# Proposed Special Review Decision PSRD2018-01, Special Review of Clothianidin Risk to Aquatic Invertebrates: Proposed Decision for Consultation

*Health Canada*

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## Web Summary

## Table of Contents



## Introduction

Health Canada is consulting Canadians on its proposed special review decision of the neonicotinoid pesticide clothianidin following a risk assessment to aquatic invertebrates.

The Pest Management Regulatory Agency (PMRA) initiated a special review of clothianidin under subsection 17(1) of the Pest Control Products Act based on a preliminary analysis of available information on the concentrations and frequency of detection of clothianidin in aquatic environments.

As required by subsection 18(4) of the Pest Control Products Act, the PMRA has evaluated the aspects of concern that prompted the special review of pest control products containing clothianidin. The aspect of concern for this review is to assess potential risk to aquatic invertebrates exposed to clothianidin applied as a seed, foliar or soil treatment.

## Uses of Clothianidin in Canada

Appendix I of Proposed Special Review Decision PSRD2018-01, Special Review of Clothianidin Risk to Aquatic Invertebrates: Proposed Decision for Consultation lists

all clothianidin products with uses that are registered under the authority of the Pest Control Products Act as of May 2018 that were subject to this special review. Clothianidin is currently found in 14 end-use products to which aquatic invertebrates may be exposed. These products may be used as a seed dressing (on canola, mustard, rapeseed, corn, wheat, various vegetable crops and potato as a seed piece treatment), foliar spray application (on turf, potato, pome fruit, stone fruit, grape, strawberry, and cucurbit vegetable crops), in-furrow (for potato) or pre-plant incorporated (for sweet potato). Foliar spray applications can be made by ground boom, airblast or aerial sprayers, depending on crop. Appendix II of PSRD2018-01 lists all registered uses of Commercial Class end-use products containing clothianidin that were subject to this special review.

# Aspects of Concern that Prompted the Special Review

This special review was initiated on 23 November 2016, at the same time the PMRA's proposed cyclical re-evaluation decision was published for imidacloprid (PRVD2016-20). The aquatic risk assessment for imidacloprid identified risks of concern to aquatic invertebrates. Clothianidin shares the same mode of action with a similar toxicity profile. Available monitoring data indicated that clothianidin was being detected at concentrations and frequencies in aquatic environments that may pose a risk to aquatic invertebrates. A preliminary assessment was conducted to determine if a special review was required. Based on the available fate, toxicity and water monitoring information for clothianidin, there were reasonable grounds to believe that the potential risk to aquatic invertebrates from the use of clothianidin may exceed the PMRA's level of concern under the current conditions of use.

The initiation of the special review was announced in REV2016-17, Initiation of Special Reviews: Potential Environmental Risk to Aquatic Invertebrates Related to the Use of Clothianidin and Thiamethoxam. The aspect of concern for this special review is to assess potential risk to aquatic invertebrates exposed to clothianidin applied as a seed, foliar or soil treatment.

# PMRA Evaluation of the Aspects of Concern

The PMRA required the pesticide manufacturer to submit all available data that are relevant to the environmental fate of clothianidin, including Canadian surface water monitoring data, and to its toxicity to aquatic invertebrates. In addition, the PMRA requested the same information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the Pest Control Products Act. In response to PMRA's requests, information was received related to the aspect of concern.

Additional data supplied by the pesticide manufacturer included information on the environmental fate of clothianidin in soil and water as well as the ecotoxicity of clothianidin and its major transformation products to aquatic invertebrates. Data on clothianidin's toxicity to aquatic invertebrates generated by Environment and Climate Change Canada (ECCC) and by academic researchers were included for this special review. A comprehensive literature review of current data relevant to the special review provided additional ecotoxicity data for clothianidin. In total, the PMRA considered acute ecotoxicity data for 39 species of aquatic invertebrates and chronic

data for 7 species, as well as higher-tier community-based endpoints from three studies. Environmental incidents of concern for aquatic invertebrates were not identified in North America.

Published and unpublished Canadian freshwater monitoring data were received from federal and provincial governments and academic researchers, pesticide manufacturers, and members of Agriculture and Agri-Food Canada's Multi-stakeholder Environmental Monitoring Working Group. Freshwater monitoring data consisted of several robust datasets often with large numbers of samples taken at high frequencies from agricultural areas from 2010 to 2017.

## Key Findings

The environmental assessment showed that, in aquatic environments in Canada, clothianidin is being measured at concentrations that are harmful to aquatic insects. These insects are an important part of the ecosystem, including as a food source for fish, birds and other animals. Based on currently available information, most outdoor uses in Canada are not sustainable. For more information on Health Canada's proposed decision for this special review of clothianidin, refer to Section Proposed Special Review Decision for Clothianidin.

## Risk Assessment Conclusions

In conducting environmental risk assessments, it is the PMRA's policy to always consider both monitoring data (when available) and estimated environmental concentrations (EECs) generated using water models as part of its overall risk assessment. Although valid monitoring data are considered preferable to modelled EECs, the weight given to these data varies depending on the circumstances.

When determining the most appropriate toxicity endpoints for consideration in the risk assessment, the PMRA considers both pesticide manufacturer submitted studies and publically available studies. The ecotoxicity data is considered in a tiered approach which consists of the following:

- the endpoint of the most sensitive species,
- a species sensitivity distribution when enough data points are available and
- mesocosm studies which considers effects at the community level.

For clothianidin, Species Sensitivity Distributions (SSDs) for both acute and chronic exposure in freshwater environments were determined. In addition, two acceptable mesocosm studies were available to assess the concentrations at which community level effects would be observed. For the chronic assessment, the endpoints from the most sensitive species, the SSD and the most sensitive mesocosm study were considered in a weight-of-evidence approach in the risk assessment.

The risk assessment based on the modelling results indicates that exposure to clothianidin may pose both an acute and chronic risk to freshwater invertebrates and a chronic risk to marine/estuarine invertebrates. Typically, modelling inputs and assumptions are conservative and the EECs generated are likely to be higher than actual concentrations present in waterbodies. For clothianidin, however, the range of surface water EECs predicted from modelling overlaps with the range of concentrations measured in surface freshwater bodies.

Acute and chronic risks to freshwater invertebrates were identified based on robust

Canadian monitoring data sets. Clothianidin concentrations occasionally exceeded the level of concern for acute risk in waterbodies associated with areas growing mixed vegetables and potatoes. Clothianidin concentrations also exceeded the acute toxicity endpoint in three wetlands located in agricultural areas of the Prairies. However, due to a lack of site information the PMRA is unable to state with certainty that these wetlands are relevant for an aquatic invertebrate risk assessment. Monitoring data likely provided an underestimate of acute exposure, as sampling typically does not capture peak concentrations.

Clothianidin concentrations detected in the following areas frequently exceeded the chronic level of concern for freshwater invertebrates (the registered methods of application of clothianidin are listed in parentheses):

- Corn and soybean growing regions (seed treatment),
- Potatoes (seed treatment, soil application or foliar spray),
- Vegetables (seed treatment or foliar spray, depending on the type), and
- Orchards and vineyards (foliar spray).

The chronic level of concern in standing and flowing waterbodies primarily associated with seed treatment uses in the Prairies was exceeded, however, there was uncertainty surrounding the duration of exposure.

Concentrations detected in some waterbodies located in regions growing potatoes and mixed vegetables exceeded the mesocosm endpoint for periods of weeks to months. This chronic exposure may result in effects at the community level, including changes in insect species abundance and species richness. Concentrations of clothianidin exceeding the community-level endpoint were also detected in other crop-growing regions, however, they were sporadic and of short duration. The occurrence of clothianidin concentrations at or above the community-level endpoint may have significant impacts on community invertebrate structure, which is a primary protection goal of the PMRA. It is also possible that effects at the community level may be observed at lower concentrations given the uncertainties identified with the most sensitive mesocosm endpoint (as discussed later in this document).

No Canadian monitoring data for clothianidin in estuarine or marine water were available to exclude the identified risks to marine/estuarine invertebrates.

# Proposed Special Review Decision for Clothianidin

The evaluation of available scientific information related to the aspects of concern indicated that the registered products containing clothianidin that are subject to this special review pose environmental risks that have not been shown to be acceptable. Therefore, under the authority of the Pest Control Products Act and based on the evaluation of currently available scientific information, Health Canada is proposing to cancel all outdoor uses of clothianidin on food and feed crops (use site categories 13 and 14), including seed treatments (use site category 10), and on turf (use site category 30), taking into account Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review. The PMRA will consider alternate risk management proposals, provided that they can achieve acceptable levels in the environment within the same timeframe.

Additional mitigation measures may be required during the phase-out period (see

Appendix VIII of PSRD2018-01).

The proposed special review decision is open for public consultation for 90 days from the date of this publication. The PMRA is inviting the public to submit comments on the proposed special review decision for clothianidin including proposals that may refine the risk assessment and risk management. Once the PMRA considers the comments and any information that are received during the public consultation period, the Agency will publish a final decision.

# Next Steps

Before making a special review decision on clothianidin, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on clothianidin. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.