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Re-evaluation Decision RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation

Pest Management Regulatory Agency

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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 turf uses for clothianidin 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 clothianidin are sold as sprays to be applied to plants and to bare soil. Clothianidin 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 clothianidin 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 clothianidin (and its breakdown products) when they visit certain flowers to collect pollen and nectar. Bees may also be accidentally sprayed or collect water containing clothianidin. Currently registered products containing clothianidin that are subject to this re-evaluation are listed in [Appendix I](#).

This document (RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation) presents the final regulatory decision ¹ for the pollinator re-evaluation of clothianidin, including the required risk mitigation measures to protect bees. Most products containing clothianidin are subject to this regulatory decision. The proposed regulatory decision published in [PRVD2017-23](#), Clothianidin 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 of RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation, 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 PRVD2017-23. All of the data that were used as the basis for the proposed re-evaluation decision are published in PRVD2017-23. Further data used in the final re-evaluation decision, including data received during the consultation period, are listed in Appendix IV of RVD2019-05.

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 clothianidin are not expected to affect bees. For some uses, mitigation measures (in other words, changes to the conditions of registration) are required to minimize exposure to bees. Mitigation measures include changes to the use pattern and label improvements. When clothianidin 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 Clothianidin

Health Canada has completed the pollinator re-evaluation of clothianidin. Under the authority of the Pest Control Products Act, Health Canada has determined that, with required amendments, continued registration of products containing clothianidin is acceptable; however, certain uses of clothianidin are cancelled to address potential risks of concern to pollinators. An evaluation of available scientific information found that some uses of clothianidin 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 of RVD2019-05, are required for all end-use products. No additional data are requested.

Risk Mitigation Measures to Protect Pollinators

Registered pesticide product labels include specific direction 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 clothianidin, 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 clothianidin 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 clothianidin:**

- Foliar application to orchard trees and strawberries, and
- Foliar application to municipal, industrial and residential turf sites.

In order to protect pollinators, **Health Canada is changing the conditions of use of clothianidin:**

- Reduce maximum number of foliar applications to cucurbit vegetables to one per season.

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

- Seed treatment of cereal crops.

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 a serious pest (the invasive brown marmorated stink bug) 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 clothianidin 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 clothianidin 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](#).

Appendix I Registered Clothianidin Products in Canada Subject to This Re-evaluation

Table 1 Registered Clothianidin Products in Canada Subject to This Re-evaluation as of 2 October 2018, excluding discontinued products and products with a submission to discontinue

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
27445	Technical Grade Active Ingredient	Sumitomo Chemical Company Inc.	Clothianidin Technical Insecticide	Solid	• Clothianidin 97.5%
27449	Commercial	Bayer CropScience Inc.	Titan Insecticide	Suspension	• Clothianidin 600 g/L

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
27453		Bayer CropScience Inc.	Poncho 600 FS Seed Treatment Insecticide	Suspension	• Clothianidin 600 g/L
27564		Bayer CropScience Inc.	Prosper FL Flowable Insecticide And Fungicide Seed Treatment	Suspension	• Clothianidin 120 g/L; • carbathiin 56 g/L; • thiram 120 g/L; • metalaxyl 4g/L
28975		Valent Canada Inc.	Nipsit Inside 600 Insecticide	Suspension	• Clothianidin 600g/L
29158		Bayer CropScience Inc.	Prosper T 200 Flowable Insecticide And Fungicide Seed Treatment	Suspension	• Clothianidin 142.8g/L; • carbathiin 50g/L; • trifloxystrobin 7.14g/L; • metalaxyl 5.36g/L
29159		Bayer CropScience Inc.	Prosper FX Flowable Insecticide And Fungicide Seed Treatment	Suspension	• Clothianidin 285.7 g/L; • carbathiin 50 g/L; • trifloxystrobin 7.14g/L; • metalaxyl 5.36 g/L
29382		Valent Canada Inc.	Clutch 50 WDG Insecticide	Water dispersible granules	• Clothianidin 50%
29383		Valent Canada Inc.	Arena 50 WDG Insecticide	Water dispersible granules	• Clothianidin 50%

Registration number	Marketing Class	Registrant	Product name	Formulation type	Guarantee
29384		Valent Canada Inc.	Clothianidin Insecticide	Water dispersible granules	• Clothianidin 50%
30362		Bayer CropScience Inc.	Emesto Quantum	Suspension	• Clothianidin 207g/L; - penflufen 66.5 g/L
30363		Bayer CropScience Inc.	Prosper Evergol	Suspension	• Clothianidin 290 g/L; • rifloxystrobin 7.15g/L; • penflufen 10.7g/L; • metalaxyl 7.15g/L
30972		Bayer CropScience Inc.	Sepresto 75 WS	Wettable powder	• Clothianidin 56.25%; • imidacloprid 18.75%
31355		Valent Canada Inc.	Nipsit Suite Canola Seed Protectant	Suspension	• Clothianidin 279 g/L; • metalaxyl 5.23 g/L; • metconazole 1.04 g/L
31357		Valent Canada Inc.	Nipsit Suite Cereals Of Seed Protectant	Suspension	• Clothianidin 30.7 g/L; • metalaxyl 9.24 g/L; • metconazole 4.62 g/L

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- 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.

- 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.
- 4 As per subsection 35(1) of the Pest Control Products Act.
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