Special Review Decision SRD2021-03

Special Review Decision: Clothianidin Risk to Aquatic Invertebrates

Final Decision Document

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Table of Contents

Special review decision

Pursuant to subsection 17(1) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a special review of all agricultural and turf uses for registered pest control products containing clothianidin. The decision to conduct the special review was based on a preliminary analysis of available information on the concentration and frequency of detections of clothianidin in the aquatic environment. 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.

Health Canada evaluated the aspect of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in Proposed Special Review Decision (PSRD2018-01), *Special Review of Clothianidin Risk to Aquatic Invertebrates: Proposed Decision for Consultation*.[1] Since the publication of PSRD2018-01 on 15 August 2018, a significant number of comments were received during the consultation period. In addition, extensive information obtained from published literature, as well as data received from registrants and environmental monitoring networks[2] was also considered.

In addition, during the consultation period, Health Canada issued a final re-evaluation decision examining the effects of clothianidin on pollinators Re-evaluation Decision RVD2019-05, *Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation. Final Decision*. This special review decision takes into consideration the additional mitigation measures put in place as a result of the pollinator re-evaluation. Health Canada has completed the special review for clothianidin, and this final special review decision has resulted in changes to the proposed regulatory decision as described in PSRD2018-01.

A reference list of information used as the basis for the proposed special review decision is included in PSRD2018-01. Further information used in the special review decision is listed in Appendix IX of this Special Review Decision (SRD). Therefore, the complete reference list of all information used in this final special review decision includes both the information set out in the list of references of the PSRD2018-01 and the information set out in Appendix IX herein.

This document presents the final regulatory decision[3] for the special review of clothianidin, including the required risk mitigation measures to protect aquatic invertebrates. All pest control products containing clothianidin that are registered in Canada for agricultural and turf uses are subject to this special review decision (see Appendix I). Appendix II lists all of the registered uses of Commercial Class end-use products containing clothianidin that were subject to this special review, taking into consideration the required use restrictions identified in RVD2019-05.

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

[2] For further details on the environmental monitoring network please refer to Section 1.5.1 of the Response to Comments.

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

Appendix III summarizes the comments received during the consultation period and provides Health Canada's responses to these comments. All of the data that were used as the basis for the proposed special review decision are published in PSRD2018-01. Additional data used in the final special review decision, including data received during the consultation period, are listed in Appendix IV for toxicity information and in Appendix VII for monitoring information.

Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing clothianidin is acceptable with additional risk mitigation measures (that is, with changes to the conditions of registration). An evaluation of available scientific information found that uses of clothianidin products meet current standards for protection of the environment when used according to revised label directions, which include mitigation measures. Label amendments, as summarized below and listed in Appendix VIII, are required.

Outcome of science evaluation

The environmental risk assessment took into consideration revisions to clothianidin uses as outlined in RVD2019-05, scientific comments received on study interpretations during consultation of PSRD2018-01, newly published relevant toxicity data and additional water monitoring data. Based on these data it was determined that the risks to aquatic invertebrates resulting from chronic exposure following application of clothianidin under certain currently registered conditions are acceptable. For uses where the risks were not shown to be acceptable, mitigation measures are required to minimize exposure to aquatic invertebrates which include changes to the use pattern or cancellation in cases when the mitigation options were not considered viable. In addition to the prescribed mitigation measures, label amendments including the addition of best management practices and label statements informing users of the toxicity to aquatic organisms are required.

Regulatory decision for clothianidin

Health Canada has completed the special review of clothianidin's risk to aquatic invertebrates. Following an evaluation of the aspect of concern, under the authority of the *Pest Control Products Act*, Health Canada has determined that, with additional risk mitigation measures, continued registration of products containing clothianidin is acceptable. An evaluation of available scientific information found that some uses of clothianidin products meet current standards for protection of aquatic invertebrate communities when used according to the revised conditions of registration, which include required amendments to label directions. Label amendments, as summarized below and listed in Appendix VIII, are required for all end-use products. Certain uses of clothianidin are cancelled as risks to aquatic invertebrates were not shown to be acceptable.

Risk mitigation measures to protect aquatic invertebrates

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures as a result of this special review decision, are summarized below. Refer to Appendix VIII (Label Amendments).

In order to protect aquatic invertebrate communities, **Health Canada is cancelling the following uses of clothianidin**:

- In-furrow application on potato.
- Seed treatment for field sown leafy vegetables and bunching onion. Planting rates for these crops exceed the maximum allowable application rate of 100 g a.i./ha.

Health Canada is changing the conditions of use of clothianidin for the following crops:

- The maximum seed treatment rate for field corn is reduced to 150 g a.i./100 kg seed. This results in the cancellation of the use for corn rootworm. No change is required for popcorn or sweet corn.
- For seed treatment uses on vegetables, the yearly maximum rate per hectare is limited to 100 g a.i./ha. This limits the planting rates used on broccoli, bulb onion, carrot, cabbage, cucumber and leek to meet this yearly maximum rate.
- The maximum foliar rate for use on cucurbits is reduced to a single application of 70 g a.i./ha per season. This results in the cancellation of use for brown marmorated stink bug.
- The maximum foliar rate for use on potatoes is reduced to a single application of 52.5 g a.i./ha per season.
- The maximum foliar rate for use on turf is reduced to a single application of 125 g a.i./ha per season. This results in the cancellation of use for hairy chinch bug, annual bluegrass weevil, bluegrass billbug and European crane fly.
- Cancellation of greenhouse seed treatment use for onion maggot and seed corn maggot on bulb onions, as these are only pests found in field production.
- New or revised spray buffer zones are required for freshwater habitats.

Next steps

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this special review decision (SRD2021-03). The risks identified are not considered imminent and serious because they are not expected to cause irreversible harm over this phase-out period. Potential effects include reduced aquatic insect abundance. Affected populations have the potential to recover following implementation of the additional restrictions which will reduce overall exposure. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels.

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*).

Similarly, users will also have the same 24-month period from the date of SRD2021-03 to transition to using the newly amended labels, which will be available on the Public Registry.

A small subset of uses were found to lack suitable alternatives for the management of serious pests (the onion maggot and seedcorn maggot) on bunching onion (seed treatment). The effective date of the special review decision for these uses will be delayed for 24 months pursuant to subsection 21(3) of the *Pest Control Products Act*. The risk to aquatic invertebrates has been determined to be acceptable over this time period because the overall exposure to aquatic invertebrates will be significantly reduced through both removal of uses to control other pests on these crops and other crops posing a risk to aquatic invertebrates. Because of the overall reduction in use, exposure, and risk to aquatic invertebrates, the continued use for 24 additional months for these clothianidin uses with no suitable alternatives is not expected to impact aquatic invertebrate populations, and is considered acceptable.

Refer to Appendix I for details on specific products impacted by this decision.

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 special review 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 by phone (1-800-267-6315) or by e-mail (hc.pmra-info-arla.sc@canada.ca).

The relevant confidential test data on which the decision is based (as referenced in PSRD2018-01 and Appendix IX of this document) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

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

Science evaluation update

1.0 Revised environmental risk assessment

The initial aquatic invertebrate risk assessment for clothianidin was provided in PSRD2018-01, *Special Review of Clothianidin Risk to Aquatic Invertebrates: Proposed Decision for Consultation*. During the public consultation, comments were received from the registrant, agricultural stakeholders and the general public on a range of issues including exposure, toxicity endpoint selection, risk assessment approach and risk mitigation. Detailed responses to the comments received on the aquatic invertebrate assessment are provided in Appendix III.

Health Canada is adopting new terminology with respect to effects-based toxicity values used in risk assessment to provide increased clarity. The term ‘endpoint’ refers to toxicity values resulting from statistical analyses of individual ecotoxicology studies (for example, NOEC or EC_{50}). The term ‘effects metric’ is used to identify effects-based values used in assessing risk. An effects metric can be an individual endpoint value from a toxicity study, however it can also be an endpoint with an applied uncertainty factor, a geometric mean of multiple endpoints, an HC_5 derived from a Species Sensitivity Distribution or a mesocosm-based endpoint). Throughout this document this distinction is made along with a clear indication of which effects metric(s) was used in the risk assessment.

The revised risk assessment takes into consideration changes to the clothianidin use pattern as required under Re-evaluation Decision RVD2019-05, *Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation*. This includes cancellation of the following uses:

- Foliar applications – pome fruit, stone fruit, strawberry

The overall risk conclusions based on consideration of all relevant information following the consultation process have resulted in changes to the proposed decision to cancel all outdoor uses presented in PSRD2018-01.

1.1 Aquatic invertebrate toxicity

The toxicity of clothianidin to aquatic invertebrates has been summarized in PSRD2018-01. However, since the publication of PSRD2018-01, comments were received from stakeholders on the validity of some of the reported toxicity endpoints. In addition, newly published information has become available on the toxicity of clothianidin to aquatic invertebrates. New and revised toxicity endpoints are highlighted in bold in Table A.4-1.

1.1.1 Revisions to toxicity endpoints reported in PSRD2018-01

Comments were received from registrants (Bayer CropScience, BASF Canada, Valent) on the validity of some chronic endpoints considered in the proposed special review decision for clothianidin (PSRD2018-01); therefore, Health Canada reassessed these endpoints.

Health Canada reassessed the 28-d growth and biomass EC_{10} endpoints for the freshwater snail *Planorbella pilsbryi* from Prosser et al. (2016; PMRA# 2712688) and found them to be unacceptable for use in the risk assessment due to the variability in measured snail weights. However, the reported endpoint for mortality (28-d LC_{10} = 19.8 (6.5–33) µg a.i./L) remains acceptable for use and has been included in Table A.4-1. For further details, see Appendix III, Comments and Responses.

Health Canada reassessed the toxicity endpoints derived for the amphipod *Hyalella azteca* (ECCC, 2017; PMRA# 2753706) based on comments received on the study design. Since publication of PSRD2018-01, the *H. azteca* results from the ECCC (2017; PMRA# 2753706) report have been published in Bartlett et al. (2019; PMRA# 2975959) and are cited as such in this document. The following estimates were determined by Health Canada as the geomean of toxicity endpoints from two independent trials within the study. They are considered acceptable for use in the risk assessment and have been included in Table A.4-1: 7-d LC_{50} = 3.76 µg a.i./L, 28-d EC_{10} growth = 0.35 µg a.i./L and 28-d LC_{10} = 2.14 µg a.i./L. For further details, see Appendix III, Comments and Responses.

1.1.2 Additional aquatic invertebrate toxicity information considered

Since the publication of PSRD2018-01, additional clothianidin toxicity data for aquatic invertebrates has become available in the open literature.

Laboratory-based single-species toxicity tests

The acute and chronic toxicity of clothianidin was investigated with two species of freshwater mussel (*Lampsilis siliquoidea* and *Villosa iris*; Salerno et al., 2018; PMRA# 2912493). Acute 24-h toxicity tests were conducted with the larval stage of *V. iris* (glochidia), and 28-d chronic tests were conducted with juvenile and adult *L. siliquoidea*. All freshwater mussel life stages tested were highly insensitive to clothianidin; no effects were observed in *V. iris* glochidia or *L. siliquoida* (juvenile or adult) up to the highest concentrations tested (24-hr EC_{50} *V. iris* glochidia > 13 800 µg a.i./L; 28-d NOEC values for juvenile and adult *L. siliquoida* are ≥ 9033 µg a.i./L).

The acute toxicity of clothianidin was investigated over 144 hours in larvae of the mosquito *Culex pipiens* (Russo et al., 2018; PMRA# 2978128). Mortality rates increased with time and in the absence of a 96-h endpoint, Health Canada determined a 72-h LC_{50} of 11.0 (9.3–13.0) µg a.i./L for use in the acute risk assessment. Although the study also examined effects on metabolic energy demands following a 24-h exposure to clothianidin, this information was not used quantitatively in the risk assessment.

The chronic toxicity of clothianidin was assessed for the midge *Chironomus dilutus* and mayfly *Neocloeon triangulifer* (Raby et al., 2018b; PMRA# 2912490) and for the cladoceran *Ceriodaphnia dubia* (Raby et al., 2018c; PMRA# 2912491). The clothianidin toxicity endpoints determined by Health Canada (NOEC or EC_{10}, depending on the most appropriate statistical analysis) and considered for use in the risk assessment were: 56-d EC_{10} survival to emergence = 0.25 (0.11–0.39) µg a.i./L for *C. dilutus*, 32-d NOEC survival to emergence = 0.23 µg a.i./L for *N. triangulifer*, and EC_{10} reproduction = 2030 (510–3550) µg a.i./L for *C. dubia*.

The chronic toxicity of clothianidin to nymphs of the common New Zealand mayfly genus *Deleatidium* spp., was assessed using 28-d exposures (Macaulay et al., 2019; PMRA# 3078943). Health Canada reassessed the mortality and immobility data for use in the chronic risk assessment. Mortality plus 28-d immobility was variable across treatment concentrations and did not show a clear dose-response relationship. Reliable regression-based EC_{10} or NOEC values could not be derived due to poor fit and were not suitable for quantitative use in the risk assessment. The variability in control mortality observed between trials with the three neonicotinoids tested, as well as variability in biological responses may be due to non-treatment related factors. Therefore, these test results were considered qualitatively only.

Field study (limnocorral enclosure) toxicity tests

A study by Maloney et al. (2018b; PMRA# 3076589) investigated the chronic effects on emergent insect abundance and community composition, and sex-ratios of Chironomidae from exposure to three neonicotinoids (imidacloprid, clothianidin, and thiamethoxam) and their mixtures using experimental in-situ enclosures (limnocorrals) in a prairie pothole wetland in Saskatchewan. Cumulative effects are not being evaluated in the current assessment and were not considered.

The results of single-compound exposures on Chironomidae abundance and biomass were considered for use in the risk assessment. There were insufficient numbers of non-dipteran taxa to allow for meaningful conclusions to be made for other insects. Neonicotinoid toxicity was time-dependent; significant effects were not evident after 28-d but were observed after 56-d of continuous exposure. Based on mean measured concentrations at the single clothianidin treatment level, a 56-d LOEC of 0.73 ± 0.21 µg a.i./L was observed for significant reductions in Chironomidae biomass and cumulative emergence rates. In addition, clothianidin was the only neonicotinoid to significantly shift sex-ratios of Chironomidae towards female-dominated populations relative to controls. However, as there is no clear indication of the potential impact of shifts in sex ratios on insect populations.

In another field study, Cavallaro et al. (2018; PMRA# 2912492) examined the effects of multiple applications of technical grade clothianidin to emergent insect communities using *in situ* wetland limnocorrals located in a permanent prairie wetland in Saskatchewan. Limnocorrals were dosed weekly for 9 weeks at a low (0.05 µg a.i./L) and high concentration (0.5 µg a.i./L) followed by a 6-week recovery period. Overall changes in community structure relative to controls were measured using multivariate statistical analysis. The majority of insect taxa identified in the study belonged to the Chironomidae family (64%), followed by caddisflies [Trichoptera] (~27%), damselflies [Zygoptera] (~2%) and phantom midges [Chaoboridae] (~4%). At no time was a significant increase or decrease in the insect community emergence detected in the clothianidin limnocorral treatments. The resulting NOEC emergence (community composition) was ≥ 0.384 μg a.i./L based on mean measured concentrations post-dosing.

Significantly earlier emergence was reported for Chironimidae and Zygopteran communities exposed to clothianidin relative to control limnocorrals. However, these endpoints were not considered quantitatively in the risk assessment as the statistical methods used to investigate changes in median time to emergence were considered inadequate. Moreover, it is uncertain whether an effect on early emergence would be discernable under natural field conditions (i.e., in the absence of enclosed limnocorrals) because of the overlapping life-stages of species from these taxa and the potential for recolonization. The ecological consequence of early Chironomidae or Zygopteran emergence, as detected under experimental conditions, is unclear.

Biomonitoring studies

Yamamuro et al. (2019; PMRA# 3076588) present a correlative study, intending to draw a link between historically declining fish stocks in Lake Shinji, Japan, with reductions in aquatic invertebrate abundance and the onset of neonicotinoid use. Health Canada does not consider the conclusions of this study, linking neonicotinoid use to effects on aquatic invertebrate abundance and indirect effects on fishery yields, to be scientifically sound and did not consider the results in a risk assessment.

In another biomonitoring study conducted in central Saskatchewan, Canada, Cavallaro et al. (2019; PMRA# 3050935) examined the effects of multiple stressors on emerging aquatic insects from wetlands impacted by intensive agricultural practices and receiving runoff from neonicotinoid-treated canola. A total of 22 semi-permanent (Class IV) wetlands of similar size and depth (~ 0.5 ha × 1 m deep), were monitored over two growing seasons. Surrounding fields were planted with canola treated with a commercially available clothianidin seed treatment; however, clothianidin, thiamethoxam, imidacloprid and acetamiprid were all recovered in measurable amounts in the wetlands. Overall, community-level responses appeared to be driven by multiple factors including neonicotinoid TEQ (toxic equivalency quotient) concentration, turbidity, and vegetation disturbance.

Although significant reductions in insect emergence were correlated with higher total neonicotinoid TEQ concentrations, the magnitude of effects were not determined. The model that best predicted emergent insect abundance also included vegetation disturbance, indicating that the presence of riparian habitat structure also plays a significant role in emergent insect population dynamics. This study is scientifically sound but cannot be used quantitatively in a risk assessment for aquatic invertebrates; it does provide qualitative evidence that multiple factors, including wetland water quality (turbidity), vegetation structure and combined neonicotinoid TEQ concentration, may affect emergent aquatic insect abundance in Prairie wetlands.

References received after establishment of effects metrics

Several references were provided to Health Canada after the effects metrics were established for the revised clothianidin risk assessment (see Table A.4-2). Health Canada has performed a cursory review and determined that they do not affect the risk assessment conclusions. Because of this, the endpoints from these additional studies have not been incorporated into the effects metrics derived for the final risk assessment.

1.2 Additional water monitoring data considered

Since the publication of the proposed special review decision document for clothianidin, PSRD2018-01, a large amount of additional Canadian water monitoring data for the years 2018 and 2019 were submitted to Health Canada. Data were provided by various members of the Environmental Monitoring Working Group (EMWG) formed as part of the Multi-Stakeholder Forum on Neonicotinoids. Members of the working group who provided data include the provincial governments of Prince Edward Island, Manitoba, Alberta, Saskatchewan and British Columbia, Ducks Unlimited Canada, the Canadian Canola Growers Association and registrant companies Bayer CropScience and Syngenta Canada Inc. Aside from the information provided by members of the EMWG, additional monitoring data from the provincial governments of Ontario and Quebec, Environment and Climate Change Canada, academia, as well as published scientific articles were available to Health Canada. The new monitoring data were used in the revised risk assessment.

In addition to the new monitoring data, monitoring data previously included in the proposed special review decision for clothianidin, including 2017 monitoring data generated by members of the EMWG were also considered.

Overall, monitoring data considered in the revised risk assessment were from areas of intensive agriculture in Prince Edward Island, New Brunswick, Nova Scotia, Quebec, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia. Samples were collected in wetlands (Prairie Provinces only), streams, rivers and lakes. For wetlands, those classified as seasonal ponds or lakes (Class III), semi-permanent ponds or lakes (Class IV), and permanent ponds or lakes (Class V) based on the classification system defined in Stewart and Kartrud (1971)[5] were considered most relevant to the aquatic invertebrate risk assessment because the water they hold would typically be present for a season or longer. While some of the wetlands considered in the final risk assessment included a few ephemeral ponds (Class I) or temporary ponds (Class II), the wetland class and the relevance to Health Canada's aquatic invertebrate risk assessment were taken into account in the interpretation of the results. Some data from drainage ditches, tile drains and irrigation canals were included in the revised assessment, though they are considered less representative of aquatic habitat to be protected, and/or were man-made structures not intended to sustain aquatic life.

[5] The wetlands were classified by the researchers using the classification system defined in Stewart, R.E. and H. A. Kartrud. 1971. Classification of natural ponds and lakes in the glaciated prairie region. Bureau of Sport Fisheries and Wildlife, U.S. Fish and Wildlife Service, Washington, D.C., USA. Resource Publication 92. 57 pp.

The revised risk assessment only included samples from sites where information was available to determine if the sites were relevant, such as coordinates, a map and/or the type of waterbody. Some sites included in the previous risk assessment did not meet these criteria and were excluded from the revised risk assessment. Agricultural runoff directly from a field, and waterbodies that dry up within a few days such as puddles or small depressions on the side of a road that are planted over in some years were not considered representative of aquatic habitat and were excluded in the revised risk assessment. Results from programs previously included in the risk assessment that had high analytical detection limits and low frequencies of detection were not included because they are not informative. Table A.7-1 lists the monitoring data that were previously considered in PSRD2018-01 but were excluded from the revised risk assessment.

A few published literature articles were submitted for consideration during the consultation period for the proposed special review decision. The data in the articles were included in the revised assessment if they included concentrations of clothianidin in Canadian surface water that were considered relevant to the aquatic risk assessment. Articles not considered included those reporting levels of neonicotinoids in edge-of-field drains (Chrétien et al., 2017), in drinking water treatment plants (Sultana et al., 2018) or in groundwater from the United States (Bradford et al., 2018).

Details of the monitoring programs considered in the final special review decision of clothianidin are summarized in Table A.7-2. Monitoring data not previously considered in PSRD2018-01 are highlighted in bold. A total of 9850 water samples were collected from 776 different sites across Canada between 2010 and 2019 (Table A.7- 3). Sixty-nine percent of the sites were monitored for one year, 22% were monitored for two years, and 10% of the sites were monitored over three to eight years (Table A.7- 4). For this assessment, one site monitored in one given year is equivalent to one monitoring site-year. Overall, there were 1197 site-years of monitoring data available. Of the total data available, 6192 (63%) of the samples and 669 (56%) of the site-years constitute new data not previously considered in the proposed special review decision for clothianidin.

Table A.7-2 demonstrates that, while each monitoring program varied, sampling was typically weekly or biweekly (every two weeks) throughout the growing season, which allowed for an estimation of chronic exposure levels in water. Some programs had more frequent sampling or had sampling immediately following precipitation events; these were more likely to capture peak concentrations. The monitoring for most programs started in the months of April or May, prior to or shortly after planting, to capture the first runoff events post-planting and in some cases, the runoff from snowmelt (in Prairie wetlands, for example). Depending on the program, the monitoring typically ended between late-August and the beginning of October.

With few exceptions, raw water monitoring data were provided with detailed ancillary information, such as: sampling locations (latitudes and longitudes, pictures of the sites, and site maps), sampling dates, types of waterbodies sampled, analytical detection limits, major land uses and crops in the watershed or in the vicinity of the sampling sites, daily precipitation data near the sampling sites, and historical precipitation information at nearby weather stations.

For some datasets in British Columbia as well as targeted monitoring studies in Prairie wetlands, neonicotinoid use information from growers was also submitted. The analytical data considered in the revised risk assessment had sensitive detection limits, well below Health Canada's effects metrics.

1.3 Revisions to the environmental risk assessment

The environmental risk assessment for clothianidin was revised following the publication of PSRD2018-01. This included revisions to clothianidin toxicity effects metrics, additional surface water modelling and new monitoring information. The revised risk assessment also takes into account the updated use pattern required for the protection of pollinators (RVD2019-05) outlined in Appendix II.

As per Health Canada standard procedures for aquatic risk assessment, risk quotients (RQs) were determined for spray drift and surface water runoff using both modelling and monitoring data. RQs are derived by dividing the estimated environmental concentration (EEC) by the effects metric (RQ = EEC ÷ effects metric). In all cases, the level of concern (LOC) for the RQs is a value of 1. If an RQ was equal to or exceeded a value of 1, it was concluded that the LOC was reached or exceeded.

1.3.1 Revisions to clothianidin effects metrics

New and revised toxicity endpoints used in the final decision are highlighted in bold in Table A.4-1. To assess environmental risks to aquatic invertebrates, Health Canada considers the availability of higher-tiered data in establishing the effects metrics used in the final regulatory decision. The effects metric chosen is based on the highest-tiered data from the following:

- The most sensitive endpoint identified for a single species, with a prescribed uncertainty factor.
- The HC_5 value (the 5^{th} percentile of the SSD), which is calculated when there is a sufficient number of acceptable laboratory endpoints . This value is an estimate of the concentration that is assumed to be protective of 95% of species in a species sensitivity distribution at the effects level considered (for example, LC_{50}, NOEC, etc.).
- When outdoor semi-field or field studies conducted under relevant exposure and environmental conditions are available, the endpoints from these studies may be used preferentially, as they can more closely reflect expected population and community-level effects in the natural environment.

Table 1 summarizes the revised effects metrics established for clothianidin. The effect metrics selected for the final regulatory decision are highlighted in bold.

Table 1 Summary of revised toxicity effects metrics for the clothianidin risk assessment for aquatic invertebrates.

Effects Metric	Value (µg a.i./L) with confidence interval, where available		Comments
	Proposed Decision (PSRD2018-01)	Final Decision	
Freshwater			
Acute most sensitive sp. ($EC/LC_{50}/2$[a])	0.825	1.0	Update for final decision: *G. fascicollis* 48-h LC_{50} = 2.0 µg a.i./L (PMRA# 2832753)
Acute HC_5 (SSD of EC/LC_{50}s)	1.5 (0.38–4.4)	**1.3 (0.32–3.9)**	Update for final decision: Measure of effects being mortality or immobilization after 48 to 96 hours of exposure. Calculated by Health Canada (n = 36).
Chronic most sensitive sp. ($NOEC/EC_x$)	0.020	**0.12**	Update for final decision: Geomean of EC_{10}/EC_{20} for adult emergence of *C. dilutus* (n = 3)[b] (PMRA# 2712687, 2873503, 2912490)
Chronic HC_5 (SSD of $NOEC/EC_x$)	0.0015 (5.1×10^{-7}–0.035)	Not calculated	Update for final decision: Not calculated by Health Canada due to a limited number of species available (n = 7) and lack of confidence in the species distribution.
Mesocosm ($NOEC/EC_x$)	0.281	**0.281**	56-d $NOEC_{14\text{-d TWA}}$[c]. Uncertainty was identified for this effects metric and was therefore used in a weight-of-evidence assessment.
Marine			
Acute most sensitive sp. ($EC/LC_{50}/2$[a])	25.5	**25.5**	*M. bahia* 96-h LC_{50} = 51 µg a.i./L (PMRA# 1194202)
Chronic most sensitive sp. ($NOEC/EC_x$)	5.1	**5.1**	*M. bahia* 39-d NOEC (PMRA# 1194204)

a For assessing risk, acute single-species endpoints are divided by a factor of two (2) to account for potential differences in species sensitivity as well as protection at the community or population level.

b 40-d EC_{20} emergence = 0.02 µg a.i./L (Cavallaro et al., 2017), 28-d EC_{20} emergence = 0.34 µg a.i./L (Maloney et al., 2018), 56-d EC_{10} survival to emergence = 0.25 µg a.i./L (Raby et al., 2018b).

c Reductions in individual species abundance and in emergent insect taxa richness were observed at 0.573 µg a.i./L; however, effects were transient and recovery was observed by the end of the 56-day study.

The bolded endpoints were established as the effects metrics for risk assessment.

Acute toxicity effects metrics

The most sensitive acute freshwater invertebrate endpoint reported in PSRD2018-01 was a 7-d sub-chronic LC_{50} for *H. azteca* (1.65 µg a.i./L) (ECCC 2017; PMRA# 2753706). For the special review decision, Health Canada has re-assessed this endpoint, now published under Bartlett et al. (2019; PMRA# 2975959), by taking the geomean of the two independent trials in the study conducted with clothianidin (geomean 7-d LC_{50} = 3.8 µg a.i./L). Therefore, the most sensitive acute freshwater invertebrate species is now the diving beetle *Graphoderus fascicollis*, with a 48-h LC_{50} of 2.0 µg a.i./L (Miles et al., 2017; PMRA# 2832753; Table A.4-1). Note that a lower endpoint (96-h EC_{50} = 1.85 µg a.i./L) is reported for *Chironomus dilutus* by de Perre et al. (2015: PMRA# 2712666), but the geomean for three studies representing this species is 3.3 µg a.i./L.

Health Canada revised the acute species sensitivity distribution (SSD) for freshwater invertebrates exposed to clothianidin, taking into consideration newly available toxicity data and comments on the data used to construct SSDs received during the consultation period (Appendix V). The revised acute SSD for clothianidin is restricted to valid endpoints for exposure periods from 48–96 hours. This more closely aligns the toxicity dataset with the peak modelled estimated environmental concentrations (EECs) by excluding endpoints from exposures greater than 96 hours. It also accounts for known effects of increasing neonicotinoid toxicity with exposure duration and excludes endpoints from exposures < 48 hours.

Updates to the endpoints in the acute SSD for clothianidin include:

- Addition of the mosquito *Culex pipiens* (72-h LC_{50} = 11.0 µg a.i./L) (Russo et al., 2018; PMRA# 2978128); and
- Removal of sub-chronic 7-d LC_{50} endpoints for *Ancyronyx* spp. (50.9 µg a.i./L) (Whiting and Lydy, 2015; PMRA# 2712690) and *Hyalella azteca* (geomean 3.8 µg a.i./L) (Bartlett et al., 2019; PMRA# 2975959).

A total of 36 species were included in the acute SSD (Appendix V). The revised HC_5 (95% CL) of 1.3 (0.32–3.9) µg a.i./L replaces the HC_5 of 1.5 (0.38–4.4) µg a.i./L reported in PSRD2018-01.

There was no change to the acute marine effects metric used in the risk assessment. One additional study on marine invertebrates was received after the establishment of the effects metrics used in the risk assessment and was determined not to change the risk profile. While a lower endpoint for one species was identified in this study this species is not relevant to the Canadian marine risk assessment.

Chronic toxicity effects metrics

Most sensitive species

The endpoint for the most sensitive species reported in PSRD2018-01 was a 40-d EC_{20} of 0.02 µg a.i./L for *C. dilutus* based on significant reductions in emergence (Cavallaro et al., 2017; PMRA# 2712687). Health Canada reassessed this study based on comments received during the consultation period for PSRD2018-01 and has confirmed that this study is scientifically sound and can be considered quantitatively in the risk assessment. However, since the publication of the proposed special review decision, an additional acceptable chronic endpoint for *C. dilutus* was published and found to be acceptable (56-d EC_{10} survival to emergence = 0.25 µg a.i./L; Raby et al., 2018b; PMRA # 2912490). For the proposed decision, Health Canada did not consider a geomean of *C. dilutus* endpoints with the other available endpoints (28-d EC_{20} emergence = 0.34 µg a.i./L; Maloney et al., 2018a; PMRA #2873503) on the basis that the shorter exposure time from Maloney et al. (2018a) may have contributed to the lower sensitivity for *C. dilutus* (PSRD2018-01). However, upon reconsideration of the data following the proposed decision, Health Canada has now used the geomean of the endpoints from the three studies above (PMRA# 2712687, 2873503 and 2912490) in establishing the effects metric used in the risk assessment to characterize the chronic toxicity to *C. dilutus*.

The resulting geomean of 0.12 µg a.i./L for *C. dilutus* is the most sensitive chronic endpoint available for clothianidin.

SSD HC_5

During the consultation period, concerns were raised about the validity of the chronic HC_5 derived for clothianidin. For the proposed decision (PSRD2018-01), Health Canada identified concerns with the chronic SSD for clothianidin and chose not to rely on it in making the proposed decision. For the special review decision, the number of chronic endpoints available for invertebrate species remains limited (n=7). The measures of effects were variable, including survival, growth and reproduction. Ideally, an SSD should reflect a common measure of effects so that the distribution reflects true variability in sensitivity and not differences in measurement endpoints. Decisions regarding the requirements for an acceptable SSD based on available data are currently made by Heatlh Canada on a case-by-case basis.

For this final decision, it was determined that, based on the available data, a robust chronic HC_5 could not be determined for clothianidin.

Mesocosm

In PSRD2018-01, Health Canada used the lowest available mesocosm 56-d NOEC of 0.281 µg a.i./L (14-d time-weighted-average concentration; PMRA# 2713555) qualitatively for the higher-tiered characterization of chronic risk. The effects metric was only used qualitatively due to (1) a lack of sufficient mayflies (Ephemeroptera) to allow for the determination of adverse effects on this sensitive taxa, (2) a relatively weak ability to detect a significant difference (i.e., a high minimum detectable difference) associated with the lowest NOEC/LOEC pair, and (3) a lack of additional data from other sources to support a determination of the toxicity endpoint being protective of aquatic invertebrate communities.

For the final decision, Health Canada has reassessed the use of this effects metric for the higher-tiered characterization of chronic risk based on comments received during the consultation period for PSRD2018-01.

Bayer CropScience argued that this value should be used as a definitive effects metric for the final decision as:

1) The dissipation in water observed in the mesocosm study is representative of clothianidin dissipation observed in prairie wetlands monitoring data;

2) A rolling average concentration over an appropriate time frame from monitoring data is appropriate for estimating aquatic invertebrate exposure against the $NOEC_{TWA}$ effects metric from the mesocosm study (failing sufficient monitoring data, the endpoint based on the initial measured concentration could be used); and

3) Based on published data by Raby et al. (2018a, 2018b) and an analysis provided to Health Canada, Ephemeroptera do not necessarily constitute the most sensitive aquatic invertebrates for clothianidin exposure.

Health Canada recognizes that Canadian monitoring data from intensively sampled wetlands in the Prairie Region that are associated with seed treatment uses generally show an annual spring/early summer peak, followed by a decline in pesticide concentrations in the water bodies; however, there are waterbodies in areas of Canada where concentrations are maintained for extended periods of time.

Health Canada agrees that it is appropriate to compare the 56-d $NOEC_{14\text{-d TWA}}$ of 0.281 µg a.i./L to moving average concentrations from the available monitoring data. There were sufficient data from a large number of sampling sites to determine a moving average concentration; as such, comparison of the initial measured concentrations from the mesocosm study against peak monitoring values was not explored. A 28-d moving average concentration was chosen as an appropriate time-frame for the clothianidin aquatic invertebrate chronic assessment to best match the overall study durations from the chronic laboratory and mesocosm studies (see Section 1.3.4). The 14-d TWA from this mesocosm study was determined because the concentrations detected in subsequent time frames were less than 20% of the initial concentration (following European Food Safety Authority (EFSA) guidance). Effects on population abundance and emergent insect diversity in Hartgers and Roessink (2015; PMRA# 2713555) were seen within the first 14 to 21 days of exposure. It is recognized that the comparison of a 14-day TWA effects metric to 28-d moving average concentrations may underestimate potential risk and therefore is a source of uncertainty.

Bayer CropScience provided information on taxa toxicity ranking, demonstrating that Ephemeropterans have a mid-level sensitivity to neonicotinoids. The ranking was based on acute toxicity data for all neonicotinoids combined, which does not allow for a direct comparison of clothianidin toxicity. For clothianidin, chronic exposure is the primary concern for aquatic invertebrates and the sensitivity on a chronic basis may not be equivalent to acute exposure. Limited data are available from chronic exposure data to clearly understand the different sensitivities of different aquatic invertebrates resulting from extended exposure. Based on available chronic laboratory data, the most sensitive Ephemeropteran was *Neocloeon triangulifer* (32-d $NOEC_{emergence}$ = 0.23 µg a.i./L; Raby et al. 2018b; PMRA# 2912490).

This laboratory-based endpoint falls between the two chronic effects metrics selected for the final risk assessment: the laboratory-based chronic effects metric for *Chironomus dilutus* (Diptera; geomean 28–56-d $EC_{10/20}$ = 0.12 µg a.i./L) and the mesocosm-based chronic effects metric (56-d $NOEC_{14\text{-d TWA}}$ of 0.281 µg a.i./L).

An additional consideration in evaluating mesocosm-based effects metrics is the reportable minimum detectable differences (MDDs) associated with the hypothesis tests establishing NOECs and LOECs. MDDs represent the estimated percent difference that would need to exist between controls and treatment levels in order to determine a statistically significant difference. Lower percent MDDs are preferable (i.e., it is desirable to be able to detect differences, if they exist). It is common for mesocosm endpoints to have higher MDDs compared to laboratory studies; this is because mesocosms typically involve lower replication and have higher variability in measurement endpoints (for example, abundance) within treatment levels. In the case of Hartgers and Roessink (2015; PMRA# 2713555), species of sensitive Diptera, Ephemeroptera and Amphipoda taxa were not well represented in the mesocosm and MDDs were generally greater than 60%, meaning that more than ~60% effect would need to occur in a treatment level in order to determine that the effect was statistically significant. Therefore, this study has a limited ability to identify significant effects.

Chronic effects metrics used in final decision

Two chronic effects metrics were used to characterize chronic risks to aquatic invertebrate communities. Due to the uncertainty associated with (1) how representative the mesocosm communities were of sensitive aquatic invertebrate species, and (2) the protectiveness of the established NOEC from the mesocosm studies, the most sensitive effects metric from mesocosm studies (56-d $NOEC_{14\text{-dTWA}}$ of 0.281 µg/L) could not be used on its own as a higher-tier effects metric. Rather, it was considered in the weight of evidence along with the effects metric for the most sensitive species from laboratory studies (geomean of 0.12 µg a.i./L for *C. dilutus*).

1.3.2 Screening level risk assessment

This screening level risk assessment for aquatic invertebrates takes into account the revised acute and chronic toxicity effects metrics for clothianidin. For a complete description of the screening level risk assessment and derivation of EECs, refer to PSRD2018-01. Transformation products of clothianidin were not expected to pose a risk to aquatic invertebrates (PSRD2018-01) and are therefore not considered further.

Using the freshwater invertebrate effects metrics highlighted in Table 1, the revised screening level assessment considered:

- The highest foliar application rate of 350 g a.i./ha to turf by ground sprayer;
- The highest seed treatment rate of 420 g a.i./ha for a variety of vegetables; and
- A representative low rate among all crops of 17.5 g a.i./ha for seed treatment to wheat.

Screening level RQs of clothianidin exceeded the LOC for freshwater and marine invertebrates for both acute and chronic exposures, with the exception of the low seed treatment rate for acute and chronic exposure to marine invertebrates (Table A.4-3).

1.3.3 Spray drift risk assessment

The risk to aquatic invertebrates was further characterized by taking into consideration the concentrations of clothianidin that could be deposited through spray drift in aquatic habitats that are 1 m downwind from the treatment area. End-use products containing clothianidin are applied by a variety of foliar spray methods that may result in spray drift, including field sprayer, airblast and aerial sprayer applications. The maximum amount of spray that is expected to deposit 1 m downwind from the application site during application by field and aerial sprayers with an ASAE (American Society of Agricultural and Biological Engineers) S572.1 fine spray droplet size is 11% and 26% respectively. For early and late airblast applications, 74% and 59% of spray is expected to deposit 1 m downwind from the application site, respectively. Given the variation in percent drift off site for each of the application methods, the assessment of potential risk from drift was assessed for the maximum cumulative application rate for each method: for field sprayers, a single application of 350 g a.i./ha for turf; for airblast spray a single application of 105 g a.i./ha for grapes (new highest airblast rate as per RVD2019-05); and for aerial spray, a cumulative application rate of 152.2 g a.i./ha for potatoes (3 × 52.5 g a.i./ha with a 7-day interval, 80^{th} percentile aquatic half-life = 141 d).

In freshwater habitats, the chronic risk from spray drift was assessed using the laboratory-based chronic effects metric and the cumulative deposit from multiple applications, where appropriate. In marine/estuarine habitats, cumulative deposit from multiple applications and chronic exposure resulting from spray drift is not expected given the high rates of water replacement due to tidal flushing. For this reason, risk from spray drift in estuarine/marine habitats is determined based on the acute effects metric and the maximum single application rate only.

The EECs and RQs for aquatic invertebrates resulting from spray drift are summarized in Table A.4-4. The RQs exceed the LOC for freshwater invertebrates exposed to clothianidin via spray drift at the highest application rates from all application methods on both an acute and chronic basis. The LOC was not exceeded for estuarine/marine invertebrates 1 m downwind from application based on acute exposure.

Mitigation in the form of spray buffer zones is required for freshwater habitats and is presented in Appendix VIII.

1.3.4 Runoff assessment methodology

The risk to aquatic invertebrate communities exposed to clothianidin via runoff was characterized using multiple lines of evidence including higher-tier (more realistic) toxicity information and exposure estimates based on crop- and region-specific modelling and monitoring information. Risk quotients were calculated with exposure estimates from both modelling and monitoring. The risk characterization was based on a weight of evidence approach, with more weight placed on the highest tier data and with less concern identified where RQs were low (near or below the LOC of 1). Where risks were identified in some Canadian watersheds, a reduction in loading through changes to the use pattern for relevant crops was required through rate reductions, reductions to the number of applications or cancellation of uses. Risk mitigation requirements were applied nationally for the main commodities where risks were identified.

Commodities and application methods

The characterization of risks from runoff considered the different commodity groups registered for clothianidin along with all the application methods registered including:

- Corn – seed treatment
- Oilseeds – seed treatment
- Wheat – seed treatment
- Vegetables – seed treatment, soil drench (sweet potato) and foliar (cucurbits)
- Potatoes – seed treatment, in-furrow and foliar
- Grapes – foliar
- Turf – foliar

Water modelling

Extensive modelling was completed using representative crops for the different commodity groups outlined. The Pesticide in Water Calculator (PWC) model was used to estimate concentrations in water resulting from runoff of clothianidin. Details on modelling inputs and assumptions are provided in Appendix VI of PSRD2018-01. The models were run for a variety of scenarios to ensure that runoff potential was assessed for a) representative application rates for each of the major application methods, and b) major crop uses across the country. The following changes were made to modelled scenarios since the previous assessment, which include consideration of the changes to the use pattern resulting from the pollinator re-evaluation decision, RVD2019-05:

- Foliar sprays: removal of strawberry and addition of grape and turf;
- Soil spray/drench: addition of sweet potato;
- In-furrow: revised to reflect increasing concentrations with depth inside the furrows; and
- Seed treatments: Current rate for wheat seed treatments registered (maximum 104.9 g a.i./ha based on planting rates).

A list of all clothianidin use scenarios selected for surface water modelling is presented in Table 2 with further details presented in Appendix VI, Table A.6-1. Modelling was based on registered application rates for clothianidin as of 31 July 2020 (Appendix II). The EECs and RQs for aquatic invertebrates resulting from surface runoff are summarized in Table A.4-5.

Table 2 Clothianidin use scenarios selected for surface water modelling

Application Method	Crops Selected
Seed treatment	• canola (32.5 g a.i./ha) • potato (381 g a.i./ha) • vegetable crops (at the high rate of 420 g a.i./ha and low rate of 4.7 g a.i./ha)[a] • corn (118 g a.i./ha)[c] • spring and winter wheat (104.9 g a.i./ha)
In-furrow	• potato (224 g a.i./ha)[c]
Soil spray/drench with incorporation	• sweet potato (1 × 224 g a.i./ha)
Foliar spray	• potato (3 × 52.5 g a.i./ha) • squash/pumpkin (1 × 105 g a.i./ha)[b] • grape (1 × 105 g a.i./ha) • turf (1 × 350 g a.i./ha)

[a] There were a variety of seed treatment rates for the vegetable crops, as such the maximum rate along with a representative low rate was modelled based on the carrot use pattern.

[b] The modelling of foliar applications of clothianidin on cucurbits was originally conducted using 2 applications at 105 g a.i./ha for the proposed special review decision and reported in PSRD2018-01. Following the pollinator re-evaluation decision (RVD2019-05), only one foliar application can be made on cucurbits, prior to bloom. Rather than updating the modelling for this crop, EECs for one instead of two applications were roughly calculated by dividing the original EECs by 2.

[c] Corn seed treatment and potato in-furrow uses modelled with 'increasing with depth' scenario.

To assess acute risks based on modelling, peak EECs were compared against the acute effects metric to generate acute RQs. The acute effects metric (HC_5 of 1.3 µg a.i./L) comes from the acute aquatic invertebrate species sensitivity distribution (see Section 1.3.1 Revisions to Clothianidin Effects Metrics).

To assess chronic risks based on modelling, 21-day EECs were compared against the two chronic effects metrics to generate chronic RQs. The chronic effects metrics are a laboratory-based geometric mean of EC_{10}/EC_{20} values of 0.12 µg/L based on emergence of *Chironomus dilutus* in three 28-day to 56-day laboratory studies, and a mesocosm-based $NOEC_{14\text{-dTWA}}$ of 0.281 µg/L from a 56-day mesocosm study, where reductions in individual species abundance and in emergent insect taxa richness were observed at the next highest concentration of 0.573 µg a.i./L (see Section 1.3.1 Revisions to Clothianidin Effects Metrics).

Water monitoring data

A large amount of monitoring data was available to represent most of the major use areas of clothianidin in Canada. Where possible, the crops grown in the region surrounding the monitoring sites were identified to help determine possible uses of clothianidin contributing to clothianidin concentrations measured in water.

To assess acute risk to aquatic invertebrates from clothianidin exposure based on monitoring data, maximum measured clothianidin concentrations for each site-year were divided by the acute effects metric to generate acute RQs. To assess chronic risk to aquatic invertebrates based on monitoring data, 28-day (approximate) moving-average concentrations were calculated for each site-year. A time-period of 28 days is within the range of exposure durations used in chronic laboratory studies and generally coincides with the period when adverse effects were seen in mesocosm toxicity studies.In calculations, Health Canada assigned a value equal to half of the limit of detection to samples where clothianidin was not detected. The maximum 28-day average of each site-year was divided by the two chronic effects metrics selected for quantitative risk assessment to generate chronic RQs.

The 28-day (approximate) moving-average concentrations of clothianidin were calculated for each site-year in one of two ways. For site-years with peak detections of clothianidin above the laboratory-based chronic effects metric of 0.12 µg/L, 28-day averages were calculated using the observed data when the sampling was frequent enough to allow for the calculation. For site-years with peak clothianidin levels below the laboratory-based chronic effects metric and for those at which the sampling regime did not allow for the calculation (for example, if only one sample was collected), a 28-day moving average was estimated using the peak concentration and an average DT_{50} of 11.3 days assuming dissipation followed single first-order kinetics. The DT_{50} used in this estimate represents the average 50% dissipation time for clothianidin observed in Prairie wetlands, presented below and in Table A.7-6. The dissipation time is consistent with the decline of clothianidin observed in mesocosm studies. The assumption that dissipation followed single first-order kinetics is considered reasonable given that the best-fitting dissipation model was almost always single first-order; however, in flowing waterbodies receiving influxes from lower order streams the presumption of exponential decline over time may not hold.

Monitoring data cannot distinguish the relative contribution of different crops and application methods to the levels detected in the watersheds, therefore, modelling estimates were relied upon to determine the relative contributions. Consideration was also given to the crop location and size within a watershed to determine the potential contribution of that crop to levels that were observed in the water.

1.3.4.1 Runoff risk assessment – modelling

Acute risk

Acute RQs for freshwater invertebrates exceeded the LOC for at least one of the modelled regions for all foliar uses (RQs up to 4.8), for in-furrow use on potatoes in Atlantic Canada (RQ of 2.0), for vegetable seed treatments at the highest application rate (RQs up to 16) and for canola seed treatment in Eastern Canada (RQs up to 2.5). The LOC was not exceeded for pre-plant soil incorporated use on sweet potato (RQs up to 0.9), potato seed piece treatment, or seed treatments for corn or wheat (spring and winter varieties) (RQs up to 0.8) (Table A.4-5).

Based on modelling results, clothianidin runoff from treated agricultural fields did not exceed the acute effects metric in estuarine/marine habitats (RQs $\leq$ 0.8) (Table A.4-5).

Chronic risk

Using the laboratory-based effects metric of 0.12 µg a.i./L, chronic RQs exceeded the LOC for all use patterns in at least one of the modelled regions (RQs of 1.5–140), with the exception of potato seed treatment uses (RQs up to 0.6) (Table A.4-5). When considering the mesocosm-based effects metric, chronic RQs exceeded the LOC for all modelled foliar applications (RQs up to 17) and for soil applications for sweet potato (RQs up to 3.3) and potato (RQs up to 6.8; Table A.4-5). The RQs for seed treatment uses of clothianidin exceeded the LOC for aquatic invertebrate communities for vegetables at the high rate of 420 g a.i./ha in all regions of Canada (RQs up to 60), but not at the low rate of 4.7 g a.i./ha (RQ up to 0.7). Risk quotients for aquatic invertebrate communities also exceeded the LOC for most modelled regions of canola (RQs of 0.8–10), for corn (RQs up to 2.2) and spring or winter wheat (RQs up to 2.8).

In the marine environment, chronic RQs based on runoff modelling exceeded the LOC for vegetable seed treatments at the highest application rate of 420 g a.i./ha in the Quebec and Atlantic regional scenarios (RQs of 1.7–3.3) (Table A.4-5).

1.3.4.2 Runoff risk assessment – water monitoring

The revised risk assessment included a total of 9850 water samples collected from 776 different sites across Canada between 2010 and 2019 (Table A.7-3). Many sites were monitored over multiple years, giving an overall total of 1197 site-years of monitoring. The monitoring data considered in the revised risk assessment, which include data previously included in the proposed special review decision as well as additional data received since the publication of PSRD2018-01 are discussed in Section 1.2 of this document.

Table A.7-5 summarizes the results of clothianidin monitoring programs across Canada. Clothianidin concentrations measured in Canadian waterbodies rarely exceeded the acute effects metric. Instances when average clothianidin concentrations exceeded the chronic effects metrics over a longer-term period of 28 days were rare in the Prairies, and slightly more frequent in waterbodies located in other regions of Canada. Because the use of neonicotinoids differs in the Prairie Provinces compared to other regions of Canada, the monitoring data from the Prairie Provinces and those from other regions of Canada are discussed separately.

1.3.4.2.1 Prairie Region

The primary use of neonicotinoids in the Prairies is as a seed treatment. Clothianidin is registered for use as a seed treatment on a variety of crops such as canola, corn, barley, wheat, and potato seed pieces. The current registered uses of clothianidin on seeds are outlined in Appendix II.

Additional water monitoring data and ancillary information from agricultural areas in Manitoba, Saskatchewan and Alberta were submitted to Health Canada since the publication of PSRD2018-01. The sites monitored include rivers, creeks, lakes, reservoirs, wetlands, irrigation canals, and tile drains. The monitoring data from the Prairie Region considered in the revised assessment were from the years 2014 to 2019. In total, 4717 surface water samples were collected from 488 different sites between 2014 and 2019, for an overall total of 645 site-years of monitoring (Table A.7-3). Of these data, 3932 (83%) of the samples and 371 (58%) of the site-years constitute new data not previously considered in the proposed special review decision for clothianidin. Between one and three years of monitoring data were available for each site (Table A.7-4).

Prairie Region rivers, creeks, lakes, reservoirs

A total of 1309 water samples were collected from 130 river, creek, lake and reservoir sites in agricultural areas across the Canadian Prairies between the years 2014 and 2019. Many sites were sampled for two or three years during this time period, adding up to a grand total of 245 monitoring site-years: 76 lakes, streams and river sites in Manitoba, 53 stream sites in Saskatchewan and 116 rivers, streams and reservoir sites in Alberta (Table A.7-2).

Between one and 22 samples were collected at each site, typically between the months of March and October; 5% (12 site-years) had only one sample collected, 53% of site-years (130) had two to four samples collected during the sampling period, 32% (79 site-years) were sampled between five and nine times, 7% (18 site-years) were sampled between ten and 13 times, and 2% (6 site-years) were sampled between 19 and 22 times in a given year. At six river sites in Manitoba, 19 to 22 polar organic chemical integrative samplers (POCIS) were deployed for periods ranging between 7 and 59 days in 2014 and 2015.

Clothianidin was detected in 44 (58%) of the 76 sites sampled in Manitoba, and in 34 (64%) of the 53 sites sampled in Saskatchewan. In Alberta, clothianidin was detected in 5 (9%) of the 53 river sites, and 17 (31%) of the 55 stream sites; it was not detected in any of the eight reservoir sites sampled.

None of the 1309 samples collected from lakes, rivers, streams and reservoirs in the Canadian Prairies between 2014 and 2019 had concentrations of clothianidin exceeding the acute effects metric of 1.3 µg/L. The maximum peak concentration of clothianidin detected in any lake, river, stream or reservoir site sampled in agricultural areas of the Canadian Prairies was 0.11 µg/L. None of the lakes, rivers, streams and reservoirs sampled had maximum 28-day moving average concentrations of clothianidin exceeding the chronic effects metrics.

Prairie Region wetlands

Data from a total of 298 different wetlands located in Saskatchewan (236), Alberta (47) and Manitoba (15) were available for the years 2014 and 2017 to 2019. Twenty-two of the Saskatchewan wetlands were sampled in both 2018 and 2019, for a total of 320 wetland site-years of monitoring across all three provinces. Based on the classification system defined in Stewart and Kartrud (1971)[6], four (1%) of the sites were ephemeral ponds (Class I), 16 (5%) were temporary ponds (Class II), 268 (84%) were either seasonal ponds or lakes (Class III) or

6 The wetlands were classified by the researchers using the classification system defined in Stewart, R.E. and H. A. Kartrud. 1971. Classification of natural ponds and lakes in the glaciated prairie region. Bureau of Sport Fisheries and Wildlife, U.S. Fish and Wildlife Service, Washington, D.C., USA. Resource Publication 92. 57 pp.

semi-permanent ponds or lakes (Class IV), and 17 (5%) were permanent ponds or lakes (Class V). Fifteen (5%) of the wetlands were not classified, but site information was available for them and they were included in the analysis because they were deemed relevant to the assessment. The wetlands were located in agricultural areas where neonicotinoids are used, most of them directly within agricultural fields or receiving drainage from all or part of the surrounding agricultural fields. Based on use information available, at least 49 of the wetlands were located within or adjacent to fields that had been planted with clothianidin-treated canola seeds in 2018 and 2019. A total of 111 wetlands were in or adjacent to fields planted with thiamethoxam-treated seeds (canola, wheat, lentil, barley, oat) in 2018 and 2019, and 18 wetlands were within fields planted with imidacloprid-treated seeds (pea, lentil, soybean) in 2017, 2018 or 2019. The land use surrounding the other wetlands for which neonicotinoid use information was not available included crops such as canola, barley, wheat, lentils, peas, oats and pasture and grass. Of these crops, canola and wheat can be treated with clothianidin. The distributions of the size and field catchment area of the sampled wetlands in neonicotinoid-treated fields were shown to be representative of those found throughout the agricultural areas of the Canadian Prairies. Wetlands within or adjacent to fields known to be treated with a neonicotinoid other than clothianidin during the year of sampling were included in the analysis even if they do not represent clothianidin exposure scenarios for the year of use. Research has shown that crops treated with neonicotinoids are frequently rotated in the Prairie Region and neonicotinoids can persist and carry over between growing seasons resulting in detections in wetlands in subsequent years (Main et al., 2014 (PMRA# 2526133); Main et al., 2016 (PMRA# 2572395)).

A total of 3050 samples were collected in Prairie wetlands. Each wetland site-year had between one and 20 samples collected between the months of April and October; 62% of wetland site-years (197) had five or more samples collected during the sampling period and 51% (162) of the site-years had ten or more samples collected in a given year.

Clothianidin was detected in 47 (96%) of the 49 wetlands near or adjacent to fields known to be planted with clothianidin-treated seeds (Table A.7-5). Overall, clothianidin was detected in 210 (66%) of the 320 wetlands monitored with concentrations typically highest in the spring both pre-plant and post-plant followed by subsequent decreases in concentrations. Concentrations of clothianidin in the spring prior to seeding were attributed to input from spring runoff of residues remaining in the soil. Increases in concentration were not common in wetlands after the months of June or July; mid-summer and late-season rainfall (after mid-July) did not commonly result in increased clothianidin concentrations in wetlands. Higher concentrations tended to be measured in smaller wetlands that had shorter distances between the planted area and the wetland and received high rainfall events.

Clothianidin dissipated rapidly and did not persist in Prairie wetlands. It was possible to calculate the 50% dissipation time (DT_{50}) of clothianidin in 40 wetlands that were sampled weekly. The DT_{50}s for clothianidin in wetlands ranged from 1.9 to 21.3 days, and the overall average was 11.3 days (Table A.7-6).

None of the wetlands had clothianidin concentrations exceeding the acute effects metric (HC_5 of 1.3 µg/L; Figure A.7-2, panel A). The maximum concentration of clothianidin detected was 0.514 µg/L.

The maximum 28-day moving average concentration of clothianidin exceeded the laboratory-based chronic effects metric of 0.12 µg/L in three (0.9%) of the 320 wetland sites sampled (Figure A.7-2, panel B). None (0%) of the 320 wetlands sampled had 28-day moving average concentrations of clothianidin exceeding the mesocosm-based chronic effects metric of 0.281 µg/L. The highest 28-day moving average concentration in Prairie wetlands was 0.157 µg/L. The highest RQ calculated using the maximum 28-day average concentration and the laboratory-based chronic effects metric was 1.3. The highest RQ calculated using the maximum 28-day average concentration and the mesocosm-based chronic effects metric was 0.6.

Prairie Region irrigation canals and tile drains

A total of 53 different irrigation canals and seven tile drain sites located in Alberta were sampled in 2017 and 2018. Eighteen of the irrigation canals and two of the tile drain sites were sampled in both years, for a total of 80 site-years of monitoring. A total of 313 samples were collected from irrigation canals and 45 samples were collected from tile drains during this time period. The tile drain sites in 2017 were draining areas planted in forage, potatoes and wheat; crop information around tile drain sites was not gathered for 2018. Irrigation canals are in areas of Alberta with the highest agricultural intensity, and their purpose is to divert water for crop irrigation. The sites monitored were part of long-term monitoring programs in Alberta’s irrigation districts. Information on crops or neonicotinoid use around the irrigation canal sites was not provided.

Clothianidin was not detected in any of the 358 samples collected from irrigation canals and drain sites sampled in Alberta between 2017 and 2018. Water from irrigation canals and tile drains are considered less representative of aquatic habitat to be protected, and/or were man-made structures not intended to sustain aquatic life.

Precipitation in the Prairie Region

As noted in PSRD2018-01, the 2017 growing season was generally drier than average in the Canadian Prairies. Daily precipitation received at sampling sites or at nearby weather stations, and 30-year normal precipitation information were available and used to assess whether the precipitation received during 2018 and 2019 growing seasons was representative of a typical year. Rainfall during the 2018 and 2019 sampling periods varied. Considering a normal precipitation range as 85%–115% of the average 30-year historical precipitation, some areas of the Canadian Prairies received below normal precipitation amounts during a given month, but normal to above normal amounts of precipitation were received during other months of the growing season. Several areas sampled experienced more wet conditions than normal. At most Prairie wetland sites, there were large precipitation events (for example, greater than 40 mm). Overall, precipitation levels received in the sampled areas of the Canadian Prairies during the 2018 and 2019 growing seasons were considered representative of a typical year.

1.3.4.2.2 Growing regions outside of the Prairies

Although clothianidin is used mainly as a seed treatment in the Prairie Region, in other areas of Canada, clothianidin is used as a seed treatment, an in-furrow drench, and a foliar spray. Some of the crops that can be treated with clothianidin include corn, potatoes, oilseeds, vegetables, wheat, grapes and turf. The recent pollinator re-evaluation decision (RVD2019-05) has resulted in changes to the use pattern for clothianidin. The current registered uses of clothianidin are listed in Appendix II.

Water monitoring data were available from 288 different sites in intensive agricultural areas of Prince Edward Island, Nova Scotia, New Brunswick, Quebec, Ontario and British Columbia (Figure A.7-1). Various types of waterways were monitored, such as streams, rivers, creeks, brooks, sloughs, lakes, and drainage ditches. Seventeen sites were sampled in the same year as part of two or three different monitoring programs; for simplicity of calculations, these were considered as separate site-years. While 80% (230) of the sites were monitored over one or two years, 5% (13 sites) had three years of data, 9% (27 sites) had four years of data, and 6% (16 sites) were sampled for five to eight years (Table A.7-4). A total of 5133 water samples from 552 site-years of monitoring were available for the time period between 2010 and 2019 (Table A.7-3). Of these data, 2260 (44%) of the samples and 298 (54%) of the site-years constitute new data not previously considered in the proposed special review decision for clothianidin. Details of the monitoring datasets are provided in Table A.7-2.

The number of samples collected per year at each site ranged from 1 to 7 in the Atlantic Provinces, from 1 to 10 in British Columbia and from 1 to 31 in Ontario and Quebec (Table A.7-2). The sampling frequency varied depending on the program. Samples were collected approximately monthly in New Brunswick and Prince Edward Island, bi-weekly (every two weeks) in British Columbia, weekly or bi-weekly (as well as rain-initiated sampling in June and July 2019) in southwestern Ontario, monthly in the Ottawa Valley (although only up to two samples were collected at each site), and every two to three days or weekly in Quebec, depending on the waterbody. Most sites in Nova Scotia were sampled only once. The sampling sites reflect coverage of agricultural watersheds in Prince Edward Island, Quebec, Ontario and British Columbia; although fewer sites were monitored in Nova Scotia and New Brunswick, the sites monitored were in intensively cropped watersheds. Sampling locations and their watersheds were typically located in areas representative of the provincial agriculture as a whole and contained examples of the highest or close to the highest densities of major crops on which clothianidin is used as a seed treatment, in-furrow or foliar application (PMRA# 2935271, 3025394 and 3070837).

The watersheds in Prince Edward Island are best characterized as small (about 200 km^2 or less) with correspondingly short river systems (generally less than 20 km from source to ocean) and can be very intensively farmed in potatoes especially. For example, both the Wilmot and Huntley watersheds are less than 50 km^2 with their main rivers from 6–12 km long, and whose land use is approximately 40% potato crops in any given year. Secondary crops are usually pastures and cereals, with a very small percentage of corn and soybean production across the island. As clothianidin use rates for some of the major Canadian crops (corn, canola, wheat and potato; not registered for use on soybeans or pulse crops) are highest on potatoes, and potatoes represent the highest percentages of the watershed area, it is reasonable to assume that clothianidin residues in Prince Edward Island water would be primarily attributed to potato farming. The monitoring sites on Prince Edward Island overlapped with all of the highest potato density areas in the province.

Only one site-year of monitoring for clothianidin was available for New Brunswick, collected in 2015 in the Big Presqu'île River as it enters the St. John River at Connell. This is a large watershed that extends across the Canada/United States border; however, agricultural intensity on both sides of the border appears to be similar (40%–50% of the watershed cropped). Potatoes and pasture are the dominant crops, each representing 15% of the watershed areas.

In Nova Scotia, monitoring was conducted in the Annapolis Valley in 2015 (one site) and 2016 (five sites). The Annapolis Valley contains the most intensively cropped areas of Nova Scotia, although agriculture is much more limited in density and area compared to Prince Edward Island, Ontario, and Quebec (according to PMRA# 2935271).

In Ontario and Quebec, sampling locations were strategically located in watersheds of varying sizes, and representative of the major cropping areas for corn, soybeans, potatoes, cereals, orchards, and vineyards and greenhouses that in most cases contained highly intensive agriculture (cropped area greater than 50% of the total watershed area). It is noted that clothianidin is not registered for use in greenhouses; greenhouses are mentioned here because they represent an important portion of the watershed. No single watershed was predominantly cereals, these are cultivated fairly evenly throughout the provinces at fairly low density (maximum 15% but generally below 5% total watershed area in Quebec and below 10% in Ontario, based on information provided in PMRA# 2935271 and 3070837).

Sites in five watersheds in the Okanagan Valley of British Columbia were sampled in 2015 (one site only), 2017 and 2018. The watersheds all contained a significant amount of cherry and apple orchards, as well as peach, plum, apricot orchards and grape vineyards. Neonicotinoids were registered for use on all these crops at the time the monitoring was conducted. Locations upstream and downstream of areas with orchard and vineyard crops were selected to try to isolate potential contributions of neonicotinoid use on these crops to concentrations in water. In addition, a total of 19 sites in the Lower Mainland of British Columbia were sampled between 2014 and 2018. Upstream and downstream sampling locations in some watersheds were selected with the aim of isolating areas of potato and vegetable production as these crops are treated with neonicotinoids as potato seed piece treatments and in vegetable production as soil drench or in row applications. Berries (blueberry, raspberry, blackberry and strawberry) were also grown in certain watersheds. Corn, nurseries, ornamentals and greenhouses were also in some watersheds. A few sites in the Lower Mainland were adjacent to mainly forested or urban areas.

Clothianidin was detected in 432 (78%) of the 552 site-years of available monitoring.

1.3.4.2.2.1 Acute risk in growing regions outside of the Prairies

Figure A.7-3 (panel A) shows the maximum concentration of clothianidin measured in each of the 552 site-years of monitoring in waterbodies located in the Atlantic Region, Quebec, Ontario and British Columbia, grouped by the major crops grown in each watershed. Clothianidin concentrations were equal to or exceeded the acute effects metric in three site-years. In total, five (0.1%) of the 5133 samples collected between 2010 and 2019 had clothianidin concentrations equal to or exceeding the acute effects metric of 1.3 µg/L. The concentrations of clothianidin measured in the five samples exceeding the acute effects metric ranged from 1.3 µg/L to 11 µg/L, and the associated RQs ranged from 1.0 to 8.5. Four of the five samples (three in 2013 and one in 2014) were from the Gibeault-Delisle Creek in Quebec, a very small watershed that is intensively cropped (12 km^2, 85% of which is cropped). The other sample was from the Wilmot River in Prince Edward Island, also small and intensively cropped (46 km^2, 85% of which is cropped). The main crops grown in the Gibeault-Delisle Creek watershed are potatoes (21%), vegetables (21%), corn (17%) and soybeans (17%). Potatoes represent 40% of the Wilmot River watershed area while cereals represent 15%.

1.3.4.2.2.2 Chronic risk in growing regions outside of the Prairies

Figure A.7-3 (panel B) shows the maximum 28-day average concentration of clothianidin in each of the 552 site-years of monitoring in waterbodies located in the Atlantic Region, Quebec, Ontario and British Columbia, grouped by the major crops grown in each watershed.

The maximum 28-day moving-average concentration of clothianidin was 2.05 µg/L in the Gibeault-Delisle Creek in 2013. The chronic risk to aquatic invertebrates was assessed by comparing the maximum 28-day concentrations of clothianidin in waterbodies with the laboratory-based chronic effects metric and the mesocosm-based effects metric separately. A summary of the maximum 28-day moving-average concentrations of clothianidin and the associated chronic RQs at the sites with exceedances of the chronic effects metrics is presented in Table A.7-7 for the laboratory-based chronic effects metric, and in Table A.7-8 for the mesocosm-based chronic effects metric. For each of the effects metrics comparisons, the risk was further characterized by examining the locations and some of the watershed characteristics where the maximum 28-day average concentrations exceeded the chronic effects metrics, and whether exceedances occurred at the same sites over multiple years. Information on the watershed size, percentage cropped, and main crops grown in the watersheds for the sites showing 28-day average clothianidin concentrations above the laboratory- and mesocosm-based chronic effects metrics is presented in Table A.7-7 and Table A.7-8, respectively.

Chronic risk characterization using the laboratory-based chronic effects metric

The maximum 28-day moving average concentration of clothianidin exceeded the laboratory-based chronic effects metric of 0.12 µg/L in 50 (9%) of all 552 site-years, from 31 (11%) out of 288 sites sampled. The 31 sites were located in 24 watersheds; 26 sites (19 watersheds; 39 site-years) were in Ontario, three sites (three watersheds; seven site-years) were in Quebec and two sites (two watersheds; four site-years) were in Prince Edward Island (Table A.7-7).

Sites with maximum 28-day average concentrations of clothianidin exceeding the laboratory-based chronic effects metric tended to be in small and intensively cropped watersheds. Only two of the 24 watersheds were larger than 80 km^2. At least 19 of the 24 watersheds had cropped areas representing greater than 60% of the total watershed area; the percentages of crops in two watersheds were not determined (Table A.7-7).

Six of the 31 sites (and 12 of the 50 site-years) were in areas where potatoes represent a large portion (10%–40%) of the watershed: the Huntley (three site-years) and Wilmot Rivers (one site-year) in Prince Edward Island; the Blanche River (two site-years), Chartier Creek (three site-years) and Gibeault-Delisle Creek (two site-years) in Quebec and the Nottawasaga Creek (one site-year), which is a small tributary to the Nottawasaga River in Ontario (Table A.7-7). As noted previously for the four listed watersheds in Ontario and Quebec, other crops such as corn, soybeans, and vegetables also represent large portions of the watersheds.

In potato-growing areas the RQs associated with the maximum 28-day average concentration of clothianidin reached or exceeded the laboratory-based chronic effects metric in 12 site-years (RQs ranging from 1.0 to 17; Table A.7-7). Three site-years had RQs between 1.0 and 1.8, two had RQs between 2.0 and 2.4, three had RQs between 3.0 and 3.6, and three site-years had RQs above 5.0 (5.7 from the Wilmot River due to a single sample above the endpoint; and 11 and 17 both from the Gibeault-Delisle Creek).

Twenty-three of the 31 sites (16 watersheds, and 36 of the 50 site-years) with maximum 28-day average concentrations of clothianidin exceeding the laboratory-based chronic effects metric were located in areas where corn and soybeans are grown (Table A.7-7). Nine of the 31 sites had 28-day averages exceeding the endpoint during more than one year: Big Creek (two site-years), Decker Creek (three site-years), Garvey Glenn (two site-years), the main Lebo Drain site (four site-years), Lebo Drain 5 (two site-years), Lebo Drain 6 (two site-years), Little Ausable Creek (two site-years), McKillop Drain (three site-years), and White Ash Creek (two site-years); all nine sites were located in Ontario.

The maximum RQs associated with the maximum 28-day average concentration of clothianidin during the 36 site-years where levels exceeded the laboratory-based chronic effects metric in corn- and soybean-growing areas ranged from 1.0 to 5.8. Twenty-eight site-years had maximum RQs between 1.0 and 1.9, five site-years had RQs between 2.0 and 2.9; two site-years had RQs between 3.0 and 3.4 and one site-year had an RQ higher than 5.0. The site-year with the risk quotient greater than 5.0 (5.8) is based on sampling using POCIS deployed over 14 days in the main Lebo Drain site in 2016. Results from grab sampling by two other programs at the same site in the same year showed 28-day averages lower than the 14-day average from POCIS, and a maximum RQ of 1.8 (2.0 considering grab sampling data from all programs together). Four drainage ditch sites (six site-years) in the Lebo Drain watershed showed 28-day average clothianidin concentrations exceeding the laboratory-based chronic effects metric. The RQs for the four drainage ditch sites ranged from 1.2 to 3.0. Drainage ditches are less appropriate for an aquatic invertebrate risk assessment because they do not represent typical aquatic habitat.

Two of the 31 sites (two of the 50 site-years) with maximum 28-day average concentrations of clothianidin above the laboratory-based chronic effects metric were located in areas of Ontario where orchards and vineyards represent greater than 50% of the watershed area (Table A.6-7). At both of these sites, the maximum 28-day average concentrations only exceeded laboratory-based chronic effects metric in one out of five years of monitoring. The maximum RQs for the two site-years where 28-day average concentrations exceeded the laboratory-based chronic effects metric were 1.1 and 1.2 (Table A.7-7).

Chronic risk characterization using the mesocosm-based chronic effects metric

The maximum 28-day average clothianidin concentrations were near or exceeded the mesocosm-based chronic effects metric of 0.281 µg/L in 15 (3%) of all 552 site-years, from 12 (4%) out of 288 sites sampled. One site with a maximum 28-day average concentration of 0.275 µg/L was included in this total because the concentration is close to the chronic mesocosm-based effects metric and the corresponding risk quotient (0.979) is 1 when rounding to one decimal. The 12 sites were from 11 watersheds. Seven sites (six watersheds; seven site-years) were in Ontario, three sites (three watersheds; five site-years) were in Quebec, and two sites (two watersheds; three site-years) were in Prince Edward Island (Table A.7-8).

Sites with maximum 28-day average concentrations of clothianidin exceeding the mesocosm-based chronic effects metric tended to be in small and intensively cropped watersheds. The watersheds for the 12 sites were all less than 65 km^2 and nine had cropped areas representing greater than 60% of the total watershed area (Table A.7-8).

Six of the 12 sites (and nine of the 15 site-years) were in areas where potatoes represent a large portion (10%–40%) of the watershed: the Huntley (two site-years) and Wilmot Rivers in Prince Edward Island, the Blanche River (two site-years), Chartier Creek and Gibeault-Delisle Creek (two site-years) in Quebec and the Nottawasaga Creek, a small tributary to the Nottawasaga River in Ontario (Table A.7-8). Corn and soybean together represent approximately 22%–34% of the watershed area for the Chartier Creek, Gibeault-Delisle Creek and Nottawasaga Creek, and vegetables represent 21% of the Gibeault-Delisle watershed. Investigative sampling at extra sites on the Nottawasaga Creek identified the main source of clothianidin measured at that site in 2019 as likely coming from clothianidin-treated potato fields in the 2019 season (PMRA# 3070837). In addition to potatoes, corn and cereals are also grown in the Blanche River watershed. Five of the six sites in potato-growing areas with 28-day averages exceeding the mesocosm-based chronic effects metric had several consecutive samples near or exceeding 0.281 µg/L. The maximum 28-day average concentrations at three of the sites, the Blanche River, the Gibeault-Delisle Creek and the Huntley River, were near or above the mesocosm-based chronic effects metric for two years of monitoring.

In potato-growing areas the RQs associated with the maximum 28-day average concentration of clothianidin were near or exceeded the mesocosm-based chronic effects metric in nine site-years (RQs ranged from 1.0 to 7.3; Table A.7-8). Six site-years had RQs between 1.0 and 1.5, one had an RQ of 2.4, and two site-years (both from the Gibeault-Delisle Creek) had RQs of 4.7 and 7.3.

The above chronic RQs are based on a no-observed-effect concentration. To further characterize the chronic risk at sites in areas where potatoes are grown, the mesocosm LOEC, which is the lowest concentration of clothianidin at which toxic effects on aquatic invertebrates were observed in the chronic mesocosm study selected for the quantitative risk assessment was used. At the LOEC of 0.573 µg/L, reductions in individual species abundance and in emergent insect taxa richness were observed; however, effects were transient and recovery was observed by the end of the 56-day study (see Section 1.3.1 Revision of Clothianidin Effects Metrics). RQs calculated using the mesocosm LOEC ranged from 0.5 to 3.6. Six site-years had RQs less than 1.0 and three site-years had RQs above 1.0 (1.2, 2.3 and 3.6).

Six of the 12 sites (and six of the 15 site-years) with maximum 28-day average concentrations of clothianidin exceeding the mesocosm-based chronic effects metric were located in corn and soybean growing areas of Ontario (Table A.7-8). Clothianidin is not registered for use on soybeans; however, clothianidin is persistent in soil and corn and soybeans are regularly rotated. Also, clothianidin is a transformation product of thiamethoxam, which is registered for use on soybeans, and thiamethoxam use can contribute to clothianidin concentrations in water. Sampling using polar organic chemical integrative samplers (POCIS) deployed over 14 days in the main Lebo Drain site in 2016 showed a maximum 14-day time-weighted average concentration above the mesocosm-based effects metric and a resulting RQ of 2.5 (RQ of 1.2 based on the mesocosm LOEC; Table A.7-8). The main Lebo Drain site was monitored for seven consecutive years between 2013 and 2019 and levels exceeded the mesocosm-based chronic effects metric only in one instance, a 14-day POCIS deployment in 2016. Aside from the POCIS result, the RQs associated with the maximum 28-day average concentration of clothianidin during the five other site-years where levels exceeded the mesocosm-based chronic effects metric in corn- and soybean-growing areas ranged from 1.0 to 1.4 (0.5 to 0.7 based on the mesocosm LOEC) (Table A.7-8). None of the waterbodies draining areas in which corn and soybean were grown showed maximum 28-day averages exceeding the effects metric during more than one year.

Contribution of the use of thiamethoxam to the presence of clothianidin in waterbodies

In soil, clothianidin is a transformation product of thiamethoxam, another registered neonicotinoid insecticide. The use of thiamethoxam may contribute to the presence of clothianidin in waterbodies. A monitoring program in Prairie wetlands investigated the potential contribution of thiamethoxam seed-treatment use to clothianidin concentrations in wetland water (PMRA# 3016892). The contribution of clothianidin from the use of thiamethoxam was examined through considering the ratio of clothianidin to thiamethoxam in wetlands identified with known thiamethoxam use.

Monitoring data from wetlands located in fields treated with thiamethoxam-treated seeds in 2018 showed that the ratio of clothianidin to thiamethoxam in wetland water is both source location- and time-dependent. Low clothianidin:thiamethoxam ratios predominate when conditions favour surface runoff or when wetlands expand and flood seeded areas early in the season; clothianidin:thiamethoxam ratios increase over the growing season if wetlands expand in size following precipitation, as thiamethoxam transforms to clothianidin in soil (PMRA# 3016892).

The majority (16 of 20) of wetland neonicotinoid water influx pulses exhibited a clothianidin:thiamethoxam ratio below 0.2, and 18 of 20 pulses were less than a ratio of 0.3. Two instances of enriched clothianidin:thiamethoxam (ratios of 0.57 and 0.63) that were observed are most likely a result of aged residues partitioning to water when flooding occurred within seeded soil adjacent to the wetland; data suggest these high ratios occur in a minority of observed influx pulses and are limited to small, ephemeral wetlands most vulnerable to runoff-induced expansion.

None of the intensively monitored Prairie wetlands adjacent to fields planted with thiamethoxam-treated seeds (56 in 2018 and 58 in 2019; 92 individual wetlands in total) had clothianidin concentrations exceeding the acute effects metric of 1.3 µg/L, the laboratory-based chronic effects metric of 0.12 µg/L or the mesocosm-based chronic effects metric of 0.281 µg/L. In one wetland sampled in 2019, the maximum peak and 28-day average clothianidin concentrations (0.27 µg/L and 0.13 µg/L, respectively) following a large precipitation event exceeded the laboratory-based chronic effects metric, but not the mesocosm-based effects metric. Following investigations using aerial photographs and soil analysis, these clothianidin concentrations were attributed to input from an adjoining canola field planted with clothianidin-treated seeds.

These results indicate that following use of thiamethoxam as a seed treatment, concentrations of clothianidin measured in wetland water were generally less than 20% those of thiamethoxam concentrations. In these wetlands, clothianidin concentrations did not exceed the acute or chronic effects metrics for clothianidin.

1.3.4.2.3 Potential reductions in clothianidin concentrations

The monitoring concentrations reported for clothianidin reflect the use pattern at the time the samples were taken.

Some of the exceedances of the acute and chronic effects metrics were observed in waterbodies associated with use on corn and orchards. As a result of the pollinator re-evaluation decision for clothianidin (RVD2019-05), use on pome fruits and stone fruits has been cancelled. As a result, the monitoring data may present conservative exposure estimates in some watersheds.

In 2015, new regulatory requirements for the sale and use of thiamethoxam-, clothianidin- and imidacloprid-treated seed in Ontario came into effect to support the province’s target to reduce the number of hectares planted with neonicotinoid-treated corn and soybean seed with a phased-in approach over several years (Government of Ontario, 2020; PMRA# 3197050)). In September 2018, the province of Quebec put in place a pesticide reduction strategy which led to regulations in 2020 that impact the use and sale of various seeds (oats, wheat, canola, barley, corn, and soybeans) treated with thiamethoxam, clothianidin, and imidacloprid (Government of Quebec, 2018; PMRA# 3197055) Given this, the impact of these programs on levels detected in the environment are currently unclear, but could reduce exposure to aquatic systems in Ontario and Quebec.

1.3.4.2.4 Overall observations based on monitoring

Clothianidin concentrations measured in Canadian waterbodies rarely exceeded the acute effects metric (HC_5 of 1.3 µg/L); five (0.05%) out of a total of 9850 samples collected had concentrations of clothianidin exceeding the acute effects metric and these five samples originated from two (0.3%) out of 775 different sites across nine provinces of Canada.

Instances where maximum 28-day average clothianidin concentrations exceeded the chronic effects metrics were rare in the Prairies. Three (0.9%) of 320 sites-years of monitoring in Prairie wetlands sampled had 28-day average concentrations of clothianidin exceeding the laboratory-based chronic effects metric of 0.12 µg/L (highest RQ of 1.3); none (0%) had 28-day average concentrations exceeding the mesocosm-based chronic effects metric of 0.281 µg/L (highest RQ of 0.6). Concentrations of clothianidin in flowing waterbodies in the Prairie Provinces did not exceed the chronic effects metrics in any of the 245 site-years of monitoring data available.

In areas outside of the Prairie Provinces, instances where maximum 28-day average clothianidin concentrations exceeded the chronic effects metrics were infrequent. Thirty-one (11%) of the 288 individual sites (24 watersheds) and 50 (9%) of the 552 site-years of monitoring available had maximum 28-day average concentrations of clothianidin in water that exceeded the laboratory-based effects metric of 0.12 µg/L. Maximum 28-day average clothianidin concentrations were near or exceeded the mesocosm-based chronic effects metric of 0.281 µg/L in 12 (4%) out of 288 sites (11 watersheds) sampled or 15 (3%) of the 552 site-years of monitoring. Waterbodies where maximum 28-day average concentrations of clothianidin exceeded the chronic effects metrics tended to be in small and intensively cropped watersheds. Concentrations exceeded the laboratory-based chronic effects metrics mainly in watersheds where corn and soybeans were grown, and also where potatoes represented large portions of the watersheds, often in combination with other crops such as corn, soybeans and vegetables.

Maximum chronic RQs were generally higher in watersheds associated with potatoes compared to areas where corn and soybean are grown. Based on the laboratory-based chronic effects metric, the highest RQs were 17 in areas associated with potatoes and 5.8 in areas associated with corn and soybeans. Using the mesocosm-based chronic effects metric, the highest RQs were 7.3 in areas associated with potatoes and 2.5 in areas associated with corn and soybeans. Further characterization using the mesocosm LOEC results in a maximum RQ of 3.6 in areas associated with potatoes and 1.2 in areas associated with corn and soybeans. With the highest concentrations generally being measured early in the growing season, soil or seed treatment application method rather than a foliar application method on potatoes are suggested.

Some of the exceedances of the acute and chronic effects metrics were observed in waterbodies associated with use on corn and orchards. With the recent federal and provincial regulatory actions discussed above, concentrations of clothianidin will likely decrease.

1.3.5 Environmental incident reports

Health Canada's incident reporting database and the USEPA's Ecological Incident Information System (EIIS) were queried for environmental incidents related to clothianidin as of 5 February 2021. No incidents involving aquatic invertebrates have been reported in Canada or the United States related to clothianidin use (PMRA# 3127643).

1.4 Uncertainties identified in the risk assessment

Health Canada has identified the following uncertainties in the quantitative assessment of the risks to aquatic invertebrates from clothianidin use in Canada.

1.4.1 Community protectiveness and recovery

The quantitative risk characterization considered effects metrics based on estimated acute effects of lethality to sensitive species (HC_5), chronic laboratory (EC_{10}/EC_{20}) effects on the sensitive Dipteran, *Chironomus dilutus* in laboratory tests, and a no-observed effects concentration (NOEC) for the most sensitive species- and community-level measures of effects from mesocosms. These metrics were selected based on their expected protectiveness of higher levels of organization, namely the aquatic invertebrate community. Given the breadth of toxicity data available, there is a reasonable degree of confidence in protectiveness of the laboratory-based effects metrics, specifically in this context. There is less confidence in the protectiveness of the mesocosm endpoint for aquatic invertebrate communities given the uncertainties associated with the lack of sustained exposure levels and representation of sensitive organisms. Refer to Section 1.3.1 for more details.

It is acknowledged that aquatic invertebrate communities may recover from clothianidin exposures. The laboratory effects metrics selected were based on responses in sensitive species, from which recovery was not observed or not assessed. However, recovery of affected species and communities was observed in the most sensitive mesocosm study based on a single exposure event. It is therefore possible that populations of aquatic invertebrates may recover in the absence of prolonged exposure, and that recolonization of affected habitats occurs over some period of time, if and when exposure is reduced.

1.4.2 Modelling

There are built in conservatisms in the modelling that may result in conservative EECs for some uses of clothianidin. These built-in conservatisms include but are not limited to annual applications for 50 years, application to 100% of the area cropped, runoff into a waterbody with no outflow, and selection of the 90^{th} percentile of the distribution of maximum 21-d yearly averages as the EEC for use in risk assessment.

Representative crops and application rates were modelled for clothianidin. Seed treatments for certain vegetable crops were characterized by a high and low representative rate. For the uses of clothianidin that were not modelled, the EECs for crops with similar rates within a given application method were used to estimate potential risk. There is uncertainty with using this approach for seed treatments due to the impact of seeding depth on the modelled estimates. For foliar uses where multiple applications were modelled, EECs for a single application were adjusted proportionally. Similarly, for uses where the maximum rate of application was modelled, EECs for a lower rate of application were also adjusted proportionally. These EECs were not derived using standard water modeling, and, as such, did not allow for a direct quantitative exposure estimate for some uses. Nevertheless, Health Canada is satisfied that the additional modelling conducted was sufficient to allow Health Canada to make conclusions on the acceptability of the risk for this special review decision.

1.4.3 Monitoring

Regarding acute exposure, monitoring data likely underestimate short-term exposure to clothianidin, as most sampling regimes are unlikely to capture peak concentrations.

For sites where 28-day moving average concentrations were calculated using observed data, the averages were based on two to nine observations. There is more certainty in averages calculated with a higher number of observations. These chronic estimates of exposure also suffer from the fact that most sampling regimes are unlikely to capture peak concentrations. Peak concentrations can have a strong influence on calculated chronic average concentrations. In the effects assessment, chronic effects metrics are based on studies with regular, and intentional early sampling of exposure concentrations. Therefore, the missed peaks in the monitoring lead to an underestimation of exposure and risk that cannot be quantified. That being said, the sampling regimes in the targeted monitoring programs are far more likely to catch peak concentrations than the monitoring data typically available to Health Canada. For many of the sites, the timing of application (which was the timing of seeding in many of the targeted monitoring programs) was known and sampling occurred before and shortly after application and continued every week or every two weeks thereafter. While there is still the possibility of missing peaks, the likelihood of capturing peak concentrations is much higher using these more robust sampling regimes.

The averages were calculated for a time-period as close to 28 days as possible; however, the sampling regime did not always allow for this. A total of 153 sites only had one sample collected per year or per season; therefore, a 28-day average could not be calculated using observed data. For site-years where a 28-day average could be calculated using the data, the time-frames for the maximum calculated averages ranged from 20 to 77 days. In 69% of cases, the timeframes for the averages were within 3 days of the targeted 28-day period and in 90% of cases, the timeframes were within 7 days of the targeted 28-day period. In addition, concentrations from POCIS deployed for periods ranging from 7 to 59 days, which represent time-weighted average concentrations over the deployment period, were used in the assessment. There is uncertainty as to what the concentrations would be over a period of time closer to 28 days.

The moving average concentrations were not calculated for all sites using observed data. For sites with peak concentrations below the laboratory-based chronic effects metric and those which did not have sufficient data points to allow for the calculation of a 28-day average, the average was calculated using the peak concentration and an average DT_{50} of 11.3 days based on data from Prairie wetlands, assuming dissipation followed single first-order kinetics. The 28-day averages estimated in this way may underestimate exposure because they do not account for potential additional input from runoff events within 28 days of the peak concentration. They may overestimate exposure where no additional inputs occurred and the dissipation rate was faster than what was assumed. The estimated 28-day averages are still expected to be below the level of concern because peak concentrations did not exceed the chronic effects metrics.

The comparisons with the chronic effects metrics are based on the maximum 28-day moving average concentration calculated for each site-year. At sites where the maximum 28-day average concentation of clothianidin exceeds the level of concern, there may still be long periods of time during the growing season when 28-day moving average concentrations are below the chronic effects metrics. In such periods, there may be an opportunity for affected populations and communities to recover from adverse effects of exposure to clothianidin.

While some sites were monitored over several years, the majority of sites were sampled for only one or two years. There is year to year variability in weather as well as clothianidin use, both of which can result in higher or lower concentrations in waterbodies. Years with above average precipitation were not well captured in the available dataset. Heavy rain events are associated with greater runoff potential.

There were uncertainties associated with the monitoring data available for consideration in the proposed special review decision for clothianidin, particularly from the Prairie Region. The uncertainties with the monitoring data were noted in PSRD2018-01. The proposed decision included monitoring data generated up until the year 2017. The additional monitoring data for the 2018 and 2019 seasons adequately addressed the major uncertainties related to monitoring data from the Prairies from 2017 and earlier because:

- While few data were available up until 2017, a large amount of new data were generated for the Prairie Region in 2018 and 2019;
- Waterbodies were typically sampled weekly to bi-weekly (every two weeks) throughout the growing season, thus allowing for the characterization of the dissipation of clothianidin and the estimation of exposure levels in waterbodies over a longer time frame, which is useful for assessing chronic exposure;
- Site information such as coordinates and waterbody type were available to assess the relevance of the waterbodies considered in the aquatic invertebrate risk assessment; and
- Whereas the weather patterns in 2017 were unusually dry in some areas of the Prairies and may have reduced runoff, making concentration estimates lower than expected in wetter years with the same levels of application, the overall precipitation levels received in 2018 and 2019 were considered to be representative of a typical year.

The monitoring data were from agricultural areas of many provinces of Canada, but there was less coverage of the Atlantic provinces, with the exception of Prince Edward Island.

Waterbodies with the highest potential exposure are lower order streams or Prairie wetlands draining clothianidin-treated fields. With the exception of targeted monitoring of Prairie wetlands in or adjacent to fields known to be planted with clothianidin-treated seeds, the monitoring data available may not be reflective of the waterbodies with the highest potential exposure for clothianidin. Some sites monitored may have been in larger watersheds with relatively low clothianidin use. With the exception of targeted monitoring programs like the ones for wetlands described above, pesticide use information on crops near sampling sites is typically not available and waterbodies sampled are not only Prairie wetlands or lower order streams. The monitoring programs sampled a range of waterbodies in agricultural areas across most provinces of Canada where neonicotinoids are likely to be used throughout the growing period. The updated monitoring information represents a much more extensive dataset than is typically available to Health Canada.

The majority of the monitoring data considered in the assessment were collected prior to the use pattern changes imposed by the pollinator assessment. A number of uses for clothianidin were discontinued (RVD2019-05) along with restrictions on other uses following the pollinator risk assessment. It is expected that these changes will reduce the levels of clothianidin in Canadian water. The full realization of these regulatory changes will not be known until fully implemented.

The impact of provincial regulations in Ontario and Quebec related to the use of clothianidin-treated seed on the levels that will reach waterbodies is not fully understood. While a decrease in concentrations is expected, the data available to date are insufficient to identify a trend.

1.4.4 Risk characterization

Concentration averaging

In both the acute and chronic quantitative risk assessments, concentrations from toxicity studies supporting the effects metrics were averaged over the targeted exposure duration. In the chronic risk assessments, concentration averaging also occurred in both the modelling and monitoring exposure assessments. The implicit underlying assumption of this averaging is that if the EEC is equivalent to the effects metric then the effects associated with the effects metric are expected, and if the EEC exceeds the effects metric then effects greater than those associated with the effects metric are expected. However, this assumption does not account for the fact that differences in concentration over the exposure period, even with an equivalent average exposure, could result in different responses. For example, with the same average concentration, a high initial concentration followed by a rapid decrease in concentration may lead to more or less severe effects than a maintained moderate concentration.

Modelling

Peak EECs were compared to an HC_5 generated with toxicity data derived from 48- to 96-hour exposures that were generally maintained throughout the study. There is some uncertainty associated with a comparison to modelled peak concentrations specifically because 48- to 96-hour exposures may lead to increased effects relative to a peak exposure of the same magnitude followed by a reduction in exposure. All else being equal, this assumption is expected to overestimate risk because concentrations in the environment are unlikely to be maintained.

Chronic modelled EECs were based on mean 21-day exposures. The chronic laboratory effects metric is based on 28–56-day exposures. Since 21-day average concentrations will generally exceed 28–56-day average concentrations in waterbodies, on this basis the RQs generated with the chronic laboratory effects metric is expected to be conservative when other uncertainties are set aside. The chronic mesocosm effects metric is based on a 56-day mesocosm test with declining concentrations. The mesocosm NOEC was calculated as a 14-day time-weighted-average calculated over the days immediately following application. The 21-day average concentrations are generally expected to fall below 14-day average concentrations. The RQs generated with the mesocosm effects metric is expected to produce RQs that are lower than if a 21-day time-weighted average were used to represent the mesocosm NOEC, or if a 14-day exposure period were used in the development of the chronic modelled EECs.

Monitoring

Peak site-year measured concentrations were compared to an HC_5 generated with toxicity data derived from 48- to 96-hour exposures that were generally maintained throughout the study. As with the acute modelling-based RQs, there is some uncertainty associated with the comparison of an instantaneous concentration, because 48- to 96-hour exposures may lead to increased effects relative to peak exposures of the same magnitude followed by a decrease in exposure over time. However, in contrast to the modelling EECs, and as acknowledged in Section 1.4.3 above, many of the maximum site-year concentrations are not expected to reflect peak exposure concentration, although the likelihood increases with increased targeted sampling.

Maximum 28-day average concentrations based on variable sample sizes within that time frame (i.e., different sampling frequency associated with different sampling programs), were compared to the chronic effects metrics. Again, the chronic laboratory effects metric is based on 28- to 56-day average concentrations, and the mesocosm effects metric is based on a 14-d time-weighted-average calculated for the NOEC treatment group. Given that all the endpoints used in the generation of the chronic laboratory effects metrics were generated with average concentrations calculated over a period at or exceeding the averaging period applied to the monitoring data, setting aside other uncertainties in the assessment, this approach is expected to be conservative. There is some uncertainty associated with the disparate averaging periods between the monitoring exposure estimates and the mesocosm effects metric. In general it is expected that 28-day average concentrations in the environment would be lower than 14-day averages, because in general, dissipation over time is expected, although it is acknowledged that this may not always be the case in flowing waterbodies that may experience influxes from runoff drift and lower order stream flow. Considering this discrepancy in isolation, it is likely to lead to an underestimation in chronic risk.

Single active ingredient risk assessment

Canadian water monitoring data show some co-occurrence of the three most commonly used neonicotinoids – thiamethoxam, clothianidin and imidacloprid. When co-occurrence of residues occurs, the effects are expected to increase. The current assessment reflects the perceived risks to aquatic invertebrates exposed to clothianidin alone and does not account for concurrent exposure to other neonicotinoids. Measured concentrations are usually dominated by the active ingredient most commonly associated with the dominant crop grown in the catchment area, such that cumulative concentrations tend not to differ substantially from the dominant neonicotinoid found.

Health Canada will determine whether a cumulative assessment is warranted following the re-evaluation of all neonicotinoids. Recent regulatory decisions for the neonicotinoids have resulted in the removal of some uses, which is likely to have an impact on risk conclusions based on historical concentration monitoring data obtained prior to the removal of uses.

1.5 Risk assessment discussion and conclusions

Health Canada's risk conclusions were based on the weight-of-evidence from an extensive amount of effects and exposure data including chronic toxicity data, surface water modelling and recent Canadian environmental monitoring data.

Risk to aquatic invertebrates from clothianidin spray drift was identified (Section 1.3.3). Mitigation in the form of spray buffer zones is required for freshwater and marine habitats and is presented in Appendix VIII.

Runoff of clothianidin into surface waters can present an acute risk to aquatic invertebrates based on surface water modelling. Acute RQs were up to 4.8 for foliar uses, up to 2.0 for in-furrow use on potatoes in Atlantic Canada, up to 16 for vegetable seed treatments at the highest application rate and up to 2.5 for canola seed treatment in Eastern Canada. Clothianidin concentrations measured in waterbodies exceeded the acute effects metric in 5 (0.1%) out of 5133 samples from 2 (0.3%) out of 288 sites sampled outside of the Prairies between 2010 and 2019. In the Prairie Provinces, none of the 4717 samples collected from 488 sites between 2014 and 2019 had clothianidin concentrations exceeding the acute effects metric.

While runoff modelling results indicate the potential for acute risks to aquatic invertebrates from some uses of clothianidin, the potential for chronic risks is greater. A discussion of the chronic risk posed by use on individual crops is presented below.

Potatoes

Potatoes are grown across Canada. Based on 2018 census data from Statistics Canada, approximately 2700 ha were planted in British Columbia, 51 000 ha in the Prairies, 31 000 ha in Ontario and Quebec and 56 600 ha in the Atlantic Region (mostly in Prince Edward Island and New Brunswick) (Statistics Canada, 2021b, PMRA# 3195974)

Clothianidin is registered for use on potatoes as a seed piece treatment (up to 12.5 g a.i./100 kg seed, equivalent to a maximum of 381 g a.i./ha), in-furrow soil application (at up to 224 g a.i./ha), or foliar application (up to 3 applications of 52.5 g a.i./ha per year). In a given year, clothianidin can be applied on potatoes using only one method of application; additional applications of any neonicotinoid via other methods on potatoes within the same year is prohibited.

RQs based on runoff modelling of seed piece treatment did not exceed the LOC when comparing against either the laboratory-based effects metric of 0.12 µg a.i./L (RQs up to 0.6) or the mesocosm-based effects metrics of 0.281 µg a.i./L **(**RQs up to 0.3). The RQs based on modelling of in-furrow soil applications at 224 g a.i./ha exceeded the LOC using the laboratory-based chronic effects metric in the Prairie Region, Ontario and Quebec (RQs of 4.1–6.8) and the Atlantic Region (RQ of 16). Using the mesocosm-based effects metric, RQs ranged from 1.7 to 6.8. The RQs based on modelling of three foliar applications exceeded the LOC in all regional scenarios modelled (RQs of 19–27 for the laboratory-based effects metric and 8.2–11 for the mesocosm-based effects metric). Estimated RQs for one foliar application based on a proportional reduction of modelled EECs ranged from 6.4 to 8.9 for the laboratory-based effects metric and from 2.7 to 3.8 for the mesocosm-based effects metric.

Monitoring data were available from potato-growing regions of Canada. Monitoring data from Alberta and Manitoba included sites in watersheds where potatoes are grown. Calculated 28-day average concentrations of clothianidin did not exceed the chronic effects metrics but use of clothianidin was not confirmed. Outside the Prairies, there were 86 site-years of data from areas where potatoes were grown, of which 57 had potatoes as a main crop. At three sites in British Columbia where clothianidin was reported to be applied to potato seed pieces in some of the fields in the watersheds in 2017 and 2018, 28-day concentrations did not exceed the LOC. Six sites in Prince Edward Island, Ontario and Quebec had maximum 28-day average clothianidin concentrations near or exceeding both chronic effects metrics, and potatoes represented 10%–40% of the area of the watersheds. Four of these sites also had other crops in the watersheds, such as corn, vegetables and cereals, which can also be treated with clothianidin. Soybeans were also grown in these watersheds, but clothianidin is not registered for use on this crop. The two other sites with exceedances of the chronic effects metrics were from Prince Edward Island, where potatoes are the main crops grown in the watersheds and the potential contribution of other crops like corn and cereals to concentrations in water is less.

The RQs based on monitoring data for these six sites (12 site-years with exceedances) with potatoes were as high as 17 using the laboratory-based effects metric. Only two of the 12 site-years had RQs above 10, both being from the Gibeault-Delisle Creek, which drains a small intensively cropped watershed where a combination of crops that can be treated with clothianidin are grown. The next highest RQ was 5.7, from the Wilmot River in Prince Edward Island, where potatoes are the main crop grown in the watershed. Using the mesocosm-based effects metric to calculate RQs for the same six sites (nine site-years with concentrations near or exceeding the effects metric), the RQs were as high as 7.3. Aside from the two site-years from Gibeault-Delisle Creek, the next highest RQ was 2.4 for the Wilmot River. In two watersheds in British Columbia, where clothianidin was reported to be applied to potato seed pieces in 2017 and 2018, concentrations did not exceed the LOC for either of the two chronic effects metrics (laboratory- and mesocosm-based). Overall, monitoring information indicates that concentrations at some sites where potatoes represent a significant portion (10%–40%) of the watershed have concentrations of clothianidin that exceed the two chronic effects metrics and the resulting RQs exceed the LOC.

The highest concentrations of clothianidin detected in the waterbodies from potato-growing areas were generally observed early in the growing season, in May and into June, which suggests potatoes were treated using a soil or seed treatment application method at planting rather than a foliar application method. This is supported by use information for neonicotinoids including clothianidin on potatoes in various provinces of Canada, which indicate the application method ranges from 100% seed piece application to 50% seed piece treatment and 50% in-furrow application depending on the province (PMRA# 2544468, 2842180, 3168173, 2935271). Aside from the above findings, monitoring data cannot distinguish the relative contribution of the three different application methods on potatoes to clothianidin concentrations in water. Therefore, modelling results were used to evaluate the relative contributions.

The modelling results described above indicate that in-furrow and foliar applications of clothianidin on potatoes are expected to result in higher clothianidin levels in water compared to seed piece treatment. Because the modelling RQs are below the LOC for seed piece treatment, the risks to aquatic invertebrates from the use of clothianidin on potato seed pieces are considered to be acceptable.

The risks from use of clothianidin on potatoes by in-furrow application require mitigation. The RQs based on the modelling of the highest rate of application for in-furrow use suggest that RQs for the lowest registered rate of application would exceed the LOC (estimated RQs for the lowest rate of application up to 9.4 based on the laboratory effects metric and up to 4.0 based on the mesocosm effects metric). Based on the above, Health Canada has determined that he risks to aquatic invertebrates from in-furrow application of clothianidin on potatoes have not been shown to be acceptable and this use will be phased out.

Based on modelling results, foliar application of clothianidin on potatoes poses risks and requires mitigation. To mitigate the potential risk to aquatic invertebrates from foliar application, the maximum number of foliar applications on potatoes has been reduced to one per season.

The cancellation of in-furrow uses and the reduction in the number of foliar applications on potatoes are expected to reduce input of clothianidin from runoff into waterbodies to acceptable levels in areas where potatoes are grown.

Grapes

Grapes are grown mainly in Ontario, British Columbia and Quebec. Based on 2018 census data from Statistics Canada for total grapes (fresh, Labrusca and Vinifera), approximately 14 700 ha were planted in Ontario, 7900 ha in British Columbia, and 1500 ha in Quebec (Statistics Canada, 2021c, PMRA# 3195975).

Clothianidin can be applied as a foliar application to grapes once per year at rates of 50–105 g a.i./ha, depending on the pest. Risk quotients from runoff modelling exceeded the LOC in all modelled regions using the laboratory-based chronic effects metric (RQs of 2.1–22). Using the mesocosm-based chronic effects metric, RQs exceeded the LOC in scenarios for Ontario, Quebec and Atlantic Canada (RQs of 3.0–9.3).

Monitoring data (43 site-years) were available for watersheds where vineyards represent an important portion of the watershed in Ontario and British Columbia (data from Quebec watersheds were mainly associated with orchards). Maximum 28-day average concentrations of clothianidin exceeded the laboratory-based chronic effects metric at only two Ontario sites (maximum RQs of 1.1–1.2). At the two sites, the maximum 28-day average concentrations only exceeded laboratory-based chronic effects metric in one out of five years of monitoring. No site had 28-day average clothianidin concentrations exceeding the mesocosm-based chronic effects metrics in sampled watersheds where vineyards represent a large portion of the watershed.

In addition to vineyards, orchards also represented an important portion of the two watersheds where the LOC was exceeded. Because the use on pome fruits and stone fruits has been cancelled as a result of the pollinator re-evaluation decision for clothianidin (RVD2019-05), the use of clothianidin in these two watersheds is expected to decrease.

The risks to aquatic invertebrates from foliar application on grapes are considered acceptable based on the monitoring data available and the expected further reductions in levels in the environment as a result of the pollinator re-evaluation decision.

Oilseeds

Based on 2018 data, more than 95% of the approximately 9.5 million hectares of oilseed production in Canada occurs in the Prairies. Approximately 40 000 hectares of canola were sown in Ontario and Quebec, compared to 9.1 million hectares in the Prairie Provinces. Only 500 hectares of mustard seeds, including the related carinata crop were reported to be planted outside of the Prairies (Statistics Canada, 2021a, PMRA# 3195909)

Clothianidin is registered on canola, rapeseed, carinata and mustard as a seed treatment only, at rates up to 45.5 g a.i./ha. Modelling for this group was done for canola, which accounts for 98% of national oilseed production, at a maximum allowable rate of 32.5 g a.i./ha. The RQs from runoff modelling exceeded the LOC in all regional scenarios based on the laboratory-based chronic effects metric but were lower in the Prairie Region scenarios (RQs of 1.8–3.1) compared to Ontario and Quebec scenarios (RQs of 14–24). Using the mesocosm-based chronic effects metric, the RQs marginally exceeded the LOC in the Prairie Region (RQ of 1.3) and in Ontario and Quebec (RQs of 6.0–10).

Targeted and non-targeted water monitoring data reflecting seed treatment use of clothianidin in the Prairie Region did not indicate a concern for chronic exposure based on either of the chronic effects metrics. Monitoring data from other regions of Canada specific to use on oilseed crops were not available to further characterize risks.

Based on the modelling and monitoring information, risks to aquatic invertebrates from the seed treatment of oilseed crops are acceptable in the Prairie Region. While modelled RQs exceed the LOC in Ontario and Quebec, the production of oilseeds in these two provinces is considerably less than in the Prairies. Furthermore, the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) recommends rotations of 3 to 4 years between canola crops (OMAFRA, 2017, PMRA# 3195973)

Given this information, the use of clothianidin on oilseed crops in Ontario and Quebec is not expected to be a significant contributor to clothianidin concentrations in water compared to use on other crops more widely grown in the region. Crop rotation is expected to reduce contributions of clothianidin compared to modelled EECs, which assumes annual applications over 50 years. Taking into consideration all the available information, the chronic risks to freshwater invertebrates associated with the use of clothianidin as a seed treatment on oilseeds are acceptable in all regions of Canada.

Corn

Based on 2018 data, 73% of the approximately 2 million hectares of corn planted in Canada are in Ontario and Quebec. The majority of corn planted in Canada is field corn, while the area of sweet corn (approximately 16 000 hectares) and popcorn (194 hectares) is much smaller (Statistics Canada, 2021a, PMRA# 3195909).

Clothianidin is registered for use on corn (field, sweet and popcorn) as a seed treatment at rates of 0.25–1.25 mg a.i./kg kernel, depending on the pest. This is equivalent to 75–375 g a.i./100 kg seed (or, 15.8–118.3 g a.i./ha) for field corn, 100–1000 g a.i./100 kg seed (or, 10.5–75.6 g a.i./ha) for sweet corn and 170–938 g a.i./100 kg seed (or, 17.1–123.8 g a.i./ha) for popcorn. Modelling for corn was done at the maximum allowable rate of 118.3 g a.i./ha for field corn. The RQs from runoff modelling in Ontario and Quebec exceeded the LOC using the laboratory-based chronic effects metric (RQs of 4.3–5.3) and marginally exceeded the LOC using the mesocosm-based chronic effects metric (RQs of 1.9–2.2).

The highest concentrations measured in waterbodies where most of the corn is grown in Canada were consistent with the modelling results. Outside of the Prairie Region, 378 site-years of data were from corn- and soybean-growing areas. In these areas, maximum 28-day average clothianidin concentrations exceeded the laboratory-based chronic effects metric in 36 site-years and exceeded the mesocosm-based chronic effects metric in six site-years. At some sites, the maximum 28-day average concentration exceeded the laboratory-based effects metric in more than one year of monitoring. Based on comparisons with the laboratory-based chronic effects metric, the maximum RQs for sites in areas where corn is grown were up to 5.8, but the majority were less than 2.0. In comparisons with the mesocosm-based chronic effects metric, the maximum RQs were up to 2.5, with all but one being less than or equal to 1.4. These RQs are in the same range as those predicted by the water models. The monitoring data from the Prairie Region did not indicate a concern for seed treatment use on corn. Clothianidin concentrations measured in flowing waterbodies, generally in Manitoba, which drain watersheds where corn is grown did not exceed either of the chronic effects metrics. Although there was no targeted sampling of wetlands in corn fields known to be planted with clothianidin-treated seeds, the monitoring of other wetlands located across the agricultural areas of Manitoba, Saskatchewan and Alberta where neonicotinoids are widely used as a seed treatment did not show concentrations exceeding the chronic effects metrics.

Because the maximum RQs based on monitoring match the modelling results and exceed the LOC in areas where most of the corn is grown in Canada, risks to aquatic invertebrates from seed treatment use on corn requires mitigation. To mitigate the potential risk to aquatic invertebrates, the maximum registered rate for seed treatment of field corn has been reduced from 375 mg a.i./100 kg seed (equivalent to up to 118.3 g a.i./ha) to 150 g a.i./100 kg seed (equivalent to up to 47.3 g a.i./ha). The rate reduction on field corn seeds is expected to lower the potential input of clothianidin in waterbodies from runoff to acceptable levels in areas where corn is grown.

The maximum rate of application of clothianidin in grams of active ingredient per hectare and the number of hectares planted in Canada are less for sweet corn than for field corn. The use of clothianidin on sweet corn is expected to contribute less to levels in water compared to use on field corn. Similarly, because the area of popcorn grown in Canada is very small, the use of clothianidin on popcorn is expected to contribute less to concentrations in water compared to use on field corn. No change to the registered rates of clothianidin on sweet corn and popcorn seeds is required.

Wheat

Based on 2018 data, 94% of the approximately 10 million hectares of wheat grown in Canada is in the Prairies. The area of wheat in Ontario and Quebec represents approximately 4% (427 100 ha) and 0.9% (95 400 ha) of the area grown nationally, respectively (Statistics Canada, 2021a, PMRA# 3195909).

Clothianidin is registered for use on wheat as a seed treatment only. Seed treatment rates for wheat range from 10–60 g a.i./100 kg seed, equivalent to 6.7–104.9 g a.i./ha. Modelling was done for both spring and winter wheat varieties using the maximum rate of application of 104.9 g a.i./ha. The RQs from the modelling of regional scenarios in the Prairies, Ontario and Quebec exceeded the LOC using the laboratory-based effects metric (RQs of 2.3–6.7) whereas, with the mesocosm-based chronic effects metric, RQs only marginally exceeded the LOC (RQs of 1.0–2.8).

The monitoring data from the Prairie Region did not indicate a concern for seed treatment use on wheat. Although there was no targeted sampling of wetlands in wheat fields known to be planted with clothianidin-treated seeds, the monitoring of other wetlands located across the agricultural areas of Manitoba, Saskatchewan and Alberta where neonicotinoids are widely used as a seed treatment did not show concentrations exceeding either of the chronic effects metrics. Similarly, there were no exceedances of the chronic effects metrics in flowing waterbodies in the Prairies. In other areas of Canada, 13 sites (11 waterbodies; 24 site-years) in areas where cereals are grown had maximum 28-day average concentrations of clothianidin exceeding the laboratory-based chronic effects metric (maximum RQ up to 5.8). At these 13 sites, wheat/cereals represented between 6% and 15% of the watershed area. Seven of the sites (seven waterbodies; eight site-years) also had maximum 28-day average concentrations exceeding the mesocosm-based chronic effects metric (maximum RQ up to 2.5). However, all these sites with exceedances of the chronic effects metrics had a greater portion of the watershed represented by corn (7%–35%) and/or potatoes (10%–40%), which can also be treated with clothianidin at higher rates of application. Outside the Prairies, clothianidin use on wheat is likely not a main contributor to the measured concentrations in water because it is not the predominant crop in watersheds.

Taking into consideration the modelling, monitoring and crop information, the chronic risks to aquatic invertebrates associated with the use of clothianidin as a seed treatment on wheat are acceptable.

Vegetables

Based on 2018 data, 85% of the 92 997 hectares of fresh vegetables planted in Canada were in Ontario and Quebec. For sweet potatoes, 98.8% of the reported 725 hectares produced in Canada were in Ontario, mainly along the northern shore of Lake Erie (Statistics Canada, 2021d, PMRA# 3195976).

Clothianidin is registered as a seed treatment on a variety of vegetable crops at rates ranging from 0.035 to 0.9 g a.i./1000 seeds, equivalent to 0.6 to 420 g a.i./ha depending on the crop. The highest rate of application in grams of active ingredient per hectare is associated with lettuce (420 g a.i./ha). The next highest rate is 275 g a.i/ha for carrots. Bunching onion seeds can be treated at a rate up to 176 g a.i./ha, while the rest of the vegetable seeds are treated at a rate of 150 g a.i./ha or less. Only one end-use product is registered for the treatment of vegetable seeds, Sepresto 75 WS (Reg. No. 30972), which is a combination product with another neonicotinoid, imidacloprid.

A representative low rate of 4.7 g a.i./ha for melon (cucurbits) was modelled as well as the highest rate of 420 g a.i./ha for lettuce. Risks based on runoff modelling were assessed for regional scenarios in Ontario and Quebec, where the majority of vegetables are grown in Canada. The RQs from runoff modelling for the low rate did not exceed the LOC based on the laboratory-based chronic effects metric (RQs up to 0.8). However, the RQs exceeded the LOC for the high rate (RQs of 57–73). Using the mesocosm-based chronic effects metric, RQs still exceeded the LOC for the high rate (RQs of 25–31).

Estimated RQs for other seed treatment rates, adjusted proportionally based on the modelling of 420 g a.i./ha for lettuce seeds, also exceed the LOC. The rate of 275 g a.i./ha registered for carrots had estimated RQs up to 48 based on the laboratory effects metric and up to 21 based on the mesocosm effects metric. The rate of 188 g a.i./ha registered for bulb onions had estimated RQs up to 21 based on the laboratory effects metric and up to 8.8 based on the mesocosm effects metric. A hypothetical rate of application of 100 g a.i./ha had estimated RQs up to 18 based on the laboratory effects metric and up to 7.5 based on the mesocosm effects metric.

Clothianidin is registered for use on sweet potatoes as a pre-plant soil incorporation application at 224 g a.i./ha prior to transplanting sweet potato slips. Modelling for Ontario showed that RQs exceeded the LOC using the laboratory-based chronic effects metric (RQ of 7.8) and the mesocosm-based chronic effects metric (RQ of 3.3).

Clothianidin is also registered as a foliar spray for the entire Crop Group 9 (cucurbits) at 70–105 g a.i./ha. Only one foliar application per year can be made on cucurbit vegetables, prior to bloom. This is as a result of restrictions to protect pollinators, which prohibit more than one pre-bloom application (RVD2019-05) and also prohibit application during bloom. There is also a pre-existing restriction preventing foliar application of clothianidin to cucurbits after the four-leaf stage, which occurs prior to bloom. Based on this set of restrictions, clothianidin can only be applied as a foliar spray on cucurbits once per year, prior to bloom. In a given year, clothianidin can be applied on cucurbits using only one method of application; additional applications of any neonicotinoid via other methods on cucurbits within the same year is prohibited. The modelling of two foliar applications at 105 g a.i./ha on cucurbits, presented in PSRD2018-01 prior to the publication of the pollinator re-evaluation decision RVD2019-05, was not updated to reflect the revised use pattern for the final special review decision. Rather, EECs from one foliar application were calculated by halving the EECs previously generated for two applications. Based on this, runoff RQs from one foliar application exceeded the LOC for scenarios in Ontario and Quebec when compared with the laboratory-based chronic effects metric (RQs of 20–21) and the mesocosm-based chronic effects metric (RQs of 8.4–8.9). Estimated RQs for one foliar application at 70 g a.i./ha, proportionally adjusted based on the previous modelling conducted, are 13–14 for the laboratory effects metric and 5.6–5.9 for the mesocosm effects metric.

Seventy-one site-years of monitoring data were available for waterbodies in areas where vegetables are grown in Quebec, Ontario and British Columbia; 44 of these site-years were from two small Ontario watersheds where tomatoes are grown (7%–11% of the watersheds) but the tomato fields were treated with another neonicotinoid at planting. In these vegetable-growing areas, three watersheds (nine sites based on the laboratory effects metric and four sites based on the mesocosm effects metric) showed maximum 28-day average clothianidin concentrations exceeding the chronic effects metrics (maximum RQ of 17 using the laboratory-based effects metric, and 7.3 using the mesocosm-based effects metric). At the site with the highest 28-day average concentrations, vegetable crops (carrots, onions, green onions and lettuce) were grown in the watershed and represent 21% of the area; however, a large amount of the watershed was represented by potatoes (21%) and corn (17%), which can also be treated with clothianidin. Field tomatoes represented 7%–11% of the area of the two other watersheds showing exceedances of the chronic effects metrics; however, use information available indicates all the field tomatoes were treated with another neonicotinoid, imidacloprid, at planting. The two watersheds also have corn (10%–20%) and wheat (9%), which can be treated with clothianidin.

While use of clothianidin on vegetables crops can contribute to levels of clothianidin in waterbodies, the relative contribution of the use of clothianidin on different vegetable crops to the levels measured in water cannot be determined using the monitoring data. If foliar application of clothianidin was used to treat vegetables in the watersheds sampled, the concentrations of clothianidin measured would likely reflect the use pattern prior to the pollinator re-evaluation decision, RVD2019-05, where two foliar applications were still allowed. As a result of the pollinator re-evaluation decision, foliar application on vegetables has been reduced to a maximum of one application. There is insufficient water monitoring data to characterize the risk from use of clothianidin as a pre-plant soil incorporation on sweet potatoes using monitoring data. For the above reasons, results of modelling were relied upon to estimate the potential relative contribution of various application methods on different vegetable crops to concentrations of clothianidin in water.

For pre-plant soil incorporation use on sweet potatoes the modelling RQs are moderate using the laboratory effects metric and low using the mesocosm effects metric. Given the size of the modelled RQs and the very limited production area for sweet potatoes in Canada, the risks to aquatic invertebrates from clothianidin use on sweet potatoes are considered acceptable.

For seed treatment and foliar applications at the highest registered rates on vegetables, the risks to aquatic invertebrates from modelling are not acceptable and require mitigation. To mitigate the risks from seed treatment uses, the maximum rate of application of treated vegetable seeds has been reduced to 100 g a.i./ha. To mitigate the risks from foliar applications to cucurbits, the maximum rate of application has been reduced to 70 g a.i./ha for the one foliar application allowed per season. The reductions in the rates of application for treated seeds and foliar uses are expected to lower input from runoff of clothianidin into waterbodies to acceptable levels in areas where vegetables are grown.

Turf

Clothianidin is registered for use as a foliar spray on turf (sod farms and golf courses only). A single application is allowed at 1.25–3.5 g a.i./100 m^2, equivalent to 125–350 g a.i./ha, depending on pest species. RQs based on runoff modelling of regional scenarios across Canada exceeded the LOC using the laboratory-based chronic effects metric (RQs of 20–40) and the mesocosm-based chronic effects metric (RQs of 8.5–17). Estimated RQs for a single application at the lowest registered rate of 125 g a.i./ha based on a proportional reduction of modelled EECs are 7–14 using the laboratory-based chronic effects metric and 3–6 using the mesocosm-based chronic effects metric. There is insufficient water monitoring data linked to use on turf to characterize the risk using monitoring data.

The area of production for sod farms and golf courses is large. Based on 2016 data, there are approximately 23 000 hectares of sod farms in Canada (Statistics Canada, 2021e, PMRA# 3195977). The total area of golf courses in Canada is unknown; however, the USEPA reports an average of about 45 ha of total turf area per golf course based on US survey data (USEPA, 2005, PMRA# 3195978).

Based on modelling results and the large area of production, the risks to aquatic invertebrates are not acceptable at the highest registered rate and mitigation for foliar application on turf is required. To mitigate the risks, the maximum rate for the single application has been reduced to 1.25 g a.i./100 m^2, equivalent to 125 g a.i./ha. This rate reduction on turf is expected to lower the potential input of clothianidin in waterbodies from runoff to acceptable levels in areas with sod farms and golf courses.

1.6 Risk mitigation required for aquatic invertebrates

1.6.1 Use restrictions

Use pattern changes are required for clothianidin and are outlined in the following table:

Crop	Method of Application	Current Rate	New Requirement
Potato	Seed piece treatment	6.2–12.48 g a.i./100 kg seed (equivalent to 119–381 g a.i/ha)	No change to use pattern required
	In-furrow	1.2–2.0 g a.i./100 m of row (equivalent to 133–223.8 g a.i./ha)	Cancellation of in-furrow uses
	Foliar	35–52.5 g a.i./ha, maximum three applications	35–52.5 g a.i./ha (one application)
Corn (field corn only; no change to sweet or popcorn)	Seed treatment	0.25–1.25 mg a.i./kernel (equivalent to 75–375 g a.i./100 kg seed, or 15.8–118.3 g a.i./ha for field corn)	Field corn: 0.5 mg a.i./kernel (equivalent to 150 g a.i./100 kg seed, or up to 47.3 g a.i./ha)
Vegetables carrot, brassica vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, and leafy vegetables)	Seed treatment	0.035–0.9 g a.i./1000 seeds (equivalent to 0.6–420 g a.i./ha, depending on crop)	Limit seeding rate for crops to a maximum of 100 g a.i./ha. Cancellation of use on bunching onions and leafy vegetables.
Sweet potato	Soil drench (pre-plant soil incorporation)	224 g a.i./ha	No change to use pattern required
Cucurbits	Foliar	70–105 g a.i./ha (one application pre-bloom only)	70 g a.i./ha (one application pre-bloom only)
Oilseeds (canola, rapeseed, mustard, caninata)	Seed treatment	150–406 g a.i./100 kg seed (equivalent to 6.8–45.5 g a.i./ha, depending on crop)	No change to use pattern required
Wheat	Seed treatment	10–60 g a.i./100 kg seed (equivalent to 6.7–104.9 g a.i./ha)	No change to use pattern required
Grape	Foliar	50–105 g a.i./ha, maximum one application	No change to use pattern required
Turf (sod farms and golf courses only)	Foliar	1.25–3.5 g a.i./100 m^2 (equivalent to 125–350 g a.i./ha), maximum one application	1.25 g a.i./100 m^2 (equivalent to 125 g a.i./ha; one application)

1.6.2 Spray buffer zones

Revised spray buffer zones based on the risks identified in this assessment will be required for the protection of freshwater habitats. Spray buffer zones were determined based on existing directions for use on product labels, including a spray quality of ASAE Fine for field and aerial sprayers. The complete spray buffer zone table and drift mitigation instructions required for clothianidin products are provided in Appendix VIII.

As for all pest control products, Health Canada will continue to encourage the adoption of best management practices for spray drift management. Required drift mitigation measures for specific application methods will be identified on product labels. Additional application restrictions to minimize spray drift are not required. The on-line spray buffer zone calculator can be used to further mitigate the potential for spray drift based on the use of coarser spray qualities and by accounting for meteorological conditions at the time of application.

List of abbreviations

<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
µg	microgram(s)
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
AAFC	Agriculture and Agri-Food Canada
ALB	aquatic life benchmarks
ALRV	aquatic life reference values
APVMA	Australian Pesticide and Veterinary Medicines Authority
ASAE	American Society of Agricultural and Biological Engineers
BMBI	Benthic Macroinvertebrate Index of Biotic Integrity
CCME	Canadian Council of Ministers of the Environment
CI	confidence interval
CLC	CropLife Canada
CWQG	Canadian Water Quality Guidelines
CWQG-PAL	Canadian Water Quality Guidelines for the protection of aquatic life
cm	centimetre(s)
d	day(s)
DFOP	double first order in parallel
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DUC	Ducks Unlimited Canada
dw	dry weight
EC_{10}	effective concentration on 10% of the population
EC_{20}	effective concentration on 20% of the population
EC	European Commission
ECCC	Environment and Climate Change Canada
EEC	estimated environmental concentration
EFSA	European Food Safety Authority
EMWG	Environmental Monitoring Working Group
EP	end-use product
FA	fraction of species affected
g	gram(s)
GHG	greenhouse gas
h	hour(s)
ha	hectare(s)
HC_5	hazardous concentration estimate that is assumed to be protective of 95% of species in a species sensitivity distribution
IORE	Indeterminate Order Rate Equation model
IPM	integrated pest management
ISO	International Organization for Standardization
Kg	kilogram(s)

K_{oc}	organic-carbon partition coefficient
L	litre(s)
LC_{10}	lethal concentration on 10% of the population
LC_{50}	median lethal concentration
LOEC	lowest observed effect concentration
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantification
m	metre(s)
mg	milligram(s)
min	minute(s)
mL	millilitre(s)
mm	millimetre(s)
N (n)	sample size
NA	not applicable
NC	not calculated
ng	nanogram(s)
NFU	National Farmers Union
NGO	non-governmental organization(s)
NOEC	no observed effect concentration
OMAFRA	Ontario Ministry of Agriculture Food and Rural Affairs
OMECC	Ontario Ministry of Environment and Climate Change
PCA	percent cropped area
PCP	Pest Control Product number
PCPA	*Pest Control Products Act*
PGQ	Producteurs de grains du Québec
PMRA	Pest Management Regulatory Agency
POCIS	polar organic chemical integrative samplers
PSRD	Proposed Special Review Decision
PWC	Pesticides in Water Calculator
RIVM	Netherlands National Institute for Public Health and the Environment
RQ	risk quotient
RVD	Re-evaluation Decision
SFO	single first order
sp.	species (singular)
spp.	species (plural)
SRD	Special Review Decision
SSD	species sensitivity distribution
t1/2	half-life
TEQ	toxic equivalency quotient
TGAI	technical grade active ingredient
TWA	time weighted average
USEPA	United States Environmental Protection Agency
USEPA EIIS	USEPA's Ecological Incident Information System

VFS	vegetative filter strip
wt	weight(s)
WQO	Water Quality Objectives

Appendix I Registered products containing clothianidin in Canada[1] that are subject to this special review decision

Table 1 Products containing clothianidin requiring (label) amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (%, g/L)
27449	Commercial	BASF Canada Inc.	Titan Insecticide	Suspension	Clothianidin 600 g/L
27453	Commercial	BASF Canada Inc.	Poncho 600 FS Seed Treatment Insecticide	Suspension	Clothianidin 600 g/L
29158	Commercial	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	Commercial	Bayer CropScience Inc.	Prosper FX Flowable Insecticide And Fungicide Seed Treatment	Suspension	Clothinidin 285.7 g/L; carbathiin 50 g/L; trifloxystrobin 7.14g/L; metalaxyl 5.36 g/L
30362	Commercial	Bayer CropScience Inc.	Emesto Quantum	Suspension	Clothianidin 207g/L; penflufen 66.5 g/L
30363	Commercial	Bayer CropScience Inc.	Prosper Evergol	Suspension	Clothianidin 290 g/L; trifloxystrobin 7.15g/L; penflufen 10.7g/L; metalaxyl 7.15g/L
30972	Commercial	Bayer CropScience Inc.	Sepresto 75 WS	Wettable powder	Clothianidin 56.25%; imidacloprid 18.75%
31355	Commercial	Valent Canada Inc.	Nipsit Suite Canola Seed Protectant	Suspension	Clothianidin 279 g/L; metalaxyl 5.23 g/L; metconazole 1.04
31357	Commercial	Valent Canada Inc.	Nipsit Suite Cereals of Seed Protectant	Suspension	Clothianidin 30.7 g/L; metalaxyl 9.24 g/L; metconazole 6.62
28975	Commercial	Valent Canada Inc.	Nipsit Inside 600 Insecticide	Suspension	Clothianidin 600g/L
29382	Commercial	Valent Canada Inc.	Clutch 50 WDG Insecticide	Water dispersible granules	Clothianidin 50%
29383	Commercial	Valent Canada Inc.	Arena 50 WDG Insecticide	Water dispersible granules	Clothianidin 50%
29384	Commercial	Valent Canada Inc.	Clothianidin Insecticide	Water dispersible granules	Clothianidin 50%

[1] as of 28 January 2021, excluding discontinued products or products with a submission for discontinuation.

Table 2 Products containing clothianidin that do not require (label) amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (%, g/L)
27445	Technical Grade Active Ingredient	Sumitomo Chemical Company Inc	Clothianidin Technical Insecticide	Solid	Clothianidin 97.5%

[1] as of 28 January 2021, excluding discontinued products or products with a submission for discontinuation

Appendix II Registered commercial class uses of clothianidin in Canada as of 31 July 2020 that are subject to this special review

Site(s)[a]	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate[b]	Maximum Number of Applications per year	Minimum Application Interval (Days)	Change in application timing based on pollinator risk (RVD2019-05)[c,d]
Use-site Category 10 – Seed and Plant Propagation Materials Food and Feed							
Canola, rapeseed	Flea beetle	Suspension	Commercial seed treatment equipment	150–406 g a.i./100 kg seed 16.0–32.5 g a.i./ha	1	Not applicable	
Carinata				150–400 g a.i./100 kg seed 6.8–44.8 g a.i./ha			
Mustard				406 g a.i./100 kg seed 18.3–45.5 g a.i./ha			
Corn (field, sweet, pop)	Corn rootworm	Suspension	Commercial seed treatment equipment	1.25 mg a.i./kernel (375 g a.i./100 kg seed) field 78.8–118.3 g a.i./ha sweet 52.5–75.6 g a.i./ha pop 85.3–123.8 g a.i./ha	1	Not applicable	
	Corn flea beetle, black cutworm, seedcorn maggot, wireworm			0.25–0.5 mg a.i./kernel (75–150 g a.i./100 kg seed) field 15.8–47.3 g a.i./ha sweet 10.5–30.3 g a.i./ha pop 17.1–49.5 g a.i./ha			
	White grub (larvae of European chafer, May/ June beetle, Japanese beetle)			0.25 mg a.i./kernel (75 g a.i./100 kg seed) field 15.8–23.7 g a.i./ha sweet 10.5–15.1 g a.i./ha popcorn 17.1 - 24.8 g a.i./ha			
Wheat	Wireworm	Suspension	Commercial seed treatment equipment	10–60 g a.i./100 kg seed 6.7–104.9 g a.i./ha	1	Not applicable	
	Aphids			30 g a.i./100 kg seed 20.2–52.47 g a.i./ha			
Potato	Aphids, Colorado potato beetle, leafhoppers, potato flea beetle	Suspension	Ground application: Seed piece treatment equipment	6.2–12.48 g a.i./100 kg seed 119–381 g a.i./ha	1	Not applicable	
	Wireworm			12.48 g a.i./100 kg seed 239–381 g a.i./ha			
Carrot	Carrot rust fly	Wettable powder	Seeds are not treated in Canada but are imported pre-treated with clothianidin.	0.035–0.068 g a.i. /1000 seed 31.5–275.4 g a.i./ha	1	Not applicable	
Leek	Onion maggot, seedcorn maggot, thrips			0.12 g a.i./1000 seed 46.2–92.4 g a.i./ha			
Onion (bulb)				0.12 g a.i./1000 seed 57.1–117.6 g a.i./ha			
Onion (bunching)				0.09 g a.i./1000 seed 176.4 g a.i./ha			

Site(s)[a]	Pest(s)	Formulation Type	Application Methods and Equipment	Application Rate[b]	Maximum Number of Applications per year	Minimum Application Interval (Days)	Change in application timing based on pollinator risk (RVD2019-05)[c,d]
Lettuce	Aphids, leafminer	Wettable powder	Seeds are not treated in Canada but are imported pre-treated with clothianidin.	0.6 g a.i./1000 seed 420 g a.i./ha	1	Not applicable	
Broccoli, cabbage	Aphids, flea beetle			0.9 g a.i./1000 seed 75.6–110.3 g a.i./ha			
Pepper	Aphids, leafminer, thrips			0.25 g a.i./1000 seed 7.5 g a.i./ha			
Tomato				0.038 g a.i./1000 seed 0.6–14.6 g a.i./ha			
Cucumber	Aphids, thrips			0.75 g a.i./1000 seed 13.8–150 g a.i./ha			
Melon				0.75 g a.i./1000 seed 2.5–4.7 g a.i./ha			
Squash				0.75 g a.i./1000 seed 1.7–18.5 g a.i./ha			
Use-site Category 13 – Terrestrial Feed Crops & Use-site Category 14 – Terrestrial Food Crops							
Potato	Colorado potato beetle, leafhoppers	Suspension	Ground application: In furrow	1.2–2 g a.i./100 m of row 132.6–223.8 g a.i./ha	1	Not applicable	
	Colorado potato beetle	Water dispersible granule					
	Aphids, Colorado potato beetle, leafhoppers		Ground and aerial application: Foliar spray	35–52.5 g a.i./ha	3	7	
Use-site Category 14 Only – Terrestrial Food Crops							
Sweet potato	European Chafer, Japanese beetle, masked chafers, Asiatic garden beetle, Oriental beetle	Water dispersible granule	Ground application: soil drench	224 g a.i./ha	1	Not applicable	
Grape	Leafhoppers	Water dispersible granule	Ground application: Foliar spray	50–70 g a.i./ha	1	Not applicable	
	Grape phylloxera, meallybug			70–105 g a.i./ha			
	Thrips			70 g a.i./ha			
	Brown marmorated stink bug			105 g a.i./ha			
Crop Group 9: Cucurbit vegetables	Cucumber beetle, squash bug, tarnished plant bug	Water dispersible granule	Ground application: Foliar spray	70 g a.i./ha	1	Not applicable	
	Brown marmorated stink bug			105 g a.i./ha			
Use-site Category 30 - Turf							
Turf (golf courses and sod farms only)	European chafer, Japanese beetle, masked chafers, Asiatic garden beetle, Oriental beetle	Water dispersible granule	Ground application: Foliar spray	125–250 g a.i./ha	1	Not applicable	
	Hairy chinch bug			175–250 g a.i./ha			
	Annual bluegrass weevil			275–350 g a.i./ha			
	Bluegrass billbug			225 g a.i./ha			
	European crane fly			275 g a.i./ha			

Source: PMRA# 3139699

[a] Crop groups are identified as listed on the end use product labels and may not be identical to the crop groups listed on the Health Canada Residue Chemistry Crop Groups website: http://hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/food-nourriture/rccg-gcpcr-eng.php

[b] g=gram; ai = active ingredient; L = litre; ha = hectare; kg= kilogram

[c] Foliar applications include the following pollinator restriction: Cucurbits - change in number of pre bloom applications from 2 to 1, one post bloom application; Potato - Do not apply during bloom; Strawberry - pre-bloom application only (removal of use based on labelled application timing); and Turf (use on golf courses and sod farms only).

[d] All foliar applications include the following pollinator restriction: Do not apply during bloom.

Appendix III Comments and responses

1.0 Comments and responses related to the environment

Of the 47,000 comments received during the consultation period, a total of 90 substantive comments related to the environment were submitted. Multiple points were made covering a wide range of subjects including endpoint selection, exposure, risk assessment approach and risk mitigation. These points are addressed individually within this Appendix.

This appendix includes the comments and responses for the proposed special review decisions for both clothianidin (PSRD2018-01) and thiamethoxam (PSRD2018-02). This is because the majority of the comments applied to both the clothianidin and thiamethoxam environmental risk assessments. Those small number of comments that were relevant to only one of the PSRDs were considered in the context of the relevant PSRD/SRD. However, because the vast majority of the comments are relevant to both PSRDs, all comments and responses related to the environment for both PSRD2018-01 and PSRD2018-02 are included in this appendix.

Because many of the substantive comments contained multiple comments on different environmental subject areas, parts of comments submitted by the same commenter may be considered under different subject headings. Thus, only the relevant parts of some comments may be presented under a specific subject heading. Due to the length and detail of scientific comments received, Health Canada has summarized the main points contained therein. Comment excerpts are presented verbatim, and are identified in italics.

1.1 Toxicity endpoints used in the risk assessment

Health Canada received a number of comments related to the selection of toxicity endpoints used in the risk assessments for both clothianidin and thiamethoxam. These comments were related to clarity of the endpoint selection, in addition to study interpretation, for a variety of studies considered.

Comment 1 (CropLife Canada) - PSRD2018-01 and PSRD2018-02

> CropLife Canada (CLC) stated that in PSRD2018-01 and PSRD2018-02, the endpoints used by the PMRA in the aquatic invertebrate risk assessments for clothianidin and thiamethoxam (0.02 µg a.i./L and 0.30 µg a.i./L, respectively) were not presented clearly and in a transparent manner. They acknowledged that the PMRA had since clarified this point.

Health Canada response

> Health Canada recognizes that the PSRDs may not have clearly indicated the endpoints used to make the proposed regulatory decision for both clothianidin and thiamethoxam. Given the limitations with the available chronic data, the Agency wanted to convey the full weight of evidence considering the HC_5, the most sensitive species, and mesocosm endpoints when available. In making the final regulatory decisions, the chronic endpoint of concern has not changed for thiamethoxam and remains the 35-d NOEC of 0.30 µg a.i./L nominal concentration, based on reductions in mayfly emergence and abundance in a

mesocosm study. However, Health Canada has re-assessed the clothianidin dataset, taking into account newly published data. For clothianidin a weight-of-evidence approach was taken where a revised chronic effects metric of 0.12 µg a.i./L based on a geometric mean of chronic laboratory toxicity data for reduction in emergence for the most sensitive species, *Chironomus dilutus* was considered along with the mesocosm effects metric of 0.281 µg a.i./L.

Comment 2 (Producteurs de grains du Québec) - PSRD2018-01 and PSRD2018-02

The PGQ noted that reference values used by Health Canada were lower than the endpoints reported in many of the studies used in the review and were lower than those proposed by the USEPA in their preliminary aquatic risk assessment (USEPA 2017; PMRA# 2862808). The following points were made:

1. Did the results obtained in mesocosm studies exclude interactions with other living organisms, organic matter, the fraction of active ingredient taken up by plants, etc.?

2. The HC_5 values used by the USEPA are higher than the values used by Health Canada. For example, the clothianidin acute HC_5 = 22 µg/L (USEPA) vs 1.5 µg/L (Health Canada) and the chronic HC_5 <0.05 µg/L (USEPA) vs 0.0015 µg/L (Health Canada). In particular, the PGQ consider the clothianidin chronic HC_5 to be excessively severe compared to other studies or the USEPA reference value; they question, given the similarity in data sources used between countries, what additional precautions did Health Canada use to arrive at the much lower chronic HC_5 for clothianidin?

3. PGQ believes that reference values obtained by SSD modelling do not require an additional safety factor of two due to conservatisms built into the modelling with ETX v2.1 software.

Health Canada response

In evaluating toxicity studies, either submitted to the Department in support of a registration, or obtained from the open literature, Health Canada critically reviews the data and statistical analyses applied to it. Evaluators may re-analyse the toxicity data if deemed appropriate. This can result in endpoints that differ from what is reported by study authors.

Higher-tier mesocosm studies are designed to account for biological and non-biological interactions occurring within the invertebrate community. The toxicity endpoints are generally based on abundance of insects present in the containers or on the number of emerged insects. Observed abundance is a result of the sum of all factors and their interactions, including direct toxicant exposure and biological interactions (for example, predation), and takes into account any partitioning of the toxicant to other parts of the test systems (for example, dissolved organic matter, plants, container walls, etc.).

As noted in the proposed special review decisions, there were differences in the approach used to establish reference values (effects metrics) between Health Canada and the USEPA. In their preliminary aquatic risk assessments for both clothianidin and thiamethoxam, the USEPA used the lowest single-species endpoints deemed acceptable for regulatory use for both acute and chronic exposures (USEPA 2017a; PMRA# 2862808, USEPA 2017b; PMRA# 2862809). In contrast, Health Canada used acceptable higher-tiered data (i.e., mesocosm effects data), when available, in decision making.

For the acute effects metrics, there were sufficient numbers of species with acceptable toxicity data for both clothianidin and thiamethoxam to derive acute HC_5 reference values using species sensitivity distributions (SSDs) (n = 36 and 37, respectively). For the chronic effects metrics, there were significant uncertainties with the chronic HC_5 values noted in PSRD2018-01 and PSRD2018-02 that precluded their use, due to the relatively low number of species in the distributions (n = 5 for clothianidin and n = 7 for thiamethoxam). Therefore, for the proposed decision, Health Canada relied on the most sensitive single-species value for clothianidin (*Chironomus dilutus* EC_{20} = 0.02 µg a.i./L), and the most sensitive mesocosm endpoint for thiamethoxam (NOEC = 0.3 µg a.i./L).

The proposed chronic clothianidin effect metric used by Health Canada in PSRD2018-01 (EC_{20} = 0.02 µg a.i./L) is based on the same effect for *C. dilutus* (reduction in emergence) used by the USEPA (2017a; PMRA# 2862808) in their preliminary risk assessment (NOEC of <0.05 µg a.i./L). From this effect dataset, Health Canada received the raw data from the study author which allowed for the determination of an EC_{20} value, whereas EPA used an unbound (less than) NOEC value. These assessments were not carried out as joint reviews between the two Agencies and, therefore, there were differences in both the data considered and the conclusions on study acceptability for use in the risk assessment. For the SRD, Health Canada has revised the chronic laboratory-based effect metric for clothianidin based on additional data received (geomean of EC_{10}/EC_{20} = 0.12 µg a.i./L for *Chironomus dilutus*). See Science Review Section 1.3.1 of this SRD for further details on the effects metrics selected for the final decision.

As per normal processes, Health Canada applies an uncertainty factor of two to the lowest single-species endpoint values for risk assessment purposes. Uncertainty factors are not applied to HC_5 values derived by SSD modelling, chronic laboratory-based effects metrics or mesocosm effects metrics. For the final clothianidin decision, SSD modelling was completed for acute exposure only. It was determined that there were insufficient data to completed a chronic SSD. See Science Review Section 1.3.1 of this SRD.

Comment 3 (Saskatchewan Ministry of Agriculture, Bayer Crop Science, BASF Canada and Valent Canada Inc.) - PSRD2018-01

Comments were received regarding the interpretation of:

Cavallaro, M.C., C.A. Morrissey, J.V. Headley, K.M. Peru and K. Liber. 2017. Comparative chronic toxicity of imidacloprid, clothianidin, and thiamethoxam to Chironomus dilutus and estimation of toxic equivalency factors. Environ. Toxicol. Chem. 36(2): 372-382. PMRA# 2712687.

Comments received highlighted concerns regarding the validity of the study, including the following points:

1. The appropriateness of using the second instar of *C. dilutus* is questioned. It was suggested that a different instar is likely to be present when the pesticides may be present in water.

2. The author's use of borosilicate glass on top of test beakers to prevent phototransformation of clothianidin and thiamethoxam. The commenter noted that phototransformation is a major route of dissipation for neonicotinoids.

3. The relevancy of the length of the exposure period. The commenter indicated that sustained concentration of clothianidin and thiamethoxam were rarely observed in Prairie water monitoring data, and therefore, effects observed from this study are not representative of the Prairie system where the majority of the use is through seed dressing.

4. The endpoint derived from this study "does not meet basic scientific validity criteria for use in science based risk management decisions because it is not repeatable, cannot be independently validated, and is not supported by other (higher tier) studies."

5. The fact that the endpoint is an order of magnitude lower than the same effects-based endpoints from other studies cannot be explained by duration of exposure and is instead likely due to control bias in the Cavallaro study, rendering its results invalid.

6. BASF Canada Inc. noted that although the proposed decision reported an EC_{20} value for sex ratio of 0.15 µg a.i./L (i.e., increase in proportion of males), there was no indication that sex ratio data was either received or analyzed by the PMRA in an attempt to verify this endpoint. It was argued that based on variability in average male percentages and a non-monotonic response, this endpoint is not reliable.

7. In the Cavallaro paper, the 40-d NOEC for emergence was reported as 0.20 µg a.i./L, which is significantly different from estimated 40-d EC_{20} value (0.02 µg a.i./L) which is an extrapolated value.

8. The test did not follow the standard test guidelines (for example, OECD and OCSPP).

9. Valent Canada Inc. considered the endpoint from this study of 0.02 µg a.i./L to be unreliable because "In a sediment-spiked C. dilutus test with clothianidin (PMRA# 2615168), the exposure duration is longer and 63-d NOEC of 1.6 µg a.i./L based on pore water concentrations is obtained." Valent Canada Inc. suggested that this 63-d NOEC be considered for the chronic risk assessment for surface water instead.

Health Canada response

Health Canada considers the results from the Cavallaro et al. (2017) study to be acceptable for use in the risk assessment. Health Canada considers the EC_{20} of 0.02 µg a.i./L based on percent emergence as reported to be a valid endpoint even though it is lower than the nominal NOEC reported by the author (0.20 µg a.i./L). Responses to the points outlined above are as follows:

1. The use of sensitive life-stages from laboratory studies is critical to understanding potential environmental risk for multi-voltine taxa, such as Chironomidae, which can have a range of age cohorts present at a given time of year. While, OECD technical guidelines recommend first instar larvae for acute and chronic studies as they are generally considered the most sensitive larval stage (for example, OECD TG #235 and 233, respectively), the use of second instar life-stage of *C. dilutus* in this study was considered appropriate, recognizing that it may not represent the most sensitive life-stage for this species. Given that the second instar life-stage may be less sensitive, the results from this study may be less conservative. Ultimately, in establishing risk to chironomids, an appropriate exposure period in the environment is taken into account when establishing estimated environmental concentrations for the risk assessment.

2. Biological and physical-chemical conditions that can affect photolysis dissipation rates of neonicotinoids in natural systems are highly variable (for example, turbidity, plant growth, water depth, etc.) and cannot be accounted for in laboratory studies. The static-renewal test design with a three-day renewal cycle, maintained exposure concentrations such that a concentration-response could be established. The use of borosilicate glass on top of the beakers is considered an acceptable practice.

3. It was argued that the exposure regime of this study is not representative of Prairie systems given that neonicotinoid levels in the Prairie region are not likely to be sustained, as neonicotinoid inputs from seed treatments occur once per year. However, laboratory-based chronic toxicity assays are often designed to deliver a constant exposure concentration over a significant portion of the life-cycle of the target organism to ensure that critical life-stages of the organism are exposed. This study has been considered alongside other chironomid studies for use in the risk assessment (see Science Section 1.3.1 of this SRD for further details)

4. While it is ideal that results from laboratory toxicity studies can be repeatable, there are many factors that can affect this. Correspondence with the author confirmed that there were no abnormalities during the study that could account for differentially high survival in the controls compared to the treatments. Higher than average control survival within this trial compared to global averages among other labs does not indicate a ‘control bias’ that would warrant normalizing responses to initial treatment effects in order to make it consistent with results from other laboratories, as recommended by the commenter. Even with some uncertainties associated with this study, Health Canada along with other jurisdictions have

classified this study as acceptable for use in a risk assessment. In their 2017 risk assessment for aquatic invertebrates, the USEPA (2017; PMRA# 2862808) supported the use of the NOEC for survival (as emergence) and dry weight of < 0.05 µg a.i./L from this study to characterize chronic risk to aquatic invertebrates. This was based on statistically significant effects at the lowest treatment level (0.046 µg a.i./L mean measured concentrations); this value corresponds closely to the EC_{20} reported by the study author and accepted by Health Canada.

5. A concentration one-order of magnitude below those associated with comparable effects is not unrealistic among toxicity responses. In the SRD for clothianidin, to account for multiple endpoints from different experiments with the same species, Health Canada used the geometric mean value of all *Chironomus dilutus* chronic emergence endpoints (0.12 µg a.i./L). This geomean is based on the following acceptable emergence endpoints: 40-d EC_{20} = 0.02 µg a.i./L (Cavallaro et al. 2017; PMRA# 2712687); 28-d EC_{20} = 0.34 µg a.i./L (Maloney et al 2018a; PMRA# 2873503); and 56-d EC_{10} = 0.25 µg a.i./L (Raby et al. 2018b; PMRA# 2912490).

6. Health Canada considered emergence to be the most sensitive endpoint from the Cavallaro et al. (2017) study for use in the clothianidin risk assessment based on the more sensitive EC_{20} value (PSRD2018-01). Health Canada did not consider results based on sex ratios to be reliable for risk assessment purposes.

7. The study-reported nominal NOEC of 0.20 µg a.i./L is based on an LOEC of 0.48 µg a.i./L identified for emergence in Figure 1B of the paper. However, Health Canada determined that the 40% reduction in emergence compared to controls occurred at both the tested mean measured concentrations of 0.046 and 0.200 µg a.i./L and was statistically significant (Williams test, $p < 0.05$). Health Canada therefore considers the NOEC to be < 0.046 µg a.i./L and supports the reported EC_{20} of 0.02 µg a.i./L.

8. Health Canada accepts studies that do not follow internationally accepted guidelines as long as the data requirement has been first met with a guideline study. Data from all sources (including published literature) are considered. These studies are reviewed by scientists that use expert judgement to determine if the studies are valid for use in a risk assessment. This particular study was highly scrutinized by Health Canada scientists including the raw data that was obtained from the study author. Health Canada’s conclusion is that this study remains valid for use in a risk assessment.

9. Valent Canada Inc. suggested that the 63-d NOEC of 1.6 µg a.i./L, based on mean measured pore water concentrations for *C. dilutus* in a spiked-sediment test with clothianidin (PMRA# 2615168), should be considered for the chronic risk assessment for surface water rather than the 40-d EC_{20} of 0.02 µg a.i./L from a spiked-water exposure study. Health Canada does not calculate risk quotients using pore water toxicity endpoints derived from spiked-sediment studies in combination with modelled surface water EECs; rather, modelled pore-water EECs are used. In spiked-sediment studies, benthic invertebrates are primarily exposed to pesticides

through contact with pore water and sediment. The water modelling used by Health Canada provides pore water estimates which are compared to the effects endpoint from the study for pore water. For the pore water risk assessment in the proposed decision, Health Canada used a 10-d NOEC of 1.1 µg a.i./L mean measured pore water concentration for *C. riparius*; PMRA# 1636640, PSRD2018-01), which is more sensitive than the value proposed by Valent.

Comment 4 (Saskatchewan Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

Comments were received regarding the interpretation of:

Basley, K. and D. Goulson. 2018. Neonicotinoids thiamethoxam and clothianidin adversely affect the colonisation of invertebrate populations in aquatic microcosms. Environ. Sci. Pollut. Res. 25(10): 9593 – 9599. https://doi.org/10.1007/s11356-017-1125-5. PMRA#2861918.

Saskatchewan Ministry of Agriculture indicated that this reference *"should have no bearing on the PMRA's decision"* given that:

- Soil for this study, although collected from a site with no history of neonicotinoid usage, was not tested for other contaminants.
- Ostracods were not introduced into the culture, however were found during analysis. Measuring the population responses for these animals is not appropriate given that initial numbers associated were not determined.
- Identifying effects of treatments on colonization by chironomids and culicids without identifying to species and acknowledging life history factors is problematic.

Health Canada response

Health Canada agrees that there were significant uncertainties in the conclusions of this study due to very high variability in organism abundance in controls and lack of analytical confirmation of exposure concentrations. This study was not considered quantitatively in the risk assessment.

Comment 5 (Saskatchewan Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

Comments were received regarding the interpretation of:

C.A. Morrissey, P. Mineau, J.H. Devries, F. Sanchez-Bayo, M. Liess, M.C. Cavallaro and K. Liber. 2015. Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review. Environment International 74: 291-303. PMRA# 2538669.

The Saskatchewan Ministry of Agriculture indicated that the neonicotinoid reference value from this study cited by Health Canada is too low as it is based on the lower 95% confidence interval of the HC_5 from a chronic toxicity SSD with 18 test species. The comments included a rationale to support that the use of the lower confidence interval is inappropriate.

Health Canada response

The lower confidence limits of the acute and chronic HC_5 values from Morrissey et al. (2015; PMRA #2538669) were for combined neonicotinoids. Morrissey et al. (2015) provided combined neonicotinoid reference values based on molar-equivalent concentrations of available neonicotinoid endpoints. Health Canada did not use the recommended values put forth by these authors in making the proposed regulatory decisions. They were provided in PSRD2018-01 and PSRD2018-02 for comparative purposes only.

Health Canada's risk assessments for clothianidin and thiamethoxam are based on the toxicity of those active ingredients alone. As such, the Health Canada did not use ecotoxicity values based on combined exposure.

When Health Canada uses species sensitivity distributions in risk assessments, the HC_5 value provided by the SSD model, and not the lower 95% confidence limit, is used in the risk quotient.

Comment 6 (Bayer CropScience, BASF Canada and Valent Canada Inc) - PSRD2018-01 and PSRD2018-02

Comments were received regarding the interpretation of:

Environment and Climate Change. 2017. Final progress report (2014-2017) to the Ontario Ministry of Environment and Climate Change. Assessment of acute and chronic toxicity of neonicotinoid insecticides to non-target aquatic species. PMRA# 2753706.

Bayer CropScience and BASF commented on the *Hyalella azteca* NOEC = 0.31 µg a.i./L for effects on body size from chronic exposure to clothianidin reported by Health Canada. The commenters indicated that this growth-based endpoint which was used in the SSD for clothianidin was derived from statistical analysis of a combined dataset from two separate experiments which should be accounted for in the statistical analysis of the data.

It was suggested that Health Canada rely on the derived endpoint from one of the trials (Trial 2), as the controls from the other trial (Trial 1) are outliers and not suitable for evaluating potential effects of the test compound. Viewing the controls as outliers is driven largely by one replicate having a particularly large wet weight per individual value. Based on a comparison of the graphs of the studies with the other five neonicotinoids tested, this particular clothianidin control value is well outside the normal range of control values. Given the outlier status of the control organisms in the clothianidin Trial 1 and statistically significant difference from control organisms in clothianidin Trial 2, the two independent datasets should not be combined. If Health Canada relies on data from clothianidin Trial 2, the NOEC will be 2.5 µg a.i./L, which is consistent with the endpoint reported by the authors in the study report.

Health Canada response

Since the publication of PSRD2018-01 and PSRD2018-02, the results from the acute and chronic exposure to *H. azteca* from this study were published in the open literature (Bartlett et al. 2019, PMRA #2975959) and reassessed by Health Canada for the final decisions for clothianidin, thiamethoxam and imidacloprid.

Health Canada agrees that the results from the multiple trials for each neonicotinoid in this study are not true replicates and should be analysed separately. While all trials were conducted at the same location under the same culturing conditions and test protocols, the trials were not conducted simultaneously. As a result, Health Canada reassessed the individual trials for each test and determined the geometric mean response for *H. azteca* exposure to each neonicotinoid to represent the effects observed in the study (see Science Review Section for more details).

Comment 7 (Bayer CropScience, BASF Canada and Valent Canada Inc) - PSRD2018-01 and PSRD2018-02

Comments were received regarding the interpretation of:

Prosser et al*. 2016. Sensitivity of the early-life stages of freshwater mollusks to neonicotinoid and butenolide insecticides. Environ. Pollut. 218:428-435. PMRA# 2712688.*

The comments received were related to the validity of the Ramshorn snail 28-d growth and biomass endpoints for clothianidin, thiamethoxam and imidacloprid. Bayer CropScience, BASF Canada, and Valent Canada Inc. indicated that the 28-d EC_{10} values for growth and biomass for clothianidin should not be considered reliable since they were extrapolated values and the low limits of the 95% confidence intervals were negative values. Also, there was a wide range in snail dry weights among the trials with all three neonicotinoids, indicating potential difficulties in measuring such small masses (µg) and apparent errors in some individual replicate dry weight data. Therefore, these endpoints should not be used for risk assessment.

Health Canada response

Health Canada agrees that anomalously high variability in mass was seen in snails at the 10 µg a.i./L treatment level of imidacloprid and thiamethoxam. The author was contacted and responded that due to the challenges of measuring such small masses (down to 1 µg), even small amounts of excess water can influence mass estimates considerably. It was also acknowledged that some snails may grow significantly more than their replicate mates, which can affect growth and biomass variability. Health Canada determined that the variability (~10x difference in mass) was too high to derive reliable endpoints at the 10 µg a.i./L treatment for imidacloprid and thiamethoxam. The same variability was not seen in the clothianidin dataset. As such, the growth data from this study was excluded when making a final regulatory decision for clothianidin, thiamethoxam or imidacloprid.

Comment 8 (BASF Canada) - PSRD2018-01 and PSRD2018-02

Comments were received regarding the interpretation of:

Maloney et al*. 2017. Cumulative toxicity of neonicotinoid insecticide mixtures to Chironomus dilutus under acute exposure scenarios. Environ Toxicol Chem 36(11):3091-3101. PMRA# 2818524.*

BASF Canada stated that "Conclusions drawn in Maloney et al. 2017 paper regarding the mixture toxicology of neonicotinoids are invalid due to errors in the analysis of the data and the inappropriateness of the data analysis method." In the PMRA EAD monograph PMRA # 2856238, it is stated "The PMRA accepts the conclusion of Maloney et al. that the cumulative acute toxicity to C. dilutus from multiple neonicotinoids appears to be more than direct additive effects of individual active ingredients." It is also indicated that the PMRA did not receive or examine the data in this study and "does not have any experience with the MIXTOX model."

The commenter suggested that had the PMRA received and reviewed the data from the authors then they might have reached different conclusions. *"Based on our review of the data set and associated analyses, errors in the calculations were made for all three binary mixture studies. Further, even if these analyses had been mathematically correct, the overall approach for fitting the models is not appropriate for the type of data collected."*

Health Canada response

The PMRA has not conducted a cumulative risk assessment for neonicotinoid mixtures in making its final regulatory decision for imidacloprid, clothianidin and thiamethoxam. In the event that a cumulative risk assessment is considered in the future, the comments on the appropriateness of the analysis by Maloney et al. (2017) on the effects of mixtures will be considered at that time. However, the 96-h LC_{50} values from the single-neonicotinoid exposure trials for clothianidin and thiamethoxam as reported in PSRD2018-01 and PSRD2018-2, respectively, are valid and were considered for the final regulatory decisions.

Comment 9 (Bayer CropScience) - PSRD2018-01

Comments were received regarding the interpretation of:

Hartgers, E.M. and I. Roessink. 2015. Outdoor study on the effects of a single pulse application of clothianidin in freshwater experimental ponds. Bayer CropScience. Unpublished report No.: THW-0392. 295 pp. PMRA# 2713555.

Comments received related to this study are associated with: (1) the use of a mesocosm-based endpoint from this study to assess risk to prairie wetlands, and suggested effects metrics (2) (2) the protectiveness of the mesocosm endpoint.

1) Mesocosm-based Chronic Endpoint for Assessing Risk to Prairie Wetlands

Bayer CropScience indicated that the dissipation in water observed in a mesocosm study with clothianidin applied as a single application is representative of clothianidin dissipation observed in prairie wetlands monitoring data. *"The concentrations tested in the mesocosms* *are much greater than concentrations expected in aquatic environments following seed treatment or in-furrow uses. Therefore, relying on a time weighted average concentration (TWA), which adjusts the exposure concentration to account for dissipation, for the most sensitive endpoint from the two mesocosms (PMRA calculated $NOEC_{TWA}$ = 0.281 µg a.i./L) is a scientifically justified and protective approach for clothianidin seed treatment and in-furrow application risk assessments."*

Bayer CropScience indicated that due to the observed dissipation in the mesocosm and the wetlands monitored, the best approach for estimating aquatic invertebrate exposures and comparing exposures in wetlands and the mesocosm is to compare 21-day time-weighted average (21-d TWA) concentrations.

In the absence of sufficient monitoring data to compute a 21-d TWA concentration, a scientifically reasonable approach is to compare the surface water monitoring concentration to the initial mesocosm concentration (0.518 µg a.i./L) for the treatment level that defines Health Canada's mesocosm-based NOEC. This is justified since the dissipation of the compound in the mesocosm is similar to what is observed in wetlands. Therefore, if the "peak" concentration in a wetland is below the initial mesocosm exposure of 0.518 µg a.i./L, then the exposure in the wetland is below a concentration expected to cause harm based on the mesocosm. While there is some uncertainty with this approach, it should be noted that there is a high degree of conservatism in the mesocosm-based endpoint as it is based on a concentration demonstrated to have no effects.

2) The Mesocosm-based Endpoint is Protective of Sensitive Aquatic Invertebrate Species

Bayer CropScience pointed out that while the submitted mesocosm study contained Ephemeroptera, statistical evaluation of potential effects could not be assessed at all time points in the studies due to low initial abundance, leading to uncertainty that the endpoint is sufficiently protective for Ephemeroptera. Recently published data address these uncertainties and demonstrate that the mesocosm-based endpoint is protective of aquatic invertebrate communities including Ephemeroptera. The following was provided as supporting information.

- Given that *Neocloeon triangulifer* is a conservative surrogate species for defining chronic endpoints for Ephemeroptera it is felt that the mesocosm endpoint of 0.281 µg a.i./L is protective of Ephemeroptera (and other aquatic invertebrates). Raby et al. 2018b reported a chronic endpoint (0.280 µg a.i./L) for clothianidin exposure to *Neocloeon triangulifer* which is identical to the mesocosm-based endpoint.
- Based on the acute data reported by Raby et al. (2018a), Bayer CropScience argued that Ephemeroptera are positioned near the middle of the average proportional rank on sensitivity for the taxonomic orders investigated, demonstrating that they are not uniquely sensitive to neonicotinoids. Using the same dataset, Diptera, the order to which midge including *Chironomus dilutus* belong, is the most sensitive order to neonicotinoids. Since midge were sufficiently represented in the mesocosm, this information provides additional support that the mesocosm-based endpoint is protective of Ephemeroptera.

Health Canada response

Health Canada agrees that Canadian monitoring data from intensively sampled wetlands in the Prairie region that are associated with seed treatment uses generally show an annual spring/early summer peak, followed by a decline in pesticide concentrations in the water bodies. Subsequent peak events are uncommon, even following large precipitation events.

The review of the Hartgers and Roessink (2015; PMRA No. 2713555) mesocosm study uncovered some uncertainties as outlined in Science Review Section 1.3.1 of this SRD that precluded the use of the 56-d $NOEC_{14\text{-d TWA}}$ of 0.281 µg a.i./L as a definitive endpoint. In the final decision, Health Canada compared the mesocosm-based 56-d $NOEC_{14\text{-d TWA}}$ to the peak 28-d rolling average concentration from the available monitoring data, including the prairie wetland data.

Taking this approach, implies that regardless of the dissipation pattern or treatment regime, mean concentrations are expected to elicit the same effects. The comparison of the 28-d rolling average from the water monitoring data to the 14-d TWA from the mesocosm study is considered suitable as the majority of adverse effects in the mesocosm study were seen between 14 and 21 days exposure, and rolling averages from monitoring data were robust over when determined over 28 days. Health Canada recognizes that this is not the most conservative approach as rolling averages from the water monitoring data over shorter durations could produce higher exposure concentrations. Other approaches to assessing the risk from endpoints derived from mesocosm studies are valid and are all accompanied by their own uncertainties. For more information on how the mesocosm endpoint was considered in the final decision assessment see Science Review Section 1.3.1 of this SRDX.

Comment 10 (Grain Farmers of Ontario) - PSRD2018-01

In PSRD2018-01, Health Canada identified uncertainties in the two mesocosm studies which calls into question the suitability of using these studies in a weight-of-evidence approach in the risk assessment. Given that only two studies were considered, the level of uncertainty associated with the conclusions made based on the limited data should be further examined. It was not clear from the risk assessment whether or not three mesocosm studies noted by the USEPA in their preliminary risk assessment (USEPA 2017), were considered. A NOEC of 1.0 µg a.i./L is referenced by the USEPA, which is greater than the Health Canada NOEC of 0.281 µg a.i./L. It was also noted that it is important to take into consideration the observed recovery of emergent insects from the two registrant-submitted mesocosm studies when interpreting the results and in turn, the selected NOEC.

Health Canada response

The three mesocosm studies noted by the USEPA in their preliminary risk assessment for clothianidin (USEPA 2017; PMRA# 2862808), were addressed by Health Canada in PSRD2018-01.

1. The USEPA report a NOEC of 1.0 µg a.i./L based on nominal concentrations from the registrant study MRID 47483004. This is referring to the study by

Memmert (2001; PMRA# 1636641). Health Canada determined a time-weighted average (TWA) NOEC of 0.54 µg a.i./L based on the same exposure concentration, due to loss of test material over time in the study chambers.

2. According to the USEPA, Miles et al. (2017) found that predator mortality increased with clothianidin concentration, along with an increase in prey survival at the highest test concentration. As noted in PSRD2018-01, Health Canada agreed that the results from the study showed that clothianidin could exert a top-down effect on food chain dynamics, but could not establish a definitive NOEC from this study for use in a risk assessment.

3. The USEPA report a NOEC of 0.5 µg a.i./L nominal concentration, based on community-level effects from the recently submitted registrant study MRID 50227907. This is referring to the study by Hartgers and Roessink (2015; PMRA# 2713555) and reviewed by Health Canada for PSRD2018-01. Health Canada determined a 14-day TWA NOEC of 0.281 µg a.i./L based on the same exposure concentration, due to loss of test material over time in the study chambers. Based on comments received regarding the acceptability of using this value as the most sensitive mesocosm effect metric for the final decision, Health Canada re-examined the uncertainties identified for this study (see Section 1.1 above). It was determined that although the results can be used to inform the risk assessment, the NOEC is not robust enough to use as a higher-tiered effect metric on its own.

Health Canada does take into consideration observed recovery of test organisms from mesocosm studies as part of a weight-of-evidence approach in assessing risk.

Comment 11 (Ducks Unlimited Canada) - PSRD2018-01

Ducks Unlimited Canada submitted a recently published research paper on clothianidin-induced metabolic changes in mosquito larvae for consideration.

Russo, R., S-B. Haange, U. Rolle-Kampcyzk, M. von Bergen, J.M. Becker and M. Liess. 2018. Identification of pesticide exposure-induced metabolic changes in mosquito larvae. Sci. Tot. Environ. 643 (2018): 1533-1541. PMRA# 2978128.

Health Canada response

Health Canada has reviewed this study and found it to be scientifically sound. Acute toxicity endpoints for the mosquito *Culex pipiens* were considered in the risk assessment for the final regulatory decision for clothianidin (see the Science Review Section).

1.2 Species sensitivity distributions (SSDs)

Comments were received from Environment and Climate Change Canada (ECCC), Saskatchewan Ministry of Agriculture, Bayer CropScience and Valent Canada Inc. related to the determination of Species Sensitivity Distributions (SSDs). These comments were generally related to the validity of the individual data points considered for inclusion in the SSDs and the model selected to represent the SSDs.

1.2.1 Consistency with Canadian Council of Ministers of the Environment Canadian Water Quality Guidelines

Comment 12 (ECCC) - PSRD2018-01 and PSRD2018-02

ECCC's comments were provided working on the assumption that the benchmarks developed in the PSRDs could be used to develop aquatic life benchmarks (ALBs) for clothianidin and thiamethoxam. ECCC reviewed the endpoints discussed in the PSRDs from the perspective of alignment with Canadian Water Quality Guidelines (CWQGs) and suggested revising the data included in the SSDs to ensure consistency with Canadian Council of Ministers of the Environment (CCME) protocols. ECCC indicated that short- and long-term SSD-based guidelines for five neonicotinoid pesticides will be undergoing CCME's review and approval process in the near future. Since receipt of this comment, CCME has published draft CWQGs for the neonicotinoids.

ECCC noted that the SSDs reported in the PSRDs, included both technical grade and formulated product endpoints where the formulated product was identified as being slightly more toxic than the technical grade. It was pointed out that this should be discussed in the assessment and raises issues for comparisons to monitoring data. CCME water quality guidelines are based solely on technical grade to remove the influence of formulants since monitoring data report the technical analyte.

Health Canada response

Aquatic Life Reference Values (ALRVs) and the Canadian Water Quality Guidelines for the Protection of Aquatic Life (CWQG-PAL) for pesticides are developed with high quality data according to parallel but somewhat different rigorously peer-reviewed assessment methods. While both the PMRA and CCME methods assess and characterize effects for protecting aquatic communities, different protocols for the derivation of benchmarks may result in different values reported.

The Canadian Council of Ministers of the Environment (CCME) uses aquatic toxicity data to develop Canadian Water Quality Guidelines for the protection of aquatic life (CWQGs-PAL). The CWQG-PAL are intended to be levels that will be protective of all forms of aquatic life and all aspects of the aquatic life cycles, including the most sensitive life stage of the most sensitive species over the long term. These levels can also be used as a trigger for further investigation, however, are not be regarded as blanket values for national environmental quality (CCME 1999). The CCME has outlined recommended applications of CWQGs including but not limited to the scientific basis for the development of site-specific Water Quality Objectives (WQOs) standards and the scientific basis for environmental regulations as outlined in Guidance on Site-Specific Application of Water Quality Guidelines in Canada. Procedures for developing the CWQG-PAL are described in CCME document A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life 2007 and require a specified dataset to establish a guideline.

In accordance with the *Pest Ccontrol Products Act*, the PMRA uses aquatic toxicity data in its ecological risk assessments to inform pesticide registration decisions. The PMRA's risk assessment procedures follow internationally accepted paradigms and are typically based on the most sensitive species tested for each taxon. Aquatic Life Reference Values (ALRVs) set acceptable levels of pesticides in surface water sources that prevent unacceptable risks to the individual groups of organisms by ensuring there is reasonable certainty of no harm, taking into account the conditions of registration. ALRVs are used as a regulatory trigger to inform the need for further investigation.

One CWQG-PAL value is derived to protect all aquatic life from fish to algae, whereas ALRVs are established for each group of organisms assessed in the Health Canada risk assessment (aquatic invertebrates, fish, algae, plants, etc.).

The CCME includes only technical grade active ingredient (TGAI) studies when setting CWQGs. In addition to the TGAI, Health Canada also considers studies with end-use products (EPs) within the risk assessment; the inclusion of an EP endpoint in an SSD would be determined on a case-by-case basis. Under Health Canada's current guidance, an EP endpoint would be included in an SSD if the EP toxicity is similar to the TGAI.

Health Canada has included data for the EPs along with the TGAI in the SSDs for the neonicotinoids. There is evidence from a small number of neonicotinoid studies to indicate that toxicity differences between TGAI and EP exposures within the same study is minimal, indicating that a formulation bias* is not evident (PMRA# 2541823, 2541839 and 2541824). For daphnids, additional acute toxicity studies available in the open literature suggest the potential for greater sensitivity to some end-use products (see toxicity summaries in Appendix IV, Table A.4-1 of this SRD and SRD2021-04); however, this relationship is not clear for crustaceans and insects that are more sensitive to neonicotinoids. This approach may be slightly more conservative than for the TGAI alone, but allows for the inclusion of a larger, more robust dataset for consideration within the SSD. This approach is consistent with that taken by the European Food Safety Authority (EFSA, 2014, PMRA# 2545413) for their imidacloprid aquatic invertebrate risk assessment.

* Formulation bias refers to an enhanced toxicological effect due to components of the product formulation other than the active ingredient.

1.2.2 Model selection

Comment 13 (ECCC) - PSRD2018-01 and PSRD2018-02

ECCC seeks clarification on why ETX was chosen to derive HC_5 values as opposed to SSDMaster which is the publicly available SSD software used by CCME to derive water quality guidelines.

Health Canada response

Numerous SSD software packages are commercially or publicly available, each differing in their underlying approaches and assumptions. ETX is supported by peer-reviewed statistical documentation (Aldenberg and Jawarska, 2000) and has historically been used by Health Canada for all SSD analyses for consistency in regulatory decision-making.

Comment 14 (ECCC) - PSRD2018-01 and PSRD2018-02

ETX is an SSD program provided by RIVM (the Netherlands National Institute for Public Health and the Environment (Vlaardingen et al*. 2004)) which uses moment matching for parameter estimation; moment matching is not able to handle censored data (Kon Kam King* et al*. 2014).*

Health Canada response

Health Canada acknowledges that ETX is not designed to account for censored data (i.e., the ETX software package treats endpoint values as definitive). To date, it has been common practice to include censored endpoint values in SSDs, despite software limitations. There is allowance for the inclusion of censored values in guidance provided by CCME (2007) and EFSA (2013). Jurisdictions have taken different approaches in terms of criteria for including censored values. Since SSDs are meant to reflect the variability in sensitivity of species, it is desirable to account for species whose censored endpoints fall outside the range of definitive endpoints. Available statistical applications that account for censored values in SSDs have yet to be fully reviewed by Health Canada. An in-depth analysis of available software will be conducted by Health Canada in the future.

CCME (Canadian Council of Ministers of the Environment). 2007. A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life 2007. Canadian Water Quality Guidelines for the Protection of Aquatic Life. http://ceqg-rcqe.ccme.ca/download/en/220

EFSA (European Food Safety Authority). 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Panel on Plant Protection Products and their Residues (PPR). EFSA Journal 2013;11(7):3290.
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.3290

Comment 15 (ECCC) - PSRD2018-01 and PSRD2018-02

In the interest of harmonization and to avoid potential confusion with CCME guidelines, ECCC would like to make PMRA aware of a new R-based SSD program (Thorley and Schwarz 2018) available at: https://poissonconsulting.shinyapps.io/ssdtools/ This program uses maximum likelihood estimation (MLE) for parameter estimation, provides a model-averaging approach for HC_5 derivation and has the ability to handle censored data. PMRA may want to consider using this program to re-run its SSDs as ECCC and CCME will likely be adopting its use for future guideline development. ECCC acknowledges that adopting these changes will result in higher HC_5s. However, we don’t anticipate revisions to the HC_5s will affect the risk assessment conclusions for these two pesticides since the HC_5s are just one set of benchmarks among a suite of benchmarks used by PMRA in its weight of evidence approach for assessing risk.

Health Canada response

Health Canada has conducted a cursory review of the SSD application developed by Poisson Consulting (ssdtools). A more comprehensive review by the PMRA of this and other recently developed or updated SSD packages will be conducted by PMRA in the future.

1.2.3 Acute SSD

Comments were received from Environment and Climate Change Canada (ECCC) related to the acute HC_5 from a fitted species sensitivity distribution (SSD). The comments related to the inclusion of unbound (censored) values, the minimum dataset required for establishing guidelines using SSDs and the validity of certain endpoints included in the SSD.

Comment 16 (ECCC) - PSRD2018-01 and PSRD2018-02

ECCC notes that 5 unbounded values [specifically, four left-censored (i.e. "<") and one right-censored (i.e. ">")] and 3 unbounded values [specifically, 3 left-censored] were included in the short-term SSD as discrete values for clothianidin and thiamethoxam, respectively. CCME (2007) does not support inclusion of left-censored data but allows right-censored data when that is the only data available for a species. ECCC recommends replacement of left-censored data with discrete or right-censored data available from Appendix III of PSRD2018-01 and PSRD2018-02.

Health Canada response:

Health Canada recognizes the uncertainties associated with including censored endpoints in SSDs. In the case of left-censored data (i.e., endpoints less than the lowest tested concentration), the actual toxicity endpoint is expected to be lower, and therefore more conservative, than the censored value derived from the study. In the case of right-censored data (i.e., endpoints greater than the highest tested concentration), the actual toxicity endpoint is expected to be higher, and therefore less conservative, than the derived censored value. In contrast to the CCME (2007) guidance, Health Canada does support the use of left-censored data when they represent the most conservative endpoints for those species. As noted by EFSA (2013) in their guidance criteria for selecting data for use in SSDs, although the use of censored endpoints should be avoided if possible, the exclusion of these data could lead to a loss of valuable information.

Comment 17 (ECCC and Valent Canada Inc) - PSRD2018-01 and PSRD2018-02

Comments were received from ECCC and Valent Canada Inc. regarding the appropriateness of using the *Hyalella* 7-d LC_{50} of 1.65 µg a.i./L as an acute endpoint in the clothianidin risk assessment. Both argued that the different exposure period was not appropriate to include in the determination of the HC_5.

Valent suggested that for the acute risk assessment it would be appropriate to base the toxicity data on exposure regimes of 48 and 96 hours as specified in related guidelines (for example, OECD and OCSPP guidelines). ECCC noted that due to the difference in exposure periods, it is recommended to remove this endpoint from the geomeans for *H. azteca* and use the 96-h EC_{50} values only.

Health Canada response

In the PSRDs for clothianidin and thiamethoxam, Health Canada considered the results from the 7-d exposure for *H. azteca* in the acute risk assessment. However, Health Canada agrees that in order to remove any potential influence of extended exposure time on the observed variability in species sensitivity to acute exposures, Health Canada limited the acute SSD to results for 48–96-hour exposure periods only. For an acute risk assessment, this allows the HC_5 value to be compared against peak surface water EECs, while 7-d sub-chronic results can be compared against EECs from a similar time frame.

Comment 18 (ECCC) - PSRD2018-02

ECCC noted that different exposure periods were used in the geomean calculations for thiamethoxam and recommended the following:

- For A. aegypti ECCC recommends removing the 72-h LC_{50} and using the 24-h LC_{50} (i.e. 183 µg/L) to represent the acute toxicity for this species.
- For Cloeon sp. ECCC recommends removing the 96-h LC_{50} and using the 48-h LC_{50} (i.e. 14 µg/L) to represent the acute toxicity for this species.
- For Cloeon dipterum. ECCC recommends removing the 96-h endpoint and recalculating the geomean with the 2 remaining 48-h EC_{50}s for this species.

Health Canada response

For the acute thiamethoxam SSD, ECCC recommended excluding endpoints of longer duration for three species (*Aedes aegypti*, *Cloeon* sp. and *Cloeon dipterum*), when endpoints from shorter duration experiments were available. All studies with these species were conducted for periods from 24- to 96 hours. For making a final regulatory decision Health Canada included endpoints from 48- to 96 hours only in the acute SSD for thiamethoxam in order to minimize potential variability in toxicity responses due to exposure times.

There is supportive evidence of delayed mortality in invertebrate species from laboratory studies for neonicotinoids. For example, Russo et al. (2018; PMRA# 2978128) observed a decrease in daily survival rates (LC_{50} values) of the mosquito *Culex pipiens* under acute exposure to clothianidin over 144 hours. Therefore, risk based on additional toxicity results from 24-h or 7-d acute studies were assessed separately.

1.2.4 Chronic SSD

Comments were received from a variety of commenters related to the chronic HC_5 SSDs presented in the clothianidin and thiamethoxam PSRDs. The comments related to the following areas:

- the validity of endpoints included in the SSDs
- the minimum number of species endpoints for SSD determination
- the inclusion of sensitive and insensitive species in the same SSD

Comment 19 (ECCC) - PSRD2018-01 and PSRD2018-02

It was noted that some recently published chronic data from Raby et al. (2018) were not included in the SSD and that there may be a need to reconcile the Raby et al. (2018) and the Cavallaro et al. (2017) data which are over an order of magnitude lower, perhaps due to procedural differences.

Health Canada response

Recently published chronic data from Raby et al. (2018b, 2018c, 2018d) have been considered for the special review decision. Comments on the validity and use of the Cavallaro et al. (2017) study are provided in Section 1.1.1 above.

Comment 20 (ECCC) - PSRD2018-01

ECCC notes that there is a large amount of uncertainty in the chronic HC_5 for clothianidin (confidence limit ranging over 5 orders of magnitude) based on a limited dataset (n = 5) of invertebrates only. ECCC recommends PMRA derive their long-term benchmark for clothianidin according to the Type B2 approach of applying an uncertainty factor to the most sensitive endpoint (CCME 2007):

- Type B2 guideline = 0.002 µg a.i./L, based on 28-d EC_{20} (emergence) in *C. dilutus* (0.02 µg a.i/L) divided by 10.

Health Canada response

Health Canada agrees with ECCC's assertion that there is a large amount of uncertainty around the chronic HC_5 for clothianidin. This point is supported by the width of the confidence limits about the HC_5. Health Canada's current protection goals for chronic exposure to wildlife do not require the use of additional safety factors on the chronic endpoints. Therefore, the recommended 10-fold safety factor used in the CCME approach is not required. Given the absence of a sufficient dataset for the derivation of a chronic SSD for clothianidin, Health Canada did not generate an HC_5 for the revised chronic risk assessment for the final regulatory decision; rather Health Canada used the geomean of available emergence endpoints for the most sensitive species, *Chironomus dilutus*. The chronic HC_5 presented in PSRD2018-01 is revoked and an HC_5 was not determined for the final regulatory decision.

Comment 21 (ECCC) - PSRD2018-02

ECCC notes that the chronic thiamethoxam SSD does not meet the CCME (2007) requirements for a Type A guideline; however, they acknowledge that because fish are relatively insensitive to neonicotinoids, they support the proposed SSD approach based on invertebrate data only. Although the invertebrate dataset meets the minimum sample size (n=7), they indicate there is a large amount of uncertainty associated with the PMRA's chronic HC_5, as indicated by the broad confidence limits ranging over 4 orders of magnitude. To reduce the observed uncertainty, ECCC recommended PMRA use the CCME's preferred endpoints for Cavallaro et al. (2017) (40-d EC_{20} sex ratio = 0.31 µg a.i./L) and ECCC (2017) (28-d EC_{10} growth = 71 µg a.i./L), using the R-based SSD program (*ssdtools*; Thorley and Schwartz 2018). The resulting recommended HC_5 based on a model-averaged distribution = 0.1 µg a.i./L (95% CI: 0.01–4.59 µg a.i./L) [best fit: LogGumbel model].

Health Canada response

Health Canada did not generate an HC_5 for the revised chronic risk assessment for the final regulatory decision on thiamethoxam and will continue to rely on the higher-tiered acceptable mesocosm endpoint identified in PSRD2018-02 in making a final regulatory decision. The chronic HC_5 presented in PSRD2018-02 is revoked and an HC_5 was not determined for the final regulatory decision.

See Science Section of SRD for further details.

Comment 22 (Saskatchewan Ministry of Agriculture) - PSRD2018-01

The Saskatchewan Ministry of Agriculture expressed concern that the Health Canada chronic HC_5 value of 0.0015 µg a.i./L for clothianidin is more than an order of magnitude lower than the USEPA reference value of <0.05 µg a.i./L for the most sensitive species (*C. dilutus*).

Health Canada response

The USEPA reference value of <0.05 µg a.i./L is based on their identified LOEC for a reduction in *C. dilutus* emergence from Cavallaro et al. (2017). Health Canada used the regression-based EC_{20} of 0.020 µg a.i./L for *C. dilutus* emergence from this same study in the derivation of the chronic HC_5 value of 0.0015 µg a.i./L presented in PSRD2018-01. As a reliable NOEC could not be established due to significant effects at the lowest treatment dose of 0.046 µg a.i./L and an acceptable EC_{20} was derived, Health Canada considers the use of the regression-based endpoint value to be appropriate for this study. However, it was also noted that due to uncertainties in the chronic SSD, the HC_5 value was not used in making the proposed regulatory decision.

Comment 23 (Valent Canada Inc. and Bayer CropScience) - PSRD2018-01

Valent Canada Inc. and Bayer CropScience both indicated that the chronic clothianidin SSD based on five endpoints is not suitable for use in a regulatory risk assessment framework. Bayer contends that Health Canada's justification for the small dataset was based on a review of Belanger et al. (2017) that is premised on an apparent misreading of this study, where it identifies minimum requirements from two regulatory agencies (Australia and New Zealand) in very limited circumstances that do not apply here (i.e., the five species are from a minimum of four phyla, which was not the case for clothianidin). In order to have confidence that an SSD-based endpoint is protective of the organisms it is intended to protect, it must include the minimum number of species-based endpoints as outlined by current global regulatory authority frameworks. It was suggested by Valent that Health Canada should be following EFSA's aquatic risk assessment guidance (EFSA, 2013), which requires 8 toxicity endpoints for different species of the relevant taxonomic groups for an invertebrate SSD analysis to establish the HC_5 value. When the number of toxicity data are less than 8, a geometric mean value should be used according to EFSA guidance. A geometric mean toxicity value for single species should also be used when two or more data are available for the same species.

Bayer CropScience further recommends that Health Canada should consider all reliable data for *Chironomus dilutus* in the assessment which may require the use of a geometric mean of endpoints from multiple studies for this species.

Health Canada response

Health Canada agrees that there were significant uncertainties associated with the limited dataset for the clothianidin chronic SSD and as a result, did not use the chronic HC_5 in making its proposed regulatory decision (PSRD2018-01). The uncertainties included the limited number of species and the mix of effects endpoints (mortality, reproduction and emergence). Consequently, the chronic HC_5 presented in PSRD2018-01 is revoked and an HC_5 was not determined for the final regulatory decision.

Health Canada agrees that a geometric mean value should be determined when two or more equivalent endpoints are available for the same species. This approach is routinely used for constructing SSDs and will also be used in the risk assessments where an SSD cannot be determined. For clothianidin a geometric mean for the most sensitive species of 0.12 µg a.i./L for *Chironomus dilutus* will be considered in the risk assessment (see Science Evaluation Section for more information).

1.2.5 Inclusion of sensitive and insensitive species

Comment 24 (Bayer CropScience) - PSRD2018-01

Bayer CropScience indicated that the SSDs should not have combined results from sensitive and insensitive organisms for either the acute or chronic distributions. They argue that in the case of clothianidin, bimodal (chronic SSD) or multimodal distributions (acute SSD) are evident and that separate SSD curves should have been fitted to the data for sensitive and insensitive (tolerant) organisms to derive thresholds for the risk assessment.

For clothianidin, Daphnia magna is an insensitive species, and should not be included in the SSD with sensitive species (for example, aquatic insects) because its inclusion results in a poor fit of the curve to the data resulting in an artificially low endpoint (5th percentile hazard concentration; HC_5). Removal of the Daphnia magna endpoint allows for the curve to be fit better to the endpoint for sensitive species which generates a more robust endpoint (HC_5) that is protective of sensitive species, and inherently protective of less sensitive organisms like Daphnia magna.

Health Canada response

The PMRA is not considering a chronic aquatic invertebrate SSD for clothianidin.

The PMRA does not support the removal of *Daphnia* (or other less sensitive species with demonstrated adverse responses to exposure), from the upper end of the distribution in the clothianidin acute SSD, because the fit of the curve is acceptable based on ETX 2.1 normality test results. The resulting acute HC_5 = 1.5 µg a.i./L is close to the lowest acute endpoint for *Graphoderus fascicollis* (48-h LC_{50} = 2.0 µg a.i./L).

1.3 Environmental fate assessment

Comment 25 (Syngenta) - PSRD2018-02

Syngenta Canada Inc. submitted two studies on thiamethoxam degradation in laboratory and outdoor soils for consideration to Health Canada.

Hilton, M.J., S.N. Emburey, P.A. Edwards, C. Dougan and D.C. Ricketts. 2018. The route and rate of thiamethoxam soil degradation in laboratory and outdoor incubated tests, and field studies following seed treatments or spray application. Pest Manage. Sci. DOI 10.1002/ps.5168. PMRA# 2935275.

Herrchen, M. 2015. Thiamethoxam – Aerobic Soil Metabolism of 14C-thiamethoxam (Foliar Applied). Final Report. DACO: 8.2.3.4.2. PMRA# 2935274.

Health Canada response

The Hilton et al. (2018) published study reports aerobic soil dissipation rates for thiamethoxam in a number of laboratory soils (i.e., OECD TG#307 studies), semi-field (i.e., soil cores held outdoors) and field soils (applied either as a spray solution or as a seed treatment). The Herrchen (2015) unpublished study is a registrant report of the OECD TG #307 studies contained within the Hilton et al. (2018) publication. The DT_{50} values reported for the various soil types were similar to the lower ranges of those previously considered in the environmental fate review for thiamethoxam and used to model surface water EECs (PSRD2018-02).

Following the publication of PSRD2018-02, Health Canada has received a significant amount of new water monitoring data for thiamethoxam levels in Canadian surface waters that were considered in the final decision. Revised inputs for aerobic soil dissipation were considered where appropriate in the risk assessment for the final regulatory decision.

1.4 Water modelling assessment

Comment 26 (Canola Council of Canada, Alberta Canola Producers Commission, Saskatchewan Canola Development Commission) - PSRD2018-01 and PSRD2018-02

A critique of Health Canada's water modelling assessment indicated that the PMRA needs to consider the uncertainties around the use of the Pesticides in Water Calculator (PWC) model. It was noted that Xie et al. (2018) have shown that the PWC model overestimates the concentration of pesticides in lentic (non-flowing) and lotic (flowing) water bodies. Xie et al. (2018) demonstrated that the model can closely simulate the greatest of maximum concentrations in an agricultural pond over a 30-year period, but overestimates the greatest of maximum concentrations under any other water body scenarios. It was also suggested that if the authors had used the entire monitoring dataset and not just the maximum concentrations, the model overprediction would have been much greater. This is not unexpected as the model has been designed to be conservative and protective.

It was argued that Health Canada had not outlined any of the uncertainties or conservatism in the PWC model and appeared to give greater weight to the data from the PWC model compared to the monitoring data generated in 2017 and previous years. There are certainly weaknesses and uncertainties within the monitoring data set, but these are concentrations that have been measured in the field as opposed to concentrations simulated by a model that is known to overpredict by orders of magnitude.

It was suggested that the PMRA provide guidance on the data that is needed to generate a robust monitoring data set that they think would reduce the uncertainty in their risk assessment, as making their risk conclusion based on the data generated from the PWC model introduces a relatively large amount of uncertainty.

Xie, Y., Luo, Y., Singhasemanon, N., Goh, K., 2018. Regulatory modelling of pesticide aquatic exposures in California's agricultural receiving waters. Journal of Environmental Quality.

Health Canada response

Health Canada recognizes the conservative nature of the PWC modelling, which is intended to protect human health and the environment. Some of the conservative assumptions are systematic, such as those built into modelling scenarios or those related to the choice of modelled water bodies. Conversely, others are specific to the modelled compound or use pattern. For example, conservative assumptions could be a result of uncertainties in the fate data or variations in agronomic practices across regions.

Health Canada uses both computer modelling and available monitoring data to estimate the potential exposure of aquatic organisms to pesticides in water. For this final special review decision, monitoring was used preferentially for the risk assessment. Modelling results were used in areas where monitoring information was not available.

The PMRA currently relies on federal, provincial and municipal departments and agencies as well as researchers to provide water monitoring data. Given the conservatisms described above, concentrations from modelling are generally considered as upper bound estimates. It is understood that a strong monitoring dataset provides a more realistic picture of potential exposure. Robust monitoring information on pesticide residues in water can significantly inform risk assessments.

The uncertainties associated with the monitoring information available to Health Canada prior to the publication of its proposed decisions on clothianidin, thiamethoxam and imidacloprid were outlined in PSRD2018-01, PRSD2018-02 and PRVD2016-20. Health Canada shared information on what is needed to make monitoring data more useful to Health Canada with members of Agriculture and Agri-Food Canada Multistakeholder Forum's Environmental Monitoring Working Group. Since the publication of the proposed decisions, a large amount of water monitoring data from several provinces across Canada have been generated and submitted to the PMRA.

The new monitoring data are of high quality, robust and address many of the uncertainties previously raised by Health Canada. They have significantly informed the updated risk assessments.

Comment 27 (Saskatchewan Ministry of Agriculture) - PSRD2018-01

The Saskatchewan Ministry of Agriculture agrees with the following PMRA statement in the PSRDs *"the EECs generated are likely to be higher than actual concentrations present in waterbodies"*. Points were made regarding modelling inputs including the following:

- *Photolysis half-life (day) – the Saskatchewan Ministry of Agriculture noted that the photolysis half-life as measured at 33.45° latitude which is associated with the Arkansas-Louisiana (USA) border. Since the major route of dissipation for clothianidin (and thiamethoxam) is photolysis, day length contributes strongly to this effect.*
    - *Day length at 33.45° is 13 hours, 52 minutes.*
    - *Day length (June in Regina), representing the southernmost latitude associated with seed treatment usage in the Canadian Prairies, is 16 hours, 26 minutes.*
    - *Day length (June in High Level, AB), near the northern limit of canola production, is 18 hours, 20 minutes.*
    - *Please see Forsythe* et al. *(Ecological Modelling 80.1 (1995): 87-95.).*
- *USEPA (EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola (PC Code 044309; DP Barcode: D278110) indicated anaerobic aquatic metabolic degradation of clothianidin with a half-life of 14 days. The USEPA model concurs with the conclusions of Bayer Crop Science in regards to their 2018 work with the Environmental Monitoring Working Group (D. Dyer Personal communication). Why did PMRA include 18.5 days in the model, this was not clear.*
- *We request that the models be re-run with relevant environmental inputs.*

Health Canada response

The model input for aqueous phototransformation was a half-life of 0.6 days based on the light intensity for Phoenix (Arizona), which lies at a latitude of 33.45°N (as reported in original study PMRA# 1194126). The current version of PWC adjusts the half-life to a default latitude of 40°N. Once the value is adjusted for latitude, the model will further adjust the value to account for light attenuation within the water column. The latter adjustment has a larger impact on photodegradation than adjusting latitude.

However, it is important to note that PWC assumes the same rate of phototransformation all year, not adjusting for variations in light intensity with time. While this may be initially perceived as an underestimation of phototransformation in the summer months (as stated in the comment), phototransformation in the winter months is likely to be overestimated. Furthermore, the model does not adjust the half-life for cloud cover, thus further favouring phototransformation. Taking all above considerations into account, the half-life used in the modelling is believed to be reasonable for risk assessment purposes.

The anaerobic half-life of 18.5 days at 20°C was calculated using PMRA standard kinetics degradation tools, following NAFTA guidance established initially in 2011 (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedure-using-nafta-guidance). This calculation was verified and confirmed to be correct. A sensitivity analysis was conducted to assess how the shorter value would impact modelling results.

Results show that water column and sediment pore water EECs pore water would be reduced by ~2% and ~6%, respectively, if the shorter half-life was used in the modelling. These changes would not affect the risk assessment conclusions. A complete revision of the surface water modelling was not conducted for the final regulatory decision.

1.5 Water monitoring assessment

1.5.1 Water monitoring program guidance

Comment 28 (Canola Council of Canada, Alberta Canola Producers Commissions, Saskatchewan Canola Development Commission, Pulse Canada, Producteurs de grains du Québec) - PSRD2018-01 and PSRD2018-02

A number of commenters indicated that meaningful guidance should be provided by Health Canada to help guide water monitoring programs so that samples are collected at the appropriate intervals with the necessary ancillary data.

Pulse Canada further suggested that a consistent, publicly funded, pan-Canadian water monitoring framework that includes other pesticides and urban contaminants of concern is needed. They acknowledged that while Health Canada is not mandated with the development or collection of water monitoring data, the Agency relies on this information to make informed decisions.

The Producteurs de grains du Québec suggested that implementing a harmonized monitoring protocol across different regions of Canada involving the sampling of waterbodies three times per week, as is being done by the province of Quebec, would allow for a more precise estimate of pesticide concentrations in waterbodies, and would result in a database of consistently collected data representative of all regions of Canada. They stated that a sampling frequency of three times per week allows for the capturing of peak concentrations, and mentioned that the exposure period in acute laboratory toxicity studies included in species sensitivity distributions is longer than two days.

Health Canada response

Health Canada provided guidance documents on monitoring data for neonicotinoids to members of Agriculture and Agri-Food Canada's Multi-stakeholder Environmental Monitoring Working Group in January 2017. Similarly, guidance on limits of detection was shared with the working group members in March 2018. Health Canada discussed the planning and results of specific water monitoring programs for the 2018 and 2019 seasons with various stakeholders including registrant companies, provincial governments, and organizations such as the Canola Council of Canada through conference calls, emails, and face-to-face meetings.

Health Canada acknowledges that a higher frequency of sampling increases the likelihood of capturing peak concentrations in waterbodies. With some exceptions like the monitoring programs in Quebec, the sampling programs typically involved weekly or biweekly sampling, which are better suited to estimate longer-term exposure levels. The uncertainty in the estimation of peak concentrations using monitoring data in relation to the potential for acute risks from exposure to clothianidin or thiamethoxam is discussed in Section 1.4.4 (Uncertainties Identified in the Risk Assessment – Monitoring).

Health Canada is in favour of a pan-Canadian monitoring framework for the development and collection of monitoring data on pesticides in water to inform its regulatory decisions. Health Canada is collaborating with stakeholders as well as Agriculture and Agri-Food Canada and Environment and Climate Change Canada to develop a framework for a National Water Monitoring Program.

1.5.2 Reporting limits

Comment 29 (Alberta Seed Processors, Valent, Saskatchewan Association of Rural Municipalities, Grain Farmers of Ontario) - PSRD2018-01 and PSRD2018-02

Comments were received related to the use of 50% of the limit of detection (LOD) when clothianidin or thiamethoxam were not detected in the sample. Alberta Seed Processors felt that by using this method the data presented in the PSRDs are a misrepresentation of the data collected as a sample without a detection should be presented as a zero value.

Valent indicated that from the viewpoint of scientifically sound risk assessment, it is inevitable that an analytical method used for monitoring must ensure the measurement of clothianidin in the actual waterbodies at the critical concentration level required for the precise evaluation. In the case of clothianidin, the LOD for monitoring should be ideally set lower than the chronic HC_5 of 0.0015 μg/L. However, when "assigning half the limit of detection to non-detected samples" in this assessment many of the concentrations reported are higher than the HC_5 given the LODs reported. Valent feels this is misleading given that these concentrations were used throughout the evaluation process to determine no acceptable risk in comparison with the level of concern (HC_5 = 0.0015 μg a.i./L). It is suggested that every non-detect sample from monitoring studies with a LOD exceeding 0.005 μg a.i./L should be described in the footnotes as "not reliable data for the accurate evaluation", be removed them from the risk assessment, and this omitted data ratio should be clarified in the document.

Similarly, the Grain Farmers of Ontario requested further clarification as to how the water monitoring datasets were assessed in the risk assessment for clothianidin, given that the chronic HC_5 value was at, or below the LOD in several surface water monitoring programs.

The Saskatchewan Association of Rural Municipalities also expressed concerns with setting non-detect (no residue) samples at 50% of the LOD and questions why this percentage has been established in the Health Canada's Science Policy Note SPN2004-01, Estimating the Water Component of a Dietary Exposure Assessment to interpret non-detects in monitoring data sets.

Health Canada response

Health Canada routinely assigns a value of 50% of the limit of detection to samples showing no detected concentrations. This method is also used by other jurisdictions to analyze water monitoring data. Health Canada acknowledges that this can lead to an overestimation of exposure, but the approach is considered conservative and protective of Canadians and their environment.

The analytical limits of all the monitoring programs considered in the final special review decisions are all well below the effects metrics for clothianidin and thiamethoxam. As such, samples showing non-detections of neonicotinoids no longer have estimated concentrations that exceed the level of concern.

1.5.3 Regional considerations

Several comments were received related to regional difference across Canada and how that may affect concentrations detected in water bodies.

Comment 30 (Saskatchewan Association of Rural Municipalities) - PSRD2018-01 and PSRD2018-02

The modelling efforts of the Estimated Environmental Concentration (EEC) excluded Alberta and those datasets from Saskatchewan and Manitoba lacked information on crops grown and neonicotinoid use within the watersheds which the PMRA indicated, "…limited our ability to relate [concentration] levels observed with a particular use [and] a site-by-site comparison of precipitation levels with the 30 year historical averages was conducted and demonstrated that precipitation levels were uncharacteristically low." SARM is not comfortable with the flawed methodology and inferior data that has been used by the PMRA to propose their decisions on Clothianidin and Thiamethoxam.

Health Canada response

Runoff EECs for clothianidin and thiamethoxam in the prairies were characterized by modelling the use of these neonicotinoids on several crops with regional scenarios and weather information for Manitoba and Saskatchewan. The modelling results were also considered representative of conditions and neonicotinoid use in Alberta. At the time of the proposed decision there were considerable uncertainties with the monitoring data available for the Prairie Region. Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies in agricultural areas of Manitoba, Saskatchewan and Alberta were submitted to

Health Canada. The monitoring data and the ancillary information submitted, which included land use and precipitation information have been considered in the revised assessment for the special reviews of clothianidin and thiamethoxam.

Comment 31 (Alberta Seed Processors, Grain Farmers of Ontario, Producteurs de grains du Québec, Saskatchewan Pulse Growers) - PSRD2018-01 and PSRD2018-02

A number of commenters expressed concerns that Health Canada extrapolated water monitoring results across the country. It was noted that the cropping practices, pesticides used and weather patterns are vastly different between different regions of Canada. The Grain Farmers of Ontario indicated the following statement made by Health Canada in the PSRD is open to debate and should not be made without consideration of the variability in site conditions that can be influenced by multiple environmental conditions.

> *"In areas where clothianidin is used but monitoring data are lacking, there is no reason to believe that detection patterns would differ compared to those observed in areas where monitoring data are available".*

Health Canada response

Health Canada recognizes the differences in cropping practices and environmental conditions between Eastern and Western Canada. Without sufficient monitoring data to account for these differences at the proposed decision stage, Health Canada used the available data and made conservative assumptions regarding potential levels of neonicotinoids in waterbodies across Canada. Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies in agricultural areas across Canada were submitted to Health Canada. The monitoring data and the ancillary information submitted, which included land use and precipitation information, and have been considered in the revised assessment for the special reviews of clothianidin and thiamethoxam.

Comment 32 (British Columbia Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

The British Columbia (BC) Ministry of Agriculture suggest that the data generated for imidacloprid in 2017 and 2018 should be used as a surrogate for clothianidin and thiamethoxam, as this represents two additional years of quality data generated from British Columbia. Over this 2-year sampling period there have been no levels of neonicotinoids detected from the five watersheds sampled in the Okanagan Valley that were above the chronic levels set by Health Canada. In 2018 there were no detections of any neonicotinoid at all from the water samples collected.

It was pointed out that imidacloprid is the preferred neonicotinoid used in the Okanagan Valley. The BC Ministry of Agriculture argues that given the similarity in fate and behaviour in the environment as indicated in PRVD2016-20, PSRD2018-02 and PSRD2018-01 and because is it known that imidacloprid was applied to crops in these watersheds, the results can be applied to clothianidin and thiamethoxam as surrogates. Therefore, given that there were no detections of imidacloprid in any of the water samples the BC Ministry of Agriculture is suggesting that the same should apply to the other neonicotinoids. With these results it would suggest that the use pattern of neonicotinoid pesticides on the crops that are grown in the Okanagan Valley do not pose any problem in the watershed and therefore registration of these pesticides on the crops in the Okanagan Valley should continue.

Health Canada response

Health Canada recognizes that the use of the neonicotinoids can be regional (i.e., where one of clothianidin, thiamethoxam or imidacloprid are used preferentially in certain areas of the country). It is not routine to extrapolate water monitoring information between different pesticide active ingredients as the use pattern for one pesticide may differ from another (even if they fall within the same family of pesticides and the fate parameters are similar). Many factors influence the presence of a particular active ingredient in waterbodies including weather and topography. However, based on levels of imidacloprid seen in the water monitoring results from the Okanagan Valley, it is expected that similar results would be observed if clothianidin or thiamethoxam were to be used in that area. It should be noted that up until the pollinator re-evaluation decisions, the registered uses of neonicotinoids in the Okanagan Valley of British Columbia was mainly on orchard and vineyard crops. Following the publication of the final pollinator decisions for clothianidin, thiamethoxam and imidacloprid, the use of these neonicotinoids on orchards crops is cancelled.

Comment 33 (Saskatchewan Ministry of Agriculture, Canola Council of Canada, Alberta Canola Producers Commission, Saskatchewan Canola Development Commission, Team Alberta) - PSRD2018-01 and PSRD2018-02

A number of commenters raised concerns regarding Health Canada's decision to place less weight on the monitoring data in 2017 given the lack of precipitation.

The Saskatchewan Ministry of Agriculture evaluated precipitation data from Environment and Climate Change Canada weather stations in five locations of Saskatchewan to assess whether differences in overall precipitation existed between years in regions generally characterized by different moisture regimes. Based on their analysis, 2017 and 2018 were not anomalously dry years throughout Saskatchewan. So, water monitoring data from this period must be considered valid and utilized in full during the evaluation process. In support of their comments on the acceptability of 2017 and 2018 water monitoring data from the province, the Saskatchewan Ministry of Agriculture included statistical summaries of their precipitation comparisons as well as an appendix of water temperatures, streamflow, precipitation and detection and concentrations of neonicotinoids at several locations in Saskatchewan.

The Canola Council of Canada, Alberta Canola Producers Commission, Saskatchewan Canola Development Commission and Team Alberta requested that Health Canada consider the actual climate conditions in Canada, during which clothianidin and thiamethoxam have been used since their registration.

They indicated that large parts of Western Canada are currently experiencing water conditions ranging from moderate to severe drought. This has been the case for the last ten years, during which time the use of clothianidin and thiamethoxam has become widespread in Western Canada.

Health Canada response

Since the publication of the proposed special review decisions, additional monitoring data and precipitation information for the Prairie Region in 2018 and 2019 was submitted to Health Canada, including daily precipitation received at sampling sites or at nearby weather stations, and 30-year normal precipitation information. Health Canada considered this information for the revised assessment.

Overall, precipitation levels received in the sampled areas of the Canadian Prairies during the 2018 and 2019 growing seasons were considered to be representative of a typical year. As such, the levels of neonicotinoids measured in waterbodies as a result of runoff in the Canadian Prairies in 2018 and 2019 are expected to represent those found in a typical year. The additional monitoring data and precipitation information for the 2018 and 2019 growing seasons addressed the uncertainties previously noted with the 2017 data. The monitoring data from the Prairies for 2017, 2018 and 2019 were considered in full in the revised assessment.

1.5.4 Chronic exposure period

Comment 34 (CropLife Canada, Saskatchewan Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

Concerns were raised related to the comparison of chronic endpoints to peak concentrations detected in the Prairie Provinces when sampling frequency was not sufficient to estimate comparable exposure estimates. CropLife Canada stated that this comparison resulted in a critical misrepresentation of the water monitoring data and an over-estimation of potential risk and that single sample concentrations should be compared to acute endpoints since they represent a short exposure period, while mean concentrations should be compared to chronic endpoints in order to evaluate risk over a longer period.

In addition, the Saskatchewan Ministry of Agriculture highlighted the need to fully understand the duration of exposure when evaluating effects in relation to the following statement from PSRD2018-01: *"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."*

Comment 35 (Canola Council of Canada, Alberta Canola Producers Commission, Saskatchewan Canola Development Commission) - PSRD2018-01 and PSRD2018-02

A number of commenters indicated that since chronic exposure likely represents the greatest driver of unacceptable risk for the neonicotinoids, an understanding of the frequency at which chronic exposure is occurring at levels of concern in Canadian surface waters and how this varies across different landscapes is important. *"Many of the samples* *taken as part of the monitoring programs available in provinces have not been taken with sufficient frequency at sites during the growing season to understand the temporal dynamics of the concentration of thiamethoxam and clothianidin in surface waters. This has resulted in PMRA taking the conservative approach of assuming that maximum, average or median concentrations reported in the monitoring data are chronic." It is felt that data on whether chronic exposure is occurring in Canada's surface waters is limited.*

Health Canada response (comment 35 and 36)

Since the publication of the proposed special review decisions, a large amount of additional monitoring data on neonicotinoid concentrations in waterbodies in agricultural areas across Canada including the Prairies were submitted to Health Canada. While each monitoring program varied, sampling was typically weekly or biweekly throughout the growing season, thereby allowing for an estimation of chronic exposure levels in water. Moving average concentrations of clothianidin and thiamethoxam over 28 days were calculated and compared to chronic toxicity endpoints in the revised assessment for the final special review decisions. While most sites had one or two years of monitoring data, some sites were monitored for up to three years in the Prairies and up to eight years in other regions of Canada. Whether levels of neonicotinoids measured at a particular site exceeded the level of concern over multiple years was a factor considered in the final special review decisions.

1.5.5 Clothianidin exposure/monitoring assessment comments

Comment 36 (Valent) - PSRD2018-01

Valent submitted a comment related to the potential contribution of the use of thiamethoxam to concentrations of clothianidin in water.

As this risk assessment report is specifically prepared for clothianidin, special care should be given for the assessment scenario in which the difference between monitoring concentration and endpoint value (HC_5) is small, taking into account possible overestimation of the former due to the transformation product of thiamethoxam.

Health Canada response

The effects metrics used in the final special review decision for clothianidin have changed since the publication of PSRD2018-01. As clothianidin is a soil transformation product of thiamethoxam, the use of thiamethoxam may contribute to the presence of clothianidin in waterbodies. Results of a monitoring program involving the intensive sampling of 92 Prairie wetlands in 2018 and 2019 were used to assess the potential contribution of thiamethoxam seed-treatment use to clothianidin concentrations in wetland water (see monitoring section, Science Evaluation Update). This information was included in the revised assessment for clothianidin.

Comment37 (Bayer CropScience) - PSRD2018-01 and PSRD2018-02

In calculating the impact of runoff from crops treated with clothianidin, the PMRA has relied on outlier data from water monitoring studies that are not representative of typical conditions. Some of the outlier data said to be from wetlands was in fact from: an ephemeral edge-of-road area which is not a true *wetland; a wetland with a very high (atypical) field to wetland area; a watercourse; and an area with abnormally high drainage conditions; none of which represent true wetland conditions. These outlier data stand in stark contrast to monitoring data from representative sites under typical conditions which show that average clothianidin concentrations are typically below the PMRA's overly conservative endpoint of 20 ng/L for the monitoring season.*

Health Canada response

Health Canada considered available monitoring data from all water body types when assessing risk for the proposed special review decisions, with the exception of ephemeral waterbodies like puddles. Site information was not available for all sites considered in the assessment for the proposed decision. Health Canada acknowledges that site information is important to assess whether a waterbody is relevant for the purposes of an aquatic risk assessment.

The assessment was revised based on the comments received, and sites for which information was not available to assess their relevance to an aquatic risk assessment were not considered in the revised assessment.

Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada were submitted to Health Canada. The sites monitored included multiple wetlands representative of those found in the Prairie Region. Health Canada considered the new monitoring data and ancillary information in the revised assessment for the special reviews of clothianidin and thiamethoxam.

Comment 38 (Bayer CropScience) - PSRD2018-01

Bayer CropScience raised concerns around the choice of endpoint for use in the clothianidin chronic risk assessment in addition to comparisons of single peak concentrations from monitoring data with chronic toxicity endpoints.

PMRA's evaluation of Prairie wetland concentrations (PSRD2018-01, p. 31), focused on comparison to the HC_5 which is no longer the chronic endpoint being used by PMRA. Therefore, at a minimum, the comparison should be to the EC_{20} value of 0.02 μg/L (20 ng/L), and more appropriately, (…) to the mesocosm endpoint of 0.281 μg/L (281 ng/L). Also, (…) clothianidin dissipates rapidly in wetlands, and therefore comparison of single point acute concentrations to chronic endpoints is not appropriate.

Health Canada response

Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada was submitted to Health Canada. The sites monitored included multiple wetlands representative of those found in the Prairie Region. Health Canada considered the new monitoring data and ancillary information in the revised assessment for the special reviews of clothianidin and thiamethoxam.

The intensive sampling of many Prairie wetlands allowed for the characterization of the dissipation of clothianidin in these waterbodies. The data allowed for an estimation of chronic exposure levels in water over a 28-day period, which is considered representative of the exposure period for laboratory and mesocosm toxicity studies. In the revised risk assessment, the 28-day average concentrations measured in the Prairie wetlands have been compared to the revised chronic toxicity endpoints for clothianidin.

Comment 39 (Bayer CropScience) - PSRD2018-01

Bayer CropScience submitted new 2018 and 2019 monitoring data and ancillary information for wetlands in the Prairies and waterbodies in two watersheds of southwestern Ontario. In addition to the data, Bayer CropScience submitted detailed comments and site- and watershed-specific analyses for new and previously considered monitoring information from sites such as wetlands in the Prairies and waterbodies in Ontario and Prince Edward Island. Bayer CropScience compared the concentrations measured with the proposed toxicity endpoints, and commented on the acceptability of clothianidin use based on their analyses.

Health Canada response

Health Canada considered all the comments, new monitoring data and ancillary information received in the revised assessment for the special review of clothianidin.

1.5.6 Thiamethoxam exposure/monitoring assessment comments

Comment 40 (Syngenta Canada Inc) - PSRD2018-02

Syngenta Canada Inc. submitted new monitoring data and ancillary information for wetlands in the Prairies in 2018 and 2019 and flowing waterbodies in Ontario in 2019. In addition to the monitoring data, Syngenta Canada Inc. submitted detailed comments and site-and watershed-specific analyses of new and previously considered monitoring information on thiamethoxam in waterbodies across Canada. Thiamethoxam concentrations in waterbodies were characterized according to the main agricultural practices, such as crop types and application methods relevant to thiamethoxam use in Western Canada, Ontario, Quebec and the Maritimes. Syngenta Canada Inc. compared the measured water concentrations with the proposed toxicity endpoints for thiamethoxam and commented on the acceptability of thiamethoxam use based on their analyses. Factors potentially reducing the use of thiamethoxam, such as provincial regulations on the sale and use of neonicotinoids in Ontario and Quebec were also discussed.

Health Canada response

Since the publication of the proposed special review decision, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada was submitted to Health Canada. Health Canada considered all the comments, new monitoring data and ancillary information received in the revised assessment for the special review of thiamethoxam.

1.6 Risk assessment

1.6.1 Definition of "acceptable risk"

Comment 41 (CropLife Canada) - PSRD2018-01 and PSRD2018-02

While CropLife Canada remains strongly supportive of the PMRA's statutory obligation to ensure registered pest control products do not pose an unacceptable risk to human health or the environment, we believe the Agency needs to clarify the definitions of "acceptable" and, by extension, "unacceptable" that were applied in the reviews detailed in PSRD2018-01 and PSRD2018-02.

Health Canada response

Subsection 2(2) of the *Pest Control Products Act* states that the health and environmental risks of a PCP are acceptable if there is reasonable certainty that no harm to human health, future generations, or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration. The determination of whether risks are acceptable involves an assessment of whether or not harm will be caused to the environment. What constitutes harm is based on the professional judgement of PMRA scientists and takes into account many variables including, but not limited to, the type of adverse effect, the duration of the adverse effect, and the type and number taxa affected. There is no definition of unacceptable risk in the Act and a decision to allow continued registration is based on whether or not the available scientific information is sufficient to give Health Canada reasonable certainty that the risks are acceptable.

1.6.2 Influence of temperature on toxicity

Comment 42 (Saskatchewan Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

The Saskatchewan Ministry of Agriculture submitted arguments that neonicotinoid toxicity is mediated by water temperature and that risk conclusions for clothianidin and thiamethoxam should consider timing of exposure. It was also requested that the risk quotients (RQ) determined by Health Canada be revisited with more realistic exposure/toxicity values that are statistically rigorous and representative of life history and metabolic considerations of the organisms.

Information was provided to support that *"time-to-effect for sublethal impairment and immobility was significantly decreased with increasing temperature"* and that aquatic insects had significantly increased neonicotinoid (imidacloprid) uptake with increasing temperatures. With this information the Saskatchewan Ministry of Agriculture stated that it is important to consider the metabolic rates of exothermic organisms like arthropods as it relates to toxicity and therefore environmental impacts.

Given that planting of treated seed occurs primarily in the spring and proximal aquatic arthropods would be subject to much cooler temperatures than those used to develop chronic endpoints, it is suggested that uptake and toxicity would be reduced under these conditions. Saskatchewan Ministry of Agriculture make the claim:

This suggests that real-world toxicity and therefore effects of these substances are likely exaggerated by laboratory results and that it is inappropriate to assume that endpoint values generated at elevated temperatures are applicable to springtime arthropod populations in temperate regions like the Canadian Prairies.

The following references were provided:

Camp A., and D.B. Buchwalter. 2016. Can't take the heat: Temperature-enhanced toxicity in the mayfly Isonychia bicolor exposed to the neonicotinoid insecticide imidacloprid. Aquatic Toxicology. 178: 49–57.

Lydy, M. J., J. B. Belden & M. A. Ternes, 1999. Effects of temperature on the toxicity of M-parathion, chlorpyrifos, and pentachlorobenzene to Chironomus tentans. Archives of Environmental Contamination and Toxicology 37: 542–547.

Milton, Texas Tech University, PhD diss., 2015

Health Canada response

Health Canada is aware that temperature-enhanced toxicity in mayfly and other insect larvae exposed to imidacloprid is observed under laboratory conditions (Camp and Buchwalter, 2016 – PMRA# 2796398, Van den Brink et al., 2016 – PMRA# 2712707). However, Health Canada considers the laboratory toxicity assays conducted under standard environmental conditions to cover relevant toxicokinetic pathways and are therefore valid for use in the risk assessment. To our knowledge there are no neonicotinoid-specific temperature correction factors for use in the risk assessment.

In addition to the influence of temperature on toxicity to aquatic insects, seasonal differences in sensitivity are reported. Notable differences in sensitivity are apparent between laboratory studies conducted with Cloeon and Caenis species collected in summer compared to fall (i.e., Roessink et al., 2013, and Van Wijngaarden and Roessink 2013, respectively). Greater sensitivity is observed with summer collected specimens. EFSA (2014) states that the season of collection may be an important parameter influencing the response of ephemeropterans. In Van den Brink et al., 2016 (PMRA 2712707), acute and chronic toxicity experiments with imidacloprid were conducted using overwintering generations of species and the results were compared with those reported by Roessink et al. 2013 (PMRA 2544385) which tested a summer generation of the same species. The same experimental setup was used in both studies. Acute and chronic toxicity was higher for both *C. dipterum* and *C. horaria* summer generation than for the winter ones. A difference in sensitivity between summer and overwintering species was also shown for two other species (*C. obscuripes* and *P. minutissuma*).

Research with imidacloprid in outdoor mesocosms also shows a seasonal difference in sensitivity for the mayfly *Cloeon dipterum*. In two outdoor mesocosm experiments, the NOEC value for *C. dipterum* larval abundance in the summer (0.243 µg a.i./L, Roessink et al. 2015; PMRA# 2744281) is much more sensitive than that determined for this species in the fall (1.52 µg a.i./L; Roessink and Hartgers 2014; PMRA# 2744280). The study test designs were almost identical with the exception that one study was conducted in summer (July 9th to September 4th; water temperatures of 15.6 to 23.7°C) and the other in the fall (October 7th to November 13th; water temperatures of 5.5 to 14.8°C). The results of the summer and fall mesocosm study are consistent with the notion of both a temperature-enhanced toxicity for *C. dipterum* and a seasonal difference in sensitivity to imidacloprid. Given the disparity in sensitivity observed between summer and fall temperature conditions, and that spring/summer are when applications of imidacloprid generally occur, Health Canada considers the more sensitive endpoint from the summer study to be of greater relevance to the risk assessment. In the case of the most sensitive clothianidin mesocosm study (Hartgers and Roessink 2015; PMRA# 2713555), the study ran from late spring to mid-summer (May 27th to July 22nd; water temperatures of 16.5 to 22.3°C) and therefore, potentially encompasses the most sensitive life stages of taxa present (with the caveat that there were insufficient numbers of mayflies in this study to draw definitive conclusions).

For each risk assessment Health Canada ensures that all endpoints used are statistically rigorous and compared to the appropriate exposure concentrations either through modelling or monitoring when calculating RQs. Health Canada will use the toxicity endpoint from the most sensitive life stage and exposure period to determine overall risk. It is also noted that, while the highest concentrations of clothianidin and thiamethoxam in waterbodies generally occur after major runoff events following spring planting, elevated concentrations later in the season (for example, June to August) in flowing waterbodies in Eastern Canada have been observed. It is therefore appropriate to use toxicity data obtained from standardized laboratory rearing conditions and field studies with exposures during the active crop growing season.

1.6.3 Biomonitoring data

Comment 43 (Bayer CropScience) - PSRD2018-01 and PSRD2018-02

Bayer CropScience argued that Health Canada did not adequately validate the risk assessment predictions for clothianidin through a Weight-of-Evidence (WoE) approach. Bayer claims that the approach presented in PSRD2018-01 was based on endpoints derived by differing methodologies (for example, single lowest endpoint vs. SSD), which is a process of evaluating the robustness and predictive power of the endpoint, but does not contribute to an overall WoE. Rather, different lines of evidence are required to evaluate risk. In support, Bayer submitted the following North American biological monitoring data that they claim show a lack of demonstrated adverse effects on aquatic invertebrates from potential direct exposure to clothianidin, or on bird species that feed on aquatic invertebrates (i.e., possible food chain disruption):

1. Saskatchewan Prairie 2017 Bio-assessment Summary

Bayer biomonitoring work in 2017 in prairie wetlands surrounded by high intensity agriculture with neonicotinoid use (McGee 2018).

2. Quebec Bio-assessment Summary

Two reports were submitted looking at Quebec biomonitoring data for aquatic invertebrates. McGee and Lagadic (2018) compared imidacloprid and clothianidin concentrations in relation to benthic invertebrate health indices in 7 Quebec streams/rivers based on previously published data. Lagadic et al. (2018) presented a preliminary analysis of Quebec Ministry of the Environment monitoring data on clothianidin concentrations and mayfly abundance in streams/rivers.

3. Analysis of the Ontario Ministry of the Environment and Climate Change (OMECC) Benthic Invertebrate Neonicotinoid Monitoring Study

Bayer obtained data from an Ontario monitoring study initiated in 2015 that includes benthic aquatic invertebrates and neonicotinoids in surface waters (OMECC 2018). Bayer compared crop management for corn and soybean in the regions investigated and the association between Chironominae and clothianidin levels detected at the sampling locations.

4. Iowa Biomonitoring Database Analysis

Bayer notes that Iowa has among the highest intensity of corn and soybean agriculture in the USA and the highest cumulative use of imidacloprid, clothianidin, and thiamethoxam (1994-2014). Since 2008 the Iowa Department of Natural Resources has sampled aquatic invertebrates along with physical-chemical conditions to create a Benthic Macroinvertebrate Index of Biotic Integrity (BMIBI). Bayer evaluated the publicly available Iowa DNR data for associations between percent cropped area (PCA) of corn and soybean and the health of the aquatic invertebrate community based on BMIBI scores.

Health Canada response

Health Canada agrees that the use of observational data from the environment can provide additional lines of evidence in making a regulatory decision based on a weight-of-evidence approach. For example, Health Canada will use verified incident reports that can reasonably demonstrate that an adverse effect is a result of exposure to a pesticide in a risk assessment. In the case of neonicotinoid exposures to aquatic invertebrates, no such incident reports have been identified. This may be due to the difficulty in observing effects in this group of organisms.

The use of biomonitoring data, as provided by Bayer CropScience, is problematic in establishing a cause-and-effect relationship for use in a risk assessment. The studies conducted in Saskatchewan (McGee, 2018; PMRA# 2862055), Quebec (McGee and Lagadic, 2018; PMRA# 2862054), Ontario (Bayer CropScience, based on OMECC 2018 data) and Iowa (Bayer CropScience based on Iowa Department of Natural Resources data) provide correlative data on aquatic invertebrate abundance and community health, but were not designed to test assumptions of causality. All assessments were made in agricultural areas impacted by neonicotinoid use, but comparisons were not available against comparable cropped reference sites free from neonicotinoid use. Therefore, it is not known what level of impact has occurred on the observed invertebrate community as a result of neonicotinoid exposure and whether other factors specific to aquatic systems in agricultural landscapes may also be playing a role in aquatic insect abundance.

From the various studies submitted, Bayer is arguing that there is no evidence of decreased macroinvertebrate abundance with the presence of neonicotinoids and in particular, clothianidin. However, there are several limitations with the available data that preclude any meaningful conclusions to be drawn regarding clothianidin exposure levels and invertebrate abundance.

- In the Saskatchewan study, the majority of wetlands dried up during the study year, measured neonicotinoid concentrations were not reported and surrounding fields were planted with imidacloprid, so any exposure to clothianidin or thiamethoxam was from historical residues only.
- In the Quebec studies, correlations were made between benthic invertebrate health indices in seven streams/rivers from agricultural regions and clothianidin or imidacloprid concentrations. However, all streams are categorized in a relatively narrow range of ‘degraded’ or ‘bad’ invertebrate health and were compared against annually-averaged neonicotinoid concentrations, which does not allow for a robust comparison against acute or chronic concentrations relevant to the risk assessment.
- In the Ontario and Iowa datasets, percent cropped area (PCA) of corn and soy are used as surrogates for clothianidin exposure.
- In the Ontario data, there was a great deal of variability in Chironominae abundance, with no apparent correlation to increasing PCA.
- In the Iowa data, there has been essentially no change in the PCA or benthic macroinvertebrate index scores over the study period. While the steady PCA scores suggest that the reported increase in total neonicotinoid use in the State may be associated with these high-use crops, water monitoring data would be required to definitively show the impact on neonicotinoid exposure levels.

Biomonitoring studies inherently have a high level of variability between sites which can be due to a number of non-toxicant related factors, such as water quality and hydrology and habitat structure. These factors can make correlative associations very difficult to separate from causal effects. In their Guidance on Aquatic Risk Assessments, EFSA (2013) cautions that it is very difficult to design monitoring programs such that results can be linked to a specific use of an active ingredient associated with a specific crop, while also excluding confounding factors. A recent study by Cavallaro et al., 2019 (PMRA# 3050935) showed that among 22 semi-permanent Saskatchewan wetlands, which all had surrounding fields planted with neonicotinoid-treated canola (predominantly with Prosper Seed Treatment containing clothianidin; Bayer CropScience), there was a positive correlation between mean neonicotinoid toxic equivalency quotient (TEQ) concentrations and reductions in total insect emergence. Here too it was not possible to determine the magnitude of effects seen within the range of measured concentrations. However, the models that best predicted emergent insect abundance also included vegetation disturbance and water turbidity, indicating that the presence of riparian habitat structure and water quality also play a significant role in emergent insect population dynamics within these geographically similar, agriculture-dominated wetlands.

Comment 44 (CropLife Canada, Dow AgroSciences Canada Inc, Saskatchewan Pulse Growers, Producteurs de grains du Québec, Saskatchewan Association of Rural Municipalities, Cereals Canada) - PSRD2018-01 and PSRD2018-02

Comments were received related to concerns that the decisions are being driven by unquantified hypothetical risks to mayfly and midge populations. CropLife Canada, Dow AgroSciences Canada Inc. and Saskatchewan Pulse Growers point out that clothianidin and thiamethoxam have been registered in Canada with over 15 years of use and are not aware of any studies or incident reports reporting concerns with mayfly or midge populations in Canada. Nor is there monitoring evidence to suggest that the use of these active ingredient will harm bird, fish or wildlife populations. In fact, some areas in Canada are reporting issues with excessive mayfly populations.[1, 2]

Noting the uncertainties in potential risks to the food chain identified by Health Canada in the proposed decisions, the Producteurs de grains du Québec suggest that rigorous studies are required to establish the risks to birds or other insects. Similarly, the Saskatchewan Association of Rural Municipalities called for additional research on impacts of neonicotinoid use on aquatic invertebrates before de-registration of either clothianidin or thiamethoxam are considered.

Cereals Canada argued that the demonstration of potential harm from a modelled prediction based on laboratory data does not always translate into a measurable impact in the open environment, as evidenced by an apparent lack of negative impacts on the mayfly populations in Canada.

1 See: https://www.citylab.com/environment/2015/05/a-millions-strong-horde-of-flies-descends-upon-a-canadian-city/394400/
2 See: https://www.cbc.ca/news/canada/manitoba/fish-fly-things-to-know-1.3676812and https://www.saobserver.net/news/mating-game-on-wings/

Health Canada response

The *Pest Control Products Act* states that the risks of a PCP are acceptable if there is reasonable certainty that no harm to human health, future generations, or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration. A lack of incident reports or reported effects to naturally occurring populations of mayflies or midges does not add to the weight of evidence that risks are acceptable. Incident reports on aquatic invertebrates are unlikely to be reported given that the effects must be observed. Available biomonitoring studies have not been conducted in a manner that would allow Health Canada to understand the effects of clothianidin and thiamethoxam on these types of organisms. In order to conduct this type of study to obtain results that can be used to support a risk assessment, a baseline understanding of the population would need to be obtained prior to any neonicotinoid inputs in the watershed, followed by yearly biomonitoring in water bodies that have known inputs of these chemicals. While anecdotal reports of strong mayfly populations is suggestive of a lack of adverse effects on those taxa in selected Canadian locations, they do not provide supportive evidence for a risk assessment. The lack of this sort of data leads to additional uncertainty.

1.6.4 Characterization of endpoint uncertainties

Comment 45 (Grain Farmers of Ontario) - PSRD2018-01

It was recommended that Health Canada provide greater transparency and details regarding the consideration of alternative methods in the risk assessment for clothianidin. It was noted that there are uncertainties associated with both the SSD and the mesocosm studies considered in the risk assessment. It was suggested that the HC_5 may be an 'ecological overinterpretation' as SSDs place an emphasis on species, not on trophic structures or ecological processes.

Health Canada response

Health Canada bases its risk assessment on the most appropriate effect metric with the highest degree of ecological relevance (i.e., a higher-tiered endpoint is preferred over a single laboratory species toxicity value). In the chronic risk assessment outlined in PSRD2018-01, Health Canada relied on the most sensitive species for the proposed effect metric, noting the uncertainties around the higher-tiered mesocosm study and the chronic SSD. As noted by the Grain Farmers of Ontario, the SSD is constructed from laboratory-derived single species toxicity endpoints; it is not designed to take into account ecological interactions between species. Rather, as with other pesticide regulatory bodies (for example, USEPA, EFSA, APVMA), Health Canada uses the HC_5 as a higher-tiered indicator of community sensitivity, based on comparable responses under controlled, reproducible laboratory conditions. The endpoints reported in PSRD2018-01 have been revisited for the final regulatory decision for clothianidin and details can be found in the Science Review Section.

Comment 46 (Pulse Canada) - PSRD2018-01 and PSRD2018-02

The PMRA identified many uncertainty factors within the thiamethoxam and clothianidin risk assessments (PSRD2018-01, PSRD2018-02). The decision to not include all regions of Canada and all crop types, variability in seeding depth, soil type, topography, and spring ground cover in minimum till cropping systems, all have an impact on the modelled and extrapolated approach taken by the PMRA. While the regulatory body is empowered to make these decisions with the mandate to protect human and ecological health, the process at which to arrive at a decision must have clear methodology. Robust and defensible science is subject to scientific peer review with clearly stated reproducible methodologies. Many of the studies that were used within the PMRA risk assessment were from academic publications and data sets that were peer reviewed, however, it was unclear why certain publications were used in the risk assessment and other studies disregarded. The importance of external peer review in the scientific process is imperative, especially by a regulatory body such as the PMRA.

Health Canada response

Health Canada assesses environmental risk based on a tiered approach. In the case of clothianidin and thiamethoxam, freshwater invertebrates were found to be at risk at the screening level, under highly conservative exposure estimates based on the highest registered use rates for each major application method. To further characterize the potential risks, a refined assessment examined an expanded use pattern covering a range of crop uses and exposure pathways through environmental modelling (for example, spray drift and runoff to surface water) and observed Canadian surface water monitoring data. The refined assessments took into account regional differences in cropping practices (for example, seeding rates, planting depths, soil types and hydrology) and observed surface water concentrations. Health Canada did not model all uses for clothianidin or thiamethoxam in making the proposed decisions; however, based on the range of uses covering high and low application rates and major representative crops for each use type (foliar, in-furrow and seed treatments), Health Canada could not determine that the risks to aquatic invertebrates were acceptable. As noted by Pulse Canada, uncertainties associated with the refined assessments were documented in the PSRDs, but were not deemed sufficient to avoid making a proposed decision for each.

Additional information received since the publication of the PSRDs has addressed some of the uncertainties identified around surface water monitoring data and provided additional ecotoxicity data to inform the risk assessments for clothianidin and thiamethoxam (see new information highlighted in the Science Review).

Health Canada agrees that robust and defensible science requires access to scientific peer review. The publication of the proposed decisions containing the risk assessments with all available references provides stakeholders the opportunity to submit scientific rationales for Health Canada’s consideration prior to making a final regulatory decision. Health Canada reviews all scientific literature from unpublished (for example, registrants) and published sources (for example, open literature) for acceptability and scientific rigour.

1.6.5 Application rates used in the risk assessment

Comment 47 (Grain Farmers of Ontario, Grain Growers of Canada, Producteurs de grains du Québec) - PSRD2018-01 and PSRD2018-02

It was noted that the screening level risk assessments were based on the highest maximum annual application rates for all uses and crops. This approach is not reflective of the actual (lower) rates used by grain farmers and that these may overestimate the actual use rate by two- or three-fold. It was recommended that Health Canada consider other application rates that more fully represent actual use conditions.

Health Canada response

While Health Canada appreciates that applicators may not always use the maximum allowable rate for a particular crop, the risk assessment must reflect the highest labelled rates to ensure that risks to the environment are acceptable for the entire range of rates legally allowed on the label. However, for uses that have a range of rates registered on the product label, Health Canada can consider all registered rates in a risk mitigation strategy, if some of the lower rates pose acceptable risks.

Comment 48 (Syngenta Canada Inc.) - PSRD2018-02

Syngenta Canada Inc. submitted the following published study for PMRA's consideration on the modelled effects of thiamethoxam on non-target aquatic invertebrates in United States farm ponds and wetlands. A separate unpublished study with supporting information was also provided.

Bartell, S.M., S.K. Nair, S. Grant and R.A. Brain. 2018. Modeling the effects of thiamethoxam on Midwestern farm ponds and emergent wetlands. Environ. Toxicol. Chem. 37(3): 738-754. PMRA# 2935276.

supported by unpublished study:

Bartell, S.M. and C.T. Woodward. 2018. Use of CASMGFP and CASMGWL to Assess Potential Effects of Thiamethoxam Exposure on Farm Pond and Wetland Communities. DACO: 8.6. PMRA# 2935278.

Comment 49 (member of the public)

A weight of evidence risk assessment of thiamethoxam use in Canadian freshwater ecosystems was submitted for PMRA's consideration.

Hanson, M., L. Baxter and G. Stephenson. 2018. A preliminary weight of evidence evaluation of the risks posed by the neonicotinoid insecticide thiamethoxam in Canadian freshwater ecosystems to aquatic organisms. Unpublished report. November 10, 2018. PMRA# 3151809.

Health Canada response

The additional studies by Bartell et al. 2018a (PMRA# 2935276) and 2018b (PMRA# 2935278), and Hanson et al. 2018 (PMRA# 3151809) outline modelling and risk assessments completed by others. These modelling approaches and assessments were not considered in making a final regulatory decision as Health Canada relied on its own risk assessment framework.

1.6.6 Cumulative exposure risk assessment of all neonicotinoids, including metabolic effects pathways

Comment 50 (Bayer CropScience) - PSRD2018-01 and PSRD2018-02

Bayer CropScience suggested that the concern around higher effects on aquatic invertebrates through co-occurrence of clothianidin, thiamethoxam and imidacloprid stated in PSRD2018-01 is unsubstantiated. It was stated that the water monitoring conducted in 2017-2018 showed that *there is typically one major residue in a wetland and the residues originate from the material applied to the surrounding field in the year of sampling. Monitoring by Morrissey (2012-2014) and Ducks Unlimited (2017) supports this finding, showing primarily one active ingredient in the wetland samples, although the use of specific neonicotinoid products in the surrounding fields was not determined.*

It was also noted that the 2017 EMWG monitoring programs show that flowing water bodies are likely to contain a mixture of residues since these waters represent residues from a wide area having a higher likelihood of use of multiple neonicotinoids and pesticides in general, although concentrations tend to be lower in these waterbodies.

Bayer CropScience requested that PMRA clarify any statement regarding co-occurrence of residues with respect to specific types of water bodies.

Comment 51 (David Suzuki Foundation) - PSRD2018-01 and PSRD2018-02

David Suzuki Foundation commented that individual assessments of neonicotinoid insecticides underestimate total risks to aquatic invertebrates due to effects from aggregate and cumulative exposures to multiple similar insecticides and recommends that Health Canada assesses aggregate, cumulative and cellular signaling effects in the special reviews. The following was provided as a rationale:

"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 (for example, 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 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]*"* [references included in original comments]

Health Canada response (comments 50 and 51)

A cumulative risk assessment for neonicotinoid exposure to aquatic invertebrates was not considered in making a regulatory decision for the special reviews of clothianidin and thiamethoxam. As noted by Bayer CropScience, Canadian surface water monitoring data do show co-occurrence to varying degrees of the three most commonly used neonicotinoids – thiamethoxam, clothianidin and imidacloprid. Health Canada acknowledges that measured concentrations are usually dominated by the active ingredient most commonly associated with the dominant crop grown in the catchment area, such that cumulative concentrations tend not to differ substantially from the dominant neonicotinoid found.

However, Health Canada acknowledges that given the similarity in the mode of action for the neonicotinoids, when co-occurrence of residues occurs, the effects are expected to increase. Recent *in situ* limnocorral studies exposing natural Chironimidae populations to binary neonicotinoid mixtures at equivalent toxicity units indicated there is potential for additive toxicity from exposures to multiple neonicotinoids under more realistic outdoor exposures (Maloney et al. 2018b).

In order to conduct a cumulative risk assessment, each neonicotinoid must be measured simultaneously from the same sample. While this has been built into recent monitoring program protocols, a few older programs did not analyze for all three neonicotinoids in the same water samples. Health Canada will determine whether a cumulative assessment is warranted following the re-evaluation of all neonicotinoids. Recent regulatory decisions for the neonicotinoids have resulted in the removal of some uses, which is likely to have an impact on risk conclusions based on historical concentration monitoring data obtained prior to the removal of uses.

Regarding the David Suzuki Foundation's comment that neonicotinoids may exert adverse effects via other mechanisms that could be relevant under cumulative exposure, the PMRA acknowledges that neonicotinoid insecticides may have sub-cellular effects on invertebrates. For example, recent research by Russo et al. (2018; PMRA# 2978128) has demonstrated that exposure to clothianidin at sub-lethal concentrations of ≤ 0.1 µg a.i./L can impact physiological metabolites and increase energy demands in the mosquito *Culex pipiens*. Understanding how neonicotinoids can impact metabolic processes is important in further understanding the mode of action for this group of insecticides. However, the link between in vitro sub-cellular effects within an organism and community-level impacts, which is the protection goal that Health Canada has established for the aquatic invertebrate community, is not clear For this reason, Health Canada relies on adverse apical effects endpoints that can directly affect invertebrate populations (for example, mortality, reproduction and growth). Long-term exposures in both laboratory and semi-field mesocosm studies for clothianidin and thiamethoxam were used to establish population- or community-level adverse effects endpoints at sub-lethal concentrations similar to those seen to elicit metabolic effects in *C. pipiens*, for example. The potential for synergistic effects from both lethal and sublethal mechanisms over chronic exposure periods was explored in binary combinations of neonicotinoid exposures in both laboratory and semi-field limnocorral studies (Maloney et al. 2018a and 2018b, respectively). There was very little indication that chronic exposure to multiple neonicotinoids would produce a greater than additive effects. In the laboratory, only one combination (imidacloprid + thiamethoxam) had a statistically significant greater-than-additive (i.e., synergistic) effect on *C. dilutus*; however that effect was considered weak (i.e., up to 10% greater than predicted) and not biologically significant. In the open water limnocorrals, mixture effects were categorized as directly additive only. Based on these data, the potential for cumulative effects from both sub-lethal and lethal effects are expected to be adequately characterized by concentration addition for tested species.

1.6.7 Inclusion of cascading ecological effects in risk assessment

Comment 52 (David Suzuki Foundation) - PSRD2018-01 and PSRD2018-02

The David Suzuki Foundation recommends that Health Canada includes an assessment of cascading effects on birds, bats, fish, and other species that rely on aquatic insects as their primary food source. The following rationale is provided:

- 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]
- Aerial insectivorous birds have undergone dramatic population declines in recent decades[18] 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]

[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.*
[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.*

Health Canada response

Direct or indirect risks to insectivorous birds or other species, from neonicotinoid contaminated food sources were not considered in the proposed decision, as the Special Reviews were undertaken to examine the risks to aquatic invertebrate communities. A complete assessment of risk to birds and mammals from contaminated food sources will be addressed as part of the cyclical re-evaluations for clothianidin and thiamethoxam.

The data needed to assess indirect effects of pesticides within Health Canada's environmental risk assessment are not available at this time. Robust data that demonstrates a causal relationship to show that exposure to pesticides at a lower trophic level results in effects at a higher trophic level is not available. In addition, there are many confounding factors that can result in the observed effects at the higher trophic levels. The protection of the aquatic invertebrate community is expected to preclude trophic cascading effects associated with these organisms as a food source.

Comment 53 (National Farmers Union) - PSRD2018-01 and PSRD2018-02

The National Farmers Union urged Health Canada to consider the potential for compounded effects on ecosystems from the use of neonicotinoid insecticides coupled with mounting losses of insect populations due to climate stress and other unknown factors. Two studies were provided that examined reductions in insect populations:

Lister, BC and A Garcia. 2018. Climate-driven declines in arthropod abundance restructure a rainforest food web. Proceedings of the National Academy of Sciences. 115 (44): E10397-E10406; DOI: 10.1073/pnas.1722477115 http://www.pnas.org/content/115/44/E10397

Hallmann CA, Sorg M, Jongejans E, Siepel H, Hofland N, Schwan H, et al. *2017. More than 75 percent decline over 27 years in total flying insect biomass in protected areas. PLoS ONE 12(10): e0185809. https://doi.org/10.1371/journal.pone.0185809*

Health Canada response

Health Canada acknowledges that there are several environmental factors, such as changing climatic conditions, habitat loss and contamination from non-neonicotinoid pollution sources that may be impacting aquatic invertebrate populations. However, such extrinsic factors are outside the scope of Health Canada's assessment for these special reviews.

1.6.8 Conservatisms and lack of real-world impact studies in risk assessment conclusions

Comment 54 (Dow AgroSciences Canada Inc.) - PSRD2018-01 and PSRD2018-02

Dow AgroSciences Canada Inc. suggested that canceling all uses of these active ingredients due to uncertainties with surface water modeling and monitoring constitutes a serious overreaction for the following reasons:

- The models did not properly account for a number of variable factors - such as seeding depth - when considering likely runoff scenarios.
- There were a number of problems with the surface water monitoring data: limits of detection were not issued by the PMRA in a timely manner, essentially invalidating a great deal of the 2017 data. Additionally, site information was not available for much of the monitoring data, and the concentrations reported by that data could not be attributed to a particular crop or use pattern.
- The PMRA's weight-of-evidence approach did not appropriately consider two outdoor mesocosm studies, which should have been weighted in a manner that reflected their superior quality.

Health Canada response

In making the proposed decision to cancel all outdoor uses of clothianidin and thiamethoxam, Health Canada could not reasonably demonstrate that the risks to aquatic invertebrates were acceptable based on the available water modelling and monitoring data for Canada. In PSRD2018-01 and PSRD2018-02, Health Canada does acknowledge the limitations with Canadian water modelling and monitoring data for clothianidin and thiamethoxam, respectively. In regards to water modelling, not all uses were modelled, but significant concerns were identified for uses that spanned the range of allowable application rates in Canada. Every effort was made to include the most relevant environmental data and agronomic practices for the regions and scenarios being modelled.

Regarding the concern of inappropriate seeding depths, Health Canada consulted with Canadian grower groups to obtain representative seeding rates and depths from across the country for these special reviews. Health Canada also included a number of recommended model improvements from the USEPA (Fry and Young, 2017) as outlined in the PSRDs, including an assessment of increasing concentrations with seeding depth for select crops. As part of the neonicotinoid-specific factors accounted for in water modelling, Health Canada incorporated a novel neonicotinoid uptake factor for seeds based on laboratory data for the related neonicotinoid imidacloprid. Given the approaches taken, Health Canada considers the EECs to be robust for the use scenarios modelled and did not re-visit modelling inputs for making a final regulatory decision. However, following changes to the allowable use patterns for thiamethoxam and clothianidin for the pollinator final decisions (RVD2019-04 and RVD2019-05, respectively), surface water modelling scenarios were updated for the aquatic special review final decisions (please see the Science Review of this SRD and SRD2021-04).

Health Canada provided guidance on limits of detection (LOD) with members of the Environmental Monitoring Working Group once the toxicity effects metrics had been established. Due to the time required to conduct a thorough review of available toxicity data and to establish appropriate effects metrics, the limits of detection could not be communicated at the beginning of the special review process. Data considered in the proposed special review decisions which had an LOD higher than the effects metrics determined at the time were not invalidated. However, there was some uncertainty in the resulting risk quotients for datasets that had a large number of samples showing no detections, because the non-detects were assigned a value equal to half the LOD.

The analytical limits of all the monitoring programs considered in the final special review decisions are all well below the revised effects metrics for clothianidin and thiamethoxam. Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada were submitted to Health Canada. The monitoring data and the detailed ancillary information submitted, which included land use information, in conjunction with region- and crop-specific modelling results, have been considered in the revised assessment for the special reviews of clothianidin and thiamethoxam. Health Canada considers the results of outdoor mesocosm studies with aquatic invertebrates as providing different measurement endpoints under more realistic exposures scenarios for the risk assessment, when the studies are scientifically sound and they are representative of the expected exposure and species present in the environment. In the case of the two registrant-supplied mesocosm studies for clothianidin, there were sufficient uncertainties in both the exposure duration and lack of representation of known sensitive species to use these results alone as definitive effects metrics.

However, the mesocosm NOEC from the most sensitive study (Hartgers and Roessink, 2015; PMRA# 2713555), was used in a weight of evidence approach in assessing clothianidin risk to aquatic invertebrates. (See Science Section 1.3.1 of this SRD for more details on how the mesocosm-based effect metric was used in the risk assessment.)

Comment 55 (Cereals Canada, Grain Growers of Canada, Team Alberta, Producteurs de grains du Québec) - PSRD2018-02

Clarification was requested from several commenters as to why the use of thiamethoxam seed treatment on spring wheat or barley was included in the phase out of all agricultural uses when the EECs from runoff for this use pattern did not exceed the mesocosm NOEC or most sensitive species EC_{10} endpoints that were the basis for the regulatory decision.

Health Canada response

When the proposed regulatory decision to cancel all outdoor uses for thiamethoxam was published it was not possible to determine with reasonable certainty that harm would not occur to aquatic invertebrates. Since the publication of PSRD2018-02, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies in agricultural areas across Canada were submitted to Health Canada. The monitoring data and the detailed ancillary information submitted, which included land use information in conjunction with crop-specific water modelling results, have been considered in the final special review decision for thiamethoxam. Please see the Science Review in SRD2021-04 for further details.

Comment 56 (Saskatchewan Pulse Growers, Canadian Seed Growers Association, Canadian Federation of Agriculture, Agricultural Producers Association of Saskatchewan) - PSRD2018-01 and PSRD2018-02

As part of a coordinated response from multiple commenters, there was concern that the proposed special review decisions for clothianidin and thiamethoxam were made based on overly conservative assumptions rather than on real life information that reflects what's happening in the field. Given the consequences to Canadian growers regarding the potential loss of access, Health Canada was urged to include, as part of the evaluation process, consideration of the potential negative impacts of withdrawing these products on human health, the environment, and the Canadian economy.

Health Canada was also requested to consider all available data — including the water monitoring data generated by the Agriculture and Agri-Food Canada Environmental Monitoring Working Group (EMWG) during the 2018 growing season — to refine the risk assessments and to work with agricultural stakeholders to understand the potential impacts that these proposed decisions will have both economically and from a human and environmental risk perspective.

Health Canada response

Health Canada is committed to working with all stakeholders of the special review decisions for clothianidin and thiamethoxam, including those from the agricultural sector, industry, other governmental departments and academia. During the consultation period for PSRDs 2018-01 and 2018-02, Health Canada received input from each of these stakeholders for consideration in making a final regulatory decision. Health Canada recognizes that there would be negative economic consequences for the cancellation of outdoor uses of clothianidin and thiamethoxam; however, economic considerations cannot outweigh risks to human health or the environment when determining appropriate mitigation measures. When registering products, Health Canada ensures the product has value for its intended uses but it does not undertake cost-benefit analyses in support of a decision. Under the Act, our risk assessments are science-based only. When a phase-out period is required for a discontinued use, the potential negative impacts of withdrawing the products on human health and the environment are considered and reflected in the length of the phase-out period.

Since the publication of the proposed special review decisions, Health Canada has continued working with the EMWG**.** A large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada were submitted to Health Canada. The monitoring data and the detailed ancillary information submitted, which included land use and precipitation information, have been considered in the revised assessment for the special reviews of clothianidin and thiamethoxam.

Comment 57 (Pulse Canada) - PSRD2018-01 and PSRD2018-02

Pulse Canada raised the concern that the toxicity endpoint values used by Health Canada in the PSRDs were different than those discussed with the Agriculture and Agri-Food Canada (AAFC) water monitoring subcommittee and provincial water monitoring in the 2017 season. Pulse Canada noted it was unclear how Health Canada's selection of species used in determining acute and chronic endpoints related to other jurisdiction's guidelines (for example, OECD, CCME). This has caused confusion amongst stakeholders regarding which studies were used as reference values in the proposed decision and around potential risk. Also, recent publications by Finnegan et al., 2017 (as cited in PSRD2018-02) and Finnegan et al. (2018) showing a lack of thiamethoxam risk to aquatic invertebrates were referenced.

Finnegan, M.C., S. Emburey, U. Hommen, L.R. Baxter, P.F. Hoekstra, M.L.Hanson, H. Thompson and M. Hamer. A freshwater mesocosm study into the effects of the neonicotinoid insecticide thiamethoxam at multiple trophic levels. Environmental Pollution (2018) 242: 1444-1457.

Health Canada response

While conducting the special reviews for clothianidin and thiamethoxam, Health Canada worked closely with AAFC and the EMWG in helping to establish goals for analytical detection limits to ensure that concentrations monitored in the environment could be used to inform the risk assessments. Health Canada indicated to the working group that the endpoints were subject to change prior to completion of the proposed decisions, pending the review of additional toxicity data that is continually being published for the neonicotinoids in the open literature. The decision of which endpoints to use in the risk assessment were based on the scientific validity of the underlying studies, which underwent a thorough peer review within Health Canada and were subsequently made available for external review through the public consultation process.

Health Canada has considered the toxicity endpoints reported by Finnegan et al. (2017) in PSRD2018-02, and has considered the mesocosm endpoints reported by Finnegan et al. (2018) in the Science Review (see Section 1.1.2).

1.6.9 Use of international risk assessment guidance

Comment 58 (Producteurs de grains du Québec) - PSRD2018-01 and PSRD2018-02

The PGQ notes that in the proposed special review decisions, Health Canada refers to areas of the reviews that comply with European Food Safety Authority guidelines for conducting aquatic risk assessments (EFSA 2013). They contend that Canada should not be using guidelines established by EFSA for making regulatory decisions in the European Union, as EFSA responds mainly to concerns expressed regarding pollinating insects, which have already been considered in Canada (i.e., PRVD2018-12 for imidacloprid).

The PGQ acknowledges the authority of the Minister in initiating the special reviews under subsection 17 (2) of the Pest Control Products Act, when concerns are identified in Organization for Economic Co-operation and Development (OECD) countries. However, they note that many OECD countries have not undertaken this re-assessment and that, even after a reassessment, they do not plan to revoke the approval of clothianidin and thiamethoxam. The PGQ believes that it is imperative that Health Canada make its own independent, science-based regulatory decisions based on the agricultural and climatic realities of Canada, and not to copy the decisions made by others.

Health Canada response

In the proposed special review decisions for clothianidin and thiamethoxam, Health Canada referred to guidance from EFSA (2013) on data requirements for constructing SSDs to determine HC5 values that could be used as effects metrics. Health Canada does not use the European risk assessment strategy for aquatic life, as described in EFSA (2013); rather, Health Canada relies on its own methods of estimating risk, based on predicted (modelled) and observed exposure levels, and our own effects assessments. For a full description of the risk assessment methods used, please see the Science Review of this SRD and SRD2021-04 for clothianidin and thiamethoxam, respectively.

As noted in Section 3.0 of PSRD2018-01 and PSRD2018-02, Health Canada’s initiation of these special reviews was triggered by subsection 17(1) of the *Pest Ccontrol Products Act* which states that the Minister shall initiate a special review where there are reasonable grounds to believe that the health or environmental risks are unacceptable. These special reviews were initiated based on concerns that clothianidin and thiamethoxam were being detected in Canadian surface waters at concentrations that may pose a risk to aquatic invertebrates. Although Health Canada can initiate special reviews on the basis of regulatory decisions in OECD countries (subsection 17(2)), this was not the case for these special reviews.

1.7 Mitigation

1.7.1 Neonicotinoid use reduction through provincial regulations

Comment 59 (Syngenta Canada Inc., Producteurs de grains du Québec) - PSRD2018-01 and PSRD2018-02

It was noted that recent changes to provincial regulations requiring agronomic justification for the sale and use of neonicotinoids in Ontario and Quebec since 2018 have the potential to reduce concentrations in the environment. The PGQ highlight that the provincial governments chose additional regulations over the banning of neonicotinoids, to maintain important uses. They feel that the implementation of new water monitoring programs, new agronomic practices (regulations) and better knowledge management tools will allow regulators to track trends in neonicotinoid concentrations and make informed mitigation decisions, rather than banning their use altogether.

Health Canada response

Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies representative of aquatic habitat in agricultural areas across Canada were submitted to Health Canada. The potential impact of the provincial regulations in Ontario and Quebec is a reduction in levels of neonicotinoids in aquatic systems; however, there are as yet, insufficient data to assess the impact of these recent regulatory changes. National registrations consider all allowable conditions of use when assessing risk, however, provinces can apply more stringent regulations than what is permitted under the *Pest Control Products Act*.

1.7.2 Use of Vegetative Filter Strips (VFS)

Comment 60 (Canola Council of Canada, Canadian Potato Council, Saskatchewan Ministry of Agriculture, Bayer CropScience, Valent Canada, Pulse Canada) - PSRD2018-01 and PSRD2018-02

The use of vegetative filter strips (VFS) to protect surface waters from the effects of clothianidin and thiamethoxam in surface runoff was mentioned in several comments, including those by the Canola Council of Canada, Canadian Potato Council, Saskatchewan Ministry of Agriculture, Bayer CropScience, Valent Canada, and Pulse Canada. A central theme to all of the VFS comments was that VFSs should be implemented, in conjunction with other Best Management Practices, as a mitigation measure as there is evidence to suggest that they can be highly effective at reducing pesticide loads in runoff.

Studies conducted by Denning et al. (2004; PMRA# 2518467) and Hladik et al. (2017; PMRA# 2866915), previously dismissed by Health Canada as “no quantifiable measure to reduce runoff of neonicotinoids into waterbodies using vegetative filter strips could be derived” (see EAD Monograph for PSRD2018-01; PMRA# 2856238), were cited heavily as evidence promoting the use of VFSs to mitigate neonicotinoid runoff. As well as these two studies, studies by Liu et al. (2002; PMRA# 3131570), Hoekstra and Hannam (2017; PMRA# 3131569), Reichenberger et al. (2019; PMRA# 3131573), Carluer et al. (2017;

PMRA# 3131565), Yu et al. (2019; PMRA# 3131578 – cited in several comments as Congrong et al. 2019), and Satkowski et al. (2018; PMRA# 3131574) were all cited to provide additional evidence promoting VFS use.

The Canola Council of Canada also indicated that conservation tillage practices and preventing tillage operations (discing, deep tillage) around wetlands can play a significant role in mitigating the movement of thiamethoxam and clothianidin to water bodies as they contribute to vegetative cover and soil organic matter. In addition to mitigating pesticide movement, VFS and conservation tillage have the potential to promote plant, insect and bird species diversity, enhance soil carbon sequestration and provide other ecosystem services such as maintenance of soil structure and fertility in agro-ecosystems (Schulte et al. 2017; PMRA# 3131576, Yu et al., 2019).

Health Canada response

Health Canada recognizes that vegetative filter strips (VFSs) can be useful tools to mitigate the effects of pesticides carried in runoff to aquatic ecosystems. Recently, Health Canada has required VFSs for pesticides with low water solubilities, high adsorption coefficients, and for those which are persistent and toxic to aquatic organisms. VFSs are more effective at trapping and retaining sorbed pesticides than soluble pesticides (USDA 2000; PMRA# 3131577, Arora et al. 2010; PMRA# 3131564, Yu et al. 2019) as the dense vegetation within a VFS slows runoff, decreasing the transport capacity of the runoff water, which increases deposition of suspended soils and the pesticides that are sorbed to them (Dillaha et al. 1986; PMRA# 3131567, Patty et al. 1997; PMRA# 3131571). Thus, Health Canada currently considers VFSs as a viable mitigation tool for pesticides with these characteristics.

Clothianidin and thiamethoxam are characterized by low soil partition coefficients and high solubilities (average K_{OC}s of 84 and 33.1 and water solubilities of 327 and 4100 for clothianidin and thiamethoxam, respectively; Table A.3.4 PSRD2018-01 and PSRD2018-02). These characteristics may make these pesticides less suitable as VFS candidates.

While evidence is starting to evolve to suggest that VFS may provide some prevention of runoff from fields for soluble mobile chemical, the studies cited have not produced robust data under a variety of meteorological and topographical settings that yield repeatable and quantifiable reductions of inputs into sensitive water bodies. At this time, based on available information, Health Canada cannot be confident that VFSs would reduce inputs of neonicotinoids to acceptable levels on a consistent basis under a variety of site specific conditions.

1.7.3 Neonicotinoid residues in fugitive dust during planting of treated seeds

Comment 61 (member of the public) - PSRD2018-01 and PSRD2018-02

One commenter provided a position paper to Health Canada in response to PSRD2018-01 and PSRD2018-02, contending that the physical loss of active ingredient from seed coatings during planting and the subsequent dust produced by vacuum planters constitutes a major source of neonicotinoid contamination in aquatic systems. Rather than adopting a full ban on neonicotinoid pesticides, he is proposing that Health Canada adopt performance-based emissions standards for producers using mitigation measures outlined in his submission. The commenter provided references to a number of research papers, both published and in-preparation for publication, to support the findings of neonicotinoid contamination in fugitive dust behind commercial vacuum-style planters.

Health Canada response

Health Canada appreciates the contribution of research and acknowledges that fugitive dust from treated seed at the time of planting may provide a source of pesticide contamination to aquatic habitats. In a series of publications, factors affecting total neonicotinoid (i.e., clothianidin + thiamethoxam) concentrations in vacuum seed-planter exhaust and dust generated from typical corn planting operations were investigated in southwestern Ontario which demonstrate that dust containing pesticides may be entering Canadian waters following planting of treated seeds. However, average levels of neonicotinoids recovered in seed-planter exhaust were generally low, with most of the data showing emissions of <0.5 g/ha or about 2.6% of what was applied to seeds (Schaafsma et al. 2018; PMRA# 3131079).

Health Canada recognizes the value in mitigating fugitive dust generation during planting and is supportive of the new ISO standard to minimize the environmental effects of fan exhaust from pneumatic systems (ISO 17962:2015). This voluntary ISO standard applies to newly manufactured planting systems; however, planting equipment may continue to be used that does not comply with the new standard. While fugitive dust may be contributing to levels of neonicotinoids in surface waters, other routes of exposure may also contribute to surface water levels (for example, foliar spray, surface runoff). The relative contribution of neonicotinoid levels in surface water from fugitive dust is not clear and expected to be small in comparison to other routes of exposure. It is not clear that mitigation of fugitive dust generation would adequately control surface water levels of neonicotinoids.

1.7.4 Agronomic best practices

Comment 62 (Pulse Canada) - PSRD2018-01 and PSRD2018-02

The Canadian pulse industry suggested that the revocation or ban of a product registration is not a mitigation of risk, and rather other risk mitigation options are preferable. Pulse Canada noted that:

a) Both the USEPA and EFSA found seed treatment to be the lowest potential risk to aquatic receptors while foliar spray application to be the highest.

b) The results of Giroux and Fortin (2010) support the recommendations for setback distance from the edge of the field to the nearest aquatic receptor.

Giroux, I. and J. Fortin, 2010. Pesticides dans l’eau de surface d’une zone maraîchère – Ruisseau Gibeault-Delisle dans les « terres noires » du bassin versant de la rivière Châteauguay de 2005 à 2007, Juin 2010, DACO: 8.6. PMRA# 2035772.

Health Canada response

Health Canada agrees that based on environmental modelling, seed treatment uses pose a lower risk than for spray applications (see Science ReviewSection 1.3.4.1 for a summary of runoff risk quotients for all application methods). Since the publication of the proposed special review decisions, a large amount of 2018 and 2019 monitoring data on neonicotinoid concentrations in waterbodies in agricultural areas across Canada including the Prairies, where the use of neonicotinoids is mainly as a seed treatment, were submitted to Health Canada. The monitoring data and the detailed ancillary information submitted, which included land use and occasionally neonicotinoid use information, have been considered in a revised assessment for the special reviews of clothianidin and thiamethoxam.

Pulse Canada indicated that the results of the Giroux and Fortin (2010) study support the use of cropping setback distances to mitigate neonicotinoid concentrations in receiving waters. The report referred to is a study of pesticide concentrations in the Gibeault-Delisle Creek, Quebec, from 2005-2007. The study shows that a large portion of the samples collected in this small stream had high concentrations of many pesticides, including imidacloprid. A large portion of the watershed was cropped, with the main crops including vegetables, along with corn and soybean. The study does not examine the role of planting setbacks in reducing pesticide contamination, but does show that under intense agricultural production, high levels of pesticides in surface waters can be expected, including imidacloprid.

In making a final regulatory decision, Health Canada considered a number of mitigation options besides cancelling the registrations for clothianidin and thiamethoxam, including runoff mitigation through the mandatory use of vegetative filter strips, spray drift mitigation through the use of spray drift buffer zones, planting locations within wetland areas, fugitive dust management, and reductions in environmental loading through use restrictions. Risk mitigation requirements, including spray drift buffer zones, rate reductions and cancellation of uses, where required, are provided in Section 1.6 of the Science Review Section of this SRD

Comment 63 (Bayer CropScience) - PSRD2018-01 and PSRD2018-02

Bayer CropScience suggested that planting practices can play a critical role in determining if neonicotinoids or other agricultural chemicals will be present in a prairie wetland. For example:

- Wetlands being present in an area where a field had been planted in the previous year, may result in higher than expected concentrations of neonicotinoids (i.e., fields being planted, regardless of the likelihood of the crop surviving or producing a healthy crop).
- Planting the crop as close as possible to a wetland, with no regard to the potential success of the crop poses two issues: (1) any vegetative filter strip area is minimized and (2) crops may not grow well in wet areas around the wetland, thus leaving bare soil areas prone to runoff and erosion.

Bayer CropScience suggested that “there is an opportunity to reduce the potential for runoff of residues by limiting the use of neonicotinoids or other agricultural chemicals in the area directly around the wetlands. Allowing these areas to grow native vegetation would allow for a better buffer for runoff and minimize potential erosion in these areas. Although the concentrations of neonicotinoids in prairie wetlands are generally below levels of concern for aquatic invertebrates, better farming practices could reduce the potential exposure further.”

Health Canada response

Health Canada is fully supportive of improved agronomic practices.

In their 2019 surface water monitoring study in Saskatchewan wetlands, Bayer CropScience concluded that higher clothianidin concentrations in wetlands were influenced in part by shorter distances from the wetland water to the planted area. A significant negative correlation was found between average clothianidin concentration and distance (up to 30 m) from the planted field (coefficient -0.34; $P = 0.039$) (PMRA# 3050881).

While this study does not allow for the determination of a definitive setback distance to mitigate potential risks to aquatic invertebrates, it does support the usefulness of planting setbacks as good agronomic practice in reducing neonicotinoid contamination.

Comment 64 (Dow AgroSciences Canada Inc.) - PSRD2018-01 and PSRD2018-02

It was suggested that once new risk mitigation measures are applied, a plan to monitor the effect of neonicotinoid levels on aquatic organisms under field conditions be developed. Mitigation measures could also include the prioritization of uses (including seed treatments, specific crops), and the review of rates and number of applications per season.

Health Canada response

Health Canada would consider field-level biomonitoring data generated by registrants in support of future registration submissions. Registrants would be encouraged to contact Health Canada to discuss potential study design and protocols prior to initiation.

As part of the risk assessments for the clothianidin and thiamethoxam special review final decisions, Health Canada has considered mitigation options for all uses exceeding the level of concern. For crops with a range of registered rates, risk was examined for lower rates and numbers of applications. For a discussion of risks identified for each of the major commodities and the resulting risk mitigation requirements, refer to Science Review Section 1.5 of this SRD.

Comment 65 (Saskatchewan Ministry of Agriculture) - PSRD2018-01 and PSRD2018-02

The Saskatchewan Ministry of Agriculture has requested that Health Canada reconsider the proposed decision as it pertains to clothianidin seed treatments for canola, and Small Grain Cereals (wheat, barley, oats) on the Canadian Prairies for the following reasons.

- This use pattern has been found to represent negligible risk to pollinators and water monitoring data shows levels of neonicotinoids that represent little risk to aquatic organisms in Saskatchewan.
- The dominant use pattern for clothianidin [and thiamethoxam] in Saskatchewan is as a seed dressing to protect canola against flea beetles whereas, applications to Small Grain Cereals are less prevalent. While it was stated that risk reduction through use reduction of clothianidin would be difficult, the Saskatchewan Ministry of Agriculture suggests that the water monitoring data presented demonstrates that only minimal use reduction is required to all but negate potential effects of the dominant use pattern on aquatic arthropod communities in Saskatchewan. In addition, given the increasing popularity of cyantraniliprole seed dressing products to protect canola seedlings, the use of neonicotinoid seed dressings is already somewhat reduced.

Health Canada response

When the proposed regulatory decision to cancel all outdoor uses was published it was not possible to determine with reasonable certainty that harm to aquatic invertebrates would not occur in the Prairie Provinces. Since the publication of the PSRDs, Health Canada has received additional high-quality water monitoring data for regions across Canada from the EMWG for 2018 and 2019. These data have been fully considered in making final regulatory decisions for clothianidin and thiamethoxam. Based on the new information received subsequent to the consultation the risk assessment was revised and now the risks have been determined to be acceptable for several uses, including seed treatment uses widely used in the prairies.

Comment 66 (Dow AgroSciences Canada Inc.) - PSRD2018-01 and PSRD2018-02

Dow AgroScience Canada Inc proposed an alternative risk management strategy which considered the following:

- *Maintain existing seed treatment uses given the lack of alternative active ingredients.*
- *Implement more restrictive buffer zones on the label.*
- *Address the uncertainties of the water modeling data and the environmental risk assessment.*
- *Establish a GLP quality three-year water monitoring program; with stakeholder engagement, to address the shortcomings of the current approach.*
- *Postpone the finalization of the Special Reviews until label restrictions are applied and new high-quality water monitoring data is available.*

Health Canada response

Since the publication of the proposed decisions, a large amount of robust monitoring data and detailed ancillary information were submitted to Health Canada and were considered in relation to risks associated with existing seed treatment uses in the final special review decisions (see Science Review of this SRD and SRD2021-04 for further details).

Health Canada has considered the use of spray buffer zones and vegetative filter strips (VFS) to mitigate neonicotinoid movement into aquatic environments. Spray buffer zones will be required to mitigate risks to aquatic invertebrates from drift associated with foliar spray applications of clothianidin and thiamethoxam (see Science Review of this SRD and

SRD2021-04 for further details). The use of VFS and planting setbacks to mitigate overland runoff to aquatic habitats is discussed in Response to Comments, Sections 1.7.2 and 1.7.4, respectively.

Health Canada is supportive of the creation of a pan-Canadian pesticide monitoring network and is actively engaged with relevant stakeholders (please refer to Section 1.5.1 of the Response to Comments for further details). However, as noted in Section 1.8.1 of the Response to Comments, Health Canada cannot postpone the finalization of the special reviews until the effectiveness of mitigation measures are assessed through new water monitoring data.

1.7.5 Runoff mitigation in nurseries

Comment 67 (Canadian Nursery Landscape Canada Association) - PSRD2018-02

Many nurseries producing containerized nursery stock collect and reuse water runoff. Runoff mitigation measures suggested for greenhouse crops should be able to be applied to containerized nursery production as well. Containerized nursery stock is grown in pots with soilless media. It is in fact this production system where root weevils are particularly destructive.

Health Canada response

As a result of the pollinator re-evaluation decision for thiamethoxam (RVD2019-04), all foliar and soil applications to outdoor and greenhouse ornamentals that will be planted outside and are attractive to pollinators have been cancelled for the protection of pollinators. Only uses on outdoor ornamentals and nursery stock that are not attractive to pollinators are supported past 11 April 2022. For nursery stock after this date, thiamethoxam can only be applied once per season at 70 g a.i./ha to coniferous evergreens and ornamental grasses.

Based on available water monitoring data from areas where nurseries are present in the watershed, concentrations of thiamethoxam did not exceed the level of concern for acute or chronic effects on aquatic invertebrates. Given these factors Health Canada supports the continued foliar use of thiamethoxam for non-pollinator attractive nursery stock.

1.7.6 Drainage water mitigation in cranberry production

Comment 68 (CETAQ – Cranberry Growers Association) - PSRD2018-02

The Cranberry Growers Association requested that Health Canada consider allowing growers to use only 1 full-rate pre-bloom application of thiamethoxam to control weevils at least two weeks before bloom. The growers would have to keep the drainage water as well as the water from the farm ponds or reservoirs on the farm for a period of at least two weeks after an application of thiamethoxam. This would prevent the pesticide residue from being discharged into the environment. This measure would be permitted for a limited amount of time until an effective alternative insecticide is available.

Health Canada response

Health Canada determined that pre-bloom and at-bloom applications of thiamethoxam to cranberries and other low-growing berries (Crop Group 13-07G) pose a risk to pollinators (PRVD2017-24). As a result, foliar applications of thiamethoxam to Crop Group 13-07G (including cranberry), are restricted to post-bloom periods only (RVD2019-04). Therefore, a single full-rate pre-bloom application on cranberries as recommended, is not supported. However, Health Canada considers a single post-bloom application of thiamethoxam at the current maximum single application rate of 70 g a.i./ha to represent a minimal risk to the aquatic invertebrates, based on the unique application conditions to cranberry crops. As noted by CETAQ, agronomic practices for cranberry production often include recirculation and/or retention of irrigation water, delaying release such that growers can keep the water on the farm for a several weeks before releasing it. Monitoring data for Prairie wetlands indicate an average 50% dissipation time of 11.6 days for thiamethoxam in surface water (see Science Review Section 1.3.4 of SRD2021-04). Given the time delay between foliar application, irrigation or flooding of cranberry fields and subsequent release of drainage water along with the dilution that will occur in the receiving waterbody, Health Canada does not object to allowing a single post-bloom application at the maximum single application rate of 70 g a.i./ha, provided retention water is held for a minimum of 30 days prior to release.

1.8 Proposed registration decision

1.8.1 Recommendation to postpone regulatory decisions for clothianidin and thiamethoxam.

Comment 69 (Canola Council of Canada, Alberta Canola Producers Commission, Saskatchewan Canola Development Commission, CropLife Canada, Dow AgroSciences Canada Inc.) - PSRD2018-01 and PSRD2018-02

Comments were received from multiple grower groups and the crop protection industry asking Health Canada to postpone making final regulatory decisions on clothianidin and thiamethoxam for the protection of aquatic invertebrates until the industry has developed effective risk mitigation measures and new high-quality water monitoring data are available.

Health Canada response

Health Canada cannot delay making a final regulatory decision until verified mitigation measures are in place. Since the publication of the Proposed Special Review Decisions for clothianidin and thiamethoxam in 2018, Health Canada has conducted numerous consultations with registrants and agricultural stakeholders, including several of the commenters, to explore possible mitigation options for the risks identified for outdoor uses of these neonicotinoids. Health Canada reviewed two additional years of high-quality Canadian water monitoring data (2018 and 2019) and additional information provided on mitigation options, such as vegetative filter strips and fugitive dust management. This information has been fully considered in making the final regulatory decisions for clothianidin and thiamethoxam.

1.8.2 Recommendations for additional regulatory actions

Comment 70 (Ducks Unlimited Canada) - PSRD2018-01 and PSRD2018-02

Ducks Unlimited Canada (DUC) supports Health Canada's decision to phase out the use of clothianidin and thiamethoxam over concerns that they may accumulate in soil and groundwater, ultimately threatening aquatic invertebrates in wetlands. DUC made the following recommendations to help support precautionary decision-making around their use:

1. *The Government of Canada should increase its efforts and investments in Canada-wide water quality monitoring and evaluation to support future policy and regulatory decisions related to pest management. It should work with provincial and territorial governments, industry, non-governmental organizations (NGOs) and the scientific community to improve data collection, research and evaluation. DUC has assisted with these efforts as part of the Environmental Monitoring Working Group of the Agriculture and Agri-Food Canada Multi-Stakeholder Forum, working with the Canola Council of Canada to better gauge the occurrence and levels of neonicotinoids in prairie wetlands.*
2. *The Government of Canada should work with industry partners, academia and interested NGOs to research, develop and promote alternative methods of pest control within an integrated pest management framework to help protect the environment without unduly compromising the competitiveness of agricultural producers.*
3. *Similar to its counterparts in Ontario and Europe, the PMRA should work with industry and other interested parties to identify appropriate strategies and timelines that will result in the reduced risk of the environmental impacts of the use of neonicotinoids, which may include a phase out of these insecticides.*

Health Canada response

Health Canada continues to work with provincial and territorial governments, industry, non-governmental organizations (NGOs) and the scientific community through working groups like the Federal/Provincial/Territorial Working Group on Pesticides, Agriculture and Agri-Food Canada's Environmental Monitoring and Mitigation Working Groups and CropLife Canada, and through participation at international conferences. Through these initiatives, Health Canada has been able to strengthen data collaborations and solicit a significant amount of high quality water monitoring data for neonicotinoids that had not previously been possible for other pesticides. The establishment of this network of researchers within Canada will also help better position Health Canada to respond to emerging pesticide issues and obtain valuable monitoring data to inform future re-evaluations and special reviews. For example, to better assist research partners in focusing their monitoring efforts, Health Canada is creating a water monitoring priorities database to identify those chemistries currently on the market that may pose the greatest risk of movement into surface and groundwaters and that may pose a risk to the environment based on their toxicity profiles. Also, through these partnerships, Health Canada has evaluated a number of potential mitigation strategies for neonicotinoids, including the use of vegetative filter strips, spray drift management, greenhouse mitigation and fugitive dust management (see Response to Comments Section 1.7 and Science Reviews).

Comment 71 (David Suzuki Foundation) - PSRD2018-01 and PSRD2018-02

The David Suzuki Foundation is 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. They also note that while precautionary label statements are currently required on clothianidin and thiamethoxam products, concentrations posing a risk to aquatic insects have been found in Canadian surface waters. They therefore recommend that Health Canada avoid reliance on precautionary label statements to reduce risks until the effectiveness of this approach can be demonstrated.

Health Canada response

In making its final decisions for the special reviews of clothianidin and thiamethoxam, Health Canada has completed a thorough re-assessment of available information, including Canadian water monitoring data and newly published aquatic invertebrate toxicity data. For uses which have been found to be acceptable for continued registration, Health Canada is satisfied the conditions of use that will be updated and specified on product labels are sufficient to mitigate potential risks to aquatic invertebrate communities.

Pest control products are only registered when the products show value and the risks to human health and the environment are acceptable when label directions are followed. The product labels contain legally-binding use directions, the contravention of which is an offence under the *Pest Control Products Act*. Labels include mandatory mitigation measures, precautionary label statements and non-mandatory best management practices. Precautionary label statements and non-mandatory best management practices are not designed to mitigate risks to acceptable levels but rather are intended to inform users of the properties of the pesticide and promote good environmental stewardship. These label statements appear on the labels of products that have already been determined to have acceptable risk based on the mandatory mitigation measures (i.e., conditions of use) imposed.

The registration of alternative pest control products allows additional tools for growers to ensure adequate pest control in addition to reducing pest resistance. Health Canada routinely encourages the responsible use of pesticides through best management practices and mandatory label restrictions.

1.8.3 Recommendation to cancel all uses of clothianidin and thiamethoxam

Comment 72 (David Suzuki Foundation) - PSRD2018-01 and PSRD2018-02

The David Suzuki Foundation contends that clothianidin and thiamethoxam present unacceptable risks to aquatic invertebrates and recommend the cancellation of all uses of both active ingredients, including greenhouse uses of thiamethoxam.

In support, they refer to the conclusions of the Task Force on Systemic Pesticides that the harmful effects of neonicotinoids on aquatic invertebrates *"have the potential to adversely alter the base of the aquatic food web"*, and to the similar conclusions in the USEPA preliminary risk assessments for clothianidin (USEPA 2017a; PMRA# 2862808) and thiamethoxam (USEPA 2017a; PMRA# 2862809) of the potential for acute and chronic risk to aquatic invertebrates.

The David Suzuki Foundation notes that there is no comprehensive Canadian approach for environmental monitoring of pesticides and that despite the extensive dataset available, significant uncertainties exist. They suggest that the detection of concentrations below the LOC should not overturn the key finding that neonicotinoid insecticides enter waterways at harmful levels in Canada, given that a) monitoring data may not capture peak concentrations and b) the overlap in modelled EECs and measured concentrations for imidacloprid previously reported by Health Canada. It was also recommended that Health Canada apply safety factors to the endpoints used in the risk assessment to account for potential issues of slow recovery, additive or synergistic effects and multiple stressors, as suggested by Morrissey et al. (2015).

Regarding greenhouse effluents, the David Suzuki Foundation is concerned that although pesticide labels may address greenhouse effluent and some provinces regulate greenhouse discharges, this does not guarantee acceptable risks. They note that despite there being no registered greenhouse uses of clothianidin (also a breakdown product of thiamethoxam), the presence of clothianidin residues near multiple greenhouse sites indicate a problem with control of wastewater from greenhouses using thiamethoxam.

It was suggested that neither a use-reduction strategy nor precautionary label statements are viable alternatives to mitigate the identified risks to aquatic invertebrates and that discontinuing use of clothianidin and thiamethoxam, along with imidacloprid, is the best approach to minimizing risks from these chemicals, to aquatic invertebrates and the ecosystems they support.

Health Canada response

Health Canada agrees that neonicotinoids have the potential to adversely affect aquatic invertebrates if exposed to concentrations high enough to cause adverse effects. The proposed decision to cancel all outdoor uses of clothianidin and thiamethoxam was based on Health Canada's inability to show acceptable risk for all outdoor uses based on the available environmental modelling and monitoring data. Health Canada did not propose the cancellation of greenhouse uses of thiamethoxam as regulations are in place that prevent the discharge of effluent or runoff to surface waters. However, the David Suzuki Foundation recommended to also cancel thiamethoxam greenhouse uses on the basis that the presence of clothianidin (also a transformation product of thiamethoxam) in waterbodies near multiple greenhouse sites "… clearly indicate a problem with control of wastewater from greenhouses using thiamethoxam".

Health Canada does not agree with this claim as other major land uses at sites adjacent to waterbodies associated with greenhouses also included crops registered for use with clothianidin, such as corn, wheat, tomatoes, vineyards, etc. (Appendix VII, PSRD2018-01). Therefore, it is not possible to discount the direct contribution of clothianidin from other uses.

Although the Government of Canada does not have a comprehensive environmental pesticide monitoring program, Health Canada has worked closely with the national Environmental Monitoring Working Group, which has coordinated an extensive surface water monitoring program for neonicotinoids across the country since 2017. The additional water monitoring data received for 2018/2019 has resolved some of the uncertainties identified in PSRD2018-01 and PSRD2018-02, by providing more frequent sampling during the growing season at individual sites and more detailed site-specific information on cropping practices. A thorough re-assessment of available monitoring data is provided in the Science Review sections for both active ingredients.

In assessing risk to aquatic invertebrates, Health Canada will apply a safety factor to the most sensitive acute endpoint for a single species if required, to account for potential differences between species that may not have been identified with the available dataset. In the case of acute toxicity data for clothianidin and thiamethoxam however, sufficient species were available to estimate the concentration expected to protect 95% of the aquatic invertebrate community at the median effect level (for example, 50% immobility or mortality). Health Canada does not apply additional safety factors to species sensitivity distributions, as the model takes into account the expected response across the entire community in question, rather than basing the endpoint on a single-species response. For assessing chronic risk, Health Canada relies on the NOEC or analogous 10% effect level for laboratory or higher-tiered field studies.

A safety factor is not applied to endpoints derived from chronic studies as these are conservative endpoints that are based on prolonged exposures and the most sensitive of either the lowest observed sub-lethal effects on growth or reproduction, or lethal effects such as mortality or lack of insect emergence.

In making the final regulatory decisions for clothianidin and thiamethoxam, the risks to aquatic invertebrates were fully re-assessed using the newly available Canadian water monitoring data from 2018/2019 and a re-assessment of currently available aquatic invertebrate toxicity data (see Science Review in this SRD and SRD2021-04 for clothianidin and thiamethoxam, respectively).

1.8.4 Recommendation to accelerate the three- to five-year phase-out period

Comment 73 (Nature Canada, David Suzuki Foundation and National Farmers Union) - PSRD2018-01 and PSRD2018-02

Multiple comments were received in support of Health Canada’s proposed decision to cancel all outdoor uses of clothianidin and thiamethoxam; all included a recommendation to accelerate the proposed three- to five-year phase-out period.

The David Suzuki Foundation and National Farmers Union (NFU) also supported the proposed cancellation of clothianidin and thiamethoxam and recommended a shortened phase-out periods that do not follow DIR2018-01. It was suggested that the proposed three to five-year timeline for phase-out would needlessly prolong environmental risks that have not been shown to be acceptable. While the Suzuki Foundation recommends immediate phase-out, the NFU advocates for a one-year phase out on cereal crops and a three-year phase-out on all other crops, given that suitable alternatives are already available on the market. The NFU also recommended that during the phase-out period the use of clothianidin and thiamethoxam restrictions should be tightened. For example, prophylactic use (routine seed treatment or spraying regardless of degree of pest pressure) should no longer be allowed, with the onus on the user to prove need before purchase.

The NFU argued that when considering “suitable alternatives to the use of the pesticide” being phased out as a result of a Special Review, Health Canada must go beyond the concept of alternative chemical products. If a new synthetic insecticide replaces neonicotinoids, it too will have negative impacts on ecosystems and will put selection pressure on pest species to evolve resistance. The NFU urges Health Canada to recognize and promote agronomic alternatives to the use of chemical pesticides and to support agricultural research, education and public policy measures to reduce pesticide use in Canadian agriculture.

Health Canada response

A significant amount of new monitoring data with auxiliary information were submitted and considered in the final decision. Based on these data, additional toxicity information and comments received during the comment period, Health Canada has revisited the risk assessment for both clothianidin and thiamethoxam. The final risk decisions for each neonicotinoid, along with the proposed mitigation measures, are outlined in the Science Evaluation Update sections of the respective SRDs. The implementation of this final special review decision was determined in accordance with the process outlined in Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review.* This Regulatory Directive provides flexibility with regard to the phase-out period dependent on the potential magnitude of harm. In the case of those uses being phased out, an imminent and serious risk to the environment was not identified; as such, implementation timelines for the phase-out period were determined as per DIR2018-01.

While Health Canada fully supports the use of agronomic best practices and recognizes the importance alternative pest control methods, its mandate is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Growers can access additional pesticide risk reduction strategies through Agriculture and Agri-food Canada’s Pest Management Centre (PMC). The Pesticide Risk Reduction (PRR) team of PMC works with growers to adopt an integrated approach to managing pests, with the goal of reducing reliance on traditional pesticides.

1.8.5 Negative environmental impacts from proposed decision

Comment 74 (Promax Agronomy Services Ltd., Pulse Canada, The Grain Growers of Canada) - PSRD2018-01 and PSRD2018-02

Several commenters raised the potential for inadvertent negative environmental and human health impacts from the proposed cancellation of neonicotinoid uses.

Promax Agronomy Services Ltd. highlighted the potential for increased risks to human health and the environment from additional foliar insecticide applications, should neonicotinoid seed treatments be banned. Cereals Canada noted that due to a lack of alternative chemical and effective agronomic approaches, effective wireworm control without neonicotinoids will require many additional hectares of land to be cultivated. This in turn could result in increased greenhouse gas (GHG) production and a reduction of soil organic matter.

Pulse Canada raised the concern that the phase out of neonicotinoid seed treatments will result in secondary impacts including more synthetic nitrogen fertilizer use, which can lead to higher emissions of the potent GHG nitrous oxide. The benefits of using pulse crops as a GHG emission reduction strategy in cereal crop rotations could be in jeopardy with the revocation of seed treatment insecticides.

The Grain Growers of Canada highlighted the important role that thiamethoxam and clothianidin seed treatments play in Integrated Pest Management (IPM) strategies in canola, wheat, barley, corn, soybean, and pulse production in Canada. Their use allows for significant reductions in the amount of active ingredient used, reducing GHG emissions by limiting tractor passes. Seed treatment use also reduces the need for foliar insecticide sprays, protecting beneficial insects and non-target organisms and promoting soil and environmental health.

Health Canada response

Following a re-evaluation or special review, Health Canada grants continued registration of a pesticide when the assessment indicates that the risks to human health and the environment, and the value, of a pesticide are considered acceptable when used according to the label directions. As part of these special reviews, Health Canada assessed the aspect of concern identified in the special review based on the currently available information (including information received during the consultation of the proposed decisions), as per subsection 18(4) of the *Pest Ccontrol Products Act*. This included a large amount of robust monitoring data and detailed ancillary information that were considered in relation to risks associated with existing seed treatment uses in the final special review decisions (see Science Review of this SRD and SRD2021-04 for further details). All uses that have shown acceptable risk to aquatic invertebrates have been proposed for continued registration.

Appendix IV Toxicity to aquatic invertebrates

Table A.4-1 Effects of clothianidin and formulated products containing clothianidin alone on aquatic invertebrates. New or revised endpoints for the SRD are highlighted in bold

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Acute							
Freshwater invertebrates							
Crustaceans - Cladocera							
Daphnia magna	Acute 48-h	Clothianidin (97.6% purity)	48-h EC_{50} > 119 000 (0% mortality/ immobilization)	Practically non-toxic	No[a]		1194141
	Acute 48-h	Clothianidin (purity not reported)	48-h EC_{50} = 109 523	Practically non-toxic	Yes		2538669 (Morrissey et al., 2015)
	Acute 48-h	Clothianidin (96% purity)	48-h EC_{50} = 25 100 (17 000–37 100) (mortality/ immobilization)	Slightly toxic	Yes		2713565
	Acute 48-h	Clothianidin (99.9% purity)	48-h EC_{50} > 500 (0% mortality/ immobilization)	Not toxic up to highest concentration tested.	No[a]		2712666 (de Perre et al., 2015)
	Acute 48-h	Clothianidin (99.8% purity)	48-h EC_{50} > 100 000 (0% mortality/ immobilization)	Practically non-toxic	No[a]		2712674
	Acute 48-h	Clothianidin (Dantotsu Flowable; 20% v/v)	48-h EC_{50} = 67 564 (48 762–98 441) (mortality/ immobilization)	Slightly toxic	Yes		2712667 (Hayasaka et al., 2013)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
	Acute 48-h	Clothianidin (FS 600 G; 47.0% purity)	48-h EC_{50} = 91 650 (64 860–129 720) (mortality/ immobilization)	Slightly toxic	Yes		2713529
	Acute 48-h	Clothianidin (600 g/L)	48-h EC_{50} = 2140 (912–5040) (mortality/ immobilization)	Moderately toxic	Yes		2712665 (Li et al., 2013)
	Acute 48-h	Clothianidin (50 WDG G; 50.3% purity)	48-h EC_{50} = 14 100 (14 000–15 000) (mortality/ immobilization)	Slightly toxic	Yes		2713564
Daphnia pulex	Acute 48-h	Clothianidin (Dantotsu Flowable; 20% v/v)	48-h EC_{50} = 31 448 (20 881–46 463) (mortality/ immobilization)	Slightly toxic	Yes		2712667 (Hayasaka et al., 2013)
Daphnia similis	Acute 48-h	Clothianidin (Poncho SC; guarantee not reported)	48-h EC_{50} = 1740 (1310–2320) (mortality/ immobilization)	Moderately toxic	Yes		2713531
Ceriodaphnia dubia	Acute 48-h	Clothianidin (Dantotsu Flowable; 20% v/v)	48-h EC_{50} = 1691 (1077–19 844) (mortality/ immobilization)	Moderately toxic	Yes		2712667 (Hayasaka et al., 2013)
	Acute 48-h	Clothianidin (≥ 98.6% purity)	48-h LC_{50} > 100 000 (0% mortality)	Practically non-toxic	No[a]	EC_{50} Not available (immobilization not recorded)	2842540 (Raby et al., 2018a)
Ceriodaphnia reticulata	Acute 48-h	Clothianidin (Dantotsu Flowable; 20% v/v)	48-h EC_{50} = 29 474 (21 076–49 968) (mortality/ immobilization)	Slightly toxic	Yes		2712667 (Hayasaka et al., 2013)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Moina macrocopa	Acute 48-h	Clothianidin (Dantotsu Flowable; 20% v/v)	48-h EC_{50} = 61 106 (42 582–106 290) (mortality/ immobilization)	Slightly toxic	Yes		2712667 (Hayasaka et al., 2013)
Crustaceans – Amphipoda							
Hyalella azteca	Acute 96-h	Clothianidin (99.9% purity)	96-h EC_{50} = 6.67 (3.88–8.97) (mobility: difficulty of swimming, lack of or erratic movements)	Very highly toxic	Yes		2712666 (de Perre et al., 2015)
			96-h LC_{50} = 12.5 (9.01–15.8)	Very highly toxic	No[b]		
	Acute 96-h	Clothianidin (analytical grade; purity not reported)	96-h LC_{50} = 9.68 (7.64–11.8)	Very highly toxic	Yes		2712690 (Whiting and Lydy, 2015)
	Sub-chronic 7-d	**Clothianidin (≥ 95% purity)**	**Geomean of 7-d LC_{50} = 3.76**	**Very highly toxic**	**No[c]**	**Update for SRD: Health Canada reported 7-d LC_{50} of 1.65 (1.55–1.75) in PSRD2018-01 based on more conservative range-finding test results. Endpoint statistically re-assessed by Health Canada based on definitive test results and to account for multiple trials conducted with the test species. Confidence limits are not available as the endpoint is a geomean of 7-d LC_{50} endpoints from two trials.**	**2975959 (Bartlett et al., 2019); previously reported as 2753706 (ECCC 2017) in PSRD2018-01**
	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 4.8 (4.1–5.6) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
			96-h LC_{50} = 5.2 (4.4–5.9)	Very highly toxic	No[b]		
Crustaceans –Isopoda							
Asellus aquaticus	Acute 48-h	Clothianidin (99% purity)	48-h EC_{50} = 67 (43–105) (mortality/ immobilization)	Very highly toxic	Yes		2712685
Caecidotea sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 537.2 (248.0–826.3) (immobilization)	Highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} = 16 085.8 (2636.6–29 534.9)	Slightly toxic	No[b]		
Crustaceans –Decopoda							
Procambarus clarkii	Acute 96-h	Clothianidin (99% purity)	96-h EC_{50} = 59 (6–137) (mortality/ immobilization)	Very highly toxic	Yes	Reported LC_{50} includes mortality + immobilization (can therefore be considered as EC_{50}).	2712686 (Barbee and Stout, 2009)
	Acute 96-h	Clothianidin (97.7% purity)	96-h EC_{50} = 599 (339–1048) (mortality and immobilization, including slow movement, difficulty walking, lying on bottom, and lack of reaction upon gentle prodding)	Highly toxic	Yes		2713537
Orconectes propinquus	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 805 (509–1462)	Highly toxic	Yes		2832753 (Miles et al., 2017)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Molluscs							
Lampsilis fasciola	Acute 48-h	Clothianidin (≥ 95% purity)	48-h LC_{50} > 478 (5.6% mortality)	Not toxic up to highest concentration tested.	Yes[d]		2712688 (Prosser et al., 2016)
Planorbella pilsbryi	Sub-chronic 7-d	Clothianidin (≥ 95% purity)	7-d LC_{50} = 4000 (2473–5528)	Moderately toxic	No[c]	7-d LC_{10} = 431 (179–682)	2712688 (Prosser et al., 2016)
Villosa iris	**Acute 24-h**	**Clothianidin (98.0% purity)**	**24-h EC_{50} > 13 800**	**Not toxic up to highest concentration tested.**	**No[c]**	**Glochidia (larval) stage tested. Limited 24-h exposure period only.**	**2912493 (Salerno et al., 2018)**
Insects – Diptera							
Chironomus riparius	Acute 48-h	Clothianidin (97.6% purity)	48-h EC_{50} = 21 (mortality/ immobilization)	Very highly toxic	Yes		1194168
	Acute 48-h	Clothianidin (99% purity)	48-h EC_{50} = 14 (4–29) (mortality/ immobilization)	Very highly toxic	Yes		2712685
	Acute 48-h	Clothianidin (purity not reported)	48-h EC_{50} = 29	Very highly toxic	Yes		3014284 (EC 2005)
	Acute 48-h	Clothianidin (FS 600 G)	48-h EC_{50} = 26.7 (17.1–41.8) (immobilization)	Very highly toxic	Yes		2713530
Chironomus dilutus	Acute 96-h	Clothianidin (99.9% purity)	96-h EC_{50} = 1.85 (1.49–2.29) (immobilization)	Very highly toxic	Yes	Effects on mobility included difficulty of swimming, lack of or erratic movements.	2712666 (de Perre et al., 2015)
			96-h LC_{50} = 2.32 (1.97–2.75)	Very highly toxic	No[b]		
	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 3.4 (2.7–5.5)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
			(immobilization)				
			96-h LC_{50} = 11.6 (6.5–16.8)	Very highly toxic	No[b]		
	Acute 96-h	Clothianidin (99.6% purity)	96-h LC_{50} = 5.93 (5.29–6.63)	Very highly toxic	Yes		2818524 (Maloney et al., 2017)
Chironomus tepperi	Acute 24-h	Clothianidin (TI 435, 200 g a.i./L SC)	24-h LC_{50} = 5.19 (3.95–6.83)	Very highly toxic	No	Qualitative endpoint. Cannot be used quantitatively in a risk assessment.	2712705 (Stevens et al., 2005)
Aedes aegypti	Acute 72-h	Clothianidin (98% purity)	72-h LC_{50} = 98 (28–114)	Very highly toxic	No	Qualitative endpoint. Cannot be used quantitatively in a risk assessment.	2841145 (Ahmed and Matsumura, 2012)
Culex pipiens	**Acute 72-h**	**Clothianidin (DANTOP Insecticide, 500 g a.i./kg; 50% guarantee)**	**72-h LC_{50} = 11.0 (9.3–13.0)**	**Very highly toxic**	**Yes**	**Exposure was up to 144-h; mortality rates increased with exposure time. Mortality was not assessed at 96-h, so Health Canada determined the 72-h LC_{50}.**	**2978128 (Russo et al., 2018)**
Insects – Trichoptera							
Cheumatopsyche brevilineata	Acute 48-h	Clothianidin (≥ 98.0% purity)	48-h EC_{50} = 4.44 (4.07–4.87) (mortality/ immobilization)	Very highly toxic	Yes		2722291 (Yokoyama et al., 2009)
Cheumatopsyche sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} = 1281.0 (423.1–2138.8)	Moderately toxic	No[b]		2842540 (Raby et al., 2018a)
			96-h EC_{50} <108.8 (100% immobilization + mortality at 108.8 µg a.i./L)	Very highly toxic	No[a]		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Insects - Ephemeroptera							
Cloeon dipterum	Acute 48-h	Clothianidin (99% purity)	48-h EC_{50} = 12 (8–16) (mortality/ immobilization)	Very highly toxic	Yes		2712685
Cloeon sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} = 3932.0 (1044.9–6833.5)	Moderately toxic	No[b]		2842540 (Raby et al., 2018a)
			96-h EC_{50} < 16.4 (100% immobilization + mortality at 16.4 µg a.i./L)	Very highly toxic	No[a]		
Ephemerella sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 18.5 (13.3–25.7) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} = 586.9 (415.0–830.0)	Highly toxic	No[b]		
Hexagenia sp.	Acute 96-h	Clothianidin (≥ 95% purity)	96-h EC_{50} = 24 (13–46) (behaviour: number of surviving animals after 96 h found inside artificial burrows)	Very highly toxic	Yes		2861091 (Bartlett et al., 2018)
			96-h LC_{50} = 2000 (150–26 000)	Moderately toxic	No[b]		
	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 5.5 (3.9–7.0) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} > 17 400	Slightly toxic	No[b]		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Isonychia bicolor	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} > 1740	Moderately toxic	No[a]		2842540 (Raby et al., 2018a)
			96-h EC_{50} < 108.8 (100% immobilization + mortality at 108.8 µg a.i./L)	Very highly toxic	Yes[d]		
McCaffertium sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} = 1328.3 (653.9–2002.7)	Moderately toxic	No[b]		2842540 (Raby et al., 2018a)
			96-h EC_{50} < 108.8 (100% immobilization + mortality at 108.8 µg a.i./L)	Very highly toxic	Yes[d]		
Neocloeon triangulifer	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} / LC_{50} = 3.5 (2.5–5.0) (mortality/ immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
Insects – Odonata							
Coenagrion sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} = 14 556.3 (7632.8–21 479.9)	Slightly toxic	No[b]		2842540 (Raby et al., 2018a)
			96-h EC_{50} < 5918.8 (100% immobilization + mortality at 5918.8 µg a.i./L)	Moderately toxic	Yes[d]		
Lestes unguiculatus	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 1245 (572–2110)	Moderately toxic	Yes		2832753 (Miles et al., 2017)
Anax junius	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 1000 (NA)	Highly toxic	Yes		2832753 (Miles et al., 2017)

Organism	Exposure	Test substance	Endpoint value (μg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Plathemis lydia	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 865 (306–2133)	Highly toxic	Yes		2832753 (Miles et al., 2017)
Insects – Plecoptera							
Agnetina, Paragnetina sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h LC_{50} = 1714.8 (1105.3–2324.2)	Moderately toxic	No[b]		2842540 (Raby et al., 2018a)
			96-h EC_{50} < 300.5 (100% immobilization + mortality at 300.5 µg a.i./L)	Highly toxic	Yes[d]		
Insects – Hemiptera							
Trichocorixa sp.	Acute 48-h	Clothianidin (≥ 98.6% purity)	48-h EC_{50} = 21.3 (11.7–30.9) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			48-h LC_{50} = 34.8 (17.1–52.5)	Very highly toxic	No[b]		
Belostoma flumineum	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 79 (52–107)	Very highly toxic	Yes		2832753 (Miles et al., 2017)
Notonecta undulata	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 59 (35–107)	Very highly toxic	Yes		2832753 (Miles et al., 2017)
Hesperocorixa atopodonta	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 56 (39–82)	Very highly toxic	Yes		2832753 (Miles et al., 2017)
Insects - Coleoptera							
Ancyronyx sp. (larvae)	Sub-chronic 7-d	Clothianidin (purity not reported)	7-d LC_{50} = 50.9 (26.6–97.3)	Very highly toxic	No[c]		2712690 (Whiting and Lydy, 2015)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Dytiscidae sp. (adults)	Acute 48-h	Clothianidin (99% purity)	48-h EC_{50} = 7 (2–14) (mortality/ immobilization)	Very highly toxic	Yes		2712685
Gyrinus sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 41.2 (30.2–52.1) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} = 62.6 (45.4–79.8)	Very highly toxic	No[b]		
Stenelmis sp.	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 84.9 (60.0–120.0) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} = 208.0 (136.5–279.4)	Highly toxic	No[b]		
Graphoderus fascicollis	Acute 48-h	Clothianidin (Arena; 0.25% purity)	48-h LC_{50} = 2 (1–5)	Very highly toxic	Yes		2832753 (Miles et al., 2017)
Oligochaetes							
Lumbriculus variegatus	Acute 96-h	Clothianidin (≥ 98.6% purity)	96-h EC_{50} = 41.7 (34.9–49.8) (immobilization)	Very highly toxic	Yes		2842540 (Raby et al., 2018a)
			96-h LC_{50} = 177.1 (145.3–207.5)	Highly toxic	No[b]		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Marine invertebrates							
Crustaceans – Decapoda							
Mysidopsis bahia	Acute 96-h	Clothianidin (97.6% purity)	96-h LC_{50} = 51	Very highly toxic	NA		1194202
Molluscs							
Crassostrea virginica	Acute 96-h	Clothianidin (97.6% purity)	96-h EC_{50} / LC_{50} > 129 100 (0% reduction in shell growth and survival)	Practically non-toxic	NA		1194203
Chronic							
Freshwater invertebrates							
Crustaceans - Cladocera							
Daphnia magna	21-d Chronic	Clothianidin (96% purity)	21-d NOEC reproduction / mortality = 120		NA	21-d EC_{50} reproduction = 7400 (4480–11 000) µg a.i./L; 21-d LC_{50} = 17 300 (5800–228 700) µg a.i./L. Health Canada assessment of NOEC reproduction differs from USEPA; EFED (2011) NOEC reproduction = 42 µg a.i./L.	1194147
Ceriodaphnia dubia	**7-d Chronic**	**Clothianidin (99.9% purity)**	**7-d EC_{10} reproduction = 2030 (510–3550)**		NA	**Reproduction based on number of neonates produced per female.**	**2912491 (Raby et al., 2018c)**
Crustaceans - Amphipoda							
Hyalella azteca	**28-d Chronic**	**Clothianidin (≥ 95% purity)**	**Geomean of 28-d EC_{10} growth = 0.35**		NA	**Update for SRD: Health Canada reported NOEC growth = 0.31 µg a.i./L in PSRD2018-01. Following comments received, the endpoint was re-assessed by Health Canada to account for multiple trials conducted with the test species. Confidence limits are not available as the endpoint is a geomean of endpoints**	**2975959 (Bartlett et al., 2019); previously reported as 2753706 (ECCC, 2017) in PSRD2018-01**

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
						from two trials.	
			Geomean of 28-d LC_{10} = 2.14		NA	Update for SRD: Health Canada reported the NOEC mortality = 1.3 µg a.i./L in PSRD2018-01. Following comments received, the endpoint was re-assessed by Health Canada to account for multiple trials conducted with the test species. Confidence limits are not available as the endpoint is a geomean of endpoints from two trials.	
Molluscs							
Planorbella pilsbryi	28-d Chronic	Clothianidin (≥ 95% purity)	28-d LC_{10} mortality = 19.8 (6.5–33)		NA	28-d LC_{50} mortality = 183 (118–248) µg a.i./L. Update for SRD: Following comments received on PSRD2018-01, the more sensitive growth and biomass endpoints reported in the original study were removed due to uncertainties in snail weights.	2712688 (Prosser et al., 2016)
Lampsilis siliquoidea	28-d Chronic	Clothianidin (98.0% purity)	28-d NOEC mortality ≥ 9033		NA	Juvenile and adult freshwater mussels. NOEC equal to highest measured concentration.	2912493 (Salerno et al., 2018)
Insects - Ephemeroptera							
Neocloeon triangulifer	32-d Chronic	Clothianidin (99.9% purity)	32-d NOEC survival to emergence = 0.23		NA	Endpoint determined by Health Canada. NOEC reported because EC_{10} could not be reliably established.	2912490 (Raby et al., 2018b)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Deleatidium spp.	**28-d Chronic**	**Clothianidin (≥ 98% purity)**	**28-d NOEC immobility + mortality = 0.02**		NA	**Qualitative endpoint only; not to be used quantitatively in a risk assessment. Endpoint determined by Health Canada. NOEC reported because EC_{10} could not be reliably established.**	**3078943 (Macaulay et al., 2019)**
Insects - Diptera							
Chironomus riparius	28-d Chronic	Clothianidin 50 WDG (50.3% purity)	28-d NOEC emergence rate = 0.38		NA	Previously reported as EC_{15} = 0.72 µg a.i./L based on nominal treatment concentrations (ERC2011-01). Nominal NOEC of 0.56 µg a.i./L re-assessed based on mean measured concentrations from Day 0 and 7.	2713553 (also 1194187)
	28-d Chronic	Clothianidin (98 ± 2% purity)	28-d NOEC emergence/sex ratio = 0.55		NA	NOEC determined by Health Canada based on mean measured concentrations from Day 0 and 7 at 0.67 µg a.i./L nominal treatment. 28-d EC_{50} emergence = 1.2 µg a.i./L nominal.	2712700
Chironomus dilutus	40-d Life-cycle bioassay	Clothianidin (99.6% purity)	14-d LC_{50} = 2.41 (1.73–2.83)		NA		2712687 (Cavallaro et al., 2017)
			40-d EC_{20} emergence = 0.02 (0.019–0.036)		NA	40-d EC_{50} emergence = 0.28 (0.20–0.33) µg a.i./L	
			14-d EC_{20} biomass = 0.89 (0.74–0.98)		NA	14-d EC_{50} biomass = 1.83 (1.74–2.08) µg a.i./L	
			40-d EC_{20} sex ratio = 0.15 (NA)		NA	40-d EC_{50} sex ratio = 0.46 (0.29–1.17) µg a.i./L	
	28-d Chronic	Clothianidin (99.6% purity)	28-d EC_{20} emergence = 0.34 (0.19–0.45)		NA	28-d EC_{50} emergence = 0.71 (0.50–0.85) µg a.i./L	2873503 (Maloney et al., 2018)
	56-d Chronic	**Clothianidin (99.9% purity)**	**56-d EC_{10} survival to emergence = 0.25 (0.11-0.39)**		NA	**Endpoint determined by Health Canada.**	**2912490 (Raby et al., 2018b)**

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Studies using treated sediments:							
Endpoints based on overlying water concentrations:							
Chironomus riparius	10-d Chronic	Clothianidin (>99% purity)	10-d NOEC mortality = 0.45		NA	10-d LC_{50} = 0.99 (0.88–1.1) µg a.i./L	1636640
			10-d NOEC dry weight = 0.12			10-d EC_{50} dry weight = 1.0 (0.89–1.2) µg a.i./L	
Endpoints based on pore water concentrations:							
Chironomus riparius	10-d Chronic	Clothianidin (>99% purity)	10-d NOEC mortality = 3.4		NA	10-d LC_{50} = 11 (9.2–13) µg a.i./L	1636640
			10-d NOEC dry weight = 1.1		NA	10-d EC_{50} dry weight = 12 (9.4–15) µg a.i./L	
Chironomus dilutus	63-d life-cycle bioassay	Clothianidin (98.6% purity)	20-d NOEC survival, growth = 3.2		NA	20-d EC/LC_{50} > 7.6 µg a.i./L. Endpoints based on overlying water not reported due to very low recoveries in overlying water.	2615168
	63-d life-cycle bioassay	Clothianidin (98.6% purity)	63-d NOEC emergence = 1.6			63-d EC_{50} emergence = 4.8 (3.9–5.8)	
Endpoints based on sediment concentrations:							
Chironomus riparius	10-d Chronic	Clothianidin (>99% purity)	10-d LC_{50} = 400 (340–460) µg a.i./kg dw		NA		1636640
			10-d NOEC mortality = 140 µg a.i./kg dw				
			10-d EC_{50} dry weight = 430 (350–520) µg a.i./kg dw				
			10-d NOEC dry weight = 51 µg a.i./kg dw				
	28-d Chronic	Clothianidin (99% purity)	28-d EC_{50} emergence = 25 µg a.i./kg dw		NA	Recoveries were low and endpoints were based on nominal exposure concentrations. The endpoints cannot be used quantitatively in a risk assessment, but may be used as qualitative evidence	2712695
			28-d NOEC emergence = 15 µg a.i./kg dw				

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
						only.	
Chironomus dilutus	63-d life-cycle bioassay	Clothianidin (98.6% purity)	20-d NOEC survival, growth = 30 µg a.i./kg dw		NA	20-d EC/LC_{50} > 60 µg a.i./kg dw	2615168
			63-d NOEC emergence = 16 µg a.i./kg dw			63-d EC_{50} emergence = 42 (35–50) µg a.i./kg dw	
Microcosm or mesocosm tests							
Multiple invertebrate species	98-d Chronic	Clothianidin 50 WG (49.3% purity)	98-d NOEC = 0.54 (emergent insect populations)		NA	Significant reductions in emergence rates of several insect species (Chironominae, Chaoboridae, Orthocladiinae, total emergence), as well as the larval densities of the chironomids in the sediment. Significant toxic effects on community parameters included taxa abundance, diversity, evenness and similarity. Toxic effects on emergent insects were observed within the first three weeks after test substance application. Sediment-dwelling chironomids recovered to control levels by 28 days post treatment and densities of all affected emergent insects as well as all community parameters recovered to control levels by 77 days post treatment. There was an insufficient abundance of Ephemeropterans to assess effects on this sensitive group of insects. NOEC determined by Health Canada as TWA concentration due to loss of test material over time in mesocosms.	1636641
	56-d Chronic	Clothianidin 50 WG (49.2%	56-d $NOEC_{14\text{-d TWA}}$ = 0.281 (reductions in individual species		NA	The NOEC (with recovery) is based on significant increases in *Chaoborus* sp.	2713555

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
		purity)	populations and in community or taxa richness)			larvae, reductions in *Plea* sp. (Hemiptera) abundance and reduction in total Hemiptera abundance and a reduction in emergent insect taxa richness. Effects were transient and recovery was observed by end of the study. A NOEC (with no recovery) of 1.0 µg a.i./L (Health Canada TWA concentration = 0.573 µg a.i./L) was reported by the study author based on the following significant effects that were observed at either the community or individual species level where no recovery was observed by the end of the study: decreases in abundance of *Asellus aquaticus* immatures and juveniles, total abundance of Crustacea and species richness of emerging insects. There was an insufficient abundance of Ephemeropterans to assess effects on this sensitive group of insects. The NOECs were determined by Health Canada as TWA concentrations due to loss of test material over time in mesocosms.	
	107-d Chronic	**Clothianidin (99.6% purity)**	**107-d NOEC Emergence (community level) ≥ 0.384**		**NA**	**Multiple applications to outdoor mesocosms. No significant effect on total insect community emergence was observed at the highest treatment level.**	**2912492 (Cavallaro et al., 2018)**

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
						Significantly earlier emergence was reported for Chironimidae and Zygoptera at the highest test concentration. However, this endpoint was not considered quantitatively in the risk assessment due to uncertainties in the statistical analysis and as an adverse impact on insect populations is not certain given the expected overlap in emergence timing and multiple generations that can occur in natural populations.	
Natural species assemblage	**56-d**	**Clothianidin (99.6% purity)**	**56-d LOEC Chironomidae cumulative emergence and biomass = 0.73 ± 0.21 µg a.i./L**		**NA**	**Multiple applications to outdoor mesocosms. LOEC reported for single compound exposure. Only one treatment level conducted, so NOEC could not be established.**	**3076589 (Maloney et al., 2018**b**)**
Marine invertebrates							
Crustaceans - Decapoda							
Mysidopsis bahia	39-d Chronic	Clothianidin (97.6% purity)	39-d NOEC reproduction = 5.1		NA	EC_{50} reproduction = 7.6 µg a.i./L	1194204
Crustaceans - Amphipoda							
Studies using treated sediments:							
Endpoints based on overlying water concentrations:							
Leptocheirus plumulosus	10-d Chronic	Clothianidin (99.4% purity)	10-d NOEC mortality = 2.03		NA	10-d LC_{50} mortality = 3.23 (2.11–4.47) µg a.i./L	2713580
Endpoints based on pore water concentrations:							
Leptocheirus plumulosus	10-d Chronic	Clothianidin (99.4% purity)	10-d NOEC mortality = 11.6		NA	10-d LC_{50} mortality = 20.4 (18.3–22.6) µg a.i./L	2713580

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Degree of toxicity	Data used in SSDs	Comments	Reference PMRA# (Publication)
Endpoints based on sediment concentrations:							
Leptocheirus plumulosus	10-d Chronic	Clothianidin (99.4% purity)	10-d NOEC mortality = 5.5 µg a.i./kg dw	NA		10-d LC_{50} mortality = 8.5 (8.0–9.0) µg a.i./kg dw	2713580

NA: Not applicable, an SSD was not constructed for these taxa;
[a] Unbound endpoint was not included as a more sensitive endpoint is available for this species or a similar taxa from another study (as per EFSA 2013 guidance)
[b] A more sensitive endpoint is available from the same study
[c] Endpoint was not included in the acute SSD as it falls outside of the 48–96 hour study duration for standard acute invertebrate toxicity tests.
[d] Unbound endpoint was included as it represents the most sensitive endpoint for this unique species (as per EFSA 2013 guidance).

Table A.4-2 References received after the end of the commenting period for PSRD2018-01 and after the establishment of effects metrics for the final regulatory decision

Reference	Study type	Comments
Macaulay (2020)	Ph.D. Dissertation. Chronic toxicity of imidacloprid, clothianidin and thiamethoxam to New Zealand mayflies.	Abstract only. Studies published under Macaulay et al. (2019; PMRA# 3078943) [clothianidin, thiamethoxam, imidacloprid], Hunn et al. (2019; PMRA# 3132594) [imidacloprid].
Schepker et al. (2019; PMRA# 3132605))	Published study. Association between neonicotinoid concentrations and invertebrate communities in US wetlands.	Not applicable for quantitative clothianidin risk assessment. Correlative biomonitoring study relating neonicotinoid concentrations and invertebrate community structure in Nebraska wetlands. Also looks at impact of vegetative buffer presence on neonicotinoid concentrations in wetlands.
Bonmatin et al. (2019; PMRA# 313259)	Published study. Survey of neonicotinoid concentrations in Belize, with accompanying probabilistic risk assessment.	Not relevant to clothianidin risk assessment. Regional risk assessment based on measured concentrations of neonicotinoids in soil, water and sediments compared against aggregate neonicotinoid threshold values. No new toxicity endpoints were reported.
Hano et al. (2019; PMRA# 3132596)	Published study. Risk assessment of neonicotinoids and fipronil in Japanese estuary.	Potential impact on clothianidin marine risk assessment, but not expected to affect overall risk conclusions. Regional risk assessment for estuarine invertebrates based on acute toxicity assays and measured concentrations. New acute 96-h EC_{50} and LC_{50} endpoints for clothianidin (lowest reported value): *Penaeus japonicus* 96-h EC_{50} = 14 (9–18) µg/L, *Crangon uritai* 96-h EC_{50} = 260 (190–320) µg/L, *Americamysis bahia* 96-h EC_{50} = 48 (41–54) µg/L. Reported endpoints are lower than current *A. bahia* 96-h EC_{50} = 51 µg/L; however, there is no change to the expected risk based on the reported endpoint for *A. bahia* and *P. japonicus* is a warm-water species endemic to African and Asian marine areas and therefore not relevant to the Canadian marine risk assessment.
Kuechle et al. (2019; PMRA# 3132597)	Published study. Factors influencing neonicotinoid concentrations in US wetland sediments.	Not applicable for quantitative clothianidin risk assessment. Environmental monitoring study relating neonicotinoid concentrations in Missouri wetland sediments to landscape features.
Carrasco-Navarro et al. (2019)	Book chapter. Neonicotinoid review.	Abstract only. Not relevant to clothianidin risk assessment. General overview of neonicotinoid impacts on the environment.

Table A.4-3 Revised screening level risk of clothianidin to aquatic invertebrates exposed at a range of seasonal application rates

Organism	Exposure	Species	Effects metric (µg a.i./L)	EEC[b] (µg a.i./L)	RQ	LOC exceeded
Freshwater organisms						
Invertebrates	Acute	36 invertebrate species	HC_5 = 1.33[a]	2.19 (low seed treatment rate)	**1.6**	**Yes**
				43.8 (maximum foliar	**33**	**Yes**

Organism	Exposure	Species	Effects metric (µg a.i./L)	EEC[b] (µg a.i./L)	RQ	LOC exceeded
				treatment rate)		
				52.6 (maximum seed treatment rate)	**40**	**Yes**
	Chronic	*Chironomus dilutus*	Geomean EC_{10}/EC_{20} = 0.12 (n = 3)	2.19 (low seed treatment rate)	**18**	**Yes**
				43.8 (maximum foliar treatment rate)	**365**	**Yes**
				52.6 (maximum seed treatment rate)	**438**	**Yes**
Marine/Estuarine organisms						
Mysid shrimp	Acute	*Mysidopsis bahia*	96-h LC_{50} ÷ 2 = 25.5	2.19 (low seed treatment rate)	0.1	No
				43.8 (maximum foliar treatment rate)	**1.7**	**Yes**
				52.6 (maximum seed treatment rate)	**2.1**	**Yes**
	Chronic		39-d NOEC reproduction = 5.1	2.19 (low seed treatment rate)	0.4	No
				43.8 (maximum foliar treatment rate)	**8.6**	**Yes**
				52.6 (maximum seed treatment rate)	**10**	**Yes**

[a] The HC_5 is the 5[th] percentile of the species sensitivity distribution for 48–96-h LC_{50} or EC_{50} endpoints (acute exposures).
[b] Estimated Environmental Concentration (EEC) based on an 80 cm water depth. For details of derivation of EECs, refer to Table A.5-1 and Table A.5-2, Appendix V, PSRD2018-01.
Bolded values indicate an exceedance of the level of concern (LOC) (RQ = 1).

Table A.4-4 Revised refined risk assessment of clothianidin for aquatic invertebrates from predicted levels of spray drift

Organism	Exposure	Species	Effects metric[a] (µg a.i./L)	EEC[b] (µg a.i./L)	RQ	LOC Exceeded
Freshwater organisms						
Invertebrates	Acute	36 invertebrate species	HC_5 = 1.33	4.8 (field sprayer)	**3.6**	**Yes**
				9.7 (airblast sprayer)	**7.3**	**Yes**
				4.9 (aerial sprayer)	**3.7**	**Yes**
	Chronic	*Chironomus*	Geomean	4.8 (field sprayer)	**40**	**Yes**

Organism	Exposure	Species	Effects metric[a] (µg a.i./L)	EEC[b] (µg a.i./L)	RQ	LOC Exceeded
		dilutus	EC_{10}/EC_{20} = 0.12 (n = 3)	9.7 (airblast sprayer)	**81**	**Yes**
				4.9 (aerial sprayer)	**41**	**Yes**
Marine/Estuarine organisms						
Mysid shrimp	Acute	*Mysidopsis bahia*	96-h LC_{50} ÷ 2 = 25.5	4.8 (field sprayer)	0.2	No
				9.7 (airblast sprayer)	0.4	No
				1.7 (aerial sprayer)[c]	0.1	No

[a] Effects metrics used in the acute exposure risk assessment (RA) are derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates. The HC_5 is the 5th percentile of the species sensitivity distribution for 48–96-h LC_{50} or EC_{50} endpoints (acute exposures).

[b] Estimated environmental concentrations (EECs) based on an 80 cm water depth and on the maximum cumulative use rates for each application method: Aerial sprayer = 3 × 52.5 g a.i./ha (potatoes) with 7-d application interval and 80th percentile $t_{1/2}$ = 141 d, EEC = 19.0 µg a.i./L; airblast = 1 × 105 g a.i./ha (grapes), EEC = 13.1 µg a.i./L; field sprayer = 1 × 350 g a.i./ha (turf), EEC = 43.8 µg a.i./L. EECs were then adjusted for expected spray drift deposit 1 m downwind: Field sprayer = 11% (ASAE Fine spray quality); aerial sprayer = 26% (ASAE Fine spray quality); airblast = 74% (early season).

[c] Marine EECs for aerial application to potatoes based on a single application only. Cumulative deposit from multiple applications is not expected given the high rates of water replacement due to tidal flushing.

Bolded values indicate an exceedance of the level of concern (RQ = 1).

Table A.4-5 Revised refined risk assessment of clothianidin for aquatic invertebrates from predicted levels of pesticide runoff

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
Freshwater organisms										
Invertebrates	Acute	36 freshwater invertebrate species	HC_5 = 1.33[a]	Foliar	Squash and pumpkin	1 × 105 g a.i./had	BC	0.39[d]	0.3	No
							ON	3.3[d]	**2.4**	**Yes**
							QC	3.0[d]	**2.2**	**Yes**
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	Prairie-MB	4.5	**3.4**	**Yes**
							ON	3.9	**2.9**	**Yes**
							QC	3.1	**2.3**	**Yes**
							Atlantic	4.1	**3.1**	**Yes**
					Grape	1 × 105 g a.i./ha	BC	0.35	0.3	No
							ON	3	**2.3**	**Yes**
							QC	1.5	**1.1**	**Yes**
							NS	1.2	0.9	No
					Turf	1 × 350 g a.i./ha	BC	6.4	**4.8**	**Yes**
							Prairie-AB	5.4	**4.1**	**Yes**
							Prairie-MB	3.3	**2.5**	**Yes**
							Prairie-SK	3.7	**2.8**	**Yes**
							ON	4.8	**3.6**	**Yes**
							QC	3.5	**2.6**	**Yes**
							Atlantic-NS	5.1	**3.8**	**Yes**
							Atlantic-PEI	5.7	**4.3**	**Yes**
				Soil: Pre-plant	Sweet potato	1 × 224 g a.i./ha	ON	1.2	0.9	No
							QC	1.1	0.8	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
				incorporated						
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	Prairie-MB	0.53	0.4	No
							ON	0.76	0.6	No
							QC	1	0.8	No
							Atlantic	2.6	**2.0**	**Yes**
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	2.56	**1.9**	**Yes**
							ON	8	**6.0**	**Yes**
							QC	10.4	**7.8**	**Yes**
							Atlantic	21.6	**16**	**Yes**
						1 × 4.7 g a.i./ha (low rate)	BC	0.028	<0.1	No
							ON	0.088	0.1	No
							QC	0.12	0.1	No
							Atlantic	0.24	0.2	No
					Canola	1 × 32.5 g a.i./ha	Prairie - SK	0.288	0.2	No
							Prairie - MB	0.44	0.3	No
							ON	2.24	**1.7**	**Yes**
							QC	3.36	**2.5**	**Yes**
					Potato	1 × 381 g a.i./ha	Prairie - MB	0.004	<0.1	No
							ON	0.0424	<0.1	No
							QC	0.0384	<0.1	No
							Atlantic	0.096	0.1	No
					Corn[e]	1 × 118.3 g a.i./ha	ON	0.608	0.5	No
							QC	0.776	0.6	No
					Spring wheat	1 × 104.9 g a.i./ha	AB north	0.304	0.2	No
							AB south	0.552	0.4	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							SK	0.4	0.3	No
							MB	0.456	0.3	No
							ON	0.392	0.3	No
							QC	0.48	0.4	No
					Winter wheat	1 × 104.9 g a.i./ha	AB north	0.576	0.4	No
							AB south	1.12	0.8	No
							SK	0.552	0.4	No
							MB	0.72	0.5	No
							ON	0.352	0.3	No
							QC	0.408	0.3	No
	Chronic	*Chironomus dilutus*	Geomean emergence = 0.12	Foliar	Squash and pumpkin	1 × 105 g a.i./ha	BC	0.29[d]	**2.4**	**Yes**
							ON	2.5[d]	**21**	**Yes**
							QC	2.4[d]	**20**	**Yes**
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	Prairie-MB	3.2	**27**	**Yes**
							ON	2.9	**24**	**Yes**
							QC	2.3	**19**	**Yes**
							Atlantic	3.1	**26**	**Yes**
					Grape	1 × 105 g a.i./ha	BC	0.25	**2.1**	**Yes**
							ON	2.6	**22**	**Yes**
							QC	1.1	**9.2**	**Yes**
							NS	0.83	**6.9**	**Yes**
					Turf	1 × 350 g a.i./ha	BC	4.8	**40**	**Yes**
							Prairie-AB	3.9	**33**	**Yes**
							Prairie-MB	2.4	**20**	**Yes**
							Prairie-SK	2.6	**22**	**Yes**
							ON	3.4	**28**	**Yes**
							QC	3	**25**	**Yes**
							Atlantic-NS	3.6	**30**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							Atlantic-PEI	4.2	**35**	**Yes**
				Soil: Pre-plant incorporated	Sweet potato	1 × 224 g a.i./ha	ON	0.93	**7.8**	**Yes**
							QC	0.86	**7.2**	**Yes**
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	Prairie-MB	0.49	**4.1**	**Yes**
							ON	0.61	**5.1**	**Yes**
							QC	0.82	**6.8**	**Yes**
							Atlantic	1.9	**16**	**Yes**
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	1.84	**15**	**Yes**
							ON	6.88	**57**	**Yes**
							QC	8.8	**73**	**Yes**
							Atlantic	16.8	**140**	**Yes**
						1 × 4.7 g a.i./ha (low rate)	BC	0.0208	0.2	No
							ON	0.0768	0.6	No
							QC	0.096	0.8	No
							Atlantic	0.184	**1.5**	**Yes**
					Canola	1 × 32.5 g a.i./ha	Prairie - SK	0.216	**1.8**	**Yes**
							Prairie - MB	0.368	**3.1**	**Yes**
							ON	1.68	**14**	**Yes**
							QC	2.88	**24**	**Yes**
					Potato	1 × 381 g a.i./ha	Prairie - MB	0.0032	<0.1	No
							ON	0.0328	0.3	No
							QC	0.0304	0.3	No
							Atlantic	0.0736	0.6	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
					Corn[e]	1 × 118.3 g a.i./ha	ON	0.52	**4.3**	**Yes**
							QC	0.632	**5.3**	**Yes**
					Spring wheat	1 × 104.9 g a.i./ha	AB north	0.272	**2.3**	**Yes**
							AB south	0.4	**3.3**	**Yes**
							SK	0.344	**2.9**	**Yes**
							MB	0.384	**3.2**	**Yes**
							ON	0.36	**3.0**	**Yes**
							QC	0.424	**3.5**	**Yes**
					Winter wheat	1 × 104.9 g a.i./ha	AB north	0.424	**3.5**	**Yes**
							AB south	0.8	**6.7**	**Yes**
							SK	0.424	**3.5**	**Yes**
							MB	0.6	**5.0**	**Yes**
							ON	0.264	**2.2**	**Yes**
							QC	0.312	**2.6**	**Yes**
		Mesocosm	56-d $NOEC_{14\text{-d TWA}}$ = 0.281	Foliar	Squash and pumpkin	1 × 105 g a.i./ha	BC	0.29[d]	**1.0**	**Yes**
							ON	2.5[d]	**8.9**	**Yes**
							QC	2.4[d]	**8.4**	**Yes**
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	Prairie-MB	3.2	**11**	**Yes**
							ON	2.9	**10**	**Yes**
							QC	2.3	**8.2**	**Yes**
							Atlantic	3.1	**11**	**Yes**
					Grape	1 × 105 g a.i./ha	BC	0.25	0.9	No
							ON	2.6	**9.3**	**Yes**
							QC	1.1	**3.9**	**Yes**
							NS	0.83	**3.0**	**Yes**
					Turf	1 × 350 g a.i./ha	BC	4.8	**17**	**Yes**
							Prairie-AB	3.9	**14**	**Yes**
							Prairie-MB	2.4	**8.5**	**Yes**
							Prairie-SK	2.6	**9.3**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							ON	3.4	**12**	**Yes**
							QC	3	**11**	**Yes**
							Atlantic-NS	3.6	**13**	**Yes**
							Atlantic-PEI	4.2	**15**	**Yes**
				Soil: Pre-plant incorporated	Sweet potato	1 × 224 g a.i./ha	ON	0.93	**3.3**	**Yes**
							QC	0.86	**3.1**	**Yes**
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	Prairie-MB	0.49	**1.7**	**Yes**
							ON	0.61	**2.2**	**Yes**
							QC	0.82	**2.9**	**Yes**
							Atlantic	1.9	**6.8**	**Yes**
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	1.84	**6.5**	**Yes**
							ON	6.88	**25**	**Yes**
							QC	8.8	**31**	**Yes**
							Atlantic	16.8	**60**	**Yes**
						1 × 4.7 g a.i./ha (low rate)	BC	0.0208	0.1	No
							ON	0.0768	0.3	No
							QC	0.096	0.3	No
							Atlantic	0.184	0.7	No
					Canola	1 × 32.5 g a.i./ha	Prairie - SK	0.216	0.8	No
							Prairie - MB	0.368	**1.3**	**Yes**
							ON	1.68	**6.0**	**Yes**
							QC	2.88	**10**	**Yes**
					Potato	1 × 381 g a.i./ha	Prairie - MB	0.0032	<0.1	No
							ON	0.0328	0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							QC	0.0304	0.1	No
							Atlantic	0.0736	0.3	No
					Corn[e]	1 × 118.3 g a.i./ha	ON	0.52	**1.9**	**Yes**
							QC	0.632	**2.2**	**Yes**
					Spring wheat	1 × 104.9 g a.i./ha	AB north	0.272	**1.0**	**Yes**
							AB south	0.4	**1.4**	**Yes**
							SK	0.344	**1.2**	**Yes**
							MB	0.384	**1.4**	**Yes**
							ON	0.36	**1.3**	**Yes**
							QC	0.424	**1.5**	**Yes**
					Winter wheat	1 × 104.9 g a.i./ha	AB north	0.424	**1.5**	**Yes**
							AB south	0.8	**2.8**	**Yes**
							SK	0.424	**1.5**	**Yes**
							MB	0.6	**2.1**	**Yes**
							ON	0.264	0.9	No
							QC	0.312	**1.1**	**Yes**
	Chronic (sediment pore water)	*C. riparius*	10-d NOEC dry wt = 1.1 (pore water)	Foliar	Squash and pumpkin	1 × 105 g a.i./ha	BC	0.075[d]	<0.1	No
							ON	0.75[d]	0.7	No
							QC	0.75[d]	0.7	No
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	Prairie-MB	0.72	0.7	No
							ON	0.57	0.5	No
							QC	0.62	0.6	No
							Atlantic	0.87	0.8	No
					Grape	1 × 105 g a.i./ha	BC	0.067	0.1	No
							ON	0.84	0.8	No
							QC	0.54	0.5	No
							NS	0.19	0.2	No
					Turf	1 × 350 g a.i./ha	BC	0.3	0.3	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							Prairie-AB	0.85	0.8	No
							Prairie-MB	0.49	0.4	No
							Prairie-SK	0.53	0.5	No
							ON	0.9	0.8	No
							QC	1.4	**1.3**	**Yes**
							Atlantic-NS	0.9	0.8	No
							Atlantic-PEI	1.2	**1.1**	**Yes**
				Soil: Pre-plant incorporated	Sweet potato	1 × 224 g a.i./ha	ON	0.21	0.2	No
							QC	0.2	0.2	No
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	Prairie-MB	0.15	0.1	No
							ON	0.15	0.1	No
							QC	0.23	0.2	No
							Atlantic	0.52	0.5	No
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	0.512	0.5	No
							ON	1.92	**1.7**	**Yes**
							QC	2.4	**2.2**	**Yes**
							Atlantic	4.72	**4.3**	**Yes**
						1 × 4.7 g a.i./ha (low rate)	BC	0.0056	<0.1	No
							ON	0.0216	<0.1	No
							QC	0.0264	<0.1	No
							Atlantic	0.0528	<0.1	No
					Canola	1 × 32.5 g a.i./ha	Prairie - SK	0.0616	0.1	No
							Prairie - MB	0.104	0.1	No
							ON	0.48	0.4	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							QC	1.12	**1.0**	**Yes**
					Potato	1 × 381 g a.i./ha	Prairie - MB	0.000 8	<0.1	No
							ON	0.008 8	<0.1	No
							QC	0.008 8	<0.1	No
							Atlantic	0.02	<0.1	No
					Corn[e]	1 × 118.3 g a.i./ha	ON	0.144	0.1	No
							QC	0.176	0.2	No
					Spring wheat	1 × 104.9 g a.i./ha	AB north	0.088	0.1	No
							AB south	0.096	0.1	No
							SK	0.104	0.1	No
							MB	0.12	0.1	No
							ON	0.112	0.1	No
							QC	0.152	0.1	No
					Winter wheat	1 × 104.9 g a.i./ha	AB north	0.168	0.2	No
							AB south	0.224	0.2	No
							SK	0.176	0.2	No
							MB	0.24	0.2	No
							ON	0.112	0.1	No
							QC	0.16	0.1	No
Marine/estuarine invertebrates										
Invertebrates	Acute	*Mysidopsis bahia*	96-h LC_{50} ÷ 2 = 25.5	Foliar	Squash and pumpkin	1 × 105 g a.i./ha	BC	0.39[d]	<0.1	No
							QC	3.0[d]	0.1	No
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	QC	3.1	0.1	No
							Atlantic	4.1	0.2	No
					Grape	1 × 105 g a.i./ha	BC	0.35	<0.1	No
							QC	1.5	0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
							Atlantic-NS	1.2	<0.1	No
					Turf	1 × 350 g a.i./ha	BC	6.4	0.3	No
							QC	3.5	0.1	No
							Atlantic-NS	5.1	0.2	No
							Atlantic-PEI	5.7	0.2	No
				Soil: Pre-plant incorporated	Sweet potato	1 × 224 g a.i./ha	QC	1.1	<0.1	No
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	QC	1	0.0	No
							Atlantic	2.6	0.1	No
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	2.56	0.1	No
							QC	10.4	0.4	No
							Atlantic	21.6	0.8	No
						1 × 4.7 g a.i./ha (low rate)	BC	0.028	<0.1	No
							QC	0.12	<0.1	No
							Atlantic	0.24	<0.1	No
					Canola	1 × 32.5 g a.i./ha	QC	3.36	0.1	No
					Potato	1 × 381 g a.i./ha	QC	0.0384	<0.1	No
							Atlantic	0.096	<0.1	No
					Corn[e]	1 × 118.3 g a.i./ha	QC	0.776	<0.1	No
					Spring wheat	1 × 104.9 g a.i./ha	QC	0.48	<0.1	No
					Winter wheat	1 × 104.9 g a.i./ha	QC	0.408	<0.1	No
	Chronic	*Mysidopsis bahia*	39-d NOEC reproduction = 5.1	Foliar	Squash and pumpkin	1 × 105 g a.i./ha	BC	0.29[d]	0.1	No
							QC	2.4[d]	0.5	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
					Potato	3 × 52.5 g a.i./ha at a 10-d interval	QC	2.3	0.5	No
							Atlantic	3.1	0.6	No
					Grape	1 × 105 g a.i./ha	BC	0.25	<0.1	No
							QC	1.1	0.2	No
							Atlantic-NS	0.83	0.2	No
					Turf	1 × 350 g a.i./ha	BC	4.8	0.9	No
							QC	3	0.6	No
							Atlantic-NS	3.6	0.7	No
							Atlantic-PEI	4.2	0.8	No
				Soil: Pre-plant incorporated	Sweet potato	1 × 224 g a.i./ha	QC	0.86	0.2	No
				Soil: In-furrow	Potato[e]	1 × 223.8 g a.i./ha	QC	0.82	0.2	No
							Atlantic	1.9	0.4	No
				Seed treatment	Vegetables	1 × 419.6 g a.i./ha (high rate)	BC	1.84	0.4	No
							QC	8.8	**1.7**	**Yes**
							Atlantic	16.8	**3.3**	**Yes**
						1 × 4.7 g a.i./ha (low rate)	BC	0.0208	<0.1	No
							QC	0.096	<0.1	No
							Atlantic	0.184	<0.1	No
					Canola	1 × 32.5 g a.i./ha	QC	2.88	0.6	No
					Potato	1 × 381 g a.i./ha	QC	0.0304	<0.1	No
							Atlantic	0.0736	<0.1	No
					Corn[e]	1 × 118.3 g a.i./ha	QC	0.632	0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[b]	Region	EEC[c] (µg a.i./L)	RQ	LOC exceeded
					Spring wheat	1 × 104.9 g a.i./ha	QC	0.424	0.1	No
					Winter wheat	1 × 104.9 g a.i./ha	QC	0.312	0.1	No

[a] The HC_5 is the 5[th] percentile of the species sensitivity distribution for the 48–96-h LC_{50} or EC_{50} at 50% confidence intervals (acute exposures).
[b] Use rate represents the maximum number of applications and rate (g a.i./ha) for a crop.
[c] EECs based on an 80 cm water depth. For comparison against acute invertebrate effects metrics based on data with 48–96-h, peak EECs were used to derive RQs. For comparison against chronic invertebrate effects metrics based on data with 21–40-d NOEC or EC_{10}/EC_{20} endpoints and 56-d mesocosm $NOEC_{14\text{-d TWA}}$, 21-day EECs were used to derive RQs. EECs for seed treatments were adjusted for 20% removal by uptake from plants.
[d] The modelling of foliar applications of clothianidin on cucurbits was originally conducted using 2 applications at 105 g a.i./ha for the proposed special review decision and reported in PSRD2018-01. Following the pollinator re-evaluation decision (RVD2019-05), only one foliar application can be made on cucurbits, prior to bloom. Rather than updating the modelling for this crop, EECs for one instead of two applications were roughly calculated by dividing the original EECs by 2.
[e] Uses on potato in-furrow and corn modelled using the "increasing with depth" scenario.
Bolded values indicate an exceedance of the level of concern (RQ = 1).

Appendix V Species sensitivity distribution (SSD)

Background information

A species sensitivity distribution (SSD) is conducted for taxonomic groups of interest where sufficient data are available. The hazardous concentration to 5% of species (HC_5) is theoretically protective of 95% of all species at the effect level used in the analysis (for example, LC_{50}, NOEC, etc.). The software program ETX 2.1 is used to generate SSDs, which was developed by RIVM (Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands.).

SSD toxicity data analysis for clothianidin

Data submitted by the registrant and published literature studies were consulted in the risk assessment process. Only those studies with acceptable quantitative effects endpoints were considered for the SSD. Additional sorting was done to separate data into taxonomic sub-groups while also accounting for appropriate test methods, exposure durations, matrices and other variables. Studies from the published literature were deemed acceptable if they reported the appropriate biologically relevant endpoints and generally followed recognized methods such as the Organisation for Economic Co-operation and Development (OECD) or similar.

Results of SSD analysis for clothianidin insecticide

An SSD was conducted for acute effects to freshwater invertebrates exposed to clothianidin. The toxicity data used in the SSD are presented in Table A.5-1, and the results are reported in Table A.5-2. The acute HC_5 is 1.33 µg a.i./L.

Table A.5-1 Toxicity data used in the species sensitivity distribution (SSD) for acute effects of clothianidin on freshwater invertebrates.

Species	Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	Reference (PMRA#)
1	*Moina macrocopa*	61 106		Hayasaka et al., 2013 (2712667)
2	*Daphnia pulex*	31 448		Hayasaka et al., 2013 (2712667)
3	*Ceriodaphnia reticulata*	29 474		Hayasaka et al., 2013 (2712667)
4	*Daphnia magna*	28 299	Geomean value (n=6)	Morrissey et al., 2015 (2538669), Noake and Geffke 2000 (2713565), Hayasaka et al., 2013 (2712667), Riebschläger 2013 (2713529), Li et al., 2013 (2712665), Noack 1999 (2713564)

Species	Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	Reference (PMRA#)
5	*Coenagrion* sp.	5918.8	Less than value (<)	Raby et al., 2018a (2842540)
6	*Daphnia similis*	1740		Morandi 2012 (2713531)
7	*Ceriodaphnia dubia*	1691.3		Hayasaka et al., 2013 (2712667)
8	*Lestes unguiculatus*	1245		Miles et al., 2017 (2832753)
9	*Anax junius*	1000		Miles et al., 2017 (2832753)
10	*Plathemis lydia*	865		Miles et al., 2017 (2832753)
11	*Orchonectes propinquus*	805		Miles et al., 2017 (2832753)
12	*Caecidotea* sp.	537.2		Raby et al., 2018a (2842540)
13	Wavy-rayed lampmussel *(Lampsilis fasciola)*	478	Greater than value (>)	Prosser et al., 2016 (2712688)
14	Agnetina, *Paragnetina* sp.	300.5	Less than value (<)	Raby et al., 2018a (2842540)
15	*Procambarus clarkii*	188	Geomean value (n=2)	Barbee and Stout 2009 (2712686), Nagasaki and Asaka 2000 (2713537)
16	*Isonychia bicolor*	108.8	Less than value (<)	Raby et al., 2018a (2842540)
17	*McCaffertium* sp.	108.8	Less than value (<)	Raby et al., 2018a (2842540)
18	*Stenelmis* sp.	84.9		Raby et al., 2018a (2842540)
19	*Belostoma flumineum*	79.0		Miles et al., 2017 (2832753)
20	*Asellus aquaticus*	67.0		Pickervance et al., 2003 (2712685)
21	*Notonecta undulata*	59.0		Miles et al., 2017 (2832753)
22	*Hesperocorixa atopodonta*	56.0		Miles et al., 2017 (2832753)
23	*Lumbriculus variegatus*	41.7		Raby et al., 2018a (2842540)
24	*Gyrinus* sp.	41.2		Raby et al., 2018a (2842540)
25	*Chironomus riparius*	21.8	Geomean value (n=4)	Mattock 2001 (1194168), Pickervance et al., 2003 (2712685), EC 2005 (3014284), Silke 2013 (2713530)

Species	Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	Reference (PMRA#)
26	*Trichocorixa* sp.	21.3		Raby et al., 2018a (2842540)
27	*Ephemerella* sp.	18.5		Raby et al., 2018a (2842540)
28	*Cloeon dipterum*	12.0		Pickervance et al., 2003 (2712685)
29	*Hexagenia* spp.	11.5	Geomean value (n=2)	Bartlett et al., 2018 (2861091), Raby et al., 2018a (2842540)
30	*Culex pipiens*	11.0		Russo et al., 2018 (2978128)
31	Dytiscidae	7.0		Pickervance et al., 2003 (2712685)
32	*Hyalella azteca*	6.8	Geomean value (n=3)	De Perre et al., 2015 (2712666), Whiting and Lydy 2015 (2712690), Raby et al., 2018a (2842540)
33	*Cheumatopsyche brevilineata*	4.4		Yokoyama et al., 2009 (2722291)
34	*Neocloeon triangulifer*	3.5		Raby et al., 2018a (2842540)
35	*Chironomus dilutus*	3.3	Geomean value (n=3)	De Perre et al., (2712666), Raby et al., 2018a (2842540), Maloney et al., 2017 (2818524)
36	*Graphoderus fascicollis*	2.0		Miles et al., 2017 (2832753)

Geomean = geometric mean

Table A.5-2 Summary of species sensitivity distribution (SSD) analysis for acute effects of clothianidin on freshwater invertebrates

Study type/ Exposure	SSD Results for freshwater invertebrates
Acute toxicity	HC_5: 1.33 µg a.i./L
	CI: 0.324–3.88 µg a.i./L FA: 1.86–9.28%
	Number of species used: 36 (48–96-h EC_{50}/LC_{50}s)
	Most sensitive species: *Graphoderus fascicollis;* 48-h LC_{50} = 2.0 µg a.i./L

HC_5 = Hazardous concentration to 5% of species.
CI = lower and upper 90% confidence level of HC_5
FA = fraction of species affected. This value reflects the lower and upper 90% confidence level of the proportion of species expected to be affected at the HC_5 value.

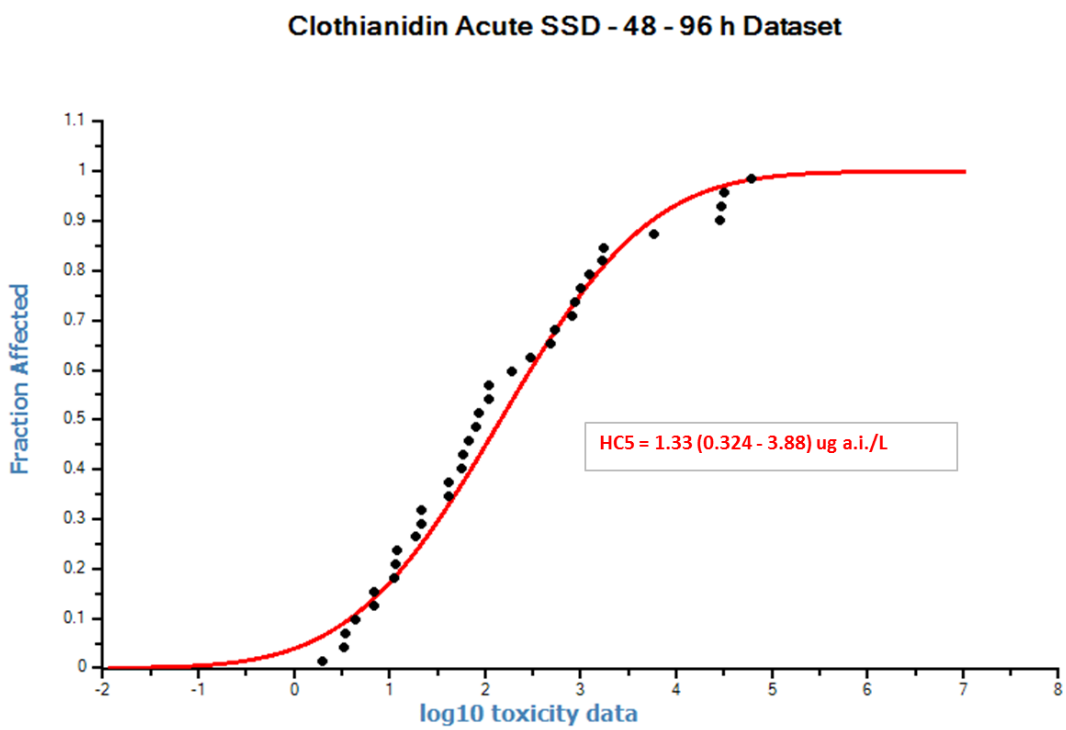


Figure A.5-1 Species sensitivity distribution (SSD) for acute toxicity of clothianidin to freshwater aquatic invertebrates.

Comments on data used in the SSDs

Data sorting for use in the SSDs:

- The measurement endpoints used within data subsets are similar (exposure units, toxicity units) and appropriate to the duration category.
- The endpoints included in all data sets are those assumed to ultimately affect survival of the test organisms or populations.

- All short-term exposure data are grouped together as “acute” (i.e., 48 hours, 96 hours, etc.) for individual taxonomic groups.
- All data which are considered to be “chronic” are grouped together for individual taxonomic groups (i.e., studies examining the survival or sub-lethal effects from long exposure periods).
- Geometric means of toxicity values are calculated for multiple endpoints for the same species.
- Where more than one measurement endpoint was available for a given study (for example, both an EC_{50} and an LC_{50} are provided, or endpoints from multiple time periods), the more sensitive endpoint is used and not a geometric mean.
- Study results which are insufficient or not compatible for inclusion in either the acute or chronic distribution groups established for the current assessment were not used. This includes for example incompatible effects levels such as EC_{25}, different or unique exposure matrix studies and units, different exposure time/method, etc.

Additional notes on data specific to the current active:

- Only endpoints from 48- to 96-hour exposure durations were included in the SSD, in order to align the dataset with the peak modelled EEC (i.e., excluding > 96-h endpoints) as well as to account for latent effects of clothianidin exposure on aquatic invertebrates (i.e., excluding < 48-h endpoints).
- Toxicity data having no effects at the highest test concentration were excluded (for example, EC50 > X) if there were other results to represent the species (consistent with EFSA (2013) guidance).
- In cases where only one study was available for a species and the resulting endpoint was unbound, i.e., a greater than or less than (</>) toxicity value, the endpoint was used to represent that species (consistent with EFSA (2013) guidance).
- There were insufficient data to construct a robust chronic SSD based on sublethal effects.

Appendix VI Summary of water modelling scenarios

Table A.6-1 Summary of application rates, timing and use patterns modelled for runoff to surface water

Region	Crop	Use pattern	Application method	Seed depth (cm)	Timing of application
BC	Vegetables (high rate)[a]	1×419.6 g a.i./ha	Seed treatment	0.6-2.5	Early-March to late-June
	Vegetables (low rate)[a]	1×4.7 g a.i./ha			
	Grape	1×105 g a.i./ha	Ground foliar	NA	Mid-June to mid-August
	Squash/pumpkin[b]	1×105 g a.i./ha	Ground foliar	NA	Early-May to late-September
	Turf	1×350 g a.i./ha	Ground foliar	NA	Late-March to mid-October
Prairie	Canola	1×32.5 g a.i./ha	Seed treatment	1.2–5	April 17 to June 28
	Spring wheat	1×104.9 g a.i./ha	Seed treatment	2.05–7.5	April 2 to June 21
	Winter wheat	1×104.9 g a.i./ha	Seed treatment	1.5–3.5	August 15 to October 31
	Potato	1×381 g a.i./ha	Seed piece treatment	7–15	Early-April to June 15
		1×223.8 g a.i./ha	In-furrow[c]	7 assumed	Early April to June 15
		3×52.5 g a.i./ha at a 10-d interval	Ground and aerial foliar	NA	Early-May to early September
	Turf	1×350 g a.i./ha	Ground foliar	NA	Late-April to mid-October
ON/QC	Canola	1×32.5 g a.i./ha	Seed treatment	0–3	April 1 to June 10
	Vegetables (high rate)[a]	1×419.6 g a.i./ha	Seed treatment	1–2	April 15 to June 25
	Vegetables (low rate)[a]	1×4.7 g a.i./ha			
	Spring wheat	1×104.9 g a.i./ha	Seed treatment	2.5	March 1 to June 1
	Winter wheat	1×104.9 g a.i./ha	Seed treatment	2.5	August 20 to November 15
	Potato	1×381 g a.i./ha	Seed piece treatment	5–12	April 15 to June 25
		1×223.8 g a.i./ha	In-furrow[c]	5	April 15 to June 25
		3×52.5 g a.i./ha at a 10-d interval	Ground and aerial foliar	NA	Mid-May to mid-August
	Corn[c]	1×118.3 g a.i./ha	Seed treatment	3.8–6.5	April 14 to June 30
	Squash/pumpkin[b]	1×105 g a.i./ha	Ground foliar	NA	Early-May to early-October
	Grape	1×105 g a.i./ha	Ground foliar	NA	Early-April to mid-October
	Turf	1×350 g a.i./ha	Ground foliar	NA	Early-April to mid-October
	Sweet potato	1×224 g a.i./ha	Pre-plant soil	10 assumed	Late-May to early-

Region	Crop	Use pattern	Application method	Seed depth (cm)	Timing of application
			incorporated	(incorporation depth)	June
Atlantic	Vegetables (high rate)[a]	1×419.6 g a.i./ha	Seed treatment	1.0	April 15 to June 20
	Vegetables (low rate)[a]	1×4.7 g a.i./ha			
	Potato	1×381 g a.i./ha	Seed piece treatment	5–15	March 20 to June 15
		1×223.8 g a.i./ha	In-furrow[c]	5	March 20 to June 15
		3×52.5 g a.i./ha at a 10-d interval	Ground and aerial foliar	NA	Late-June to mid-September
	Grape	1×105 g a.i./ha	Ground foliar	NA	Mid-May to mid-June
	Turf	1×350 g a.i./ha	Ground foliar	NA	Early-April to mid-October

NA = not applicable

[a] There were a variety of seed treatment rates for the vegetable crops, as such the maximum rate along with a representative low rate was modelled based on a carrot scenario.

[b] The modelling of foliar applications of clothianidin on cucurbits was originally conducted using 2 applications at 105 g a.i./ha for the proposed special review decision and reported in PSRD2018-01. Following the pollinator re-evaluation decision (RVD2019-05), only one foliar application can be made on cucurbits, prior to bloom. Rather than updating the modelling for this crop, EECs for one instead of two applications were roughly calculated by dividing the original EECs by 2.

[c] Corn seed treatment and potato in-furrow uses modelled with ‘increasing with depth’ scenario.

Appendix VII Summary of monitoring analysis

Table A.7-1 Water monitoring programs excluded from the revised assessment but which had been previously considered in the proposed special review decision for clothianidin, PSRD2018-01

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit unless otherwise specified (µg/L)	Year	Number of sites	Total number of samples
Health Canada Bee Mortality Incident Monitoring, unpublished (PMRA# 2548877)	Quebec	ditch	0.001 (LOQ)	2013	1	1
	Ontario	creeks, ponds, streams	0.001 (LOQ)	2013	42	42
			0.0022	2014	14	14
	Manitoba	creek	0.001 (LOQ)	2013	1	1
	Reason for exclusion: Sampling occurred in areas where bee mortality incidents occurred; the program was not designed to monitor aquatic habitats near areas of clothianidin use.					
Health Canada Hive Monitoring Program, unpublished (PMRA# 2548876)	Quebec	stream	0.0022	2014	1	1
	Ontario	streams, culverts, ditches	0.0022	2014	5	5
	Manitoba	streams, culverts, ditches	0.0022	2014	3	3
	Reason for exclusion: Sampling occurred near bee hives; the program was not designed to monitor aquatic habitats near areas of clothianidin use.					
Environment Canada, as cited in Mineau and Palmer, 2013 (PMRA# 2526820)	Ontario	creeks and rivers	0.00176	2011	13	15
	Reason for exclusion: Only one or two samples per site for the year 2011 were cited in the report, with little or no site information available. Raw data and site information from Environment and Climate Change Canada for subsequent years in most of the waterbodies were available.					
Ontario Ministy of the Environment and Ontario Ministry of Agriculture and Food, 2013 (PMRA# 2523836, 2759002)	Ontario	creeks and rivers	0.08	2012–2014	20	298
	Reason for exclusion: The analytical detection limit is high compared to other monitoring datasets available, making non-detects difficult to interpret. The detection frequency was low compared to other programs; there were no detections at any site except two, where only one sample at each of the two sites had concentrations above the analytical limit of detection. More useful and more recent monitoring data for these sites were available for 2015–2018, which had a much lower analytical detection limit.					

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit unless otherwise specified (µg/L)	Year	Number of sites	Total number of samples
Ontario Ministry of Environment and Climate Change, 2016 (PMRA# 2710505)	Ontario	waste water treatement plant influent and effluent	0.005	2016	5	32
	Reason for exclusion: Samples were from waste water treatement plants. There were no detections. There was limited site information available. The data are not particularly useful to the risk assessment for aquatic invertebrates.					
Schaafsma et al., 2015 (PMRA# 2526184)	Ontario	Ditches and drainage tile outlets within 0 to 100 metres from the perimeter of corn fields	0.0017	2013	12	30
	Reason for exclusion: The samples were taken from ditches or tile drains directly in the perimeter of corn fields (from 0 to 100 metres). These samples would be considered agricultural runoff and are not representative of aquatic habitat. Maximum concentrations of clothianidin measured in these water samples at the edge-of-field are highly conservative (16.2 µg/L in ditches and 3.6 µg/L in drainage tile outlets). The results of this study will be considered in a general sense in the assessment of the use of clothianidin on corn, but will not be used quantitatively.					
Main et al., 2014 (PMRA# 2526133, 2612760)	Saskatchewan	wetlands	0.0011–0.0026 (LOQ)	2012–2013	138	442
	Reason for exclusion: Wetlands were sampled once in the spring, summer and fall of 2012 and in the spring of 2013. The wetland classes ranged from temporary ponds to permanent ponds. Crops in the fields where the wetlands were sampled were provided; however, site locations were not identified. The data contain some of the highest levels detected, but the sites consist, at least in part, of sites not relevant to aquatic risk assessments. Without information on site location, an assessment of the relevance of the detections to an aquatic risk assessment cannot be made. Other wetland datasets that have season-long sampling and large amounts of ancillary info such as site location, wetland characterization info, precipitation data, crop information were available and were more useful to the assessment.					
Main et al., 2015 (PMRA# 2608629, 2612762)	Saskatchewarn	wetlands	0.0011 (LOQ)	2012	134	134
				2013	144	144
	Reason for exclusion: A total of 134 wetlands were sampled in the summer of 2012 (same data as from PMRA# 2526133, 2612760) and 144 wetlands were sampled in summer of 2013. No site descriptions, wetland classes, site locations or ancillary information was provided other than the previous year's crop and the present year's crop. Without information on site location, an assessment of the relevance of the detections to an aquatic risk assessment cannot be made. Only a single sample was collected in each wetland, with the					

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit unless otherwise specified (µg/L)	Year	Number of sites	Total number of samples
	exception of 11 wetlands for which the raw data file showed three samples were collected over a 28-day period (between June 22 and July 20, 2013). Results were within the range of those for more recent wetland datasets that have season-long sampling and large amounts of ancillary info such as site location, wetland characterization info, precipitation data, and crop information.					
Main et al., 2016 (PMRA# 2572395, 2612761)	Saskatchewan	wetlands	0.0008	2014	16	16
	Reason for excluding: The site locations were not specified other than on a map of surrounding fields in the published article. The article states that all wetlands were less than one hectare in size, ranged in initial depth from 20 cm to over 1 metre and were randomly chosen based on consistent timing of availability after ice-off. Six of the 16 wetlands (38%) are temporary wetlands and are less relevant to an aquatic invertebrate risk assessment, but these wetlands were not identified in the data. Results were within the range of those for more recent wetland datasets that have season-long sampling and large amounts of ancillary info such as site location, wetland characterization info, precipitation data, and crop information.					
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	wetlands	0.0016	2014	49	49
	Reason for exclusion: 49 of 115 sites were excluded from the analysis as they were predominantly low areas/edge of road that generally represent areas where water temporarily collects during wet periods, but are not distinct wetlands, ditches or streams. The sites were only sampled once. The remaining 46 sites were considered to be typical Prairie wetlands, and were included in the assessment. NOTE: While all the data were presented in PSRD2018-01, the subset of 46 sites considered relevant were also presented separately in that document.					

LOQ = limit of quantification

Table A.7-2 Summary of water monitoring programs considered in the final special review decision of clothianidin. New monitoring data not previously considered in the proposed special review decision are highlighted in bold

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[a]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Environment and Climate Change Canada (PMRA# 2745820, 2834289)	New Brunswick, Nova Scotia, Prince Edward Island	Rivers, brooks	0.00176	2015	May 21–Sep 12	3	19	6–7	1–42
				2016	Aug 17–Sep 14	6	8	1–3	1–15

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[a]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Department of Communities, Land and Environment (PMRA# 2745506, 2468268, 2845169, 3169038)	Prince Edward Island	Streams	0.01	2010	Jul 14–Aug 12	3	12	4	8–21
				2011	Jul 20–Sep 14	3	12	4	15–21
				2012	Jul 19–Sep 19	3	12	4	20–21
				2013	Jul 22–Sep 18	3	12	4	15–26
				2014	Jul 29–Sep 9	3	12	4	3–20
				2015	Jul 21–Sep 16	3	12	4	5–29
				2017	Jun 15–Oct 5	9	45	5	7–41
			0.0054–0.01	**2018**	**May 29–Oct 1**	**9**	**54**	**6**	**19–29**
Ministère de l'Environnement et de la Lutte contre les changements climatiques (PMRA# 2523837, 2544468, 2561884, 2709791, 2709792, 2709793, 2821394, 2821395, 2895037, 2929764, 2965069)	Quebec	Rivers, streams	0.001–0.005	2010	May 9–Aug 23	4	113	27–30	2–9
				2011	May 5–Aug 31	2	58	27–31	1–9
				2012	May 20–Aug 30	16	295	10–30	1–14
				2013	May 16–Aug 28	15	269	10–30	2–15
				2014	May 15–Aug 27	16	276	9–30	1–12
				2015	May 14–Aug 26	16	271	1–30	1–8
				2016	May 15–Aug 28	10	220	9–30	1–14
				2017	May 23–Aug 31	17	288	9–30	1–12
				2018	**May 16–Aug 30**	**17**	**323**	**5–30**	**1–22**
Montiel-León et al., 2019 (PMRA# 2991134)	Quebec	St. Lawrence River and tributaries	0.001	**2017**	**Jul 9–Jul 16**	**68**	**68**	**1**	**NA**
Environment and Climate Change Canada (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	Ontario	Streams	0.0007–0.00176	2012	Apr 16–Nov 22	12	158	5–17	1–63
				2013	Apr 9–Dec 4	18	161	1–14	8–69
				2014	Apr 14–Dec 3	9	111	7–14	10–56
				2015	Feb 16–Oct 22	11	135	6–14	7–70
				2016	Apr 11–Jul 20	11	62	4–6	13–35
Ministry of Environment, Conservation and Parks (PMRA# 2712893, 3032989) (Stream Monitoring Program)	Ontario	Streams	0.005	2015	Apr 10–Nov 11	5	95[b]	17–23[b]	1–35[c]
				2016	**Apr 25–Oct 22**	**5**	**86[b]**	**15–19[b]**	**1–30[c]**

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[a]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Ministry of the Environment, Conservation and Parks in collaboration with Ontario Ministry of Agriculture, Food and Rural Affairs (PMRA# 3070884, 3157906) (Pesticide Network)	Ontario	Streams	0.002	**2015**	**Apr 27–Nov 24**	**17**	**85**	**2–7**	**7–142**
				2016	**Feb 10–Dec 05**	**17**	**119**	**6–9**	**4–83**
				2017	**Mar 27–Nov 28**	**18**	**121**	**3–10**	**4–155**
				2018	**Jan 23–Dec 10**	**19**	**137**	**1–8**	**6–140**
Bayer CropScience Canada (PMRA# 2818733, 2936038, 3050884)	Ontario	Creeks, drainage ditches in the Leamington area	0.002–0.01	2017	May 4–Oct 19	15	164[d]	8–13	12–57
				2018	**May 11–Oct 18**	**15**	**281**	**8–22**	**5–48**
				2019	**May 2–Sep 13**	**15**	**296**	**19–20**	**5–15**
Syngenta Canada (PMRA# 3070837)	Ontario	Rivers, creeks	0.002	**2019**	**Apr 16–Oct 09**	**10[e]**	**209[e]**	**28–30**	**2–9**
Metcalfe et al., 2018 (PMRA# 2945668)	Ontario	Rivers, streams	Grab sampling: 0.001–0.006	**2016**	**May 23–Jun 22**	**Grab sampling: 6**	**Grab sampling: 18**	**Grab sampling: 3**	**14**
			POCIS: 0.0001–0.0021			**POCIS: 18**	**POCIS: 36**	**POCIS: 2**	
Environment and Climate Change Canada (PMRA# 2785041)	Ontario, Quebec (one site)	Drainage ditches in the Ottawa area (one site in Quebec)	0.00025	**2014**	**Jun 6–Jul 15**	**31**	**58**	**1–2**	**27–32**
		Streams, ponds	0.00025	2015	Jun 10–Jul 10	16	31	1–2	28
			0.0001	2016	Jun 15–Jul 15	16	32	2	28
Environment and Climate Change Canada (PMRA# 2745819)	Manitoba, Saskatchewan, Alberta	Rivers	0.00176	2014	May 5–Sep 17	4	19	1–7	8–42
				2015	Apr 8–Dec 8	4	25	5–8	14–63
				2016	May 10–Jun 22	2	3	1–2	42

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[a]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Ducks Unlimited Canada (PMRA# 2847073, 2847083, 3167980)	Manitoba, Saskatchewan, Alberta	Wetlands	0.01	2017–**2018**	Jun 20–29, 2017; Sep 21–28, 2017; **May 5–15, 2018**	**60**	**133**	**1–3**	**90–322**
Ministry of Agriculture (PMRA# 2849359, 2849370, 3167930)	Manitoba	Rivers, creeks, lakes	0.0054	2017	Jun 5–Oct 18	33	94	2–3	15–103
				2018	**Apr 4–Oct 30**	**33**	**129**	**3–4**	**20–98**
Challis et al., 2018 (PMRA# 2879350)	Manitoba	Rivers	Not reported	**2014–2015**	**May 28–Oct 21, 2014; Apr 29–Oct 7, 2015**	**6**	**127[f]**	**19–22**	**7–59**
Ministry of Agriculture and Water Security Agency (PMRA# 2849265, 2849266, 3167960, 3169037)	Saskatchewan	Streams	0.0054	2017	Mar 23–Sep 26	15	136	7–12	4–62
				2018	**Apr 16–Aug 30**	**17**	**133**	**5–11**	**4–32**
				2019	**Mar 25–Jul 30**	**16**	**119**	**1–10**	**4–81**
Bayer CropScience Canada (PMRA# 2818735, 2921988, 2921990, 2935288, 3050880, 3050882)	Saskatchewan	Wetlands in fields planted with imidacloprid-treated seeds	0.002–0.0075	2017–**2018**	May 4–Sep 21, 2017; **Apr 26–May 3, 2018 (post-melt, pre-seed)**	**6**	**49**	**7–12**	**10–258**
			0.002	**2018**	**May 1–Sep 13**	**6**	**98**	**7–20**	**3–15**
			0.002	**2019**	**Apr 23–Aug 28**	**6**	**106**	**9–20**	**2–28**
		Wetlands in fields planted with clothianidin-treated seeds	0.002	**2018**	**May 3–Sep 13**	**25**	**418**	**11–19**	**3–28**
			0.002	**2019**	**May 6–Aug 28**	**23**	**382**	**12–18**	**3–10**
Syngenta Canada (PMRA# 2947434, 3070838)	Saskatchewan	Wetlands in fields planted with thiamethoxam-treated seeds	0.002	**2018**	**May 14–Oct 2**	**56**	**790**	**5–17**	**4–44**
	Manitoba, Saskatchewan, Alberta	Wetlands in fields planted with thiamethoxam-treated seeds	0.002	**2019**	**Apr 30–Oct 6**	**58**	**834**	**2–19**	**3–67**

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[a]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	Wetlands, stream	0.0012–0.0016	2014	Jun 24–Jul 5	46[g]	46[g]	1	NA
Canadian Canola Growers Association (PMRA# 3169611)	Saskatchewan, Alberta	Wetlands	0.0054	**2019**	**May 13–Jul 12**	**17**	**135**	**4–9**	**3–22**
Ministry of Agriculture and Forestry (PMRA# 2842307, 2842433, 3167974)	Alberta	Rivers	0.0054	2017	Jun 1–Sep 21	28	110	3–4	12–59
				2018	**Mar 12–Sep 19**	**23**	**148**	**5–7**	**12–57**
		Streams	0.0054	2017	May 16–Jul 21	29	66	1–3	1–13
				2018	**Mar 27–Sep 28**	**26**	**183**	**20–61**	**1–63**
		Wetlands	0.0054	**2018**	**Apr 24–Sep 27**	**18**	**49**	**1–9**	**6–83**
		Reservoirs	0.0054	**2018**	**Jun 14–Aug 30**	**8**	**15**	**1–2**	**70–75**
		Irrigation canals[h]	0.0054	2017	May 29–Aug 28	50	194	3–4	25–35
				2018	**Apr 4–Sep 24**	**21**	**119**	**5–7**	**13–62**
		Tile drains[h]	0.0054	2017	May 25–Aug 24	3	8	2–4	11–56
				2018	**Apr 24–Sep 10**	**6**	**37**	**4–7**	**13–57**
Environment and Climate Change Canada (PMRA# 2707947, 2889992)	British Columbia	Rivers, creeks, sloughs	0.00176	2014	May 14–Sep 15	5	35	7	19–22
				2015	May 5–Dec 29	7	54	2–9	13–65
				2016	Jun 29–Sep 26	6	30	5	17–26
Ministry of Agriculture (PMRA# 2842180, 3168173)	British Columbia	Rivers, streams	0.005	2017	Jun 7–Sep 12	15[i]	120	8	12–16
				2018	**May 8–Sep 26**	**15[i]**	**120**	**7–10**	**13–28**

NA = not applicable; POCIS = polar organic chemical integrative samplers

[a] Duplicate samples were not included in the sample count. Results from duplicate samples were averaged in calculations.

[b] Multiple samples were collected during wet events. Only one sample was counted per wet event.

[c] Sampling intervals were less than one day during wet events. These short intervals were not included in the summary of sampling intervals.

[d] Excludes five samples collected in the wrong location downstream from LD2 between July and October 2017.

[e] Includes additional sampling on two occasions at three sites on the Nottawasaga Creek.

[f] Results were averages of triplicate deployments of POCIS.

[g] Only results from a subset of the sites from this data set (45 wetlands and 1 stream out of 115 sites) were considered relevant for an aquatic risk assessment and are included here.

[h] Irrigation canals and tile drains may not be representative of aquatic habitat.

[i] Excludes a site with no pesticide use in the watershed (No-Pesticide Check).

Table A.7-3 Summary of the number of samples collected, sampling sites, and site-years of monitoring data considered in the final special review decision for clothianidin

	Samples	Sites	Site-years[a]
Data previously considered in PSRD2018-01			
Prairie Provinces	785	270	274
Rivers, creeks, lakes, reservoirs	455	112	116
Wetlands	128	105	105
Irrigation canals	194	50	50
Tile drains	8	3	3
Other Regions of Canada	2873	136	254
Streams, rivers, creeks, brooks, sloughs, lakes	2873	136	254
Drainage ditches	0	0	0
New data not previously considered			
Prairie Provinces	3932	383	371
Rivers, creeks, lakes, reservoirs	854	113	129
Wetlands	2922	243	215
Irrigation canals	119	21	21
Tile drains	37	6	6
Other Regions of Canada	2260	199	298
Streams, rivers, creeks, brooks, sloughs, lakes	1910	156	248
Drainage ditches	350	43	50
Total Prairie Provinces	**4717**	**488**	**645**
Total Other Regions of Canada	**5133**	**288**	**552**
Grand Total	**9850**	**776**	**1197**

[a] One site monitored in one given year is equivalent to one monitoring site-year.

Table A.7-4 Number and percentage of sampling sites in Canada, grouped according to the number of years (1–8) of monitoring data available from each site

	Number of sampling sites (percentage of sites), grouped by the number of years of monitoring available from each site							
	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
Prairie Region (n=488)	347 (71%)	125 (26%)	16 (3%)	0 (0%)	0 0%)	0 (0%)	0 (0%)	0 (0%)
Other Regions (n=288)	185 (64%)	45 (16%)	14 (5%)	29 (10%)	5 (2%)	2 (< 1%)	6 (2%)	2 (< 1%)
Overall (n=776)	**532 (69%)**	**170 (22%)**	**30 (4%)**	**29 (4%)**	**5 (< 1%)**	**2 (< 1%)**	**6 (< 1%)**	**2 (< 1%)**

Table A.7-5 Summary of clothianidin concentrations measured in Canadian waterbodies between 2010 and 2019, and number and percentage of sites with detections exceeding acute and chronic effects metrics. Non-detects were assigned a value equivalent to half of the analytical limit of detection

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (µg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
Environment and Climate Change Canada (PMRA# 2745820, 2834289)	New Brunswick, Nova Scotia, Prince Edward Island	Rivers, brooks	0.00176	2015	3	3 (100%)	0.0386	0 (0%)	0 (0%)	0 (0%)
				2016	6	5 (83%)	0.0574	0 (0%)	0 (0%)	0 (0%)
Department of Communities, Land and Environment (PMRA# 2745506, 2468268, 2845169, 3169038)	Prince Edward Island	Streams	0.01	2010	3	0 (0%)	0.005	0 (0%)	0 (0%)	0 (0%)
				2011	3	0 (0%)	0.005	0 (0%)	0 (0%)	0 (0%)
				2012	3	2 (67%)	0.03	0 (0%)	0 (0%)	0 (0%)
				2013	3	0 (0%)	0.005	0 (0%)	0 (0%)	0 (0%)
				2014	3	2 (67%)	0.02	0 (0%)	0 (0%)	0 (0%)
				2015	3	3 (100%)	0.24	1 (33%)	0 (0%)	0 (0%)
				2017	9	7 (78%)	1.3	2 (22%)	1 (11%)	0 (0%)
			0.0054–0.01	2018	9	7 (78%)	0.64	1 (11%)	1 (11%)	0 (0%)

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (µg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
Ministère de l'Environnement et de la Lutte contre les changements climatiques (PMRA# 2523837, 2544468, 2561884, 2709791, 2709792, 2709793, 2821394, 2821395, 2895037, 2929764, 2965069)	Quebec	Rivers, streams	0.001–0.005	2010	4	3 (75%)	0.15	3 (75%)	0 (0%)	0 (0%)
				2011	2	0 (0%)	0.047	0 (0%)	0 (0%)	0 (0%)
				2012	16	8 (50%)	0.37	8 (50%)	1 (6%)	0 (0%)
				2013	15	7 (47%)	11	7 (47%)	2 (13%)	1 (7%)
				2014	16	6 (38%)	6.9	6 (38%)	2 (13%)	1 (6%)
				2015	16	3 (19%)	0.52	3 (19%)	1 (6%)	0 (0%)
				2016	10	5 (50%)	0.34	5 (50%)	2 (20%)	0 (0%)
				2017	17	4 (24%)	0.68	4 (24%)	3 (18%)	0 (0%)
				2018	17	3 (18%)	0.37	3 (18%)	2 (12%)	0 (0%)
Montiel-León et al., 2019 (PMRA# 2991134)	Quebec	St. Lawrence River and tributaries	0.001	2017	68	31[e] (46%)	0.07	0 (0%)	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	Ontario	Streams	0.0007–0.00176	2012	12	11 (92%)	0.119	0 (0%)	0 (0%)	0 (0%)
				2013	15[6]	14 (93%)	0.182	5 (33%)	0 (0%)	0 (0%)
				2014	9	8 (89%)	0.399	1 (11%)	0 (0%)	0 (0%)
				2015	11	10 (91%)	0.378	6 (55%)	1 (9%)	0 (0%)
				2016	11	10 (91%)	0.389	2 (18%)	1 (9%)	0 (0%)
Ministry of Environment, Conservation and Parks (PMRA# 2712893, 3032989) (Stream Monitoring Program)	Ontario	Streams	0.005	2015	5	5 (100%)	0.52	5 (100%)	3 (60%)	0 (0%)
				2016	5	5 (100%)	1.1	5 (100%)	2 (40%)	0 (0%)
Ministry of the Environment, Conservation and Parks in collaboration	Ontario	Streams	0.002	2015	17	17 (100%)	0.46	10 (59%)	6 (35%)	0 (0%)
				2016	17	17 (100%)	0.11	6 (35%)	1 (6%)	0 (0%)
				2017	18	17 (94%)	0.075	5 (28%)	1 (6%)	0 (0%)
				2018	19	18 (95%)	0.064	4 (21%)	1 (5%)	0 (0%)

Program	Province	Type of waterbody	Limit of detection or reporting limit (μg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (μg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
with Ontario Ministry of Agriculture, Food and Rural Affairs (PMRA# 3070884, 3157906) (Pesticide Network)										
Bayer CropScience Canada (PMRA# 2818733, 2936038, 3050884)	Ontario	Creeks, drainage ditches in the Leamington area	0.002–0.01	2017	15	15 (100%)	0.502	9 (60%)	2 (13%)	0 (0%)
				2018	15	15 (100%)	0.375	5 (33%)	1 (7%)	0 (0%)
				2019	15	15 (100%)	0.142	2 (13%)	0 (0%)	0 (0%)
Syngenta Canada (PMRA# 3070837)	Ontario	Rivers, creeks	0.002	2019	10[f]	10 (100%)	0.515	5 (50%)	1 (10%)	0 (0%)
Metcalfe et al., 2018 (PMRA# 2945668)	Ontario	Rivers, streams	Grab sampling: 0.001–0.006 POCIS: 0.0001–0.0021	2016	Grab sampling: 6 POCIS: 18	Grab sampling: 6 (100%) POCIS: 18 (100%)	Grab sampling: 0.774 POCIS: 0.6957	Grab sampling: 2 (33%) POCIS: 1 (6%)	Grab sampling: 1 (17%) POCIS: 1 (6%)	Grab sampling: 0 (0%) POCIS: NC[h]
Environment and Climate Change Canada (PMRA# 2785041)	Ontario	Drainage ditches in the Ottawa area	0.00025	2014	31	27 (87%)	0.42	1 (3%)	1 (3%)	0 (0%)
		Streams, ponds	0.00025	2015	16	13 (81%)	0.16	1 (6%)	0 (0%)	0 (0%)
			0.0001	2016	16	14 (88%)	0.032	0 (0%)	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2745819)	Manitoba, Saskatchewan, Alberta	Rivers	0.00176	2014	4	3 (75%)	0.0455	0 (0%)	0 (0%)	0 (0%)
				2015	4	3 (75%)	0.0171	0 (0%)	0 (0%)	0 (0%)
				2016	2	1 (50%)	0.0096	0 (0%)	0 (0%)	0 (0%)

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (µg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
Ducks Unlimited Canada (PMRA# 2847073, 2847083, 3167980)	Manitoba, Saskatchewan, Alberta	Wetlands	0.01	2017–2018	60	17 (28%)	0.5141	1 (2%)	1 (2%)	0 (0%)
Ministry of Agriculture (PMRA# 2849359, 2849370, 3167930)	Manitoba	Rivers, creeks, lakes	0.0054	2017	33	14 (42%)	0.0554	0 (0%)	0 (0%)	0 (0%)
				2018	33	20 (60%)	0.0625	0 (0%)	0 (0%)	0 (0%)
Challis et al., 2018 (PMRA# 2879350)	Manitoba	Rivers	Not reported	2014–2015	6	6 (100%)	0.0317[g] (7days)	0 (0%)	0 (0%)	NC[h]
Ministry of Agriculture and Water Security Agency (PMRA# 2849265, 2849266, 3167960, 3169037)	Saskatchewan	Streams	0.0054	2017	15	6 (40%)	0.0592	0 (0%)	0 (0%)	0 (0%)
				2018	17	13 (76%)	0.1105	0 (0%)	0 (0%)	0 (0%)
				2019	16	12 (75%)	0.0352	0 (0%)	0 (0%)	0 (0%)
Bayer CropScience Canada (PMRA# 2818735, 2921988, 2921990, 2935288, 3050880, 3050882)	Saskatchewan	Wetlands in fields planted with imidacloprid -treated seeds	0.002–0.0075	2017–2018	6	6 (100%)	0.0232	0 (0%)	0 (0%)	0 (0%)
			0.002	2018	6	6 (100%)	0.365	3 (50%)	1 (17%)	0 (0%)
			0.002	2019	6	6 (100%)	0.0542	0 (0%)	0 (0%)	0 (0%)
		Wetlands in fields planted with clothianidin-treated seeds	0.002	2018	25	25 (100%)	0.268	1 (4%)	0 (0%)	0 (0%)
			0.002	2019	23	21 (91%)	0.1593	2 (9%)	0 (0%)	0 (0%)

Program	Province	Type of waterbody	Limit of detection or reporting limit (μg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (μg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
Syngenta Canada (PMRA# 2947434, 3070838)	Saskatchewan	Wetlands in fields planted with thiamethoxam-treated seeds	0.002	2018	56	53 (95%)	0.1085	0 (0%)	0 (0%)	0 (0%)
	Manitoba, Saskatchewan, Alberta	Wetlands in fields planted with thiamethoxam-treated seeds	0.002	2019	58	52 (90%)	0.27	1 (2%)	0 (0%)	0 (0%)
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	Wetlands, stream	0.0012–0.0016	2014	46[i]	13 (28%)	0.389	2 (15%)	1 (8%)	0 (0%)
Canadian Canola Growers Association (PMRA# 3169611)	Saskatchewan, Alberta	Wetlands	0.0054	2019	17	8 (47%)	0.0223	0 (0%)	0 (0%)	0 (0%)
Ministry of Agriculture and Forestry (PMRA# 2842307, 2842433, 3167974)	Alberta	Rivers	0.0054	2017	28	2 (7%)	0.0285	0 (0%)	0 (0%)	0 (0%)
				2018	23	3 (13%)	0.0088	0 (0%)	0 (0%)	0 (0%)
		Streams	0.0054	2017	29	3 (10%)	0.0204	0 (0%)	0 (0%)	0 (0%)
				2018	26	14 (54%)	0.0365	0 (0%)	0 (0%)	0 (0%)
		Wetlands	0.0054	2018	18	3 (17%)	0.014	0 (0%)	0 (0%)	0 (0%)
		Reservoirs	0.0054	2018	8	0 (0%)	0.0027	0 (0%)	0 (0%)	0 (0%)
		Irrigation canals[j]	0.0054	2017	50	0 (0%)	0.0027	0 (0%)	0 (0%)	0 (0%)
				2018	21	0 (0%)	0.0027	0 (0%)	0 (0%)	0 (0%)
		Tile drains[j]	0.0054	2017	3	0 (0%)	0.0027	0 (0%)	0 (0%)	0 (0%)
				2018	6	0 (0%)	0.0027	0 (0%)	0 (0%)	0 (0%)

Program	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (%) of sites with detections	Maximum concentration[a] (µg/L)	Number (%) of sites with detections exceeding the laboratory-based chronic effects metric[b]	Number (%) of sites with detections exceeding the mesocosm-based chronic effects metric[c]	Number (%) of sites with detections exceeding the acute effects metric[d]
Environment and Climate Change Canada (PMRA# 2707947, 2889992)	British Columbia	Rivers, creeks, sloughs	0.00176	2014	5	0 (0%)	0.0009	0 (0%)	0 (0%)	0 (0%)
				2015	7	1 (14%)	0.011	0 (0%)	0 (0%)	0 (0%)
				2016	6	1 (17%)	0.0021	0 (0%)	0 (0%)	0 (0%)
Ministry of Agriculture (PMRA# 2842180, 3168173)	British Columbia	Rivers, streams	0.005	2017	15[k]	3 (20%)	0.163	1 (7%)	0 (0%)	0 (0%)
				2018	15[k]	3 (20%)	0.0848	0 (0%)	0 (0%)	0 (0%)

NC = not calculated

[a] Non-detects were assigned a value equal to half the limit of detection.

[b] Laboratory-based chronic effects metric = 0.12 µg/L (geometric mean of EC_{10}/EC_{20} values based on emergence of *Chironomus dilutus* in three 28- to 56-day laboratory studies; see Section 1.3.1 Revisions to Clothianidin Effects Metrics)

[c] Mesocosm-based chronic effects metric = 0.281 µg/L (14-day time-weighted average concentration NOEC based on reductions in individual species populations and in community or taxa richness observed at 0.573 µg/L in a 56-day mesocosm study; see Section 1.3.1 Revisions to Clothianidin Effects Metrics)

[d] Acute effects metric = 1.3 µg/L (HC_5 from an acute aquatic invertebrate species sensitivity distribution; see Section 1.3.1 Revisions to Clothianidin Effects Metrics)

[e] Number of detections was calculated by the reviewer based on the provided sample size and detection frequency.

[f] Includes additional sampling on two occasions at three sites on the Nottawasaga Creek.

[g] Concentrations in this study are time-weighted averages over timeframes of 7 to 59 days.

[h] Comparisons with the acute effects metric were not done, and risk quotients for acute exposure were not calculated as the sampling was conducted using polar organic chemical integrative samplers (POCIS), and concentrations measured represent time-weighted-average exposures for deployment periods of 14 days for the study by Metcalfe et al., 2018 (PMRA# 2945668) or ranging from 7 to 59 days for the study by Challis et al., 2018 (PMRA# 2879350).

[i] Only results from a subset of the sites from this data set (45 wetlands and 1 stream out of 115 sites) were considered relevant for an aquatic risk assessment and are included here.

[j] Irrigation canals and tile drains may not be representative of aquatic habitat.

[k] Excludes results from a site with no pesticide use in the watershed (No-Pesticide Check).

Table A.7-6 Dissipation of clothianidin in Prairie wetlands within or adjacent to fields planted with neonicotinoid-treated seeds

Site	Year	DT_{50} (days)	Representative half-life (days)	Kinetics[a]	Data Set (PMRA#)
CENT0001-C0401	2018	12	29.1	IORE	Bayer CropScience (PMRA# 2921990)
CENT0001-C0402	2018	4	7.3	IORE	Bayer CropScience (PMRA# 2921990)
CENT0001-C0406	2018	11.5	11.5	SFO	Bayer CropScience (PMRA# 2921990)
CENT0002-05	2019	11.8	11.8	SFO	Bayer CropScience (PMRA# 3050880)
CENT0002-06	2019	13.6	13.6	SFO	Bayer CropScience (PMRA# 3050880)
CETI0001-C0502	2018	14.1	14.1	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0503	2018	2.5	10.3	IORE	Bayer CropScience (PMRA# 2935288)
CETI0001-C0504	2018	21.3	21.3	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0508	2018	11.6	11.6	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0510	2018	1.9	10.8	IORE	Bayer CropScience (PMRA# 2935288)
CETI0001-C0511	2018	12.8	12.8	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0512	2018	9.2	9.2	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0513	2018	13.3	13.3	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0514	2018	8	8	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0516	2018	8.9	8.9	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0517	2018	13.7	13.7	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0518	2018	9.8	16.8	DFOP	Bayer CropScience (PMRA# 2935288)
CETI0001-C0519	2018	17	17	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0520	2018	14.4	14.4	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0522	2018	11.5	11.5	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0524	2018	6.9	6.9	SFO	Bayer CropScience (PMRA# 2935288)
CETI0001-C0525	2018	6.4	6.4	SFO	Bayer CropScience (PMRA# 2935288)
CETI0004-02	2019	15	15	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-06	2019	14.1	14.1	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-20	2019	9.1	9.1	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-21	2019	7.6	7.6	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-22	2019	11.3	11.3	SFO	Bayer CropScience (PMRA# 3050882)
CH1	2018	7.9	7.9	SFO	Syngenta Canada (PMRA# 2947434)
CS1	2018	16.1	16.1	SFO	Syngenta Canada (PMRA# 2947434)
CS3	2018	14.4	14.4	SFO	Syngenta Canada (PMRA# 2947434)
DD1	2018	14.4	14.4	SFO	Syngenta Canada (PMRA# 2947434)
DK4	2018	12.1	12.1	SFO	Syngenta Canada (PMRA# 2947434)
DW1	2018	10.1	10.1	SFO	Syngenta Canada (PMRA# 2947434)
DW3	2018	12	12	SFO	Syngenta Canada (PMRA# 2947434)

Site	Year	DT_{50} (days)	Representative half-life (days)	Kinetics[a]	Data Set (PMRA#)
DW4	2018	13.4	13.4	SFO	Syngenta Canada (PMRA# 2947434)
RL4	2018	10.7	10.7	SFO	Syngenta Canada (PMRA# 2947434)
RL5	2018	8.1	8.1	SFO	Syngenta Canada (PMRA# 2947434)
RL6	2018	16	16	SFO	Syngenta Canada (PMRA# 2947434)
RL7	2018	12.1	12.1	SFO	Syngenta Canada (PMRA# 2947434)
SB4	2018	10.9	10.9	SFO	Syngenta Canada (PMRA# 2947434)
Overall	***N***	***40***			
	Average	***11.3***			

[a] The DT_{50} is from the curve that better fits the data; can be from a single first-order exponential function (SFO), double first-order in parallel (DFOP) or indeterminate order rate equation (IORE). The representative half-life could be used in modelling if different from the DT_{50} when the decline is not exponential (that is, when the decline follows DFOP or IORE), in which case it is a conservative approximation of the first-order decline.

Table A.7-7 Summary of the 50 site-years from 31 sites (24 watersheds) with maximum 28-day moving average concentrations of clothianidin exceeding the laboratory-based chronic effects metric of 0.12 µg/L in the Atlantic Region, Quebec, Ontario and British Columbia

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
Huntley River, Prince Edward Island (PMRA# 2745506, 2468268, 2845169, 3169038)	18.4 (85%)	potato (40%), pasture (20%), cereals (15%)	3 out of 4 2015, 2017, 2018	2015: 0.127 2017: 0.275 2018: 0.433	2015: 28 d (3) 2017: 35 d (2) 2018: 28 d (2)	2015: 1.1 2017: 2.3 2018: 3.6	In 2015, the average is influenced by one sample above the laborator-based chronic effects metric. All samples collected in 2017 and 2018 have concentrations exceeding the laboratory-based chronic effects metric.
Wilmot River, Prince Edward Island (PMRA# 2745506, 2468268, 2845169, 3169038)	46 (85%)	potato (40%), pasture (20%), cereals (15%)	1 out of 5 2017	0.68	41 d (2)	5.7	Maximum average is influenced by a single acute peak above the chronic effects metric. The time frame for the average is 41 days and based on two values; there is uncertainty about what the average would be over 28 days and with more values. Only one sample in 2017 and two samples in 2018 out of a total of 28 samples collected over five years are at or exceed the laboratory-based chronic effects metric.

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
Blanche River, Quebec (PMRA# 2544468, 2821395, 2929764)	27.3 (20%)	potato (12%)	2 out of 3 2017, 2018	2017: 0.283 2018: 0.284	2017: 28 d (9) 2018: 27 d (9)	2017: 2.4 2018: 2.4	Almost all samples collected in 2017 and 2018 had concentrations exceeding the chronic effects metric.
Chartier Creek, Quebec (PMRA# 2523837, 2544468, 2821395, 2929764)	5.2 (85%)	Potato (34%), corn (17%), soybean (9%), cereals (9%)	3 out of 4 2012, 2017, 2018	2012: 0.161 2017: 0.281 2018: 0.21	2012: 28 d (9) 2017: 28 d (9) 2018: 28 d (9)	2012: 1.3 2017: 2.3 2018: 1.8	In 2012, 2017 and 2018, the majority of the samples collected in May and June had concentrations exceeding the chronic effects metric. Several consecutive samples collected in August of 2012 and 2017 also had concentrations exceeding the chronic effects metric.
Gibeault-Delisle Creek, Quebec (PMRA# 2709793, 2821394)	12 (85%)	Potato (21%), vegetable (21%), corn (17%), soybean (17%)	2 out of 2 2013, 2014	2013: 2.045 2014: 1.318	2013: 25 d (8) 2014: 29 d (9)	2013: 17 2014: 11	The majority of samples collected in 2013 and 2014 had concentrations exceeding the chronic effects metric.
Sturgeon Creek, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2818733, 2834287, 2936038, 3050884)	22.5 (63%)	Soybean (27%), corn (10%), greenhouse (9%), tomato (7%)	1 out of 8 2016	0.327	35 d (2)	2.7	Only one sample in 2015 and two samples in 2016, out of 312 samples collected weekly over eight years had concentrations exceeding the chronic effects metric.
Little Ausable Creek, Ontario (PMRA# 2712893, 3032989)	64 (90%)	Corn (35%), soybean (35%), cereals (15%)	2 out of 2 2015, 2016	2015: 0.184 2016: 0.404	2015: 32 d (3) 2016: 24 d (5)	2015: 1.5 2016: 3.4	Three consecutive bi-weekly samples between June 7 and July 9, 2016 had concentrations exceeding the chronic effects metric. In 2015, at most, two consecutive samples on two occasions collected 10 to 18 days apart had concentrations exceeding the chronic effects metric
North Creek, Ontario (PMRA# 2712893, 3032989, 3070837)	36.5 (70%)	Soybean (40%), corn (10%)	1 out of 3 2015	0.353	24 d (3)	2.9	Three samples collected within 24 days had concentrations exceeding the chronic effects metricin 2015. Only two other samples (one in October 2015 and one in October 2016) had concentrations exceeding the chronic effects metric.
Otter Creek,	58 (72%)	Corn (32%),	1 out of 4	0.29	21 d (2)	2.4	Two consecutive samples collected 21 days apart

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
Ontario (PMRA# 2945668, 3070884, 3157906)		soybean (25%), wheat (14%)	2018				had concentrations exceeding the chronic effects metric. There is uncertainty as to whether the average concentration would exceed the chronic effects metric over 28 days.
Nottawasaga Creek (a small tributary to the Nottawasaga River), Ontario (PMRA# 2523839, 2703534, 2834287, 3070837)	30 (39%)	Soybean (15%), potato (10%), corn (7%), cereals (6%)	1 out of 3 2019	0.373	29 d (5)	3.1	All 11 samples collected between April 23 and June 25, 2019 had concentrations exceeding the chronic effects metric.
Lebo Drain, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2818733, 2834287, 2936038, 2945668, 3050884, 3070884, 3157906)	25.9 (86%)	Soybean (40%), corn (20%), cereals (9%), tomato (11%), greenhouse (3%)	**Main Lebo Drain site**				
			3 out of 7 2015, 2016 (2 out of 3 programs), 2017	2015: 0.215 2016: Metcalfe et al., 2018 (POCIS): 0.6957; MECP and OMAFRA: 0.22 All programs: 0.234 2017: 0.1353	2015: 26 d (2) 2016: Metcalfe et al., 2018 (POCIS): 14 d (1); MECP and OMAFRA: 27 d (2) All programs: 27 d (3) 2017: 29 d (3)	2015: 1.8 2016: Metcalfe et al., 2018 (POCIS): 5.8 MECP and OMAFRA: 1.8 All programs: 2.0 2017: 1.1	POCIS sampling in 2016 by Metcalfe et al. (2018) are based on 14-day deployments and there is uncertainty if the average would be below the endpoints over 28 days. The Metcalfe et al. (2018) data from grab sampling rather than the POCIS sampling were used in the overall calculations. The highest averages in 2015, 2016 and 2017 were influenced by single samples exceeding the chronic effects metric. Only one instance occurred in the seven years of monitoring where two consecutive samples had concentrations exceeding the chronic effects metric.
			Other sites in the watershed–Creeks				
			1 out of 3 years in 2 out of 6 sites LD3 (2017), LD9 (2017)	LD3 (2017): 0.1669 LD9 (2017): 0.1323	LD3 (2017): 57 d (2) LD9 (2017): 29 d (3)	LD3 (2017): 1.4 LD9 (2017): 1.1	Concentrations above the chronic effects metric were not observed at any creek site in consecutive samples collected between 2017 and 2019. In 2017, the 28-day average exceeding the chronic effects metric at two sites was influenced by a single sample on a single date (July 13). Concentrations were not above the chronic effects metricat any site at any other time in 2017. Only one sample from one site had concentrations excedding the chronic effects metric in 2018.
			Other sites in the watershed–Drainage ditches				
			2 out of 3 years in 4 out of 8 sites	LD4 (2017): 0.3634	LD4 (2017): 28 d (3)	LD4 (2017): 3	Drainage ditches may not be representative of aquatic habitat.

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
			LD4 (2017), LD5 (2017, 2018), LD6 (2017, 2018), LD10 (2017)	LD5 (2017): 0.1418 LD5 (2018): 0.1448 LD6 (2017): 0.2261 LD6 (2018): 0.2292 LD10 (2017): 0.2534	LD5 (2017): 28 d (3) LD5 (2018): 29 d (5) LD6 (2017): 28 d (3) LD6 (2018): 29 d (5) LD10 (2017): 28 d (3)	LD5 (2017): 1.2 LD5 (2018): 1.2 LD6 (2017): 1.9 LD6 (2018): 1.9 LD10 (2017): 2.1	Several consecutive samples in drainage ditches had concentrations exceeding the chronic effects metric in 2017 and 2018, but not 2019.
Thames River, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287, 2945668, 3070884, 3157906)	4400 (61%)	corn (29%), soybean (24%)	1 out of 6 2015 (2 out of 2 programs)	ECCC: 0.1669 MECP and OMAFRA: 0.13 All programs: 0.1677	ECCC: 35 d (3) MECP and OMAFRA: 42 d (2) All programs: 35 d (4)	ECCC: 1.4 MECP and OMAFRA: 1.1 All programs: 1.4	Out of 81 samples collected over six years, only two samples collected eight days apart as part of two different programs exceeded the chronic effects metric. An additional site in the Upper Thames River was monitored in 2019 and none of the 30 samples collected had concentrations exceeding the chronic effects metric.
Big Creek, Ontario (PMRA# 2523839, 2703534, 2712893, 2834287, 3032989)	55 (90%)	corn (15%), soybean (60%)	2 out of 3 2015, 2016	2015: 0.1563 2016: 0.19	2015: 27 d (3) 2016: 32 d (3)	2015: 1.3 2016: 1.6	In 2015, the maximum average is influenced by a single sample with concentrations exceeding the chronic effects metric; all other samples collected in 2015 had concentrations below the chronic effects metric. In 2016, three consecutive bi-weekly samples between June 6 and July 8 had concentration exceeding the chronic effects metric.
Garvey Glenn, Ontario (PMRA# 2712893, 3032989)	12.9 (80%)	Corn (35%), soybean (35%), cereals (15%)	2 out of 2 2015, 2016	2015: 0.12 2016: 0.126	2015: 23 d (3) 2016: 21 d (2)	2015: 1.0 2016: 1.1	In 2015, the maximum average is influenced by a single sample with a concentration exceeding the chronic effects metric. All other samples collected in 2015 had concentrations below the chronic effects metric. In 2016, only two samples (one in mid-May and one in mid-September) had concentrations exceeding the chronic effects metric. The timeframe for the maximum averages in both 2015 and 2016 are shorter than 28-days and are

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
							equal to or only slightly higher than the chronic effects metric. There is uncertainty if the averages would exceed the chronic effects metric over 28-days.
White Ash Creek, Ontario (PMRA# 2712893, 3032989)	75.8 (85%)	corn (60%), soybean (20%)	2 out of 2 2015, 2016	2015: 0.172 2016: 0.1898	2015: 23 d (2) 2016: 34 d (4)	2015: 1.4 2016: 1.6	In 2015, only one sample had a concentration exceeding the chronic effects metric. In 2016 the maximum average was influenced by a rain event on June 5th and 6th, which resulted in a pulse of clothianidin. All other samples with the exception of one sample on August 2nd had concentrations below the chronic effects metric.
Boomer Creek, Ontario (PMRA# 2945668, 3070884, 3157906)	71 (43%)	corn (23%), wheat (10%)	1 out of 4 2015	0.233	43 d (3)	1.9	Only two samples collected eight days apart in 2015 had concentrations exceeding the chronic effects metric. None of the other 31 samples collected over four years had concentrations exceeding the chronic effects metric.
Decker Creek, Ontario (PMRA# 2945668, 3070884, 3157906)	17.7 (69%)	corn (26%), soybean (33%), wheat (10%)	3 out of 4 2015, 2016 (1 out of 2 programs), 2017	2015: 0.188 2016: MECP and OMAFRA: 0.145 2017: 0.24	2015: 34 d (2) 2016: MECP and OMAFRA: 28 d (2) 2017: 28 d (2)	2015: 1.6 2016: MECP and OMAFRA: 1.2 2017: 2.0	The maximum average in 2015 was influenced by one sample with aconcentration exceeding the chronic effects metric. In 2016 and 2017, two consecutive samples collected 28 days apart had concentrations near or exceeding the chronic effects metric. There were no grab samples collected at this site in 2016 by Metcalfe et al. (2018) to calculate an average for all programs together.
Gregory Creek, Ontario (PMRA# 2945668, 3070884, 3157906)	59 (76%)	corn (33%), soybean (28%), wheat (14%)	1 out of 4 2018	0.144	77 d (2)	1.2	For 2018, there is uncertainty about the maximum average concentration because the timeframe between the two samples used to calculate the average is long (77 days).

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using laboratory-based chronic effects metric of 0.12 µg/L[b]	Comments
McKillop Drain, Ontario (PMRA# 2945668, 3070884, 3157906)	45 (66%)	corn (28%), soybean (33%)	3 out of 4 2015, 2016 (1 out of 2 programs), 2017	2015: 0.13 2016: MECP and OMAFRA: 0.18 2017: 0.15	2015: 21 d (2) 2016: MECP and OMAFRA: 34 d (2) 2017: 27 d (2)	2015: 1.1 2016: MECP and OMAFRA: 1.5 2017: 1.3	In 2015, there were four consecutive monthly samples with concentrations near or exceeding the chronic effects metric. In 2016 and 2017, the maximum averages are influenced by one sample with a concentration exceeding the chronic effects metric.
Whitemans Creek, Ontario (PMRA# 2945668, 3070884, 3157906)	384 (63%)	corn (29%), soybean (22%)	1 out of 4 2015	0.147	27 d (2)	1.2	In 2015, the maximum average was influenced by a single sample with a concentration exceeding the chronic effects metric. In the four years of sampling, only one out of 31 samples had a concentration exceeding the chronic effects metric.
Iroquois3 (drainage ditch), Ontario (PMRA# 2785041)	not determined	corn, soybean (percentages not determined)	1 out of 1 2014	0.2199	27 d (2)	1.8	Only one out of the total of two samples collected 27 days apart had a concentration exceeding the chronic effects metric. The sampling location is a drainage ditch which may not be representative of aquatic habitat.
Kirkwood (stream), Ontario (PMRA# 2785041)	not determined	corn, soybean (percentages not determined)	1 out of 2 2015	0.135	28 d (2)	1.1	In 2015, only one out of the total of two samples collected 28 days apart had a concentration exceeding the chronic effects metric. The two samples collected in 2016 had a concentration exceeding the chronic effects metric.
Two Mile Creek, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	24.4 (65%)	orchard/vineyard (59%)	1 out of 5 2014	0.1351	28 d (3)	1.1	The maximum average in 2014 is influenced by a single acute peak with concentrations exceeding the chronic effects metric. No other sample out of the total of 60 samples collected over five years had concentrations exceeding the chronic effects metric.
Prudhomme Creek, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	10 (59%)	orchard/vineyard (51%)	1 out of 5 2015	0.1408	34 d (3)	1.2	In 2015, the highest average is influenced by a single sample exceeding the chronic effects metric; all others had concentrations well below. Out of a total of 58 bi-weekly samples collected over five years, only two samples had concentrations exceeding the chronic effects metric (one in 2015 and one in 2016).

ECCC = Environment and Climate Change Canada; MECP = Ministry of the Environment, Conservation and Parks; OMAFRA = Ontario Ministry of Agriculture, Food and Rural Affairs

[a] Risk Quotient = maximum 28-day average concentration ÷ chronic effects metric

[b] Laboratory-based chronic effects metric = 0.12 µg/L (geometric mean of EC_{10}/EC_{20} values based on emergence of *Chironomus dilutus* in three 28- to 56-day laboratory studies; see Section 1.3.1 Revisions to Clothianidin Effects Metrics)

Table A.7-8 Summary of the 15 site-years from 12 sites (11 watersheds) with maximum 28-day average concentrations near or exceeding the mesocosm-based effects metric of 0.281 µg/L in the Atlantic Region, Quebec, Ontario and British Columbia

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using mesocosm-based chronic effects metrics (NOEC of 0.281 µg/L and LOEC of 0.573 µg/L)[b]	Comments
Huntley River, Prince Edward Island (PMRA# 2745506, 2468268, 2845169, 3169038)	18.4 (85%)	potato (40%), pasture (20%), cereals (15%)	2 out of 4 2017, 2018	2017: 0.275 2018: 0.433	2017: 35 d (2) 2018: 28 d (2)	2017: NOEC: 1.0 LOEC: 0.5 2018: NOEC: 1.5 LOEC: 0.8	In 2017, the maximum 28-day average is only slightly below the chronic effects metric; three consecutive monthly samples have concentrations near or exceeding the chronic effects metric. In 2018, the average is influenced by a single peak with concentrations exceeding the chronic effects metric.
Wilmot River, Prince Edward Island (PMRA# 2745506, 2468268, 2845169, 3169038)	46 (85%)	potato (40%), pasture (20%), cereals (15%)	1 out of 5 2017	0.68	41 d (2)	NOEC: 2.4 LOEC: 1.2	The maximum average is influenced by a single peak with concentrations exceeding the chronic effects metric. Only one sample out of a total of 28 samples collected over five years exceeded the chronic effects metric. All other samples had concentrations well below the chronic effects metric. The time frame for the average is 41 days and based on two values; there is uncertainty about what the average would be over 28 days and with more values.
Blanche River, Quebec (PMRA# 2544468, 2821395, 2929764)	27.3 (20%)	potato (12%)	2 out of 3 2017, 2018	2017: 0.283 2018: 0.284	2017: 28 d (9) 2018: 27 d (9)	2017: NOEC: 1.0 LOEC: 0.5 2018: NOEC: 1.0 LOEC: 0.5	In 2017 and 2018, samples collected three to four days apart had concentrations consistently near or slightly exceeding the chronic effects metric.
Chartier Creek, Quebec (PMRA# 2523837, 2544468, 2821395, 2929764)	5.2 (85%)	Potato (34%), corn (17%), soybean (9%), cereals (9%)	1 out of 4 2017	0.281	28 d (9)	NOEC: 1.0 LOEC: 0.5	In 2017, five out of seven samples collected over a three-week period had concentrations equal to or exceeding the chronic effects metric.
Gibeault-Delisle Creek, Quebec (PMRA# 2709793, 2821394)	12 (85%)	Potato (21%), vegetable (21%), corn (17%), soybean (17%)	2 out of 2 2013, 2014	2013: 2.045 2014: 1.318	2013: 25 d (8) 2014: 29 d (9)	2013: NOEC: 7.3 LOEC: 3.6 2014: NOEC: 4.7 LOEC: 2.3	The majority of samples collected in 2013 and 2014 had concentrations exceeding the chronic effects metric.

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using mesocosm-based chronic effects metrics (NOEC of 0.281 µg/L and LOEC of 0.573 µg/L)[b]	Comments
Sturgeon Creek, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2818733, 2834287, 2936038, 3050884)	22.5 (63%)	Soybean (27%), corn (10%), greenhouse (9%), tomato (7%)	1 out of 8 2016	0.327	35 d (2)	NOEC: 1.2 LOEC: 0.6	Only one out of 312 samples collected over eight years had a concentration exceeding the chronic effects metric.
Little Ausable Creek, Ontario (PMRA# 2712893, 3032989)	64 (90%)	Corn (35%), soybean (35%), cereals (15%)	1 out of 2 2016	0.404	24 d (5)	2016: NOEC: 1.4 LOEC: 0.7	In 2016, the average is influenced by two samples collected one day apart in mid-May with concentrations exceeding the chronic effects metric. Only one other sample in mid-August had a concentration exceeding the chronic effects metric.
North Creek, Ontario (PMRA# 2712893, 3032989, 3070837)	36.5 (70%)	Soybean (40%), corn (10%)	1 out of 3 2015	0.353	24 d (3)	NOEC: 1.3 LOEC: 0.6	In 2015, the average is influenced by two samples collected 10 days apart with concentrations exceeding the chronic effects metric. No other samples out of the 63 samples collected over three years had concentrations exceeding the chronic effects metric.
Otter Creek, Ontario (PMRA# 2945668, 3070884, 3157906)	58 (72%)	Corn (32%), soybean (25%), wheat (14%)	1 out of 4 2018	0.29	21 d (2)	NOEC: 1.0 LOEC: 0.5	In 2018, the average, which is only slightly above the chronic effects metric is based on two samples collected 21 days apart; there is uncertainty if the average would still exceed the chronic effects metric over 28 days.
Nottawasaga Creek (a small tributary to the Nottawasaga River), Ontario (PMRA# 2523839, 2703534, 2834287, 3070837)	30 (39%)	Soybean (15%), potato (10%), corn (7%), cereals (6%)	1 out of 3 2019	0.373	29 d (5)	NOEC: 1.3 LOEC: 0.7	In 2019, five out of six samples collected between April 30 and June 4 had concentrations exceeding the chronic effects metric.
Lebo Drain, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2818733, 2834287, 2936038, 2945668, 3050884, 3070884, 3157906)	25.9 (86%)	Soybean (40%), corn (20%), cereals (9%), tomato (11%), greenhouse (3%)	**Main Lebo Drain site**				
			1 out of 7 2016 (1 out of 3 programs)	Metcalfe et al. (2018) (POCIS): 0.6957; ECCC: 0.012; MECP and OMAFRA: 0.22 All programs: 0.234	Metcalfe et al. (2018) (POCIS): 14 d (1); ECCC: NA[c] MECP and OMAFRA: 27 d (2)	Metcalfe et al. (2018) (POCIS): NOEC: 2.5 LOEC: 1.2 ECCC: NOEC: < 0.1 LOEC: < 0.1	POCIS sampling in 2016 by Metcalfe et al. (2018) are based on 14-day deployments and there is uncertainty if the average would be below the endpoints over 28 days. The Metcalfe et al. (2018) data from grab sampling rather than the POCIS sampling were used in the overall calculations. Looking at overall data for 2016, the 28-day average concentrations did not exceed the chronic

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-day (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[a] calculated using mesocosm-based chronic effects metrics (NOEC of 0.281 µg/L and LOEC of 0.573 µg/L)[b]	Comments
					All programs: 27 d (3)	MECP and OMAFRA: NOEC: 0.8 LOEC: 0.4 All programs: NOEC: 0.8 LOEC: 0.4	effects metric.
			Other sites in the watershed–Creeks				
			0 out of 3 years in 0 out of 6 sites	No creek site had 28-day average concentrations exceeding the chronic effects metric.			
			Other sites in the watershed–Drainage ditches				
			1 out of 3 years in 1 out of 8 sites LD4 (2017)	LD4 (2017): 0.3634	LD4 (2017): 28 d (3)	LD4 (2017): NOEC: 1.3 LOEC: 0.6	Drainage ditches may not be representative of aquatic habitat. In 2017 at LD4, the average was influenced by two consecutive samples collected 14 days apart with concentrations exceeding the chronic effects metric. No other samples had concentrations exceeding the chronic effects metric.

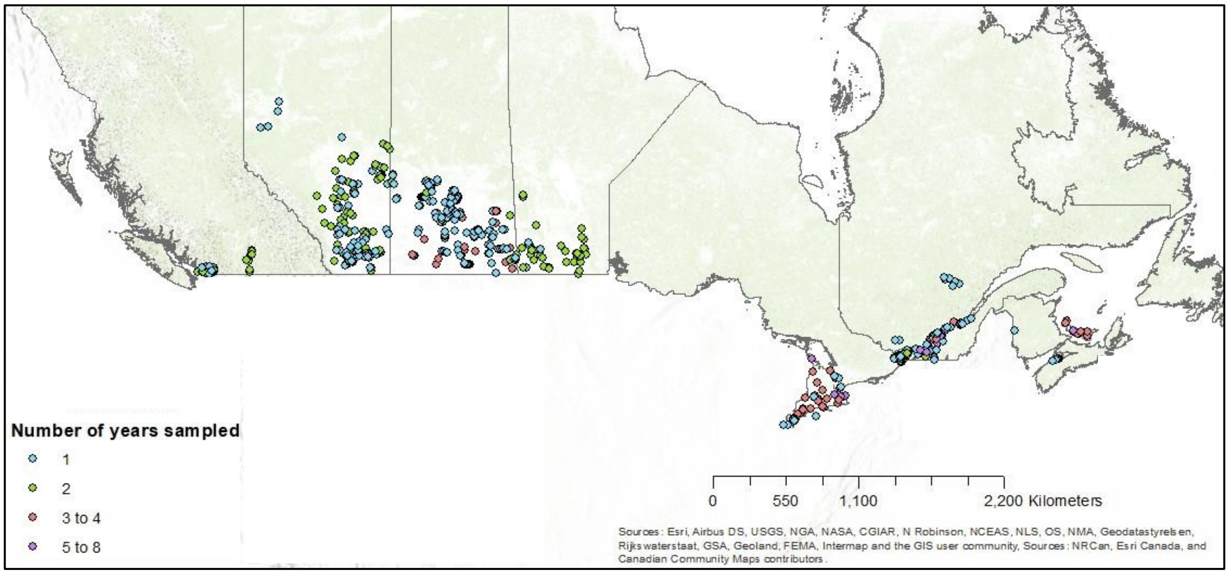
NOEC = no observable effect concentration; LOEC = lowest observable effect concentration; ECCC = Environment and Climate Change Canada; MECP = Ministry of the Environment, Conservation and Parks; OMAFRA = Ontario Ministry of Agriculture, Food and Rural Affairs; NA = not applicable

[a] Risk Quotient = maximum 28-day average concentration ÷ chronic effects metric

[b] Mesocosm-based chronic effects metric = 0.281 µg/L (14-day time-weighted average concentration NOEC based on reductions in individual species populations and in community or taxa richness observed at 0.573 µg/L (LOEC) in a 56-day mesocosm study; see Section 1.3.1 Revisions to Clothianidin Effects Metrics)

[c] Twenty-eight day average was estimated using the maximum concentration measured and a DT_{50} of 11.3 days, assuming dissipation followed single first-order kinetics.

Figure A.7-1 Location of clothianidin water monitoring sites in Canada between 2010 and 2019, identified based on the number of years of sampling conducted at each site



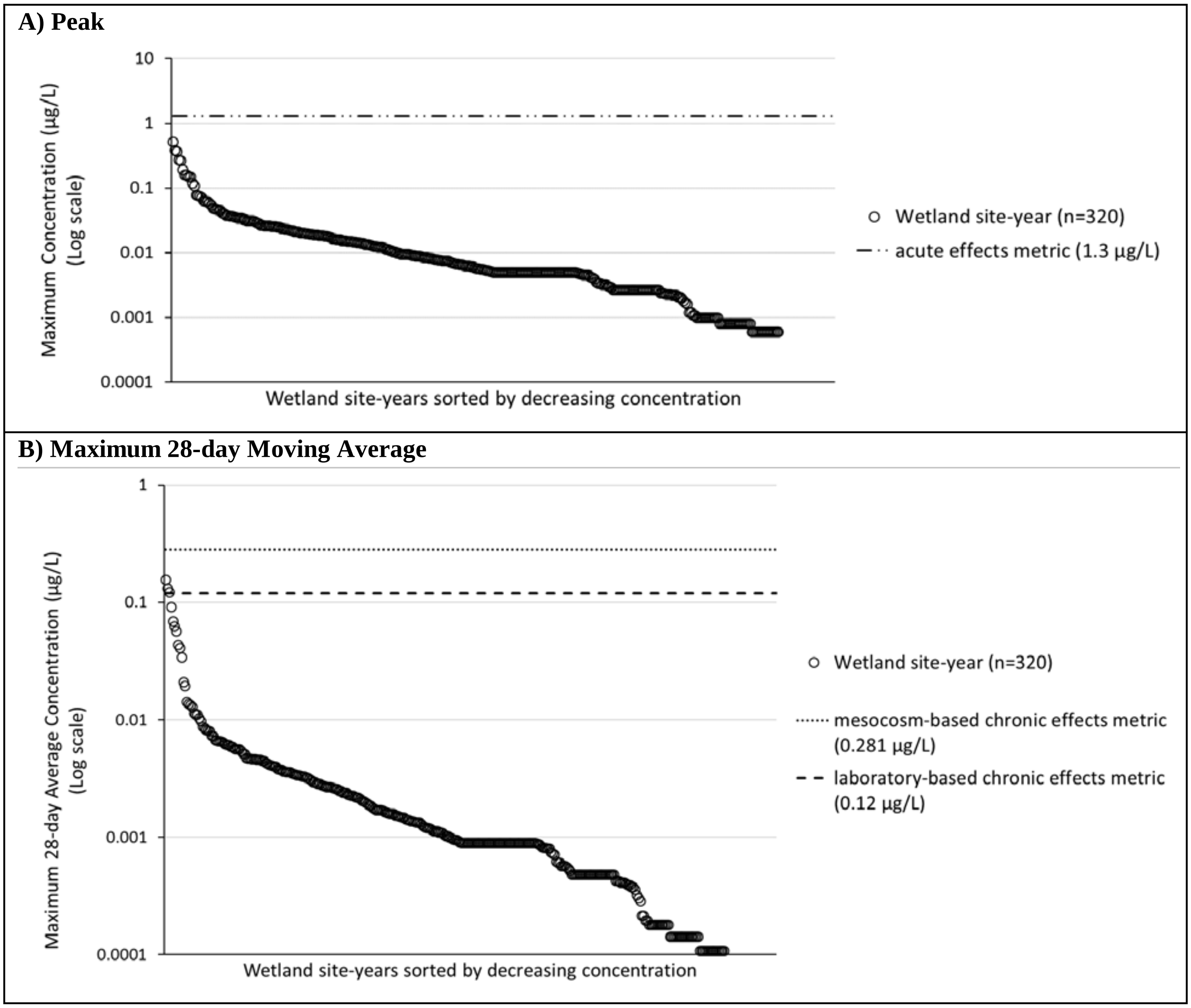
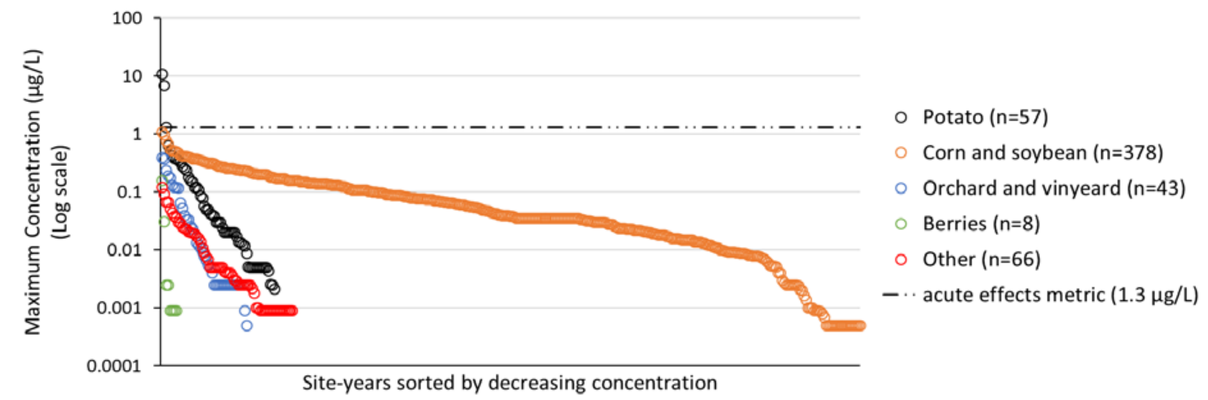


Figure A.7-2 A) Peak and B) maximum 28-day moving average concentrations (µg/L) of clothianidin measured in Prairie wetlands between 2014 and 2019, and comparison with acute and chronic effects metrics for aquatic invertebrates.

The black circles represent the concentrations for each of the 320 site-years of monitoring, sorted by decreasing concentration. The 28-day average concentrations were calculated using observed data only in wetlands with peak concentrations exceeding the laboratory-based chronic effects metric; for the other sites, the 28-day average concentration was estimated using the peak concentration and an average DT_{50} of 11.3 days assuming dissipation followed single first-order kinetics.

A) Peak



B) Maximum 28-day Moving Average

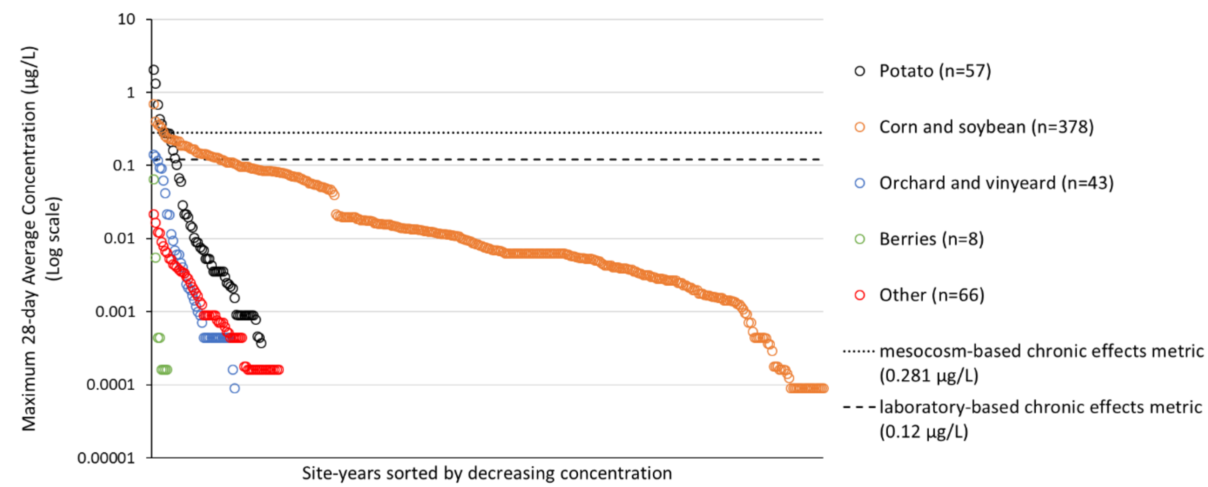


Figure A.7-3 A) Peak and B) maximum 28-day moving average concentrations (µg/L) of clothianidin measured in 288 sites (total of 552 site-years of monitoring) in the Atlantic Region, Quebec, Ontario and British Columbia sampled between 2010 and 2019, by main crops grown in the watershed, and comparison with the acute and chronic effects metrics for aquatic invertebrates.

Each circle represents a site-year of monitoring, and they are sorted by decreasing concentration. The 28-day average concentrations were calculated using observed data only for sites with peak concentrations exceeding the laboratory-based chronic effects metric; for the other sites, the 28-day average concentration was estimated using the peak concentration and an average DT_{50} of 11.3 days assuming dissipation followed single first-order kinetics.

Appendix VIII Label amendments required for products containing clothianidin

The label amendments required below do not include all label requirements for individual products, such as disposal statements, and precautionary statements. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

Label amendments required for all commercial class products

Under the DIRECTIONS FOR USE, the following label revisions are required:

- Cancelled uses to be removed from product labels:
  - Seed treatment for field sown leafy vegetables, and bunching onion and listed pests.
  - Greenhouse seed treatment use on bunching onion for onion maggot and seed corn maggot.
  - Seed treatment application for corn rootworm on field corn.
  - In-furrow application on potato and listed pests.
  - Foliar application for hairy chinch bug, annual bluegrass weevil, bluegrass billbug, and European crane fly on turf.
  - Foliar application for brown marmorated stink bug on cucurbit vegetables.

Revise the application instructions so to reflect the revised application rates, maximum number of applications per year, and re-application intervals according to required risk mitigation measures as outlined in Table 1, for each crop currently registered on the label and granted continuing registration.

Table 1 Use directions changes required for clothianidin

Crop	Method of Application	Current Rate	New Requirement
Potato	In-furrow	1.2–2.0 g a.i./100 m of row (equivalent to 133–223.8 g a.i./ha)	Cancellation of in-furrow uses
	Foliar	35–52.5 g a.i./ha, maximum three applications	35–52.5 g a.i./ha (one application)
Corn (field corn only)	Seed treatment	0.25–1.25 mg a.i./kernel (equivalent to 75–375 g a.i./100 kg seed, or 15.8–118.3 g a.i./ha for field corn)	Field corn: 0.5 mg a.i./kernel (equivalent to 150 g a.i./100 kg seed, or up to 47.3 g a.i./ha)

Crop	Method of Application	Current Rate	New Requirement
Vegetables (carrot, brassica vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, and leafy vegetables)	Seed treatment	0.035–0.9 g a.i./1000 seeds (equivalent to 0.6–420 g a.i./ha, depending on crop)	Limit seeding rate for crops to a maximum of 100 g a.i./ha. Cancellation of use on bunching onions and leafy vegetables.
Cucurbits	Foliar	70–105 g a.i./ha (one application pre-bloom only)	70 g a.i./ha (one application pre-bloom only)
Turf (sod farms and golf courses only)	Foliar	1.25–3.5 g a.i./100 m^2 (equivalent to 125–350 g a.i./ha), maximum one application	1.25 g a.i./100 m^2 (equivalent to 125 g a.i./ha; one application)

For PCP#s 29382, 29383, 29384:

Add to ENVIRONMENTAL PRECAUTIONS:

Toxic to aquatic organisms. Observe spray buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Add to DIRECTIONS FOR USE:

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

<u>Field sprayer application</u>: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Reduce drift caused by turbulent wingtip vortices. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Apply only by fixed-wing or rotary aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Use Precautions

Apply only when meteorological conditions at the treatment site allow for complete and even crop coverage. Apply only under conditions of good practice specific to aerial application as outlined in the National Aerial Pesticide Application Manual, developed by the Federal/Provincial/Territorial Committee on Pest Management and Pesticides.

Operator Precautions

Do not allow the pilot to mix chemicals to be loaded onto the aircraft. Loading of premixed chemicals with a closed system is permitted.

It is desirable that the pilot have communication capabilities at each treatment site at the time of application.

The field crew and the mixer/loaders must wear chemical resistant gloves, coveralls and goggles or face shield during mixing/loading, cleanup and repair. Follow the more stringent label precautions in cases where the operator precautions exceed the generic label recommendations on the existing ground boom label.

All personnel on the job site must wash hands and face thoroughly before eating and drinking. Protective clothing, aircraft cockpit and vehicle cabs must be decontaminated regularly.

Product Specific Precautions

Read and understand the entire label before opening this product. If you have questions, call the manufacturer at (XXX)YYY-ZZZZ or obtain technical advice from the distributor or your provincial agricultural representative. Application of this specific product must meet and/or conform to the following:

Volume: Apply the recommended rate in a minimum spray volume of 45 litres per hectare.

SPRAY BUFFER ZONES

A spray buffer zone is NOT required for:

- uses with hand-held application equipment permitted on this label,
- in-furrow, soil drench or soil incorporation applications.

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of application	Crop		Buffer Zones (metres) Required for the Protection of Freshwater Habitat of Depths:	
			Less than 1 m	Greater than 1 m
Fild sprayer	Potato		10	4
	Cucurbit vegetables		10	5
	Grape		15	5
	Turf		15	10
Airblast	Grape	Early growth stage	35	25
		Late growth stage	25	15
Aerial	Potato	Fixed wing	100	35
		Rotary wing	95	30

[Note: The spray buffer zones presented in this table are for all crops listed in PCP#s 29382, 29383, 29384. Care must be taken to ensure that only the applicable crop uses are added to the appropriate labels.]

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) spray buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The spray buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Spray Buffer Zone Calculator on the Pest Management Regulatory Agency website.

Cancelled uses with an extended phase out schedule

Cancellation of the following uses will be delayed for an additional two years (Note: The extended use of two years is only for the crop and pest combinations below, references to allother pests on bunching onion must be removed from all affected labels):

- Field application of seed treatment on bunching onion.

The following table must be added to the PRINCIPAL DISPLAY PANEL of the label:

Cancellation date for cancelled uses with an extended phase out period

Crop	Pest	Last Date of Use
Bunching onions (seed treatment)	onion maggot and seedcorn maggot	March 31st 2025

Appendix IX List of References

A Registrants Submitted Studies/Information

Environmental Fate and Effects Assessment

Unpublished Information

PMRA Document Number	Reference
2744280	2014. Outdoor microcosm study to the effects of imidacloprid SL 200 on the mayfly *Cloeon dipterum* and its dissipation from water at two different light intensities. DACO: 9.3.6
2744281	2015. Amendment - Outdoor microcosm study to the effects of imidacloprid SL 200 on the summer generation of the mayfly *Cloeon dipterum*. DACO: 9.3.6
2862054	2018. Correlative Evaluation of Neonicotinoid Surface Water Concentrations and Aquatic Invertebrate Benthic Health Metrics in Quebec Streams/Rivers - Final Report. DACO: 9.9
2862055	2018. Assessment of Benthic Invertebrates in Wetlands of Saskatchewan, Canada - Final Progress Report. DACO: 9.9
3050881	2019, 2019 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada - Final Report, DACO: 8.6

Water Monitoring Assessment

Unpublished Information

PMRA Document Number	Reference
2818735	2017, Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2921988	2018, Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada - Spring 2018 Update, DACO: 8.6.1,8.6.2
2921990	2018, 2018 Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2935286	2018, 2018 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2935288	2018, 2018 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2935289	2018, 2018 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2

PMRA Document Number	Reference
2936038	2018, Ontario Surface Water Monitoring Study – 2018 Final Report: Investigation of Potential Sources of Imidacloprid in Waterways of the Lebo Drain and Sturgeon Creek Watersheds. October 21, 2018 (corrections November 15, 2018), DACO: 8.6.1,8.6.2
3050880	2019, 2019 Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada - Final Report, DACO: 8.6
3050881	2019, 2019 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada - Final Report, DACO: 8.6
3050882	2019, 2019 Clothianidin Surface Water Monitoring Study in Saskatchewan, Canada - Final Report, DACO: 8.6
3050884	2019, Ontario Surface Water Monitoring Study - 2019, Investigation of Potential Sources of Imidacloprid in Waterways of the Lebo Drain and Sturgeon Creek Watersheds – Final Report, DACO: 8.6
2935271	2018, Syngenta Canada Response to PMRA PSRD2018-02 – Thiamethoxam, DACO: 8.1
2947433	2018, Amendment No. 1 to Final Report TK0384563 - Surface Water Monitoring to Determine Concentration and Dissipation of Thiamethoxam (CGA293343) and Other Neonicotinoids in Wetlands in Saskatchewan Canada, DACO: 8.6
2947434	2018, PMRA TK0384563 Master Data - Excel File, DACO: 8.6
3016892	2019, Thiamethoxam Technical Response – Enriched Ratios of Clothianidin to Thiamethoxam, DACO: 8.6.1
3025394	2019, Thiamethoxam Interim Data – 2019 Prairie Wetland and Ontario Watersheds Water Monitoring Studies, DACO: 8.1
3070837	2019, Ontario watersheds 2019_Dec 17 2019 Final report, DACO: 8.6
3070838	2019, Prairie wetlands 2018_2019_Dec 17 2019 Final report, DACO: 8.6

B Additional Information Considered

Environmental Fate and Effects Assessment

Published Information

PMRA Document Number	Reference
2035772	Giroux, I., and J. Fortin, 2010, Pesticides dans l’eau de surface d’une zone maraîchère - Ruisseau Gibeault-Delisle dans les « terres noires » du bassin versant de la rivière Châteauguay de 2005 à 2007, ministère du Développement durable, de l’Environnement et des Parcs, Direction du suivi de l’état de l’environnement et Université Laval, Département des sols et de génie agroalimentaire, DACO: 8.6

PMRA Document Number	Reference
2541823	Tisler, T., A. Jemec, B. Mozetic and P. Trebse. 2009, Hazard identification of imidacloprid to aquatic environment. Chemosphere. 76: 907-914, DACO: 9.3.2,9.5.2.3,9.8.2
2541824	Jemec, A, T. Tisler, D. Drobne, K. Sepcic, D. Fournier and P. Trebse. 2007. Comparative toxicity of imidacloprid, of its commercial liquid formulation and of diazinon to a non-target arthropod, the microcrustacean *Daphnia magna*. Chemosphere. 68: 1408-1418, DACO: 9.3.3
2541839	Stoughton, S.J., K. Liber, J. Culp and A. Cessna. 2008, Acute and chronic toxicity of imidacloprid to the aquatic invertebrates *Chironomus tentans* and *Hyalella azteca* under constant- and pulse-exposure conditions. Arch. Environ. Contam. Toxicol. 54: 662-673, DACO: 9.3.4,9.3.5
2544385	Roessink, I., L.B. Merga, H.J. Zweers and P.J. Van den Brink. 2012. The neonicotinoid imidacloprid shows high chronic toxicity to mayfly nymphs. Environ. Toxicol. Chem: 32(5): 1096-1100, DACO: 9.3.5
2545413	European Food Safety Authority, 2014, Peer Review Report on Imidacloprid (Art. 21), DACO: 12.5.9
2712688	Prosser, R.S. et al., 2016, Sensitivity of the early-life stages of freshwater mollusks to neonicotinoid and butenolide insecticides, Environmental Pollution 218: 428-435, DACO: 9.3.4
2796398	Camp, A.A. and D.B Buchwalter. 2016. Can’t take the heat: Temperature-enhanced toxicity in the mayfly Isonychia bicolor exposed to the neonicotinoid insecticide imidacloprid. Aquat. Toxicol. 178: 49-57, DACO: 9.3.4
2862808	United States Environmental Protection Agency, 2017, Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Clothianidin, DACO: 12.5.8, 12.5.9
2912490	Raby, M., X. Zhao, C. Hao, D.G. Poirier and P.K. Sibley, 2018b, Chronic toxicity of 6 neonicotinoid insecticides to *Chironomus dilutus* and *Neocloeon triangulifer*, Environmental Toxicology and Chemistry 37(10): 2727-2739, DACO: 9.3.4,9.9
2912491	Raby, M., X. Zhao, C. Hao, D.G. Poirier and P.K. Sibley, 2018c, Relative chronic sensitivity of neonicotinoid insecticides to *Ceriodaphnia dubia* and *Daphnia magna*, Ecotoxicology and Environmental Safety 163: 238-244, https://doi.org/10.1016/j.ecoenv.2018.07.086, DACO: 9.3.4,9.9
2912492	Cavallaro, M.C., K. Liber, J.V. Headley, K.M. Peru and C.A. Morrissey, 2018, Community-level and phenological responses of emerging aquatic insects exposed to three neonicotinoid insecticides: An in situ wetland limnocorral approach, Environmental Toxicology and Chemistry 37(9): 2401-2412, DACO: 9.3.4,9.9

PMRA Document Number	Reference
2912493	Salerno, J., C.J. Bennett, E. Holman, P.L. Gillis, P.K. Sibley and R.S. Prosser, 2018, Sensitivity of multiple life-stages of 2 freshwater mussel species (Unionidae) to various pesticides detected in Ontario (Canada) surface waters, Environmental Toxicology and Chemistry 37(11): 2871-2880, DACO: 9.3.4,9.9
2975959	Bartlett A.J., A.M. Hedges, K.D. Intini, L.R. Brown, F.J. Maisonneuve, S.A. Robinson, P.L. Gillis and S.R. de Solla, 2019, Acute and chronic toxicity of neonicotinoid and butenolide insecticides to the freshwater amphipod, *Hyalella azteca*, Ecotoxicology and Environmental Safety 175: 215-223, https://doi.org/10.1016/j.ecoenv.2019.03.038, DACO: 9.3.4,9.9
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3050935	Cavallaro, M.C., A.R. Main, K. Liber, I.D. Phillips, J.V. Headley, K.M. Peru and C.A. Morrissey, 2019, Neonicotinoids and other agricultural stressors collectively modify aquatic insect communities, Chemosphere 226: 945-955, DACO: 8.6
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3078943	Macaulay, S.J., K.J. Hageman, R.E. Alumbaugh, S.M. Lyons, J.J. Piggott and C.D. Matthaei, 2019, Chronic toxicities of neonicotinoids to nymphs of the common New Zealand mayfly *Deleatidium* spp., Environmental Toxicology and Chemistry 38(11): 2459-2471, DACO: 9.3.4,9.9
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3131567	Dillaha, T.A., J.H. Sherrard, and D. Lee. 1986. Long-term effectiveness and maintenance of vegetative filter strips. Virginia Water Resources Research Center, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, US, Bulletin 153. DACO: 8.6

PMRA Document Number	Reference
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3131571	Patty, L., B. Réal., and J.J. Gril. 1997. The use of grassed buffer strips to remove pesticides, nitrate and soluble phosphorus compounds from runoff water. Pestic. Sci. 49: 243-251, DACO: 8.6
3131573	Reichenberger, S. R. Sur, C. Kley, S. Sittig, and S. Mults. 2019. Recalibration and cross-validation of pesticide trapping equations for vegetative filter strips (VFS) using additional experimental data. Sci. Tot. Environ. 647: 534-550, DACO: 8.6
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3131577	USDA. 2000. Conservation buffers to reduce pesticide losses. United States Department of Agriculture, Natural Resources Conservation Service. March 2000, DACO: 8.6
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