



November 13, 2018

Pest Management Regulatory Agency
 Health Canada
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Re: Special reviews of clothianidin and thiamethoxam for risks to aquatic invertebrates, PSRD2018-01 and PSRD2018-02

To Whom It May Concern:

Please find attached the comments of the undersigned environmental and conservation organizations on the special reviews of clothianidin and thiamethoxam risks to aquatic invertebrates, PSRD2018-01 and PSRD2018-02.

Clothianidin and thiamethoxam pose unacceptable risks to the environment and we agree that their use should be discontinued in Canada. In addition, we have a number of concerns with the proposed special review decisions. In particular, the proposed three to five year timeline for phase-out would needlessly prolong environmental risks that have not been shown to be acceptable. We strongly recommend accelerating the phase-out timeline and repealing the *Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review*, to be consistent with the *Pest Control Products Act*.

We note that the European Union is moving much more quickly to implement its comprehensive ban on outdoor agricultural uses of clothianidin, thiamethoxam and imidacloprid. The European Commission approved regulations in May 2018 that member states must implement by December 19, 2018 – in just seven months.

While the attached comments address risks to aquatic invertebrates, the aspect of concern examined in PSRD2018-01 and PSRD2018-02, we wish to underscore our broader concerns about evidence that the widespread use of neonicotinoids harms a large number of non-target species – including insect pollinators – in aquatic ecosystems. Many species of the group of pollinators known as hoverflies are aquatic invertebrates in their larval stage.

We are also concerned that recent decisions to register new systemic insecticides could ultimately undermine risk reduction goals of the proposed phase out of imidacloprid, clothianidin and thiamethoxam.

Finally, we note that precautionary label statements are currently required on clothianidin and thiamethoxam products to reduce risks to aquatic habitat. Yet concentrations posing a risk to aquatic insects have been found in Canadian surface waters where products containing these active ingredients are used in agriculture *despite the label statements*. We therefore conclude that precautionary label statements cannot be solely relied upon to protect against environmental risks. We recommend the PMRA launch an initiative to evaluate the effectiveness of precautionary label statements in reducing risks from pesticides and avoid reliance on precautionary label statements to reduce risks until the effectiveness of this approach can be demonstrated.

In addition to this submission on the proposed special review decisions, we are also submitting separate comments on the related thiamethoxam proposed registration decisions, PRD2018-13 and PRD2018-14.

We appreciate the opportunity to comment and would be pleased to discuss with you the issues raised in our submission and provide additional information, if needed.

Sincerely,

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November 13, 2018

Comments on the special reviews of clothianidin and thiamethoxam risks to aquatic invertebrates, PSRD2018-01 and PSRD2018-02

SUMMARY

- Environmental risks from clothianidin and thiamethoxam products have not been shown to be acceptable; we agree these products should not be registered for use in Canada.
- The risk assessments should take into account the aggregate and cumulative risks from multiple neonicotinoid insecticides, as well as potential for ecological cascade effects, which would reinforce the findings and underline the need for immediate cancellation.
- The special reviews should consider all registered uses of clothianidin and thiamethoxam.
- A three to five year delay in prohibiting unacceptable uses of clothianidin and thiamethoxam is unjustified and will prolong environmental risks.

DETAILED COMMENTS

A. Clothianidin and thiamethoxam present unacceptable risks to aquatic invertebrates

The Task Force on Systemic Pesticides concluded that the harmful effects of neonicotinoids on aquatic invertebrates “have the potential to adversely alter the base of the aquatic food web” and processes central to freshwater ecosystem services:

Freshwater ecosystems provide an important array of ecosystem services, ranging from clean drinking water and irrigation water to industrial water, water storage, water recreation, and an environment for organisms that support fish and other important foods. Invertebrates make up a large proportion of the biodiversity in freshwater food chains and are a critical link for transfer of energy and nutrients from primary producers to higher trophic levels both in the aquatic and terrestrial ecosystems. Thus, alteration of invertebrate abundance, physiology, and life history by insecticides can have a serious impact on services provided by freshwater ecosystems. Equally, their role in decomposition of organic matter and nutrient cycling offers an essential purification service of water used for human consumption or to support aquatic life.¹

The PMRA assessments confirm that estimated environmental concentrations of both clothianidin and thiamethoxam in aquatic environments in Canada may pose acute and chronic risks to invertebrates. The U.S. Environmental Protection Agency reached a similar conclusion in its preliminary aquatic risk assessments.²

Canada lacks a comprehensive approach for environmental monitoring of pesticides, and this results in a key knowledge gap.³ An exceptionally robust water monitoring dataset was available to support the special reviews of clothianidin and thiamethoxam, although data from some sites were only available for a single year and involved significant uncertainties. Monitoring is meant to flag hazardous levels of pesticides, and sporadic lower detections that may result from unusual weather or other factors. Sporadic lower detections do not overturn the key finding that neonicotinoid insecticides *do enter* waterways at harmful levels in Canada; especially considering that results from monitoring in other countries where neonicotinoids are used also show concentrations in water that exceed thresholds for negative impacts on aquatic species.⁴

The values used in the assessment may well underestimate environmental contamination. In the case of monitoring data, sampling generally does not capture peak concentrations. In the case of estimated environmental concentrations, which are typically considered to be higher than actual environmental concentrations due to conservative assumptions in the model, the PMRA notes that imidacloprid monitoring data overlaps with the range of surface water concentrations predicted from modelling. Therefore, the estimated environmental concentrations cannot be considered conservative.

¹ Van der Sluijs, J. P. et al (2015). "Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning." *Environ Sci Pollut Res* 22: 148.

² U.S. EPA, Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Clothianidin, November 27, 2017; U.S. EPA, Preliminary Risk Assessment to Support the Registration Review of Thiamethoxam, November 29, 2017.

³ Anderson, J.C., C. Dubetz and V.P. Palace (2015). "Neonicotinoids in the Canadian aquatic environment: A literature review on current use products with a focus on fate, exposure, and biological effects." *Sci Total Environ* 505: 409-422.

⁴ Anderson, J.C., C. Dubetz and V.P. Palace (2015). "Neonicotinoids in the Canadian aquatic environment: A literature review on current use products with a focus on fate, exposure, and biological effects." *Sci Total Environ* 505: 409-422.

With respect to the endpoints considered in the assessments, the application of additional safety factors should be considered to account for potential issues of slow recovery, additive or synergistic effects and multiple stressors, as suggested by Morrissey et al.⁵

We agree that neither a use-reduction strategy nor precautionary label statements are viable alternatives to mitigate the identified risks to aquatic invertebrates. As the PMRA notes, it is not possible to accurately predict which uses must be reduced — and by how much — to achieve “acceptable” risk levels. Furthermore, a use-reduction strategy could be undermined over time by shifting use patterns. The PMRA already requires precautionary label statements intended to reduce water contamination on all pest control products containing clothianidin and thiamethoxam, but this approach is demonstrably inadequate for these pesticides. Despite label statements, levels of clothianidin and thiamethoxam posing a risk to aquatic insects have been found in Canadian surface waters in agricultural areas where products containing these active ingredients are used. Discontinuing use of clothianidin and thiamethoxam, along with imidacloprid, is the best approach to minimize risks from these chemicals, to aquatic invertebrates and the ecosystems they support. This is all the more necessary given that other neonicotinoid and neonicotinoid-like insecticides are registered for use in Canada, and additional neurotoxic insecticides are currently proposed for registration (such as afidopyropen⁶).

Environmental concentrations of neonicotinoids (and their breakdown products) are likely to persist in aquatic and terrestrial ecosystems for a period of time after these pesticides are no longer used. This environmental persistence underscores the need for immediate action to prevent further environmental contamination and allow recovery to begin. A Danish study published in 2015 found that the cocktail of pesticide residues in stream water and sediments, including now-banned “legacy” compounds, exceeded thresholds for key indicator species, and concluded that this is a major weakness in the pesticides assessment process.⁷

Recommendation 1: Cancel the main uses of clothianidin and thiamethoxam to reduce risks to aquatic invertebrates, as proposed.

⁵ Morrissey, C.A. et al (2015). “Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review.” *Environ. Int.* 74: 291-303.

⁶ Consultation on Afidopyropen; Sefina Insecticide; Versys Insecticide, Proposed Registration Decision PRD2018-15. <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2018/afidopyropen-sefina-insecticide-versys-insecticide/document.html>

⁷ Rasmussen, Jes J., Peter Wiberg-Larsen, Annette Baatrup-Pedersen, Nina Cedergreen, Ursula S. McKnight, Jenny Kreuger, Dean Jacobsen, Esben A. Kristensen, and Nikolai Friberg. “The Legacy of Pesticide Pollution: An Overlooked Factor in Current Risk Assessments of Freshwater Systems.” *Water Research* 84 (November 1, 2015): 25–32. <https://doi.org/10.1016/j.watres.2015.07.021>.

B. Individual assessments of neonicotinoid insecticides underestimate total risks to aquatic invertebrates due to effects from aggregate and cumulative exposures to multiple similar insecticides.

PMRA recognizes that multiple neonicotinoid insecticides with a common mode of action are often present in the same environment. Thiamethoxam can be transformed into clothianidin, and therefore the impact of exposure to multiple neonicotinoids will be higher than for exposure to thiamethoxam or clothianidin alone. Assessing aggregate and cumulative effects would reinforce the conclusions and inform regulatory action. At a minimum, environmental concentrations of similar insecticides also acting as insect nicotinic receptors (the mechanism of toxicity at the nerve synapse) should be summed.

Aggregate and cumulative effects of neonicotinoids in the presence of other agricultural chemicals should also be considered. The most recent report from Quebec's pesticide monitoring program in corn- and soy-growing areas notes that the presence of multiple neonicotinoids in waterways already contaminated by other agricultural pesticides will have consequences for aquatic species, and that in some cases populations of benthic macroinvertebrates are already in poor or precarious health.⁸

Neonicotinoid insecticides may exert adverse effects via other mechanisms, as well, where cumulative effects would be relevant. In particular, cellular signalling via chemicals (e.g., hormones in the endocrine system) is a primitive but evolutionarily preserved mechanism to orchestrate development, metabolism, reproduction and other determinants of viability of species.⁹ Understanding of endocrine effects is advancing rapidly, but presently any finding of such activity should flag concern and the need for precaution. Recent research indicates that neonicotinoid insecticides affect breast cancer cells via the VEGF pathway,¹⁰ and that clothianidin alters immune response *in vitro*.¹¹ In the context of other chemicals such as

⁸ Giroux, I. (2015). *Présence de pesticides dans l'eau au Québec : Portrait et tendances dans les zones de maïs et de soya – 2011 à 2014*. Québec, ministère du Développement durable, de l'Environnement et de la Lutte contre les changements climatiques, Direction du suivi de l'état de l'environnement <<http://www.mdelcc.gouv.qc.ca/eau/flrivlac/pesticides.htm>>

⁹ Pires-daSilva, André, and Ralf J. Sommer. "The Evolution of Signalling Pathways in Animal Development." *Nature Reviews Genetics* 4, no. 1 (January 2003): 39–49. <https://doi.org/10.1038/nrg977>.

¹⁰ Caron-Beaudoin, Élyse, Rachel Viau, and J. Thomas Sanderson. "Effects of Neonicotinoid Pesticides on Promoter-Specific Aromatase (CYP19) Expression in Hs578t Breast Cancer Cells and the Role of the VEGF Pathway." *Environmental Health Perspectives* 126, no. 04 (April 26, 2018). <https://doi.org/10.1289/EHP2698>.

¹¹ Prisco, Gennaro Di, Marco Iannaccone, Flora Ianniello, Rosalba Ferrara, Emilio Caprio, Francesco Pennacchio, and Rosanna Capparelli. "The Neonicotinoid Insecticide Clothianidin Adversely Affects Immune Signaling in a Human Cell Line." *Scientific Reports* 7, no. 1 (October 18, 2017): 13446. <https://doi.org/10.1038/s41598-017-13171-z>.

ultraviolet filters (in sunscreens), endocrine disruption that was flagged as impairing development in aquatic life was found to exist in higher animals.^{12, 13, 14, 15, 16}

Use of systematic review methodology could improve quality and efficiencies of pesticide re-evaluations and special reviews, for prompt examination and responses as data becomes available and with rapidly evolving toxicological science.

Recommendation 2: Assess aggregate, cumulative and cellular signalling effects in the special reviews.

C. Ecological cascading effects are relevant and reinforce the conclusions of the risk assessment

The PMRA notes that aquatic insects are an important food source for fish, birds and other animals but does not consider ecological cascading effects in the assessments. Properly assessing these ecological cascading effects would reinforce the findings of the risk assessment and inform risk management action.

Insectivorous bird species, which rely on insects as their only food source, can be directly affected by neonicotinoids in two ways: 1) through the ingestion of prey contaminated by the pesticide, causing lethal or sub-lethal effects, or 2) indirectly, through cascading effects causing loss of insect food supply.¹⁷

¹² Ozáez, Irene, Gloria Morcillo, and José-Luis Martínez-Guitarte. "Ultraviolet Filters Differentially Impact the Expression of Key Endocrine and Stress Genes in Embryos and Larvae of *Chironomus Riparius*." *Science of The Total Environment* 557–558 (July 1, 2016): 240–47. <https://doi.org/10.1016/j.scitotenv.2016.03.078>.

¹³ Ozáez, Irene, Gloria Morcillo, and José-Luis Martínez-Guitarte. "The Effects of Binary UV Filter Mixtures on the Midge *Chironomus Riparius*." *Science of The Total Environment* 556 (June 15, 2016): 154–62. <https://doi.org/10.1016/j.scitotenv.2016.02.210>.

¹⁴ Corinaldesi, Cinzia, Elisabetta Damiani, Francesca Marcellini, Carla Falugi, Luca Tiano, Francesca Brugè, and Roberto Danovaro. "Sunscreen Products Impair the Early Developmental Stages of the Sea Urchin *Paracentrotus Lividus*." *Scientific Reports* 7 (August 10, 2017). <https://doi.org/10.1038/s41598-017-08013-x>.

¹⁵ Downs, C. A., Esti Kramarsky-Winter, Roe Segal, John Fauth, Sean Knutson, Omri Bronstein, Frederic R. Ciner, et al. "Toxicopathological Effects of the Sunscreen UV Filter, Oxybenzone (Benzophenone-3), on Coral Planulae and Cultured Primary Cells and Its Environmental Contamination in Hawaii and the U.S. Virgin Islands." *Archives of Environmental Contamination and Toxicology* 70, no. 2 (February 1, 2016): 265–88. <https://doi.org/10.1007/s00244-015-0227-7>.

¹⁶ Wang, Jiaying, Li Meng Pan, Shenggan Wu, Liping Lu, Yiwen Xu, Yanye Zhu, Ming Guo, and Shulin Zhuang. "Recent Advances on Endocrine Disrupting Effects of UV Filters." *International Journal of Environmental Research and Public Health* 13, no. 8 (August 2016). <https://doi.org/10.3390/ijerph13080782>.

¹⁷ Gibbons, D., C. Morrissey, and P. Mineau. 2015. A review of the direct and indirect effects of neonicotinoids and fipronil on vertebrate wildlife. *Environmental Science and Pollution Research* 22(1):103–118.

Aerial insectivorous birds have undergone dramatic population declines in recent decades¹⁸ and several are now listed under the Canadian *Species at Risk Act*.¹⁹ These bird species occur across the country, with different life history strategies and ecologies. The common denominator among these bird species, and the most likely leading cause of these declines, is their sole reliance on insects as their main food source. A study conducted in the Netherlands clearly demonstrated that declines in insect-eating birds were linked to higher surface-water concentrations of imidacloprid.²⁰ The cascading effects of neonicotinoid-caused food chain disruption are significant and underlines the need for their immediate cancellation.

Recommendation 3: Include in the assessment cascading effects on birds, bats, fish, and other species that rely on aquatic insects as their primary food source, as further evidence that the use of neonicotinoids should be immediately cancelled.

D. All registered uses of clothianidin and thiamethoxam have the potential to affect aquatic invertebrates.

We are concerned that the proposed special review decisions provide for continued registration of greenhouse uses of thiamethoxam, “provided wastewater mitigation instructions on product labels are followed.” In the proposed re-evaluation decision for imidacloprid, the PMRA proposed to phase out greenhouse uses along with other agricultural uses; in our view, this more comprehensive approach is preferable.

As noted in the assessments, precautionary label statements designed to reduce risks to aquatic ecosystems are currently required on all registered clothianidin and thiamethoxam products, including greenhouse uses of thiamethoxam. Despite these label statements, clothianidin and thiamethoxam are present in aquatic environments in Canada at concentrations that are harmful to aquatic insects. The PMRA provides no evaluation of the effectiveness of label requirements in mitigating risks from greenhouse uses, nor any analysis of its conclusion that risks to aquatic insects from greenhouse uses are acceptable.

We are concerned that Health Canada and the PMRA lack capacity to properly monitor compliance and enforce label requirements.

Indeed, despite there being no registered greenhouse uses of clothianidin, we note that the water monitoring data reported in the clothianidin special review indicates clothianidin residues near

¹⁸ Twenty-two of twenty-six species have declined.

¹⁹ Barn Swallow (*Hirundo rustica*), Bank Swallow (*Riparia riparia*), Common Nighthawk (*Chordeiles minor*), Chimney Swift (*Chaetura pelagica*), Eastern Whip-poor-will (*Antrostomus vociferus*), Eastern Wood-Pewee and Olive-sided Flycatcher (*Contopus cooperi*).

²⁰ Hallman et al. 2014. Declines in insectivorous birds are associated with high neonicotinoid concentrations. *Nature*. doi:10.1038/nature13531.

multiple greenhouse sites. As clothianidin is a known chemical breakdown product of thiamethoxam, these data clearly indicate a problem with control of wastewater from greenhouses using thiamethoxam.

Although pesticide labels may address greenhouse effluent and some provinces regulate greenhouse discharges, this does not guarantee acceptable risks from clothianidin and thiamethoxam. For example, under Ontario regulations, no discharge permit is required if wastewater is discharged into a sanitary sewer. However, a study in Germany measured *higher* concentrations of neonicotinoids in streams downstream from wastewater treatment plants, compared to concentrations upstream,²¹ indicating that wastewater treatment facilitates may not be effective in removing neonicotinoids from discharge water (and indeed may be a main source of contamination in some aquatic environments).

Furthermore, neonicotinoid residues remain in greenhouse stock and soil following application of these pesticides. This can contribute to environmental contamination, including risks to aquatic insects, when the plants (as well as the soil containing them) are eventually transplanted outdoors.

Recommendation 4: Cancel all registered uses of clothianidin and thiamethoxam, including greenhouse uses.

E. A three- to five-year delay in phasing out clothianidin and thiamethoxam would needlessly prolong environmental risks

The proposed special review decisions contemplate a three- to five-year phase-out period following publication of the final re-evaluation decision, with reference to the *Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review* (the Directive). In this scenario, current use patterns could continue until 2020 or 2022 or beyond, depending on when the final decision is published. This delay is unacceptable in view of the PMRA's conclusion that the registered products containing clothianidin and thiamethoxam that are subject to these special reviews "pose environmental risks that have not been shown to be acceptable."

The proposed decision does not demonstrate that the risks are acceptable in the phase-out period, and does not demonstrate that there are no suitable alternatives. Accordingly, the proposed phase out period is unlawful pursuant to subsection 21 of the *Pest Control Products Act*. The Act describes alternatives as "alternative, non-toxic, ecological pest control approaches, strategies and

²¹ Münze, Ronald, Christin Hannemann, Polina Orlinskiy, Roman Gunold, Albrecht Paschke, Kaarina Foit, Jeremias Becker, et al. "Pesticides from Wastewater Treatment Plant Effluents Affect Invertebrate Communities." *Science of The Total Environment* 599–600 (December 1, 2017): 387–99. <https://doi.org/10.1016/j.scitotenv.2017.03.008>.

products.” The Minister does not analyze suitable alternatives in the proposed decision and does not apply the standard of acceptable risk for a period of time set out in the Act. Accordingly, the Minister has no jurisdiction to phase-out products upon the finalization of the special review. Nor is there any legislative authority for delaying the implementation of a re-evaluation or special review that is completed. The proposed decision does not provide any clear rationale for phase-out and does not comply with the requirements of the Act.

The Directive fails to implement the mandatory standards in the *Pest Control Products Act* and is unlawful. Section 21(2) of the Act provides that where products do not pose acceptable risks the Minister shall amend the registration to ensure acceptable risk or cancel the registration. Section 21(3) provides very limited jurisdiction for the Minister to delay the effective date of cancellation or amendment only where there is both no suitable alternative and the risks are acceptable until the delayed date of cancellation or amendment. After the date of cancellation, the Minister may allow the use of stocks in Canada at the time of cancellation. Cancellation itself may not be delayed to dispose of stocks.

The Directive provides that the effective date of cancellation or amendment may be delayed where risks are not considered “imminent or serious.” This is a markedly different standard than that of acceptable risk for a specific period of time used in Section 21(3). The Directive also does not require that the absence of a suitable alternative be demonstrated. The Directive also purports to permit unacceptable uses beyond the period required for disposing of stocks addressed in Section 21(5) and does not ensure that disposing of stocks is “necessary for carrying out the purposes of this Act.” Finally, the Directive purports to allow a delay in the implementation date of the re-evaluation or special review without any legislative authority.

Recommendation 5: Immediately cancel all uses of clothianidin and thiamethoxam that pose unacceptable risks and implement any proposed amendments without further delay pursuant to s.21(2) of the Pest Control Products Act.

Annex 1: List of Recommendations

1. Cancel the main uses of clothianidin and thiamethoxam to reduce risks to aquatic invertebrates, as proposed.
2. Assess aggregate, cumulative and cellular signalling effects in the special reviews.
3. Include in the assessment cascading effects on birds, bats, fish, and other species that rely on aquatic insects as their primary food source, as further evidence that the use of neonicotinoids should be immediately cancelled.
4. Cancel all registered uses of clothianidin and thiamethoxam, including greenhouse uses.
5. Immediately cancel all uses of clothianidin and thiamethoxam that pose unacceptable risks and implement any proposed amendments without further delay pursuant to s.21(2) of the *Pest Control Products Act*.