. https://doi.org/10.1098/rspb.2006.3721.

worldwide. From 1961 to 2006, pollinator-dependent crops contributed 16.7% more to agricultural production in the developed world,[7] and it is understood that this percentage will continue to rise based on increased consumption of pollinator dependent crops (e.g. canola is an exemplary case in Canadian agriculture).[8]

When public health researchers conducted a study to determine how people around the world might be affected by the total loss of pollinators, such as bees, they estimated that global fruit supplies would decrease by 23%, vegetables by 16%, and nuts and seeds by 22%. Further, they predicted that these changes in food supplies could increase global deaths from chronic and nutrition-related diseases by 1.42 million people per year.[9]

The widespread use of neonicotinoids has led to pollinator losses and other adverse ecosystem impacts that erode biodiversity and threaten ecological services upon which we, as human are dependent for food, clothing and shelter. **We therefore call for the immediate deregistration of clothianadin and thiamethoxam, as well as other neonicotinoids.** In light of significant new evidence that neonicotinoids are unnecessary in agriculture, we recommend supporting farmers in the transition to less toxic alternative pest management strategies, including through capacity-building programs. These and other recommendations are summarized in Appendix A and discussed below in further detail.

We are concerned that Canada continues to lag behind other OECD countries in the regulation of neonicotinoids. We are also concerned that the PMRA continues to maintain a piecemeal approach to risk assessments on neonicotinoids, making at least 10 separate risk assessments over 8 years. This disjointed approach does not appropriately reflect scientific concerns of ecosystem-level impacts, nor does it acknowledge the extensive and concurrent application of these top-selling insecticides in Canada which results in widespread ecosystem-level contamination. A more comprehensive ecosystem-level approach is needed in the regulatory assessment of all pesticides, including neonicotinoids that are so heavily present in our environment.

We focus our comments on the following issues:

- **I The proposed phase-out of certain uses**
- **II The scope of the assessments is too narrow**
- **III Risks to pollinators from contamination of the broader environment**
- **IV Crops harvested before bloom**
- **V The value of clothianidin and thiamethoxam is limited and over-rated**
- **VI International context**

We note that the PMRA has taken the position that it is carrying out consultation regarding the proposed registration decisions (PRD 2017-17 and PRD 2017-18) under s. 28(1)(c) of

[7] Aizen, Marcelo A., and Lawrence D. Harder. "The Global Stock of Domesticated Honey Bees Is Growing Slower Than Agricultural Demand for Pollination." *Current Biology* 19, no. 11 (June 2009): 915–18. https://doi.org/10.1016/j.cub.2009.03.071.

[8] Schulp, C.J.E., S. Lautenbach, and P.H. Verburg. "Quantifying and Mapping Ecosystem Services: Demand and Supply of Pollination in the European Union." *Ecological Indicators* 36 (January 2014): 131–41. https://doi.org/10.1016/j.ecolind.2013.07.014.

[9] Smith, Matthew R, Gitanjali M Singh, Dariush Mozaffarian, and Samuel S Myers. "Effects of Decreases of Animal Pollinators on Human Nutrition and Global Health: A Modelling Analysis." *The Lancet*, July 2015. https://doi.org/10.1016/S0140-6736(15)61085-6.

the *Pest Control Products Act* (the "**PCPA**"). However, it is our position that consultation on the proposed registration decisions is required under s. 28(1)(a) of the PCPA given that data are being evaluated on a prior conditional and thus incomplete registration. In addition, consultation regarding the proposed re-evaluation decisions (PRVD 2017-23 and PRVD 2017-24) is required under s. 28(1)(b) of the PCPA. As such, both the proposed registration decisions and proposed re-evaluation decisions are subject to s. 35(1) of the PCPA, and we submit these comments for consideration in all four decisions.

I. The proposed phase-out of certain uses

We urge the PMRA to move forward immediately with the proposed deregistration of clothianidin as a foliar application to orchard trees and strawberries, and as a foliar application to municipal, industrial and residential turf sites. We also urge the PMRA to move forward immediately with the proposed deregistration of thiamethoxam for: foliar and soil applications to ornamental crops that will result in pollinator exposure; soil applications to berry crops, cucurbit crops and fruiting vegetables; and foliar applications to orchard trees.

Considering the PMRA does not expect to publish the final re-evaluation decisions until December 2018 – more than six years after the pollinator re-evaluations were launched – further delays in the implementation of risk mitigation measures should be avoided. Every additional season that these products remain in use prolongs unacceptable risks to crucial pollinators and worsens the problem of environmental contamination.

These products were not subjected to an appropriate risk assessment with comprehensive data when they were first registered, and never should have been registered. There have already been extensive delays in PMRA risk assessments and decision-making. A prolonged phase-out is not justified.

Recommendation 1: The PMRA should immediately deregister clothianidin and thiamethoxam uses/products proposed for phase-out without any further delay.

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.[10] 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.[11]

[10] For example, the EU moratorium extends to corn and rapeseed and prohibits the use of neonic-treated seeds for target crops, whereas the PMRA proposes no regulatory action on these uses.
[11] https://www.efsa.europa.eu/en/topics/topic/bee-health

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.[12]

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.

Recommendation 2: PMRA should revise its risk assessment conclusions to recognize the *overall* risk to pollinators and phase out all outdoor uses.

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.[13] 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.

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 2015-16 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.

[12] EFSA. Neonicotinoids: risks to bees confirmed. News release. February 28, 2018.
[13] Remoundou, Kyriaki, Mary Brennan, Andy Hart, and Lynn J. Frewer. "Pesticide Risk Perceptions, Knowledge, and Attitudes of Operators, Workers, and Residents: A Review of the Literature." *Human and Ecological Risk Assessment: An International Journal* 20, no. 4 (July 4, 2014): 1113–38. https://doi.org/10.1080/10807039.2013.799405.

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.

In addition to this overall concern with label modifications to mitigate risk, we note inconsistencies in the PMRA's risk assessment decisions regarding which products will require label modifications. There are inconsistencies between different sections within each consultation and additional inconsistencies across translations from French to English. Using PRVD2017-23 as an example, the content of Table 4 in both language versions does not mention any crop group, which is in contradiction with all previous sections that list crop groups; the crop groups identified in corresponding sections on page 2 of the English version and page 3 of the French version differ; and the descriptions of crop groups found in the French document often differ from one section to another.

These inconsistencies, alongside the patchwork of use restrictions proposed in PRVD2017-23 and PRVD2017-24 reinforce our broader concerns with the PMRA's ability to ensure compliance. We believe that tinkering with label requirements on multiple products is not a credible response to the immediate ecological risks posed by these pesticides.

Recommendation 3: In the absence of a full ban on these pesticides, investigate the effectiveness of label statements in reducing ecological risks and increase capacity to ensure monitoring and compliance.

II. The scope of the assessments is too narrow

a) PRVD2017-23 and PRVD2017-24 do not evaluate risks to all pollinators, despite known risks, and do not acknowledge this limitation.

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.

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.[14,15,16,17,18] 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.[19,20] According to the Worldwide Integrated Assessment of the Impact of Systemic Pesticides on Biodiversity and Ecosystems,[21] "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.[22] Kearns and Inouye[23] and Ollerton et al[24] 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,[25] 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.

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[14] Buchmann SL (1997) *The forgotten pollinators*. Island Press, Washington, DC, p 312.
[15] Klein *et al* 2007, *op cit*.
[16] De Luca, Paul A, and Mario Vallejo-Marín. "What's the 'Buzz' about? The Ecology and Evolutionary Significance of Buzz-Pollination." *Current Opinion in Plant Biology* 16, no. 4 (August 2013): 429–35. https://doi.org/10.1016/j.pbi.2013.05.002.
[17] Ghanem, Simon J., and Christian C. Voigt. "Increasing Awareness of Ecosystem Services Provided by Bats." In *Advances in the Study of Behavior*, 44:279–302. Elsevier, 2012. https://doi.org/10.1016/B978-0-12-394288-3.00007-1.
[18] Vanbergen, Adam J, and the Insect Pollinators Initiative. "Threats to an Ecosystem Service: Pressures on Pollinators." *Frontiers in Ecology and the Environment* 11, no. 5 (June 2013): 251–59. https://doi.org/10.1890/120126.
[19] Bartomeus, Ignasi, Mia G. Park, Jason Gibbs, Bryan N. Danforth, Alan N. Lakso, and Rachael Winfree. "Biodiversity Ensures Plant-Pollinator Phenological Synchrony against Climate Change." Edited by Micky Eubanks. *Ecology Letters* 16, no. 11 (November 2013): 1331–38. https://doi.org/10.1111/ele.12170.
[20] LaBar, Thomas, Colin Campbell, Suann Yang, Réka Albert, and Katriona Shea. "Global versus Local Extinction in a Network Model of Plant–pollinator Communities." *Theoretical Ecology* 6, no. 4 (November 2013): 495–503. https://doi.org/10.1007/s12080-013-0182-8.
[21] Chagnon *et al*, 2015, *op. cit*.
[22] Kim, Ke Chung. "Biodiversity, Conservation and Inventory: Why Insects Matter." *Biodiversity and Conservation* 2, no. 3 (June 1993): 191–214. https://doi.org/10.1007/BF00056668.
[23] Kearns, Carol Ann, and David William Inouye. "Pollinators, flowering plants, and conservation biology: much remains to be learned about pollinators and plants." *BioScience*, vol. 47, no. 5, 1997, p. 297-307.
[24] Ollerton, Jeff, Rachael Winfree, and Sam Tarrant. "How Many Flowering Plants Are Pollinated by Animals?" *Oikos* 120, no. 3 (March 2011): 321–26. https://doi.org/10.1111/j.1600-0706.2010.18644.x.
[25] Benadi, Gita, Nico Blüthgen, Thomas Hovestadt, and Hans-Joachim Poethke. "When Can Plant-Pollinator Interactions Promote Plant Diversity?" *The American Naturalist* 182, no. 2 (August 2013): 131–46. https://doi.org/10.1086/670942.

Recommendation 4: 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.

b) Both acute and long-term cumulative and synergistic effects on pollinators were not thoroughly considered.

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.

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.”[26] 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[27] provide evidence of additivity and synergisms of toxic mechanisms of action between neonicotinoids and other pesticide active ingredients.

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 ahd biomarkers of physiological stress than those in untreated fields suggesting an indirect weakening of honeybee health via induction of stress and increased pathogen loads.[28] A second year of study on these hives found

[26] PRVD 2017-24, *op. cit* p.9.
[27] Iwasa, Takao, Naoki Motoyama, John T. Ambrose, and R.Michael Roe. “Mechanism for the Differential Toxicity of Neonicotinoid Insecticides in the Honey Bee, Apis Mellifera.” *Crop Protection* 23, no. 5 (May 2004): 371–78. https://doi.org/10.1016/j.cropro.2003.08.018.
[28] Alburaki, Mohamed, Sébastien Boutin, Pierre-Luc Mercier, Yves Loublier, Madeleine Chagnon, and Nicolas Derome. “Neonicotinoid-Coated Zea Mays Seeds Indirectly Affect Honeybee Performance and Pathogen Susceptibility in Field Trials.” Edited by Cesar Rodriguez-Saona. *PLOS ONE* 10, no. 5 (May 18, 2015): e0125790. https://doi.org/10.1371/journal.pone.0125790.

similar results.[29] 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.

Recommendation 5: The PMRA should assess synergistic effects of neonics with fungicides, and the cumulative risks of all neonics including their degradation products.

c) The body of literature considered by the PMRA is mostly unpublished data.

The *Pest Control Products Act* puts the onus on the registrant to persuade the Minister that the health and environmental risks and the value of the pest control product are acceptable. To persuade the Minister the registrants submit unpublished data and public review of these studies can only occur briefly, after a proposed decision is made, and through the PMRA's Reading Room. While the Act states that the Minister must consider the data and studies provided by the registrants, it also allows her to consider any additional information, such as peer reviewed published papers. The Minister must determine if the health and environmental risks and the value of the pest control product are acceptable, and in doing so she should use her authority to fully review the relevant scientific literature.

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

[29] Alburaki, M., B. Cheaib, L. Quesnel, P.-L. Mercier, M. Chagnon, and N. Derome. "Performance of Honeybee Colonies Located in Neonicotinoid-Treated and Untreated Cornfields in Quebec." *Journal of Applied Entomology* 141, no. 1–2 (February 2017): 112–21. https://doi.org/10.1111/jen.12336.

PMRA's forthcoming pollinator risk assessment for imidacloprid but this may not account for the entire difference.

Recommendation 6: The PMRA should assess all relevant data and studies, including those referenced in EFSA.

III. 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,[30,31,32,33] 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.

a) Limiting foliar application frequencies or application periods will not prevent contamination.

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.

Recent findings in ecotoxicology suggest that some chemicals, including neonicotinoids, can produce toxic effects at any concentration provided a sufficiently long time of exposure[34,35]

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[30] Ontario Agency for Health Protection and Promotion (Public Health Ontario), Somers N., Chung R. Case study: Neonicotinoids. Toronto, ON: Queen's Printer for Ontario; 2014. https://www.publichealthontario.ca/en/eRepository/Case_Study_Neonicotinoids_2015.pdf

[31] Anderson, J.C., C. Dubetz, and V.P. Palace. "Neonicotinoids in the Canadian Aquatic Environment: A Literature Review on Current Use Products with a Focus on Fate, Exposure, and Biological Effects." *Science of The Total Environment* 505 (February 2015): 409–22. https://doi.org/10.1016/j.scitotenv.2014.09.090.

[32] Main, Anson R., John V. Headley, Kerry M. Peru, Nicole L. Michel, Allan J. Cessna, and Christy A. Morrissey. "Widespread Use and Frequent Detection of Neonicotinoid Insecticides in Wetlands of Canada's Prairie Pothole Region." Edited by Christopher Joseph Salice. *PLoS ONE* 9, no. 3 (March 26, 2014): e92821. https://doi.org/10.1371/journal.pone.0092821.

[33] Health Canada, Pest Management Regulatory Agency, Inititation of Special Reviews: Potential Environmental Risk to Aquatic Invertebrates Related to the Use of Clothianidin and Thiamethoxam. Re-evaluation Note REV 2016-17. 23 November 2016.

[34] Tennekes H.A. "The Significance of the Druckrey-Küpfmüller Equation for Risk Assessment - The Toxicity of Neonicotinoid Insecticides to Arthropods Is Reinforced by Exposure Time." *Toxicology* 276, no. 1 (September 2010): 1–4. https://doi.org/10.1016/j.tox.2010.07.005.

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.[36]

Recommendation 7: Limiting foliar application frequencies or application periods will not prevent environmental contamination. All foliar uses should be immediately deregistered.

b) Dust mitigation measures are insufficient to prevent environment contamination and protect pollinators.

Studies have documented extensive dust drift to adjacent farms during treated seed sowing.[37] The proposed re-evaluation decisions, PRVD 2017-23 and PRVD 2017-24, 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 overtime.

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.

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

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[35] Rondeau, Gary, Francisco Sánchez-Bayo, Henk A. Tennekes, Axel Decourtye, Ricardo Ramírez-Romero, and Nicolas Desneux. "Delayed and Time-Cumulative Toxicity of Imidacloprid in Bees, Ants and Termites." *Scientific Reports* 4, no. 1 (May 2015). https://doi.org/10.1038/srep05566.
[36] Chagnon *et al* 2015, *op.cit.*
[37] Krupke, C. H., J. D. Holland, E. Y. Long, and B. D. Eitzer. "Planting of Neonicotinoid-Treated Maize Poses Risks for Honey Bees and Other Non-Target Organisms over a Wide Area without Consistent Crop Yield Benefit." Edited by Sarah Diamond. *Journal of Applied Ecology* 54, no. 5 (October 2017): 1449–58. https://doi.org/10.1111/1365-2664.12924.

behaviour, and the abilities of colonies to sustain a laying queen overtime.[38] 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."[39]

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 references 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.[40] 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[41] 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[42] 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

[38] Tsvetkov, N., O. Samson-Robert, K. Sood, H. S. Patel, D. A. Malena, P. H. Gajiwala, P. Maciukiewicz, V. Fournier, and A. Zayed. "Chronic Exposure to Neonicotinoids Reduces Honey Bee Health near Corn Crops." *Science* 356, no. 6345 (2017): 1395–1397.
[39] *Ibid*, at pp. 1396-97.
[40] Woodcock, B. A., J.M. Bullock, and et al. "Country-Specific Effects of Neonicotinoid Pesticides on Honey Bees and Wild Bees." *Science* 356 (2017): 1393–95.
[41] Rundlöf, Maj, Georg K. S. Andersson, Riccardo Bommarco, Ingemar Fries, Veronica Hederström, Lina Herbertsson, Ove Jonsson, et al. "Seed Coating with a Neonicotinoid Insecticide Negatively Affects Wild Bees." *Nature*, April 22, 2015. https://doi.org/10.1038/nature14420.
[42] Douglas, Margaret R., and John F. Tooker. "Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops." *Environmental Science & Technology* 49, no. 8 (April 21, 2015): 5088–97. https://doi.org/10.1021/es506141g.

were treated with thiamethoxam.[43] This translates into nearly 2.5 million hectares planted with thiamethoxam and clothianidin-treated corn and soybean seed alone;[44] 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

Recommendation 8: 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.

IV. Crops harvested before bloom

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".[45]

Recommendation 9: 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.

V. The value of clothianidin and thiamethoxam is limited and over-rated

PRVD2017-23 and PRVD2017-24 refer to the value assessment of the use of neonicotinoid corn and soybean seed treatments, which the PMRA published for consultation in 2016.[46]

[43] Health Canada, Pest Management Regulatory Agency, Value Assessment of Corn and Soybean Seed Treatment Use of Clothianidin, Imidacloprid and Thiamethoxam, Re-evaluation Note REV2016-03, 6 January 2016.
[44] Calculated based on seeded areas in 2013 as reported by Statistics Canada in the summary table *Field and special crops (seeded areas)*. http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/prim11a-eng.htm
[45] Canadian Seed Growers' Association. Seed Indsutry Stats. http://seedgrowers.ca/seed-industry-stats/
[46] Health Canada, Pest Management Regulatory Agency, Value Assessment of Corn and Soybean Seed Treatment Use of Clothianidin, Imidacloprid and Thiamethoxam, Re-evaluation Note REV 2016-03, 6 January 2016. Hereinafter REV 2016-03.

REV 2016-03 concludes that neonicotinoids add limited value to corn and soybean production in Canada (just 3.2 to 3.6 per cent of the national farm gate value for corn, and 1.5 to 2.1 per cent for soybean).

REV2016-03 also refers to the need to seek additional information to finalize the value assessment for both corn and soybean seed treatment stating that: “In order to fully assess the economic value of clothianidin and thiamethoxam seed treatments to the Canadian corn and soybean industries, quantitative, more real-world information on typical pest population levels relative to economic thresholds is needed.”[47] It appears the PMRA has not collected such information for either corn or soybeans or any of the many other crops for which seed treatments would be allowed under the proposed registration decisions in PRD 2017-17 and 2017-18.

Rather, despite the information gaps noted in REV2016-03, the PMRA fails to review new research on value in PRVD2017-23 and PRVD2017-24, stating that there was no additional information required beyond the previous value assessment conducted in 2016. We are left to conclude that the PMRA identified a knowledge gap in 2016 (and only with respect to corn and soybeans), did not fill it with new information nor issue a Section 12 notice to registrants to fill it, and instead now applies this limited value assessment to multiple additional treated seed crops. We see no documentation or even a summary of how the PMRA has investigated the efficacy of these multiple seed treatments as per PCPA requirements.

In addition, the PMRA states in both PRVD2017-23 and PRVD2017-24 that economic benefits from using treated seeds depend on whether pest pressures warrant the treated seeds in the first place, but go on to rationalize use by saying that it is challenging to identify pests before planting. This conclusion fails to consider the 2018 review by the Task Force on Systemic Pesticides[48] that identifies reliable early detection methods to assess the risks of pest presence, methods that have been successfully applied in other countries at low cost. Furthermore, the small remaining risk to individual farmers of economic losses due to pest damage can be mitigated through an insurance arrangement developed in Italy, which has been demonstrated to be more cost-effective and has no negative environmental effects.

Despite the REV 2016-03 conclusion noting very modest value of corn and soybean seed treatments, the true value is probably even less. The Task Force on Systemic Pesticides reviewed over 200 peer-reviewed studies from around the world and 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 neonics cause adverse collateral effects on beneficial species, which undermines their overall value to agriculture.[49]

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[47] *Ibid*, p.4.

[48] Furlan, Lorenzo, Alberto Pozzebon, Carlo Duso, Noa Simon-Delso, Francisco Sánchez-Bayo, Patrice A. Marchand, Filippo Codato, Maarten Bijleveld van Lexmond, and Jean-Marc Bonmatin. “An Update of the Worldwide Integrated Assessment (WIA) on Systemic Insecticides. Part 3: Alternatives to Systemic Insecticides.” *Environmental Science and Pollution Research*, February 25, 2018. https://doi.org/10.1007/s11356-017-1052-5..

[49] *Ibid*.

The Task Force makes five central points:

- **The use of neonic-treated seeds does not increase crop yields in most cases.** *For example, in a seminal study[50] by Krupke and colleagues, in field studies planting treated corn seeds over a three-year period did not benefit yeilds. This finding is consistent with results of experiments and assessments on oilseed rape in the EU as well as on soybean in the US (as concluded by the USEPA Biological and Economic Analysis Division).[51]*

  This research calls into question the utility of treated seeds. If the economic injury level is not surpassed in most cases, productivity does not drop if seed treatments are withdrawn, and farmer revenues are protected while farmer expenses decrease (assuming treated seeds are sold at a premium).

- **Pest resistance is increasing, reducing the efficacy of neonicotinoids**
  Pest resistance has been increasing over the past 2 decades of neonicotinoid use, and insect resistance to insecticides is an inevitable phenomenon that undermines the value of any insecticide.

  Since the introduction of clothianidin in 2000, 4 pest insect species (over a total of 40 cases) have been reported to have developed resistance to clothianidin worldwide. Since the introduction of thiamethoxam in 1998, 15 pest insect species (over a total of 205 cases) have been reported to have developed resistance to thiamethoxam worldwide.[52]

- **Early and reliable detection methods to assess the risks of pest presence exist, at low costs**
  A 29-year, large-scale study characterized factors that increase risk of wireworm damage. Assessing the risk of wireworm damage provides a solid basis for identifying farmland that can be left untreated, without any risk of yield reduction – instead of indiscriminately using neonics on a prophylactic basis. Based on this, a model was developed in Italy to predict which fields are at high risk of pest problems, in order to appropriately establish a pest management plan. Findings in North-East Italy show 96 per cent of corn fields do not need any insecticide treatment because relevant pest threats are not present above the economic damage level.[53]

- **Effective strategies are available to protect farmers against economic risks and achieve efficient pest control – e.g., the "mutual fund" (MF) model, a novel insurance method designed to protect farmers against crop failure**
  The collective insurance program in Italy is a strong example of a fiscal incentive that

[50] Krupke *et al* 2017, *op. cit.*
[51] USEPA, Biological and Economic Analysis Division. "Benefits of Neonicotinoid Seed Treatments to Soybean Production," October 2014. https://www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf
[52] Insecticide Resistance Action Committee (IRAC). 2018. Anthropod Pesticide Resistance Database. East Lansing (Michigan, USA): Michigan State University. Access to the database: www.pesticidderesistance.org/search.php
[53] Furlan *et al*, 2018, *op. cit*.

supports Integrated Pest Management. Farmers can invest in the insurance program only if they commit to using IPM. The result for farmers is spending of only 10% of expenses previously put towards pesticides now directed towards insurance payments, and farmer revenues are stable or increasing.

- **All scenarios – whether using IPM and/or insurance cover – are cheaper than using neonic-treated seeds**

Together, these findings not only serve to fill the knowledge gap the PMRA refers to in REV2016-03 but more importantly, support the fact that the systematic use of treated seeds in Canada can no longer be defended in value and risk assessments.

Recommendation 10: The PMRA must revisit its value assessment for clothianidin and thiamethoxam seed treatments in light of the latest findings of the Task Force on Systemic Pesticides.

Recommendation 11: The PMRA should work with other agencies to support and expand training in IPM and pest assessment techniques, as well as the development of insurance mechanisms, to further reduce risks at the farm level.

VI. International context

The sections on the international regulatory context in PRVD2017-23 and PRVD2017-24 are incomplete. Many jurisdictions ban or restrict the use of clothianidin and thiamethoxam, including for seed treatments. Italy prohibited all neonic seed treatments in 2008. As previously noted, in 2013, the European Union restricted the use of seeds treated with clothianidin, thiamethoxam and imidacloprid for several crops including corn, oilseed rape and sunflower. The risk assessment informing this decision concluded that products containing these neonics pose high acute risks to bees due to exposure to neonic residues in dust during sowing of bee-attractive crops, as well as from exposure to neonic-contaminated pollen and nectar.

As discussed above, EFSA has now completed the update to its earlier assessment. A review of 588 studies completed by EFSA in February 2018 concluded that most uses of neonics, including clothianidin and thiamethoxam, pose significant risks to both honey bees and wild bees, including bumblebees and solitary bees. The European Commission is proposing to extend the current restrictions to ban all outdoor agricultural uses of neonics.

France will phase out all uses of clothianidin, thiamethoxam and imidacloprid starting in September 2018.

In Canada, two provinces have adopted regulations to limit the use of seeds treated with neonics, including clothianidin and thiamethoxam, except when pest problems are demonstrated. In Ontario, regulatory measures beginning on July 1, 2015 have aimed to reduce the use of neonic-treated seeds for corn and soybean by 80%. This target was based on an evaluation that found that only 20% of the 5 million acres of corn and soybean farmed in the province demonstrated a need for treated seeds to deal with pest problems. More

recently, Quebec announced new regulations to ban the use of clothianidin and thiamethoxam, for seed treatments and other uses, unless the use is justified.

Recommendation 12: 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.

Conclusion

Based on advancing science that reveals significant risks to pollinators from neonicotinoids, global systematic reviews that confirm the availability of cost-effective alternatives to neonicotinoids as well as their limited value/efficacy, and regulatory precedents for bans elsewhere, we call on the PMRA to strengthen the proposed decisions in PRVD2017-23 and PRVD2017-24 with a complete phase-out of these neonicotinoids. We also call on Canada to invest in improved monitoring of pesticides in the environment and impacts.

In sum, the PMRA's proposed risk mitigation strategies in PRVD2017-23 and PRVD2017-24 do not go far enough to protect pollinator health and any proposed risk mitigation short of a complete and immediate deregistration of neonicotinoids does not align with the conclusions of the body of peer-reviewed literature on the subject.

Appendix A: List of Recommendations

Recommendation 1: The PMRA should immediately deregister clothianidin and thiamethoxam uses/products proposed for phase-out without any further delay.

Recommendation 2: PMRA should revise its risk assessment conclusions to recognize the *overall* risk to pollinators and phase out all outdoor uses.

Recommendation 3: In the absence of a full ban on these pesticides, investigate the effectiveness of label statements in reducing ecological risks and increase capacity to ensure monitoring and compliance.

Recommendation 4: 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.

Recommendation 5: The PMRA should assess synergistic effects of neonics with fungicides, and the cumulative risks of all neonics including their degradation products.

Recommendation 6: The PMRA should assess all relevant data and studies, including those referenced in EFSA.

Recommendation 7: Limiting foliar application frequencies or application periods will not prevent environmental contamination. All foliar uses should be immediately deregistered.

Recommendation 8: 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.

Recommendation 9: 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.

Recommendation 10: The PMRA must revisit its value assessment for clothianidin and thiamethoxam seed treatments in light of the latest findings of the Task Force on Systemic Pesticides.

Recommendation 11: The PMRA should work with other agencies to support and expand training in IPM and pest assessment techniques, as well as the development of insurance mechanisms, to further reduce risks at the farm level.

Recommendation 12: 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.