Re-evaluation Decision RVD2021-05

Imidacloprid and Its Associated End-use Products

Final Decision

(publié aussi en français)

19 May 2021

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2021-5E (print version)
H113-28/2021-5E-PDF (PDF version)

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Re-evaluation decision for imidacloprid and associated end-use products

Under the authority of the *Pest Control Products Act,* all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Imidacloprid is a broad spectrum neonicotinoid insecticide. It is used to manage insects on a large number of agricultural crops, ornamental plants, trees, turf, indoor and outdoor structural sites, and as spot-on application to pets. Imidacloprid products are applied using ground, aerial and seed treatment equipment, tree injection applicators, granular spreaders, pressurized spray cans, brush or paint rollers, spot-on applicators to pets, and as a bait and in bait stations. Currently registered products containing imidacloprid can be found in the Pesticide Label Search and in Appendix I.

The Proposed Re-evaluation Decision PRVD2016-20, *Imidacloprid*,[1] containing an evaluation of imidacloprid and proposed decision, underwent a 120 day consultation period ending on 23 March 2017. PRVD2016-20 proposed the phase-out of all the agricultural and a majority of non-agriculture uses of imidacloprid due to risks to aquatic organisms. Since publication of PRVD2016-20, Health Canada received comments and information relating to the health, environmental and value assessments of imidacloprid. Commenters are listed in Appendix III and the comments are summarized in Appendix IV along with the Health Canada responses. The comments and new data/information received resulted in revisions to the occupational and environmental risk assessments (see Science Evaluation Update), and resulted in changes to the proposed re-evaluation decision as described in PRVD2016-20.

Risks to bees and other pollinators were not a part of this re-evaluation as they were addressed in Health Canada's final re-evaluation decision specifically examining the effects of imidacloprid on pollinators RVD2019-06, *Imidacloprid and Its Associated End-use Products: Pollinator Re-evaluation*. The mitigation measures put in place as a result of the pollinator re-evaluation are taken into consideration in this re-evaluation decision. The environmental risk of imidacloprid resulting from tree injection uses was previously assessed (ERC2011-03, PRD2016-16 and RD2016-28).

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2016-20, and further information used in the final re-evaluation decision is listed in Appendix XII of this document. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in PRVD2016-20 and the information set out in Appendix XII herein.

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

This document presents the final re-evaluation decision[2] for the re-evaluation of imidacloprid, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing imidacloprid that are registered in Canada are subject to this re-evaluation decision.

Science evaluation summary

An evaluation of the human health risks associated with imidacloprid has concluded that all uses are acceptable for continued registration with revised label instructions. Some occupational scenarios require revised label directions. Also, some spot-on pet product labels must be brought to current standards. Updates to the assessment can be found in the Science Evaluation Update and Appendix V.

Extensive comments and data related to the aquatic invertebrate risk assessment were received. New information included additional toxicity studies and water monitoring data from across Canada. There has been no change to the environmental risk conclusions for turf and lawn uses, and these uses are cancelled. Updates to the assessment of agricultural uses resulted in changes to some of the previous conclusions. Certain uses were not shown to be acceptable and are cancelled. Details are presented in the Science Evaluation Update as well as Appendices VII, VIII, IX and X.

Updates were made to the bird and mammal risk assessment based on comments and new information received. Details are presented in the Science Evaluation Update and Appendix VI. Risks related to the consumption of imidacloprid-treated seeds by birds and mammals were not shown to be acceptable for some exposure scenarios. Changes to the registrations of some seed treatment uses are required.

Imidacloprid has value as an insecticide used in agriculture, around structures and on pets. Health Canada heard from a number of Canadians on the value of products containing imidacloprid, including information on alternatives which were considered when making the final decision.

Re-evaluation decision for imidacloprid

Health Canada has completed the re-evaluation of imidacloprid. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of most products containing imidacloprid is acceptable. An evaluation of available scientific information found that most uses of imidacloprid products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration, which includes new mitigation measures. However, certain uses of imidacloprid are cancelled to address potential risks of concern to the environment. Cancelled uses are listed in the Risk mitigation measures Section below. Label amendments, as summarized below and listed in Appendix XI, are required.

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

Risk mitigation measures

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 mitigation measures, as a result of the re-evaluation of imidacloprid, are summarized below. Refer to Appendix XI for details.

Cancelled uses due to risks to the environment:

- Seed treatment for corn flea beetle on field and sweet corn. The rate for this pest exceeds the maximum allowable rate of 13 g a.i./80 000 seeds for field corn and 67.2 g a.i./100 kg seed for sweet corn.
- Seed treatment: direct field seeding of brassica vegetables (such as broccoli and cabbage) and leafy vegetables (such as lettuce) and listed pests. Continued registration for transplants only.
- In-furrow application on brassica, leafy, and root and tuber vegetables (including potato) and listed pests. The use on these crops is cancelled due to the maximum application rate being reduced to 100 g a.i./ha or because the maximum allowable rate will be exceeded based on the row spacing for these crops.
- In-furrow application on tobacco and listed pests.
- Soil drench application on brassica, leafy, and root and tuber vegetables (including potato, excluding sugar beet) and listed pests. The use on these crops is cancelled due to the maximum application rate being reduced to 86.6 g a.i./ha or because the maximum allowable rate will be exceeded based on the row spacing for these crops.
- Field application of tray plug drench application on leafy vegetables and listed pests. The use on these crops is cancelled due to the maximum application rate being reduced to 86.6 g a.i./ha.
- Foliar and granular application on turf and listed pests.
- Foliar application on lowbush blueberry and listed pests.

Human health

To protect workers and those entering treated areas, the following risk-reduction measures are required for continued registration of imidacloprid in Canada:

- Changes to personal protective equipment (PPE) and engineering controls for seed treatment uses.
- Update current ventilation statement on the Temprid SC label to include the requirement that ventilation must also occur during application to mitigate inhalation exposure of applicators, as well as any occupants that may enter treated areas following the 6-hour re-entry interval.
- Update commercial labels to current standards by including restricted entry intervals and/or spray drift precautions when they are absent, and clarification that the use in greenhouses is not allowed for uses only registered for outdoor areas.

To better inform the consumer as to the possible effects that may occur following product use, and to clarify the use directions on product labels, the following risk-reduction measure is required for continued registration of imidacloprid in Canada:

- Update labels for spot-on products that have not already been updated according to the 2019 Guidance Document, *Label Improvements for Spot-on Pesticides Used on Companion Animals*.

Environment

To protect the environment, the following changes to the conditions of use of imidacloprid are required for the following crops:

- Field corn seed treatment: Maximum application rate reduced to 13 g a.i./80 000 seeds.
- Sweet corn seed treatment: Maximum application rate reduced to 67.2 g a.i./100 kg seed.
- Soybean seed treatment: Maximum application rate reduced to 62.5 g a.i./100 kg seed.
- Vegetable seed treatment: Lettuce, broccoli and cabbage seed treatment restricted to crops grown or started (transplant) in greenhouse (no direct seeding to fields permitted).
- Vegetable, potato, legume (except soybean) and tobacco foliar applications: Maximum number of applications reduced to one (1) per season.
- Soybean foliar application: Maximum number of applications reduced to one (1) per season, and maximum application rate reduced to 24.4 g a.i./ha.

Greenhouse uses (soil drench, transplant tray plug drench) are permitted to continue provided that measures are in place to prevent releases, effluent or runoff from greenhouses containing this product from entering lakes, streams, ponds, or other waters. In addition, greenhouses using closed recirculation system (for example, closed chemigation system), the following is required:

- a third-party audit that validates the facility's closed recirculation system and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

To protect the environment, the following risk-reduction measures are also required on the label:

- Spray buffer zones are required to mitigate risks from spray drift.
- Standard label statements to inform users of the potential toxic effects to sensitive biota.
- Additional restrictions for use of treated seed, including revisions to seed disposal instructions and the prohibition of broadcast seeding of treated seed.

Required label amendments for all products, where applicable:

- Remove any instructions and/or references from the label for all uses being cancelled, and update the directions for use instructions for any uses with mitigation requirements, as outlined in this re-evaluation decision. This includes but is not limited to application rates, maximum number of applications per year, and re-application intervals.

- Labels are to state the product rates. Any label changes that are required to convert active ingredient rates to product rates must be made by the registrants, and must factor in any formulation-specific calculations, such as specific gravity.
- Labels with structural uses must be amended to adopt the revised definitions for application types outlined in the 2020 PMRA publication PMRA Guidance Document, Structural Pest Control Products: Label Updates.

Next steps

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

Amended products

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 decision document. 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.

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

Cancelled products

Products that are cancelled will be phased out following the implementation timeline outlined below.

- One (1) year of sale by registrant from the publication date of this decision document, followed by;
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

The transition periods for required amendments and product cancellations will allow for an orderly and safe implementation of these new restrictions and should reduce the risk of product misuse or the improper disposal of products as users switch to alternatives, where required. The risks identified are not considered imminent and serious because they are not expected to cause irreversible harm over these phase-out periods. This approach is consistent with Health Canada's current policy and practice with respect to phase out of uses and products as a result of a re-evaluation (Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*).

Cancelled use with extended phase-out

European chafer on the root vegetable ginseng (soil drench) was found to lack suitable alternatives. The effective date of the re-evaluation decision for this use will be delayed for 24 months pursuant to subsection 21(3) of the *Pest Control Products Act*.

The environmental risks have been determined to be acceptable over this time period on the basis of the current relatively small and fragmented growing areas associated with this crop. Therefore, the continued use for 24 additional months for this imidacloprid use with no suitable alternatives is considered acceptable.

Other information

Any person may file a notice of objection[3] regarding this decision on imidacloprid and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service 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 PRVD2016-20 and in Appendix XII 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.

[3] As per subsection 35(1) of the *Pest Control Products Act.*

Science evaluation update

1.0 Introduction

Imidacloprid is a neonicotinoid insecticide used by commercial applicators and growers to manage insects on a large number of agricultural crops, trees and turf. It can also be used at home to manage insects on lawns, as well as fleas or ticks on pets. It is applied using ground, aerial and seed treatment equipment, tree injection applicators, bait stations and spot-on applicators to pets.

Following publication of the proposed re-evaluation decision, Health Canada received comments and information relating to the health, environmental and value assessments of products containing imidacloprid. While this did not result in any changes to the toxicology reference values for the health risk assessment, the comments and new data/information resulted in revisions to the occupational and environmental risk assessments. Moreover, updates to risk mitigation measures have also been made based on incident reports. In turn, this has resulted in changes to the proposed re-evaluation decision as described in PRVD2016-20, *Imidacloprid*.

2.0 Revised health risk assessment

2.1 Occupational exposure and risk assessment

Occupational and residential exposure and risk assessments were conducted for PRVD2016-20. At that time, data from a seed treatment study for wheat (PMRA#1335563) was used to assess the risk to commercial mixer/loader/applicators (M/L/A) from corn seed treatment and was considered to be protective of the risk to both M/LA and bagger/sewer/stackers (B/S/S), as the dermal unit exposure value for M/L/A (265.7 µg/kg a.i.) in the wheat study is higher than the B/S/S unit exposure estimate from the corn seed treatment study (114 µg/kg a.i.) (PMRA# 1885209). However, upon further examination, it was determined that the inhalation unit exposure value (2.47 µg/kg a.i.) from the wheat study is lower than the B/S/S value (18.7 µg/kg a.i.) from the corn study, which would have underestimated the inhalation and combined risk to B/S/S in PRVD2016-20.

The unit exposure values for applicators from the corn study are similar to the M/L/A values from the wheat study. However, the corn study used a closed transfer system as compared to the open mix/load system used in the wheat study. As such, M/L/A exposure is expected to be higher for corn seed versus wheat seed when the mix/load system is considered. This is also evident within the corn study where both corn and canola seeds were tested. The applicator and B/S/S unit exposure estimates for corn are significantly higher than the estimates for canola at the same personal protection equipment level. Thus, based on this further analysis, there is a higher potential for worker exposure to corn seed treatment as compared to the other seed types. In turn, the corn seed treatment exposure assessment has been updated as part of this final decision with the use of the corn seed treatment data instead of the wheat data. The unit exposure values for the seed treatment studies are summarized in Appendix V, Table 1.

The unit exposure estimates were updated for applicators and B/S/S corn seed treatment workers. The rates were also updated to reflect the lower rates (48.8 g a.i./100 kg seed) used in the environmental assessment. All other inputs remain the same as the risk assessment in PRVD2016-20. The combined margin of exposure (MOE) was greater than the target of 100 for seed treatment workers and, therefore, is shown to be acceptable. The results are found in Appendix V, Table 2.

Corn seed treatment labels must be updated to reflect that a closed mix/load system is required for treating corn seed, as the updated exposure and risk estimates are based on data for a closed system instead of an open system.

2.2 Residential and aggregate exposure and risk assessment

Two new imidacloprid turf transferable residues (TTR) studies were submitted to Health Canada. One study (PMRA #2638509) was submitted in 2016 through the incident reporting program, while the other study was submitted in 2020 for the re-evaluation (PMRA #3129235). The studies used liquid based formulations that are relevant to the residential post-application and aggregate risk assessment for liquid based turf products. Currently there are two registered commercial liquid based products in Canada formulated as a wettable powder in water soluble packaging (WSP). There are also commercial and domestic granular turf products registered for imidacloprid. The TTR studies are not relevant to the assessments for granular products.

Both of the submitted studies are considered acceptable for use in the risk assessment. Three sites were tested in each study and two test plots were treated per test site. In the 2016 study, one plot was irrigated immediately after the application, while the other plot was not irrigated. In the 2020 study, one plot was sprayed with medium size droplets, while the other plot was sprayed with coarse size droplets. Both plots were not irrigated in the 2020 study. The peak TTR results are provided in Appendix V, Table 3. The dissipation rate data is not reported as it is not required based on the current use pattern, which allows for a maximum of one application per year. The peak TTR data from the test sites most representative of Canadian climatic conditions were chosen for risk assessment purposes. These include the Kansas site from the 2016 study and the Pennsylvania site from the 2020 study. For the Pennsylvania site, the peak TTR was the same for both treatment plots sprayed with either medium or coarse droplets. The selected TTRs are coincidently the median estimate of the three test sites in each study.

The peak TTRs are significantly higher (2.6-12.3%) in the non-irrigated plots in the 2016 study when compared to the 2020 study (0.4-1.7%). The difference is likely due to spray volume changes that were made in the 2020 study (780-830 L/ha versus 240-490 L/ha). The 2020 study (PMRA #3116354) was conducted in accordance with current turf application methods used by US lawn care operators with the spray volume recommended on US imidacloprid labels (a spray volume is not specified on the Canadian labels). An increase in water volume may have increased imidacloprid penetration to the soil and reduced the residues on turf surface. This is supported by data from the 2016 study, where TTRs were significantly lower when the turf was immediately irrigated after application.

Residential post-application (dermal and hand-to-mouth exposure) and aggregate risk assessments were updated with the new TTR estimates. All other inputs from the PRVD 2016-20 assessment remains the same. Three different peak TTRs and scenarios were assessed:

- Peak TTR of 9.0% based on non-irrigated turf using a low spray volume (2016 study)
- Peak TTR of 1.3% based on non-irrigated turf using a high spray volume (2020 study)
- Peak TTR of 0.2% based on irrigated turf using a low spray volume (2016 study)

The updated turf assessments are presented in Appendix V, Tables 4-6. The post-application and aggregate risks were greater than the target MOE of 100 and were acceptable for the non-irrigated/high spray volume (Aggregate MOE > 280) and irrigated/low spray volume use scenarios (Aggregate MOE > 590). However, the risks were not acceptable for the non-irrigated/low spray volume scenario (Aggregate MOE = 62). Thus, risk to WSP turf products are acceptable provided that the turf site is irrigated immediately after application. As irrigation is not feasible for all use sites (for example, sites that do not have access to a water source such as cemeteries or parks), a minimum spray volume of 800 L/ha is required. The imidacloprid WSP turf labels would need to be amended to include the water volume requirement that is necessary during application. However, this change will not be required at this time as turf use will be cancelled due to environmental risks.

2.3 Health and value incident reports

Since the review for the proposed decision (i.e., from 8 September 2015 to 8 December 2020), 110 human and 7808 domestic animal incidents involving imidacloprid were submitted to Health Canada.

The majority of these human and domestic animal incidents involved domestic-class products containing imidacloprid, notably spot-on products for use on cats and dogs to control of fleas and ticks. Most of the reported spot-on products were co-formulated with permethrin and/or pyriproxyfen. In human incidents, most of the reported effects were classified as minor in severity and included eye and/or skin irritation. Exposure to the products containing imidacloprid occurred either during application of the product to a pet or contact with a treated pet. In domestic animals, minor skin or gastrointestinal effects were most commonly reported following treatment with a spot-on product containing imidacloprid. These patterns are consistent with the incident report trends discussed in PRVD2016-20. The product labels of spot-on companion animal products will be updated as per the PMRA Guidance Document, *Label Improvements for Spot-on Pesticides Used on Companion Animals* (published 6 December 2019), to better inform consumers on the possible effects that may occur in animals following the use of imidacloprid products. The product labels of the majority of the spot-on products are being amended in the manner proposed in this guidance document, with the exception of 4 spot-on products containing imidacloprid (Registration Numbers 33626, 33627, 33628, 33629), which were registered immediately prior to the publication of the 2019 Guidance Document. The label amendments outlined in the Guidance Document will therefore be implemented for these products as part of this re-evaluation decision.

A subset of human incidents received by Health Canada following the publication of the PRVD involved a new commercial-class product, Temprid SC (Registration Number 32524), which contains imidacloprid and β-cyfluthrin. This product was registered for use in Canada in 2017 as a residential structural product. Most incidents involving Temprid SC were reported to occur following re-entry into a treated indoor residential site. The product label already requires a 6-hour re-entry interval following application and includes precautionary ventilation statements. Based on the information available, these directions did appear to be followed in the majority of the reported incidents; however, people reported minor to moderate symptoms including respiratory and eye effects, headache, dizziness and nausea upon re-entry after the 6-hour re-entry interval. Therefore, further risk mitigation is required to reduce the likelihood of exposure upon re-entry into a residential site treated with Temprid SC. Consequently, the ventilation statement on the label, which is intended for the commercial applicator, must be updated to the current ventilation precautionary statement currently found in in the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* (published 28 February 2020). However, this statement will be modified to include the requirement that ventilationthere must also occur during application to mitigate inhalation exposure of applicators, as well as any occupants that may enter treated areas following the 6-hour re-entry interval. Therefore, the commercial applicator will need to ensure that ventilation occurs both during **and** after application of Temprid SC to an indoor residential site (see Appendix XI).

3.0 Revised environmental risk assessment

The initial environmental risk assessment for imidacloprid was provided in PRVD2016-20, *Imidacloprid.* 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 IV.

To provide additional clarity, the following terminology is being used with respect to effects-based toxicity values used in the risk assessment: The term 'endpoint' refers to toxicity values resulting from statistical analyses of individual ecotoxicology studies (for example, NOEC or EC_{50}). In addition, 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 imidacloprid use-pattern required under Re-evaluation Decision RVD2019-06, *Imidacloprid and Its Associated End-use Products: Pollinator Re-evaluation*. This includes cancellation of the following uses:

- Foliar application - pome fruit, stone fruit, certain tree nuts with high pollinator attractiveness, and the herbs lavender and rosemary

- Soil applications - legume vegetables, fruiting vegetables, cucurbit vegetables, herbs harvested after bloom, small fruit and berries (caneberry; bushberry; low-growing berry; berry and small fruit vine excluding grapes);
- Soil application - ornamentals that will result in pollinator exposure.

The overall risk conclusions based on consideration of all relevant information during the consultation process have resulted in changes to the proposed decision to cancel all outdoor uses presented in PRVD2016-20.

Portions of the original environmental assessment remain unchanged, and the reader is referred to PRVD2016-20 for further details of these elements:

- General fate and behaviour of imidacloprid in the environment,
- Toxicity of imidacloprid and risk conclusions for terrestrial invertebrates (excluding pollinators), terrestrial plants, algae, aquatic plants, amphibians and fish.

3.1 Environmental incident reports

Since the publication of PRVD2016-20 and up to 11 February 2021, no new environmental incidents have been reported to Health Canada.

Since the publication of PRVD2016-20, the USEPA published preliminary terrestrial and aquatic risk assessments (USEPA 2016, PMRA# 3200022; USEPA 2017, PMRA# 3199271) and an interim proposed decision document for imidacloprid (USEPA 2020; PMRA# 3199246). These documents discuss additional US incidents that were not presented in PRVD2016-20.

Excluding incidents involving exclusively pollinators (covered in PRVD2018-12 and RVD2019-06), there are three incidents that the USEPA references (USEPA 2017, PMRA# 3199271; USEPA 2020; PMRA# 3199246) that were not presented in PRVD2016-20. One incident was reported in 2004 and involved the misuse of a granular imidacloprid product on a golf course. Bullhead fish (*Ameriurus sp.*) were reportedly affected; no residue analyses were documented and USEPA classified the certainty of the cause of effects being attributed to imidacloprid as 'unlikely' (USEPA 2016; PMRA# 3200022). Twenty-five dead American goldfinches (S*pinus tristus*) were reported in 2017 following a drench application (registered use) of imidacloprid in California (USEPA 2017; PMRA# 3199271). Birds were exposed to imidacloprid following drench treatment of elm trees. Residue analysis was conducted and imidacloprid was detected in the digestive tracts. All birds that were examined contained grass seed. The USEPA deemed the incident probably associated with the imidacloprid use. Soil drench of trees is not a registered use of imidacloprid in Canada. A third incident involved bird mortalities associated with imidacloprid seed treatment (this incident is discussed further in Section 3.2).

The USEPA provided additional information on incidents that were reported in PRVD2016-20 that are relevant to the risk assessment. One incident that was previously reported as a bird incident involved other taxa. This incident was reported in 2006 and involved the registered use of an imidacloprid home/lawn product (exact formulation was not reported).

A homeowner reported the death of two sparrows, one earthworm and 12 bees on the day after application and watering of the product. A third dead sparrow was later discovered. No residue analysis was possible. The USEPA classified this incident as possibly caused by imidacloprid use.

Since the publication of PRVD2016-20, two additional articles in the open literature reporting on incidents involving seed treatment uses of imidacloprid were obtained and reviewed by Health Canada (Millot et al. 2017, PMRA# 2945924; Botha et al. 2018, PMRA# 3199200). All incidents deemed relevant to the revised assessment, including those presented in PRVD2016-20, are discussed in Sections 3.2 and 3.3).

3.2 Terrestrial vertebrates

The registrant submitted information during the consultation period in support of refining the terrestrial vertebrate risk assessment. The bulk of the information submitted focused on the potential impacts to granivorous bird species resulting from ingestion of imidacloprid treated seed. New information relevant to the terrestrial vertebrate risk assessment was also obtained from the open literature and recent international incident reports.

The terrestrial vertebrate assessment was updated to reflect a revised avian acute effects metric for all relevant uses of imidacloprid. The bird and mammal assessment for seed treatments was further revised considering information reviewed since the publication of PRVD2016-20.

3.2.1 Revision of the acute avian effects metric

In the risk assessment supporting the proposed decision (PRVD2016-20) an acute avian HD_5 of 8.07 mg a.i./kg bw (the estimated fifth percentile of acute oral avian LD_{50}s) from a species sensitivity distribution (SSD) was used as the screening-level effects metric.

A registrant-commissioned report (PMRA# 2744282) suggested that three of the acute oral toxicity studies considered in the proposed decision, and included in the SSD supporting the proposed decision, should not have been found acceptable for use in risk assessment. None of the studies provided adequate descriptions of study designs and conditions, and two of the studies used five birds or less per treatment level. Health Canada acknowledges that these studies should not have been considered in the acute avian risk assessment, and they were removed in the revised risk assessment. The endpoints that were reported for these studies in PRVD2016-20 were as follows:

- Acute LD_{50} of 35 mg a.i./kg bw (TGAI, 94.8% a.i.) for canary (*Serinus canaria*; PMRA# 1157923);
- Acute LD_{50} of 15 mg a.i./kg bw for grey partridge (*Perdix perdix*; Grolleau 1990, Mineau and Palmer 2013, PMRA# 2544546); and
- Acute LD_{50} of 25 mg a.i./kg bw for rock dove (*Columbia livia*; Grau 1987, Mineau and Palmer 2013, PMRA# 2544546).

The registrant-commissioned report (PMRA# 2744282) also cited three acute avian toxicity studies that were not considered in the initial review; however, these studies were not available to Health Canada for review and were not considered in the revised risk assessment.

- Acute oral LD_{50} of ~ 100 mg a.i./kg bw (test substance 95.3% a.i.) for domestic duck (Watanabe 1989; M-033880-01-1)
- Acute oral LD_{50} of >384 mg a.i./kg bw (Clothianidin + Imidacloprid FS600; 28.9% clothianidin, and 19.2% imidacloprid) for northern bobwhite (Christ 2016; M-557718-02-1)
- Acute oral LD_{50} of 17 mg a.i./kg bw (Confidor WG 70) for Japanese quail (Shmuck 1997; M-024616-01-2)

According to the registrant-commissioned report (PMRA# 2744282), the domestic duck endpoint was not statistically determined. The northern bobwhite endpoint is based on exposure that included an active ingredient other than imidacloprid. The Japanese quail endpoint is from a test conducted with an end-use product that is not registered in Canada, and it is not clear if this product is comparable to any product registered in Canada. For these reasons it was determined that these studies would not be influential in the revised risk assessment and they were not requested.

With the removal of the three invalid avian endpoints, there are no longer enough species to allow for the derivation of an acute SSD. As a result, Health Canada's revised avian risk assessment relied on the most sensitive acute oral toxicity endpoint (LD_{50} of 31 mg a.i./kg bw for Japanese quail (*Coturnix japonica*; PMRA# 1157924)). For the revised acute avian screening-level risk assessment, 3.1 mg a.i./kg bw/d was used as the effects metric (most sensitive LD_{50} divided by an uncertainty factor of 10). Exposure estimates were divided by the acute effects metric to generate risk quotients (RQ = estimated exposure/effects metric). When RQ values exceed the level of concern (LOC=1), additional risk characterization was required to inform risk mitigation decisions.

3.2.2 Additional avian toxicological information from the open literature

Additional avian studies from the open literature were available after publication of the Proposed Re-evaluation Decision (PRVD2016-20):

- MacDonald A. M., et al., 2018, Neonicotinoid detection in wild turkeys (*Meleagris gallopavo silvestris*) in Ontario, Canada. Environmental Science and Pollution Research PMRA# 2945927
- Bishop et al., 2018, Hummingbirds and Bumble Bees Exposed to Neonicotinoid and Organophosphate Insecticides in the Fraser Valley, British Columbia, Canada. - Environmental Toxicology and Chemistry Volume 9999, Number 9999, 1 to 10. PMRA# 2945928
- Eng et al., 2017, Imidacloprid and chlorpyrifos insecticides impair migratory ability in a seed-eating songbird. Nature: Scientific Reports 7: 15176. DOI:10.1038/s41598-017-15446-x PMRA# 2945930
- Eng et al., 2019, A neonicotinoid insecticide reduces fueling and delays migration in songbirds. PMRA# 3077486 (Supplemental Material: PMRA# 3077488)

- Hao et al., 2018, Part-per-trillion LC-MS/MS determination of neonicotinoids in small volumes of songbird plasma. Science of the Total Environment 644:1080–1087. PMRA# 2945929

Collectively, these studies demonstrate that neonicotinoids are detected in wild birds in Canada (i.e., wild turkeys, hummingbirds and songbirds).

Eng et al. (2017; PMRA# 2945930) demonstrates that seed-eating songbirds dosed with environmentally relevant concentrations of imidacloprid may result in changes to migratory orientation. In a subsequent study (Eng et al., 2019 PMRA# 3077486), this effect was not observed at similar doses under field conditions, however, decreased food consumption and body mass post ingestion was observed in both studies. These results provide evidence that seed-eating songbirds using agricultural landscapes as migratory stopovers may be exposed to biologically relevant concentrations of imidacloprid that could potentially affect body condition during a critical life stage and disrupt the timing/success of migration.

Bishop et al. (2018; PMRA# 2945928) provides monitoring data that demonstrates bees and hummingbirds in the Fraser Valley in British Columbia are exposed to various pesticides (including neonicotinoids) in the field. Hummingbirds would be exposed through consumption of nectar. There have been changes to the use pattern in blueberry as a result of the pollinator re-evaluation (PRVD2018-12 and RVD2019-06) that will reduce exposure to imidacloprid to hummingbirds through blueberry nectar.

3.2.3 Foliar application risk assessment

Foliar applications of imidacloprid are currently allowed on a variety of crops in Canada (Appendix II). To assess risks to birds and mammals associated with ingestion of contaminated feed items, the single highest application rate (281.25 g a.i./ha used on turf) was considered at the screening-level. See PRVD2016-20 for a description of how estimated exposure concentrations were calculated.

Risk was further characterized by considering risk quotients derived for a range of potential exposures (soybean: 24.4 g a.i./ha, and raspberry: 112 g a.i./ha × 3 at 7-day intervals respectively), in addition to turf, on- and off-field, at upper bound and mean estimated residue values. Other lines of evidence were also considered, including the propensity of terrestrial vertebrates to acquire 100% of their diet from treated fields (PRVD2016-20). Because the acute avian effects metric was revised, acute risk quotients were amended for birds (Appendix VI, Tables 1 through 3).

Based on Health Canada's review of incident reports in Canada, the United States, there are no reports of adverse effects in terrestrial vertebrates from the use of imidacloprid-containing products applied as foliar spray.

The updated acute avian risk quotients for foliar uses of imidacloprid are slightly higher than in PRVD2016-20; however, risks to bird and mammal populations from direct exposure to imidacloprid via residues on feed items remain acceptable. Label statements informing users of the potential hazards to terrestrial vertebrates are required.

3.2.4 Granular application risk assessment

Imidacloprid is registered for use in pesticide granules applied to turf to control various insect larvae (Appendix II). There is the potential for birds and mammals to ingest imidacloprid-containing granules after they have been applied to turf. Birds and mammals might consume granules incidentally, birds may also take granules as grit. A screening-level risk assessment was carried out assuming that birds and mammals consume their estimated daily food ingestion rate (as a dry weight mass) of granules (PRVD2016-20). This assessment included both currently registered commercial granular products (Merit Granular, PCP 25933, 0.5% imidacloprid; Quali-pro Imidacloprid 0.5 Granular Insecticide, PCP 29185, 0.5% imidacloprid). The number of granules to reach the acute avian effects metric (Appendix VI, Table 4), and the associated screening-level risk quotients (Appendix VI, Table 5) were amended in accordance with the revised effects metric.

In PRVD2016-20 several other lines of evidence were considered in the characterization of risk to birds (including information related to grit ingestion). Chiefly, it was noted that granular pesticides containing imidacloprid in Canada have labels which specify that irrigation or rainfall of 5-10 mm occur within 12 to 24 hours of granule application to ensure the active ingredient moves through the treated thatch. This prescribed watering limits the time frame during which birds and mammals might ingest granules from the surface of treated turf.

The USEPA reported one incident in 1998 in which seven dead birds were reported following the registered use of a home/lawn granular grub control product containing imidacloprid (USEPA, 2017; PMRA# 3199271). Tissue analyses were not provided, and the USEPA classified the incident as possibly attributed to imidacloprid. It is unknown whether or not the application rate and conditions of use were comparable to those prescribed in Canada.

Risks associated with granular use of imidacloprid are considered acceptable with a reduction (from 24 to 12 hours) in the time between application and irrigation or rainfall. The following label statement would need to appear on granular pesticides containing imidacloprid:

- The granules must be watered within 12 hours after application by sufficient irrigation (5–10 mm) to ensure the active moves through the thatch.

In addition, label statements informing users of the potential hazards to terrestrial vertebrates would also be required. However, these changes will not be required at this time as turf use will be cancelled due to risks to aquatic organisms.

3.2.5 Seed treatment risk assessment

3.2.5.1 Screening-level risk assessment

Imidacloprid seed treatments are registered on a number of agricultural crops (Appendix II). Treated seed may be consumed by birds and mammals after planting in fields. At the screening level, potential risks of concern to birds and mammals were identified for all seed treatment uses. The highest RQs of each use ranged from 25 (cereal) to 11468 (lettuce), for small birds acutely exposed via diet. For mammals the highest RQs of each use ranged from 2.3 (cereal) to 1075 (lettuce), for small individuals exposed chronically (Table 6 of Appendix VI presents revised acute avian RQs, all other RQs are reported in PRVD2016-20). As the level of concern was exceeded for all uses at the screening level, additional information was considered to further characterize risks to birds and mammals.

3.2.5.2 Further risk characterization

The risk assessment has been further characterized by taking into consideration:

- The number of seeds required to reach the screening-level effects metric (LD_{50}/10) and the acute avian LD_{50};
- Availability of imidacloprid treated seed;
- Bird behaviour with respect to seed ingestion; and
- Field studies and incident reports.

3.2.5.2.1 Seeds required to reach screening-level effects metric (LD_{50}/10) and LD_{50}

The estimated number of seeds required to reach the acute screening-level effects metrics for birds was updated to reflect the revised avian effects metric and is presented in Appendix VI, Table 7. In this revised assessment, the lowest number of seeds required to reach the effects metric is 0.1 of a seed (for 20 g birds ingesting corn and some legumes). For larger birds (1000 g) 5 to 1023 seeds would be required to reach the acute screening-level effects metric, depending on the crop and application rate. The number of seeds required by birds to reach these screening-level effects metrics represent a small fraction of their estimated daily food intake. For the acute screening-level effects metric, 0.008% (small birds consuming lettuce seed) to 53% (large birds consuming treated cereal seeds at the lowest label rate) of estimated daily food intake as treated seed is required.

The number of seeds required to reach the LD_{50} for each seed treatment (i.e., 10× the seeds required to reach the screening-level effects metric of LD_{50}/10 presented in Appendix VI, Table 7) was considered. Several treated seed crops have enough imidacloprid on just a few seeds or less to reach the LD_{50}; these include: some legumes including soybean, corn (sweet and field), broccoli, cabbage and lettuce.

3.2.5.2.2 Availability of treated seed for consumption

The screening-level risk assessment assumes unlimited accessibility of treated seed, however, there are several factors that limit the availability of imidacloprid-treated seed.

3.2.5.2.2.1 Greenhouse transplant crops

Seeds planted in greenhouse and transplanted to the field are not available for ingestion. Peppers and tomatoes commercially grown in Canada are not generally directly seeded to fields; they are either grown in greenhouse or transplanted to fields after emergence in greenhouses. Broccoli, cabbage, lettuce, bulb vegetables, cucumber, melon and squash are also sometimes transplanted, but are also directly seeded to fields.

3.2.5.2.2.2 Buried and unburied seeds following planting

With few exceptions, seeds are typically planted in fields with seed drilling equipment. Broadcast application of cereal and canola seed appears to be relied on under circumstances when field conditions preclude the use of standard seeding equipment.

In most seeding scenarios, seeds are buried to a standardized nominal depth that is recommended for the crop being planted. De Snoo and Luttik (2004; PMRA# 2439879) recommended the use of 0.5%, 3.3% and 9.2% of seeding rate remaining at the surface following precision drilling, standard drilling in spring, and standard drilling in the fall, respectively. A more recent review of available information regarding seeding efficiency conducted by Health Canada has confirmed that these suggested estimates remain valid.

In the seed treatment risk assessment for imidacloprid, the estimated fraction of seed remaining at the surface was assumed to be 0.5% (precision drill) for corn and 3.3% (standard spring drilling) for all other crops. It is not clear whether the standard spring drilling assumptions are realistic for all seed-treatments. There is some indication that vegetable crops may be precision drilled; however, the degree of adoption of precision drilling of vegetable seeds across the country is unknown. Some cereal crops are sown in the fall; however, surface seed estimates were not generated for this exposure scenario.

Based on the assumptions articulated above and seeding rate ranges collated by Health Canada, the estimated area required to be depredated of surface seeds by an individual to reach the revised screening-level LOC was calculated (Appendix VI, Table 7).

Seed spills are not an uncommon occurrence. Studies suggest that they often occur at the entrance of fields, and in headlands (for example, Roy and Coy 2020; PMRA# 3173895). This risk assessment does not address risk associated with wildlife consuming treated seed from spills. Growers are obliged to ensure that seed spills are cleaned up in accordance with the label.

3.2.5.2.2.3 Emergence

Seeds of the crops currently registered for imidacloprid seed treatment typically emerge one to two weeks after planting. Seeds of some crop species that are left on the surface after planting are not likely to readily emerge, particularly those that are required to be planted at greater depth. Seeds that have emerged are no longer available for consumption (as seeds). Seedlings can be taken and consumed by wildlife; however, this exposure scenario was not considered in the current risk assessment. It was assumed that dissipation of the active ingredient from treated seed would result in negligible risk to wildlife from ingestion of seedlings.

3.2.5.2.2.4 Dissipation

During the consultation period for PRVD2016-20, the registrant provided a summary of three field studies (PMRA# 2744282) that investigated dissipation of imidacloprid concentrations from wheat and barley seeds. Two of these studies (PMRA# 1191040 and PMRA# 1191041) were available for review.

The first study (PMRA# 1191040) was conducted in Great Britain. Wheat seeds at two field study sites were treated with 318 and 333 mg a.i./kg seed. After 24 hours, 17 and 75 mg a.i./kg seed remained (70% to 95% dissipation). This rapid dissipation was attributed to rainfall after seeding.

The second study (PMRA# 1191041) was conducted in France in the fall of 1997 (recorded temperature ranged from –0.3 to 22.9 ºC). Barley seeds were treated (602 to 1118 mg a.i./kg seed) with imidacloprid and drilled in three different field locations. Surface seeds were collected up to ten days after drilling. Imidacloprid concentration on seeds decreased by >70% within one week of drilling. At two sites, precipitation in the first few days after drilling was observed leading to more than 50% decrease in imidacloprid concentration in that time frame. At the third site, significant precipitation was not observed until seven days after drilling; however, 50% dissipation of imidacloprid from the treated seed was observed by five days post-drilling despite the lack of a significant rainfall.

In the third study discussed in the registrant-commissioned review (PMRA# 2744282; not submitted to Health Canada), it was reported that imidacloprid treated barley seed lost 90% of the active ingredient within seven to nine days after drilling. This rapid loss was attributed to heavy rainfall. The rate of application of imidacloprid to the seeds, the location and number of fields, and the environmental conditions of this study were not reported.

A recent field study conducted in northern Minnesota examined imidacloprid-treated soybean seeds that were left on the soil surface of tilled fields in two separate years for a period up to 30 days (Roy et al. 2019; PMRA# 3122176). A dissipation half-life of 4.7 days was reported. The authors noted that a third of the days were sunny and precipitation occurred on eight and six days in the first and second year, respectively. Concentrations on seed were close to 1000 mg a.i./kg initially in both years and fell to less than 100 mg a.i./kg in 2016 and less than 10 mg a.i./kg seed in 2017 by the end of the 30-day trials.

3.2.5.2.3 Bird and mammal behaviour with respect to treated seed ingestion

The screening-level assessment assumes birds and mammals consume treated seed exclusively, to reach their estimated daily food intake requirements. Although empirical data are limited, a number of factors related to foraging behaviour and food ingestion are discussed below.

3.2.5.2.3.1 Bait station data

PRVD2016-20 contained a summary of reviewed studies that looked at the amount of seed of different types taken per visit by birds from bait stations placed in agroecosystems (Prosser and Hart 2005, PMRA# 2574060; Smith 2006, PMRA #2574059). Seed types investigated included: oilseed, corn, field pea, barley, wheat, oat, sugar beet and grass seed.

Birds of various sizes were observed consuming seeds; from 18 to 30g (small birds), 80 to 125g (medium birds) and 450 to >1000g (large birds). The number of visits recorded for each bird species for which seed consumption was counted varies depending on seed type and species (for example, for wheat just one jackdaw visit and up to 395 visits for robin). Also, the number of seeds taken varied widely between species and seed types. Field peas were generally taken in lower numbers per visit than other seeds. Some bird species took on average hundreds of cereal seeds per visit (for example, pheasant, partridge), and thousands of oilseeds (stock dove and woodpigeon). Smaller birds tended to take fewer seeds per visit. Corn seed was not eaten whole by some small birds (chaffinch, house sparrow and tree sparrow). These small birds would either break up seed or eat fragments of seeds broken up by other birds. Despite eating only fragments, small birds still ate a considerable amount of corn, with the mean species average number of seeds taken per visit ranging three to four seeds, with a maximum of 11 seeds in one visit by a tree sparrow. No grass seed was taken by any birds.

In the proposed decision (PRVD2016-20) it was demonstrated that birds can take enough untreated seed from bait stations in a single visit to reach the screening-level effects metrics.

There are differences in the characteristics and presentation of treated seed following sowing, compared to untreated seed offered in bait stations that are expected to influence seed ingestion by birds. There is little information available that directly addresses bird consumption of sown treated seeds from fields. Expectations around bird behaviour for ingesting sown seed, in combination with other considerations such as learned avoidance behaviour, are discussed further below.

3.2.5.2.3.2 Seed ingestion from spills of treated seed

A new study (Roy and Coy 2020; PMRA# 3173895) examined the propensity of wildlife to forage on imidacloprid treated seed made available for a number of weeks in simulated spills (1,000 corn or soybean seeds). Only soybean was treated with imidacloprid. Mammals seemed to consume seed more readily than birds after simulated spills were initiated. Many different species of birds and mammals were seen foraging from the simulated spills. No small birds were observed consuming the treated soybean seeds, which were predominantly taken by pheasant.

3.2.5.2.3.3 Dehusking

Seed treatments are applied to the exterior of the seed and dehusking can considerably reduce exposure associated with whole seed ingestion. Dehusking can be an important mechanism to reduce exposure to imidacloprid for some granivorous bird species and some seed types. However, birds do not always dehusk seed (Prosser and Hart, 2005; PMRA# 2574060).

3.2.5.2.3.4 Laboratory acceptance/repellency studies

Two studies looking at bird avoidance of imidacloprid treated seed were reviewed in PRVD2016-20 (Avery et al., 1993; PMRA# 2574061; Avery et al., 1994; PMRA# 2681691). Avoidance was demonstrated and attributed to post-ingestional distress. Two other studies were found and reviewed after the proposed decision (Avery et al., 1997, PMRA# 3194439; Lopez-Antia et al., 2014, PMRA# 3194446). In addition, during the comment period for PRVD2016-20, a review of 35 avian trials investigating bird avoidance of imidacloprid treated seed was submitted by a registrant (Hancock and Gates 2016; PMRA# 2744282).

Collectively, these studies looked at avoidance of treated cereals, corn, legumes, oilseeds, rice and other crops. Seventeen different species of birds were used in these tests, including: boat-tailed grackle, brown-headed cow bird, common pheasant, diamond dove, grey partridge, house finch, house sparrow, Japanese quail, mallard, mourning dove, northern bobwhite, pigeon, red-legged partridge, red-winged blackbird, ringed turtle dove, rook and zebra finch. The highest treatment rates in each study ranged from 350 to 14000 mg a.i./kg seed (based on Health Canada's interpretation of reported rates), and in most cases the rates that were tested on seed that is registered for imidacloprid seed treatment use in Canada were higher than the current maximum rates allowed in Canada.

In general, these studies show that birds exposed to relatively high rates of imidacloprid on seed, with both choice and no choice of alternative foods, tend to avoid ingesting treated seed after initial dietary exposure. They also tend to survive exposures of both short (hours) and longer durations (days), both with and without considerable food deprivation beforehand (with very few mortalities reported). In many cases there were obvious signs of intoxications, from which birds were generally reported to recover. The reviewed experiments examined avoidance behaviour in a number of bird species; however, small birds were only represented by finches and sparrows tested mainly with treated cereals. While the seed types studied do overlap with crops registered for imidacloprid seed treatment in Canada (cereals, corn, legumes), a number of other seed types are registered for imidacloprid seed treatment use in Canada for which no avoidance data are available.

3.2.5.2.3.5 Seed pelletization and colour

Seed pelettization and seed colour may affect attractiveness and palatability for birds and mammals. Although pelletized seed would not look like raw seed, it is unknown what specific characteristics might limit ingestion by some birds or mammals. There is some evidence to suggest that some birds may prefer red seed over green/blue seed (Smith 2006; PMRA# 2574059), and that birds exposed to treated coloured seed may subsequently have a preference for natural coloured seed, however comprehensive data is lacking.

3.2.5.2.3.6 Expected foraging behaviour

Determining if enough birds will scavenge a field that is newly planted with treated seed to result in effects at the population level is challenging. As small birds are at most risk, consideration of feeding habits is important, however scientific information is lacking. As mentioned earlier in the discussion of bait station data, there is also little information available that directly addresses bird consumption of sown treated seed from fields. A number of assumptions were made regarding bird behaviour and are discussed below. Quantitative empirical evidence to support or refute these assertions were not reviewed in this assessment.

Prior to planting, birds rely on food sources other than seeds planted by farmers. When planting occurs, the birds' regular food sources remain available to them. The planted field is expected to have a certain number of exposed seeds, but they are found sparsely in the field and the bird must use energy to forage for treated seed. As a bird forages in a newly planted field for seeds, other food items may be available in the field; for example, forage remaining from previous crops, other seeds that are found near the field margins from wild plants, insects and other food items all may be found in greater abundance than the treated seed.

It is assumed that birds may consume a treated seed, but the amount of time needed to find the next seed and distraction of other food sources would likely reduce the chances of a bird consuming enough seed to reach the LD_{50} before learned avoidance develops.

The eating habits of birds will vary based on species and environment. Smaller sized birds are conscious of predators and are known to reside in areas with sufficient cover (hedges, trees, grasses, shelters, etc.). It is unclear if small birds would spend long periods of time in a newly seeded field without cover. It is considered likely that small birds may move in and out of newly seeded field to take seed opportunistically, while long periods of foraging would seem unlikely. After taking a seed, the bird would likely return to the relative safety of a shelter and consume the seed before returning for more. Given the learned avoidance due to toxic effects of imidacloprid treated seed, it is likely that a bird exhibiting this behaviour would learn to avoid the seed as food before reaching the level of consumption that could result in death.

3.2.5.2.4 Concurrent exposure with other neonicotinoids

An imidacloprid seed treatment registered for use on vegetables also contains another neonicotinoid. Sepresto 75 WS Insecticide (PCP 30972) contains imidacloprid at 18.75% of the formulation, and clothianidin at 56.25%. Based on Health Canada's most recent effects assessment of clothianidin, clothianidin is less toxic to birds than imidacloprid, and comparably toxic to mammals on an acute basis (REG2004-06). Sepresto 75 WS Insecticide is currently registered for use on vegetables. The expected increased toxicity due to the concurrent occurrence of clothianidin on treated vegetable seed was considered in the conclusions and required mitigations.

3.2.5.2.5 Field studies of exposure and effects to wildlife

During the comment period for PRVD2016-20, summaries of a number of avian field studies conducted with imidacloprid were provided by a registrant. The studies were designed to evaluate exposure and effects to granivorous birds following drilling of imidacloprid treated wheat, barley and sugar beet seeds. Only two of these studies were available for full review by Health Canada (PMRA# 1191040 and 1191041); the remaining studies cited by the registrant were not submitted to Health Canada and could not be reviewed. The studies that were made available to Health Canada were both European evaluations of the impact of drilling imidacloprid treated winter cereals on wildlife. Neither study reported significant effects on wildlife populations due to imidacloprid treated seed drilling. Some noted deficiencies of the studies include rapid degradation of imidacloprid due to high moisture content of soil and precipitation, no bird carcasses were analyzed for residues, evidence of predation of carcasses and habitat differences based on the studies having been conducted in Europe.

A registrant sponsored report was also submitted which examines population trends of various insectivorous bird species (swift and swallows) in Ontario, Quebec and Saskatchewan relative to the introduction of neonicotinoid insecticides (McGee et al. 2017; PMRA# 2744286). Bird survey data was used from the North American Breeding Bird Survey (BBS) which contains long-term, large scale population data for over 400 breeding species. The registrant claims that the trends from the analysis do not support an association between the use of neonicotinoids and trends in North American avian populations for swift and swallows. Given the limitations of the

BBS data when used in this type of analysis (i.e., once a year visual and auditory observation across small transects that may or may not be representative of agricultural areas where neonicotinoids are used) it is difficult to make a definitive association (or lack thereof) between the decline of swift and swallows in Canada and neonicotinoid use.

Declining populations of farmland and grassland bird populations have been observed in Canada and many of these species are considered at risk in Canada, including some of the insectivorous species listed in PMRA# 2744286 (for example, Bank swallow, Barn swallow and Chimney swift). The cause of these avian population declines has primarily been associated with habitat loss (agricultural intensification) and the impact of insecticides (directly and indirectly by reducing insect prey (for example, Mineau and Whiteside 2013; PMRA# 2947454). The evidence examining the impact of pesticides to birds at the population level, however, is of an equivocal nature because it is based on correlative analyses of observational data (for example, PMRA# 2576352 reports significant negative correlations between imidacloprid surface water concentrations and insectivorous bird populations in the Netherlands). Such associations between specific pesticide use and bird populations do not prove causality as the observed pattern may be explained by unknown factors not considered (for example, habitat loss, other pesticides, food supply during migration and during winter, predation).

3.2.5.2.6 Incident reports

Incident reports involving imidacloprid treated seed and avian mortalities have been reported in the United States, France and South Africa.

In France, a review by Millot et al. (2017; PMRA# 2945924) looked at wildlife mortality incidents (1995-2014). Over the 19 years, there were 101 incidents (734 dead animals) linked to imidacloprid seed treatments in which toxicological analyses detected imidacloprid residues in carcasses.

The 2017 USEPA Preliminary Terrestrial Risk Assessment of Imidacloprid (PMRA# 3199271) reports ~200 dead red-winged blackbirds (New Jersey, US), where imidacloprid-treated wheat seed was known to be used. Although residue analysis did not show the presence of imidacloprid in the birds, examined birds did have wheat seed in their stomachs. The USEPA deemed the incident possibly associated with the use of imidacloprid on wheat seed.

In South Africa, an incident was reported in which cape spurfowl (*Pternistis capensi*s) and greywing francolin (*Francolinus africanus*) were affected by exposure to cereal seeds treated with imidacloprid in May 2017 (Botha et al. 2018; PMRA# 3199200). The concentration of imidacloprid applied to the treated barley and wheat seed is not reported and it is not known if the conditions of the use of the treated seed were consistent with those prescribed in Canada.

It is unknown whether the rates on seeds in the reported incidents presented above are comparable to Canadian registered rates. It is also unknown whether or not the conditions of use of the treated seed were consistent with those prescribed in Canada.

3.2.5.3 Treated seed risk assessment conclusions

Some effects to individual birds and mammals may be tolerable if the risks to populations are determined to be acceptable. It is however, acknowledged that the quantitative relationship between individual- and population-level effects has not been explored in the current assessment and is expected to vary between populations.

Bait station tests show that some types of untreated seeds are consumed by birds of all sizes. Consumption of treated seed by birds and mammals is limited due to spill cleanup, seed burial at planting, seed emergence and dissipation of imidacloprid. There is strong evidence that birds learn to avoid consuming imidacloprid treated seed after experiencing post-ingestional distress. Although avoidance data are lacking for mammals, animals in laboratory toxicity tests did tend to reduce feed consumption, like birds, at higher dietary concentrations of imidacloprid. Field studies, with noted deficiencies, have found little evidence of effects on wildlife from treated seed applications. Although incidents of bird mortality related to imidacloprid seed treatments have been reported in the United States, France and South Africa (all associated with cereals; application rates and method of application unknown), no incidents have been reported in Canada; however, a lack of reported incidents does not preclude mortalities or unacceptable risks.

The conclusions rely in particular on the following information:

- The strong propensity for birds to avoid imidacloprid treated seed after experiencing post-ingestional distress.
- The limited window in which treated seed would be available, and still present an ingestion risk of concern to birds and mammals after planting.

Given the limited window in which treated seed would be available to birds and mammals after planting, it seems unlikely that wildlife could experience chronic dietary exposure to treated seed that could manifest in population-level effects. Chronic risks to birds and mammals were found to be acceptable.

It was determined that acute risks to birds and mammals would be considered acceptable if small birds (20 g; theoretically the most at risk of modelled taxa) would have to consume multiple seeds to reach the most sensitive oral gavage LD_{50}, or if the estimated area required to forage the seeds required to reach the LD_{50} was relatively large. If only a few seeds are required to reach the LD_{50} and those seeds can be obtained from a relatively small foraging area (assuming a certain number of seeds remain on the surface after planting and spills are cleaned up), then the risk to bird and mammal populations was deemed unacceptable (with few crop-specific exceptions). In these cases, a lethal dose may be consumed before birds learn to avoid the seed. In these cases, mitigation is required.

There are limitations with this approach. The LD_{50} considered is the oral gavage dose that is estimated to cause 50% mortality in the sensitive laboratory-tested species, Japanese quail. Birds ingesting this LD50, or less, can still acquire a lethal dose. Birds may be as, or more sensitive to imidacloprid, and may obtain a lethal dose with fewer seeds.

Further, birds experiencing sublethal effects may be at increased risk of mortality due to indirect effects (for example, predation). It is expected that the opportunities for sublethal effects are limited to a relatively narrow time frame after seeding and not likely to translate to population-level effects.

The approach taken relies heavily on the considerable avoidance data for birds. Avoidance studies were carried out in laboratories and enclosed aviaries. The feeding behaviour of birds under these conditions may differ from feeding behaviour in the wild. While avoidance studies were conducted with a variety of species, it is possible that untested species are more or less inclined to avoid imidacloprid treated seed. No avoidance studies were carried out with mammals. Mammals appear to be less sensitive to imidacloprid than birds and it is assumed that the mitigations put in place to protect birds will also protect mammals; however, mammals may be more or less inclined to avoid imidacloprid treated seed than birds. Reduced food ingestion in toxicity studies indicates that mammals may also avoid imidacloprid treated seed.

As a result of the seed treatment risk assessment for birds and mammals, mitigation is required for the following uses:

- Reductions in rates applied to sweet corn and field corn: Currently only 1-2 seeds are required for a small bird to reach the most sensitive oral gavage LD_{50}. The surface area required to expect this number of seeds on the surface is $\geq$ 16 m^2, which is relatively high due to precision drilling. The basis for the need for mitigation is that a single seed could lead to a lethal dose for a small bird.
- Broccoli and cabbage cannot be directly seeded in fields. Currently two seeds are required for a small bird to reach the LD_{50}, and it is estimated that these seeds can be acquired from the surface of a field in 6 to 8 m^2. Since there is no lower efficacious rate for broccoli and cabbage, these seeds can no longer be directly seeded in fields due to unacceptable risk to wildlife.
- Lettuce cannot be directly seeded in fields. Currently three seeds are required for a small bird to reach the LD_{50}. It is estimated that these seeds can be acquired from the surface of a planted field in 0.6 to 1 m^2. Since there is no lower efficacious rate for lettuce, these seeds can no longer be directly seeded in fields due to unacceptable risk to wildlife.

Transplant after emergence of broccoli, cabbage and lettuce poses an acceptable risk due to seed no longer being available for consumption, as well as the dissipation of active ingredient from the plant.

Several of the legume seeds that can be treated with imidacloprid, including soybean, only require one seed for small birds to reach the most sensitive acute oral gavage LD_{50}. These uses were deemed acceptable based on evidence indicating that birds generally do not find soybean and other legume seeds appealing.

Other label amendments are also required to reduce risks to granivorous birds and mammals.

- Broadcast seeding is known to occur for some crops like cereals and oilseeds. The current risk assessment does not account for broadcast seeding. Broadcasting seeding poses an unacceptable risk to birds and mammals due to large quantity of treated seed that would be

available at the field surface. As a result, broadcast seeding must be prohibited and the prohibition explicitly included on all product labels.
- Product labels currently recommend overseeding in headlands as a method to dispose of treated seed. This practice is expected to result in higher numbers of seeds on the surface in headlands, decreasing the foraging area required by birds to reach a lethal dose. Small birds are expected to forage at field edges. Given that small birds are at highest risk from treated seed, it is reasonable to require alternative disposal methods in the interest of protecting sensitive wildlife. Labels must be amended to include a prohibition on the practice of overseeding in headlands and provide alternative instructions for disposal of excess seed.

3.2.5.4 Risk mitigations for terrestrial vertebrates potentially exposed to imidacloprid by ingestion of treated seed

Based on the environmental assessment conducted for birds and mammals potentially exposed to imidacloprid from ingestion of treated seed, the following mitigation measures are required:

- The maximum rate on sweet corn is reduced from 2500 mg a.i./kg seed to 672 mg a.i./kg seed.
- The maximum rate on field corn is reduced from 1800 mg a.i./kg seed to 486 mg a.i./kg seed.
- Broccoli, cabbage and lettuce seed treated with imidacloprid must be started in a greenhouse and cannot be directly seeded to fields. Transplants can be sown in fields after seedling emergence.
- Broadcast seeding must be explicitly prohibited for imidacloprid-treated seed on all labels.
- Currently some product labels recommend overseeding in headlands as a method to dispose of treated seed. Product labels must be amended to include a prohibition on the practice of overseeding in headlands as a means of disposing of excess seed.
- Hazard statements communicating the toxicity of imidacloprid to birds and mammals must appear on all imidacloprid seed treatment labels.

3.3 Aquatic invertebrates

3.3.1 Aquatic invertebrate toxicity

The toxicity of imidacloprid to aquatic invertebrates has been summarized in PRVD2016-20. However, since the publication of PRVD2016-20, 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 imidacloprid to aquatic invertebrates. New and revised toxicity endpoints are highlighted in bold in Appendix VII, Table 1.

3.3.1.1 Revisions to toxicity endpoints reported in PRVD2016-20

3.3.1.1.1 Acute freshwater

In PRVD2016-20 acute endpoints reported for *Chydorus sphaericus*, *Cypretta sueratti*, *Cypridopsis vidua* and *Ilyocypris vidua* from Sánchez-Bayo and Goka (2006; PMRA# 2541831) were based on exposures that occurred with 16:8 hours of light: dark in the laboratory. In this same study, endpoints were also reported for dark exposures only. According to OECD 202, a

16-hour light and 8-hour dark cycle is recommended; however, complete darkness is also acceptable, especially for test substances unstable in light. As a result, the risk assessment was updated to consider both acute toxicity endpoints determined under light and dark, and dark only conditions for each of these test species. In the acute species sensitivity distribution (SSD) both values were included in a geometric mean, representing a central estimate of the EC_{50} for the species.

In PRVD2016-20 two acute immobilization endpoints were reported for *Cloeon dipterum*: two 96-hour EC_{50} values of 1.02 µg a.i./L (Roessink et al. 2013; PMRA# 2544385) and 12 µg a.i./L (Wijngaarden and Roessink 2013 as cited in EFSA 2014; PMRA# 2545413). The former endpoint came from summer collected specimens, whereas the latter came from fall collected specimens. Following publication of the proposed decision, Health Canada reviewed an additional study investigating the toxicity of imidacloprid to several aquatic invertebrate species, including *Cloeon dipterum* (Van den Brink et al. 2016; PMRA# 2712707). In Van den Brink et al. (2016) endpoints from fall collected specimens were compared with endpoints reported by Roessink et al. (2013; PMRA# 2544385; summer collected specimens). In addition, two mesocosm studies were also reviewed by Health Canada that specifically looked at effects of imidacloprid on abundance of *Cloeon dipterum* in summer and fall (PMRA# 2744281and 2744280). Collectively, the results suggest there are seasonal differences in sensitivity of *C. dipterum* to imidacloprid, with summer specimens apparently more sensitive to exposure than those collected in fall. It was determined that endpoints derived from specimens collected in summer would be considered over endpoints based on fall/overwintering generations. As a result, only the 96-hour EC_{50} for immobilization of 1.02 µg a.i./L (Roessink et al. 2013; PMRA# 2544385; summer collected specimens) was considered as a representative laboratory endpoint in the revised aquatic risk assessment for *Cloeon dipterum*.

Similarly, in PRVD2016-20 two acute immobilization endpoints were reported for the mayfly larvae of *Caenis horaria*: a 96-hour EC_{50} of 1.77 µg a.i./L (Roessink et al. 2013; PMRA# 2544385) and a 72-hour EC_{50} of 17 µg a.i./L (Wijngaarden and Roessink 2013 as cited in EFSA 2014; PMRA# 2545413). The latter endpoint for *Caenis horaria* is based on a test with 30% control mortality. This degree of mortality in controls is unacceptably high. The EC_{50} endpoint value for this species should not have been considered in the initial aquatic invertebrate risk assessment and was not included in the updated risk assessment. Following publication of the proposed decision, Health Canada reviewed an additional study investigating the toxicity of imidacloprid to *Caenis horaria* (Van den Brink et al. 2016; PMRA# 2712707). Endpoints from fall collected specimens were compared with endpoints reported by Roessink et al. (2013; PMRA# 2544385). As with *Cloeon dipterum*, the data suggest that summer specimens of *Caenis horaria* are more sensitive than fall specimens. As a result, only the 96-hour EC_{50} of 1.77 µg a.i./L (Roessink et al. 2013; PMRA# 2544385; summer collected specimens) was considered as a representative laboratory endpoint in the revised aquatic risk assessment for *Caenis horaria*.

In PRVD2016-20, the acute endpoint for immobilization of *Gammarus pulex* from Roessink et al. (2013; PMRA# 2544385) was a 96-hour EC_{50} reported as 18.3 µg a.i./L (this was from spring collected specimens). However, after the publication of the proposed decision it was determined that the control mortality in the test was unacceptably high (33%). The authors note that dissolved oxygen decreased drastically during the acute test performed with *G. pulex*. As a result, this endpoint was not considered in the revised aquatic invertebrate risk assessment.

In PRVD2016-20, the acute endpoint for immobilization of *Asellus aquaticus* from Roessink et al. (2013; PMRA# 2544385) was a 96-hour EC_{50} reported as 119 µg a.i./L (this was from spring collected specimens). This endpoint, while valid, was not considered in the revised assessment because a lower endpoint from a newly reviewed study (Van den Brink et al. 2016; PMRA# 2712707) was available with specimens collected in the fall that appeared to be slightly more sensitive.

From an unpublished study (PMRA# 1155859), Health Canada reported a 96-hour LC_{50} of 526 µg a.i./L for *Hyalella azteca*. In the revised assessment, the immobilization endpoint from the study was considered instead of the lethality endpoint. The immobilization endpoint is a 96-hour EC_{50} of 55 µg a.i./L.

3.3.1.1.2 Chronic freshwater

In the chronic effects assessment in PRVD2016-20, median effects endpoints (EC_{50} values) reported for *Chironomus riparius* (EFSA 2008, PMRA# 2332663; original study PMRA# 2523501), *Asellus aquaticus*, *Gammarus pulex*, *Chaoborus obscuripes*, *Sialis lutaria*, *Plea minutissima*, *Caenis horaria* and *Cloeon dipterum* (EFSA 2014 (PMRA# 2545413); original study Roessink et al. (2013; PMRA# 2544385)) were considered. In the final assessment, estimated low effects levels (i.e., EC_{10} or EC_{20} values) were considered from these and other studies instead of EC_{50} values. This change was made because low effect-level endpoints are preferred in chronic risk assessment, and sufficient low-effects endpoints were made available to generate a low-effects-level SSD for chronic exposure following the publication of PRVD2016-20.

All updated endpoints are presented in Appendix VII, Table 1. Appendix VIII discusses the species sensitivity distributions developed with the selected acceptable toxicity endpoints.

3.3.1.1.3 Acute marine/estuarine

In PRVD2016-20 an acute 48-hour LC_{50} of 130 µg a.i./L reported for *Aedes taeniorhynchus* from USDA 2005 (PMRA# 2334762) was considered. Following the publication of PRVD2016-20, Health Canada reviewed the original study, Song et al. (1997; PMRA# 2541668) included in USDA (2005)), and determined that the 48-hour LC_{50} for *Aedes taeniorhynchus* is 13 µg a.i./L. This endpoint was used in the revised risk assessment.

3.3.1.1.4 Additional aquatic invertebrate toxicity information

Since the publication of PRVD2016-20, additional imidacloprid toxicity data for aquatic invertebrates has become available in the open literature. All of the studies presented below were deemed acceptable by Health Canada. All relevant new and revised toxicity endpoints for freshwater invertebrates can be found in Appendix VII, Table 1.

3.3.1.1.5 Laboratory-based single-species toxicity tests

Acute

Two additional studies provide acceptable uncensored acute endpoints for *Daphnia magna* (Loureiro et al. 2010; PMRA# 2945939; Li et al. 2013; PMRA# 2712665). Louriero et al. 2010 conducted a study to investigate the acute toxicity and sublethal response of *D. magna* to imidacloprid following OECD guideline 202. The 48-hour LC_{50} value for *D. magna* was 97000 µg a.i./L. A 24-hour EC_{50} of 3700 µg a.i./L was reported based on feeding inhibition. Li et al. 2013 reported on the toxicity imidacloprid to *D. magna* following OECD No. 202 guidelines. A 48-hour EC_{50} of 998 (566 – 1760) µg a.i./L was reported.

A series of acute toxicity tests were conducted by Uragayla et al. (2015; PMRA# 2841146) investigating the toxicity of technical grade imidacloprid to the Dipterans *Anopheles stephensi*, *Culex quinquefaciatus* and *Aedes aegypti* following World Health Organization (2005) guidelines for laboratory and field testing of mosquito larvicides. The authors reported the following 72-hour LC_{50}s: 49 µg a.i./L for *A. stephensi* (SS strain – Nadiad), 66 µg a.i./L for *A. stephensi* (RR strain – Goa), 20 µg a.i./L for *C. quinquefaciatus*, and 210 µg a.i./L for *A. aegypt*i.

Van den Brink et al. (2016; PMRA# 2712707) investigated the acute toxicity of imidacloprid to overwintering *Cloeon dipterum* and a number of overwintering generations of other aquatic invertebrate species (*Caenis horaria, Plea minutissima, Chaoborus obscruripes, Asellus aquaticus and Gammarus pulex*). The effects of temperature and chronic exposure (28-d; discussed below with other new chronic effects data) were also explored for *Cloeon dipterum*. The tests were static renewal, and followed the methods presented in the earlier reviewed study, Roessink et al. (2013; PMRA# 2544385). The authors reported acute 96-hour EC_{50}s of 49 µg a.i./L and 78 µg a.i./L for fall collected specimens of *Gammarus pulex* and *Asellus aquaticus*, respectively. Endpoints from other species from this study were not considered in the derivation of effects metrics for the risk assessment because acceptable endpoints from spring/summer collected specimens were available and found to be more sensitive (see Appendix VII, Table 1).

Maloney et al. (2017; PMRA# 2818524) conducted acute static 96-hour imidacloprid toxicity tests with the larval midge *Chironomus dilutus* following the ECCC 1997 Technical Report EPS 1/RM/32 guideline. A median lethal concentration (LC_{50}) value of 4.63 µg a.i/L was reported.

Raby and Sibley (2017; PMRA# 2832452, 2832453) and Raby et al. (2018; PMRA# 2842540) present tests of acute toxicity of imidacloprid to numerous freshwater invertebrates, with the latter reference publishing the results from the former unpublished Ph.D. research data summary (which was previously reviewed by Health Canada). The static 48- or 96-hour tests followed various test guidelines that were selected for the test species. The following 96-hour EC_{50} values for immobilization were used quantitatively in the revised risk assessment: 23 µg a.i./L for *Cloeon* sp., 11 µg a.i./L for *Ephemerella* sp., 11 µg a.i./L for *McCaffertium* sp., 3 µg a.i./L for *Neocloeon triangulifer*, 58 µg a.i./L for *Gyrinus* sp., 99 µg a.i./L for *Stenelmis* sp., <6.4 µg a.i./L for *Micrasema* sp., 176 µg a.i./L for *Cheumatopsyche* sp., 5.8 µg a.i./L for *Isonychia bicolor*, 321 µg a.i./L for *Caecidotea* sp., 177 µg a.i./L for *Hyalella azteca*, 2.5 µg a.i./L for *Chironomus dilutus* and 32.4 µg a.i./L for *Lumbriculus variegatus*. For *Trichocorixa* sp. a 48-hour EC_{50} of 63 µg a.i./L was reported.

A 96-h LC_{50} of 9321 µg a.i./L for *Hexagenia* sp. was reported by Raby et al. (2018; PMRA# 2842540), but an immobilization endpoint was not calculated. ECCC 2017 (PMRA# 2753706) investigated the 96-hour acute toxicity of imidacloprid to *Hexagenia* spp. using methods described in Milani et al. 2003 (Environ Toxicol Chem 22(4): 845–854). An LC_{50} of 900 µg a.i./L and a lower EC_{50} value of 10 µg a.i/L were reported based on number of surviving animals inside artificial burrows (which was considered representative of mobility impairment). This lower endpoint was used in the revised assessment. The results of the acute tests with *Hexagenia* spp. were subsequently published in Bartlett et al. (2018; PMRA# 2861091).

Camp and Buchwalter (2016; PMRA# 2796398) conducted various tests to investigate the relationship between temperature and the time-to-effect from acute imidacloprid exposure for the mayfly *Isonychia bicolor*. Standard guidelines were not followed, but the methodology was considered acceptable. The authors reported a 96-h immobilization EC_{50} of 5.8 µg/L. This value was used in the revised risk assessment.

For *Caenis* sp., Raby et al. (2018; PMRA# 2842540) reported <21.8 µg a.i./L for both the LC_{50} and EC_{50} from a 96-hour exposure. Since an uncensored 96-hour EC_{50} of 1.77 µg a.i./L was available for *Caenis horaria* from Roessink et al. (2013; PMRA# 2544385), the value reported by Raby et al. (2018; PMRA# 2842540) was not used in the revised assessment.

Raby et al. (2018; PMRA# 2842540) reported a 96-h LC_{50} of 3462 µg a.i./L and an EC_{50} for immobilization of < 5437 µg a.i./L for *Coenagrion* sp.; however, these results were deemed unreliable by Health Canada, and were not used in the revised assessment. A 48-h LC_{50} of >102000 µg a.i./L was reported for *Daphnia magna*. As other lower uncensored LC_{50} and EC_{50} values were available for this species, these values were not used in the revised risk assessment.

Salerno et al. (2018; PMRA# 2912493) investigated the toxicity of imidacloprid to the freshwater mussel *Villosa iris* in a 24-hour test that followed ASTM-E2455-06. The author reported an EC_{50} of > 16800 µg a.i./L. As this endpoint was censored and the test was of short duration, this result is used only qualitatively in the revised acute risk assessment.

The acute toxicity of imidacloprid to the wavy-rayed lampmussel (*Lampsilis fasciola*) glochidia was investigated by Prosser et al. (2016; PMRA# 2712688) using ASTM E2455-06. No significant adverse effect was found after 48-hours of exposure and the authors reported an EC_{50} of > 688 µg a.i./L. This endpoint was used in the quantitative revised risk assessment.

Chronic

In a 28-d chronic test, Brun (2009; PMRA# 2693972) investigated effects imidacloprid on *Chironomus riparius* following OECD Guideline 219 “Sediment-Water Chironomid Toxicity Test Using Spiked Water (2004)”. Endpoints were recalculated based on time weighted average concentrations of measured concentrations in the overlying water. Time-weighted average endpoints calculated by Health Canada were: 28-d exposures emergence EC_{50} of 1.14 µg a.i./L, emergence NOEC of 0.66 µg a.i./L, development EC_{50} > 1.39 µg a.i./L and developmental NOEC 1.39 µg a.i./L.

Brun (2010; PMRA# 2693971) reported on a 28-day chronic imidacloprid toxicity test with *Chironomus riparius* following the same test guideline as Brun (2009). Endpoints were recalculated based on time weighted average concentrations of measured concentrations in the overlying water. Time-weighted average endpoints calculated by Health Canada were: 28-d exposure emergence EC_{50} of 1.11 µg a.i./L, emergence NOEC of 96 µg a.i./L, development EC_{50} > 1.81 µg a.i./L and developmental NOEC 1.81 µg a.i./L. The emergence NOEC values from Brun (2009, 2010) were used quantitatively in the revised assessment.

Prosser et al. (2016; PMRA# 2712688) reported a 28-day imidacloprid toxicity test with *Planorbella pilsbryi*. Due to anomalously high reported dry weights for individual snails, the growth endpoints from this study were deemed unacceptable for consideration in the revised risk assessment. The author-reported mortality endpoints of: LC_{10} = 45.7 µg a.i./L, LC_{25} = 171.7 µg a.i./L and LC_{50} 645.6 µg a.i./L. The low effects endpoint (LC_{10}) was used quantitatively in the revised risk assessment.

Van den Brink et al. (2016; PMRA# 2712707) reported a 28-day imidacloprid toxicity test with *Cloeon dipterum* and reported an EC_{10} of 4 µg a.i./L and an EC_{50} of 68 µg a.i./L. More sensitive values were reported for spring/summer individuals by Roessink et al. (2013; PMRA# 2544385) were considered in the risk assessment as there is strong evidence of seasonal differences in sensitivity for this species.

The toxicity of imidacloprid was characterized under 28-day chronic exposure scenarios using the larval *midge Chironomus dilutus* as a representative aquatic insect species (Maloney et al., 2018; PMRA# 2873503). The culturing and toxicity assays followed ECCC 1997 (Technical report EPS 1/RM/32). The authors reported 28-d EC_{20} and EC_{50} values of 14 and 5 µg a.i./L, respectively. The former was used quantitatively in the revised risk assessment.

The chronic toxicity of imidacloprid was assessed for the midge *Chironomus dilutus* (56 days) and mayfly *Neocloeon triangulifer* (32 days) (Raby et al. 2018; PMRA# 2912490). Toxicity tests for *C. dilutus* were based on a modified version of USEPA 2000 guideline ("Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates"); tests with *N. triangulifer* followed methods outlined in Soucek and Dickenson (2015). Health Canada re-calculated the chronic survival to emergence endpoints for *C. dilutus* (56-d EC_{10} = 9.89 µg a.i./L) and *N. triangulifer* (32-d EC_{10} = 1.12 µg a.i./L) using CETIS v.1.9.5.5 statistical software. These values were used in the revised chronic risk assessment.

Raby et al. (2018; PMRA# 2912491) reported on imidacloprid chronic toxicity tests for the cladoceran *Ceriodaphnia dubia* and *Daphnia magna*. Toxicity tests for *C. dubia* followed Environment Canada 2007 guidelines (Biological Test Method: Test of Reproduction and Survival Using the Cladoceran *Ceriodaphnia dubia* - EPS 1 RM/21).); tests with *D. magna* followed OECD 2012, Test No. 211: *Daphnia magna* Reproduction Test. The reproductive EC_{10} values reported by the authors (1360 µg a.i./L for *C. dubia* and 2690 µg a.i./L for *D. magna*) were used in the revised chronic risk assessment.

Salerno et al. (2018; PMRA# 2912493) reported on a 28-day toxicity test with *Lampsilis siliquoidea*. Although no guideline was specified for the test, the methodology was deemed reasonably sound by Health Canada. No significant effects were observed up to the highest test concentration (NOEC of ≥ 9121 µg a.i./L). This endpoint is valid and was considered in the revised chronic risk assessment but was not included in the chronic species sensitivity distribution (SSD) because no effects were observed at this highest test concentration, and slightly better fit was achieved without this datapoint (SSDs are presented in Appendix VIII).

ECCC (2017; PMRA# 2753706) investigated the sub-acute and chronic toxicity of imidacloprid to *Hyalella azteca*. The results were subsequently published in Bartlett et al. (2019; PMRA# 2975959). Using ECCC 2013 (Technical Report EPS 1/RM/33) guidelines, the author-reported endpoints were based on data combined from a number of different trials. Health Canada re-analysed the toxicity data (7-d mortality, 28-d growth and 28-d mortality) on a per trial basis. The results were then combined, where appropriate, in a geomean. For 7-day mortality the LC_{50} was > 125 µg a.i./L in two of the trials. The LC_{50} from the other two trials were 163.7 and 241.4 µg a.i./L (the geomean was taken of these uncensored values since these results do not disagree with the censored values). Only the third trial allowed the calculation of a valid EC_{10} (9.47 µg a.i./L). A geomean was taken of this EC_{10} and the lowest NOEC value for use in the risk assessment. For 28-day mortality the following LC_{10} values were estimated by Health Canada: 23.9, 9.62, 15.2 and 3.16 µg a.i./L. The more sensitive growth endpoints were used quantitively in the revised risk assessment.

3.3.1.1.6 Mesocosm studies

A mesocosm study (unpublished report, 2015; PMRA# 2744281) investigated the potential effects of imidacloprid on the mayfly (*Cloeon dipterum*); the study design was similar to that of another study previously considered in Health Canada's initial review (Unpublished report, 2014; PMRA# 2744280) with two applications with a 21-day interval. The main difference being that the 2015 study was conducted in summer instead of fall. The application of imidacloprid resulted in a significant decline in larval abundance and emergence of *Cloeon dipterum* at concentrations as low as a nominal 0.608 µg a.i./L and a NOEC of 0.243 µg a.i./L (data were reanalysed by Health Canada). Twenty-eight-day time-weighted-average (TWA) concentrations were estimated for these treatment levels for use in the revised risk assessment (NOEC = 0.16 µg a.i./L and LOEC = 0.382 µg a.i./L, 28-d TWA). Based on a comprehensive review of available mesocosm studies, the NOEC from this study was deemed the most appropriate endpoint for quantitative use in the revised risk assessment. Based on compared TWA concentrations, it represents the most sensitive chronic endpoint for population-level effects from an acceptable, and fully reliable study.

Cavallaro et al. (2018; PMRA# 2945937) reports on an *in situ* wetland limnocorral study investigating the effects of multiple applications of imidacloprid to emergent insect communities over a 15-week period. The study authors report a significant effect on total community emergence response (NOEL = 0.05 µg a.i./L – nominal, 0.045 µg a.i./L mean measured); this effect was weak and associated with increased emergence on a single occasion. Health Canada does not consider this subtle effect to be of ecological significance. Early emergence was also reported for Chironimidae exposed to imidacloprid. However, Health Canada considers the statistical methods used by the study authors to investigate changes in median time to emergence to be inadequate. Moreover, it is uncertain whether an effect on early emergence would be discernable under unrestricted field conditions (i.e., in the absence of enclosed limnocorrals) because of the multi-voltine nature of this taxa and unrestricted potential for recolonization. As such, the ecological relevance (or consequence) of early Chironomidae emergence (as detected for imidacloprid treatments under experimental conditions) is unclear.

Williams and Sweetman (2019; PMRA# 3119449) used field-based mesocosms to investigate the effects of multiple pulses of imidacloprid (three pulses at 1-week intervals) over a 77-day period. A significant decrease in the emergence of adult chironomids was observed at 2 and 20 µg a.i./L (nominal), with the subfamilies Chironominae and Tanypodinae showing a greater sensitivity than the members of the subfamily Orthocladiinae (NOEL = 0.2 µg a.i./L nominal).

Mesocosm toxicity endpoints considered in the revised assessment are summarized in Appendix VII, Tables 2 through 4.

3.3.2 Additional water monitoring data considered

Since the publication of the proposed re-evaluation decision document for imidacloprid, PRVD2016-20, a large amount of additional Canadian freshwater monitoring data for the years 2017, 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, 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 for freshwater invertebrates. A revised assessment of the risks to marine/estuarine invertebrates using monitoring data was not conducted.

In addition to the new monitoring data, monitoring data previously included in the proposed re-evaluation decision for imidacloprid were also considered. Overall, monitoring data included 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)[4] 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

[4] 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.

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.

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. Appendix X, Table 1 lists the monitoring data that were previously considered in PRVD2016-20 but were excluded from the revised risk assessment.

Details of the monitoring programs considered in the final re-evaluation decision of imidacloprid are summarized in Appendix X, Table 2. Monitoring data not previously considered in PRVD2016-20 are highlighted in bold. A total of 8924 water samples were collected from 765 different sites across Canada between 2005 and 2019 (Appendix X, Table 3). Sixty-eight percent of the sites were monitored for one year, 23% were monitored for two years, and 9% of the sites were monitored over three to eight years (Appendix X, Table 4). For this assessment, one site monitored in one given year is equivalent to one monitoring site-year. Overall, there were 1155 site-years of monitoring data available. Of the total data available, 8088 (91%) of the samples and 1049 (91%) of the site-years constitute new data not previously considered in the proposed re-evaluation decision for imidacloprid.

Appendix X, Table 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, 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 the Health Canada's effects metrics.

3.3.3 Revisions to the aquatic invertebrate risk assessment

The environmental risk assessment for imidacloprid was revised following the publication of PRVD2016-20. This included revisions to imidacloprid 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 (RVD2019-06) 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.

3.3.3.1 Revisions to imidacloprid effects metrics

New and revised toxicity endpoints used in the final decision are highlighted in bold in Appendix VII, Table 1 and Table 3. 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 consideration in the aquatic risk assessment as outlined in the following sections. The effect metrics selected for the final regulatory decision are highlighted in bold.

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

Effects metric	Value (µg a.i./L) with confidence interval, where available		Comments
	Proposed decision (PRVD2016-20)	Final decision	
Freshwater			
Acute most sensitive sp. ($EC/LC_{50}/2^a$)	0.33	0.33	Mayfly larvae (*Epeorus longinamus*) 96-h LC_{50} = 0.65 µg a.i./L
Acute HC_5 (SSD of EC/LC_{50}s)	0.36 (0.075 – 1.1)	**0.54** (0.18 – 1.27)	Calculated by Health Canada (n = 48).
Chronic most sensitive sp. ($NOEC/EC_x$)	0.024	0.024	Mayfly larvae emergence (*Cloeon dipterum*)
Chronic HC_5 (SSD of $NOEC/EC_x$)	0.041 (0.0016 – 0.266)	0.011 (0.0005 – 0.077)	Calculated by Health Canada (n = 14).
Mesocosm ($NOEC/EC_x$)	Not considered	**0.16**	Higher tier effect metric (*Cloeon dipterum*); 28-day TWA NOEC[b]
Marine			
Acute most sensitive sp. ($EC/LC_{50}/2^a$)	HC_5 = 1.37 (0.00093 – 35.9)	**6.5**	Mosquito *(Aedes taeniorhynchus)* 48-h LC_{50} = 13 µg a.i./L
Chronic most sensitive sp. ($NOEC/EC_x$)	0.33	**0.33**	28-d NOEC *M. bahia* (reduced growth of first generation)

[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] Significant effects on *Cloeon dipterum* abundance (adult and larvae) were observed at 0.38 µg a.i./L (28-d TWA) in a 57-day mesocosm study, effects were observed at this treatment level on sampling intervals of Day 16 and 23; the treatment was two applications with a 21-d retreatment interval.
Bolded endpoints were established as the effects metrics for risk assessment.

3.3.3.1.1 Acute toxicity effects metrics

Health Canada revised the acute species sensitivity distribution (SSD) for freshwater invertebrates exposed to imidacloprid, taking into consideration newly available toxicity data (Appendix VIII). The revised acute SSD for imidacloprid is restricted to valid endpoints from exposure periods of 48 – 96 hours (the SSD presented in PRVD2016-20 also met this criterion). This criterion is meant to appropriately align the toxicity dataset with the modeled estimated environmental concentrations (EECs; 90[th] percentile of annual maximum 24-hour averages from 50-year simulations). Health Canada updated the acute and chronic SSDs for imidacloprid exposure to aquatic invertebrates, taking into consideration comments received during the consultation period (i.e, recommendations on data handling), newly available toxicity data, as well as data that were not captured during the initial risk assessment. A total of 48 and 14 toxicity endpoints were included in acute and chronic SSD. The revised acute and chronic HC_5 values of 0.54 (0.18 – 1.27 µg a.i./L) and 0.011 (0.0005 – 0.077 µg a.i./L) replace the acute and chronic HC_5 values reported in PRVD2016-20, 0.36 (0.075 – 1.1 µg a.i./L) and 0.041 (0.0016 – 0.266 µg a.i./L), respectively.

Details regarding the calculation of the revised acute and chronic HC_5 values (i.e., estimation method and data handling, study endpoints and study references) are provided in Appendix VIII - SSD analysis.

For marine invertebrates, some of the acute laboratory endpoints originally accepted for SSD analysis were reconsidered which resulted in an insufficient number of acceptable endpoints for SSD analysis. As a result, the most sensitive acute marine invertebrate endpoint was used to update the risk assessment (48-h LC_{50} = 13 µg a.i./L for *Aedes taeniorhynchus*).

3.3.3.1.2 Chronic toxicity effects metrics

Most sensitive species

The endpoint for the most sensitive species reported in PRVD2016-20 was a 28-d EC_{10} of 0.024 µg a.i./L for *Cloeon dipterum* based on significant reductions in emergence (Roessink et al. 2013; PMRA# 2544385). This endpoint remains the most sensitive chronic endpoint for aquatic invertebrates.

SSD HC_5

Health Canada revised the chronic SSD for freshwater invertebrates exposed to imidacloprid, taking into consideration newly available toxicity data and comments on the data used to construct the SSD. In the revised SSD low effects endpoints (for example, NOEC, EC_{10}, EC_{20}) were used instead of EC50 values.

Updates to the endpoints in the chronic SSD are presented in Appendix VIII. The revised HC_5 (95% CL) of 0.011 (0.0005 – 0.077 µg a.i./L) replaces the HC_5 of 0.041 (0.0016 – 0.266 µg a.i./L) reported in PRVD2016-20.

Mesocosm

In PRVD2016-20 a mesocosm-based effects metric was not considered. Since the publication of the proposed decision, Health Canada has updated its initial assessment of higher tier aquatic data. A comprehensive comparison and analysis of statistically significant adverse effects of imidacloprid on aquatic invertebrate apical, population and community level measurements was conducted. The purpose of this effects assessment was to determine whether these data could be used to support an effects metric for use in the quantitative risk characterization of aquatic invertebrates. The effects assessment considered a total of 27 higher tier aquatic studies, of which most are mesocosm studies. Based on the review of toxicity endpoints from mesocosm studies investigating the effects of imidacloprid, a deterministic effects metric of 0.16 µg a.i./L 28-d TWA was determined for use in the quantitative risk assessment. This effects metric is the NOEC established for *Cloeon dipterum* abundance (larvae and emergent adults; PMRA# 2744281). Mesocosm toxicity endpoints considered in the revised assessment are summarized in Appendix VII, Tables 2 through 4.

Chronic effects metrics used in final decision

The chronic effects metrics used in the final decision are the highest-tiered data available for freshwater and marine invertebrates: the mesocosm 28-d TWA NOEC of 0.16 µg a.i./L for freshwater invertebrates and the 28-d NOEC of 0.33 µg a.i./L for marine invertebrates (Table 1).

The chronic HC_5 for freshwater aquatic invertebrates was not considered quantitatively in the final decision because Health Canada felt that the breadth and quality of mesocosm data was sufficient to support the use of the higher-tier effects metric only.

3.3.3.2 Screening level aquatic invertebrate risk assessment

This screening level risk assessment for aquatic invertebrates takes into account the revised acute and chronic toxicity effects metrics for imidacloprid. For a complete description of the screening level risk assessment and derivation of EECs, refer to PRVD2016-20. Transformation products of imidacloprid were not expected to pose a risk to aquatic invertebrates (PRVD2016-20) and are therefore not considered further.

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

- The highest maximum annual application rate registered for use on crop group 5 – Brassica (cole) leafy vegetables (520 g a.i./ha; the application method is soil drench / in furrow).

Screening level RQs of imidacloprid exceeded the LOC for freshwater and marine invertebrates for both acute and chronic exposures (Appendix VII, Table 5).

3.3.3.3 Spray drift risk assessment

The risk to aquatic invertebrates was further characterized by taking into consideration the concentrations of imidacloprid that could be deposited through spray drift in aquatic habitats that are 1 m downwind from the treatment area. End-use products containing imidacloprid 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 281.3 g a.i./ha for turf, for airblast sprayers, a cumulative application rate of 327.6 g a.i./ha for raspberries (3 × 112 g a.i./ha, 7-day application interval) and for aerial sprayers, a cumulative rate of 144.4 g a.i./ha for potatoes and soybeans (3 × 49 g a.i./ha, 5-day application interval). The 80^{th} percentile aquatic half-life of 191 days was used to determine cumulative rates.

In freshwater habitats, the chronic risk from spray drift was assessed using the 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 minimum and maximum single application rate only (soybean and raspberry, respectively).

The EECs and RQs for aquatic invertebrates resulting from spray drift are summarized in Appendix VII, Table 6. The RQs exceed the LOC for freshwater invertebrates exposed to imidacloprid via spray drift at the highest application rates from all application methods on an acute and chronic basis. For marine invertebrates, the acute RQs exceed the LOC for airblast sprayer, but do not exceed the LOC for fieldsprayer or aerial sprayer application methods.

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

3.3.3.4 Runoff assessment methodology

The risk to aquatic invertebrate communities exposed to imidacloprid 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 imidacloprid along with all the application methods registered including:

- Corn – seed treatment
- Soybeans – seed treatment and foliar
- Legumes / pulses – seed treatment and foliar
- Oilseeds – seed treatment
- Cereals – seed treatment
- Vegetables – seed treatment, soil drench, in-furrow and foliar
- Potatoes – seed treatment, in-furrow, soil drench and foliar
- Grapes – soil drench and foliar
- Berries – foliar
- Outdoor ornamentals (evergreens and grasses only) – soil drench
- Turf – foliar and granular
- Tree nuts – foliar
- Peanuts – in-furrow, transplant water soil drench and foliar
- Tobacco – in-furrow and foliar

- Hops – foliar
- Herbs – in-furrow and foliar
- Christmas trees – foliar
- Greenhouse – soil drench, transplant tray plug drench

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 imidacloprid. Details on modelling inputs and assumptions are provided in Appendix IX. 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, RVD2019-06:

- Foliar sprays: modelling for seven crops (blueberry, raspberry, grape, tomato, soybean, potato and turf);
- In-furrow: potato, other root/tuber vegetables, and brassica vegetables;
- Soil spray/drench: grapes and brassica vegetables; and
- Seed treatments: modelled for nine seed treatment crops (barley, canola, chickpeas, field corn, faba beans, dry field peas, potatoes, soybeans and spring wheat).

A list of all imidacloprid use scenarios selected for surface water modelling is presented in Table 2 with further details presented in Appendix IX, Table 2. Modelling was based on registered application rates for imidacloprid as of June 19, 2020 (Appendix II). The EECs and RQs for aquatic invertebrates resulting from surface runoff are summarized in Appendix VII, Table 7.

Table 2 Imidacloprid use scenarios selected for surface water modelling

Application method	Crops selected
Seed treatment	• Barley (36.33 g a.i./ha) • Canola (64.16 g a.i./ha) • Field corn (56.8 g a.i./ha)[a] • Pea/dry (246.25 g a.i./ha) • Potato (280 g a.i./ha) • Soybean (157.5 g a.i./ha)[a] • Wheat, spring (52.47 g a.i./ha) • Chickpea (96.88 g a.i./ha) • Faba bean (232.5 g a.i./ha)
In-furrow[a]	• Potato (1 × 100 g a.i./ha and 1 × 480 g a.i./ha) • Other root/tuber vegetables (1 × 100 a.i./ha and 1 × 408 g a.i./ha) • Brassica (1 × 86.6 g a.i./ha and 1 × 520 g a.i./ha)

Application method	Crops selected
Soil drench	• Grapes (1 × 100 g a.i./ha and 1 × 480 g a.i./ha)[a] • Brassica (1 × 86.6 g a.i./ha and 1 × 520 g a.i./ha)
Foliar	• Blueberry (1, 2 and 3 × 42 g a.i./ha) • Raspberry (1, 2 and 3 × 112 g a.i./ha) • Grapes (1 and 2 × 48 g a.i./ha) • Tomato (1, 2 and 3 × 49 g a.i./ha) • Soybean (3 × 24.4 g a.i./ha and 3 × 49.9 g a.i./ha) • Potato (1, 2 and 3 × 49 g a.i./ha) • Turf (1 × 281 g a.i./ha)

[a] Corn and soybean seed treatments, in-furrow uses and hill drench use on grapes were modelled with 'increasing with depth' scenario.

To assess acute risks based on modelling, 24-hour EECs were compared against the acute effects metric to generate acute RQs. The acute effects metric (HC_5 of 0.54 µg a.i./L) comes from the acute aquatic invertebrate species sensitivity distribution (see Section 3.3.3.1, Revisions to Imidacloprid Effects Metrics).

To assess chronic risks based on modelling, 21-day EECs were compared against the chronic effects metric to generate chronic RQs. The chronic effects metric is a mesocosm-based 28-day TWA NOEC of 0.16 µg/L from a 57-day mesocosm study, where significant effects on *Cloeon dipterum* abundance (adult and larvae) were observed at 0.38 µg a.i./L (see Section 3.3.3.1, Revisions to Imidacloprid Effects Metrics).

Water monitoring data

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

A revised assessment of the risks to marine/estuarine invertebrates using monitoring data was not conducted. To assess acute risk to aquatic invertebrates from imidacloprid exposure based on monitoring data, maximum measured imidacloprid 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 imidacloprid was not detected. The maximum 28-day average of each site-year was divided by the chronic effects metric selected for quantitative risk assessment to generate chronic RQs.

The 28-day (approximate) moving average concentrations of imidacloprid were calculated for each site-year in one of two ways. For site-years with peak detections of imidacloprid above the chronic effects metric of 0.16 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 imidacloprid levels below the 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 9.6 days assuming dissipation followed single first-order kinetics. The DT_{50} used in this estimate represents the average 50% dissipation time for imidacloprid observed in Prairie wetlands, presented below and in Appendix X, Table 6. The dissipation time is consistent with the decline of imidacloprid observed in mesocosm studies. The assumption that dissipation followed single first-order kinetics is considered reasonable given that the best-fitting dissipation model was 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.

One section of the assessment focusses on extensive investigative monitoring conducted during the 2017 to 2019 growing seasons to identify the source of elevated concentrations of imidacloprid measured in two Ontario watersheds (Lebo Drain and Sturgeon Creek). Sampling locations were strategically located in the two watersheds to determine whether the inputs were from greenhouse or field uses of imidacloprid. The results of the investigative sampling are discussed separately in this assessment. Data from sites receiving input from greenhouses were subsequently excluded from the overall assessment of the levels of imidacloprid in water as a result of field uses.

3.3.3.4.1 Runoff risk assessment – modelling

Acute risk

For freshwater invertebrates, acute RQs exceeded the LOC for most foliar uses modelled (Appendix VII, Table 7), with RQ values up to 19 for three foliar applications per season on raspberries. Acute RQs were up to 24 for in-furrow application at the highest application rate, up to 31 for soil drench application at the highest application rate and up to 5.6 for seed treatments. For marine invertebrates, acute RQs based on modelling only marginally exceeded the LOC; RQs were up to 1.5 for foliar applications, up to 2.0 for in-furrow uses, up to 2.6 for soil drench uses and up to 1.2 for seed treatments.

Chronic risk

Chronic RQs were consistently lowest with the British Columbia regional scenario, and highest, in many cases, for the Atlantic Region (Appendix VII, Table 7). Chronic RQs for freshwater invertebrates exceeded the LOC in at least one modelled region for all foliar, in-furrow and soil drench use patterns modelled (RQs of 1.0 – 51). For seed treatments, RQs were up to 36 but did not exceed the LOC (RQs <1) for potato seed piece and chickpea uses. Chronic RQs for marine invertebrates were up to 15 for foliar uses. For in-furrow and soil drench use, RQs did not exceed the LOC for grapes, but they exceeded the LOC for other modelled uses (RQs up to 25 at the higher rate on brassica vegetables).

Chronic RQs for seed treatment uses did not exceed the LOC for potato seed piece and barley uses but exceeded the LOC in at least one regional scenario relevant to marine invertebrates for the remaining crops modelled (RQs up to 18).

3.3.3.4.2 Runoff risk assessment – water monitoring

The revised risk assessment for freshwater invertebrates included a total of 8962 water samples collected from 779 different sites across Canada between 2005 and 2019 (Appendix X, Table 3). Many sites were monitored over multiple years, giving an overall total of 1169 site-years of monitoring. The monitoring data considered in the revised risk assessment, which include data previously included in the proposed re-evaluation decision as well as additional data received since the publication of PRVD2016-20 are discussed in Section 3.3.2 of this document.

Appendix X, Table 5 summarizes the results of imidacloprid monitoring programs across Canada. Imidacloprid concentrations exceeded the acute effects metric in a few Canadian waterbodies and in particular in two watersheds from the Leamington area of Ontario. Instances when imidacloprid concentrations exceeded the chronic effects metric over a longer-term period of 28 days were infrequent, with the exception of sites located in the same two Ontario watersheds from the Leamington area where exceedances were frequent.

Detailed investigative sampling was conducted during the 2017, 2018 and 2019 seasons to identify the source of the high levels of imidacloprid measured in the two watersheds from the Leamington area of Ontario. Between 2012 and 2019, 18 sites (49 site-years) were identified as receiving inputs from greenhouses and were excluded from the analyses of the water concentrations as a result of field uses of imidacloprid. The results of the investigative sampling are discussed separately in this assessment.

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.

3.3.3.4.2.1 Prairie region

The primary use of neonicotinoids in the Prairies is as a seed treatment. Imidacloprid is registered for use as a seed treatment on a variety of crops such as canola, corn, soybeans, lentils, beans, peas, barley, wheat, oats, potato seed pieces and a number of other vegetable crops. The current registered use of imidacloprid on seeds is 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 PVRD2016-20. The sites monitored include rivers, creeks, lakes, reservoirs, wetlands, irrigation canals, and tile drains. The monitoring data for the Prairie Region considered in the revised assessment were for the years 2014 to 2019. In total, 4717 surface water samples were collected from 488 different sites between the years 2014 and 2019, for an overall total of 645 site-years of monitoring (Appendix X, Table 3).

Of these data, 4671 (99%) of the samples and 599 (93%) of the site-years constitute new data not previously considered in the proposed re-evaluation decision for imidacloprid. Between one and three years of monitoring data were available for each site (Appendix X, Table 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 of the Canadian Prairies between the years 2014 and 2019. Many sites were sampled in 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 (Appendix X, Table 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.

Imidacloprid was detected in 27 (36%) of the 76 sites sampled in Manitoba, and in 20 (38%) of the 53 sites sampled in Saskatchewan. In Alberta, imidacloprid was detected in 5 (9%) of the 53 river sites, and 9 (16%) 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, creeks and reservoirs in the Canadian Prairies between 2014 and 2019 had concentrations of imidacloprid exceeding the acute effects metric of 0.54 µg/L. The maximum peak concentration of imidacloprid detected in lake, river, stream or reservoir sites 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 imidacloprid exceeding the chronic effects metric.

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)[5], 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 semi-permanent ponds or lakes (Class IV), and 17 (5%) were permanent ponds of 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

[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.

of them direcly within agricultural fields or receiving drainage from all or part of the surrounding agricultural fields. Based on use information available, at least 18 wetlands were within fields planted with imidacloprid-treated seeds (pea, lentil, soybean) in 2017, 2018 or 2019. At least 111 wetlands were in or adjacent to fields planted with thiamethoxam-treated seeds (canola, wheat, lentil, barley, oat) in 2018 and 2019. 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. 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, barley, wheat, lentils, peas and oats can be treated with imidacloprid. 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 imidacloprid during the year of sampling were included in the analysis even if they do not represent imidacloprid 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 site-years) of site-years had ten or more samples collected in a given year.

Imidacloprid was detected in 16 (89%) of the 18 wetlands near or adjacent to fields known to be planted with imidacloprid-treated pea, lentil and soybean seeds at or higher than recommended seeding rates for the regions (Appendix X, Table 5). Overall, imidacloprid was detected in 79 (25%) of the 320 wetlands monitored. The low overall detection frequency is not unusual, considering that another neonicotinoid, either clothianidin or thiamethoxam, was known to have been used as a seed treatment in surrounding fields in 50% (159) of the site-years. In these 159 site-years, imidacloprid was detected in 39 (25%) of them, suggesting that there was carry-over of imidacloprid in fields and subsequent runoff of residues the subsequent year or there was runoff from adjacent fields planted with imidacloprid-treated seeds.

Imidacloprid concentrations were typically highest in the spring both pre-pant and post-plant followed by subsequent decreases in concentrations. Concentrations of imidacloprid 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 imidacloprid 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.

Imidacloprid dissipated rapidly and did not persist in Prairie wetlands. It was possible to estimate the 50% dissipation time (DT_{50}) of imidacloprid in 12 wetlands that were sampled weekly. The DT_{50}s for imidacloprid in wetlands ranged from 4.8 to 18.8 days, and the overall average was 9.6 days (Appendix X, Table 6).

None of the wetlands had imidacloprid concentrations exceeding the acute effects metric (HC_5 of 0.54 µg/L; Figure 2, panel A of Appendix X). The maximum concentration of imidacloprid detected was 0.2 µg/L in July 2014 near a pea field. No information on neonicotinoid use in the fields surrounding the wetland was available, but it is reasonable to assume the pea field was planted with imidacloprid-treated seeds. The dissipation of imidacloprid at this site could not be characterized using observed data because only one sample was collected at that site. The second highest concentration of imidacloprid detected at any site was very similar to the maximum detected concentration, 0.19 µg/L following a large (greater than 40 mm) precipitation event in late June 2019. The wetland was in or adjacent to a field planted with imidacloprid-treated pea seeds. At that site, imidacloprid dissipated rapidly; imidacloprid concentrations had declined to 0.08 µg/L within 8 days; the DT_{50} for imidacloprid at that site was 9.9 days, based on single first-order kinetics.

None (0%) of the 320 sampled wetlands had 28-day moving average concentrations of imidacloprid exceeding the chronic effects metric of 0.16 µg/L (Appendix X, Figure 2, panel B). The highest 28-day moving average concentration in Prairie wetlands was 0.09 µg/L, calculated using observed data at the site where the second highest maximum peak concentration of 0.19 µg/L was observed. The highest RQ calculated using the maximum 28-day average concentration and the 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 around the irrigation canal sites was not provided.

Imidacloprid was detected in 8 (11%) of the irrigation canal samples collected in Alberta between 2017 and 2018; it was not detected in any of the tile drains sampled. Imidacloprid concentrations did not exceed the chronic effects metric in any sample from irrigation canals or tile drain sites. The maximum concentration of imidacloprid detected in irrigation canals was 0.07 µg/L. 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

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 to be representative of a typical year.

3.3.3.4.2.2 Growing regions outside of the Prairies

Although imidacloprid is used mainly as a seed treatment in the Prairie Region, in other areas of Canada, imidacloprid is used as a seed treatment, an in-furrow drench, a foliar spray and a granule (turf only) in the field as well as a soil drench or transplant tray plug drench in greenhouses. Some of the crops that can be treated with imidacloprid include corn, soybeans, oilseeds, legumes, cereals, potatoes, many vegetable crops, berries, turf and some ornamentals. The recent pollinator re-evaluation decision (RVD2019-06) has resulted in changes to the use pattern for imidacloprid. The current registered uses of imidacloprid are listed in Appendix II.

Water monitoring data were available from 291 different sites in intensive agricultural areas of Prince Edward Island, Nova Scotia, New Brunswick, Quebec, Ontario and British Columbia (Appendix X, Figure 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 82% (238) of the sites were monitored over one or two years, 7% (21 sites) had three years of data, 8% (22 sites) had four years of data, and 3% (10 sites) were sampled for five to eight years (Appendix X, Table 4). A total of 4245 samples were collected from 524 site-years of monitoring were available for the time period between 2005 and 2019 (Appendix X, Table 3). Of these data, 3455 (81%) of the samples and 464 (88%) of the site-years constitute new data not previously considered in the proposed re-evaluation decision for imidacloprid. Details of the monitoring datasets are provided in Appendix X, Table 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 (Appendix X, Table 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 imidacloprid can be 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, especially in potatoes. For example, both the Wilmot and Huntley watersheds are less than 50 km^2 with their main rivers being 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 imidacloprid use rates for the major Canadian crops (corn, soybean, pulse, canola, cereals and potato) are highest on potatoes and potatoes represent the highest percentages of the watershed area, it is reasonable to assume that imidacloprid 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 cropping density areas in the province.

Only one site-year of monitoring for imidacloprid 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, vineyards, and greenhouses that in most cases contained highly intensive agriculture (cropped fraction greater than 50% of the total watershed area). 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 slected 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.

Imidacloprid was detected in 341 (66%) of the 524 site-years of available monitoring.

Investigation of potential sources of high concentrations in waterways of the Lebo Drain and Sturgeon Creek watersheds in Ontario

Monitoring data from Environment and Climate Change Canada (ECCC) between 2012 and 2016 indicated elevated levels of imidacloprid in the Lebo Drain and Sturgeon Creek watersheds in southwestern Ontario. Yearly maximum concentrations measured by ECCC during this time frame ranged from 2.5 to 4 µg/L in Lebo Drain and from 0.8 to 10.4 µg/L in Sturgeon Creek (Appendix X, Table 7). Analysis of neonicotinoid concentrations in these two waterbodies and others in southwestern Ontario showed that imidacloprid concentrations were higher in areas associated with greenhouse and vegetable uses, based on data from 2012 to 2014 (Struger et al., 2017; PMRA# 2703534). The high concentrations of imidacloprid in Lebo Drain and Sturgeon Creek and the association between imidacloprid concentrations and use in greenhouses and vegetables in Ontario were part of the rationale in PRVD2016-20 to phase-out outdoor and greenhouse uses of imidacloprid.

Since the publication of PRVD2016-20, expanded multivariate statistical analyses of monitoring data from southwestern Ontario for the years 2012 to 2015 conducted by Bayer CropScience confirmed a strong association among imidacloprid concentrations and greenhouses and other agricultural crops (potatoes, vegetables) (Report 4 in PMRA# 2818731).

In May 2017, Bayer CropScience initiated a detailed investigative monitoring study in the Lebo Drain and Sturgeon Creek watersheds to determine the origin of the high concentrations of imidacloprid in these waterways.

The Lebo Drain and Sturgeon Creek watersheds are in the Leamington area in southwestern Ontario, which has the largest concentration of vegetable greenhouses in Canada. The main crops grown in the greenhouses are cucumbers, tomatoes, and peppers. Imidacloprid is used in many greenhouses at least once per year for the control of aphids and whiteflies (PMRA# 2818731). At the time of the sampling, imidacloprid was used as a soil application on all commercial tomato fields in the Leamington area. Additionally, imidacloprid may be used as a seed treatment on soybean, which is the main row crop in the area, and winter wheat. Based on use information provided by stakeholders, 40% of soybeans are treated with neonicotinoids, with the majority being thiamethoxam, and reportedly very little imidacloprid (though an exact proportion was not provided). Approximately 30% of wheat is treated with neonicotinoids, with half of this being treated with imidacloprid (PMRA# 2818731).

Corn is also a row crop grown in the area, but there is very little reported use of imidacloprid on corn seed in Canada, as stated in REV2016-03. As of 2013, virtually all field corn planted in Canada was treated with other neonicotinoids, either thiamethoxam or clothianidin. The registered uses of imidacloprid on tomatoes, soybeans, and wheat are summarized in Appendix II.

Program design

Initially in 2017, samples were taken in five locations in the Lebo Drain watershed and in three locations in the Sturgeon Creek watershed. As detections were observed, additional sampling sites were added to determine the sources of imidacloprid. The monitoring continued in 2018 and 2019.

The primary sampling sites were the same as those used in the monitoring program conducted by ECCC between 2012 and 2016. The two primary sites were also monitored by the Ontario Ministry of Environment, Conservation and Parks in collaboration with the Ontario Ministry of Agriculture and Rural Affairs between 2015 and 2018 and by Metcalfe et al., 2018 (PMRA# 2945668) in 2016. The other sampling locations selected for the investigative monitoring program were mostly small agricultural drainage ditches or creeks, which included some samples from small pooling areas since the flowing portion of the ditch or creek was often not deep enough for sampling.

General details of the investigative monitoring are summarized in Appendix X, Table 2. In total, samples were collected from fifteen sites in each of the 2017, 2018, and 2019 growing seasons. The number and location of sites as well as the frequency and timing of sampling varied depending on the year.

Collected ancillary information included the main agriculture within two kilometers of the sampling sites and daily precipitation from weather stations near the sampling sites. To help confirm whether imidacloprid was being released from greenhouses, water samples were also analyzed for propamocarb (used primarily in greenhouses for the control of root rot diseases in hydroponic systems) as it serves as an indicator of water losses from greenhouses. Soybean plants from fields upstream of some sampling sites were analyzed for neonicotinoids to determine whether imidacloprid seed-treatment on soybeans was contributing to concentrations in water. Information provided by the Ontario Greenhouse Vegetable Growers (OGVG) association confirmed use of products containing imidacloprid in the days leading up to some of the high concentrations measured in water. Engineering firms were hired by two greenhouse operators in 2017 to conduct dye tests and fix detected leaks.

Results of the investigative sampling

Precipitation levels in the Leamington area of Ontario in 2017–2019 were normal (within 85% to 115% of historical levels).

As observed in previous years of monitoring conducted by ECCC, elevated concentrations of imidacloprid at the main Lebo Drain and Sturgeon Creek sites were observed between 2017 and 2019 (maximum yearly concentrations from 0.63 µg/L to 19 µg/L in Lebo Drain and from 0.48 to 2.5 µg/L in Sturgeon Creek; Appendix X, Table 7). Concentrations at these sites were generally lower in 2018 and 2019 than previous years, mainly because of lower peak concentrations.

Multiple lines of evidence suggest that high concentrations of imidacloprid were coming from greenhouses as opposed to field uses of imidacloprid.

The highest concentrations of imidacloprid in the Lebo Drain and Sturgeon Creek watershed were observed in areas downstream of greenhouses (Appendix X, Tables 8 and 9, respectively). Concentrations of imidacloprid were lower at sites with minimal or no potential to receive input from greenhouses (sites LD3, LD4, LD6, LD13, SC2 and LE1).

Timing of peak concentrations rarely matched high precipitation events, indicating that the use of imidacloprid on field crops was not likely the source of the imidacloprid peaks. High concentrations of imidacloprid occurred during periods with little precipitation. The primary inputs to the waterbodies during dry periods would be any discharge from greenhouses and contributions from irrigation runoff/drainage from tomato fields. Information provided by stakeholders (PMRA# 2818731) indicates 95% of tomato fields in the area employ drip irrigation, which limits the potential runoff from these fields during dry periods.

Investigations by the OGVG association revealed imidacloprid was used in greenhouses adjacent to sites showing high detections in water.

Investigations at two greenhouses upstream of sites LD5 and LD9 confirmed leaks in the recirculation systems in 2017. In one case, a 0.5 acre portion of the greenhouse was not connected to the recirculation system and effluent was released directly through a drain. Soybean plants upstream of LD5 were shown to not be a potential source of imidacloprid in 2017.

Taking into consideration the timing and magnitude of imidacloprid concentrations, the presence of propamocarb at locations downstream of greenhouses, and the ancillary data collected, it was concluded that loss of water from greenhouses is the likely cause of the high concentrations of imidacloprid observed in the Lebo Drain and Sturgeon Creek waterways. Tomatoes and a small percentage of winter wheat and soybean may also be responsible for some imidacloprid found in the waterways. That being said, imidacloprid concentrations at sites with little or no potential input from by greenhouses were low for the time period sampled, even following large precipitation events, suggesting field residues are not a main contributor of imidacloprid in the Sturgeon Creek and Lebo Drain watersheds.

The release of imidacloprid product or of effluent containing imidacloprid from greenhouses is prohibited. As the investigation progressed in 2017 and some greenhouses were found to release high levels of imidacloprid in the watersheds, Bayer CropScience approached the OGVG and a mitigation proposal was developed in collaboration with the Canadian Horticultural Council and CropLife Canada. The mitigation proposal was submitted to Health Canada in the fall of 2017 through the Mitigation Working Group formed as part of the Multi-Stakeholder Forum on Neonicotinoids. The mitigation strategy includes the use of tracer dye tests to ensure there is no loss of product from greenhouses to the environment. The mitigation strategy proposed in 2017 was further developed through the winter of 2018 and was distributed to OGVG members as a voluntary abatement plan. While there was some uptake, given the critical nature of the findings, OGVG elected to proceed with a pilot project to ground truth the mitigation strategy. The pilot project aimed to address 600 acres of greenhouse production in the study region with the aim of further refining a dye test protocol to ensure consistent application and the ability to verify findings. Bayer CropScience shared the 2019 monitoring results, still showing potential releases from greenhouses, with the OGVG in order for them to conduct further audits among their members.

In 2018, an industry-led Committee on Protected Agriculture Stewardship, chaired by CropLife Canada, was formed to address concerns regarding releases from greenhouses. Members of the committee included the Canadian Horticultural Council, Flowers Canada, the Canadian Nursery Landscape Association, Mushrooms Canada and the Cannabis Council of Canada, as well as registrant companies. Health Canada and Agriculture and Agri-Food Canada (AAFC) played an advisory role to this industry-led initiative. The Committee developed a greenhouse accreditation program as a risk mitigation for greenhouse releases. Further discussion of the mitigation of risks to aquatic invertebrates from the release of imidacloprid due to leaks in greenhouse recirculation systems is discussed in Section 3.3.5.17.

Field and urban uses in growing regions outside of the Prairies

The 2017–2019 data from Bayer CropScience for 18 sites within two kilometres downstream of greenhouses in the Lebo Drain and Sturgeon Creek watersheds (the main Lebo Drain site, LD2, LD5, LD7, LD8, LD9, LD10, LD11, LD12, LD14, RR1, the main Sturgeon Creek Site, SC3, SC4, SC5, SC6, SC8, and SC9) were excluded from further analysis of the risk to aquatic invertebrates because the high concentrations of imidacloprid in water were shown to be coming from greenhouses. Based on this information, the data from Environment and Climate Change Canada at the main Lebo Drain and Sturgeon Creek sites between 2012 and 2016 were also excluded, along with data from the Ministry of the Environment, Conservation and Parks in collaboration with Ontario Ministry of Agriculture, Food and Rural Affairs between 2015 and 2018, and Metcalfe et al., 2018 (PMRA# 2945668) at the main Lebo Drain site in 2016. The contribution of field uses of imidacloprid to water concentrations at these sites would be masked by releases from greenhouses. The monitoring data excluded from further analysis amounts to 743 samples from 18 sites between 2012 and 2019, for a total of 49 site-years.

Excluding the data from the Lebo Drain and Sturgeon Creek sites within two kilometres downstream of greenhouses, a total of 3502 samples were collected from 273 sites in Prince Edward Island, Nova Scotia, New Brunswick, Quebec, Ontario and British Columbia, for a total of 475 site-years of monitoring between 2005 and 2019. Imidacloprid was detected in 292 (61%) of the 475 site-years of available monitoring.

Acute risk in growing regions outside of the Prairies

Appendix X, Figure 3 (panel A) shows the maximum concentration of imidacloprid measured in each of the 475 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. Imidacloprid concentrations exceeded the acute effects metric of 0.54 µg/L in 11 (2%) of all 475 site-years, from eight (3%) out of 273 sites sampled. The eight sites were from seven watersheds. Twenty-one samples from these waterbodies exceeded the acute effects metric; the concentrations of imidacloprid exceeding the acute effects metric ranged from 0.54 µg/L to 7.77 µg/L. The RQs for the 21 samples ranged from 1.0 to 14; one sample had an RQ greater than 10; four samples had RQs between 5.0 and 10; seven samples had RQs between 2.0 and 4.9; and nine of the samples had RQs less than 2.0 (Appendix X, Table 10).

The acute risk to aquatic invertebrates was further characterized by examining the locations and some of the watershed characteristics where maximum concentrations exceeded the acute effects metric 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 eight sites (11 site-years in seven watersheds) showing concentrations of imidacloprid exceeding the acute effects metric is presented in Appendix X, Table 10.

Sites with concentrations of imidacloprid exceeding the acute effects metric tended to be in small, intensively cropped watersheds. Six of the seven watersheds were less than 100 km^2, and the cropped areas represented greater than 60% of the total watershed area (Appendix X, Table 10).

Three sites with exceedances of the acute effects metric were located in Quebec (Gibeault-Delisle Creek, Rousse Creek, and station 4 on Saint-Pierre Lake), four sites were located in Ontario (North Creek, Big Creek, Lebo Drain 4 and Lebo Drain 6) and one site was located in British Columbia (Nicomekl River, upstream site). The main crops grown in the watersheds in each of these sites are described below, by province:

- In Quebec, Gibeault-Delisle Creek is a very small watershed where potatoes occupy a large portion (21%) of the watershed, along with other crops such as vegetables (21%), corn (17%) and soybeans (17%). Orchards and vineyards occupy a large portion (12%) of the watershed of Rousse Creek, along with vegetable crops (18%), corn (12%), and soybeans (12%). Input of water and therefore of imidacloprid at the station 4 site on Saint-Pierre Lake would likely be from the southern shore of the lake because the channel, which has water from Lake Ontario, separates the sources of water from the north and south shore. Mixed crops, corn and soybeans are the main crops grown in the watersheds of the southern shore tributaries of Saint-Pierre Lake.
- In Ontario, corn (10%–15%) and soybeans (40%–60%) are the main crops grown in the North Creek and Big Creek watersheds. The field uses of imidacloprid that could have contributed to concentrations of imidacloprid in Lebo Drain sites LD4 and LD6 in 2017 include tomatoes and a smaller areas of winter wheat and soybean. The available use and rate information for imidacloprid on tomatoes, soybeans and wheat suggest that in the Lebo Drain watershed, use of imidacloprid on tomatoes may have been a greater contributor to the levels measured in water than use on row crops such as wheat or soybeans.
- In British Columbia, the main crops grown near the upstream site on the Nicomekl River in British Columbia are berries, nurseries and ornamentals. The upstream site had higher concentrations than the downstream site, indicating the main contributor to imidacloprid concentrations in the sampled section of the Nicomekl River is likely use on crops near the upstream site rather than on crops between the upstream and downstream sites (potatoes, vegetables, corn, berries). Additional monitoring data to further isolate the source of imidacloprid in the Nicomekl River were not available.

With the exception of Big Creek, where nine samples between mid-June and mid-October exceeded the acute effects metric, imidacloprid concentrations at the other seven sites exceeded the acute effects metric in one or two samples during the growing season. With the exception of three sites (Gibeault-Delisle Creek in Quebec, North Creek in Ontario and the Nicomekl River upstream site in British Columbia), concentrations of imidacloprid measured above the acute effects metric at the other five sites were not observed in more than one year.

Chronic risk in growing regions outside of the Prairies

Appendix X, Figure 4 shows the maximum 28-day average concentration of imidacloprid measured in each of the 475 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 imidacloprid exceeded the chronic effects metric of 0.16 µg/L in 17 (4%) of all 475 site-years, from 11 (4%) out of 273 sites sampled. Seven of the eight sites with concentrations exceeding the acute effects metric also had maximum 28-day concentrations exceeding the chronic effects metric. The highest 28-day moving average concentration of imidacloprid was 2.77 µg/L (Gibeault-Delisle Creek in 2006). A summary of the maximum 28-day moving average concentrations of imidacloprid and the associated chronic RQs in each of the 17 site-years from 11 sites is presented in Appendix X, Table 11.

The RQs for the 17 site-years of monitoring with maximum 28-day moving average concentrations above the chronic effects metric ranged from 1.2 to 17; two site-years had RQs of 17; five site-years had RQs between 3.0 and 5.9; two site-years had risk quotients between 2.0 and 2.9; and eight site-years had RQs less than 2.0 (Appendix X, Table 11).

The above chronic RQs are based on a no-observed-effect concentration. To further characterize the chronic risk, the lowest concentration of imidacloprid at which toxic effects on aquatic invertebrates were observed in the chronic mesocosm study, the LOEC, can be used. The 28-day time-weighted average mesocosm LOEC was 0.38 µg/L. At this concentration, significant effects on *Cloeon dipterum* abundance (adult and larvae) were observed (see Section 3.3.3.1, Revisions to Imidacloprid Effects Metrics). RQs calculated using the LOEC instead of the NOEC for the above-mentioned 17 site-years of monitoring ranged from to 0.5 to 7.3; two site-years had RQs above 7.0; six site-years had RQs between 1.0 and 2.2; and nine site-years had RQs less than 1.0 (Appendix X, Table 11).

The risk to aquatic invertebrates was further characterized by examining the locations and some of the watershed characteristics where the maximum 28-day average concentrations exceeded the chronic effects metric, 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 11 sites showing 28-day average imidacloprid concentrations above the chronic effects metric is presented in Appendix X, Table 11. The 11 sites were from eight watersheds; three of the sites were located within the Lebo Drain watershed in Ontario (a creek site, LD3, and two drainage ditch sites LD4 and LD6), and two sites were on the Nicomekl River in British Columbia.

Seven of the sites (five watersheds) with exceedances were in Ontario, two sites (two watersheds) were in Quebec, and two sites (one watershed) were in British Columbia (Appendix X, Table 11).

Sites with maximum 28-day moving average concentrations of imidacloprid exceeding the chronic effects metric tended to be in small, intensively cropped watersheds. The eight watersheds were less than 100 km^2, and the cropped areas represented greater than 60% of the total watershed area (Appendix X, Table 11).

Four of the 17 site-years with 28-day moving average concentrations of imidacloprid exceeding the chronic effects metric were from three waterbodies in areas where corn (10%–28%) and soybeans (33%–60%) represent a large portion of the watershed (Big Creek, North Creek (two site-years) and McKillop Drain, in Ontario; Appendix X, Figure 4 and Table 11). While imidacloprid is typically not used on corn, it is used on soybeans and the crops are regularly rotated. Three of the 17 site-years were from Gibeault-Delisle Creek. As mentioned previously, this is a very small watershed where potatoes occupy a large portion of the watershed, along with other crops such as vegetables, corn and soybeans. Four site-years were from watersheds where orchards and vineyards occupy a large portion of the watershed: Two Mile Creek in Ontario, and Rousse Creek in Quebec. Rousse Creek also has a large portion of the watershed represented by vegetable crops, corn, and soybeans.

Three of the site-years with 28-day moving average concentrations of imidacloprid exceeding the chronic effects metric were from sites in the Lebo Drain watershed in 2017: LD3, LD4 and LD6. The field uses of imidacloprid that could be contributing to concentrations in these waterways include tomatoes and a smaller area of winter wheat and soybean. The available use and rate information for imidacloprid on tomatoes, soybeans and wheat suggest that in the Lebo Drain watershed, use of imidacloprid on tomatoes may have been a greater contributor to the levels measured in water than use on row crops such as wheat or soybeans.

Three of the site-years with 28-day moving average concentrations of imidacloprid exceeding the chronic effects metric were from sites on the Nicomekl River: two site-years at the upstream site, and one site-year at the downstream site. The upstream site had higher concentrations than the downstream site, indicating the main contributor to imidacloprid concentrations in the sampled section of the Nicomekl River is likely use on crops near the upstream site (berries, nurseries, ornamentals) rather than on crops between the upstream and downstream sites (potatoes, vegetables, corn, berries). Additional monitoring data to isolate the source of imidacloprid in the Nicomekl River were not available.

Out of the eight sites with maximum 28-day average concentrations of imidacloprid exceeding the chronic effects metric, one site in Quebec, two sites in Ontario and one site in British Columbia had exceedances in more than one year of monitoring (Quebec: Gibeault-Delisle Creek (three site-years); Ontario: Two Mile Creek (three site-years), North Creek (2 site-years); British Columbia: Nicomekl River, upstream site (two site-years) (Appendix X, Table 11). The other five sites did not show 28-day average concentrations of imidacloprid above the chronic effects metric in more than one year of monitoring.

3.3.3.4.2.3 Potential reductions in imidacloprid concentrations

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

Many of the exceedances of the acute and chronic effects metrics were observed in waterbodies associated with use on soybeans, tomatoes, orchards and vineyards. As a result of the pollinator re-evaluation decision for imidacloprid (RVD2019-06), use on pome fruits and stone fruits has been cancelled, and only post-bloom application is allowed on some tree nuts. Soil application of imidacloprid on grapes is unchanged as a result of the pollinator re-evaluation, while foliar application on grapes can no longer occur during bloom. Soil application of imidacloprid for tomatoes has been cancelled as a result of the pollinator re-evaluation decision. 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 further reduce exposure to aquatic systems in Ontario and Quebec.

3.3.3.4.2.4 Overall observations based on monitoring

A detailed investigative monitoring study conducted in the Lebo Drain and Sturgeon Creek watersheds of Ontario between 2017 to 2019 demonstrated that the origin of high concentrations of imidacloprid measured in these two watersheds was release from greenhouses. While concentrations tended to decrease from 2017 to 2019 following efforts to fix leaks from greenhouses, there was continued evidence of input from greenhouses during the 2019 season. The monitoring data from sites downstream of greenhouses were excluded from analyses of risk to aquatic invertebrates because the contribution of field uses of imidacloprid to water concentrations at these sites would be masked by releases from greenhouses.

Excluding these data, imidacloprid concentrations measured in Canadian waterbodies rarely exceeded the acute effects metric (HC_5 of 0.54 µg/L). Concentrations of imidacloprid did not exceed the acute effects metric in waterbodies sampled in the Prairie Provinces. Imidacloprid concentrations exceeded the acute effects metric in 11 (2%) of the 475 site-years of monitoring, and in eight (3%) of the 273 sites sampled in Atlantic Canada, Quebec, Ontario and British Columbia. Twenty-one samples from these waterbodies exceeded the acute effects metric and the maximum RQ was 14. The RQs from nine of the 21 samples were less than 2.0.

Maximum 28-day average imidacloprid concentrations did not exceed the chronic effects metric in the Prairies. In areas outside of the Prairie Provinces, 11 (4%) of the 273 individual sites and 17 (4%) of the 475 available site-years of monitoring available had maximum 28-day average concentrations of imidacloprid in water that exceeded the chronic effects metric. The highest chronic RQ was 17; the chronic RQs were less than 3.0 in ten of the 17 site-years where exceedances of the chronic effects metric were observed. Further characterization using the mesocosm LOEC results in a maximum RQ of 7.3 and RQs of less than 1.0 for nine of the 17 site-years.

Waterbodies where maximum and 28-day average concentrations of imidacloprid exceeded the acute or chronic effects metrics tended to be in small and intensively cropped watersheds.

Many of the exceedances of the acute and chronic effects metrics were observed in waterbodies associated with use on soybeans, tomatoes, orchards and vineyards. With recent federal and provincial regulatory actions discussed above, concentrations of imidacloprid will likely decrease.

3.3.4 Uncertainties identified in the risk assessment

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

3.3.4.1 Community protectiveness and recovery

The quantitative risk characterization considered effects metrics based on estimated acute effects of lethality to sensitive species (HC_5) and a no-observed effects concentration (NOEC) for abundance of the most sensitive species 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 (refer to Appendix VII, Table 1), there is a reasonable degree of confidence in protectiveness of the effects metrics, specifically in this context.

It is acknowledged that aquatic invertebrate communities may recover from imidacloprid exposures. The effects metrics selected were based on responses in sensitive species. Recovery was not assessed in acute studies supporting the HC_5 effects metric. Recovery from effects at the LOEC in the mesocosm study were observed for combined adult and larval abundance of *Cloeon dipterum*, but was not established for the separate lifestages (note: mesocosms were enclosed). It is possible that populations recover, and that recolonization of affected habitats occurs over some period of time if and when exposure is reduced. 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.

3.3.4.2 Modelling

There are built in conservatisms in the modelling that may result in conservative EECs for some uses of imidacloprid. 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 90th 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 imidacloprid. For the uses of imidacloprid that were not modelled, the EECs for crops with similar rates within each 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 re-evaluation decision.

3.3.4.3 Monitoring

Regarding acute exposure, monitoring data likely underestimate short-term exposure to imidacloprid, 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 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 156 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 22 to 49 days. In 86% of cases, the time frames for the averages were within 3 days of the targeted 28-day period and in 96% 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 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 9.6 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 metric.

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

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 imidacloprid 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.

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 imidacloprid-treated fields. With the exception of targeted monitoring of Prairie wetlands in or adjacent to fields known to be planted with imidacloprid-treated seeds, the monitoring data available may not be reflective of the waterbodies with the highest potential exposure for imidacloprid. Some sites monitoring may have been in larger watersheds with relatively low imidacloprid 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 imidacloprid were discontinued (RVD2019-06) along with restrictions on other uses following the pollinator risk assessment. It is expected that these changes will reduce the levels of imidacloprid 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 imidacloprid-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.

3.3.4.4 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
The 24-hour modelled EECs were compared to an HC_5 generated with toxicity data derived primarily 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 effects metric is based on a 57-day mesocosm test with two applications 21 days apart. Significant effects on *Cloeon dipterum* abundance (adult and larvae) were observed at 0.38 µg a.i./L (28-day TWA).

Monitoring
Peak site-year measured concentrations were compared to an HC_5 generated with toxicity data derived primarily 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, many of the maximum site-year concentrations are not expected to reflect peak exposure concentration, although the likelihood increases with increased targeted sampling.

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 imidacloprid along 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.

3.3.5 Aquatic invertebrate 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 imidacloprid spray drift was identified (Section 3.3.3.3). Mitigation in the form of spray buffer zones is required for freshwater and marine habitats and is presented in Appendix XI.

Runoff of imidacloprid into surface waters can present an acute risk to aquatic invertebrates based on surface water modelling. Acute RQ values were up to 19 for foliar uses, up to 24 for in-furrow application at the highest application rate, up to 31 for soil drench application at the highest application rate and up to 5.6 for seed treatments. For marine invertebrates, acute RQs based on modelling only marginally exceeded the LOC; RQs were up to 1.5 for foliar applications, up to 2.0 for in-furrow uses, up to 2.6 for soil drench uses and up to 1.2 for seed treatments. Imidacloprid concentrations measured in waterbodies exceeded the acute effects metric for freshwater invertebrates in eight (3%) out of 273 sites sampled and in 11 (2%) of 475 site-years of data available from outside of the Prairies between 2005 and 2019. In the Prairie Provinces, none of the 4717 samples collected from 488 sites between 2014 and 2019 had imidacloprid concentrations exceeding the acute effects metric.

While runoff modelling and monitoring results indicate the potential for acute risks to aquatic invertebrates from some uses of imidacloprid, the potential for chronic risks is greater. A discussion of the chronic risk posed by use on individual crops is presented below. The mitigation measures required to reduce identified risks to aquatic invertebrates from chronic exposure are also expected to reduce the risks from acute exposure to acceptable levels.

3.3.5.1 Corn and soybeans

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).

Most of the approximately 2.55 million hectares of soybeans planted in Canada are in Ontario and Quebec (62%), followed by the Prairies (37%), based on 2018 data (Statistics Canada, 2021a; PMRA# 3195909).

Imidacloprid is registered for use on corn (field, seed, and sweet) as a seed treatment only, at rates of 13–48 g a.i./80 000 seeds for field corn and 67.2–250 g a.i./100 kg seed for sweet corn, depending on the pest. This is equivalent to 37.8 –56.8 g a.i./ha for field corn seed production only, 10.1–15.1 g a.i./ha for field corn including seed production, and 3.5–37.8 g a.i./ha for sweet corn.

Modelling for corn was done at the maximum allowable rate of 56.8 g a.i./ha for field corn for seed production. For freshwater invertebrates, the RQs from runoff modelling exceeded the LOC in Atlantic Canada (RQ of 4.4) and did not exceed or only marginally exceeded the LOC in other regional scenarios across Canada (RQs of 0.9 to 1.4). Similarly, for marine invertebrates, the RQs from modelling marginally exceeded the LOC in Atlantic Canada (RQ of 2.1) and did not exceed the LOC in other regional scenarios relevant for marine exposures (RQs up to 0.6).

Imidacloprid is registered as a seed treatment on soybean at rates of 6.25–125 g a.i./100 kg seed. This is equivalent to 35.6–157.5 g a.i./ha. Imidacloprid can also be used on soybeans as a foliar application after bloom (up to 3 applications of 24.4–49 g a.i./ha per year). When imidacloprid is used as a seed treatment on soybeans, additional application of any neonicotinoid via other methods is prohibited. Both seed treatment and foliar uses were modelled for surface water runoff. For freshwater invertebrates, seed treatment uses of soybean resulted in chronic RQs above the LOC (RQs of 3.4 to 9.4 across the country). For marine invertebrates, seed treatment uses of soybean resulted in chronic RQs not exceeding or only marginally exceeding the LOC in regional scenarios relevant for marine exposures (RQs up to 1.2).

Modelling of three foliar applications at 49.9 g a.i./ha per year to soybean resulted in RQs for freshwater invertebrates above the LOC (RQs of 10–18 in regional scenarios across the country except British Columbia, for which the RQ was 1.3). Modelling of three foliar applications at the minimum registered application rate of 24.4 g a.i./ha also resulted in RQs for freshwater invertebrates above the LOC (RQs of 4.9–8.8 in regional scenarios across the country except British Columbia, for which the RQ was 0.6). Estimated RQs for a single foliar application of 24.4 g a.i./ha were 2–3 for freshwater invertebrates, based on proportional adjustments of the modelling results for three foliar applications.

For marine invertebrates, the RQs from modelling of three foliar applications at 49.9 g a.i./ha to soybean resulted exceeded the LOC (RQs up to 8.5). The RQs from modelling of three foliar applications at 24.4 g a.i./ha were up to 4.2 for marine invertebrates.

The highest concentrations measured in waterbodies where most of the corn and soybeans are grown in Canada (mainly Eastern Canada) were consistent with the modelling results. Outside the Prairie Region, 298 site-years of data were from corn- and soybean-growing areas. In these areas, maximum 28-day average imidacloprid concentrations exceeded the chronic effects metric in four site-years. At one site, the maximum 28-day average concentration exceeded the chronic effects metric in more than one year of monitoring. The RQs for the four site-years in areas where corn and soybeans are grown were up to 17 (RQs were 1.2, 2.9, 5.2 and 17). These RQs are in the same range as those predicted by the water models. The maximum 28-day concentrations observed at some of the sites were near or exceeded the LOEC of 0.38 µg a.i./L for *Cloeon dipterum* abundance (adult and larvae), associated with the chronic effects metric (NOEC of 0.16 µg/L). Because there is very little reported use of imidacloprid on corn, the main contributor to levels in water in these waterbodies is likely coming from other crops in the watershed, like soybean, which has a maximum rate of application 2.8 times higher than the maximum application rate for corn (157.5 g a.i./ha for soybean compared to 56.8 g a.i./ha for field corn for seed production only). Concentrations in water are expected to increase if use on corn increases.

Because there is very little reported use of imidacloprid on corn, the monitoring data for imidacloprid in areas where corn is grown may not reflect a large contribution from use on corn. Clothianidin data from Ontario and Quebec, where most of the corn is grown in Canada, were used to estimate potential imidacloprid exposure if it were to be used more extensively on corn in this region. Clothianidin is not registered for use on soybeans, thus concentrations in waterbodies in the corn and soybean areas of these two provinces are likely mainly due to use on corn. The registered rate of clothianidin on field corn is up to 118.3 g a.i./ha, which is 2.1 times higher than the maximum application rate of imidacloprid on field corn for seed production only. Twenty-two site-years (16 sites in 12 watersheds) have maximum 28-day average concentrations of clothianidin exceeding the chronic effects metric for imidacloprid. The maximum 28-day concentrations of clothianidin in these 22 site-years range from 0.17µg/L to 0.7 µg/L. Using these concentrations with the imidacloprid chronic effects metric, the resulting maximum RQs range from 1.0 to 4.3 (the second highest RQ is 2.5).

The monitoring data from the Prairie Region did not indicate a concern for seed treatment use on corn or soybeans. Imidacloprid concentrations measured in flowing waterbodies, generally in Manitoba and Saskatchewan, draining watersheds where corn and soybeans are grown did not exceed the chronic effects metric. There was targeted sampling of two wetlands in fields known to be planted with imidacloprid-treated soybean seeds but no targeted sampling of wetlands in fields known to be planted with imidacloprid-treated corn seeds. The monitoring of other wetlands located across the agricultural areas of Manitoba, Saskatchewan and Alberta where neonicotinoids are commonly used as a seed treatment did not show concentrations exceeding the chronic effects metric.

Water monitoring cannot distinguish between the relative contribution of seed treatment and foliar application methods of imidacloprid on soybeans to imidacloprid concentrations in water. Modelling results indicate RQs from both seed treatment and foliar application to soybeans can exceed the LOC, more so for foliar applications.

Because the maximum RQs based on monitoring match the modelling results and some 28-day average concentrations are near or exceed the mesocosm LOEC in areas where most of the corn and soybeans are grown in Canada, the use of imidacloprid on corn and soybeans poses risks and requires mitigation. To mitigate the potential risk to aquatic invertebrates, the maximum registered rate for seed treatment of field corn (including seed corn production) has been reduced from 48 g a.i./80 000 seeds to 13 g a.i./80 000 seeds.

The maximum rate of application of imidacloprid 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 imidacloprid on sweet corn is expected to contribute less to levels in water compared to use on field corn. No change to the registered rates of imidacloprid on sweet corn seeds is required.

To mitigate the potential risk to aquatic invertebrates from uses of imidacloprid on soybeans, the maximum registered seed treatment rate of imidacloprid on soybeans has been reduced to 62.5 g a.i./100 kg seed. Furthermore, the maximum number of foliar applications of imidacloprid on soybeans per year has been reduced from three (3 × 49 g a.i./ha) to one (1 × 24.4 g a.i./ha).

The rate reductions on field corn and soybean seeds and the reduced number of foliar applications allowed per year on soybeans are expected to lower the potential input of imidacloprid in waterbodies from runoff to acceptable levels in areas where corn and soybeans are grown.

3.3.5.2 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).

Imidacloprid is registered on canola, rapeseed, and mustard as a seed treatment only. Modelling for oilseeds was done for canola, which accounts for 98% of national oilseed production, at a maximum application rate of 64.16 g a.i./ha. For freshwater invertebrates, the RQs based on modelling only marginally exceeded the LOC for scenarios in the Prairie Region (maximum RQs ≤ 1.3) but exceeded the LOC for scenarios from Ontario and Quebec (RQs of 17–36). For marine invertebrates, modelled RQs for the seed treatment use on canola resulted in chronic RQs exceeding the LOC (RQs up to 18).

Targeted and non-targeted water monitoring data reflecting seed treatment use of imidacloprid in the Prairie Region did not indicate a concern for chronic exposure. 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 for other regional scenarios in Canada, particularly 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 imidacloprid on oilseed crops in Ontario and Quebec is not expected to be a significant contributor to imidacloprid concentrations in water compared to its use on other crops more widely grown in the region. Crop rotation is expected to reduce contributions of imidacloprid compared to modelled EECs, which assumes annual applications over 50 years. Taking into consideration all the available information, the chronic risks to aquatic invertebrates associated with the use of imidacloprid as a seed treatment on oilseeds are acceptable in all regions of Canada.

3.3.5.3 Cereals (excluding corn)

Based on 2018 data for barley, wheat and oats, 94% of the approximately 14 million hectares of these cereals in Canada is in the Prairies. The area of these cereals in Ontario and Quebec represents approximately 3.5% (approximately 493 000 ha) and 1.6% (approximately 224 000 ha) of the area grown nationally, respectively (Statistics Canada, 2021a; PMRA# 3195909).

Imidacloprid is registered only as a seed treatment on barley, wheat and oats at rates of 10 – 30 g a.i./100 kg seed (equivalent to 5.4 – 52.5 g a.i./ha, depending on the crop). Modelling was conducted using the maximum rate of application on representative crops of barley (36.3 g a.i./ha) and wheat (52.5 g a.i./ha), which represent 90% of the cereal crops (excluding corn) in Canada (Statistics Canada, 2021a; PMRA# 3195909). The RQs from the modelling of regional scenarios in the Prairies, Ontario and Quebec marginally exceeded the LOC (RQs of 1.1 – 1.9). Spring wheat modelled in Atlantic Canada had the highest RQ of all scenarios modelled for the cereal crops (RQ of 3.8). For marine invertebrates, modelled RQs for the seed treatment use on cereals resulted in chronic RQs only marginally exceeding the LOC (RQs up to 1.8).

Targeted and non-targeted water monitoring data reflecting seed treatment use of imidacloprid in the Prairie Region did not indicate a concern for chronic exposure. In other areas of Canada, three sites (one watershed; three site-years) in areas where cereals are grown (9% of the watershed) maximum 28-day average concentrations of imidacloprid exceeded the chronic effects metric (maximum RQ up to 4.0). However, the sites with exceedances had a greater portion of the watershed represented by soybeans (40%), corn (20%) and tomatoes (11%), which can also be treated with imidacloprid. Outside the Prairies, imidacloprid use on cereals is likely not a main contributor to the measured concentrations in water because they are 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 imidacloprid as a seed treatment on barley, wheat and oats are acceptable.

3.3.5.4 Legumes/pulses (excluding soybeans)

Based on 2018 data for dry beans (excluding soybeans), chickpeas, faba beans, lentils and dry peas, more than 97% of the 3.3 million hectares grown in Canada are grown in the Prairies (Statistics Canada, 2021a; PMRA# 3195909). In contrast, 88% of the approximately 20 000 ha of fresh beans and peas are grown in Ontario and Quebec (Statistics Canada, 2021d; PMRA# 3195976).

Imidacloprid is registered as a seed treatment for use on a variety of legumes including dry and field beans, dry and field peas, Jackbean, chickpeas, fava beans and lentils. Modelling was done using the maximum rate of application for representative crops of field peas (246.25 g a.i./ha), fava beans (232.5 g a.i./ha) and chickpeas (96.88 g a.i./ha). For freshwater invertebrates, the RQs based on water modelling of field peas seed treatment exceeded the LOC (RQ of 4.6 in the Prairies, 2.7 in Ontario and 5.4 in Quebec). For fava bean seed treatments, the RQs from modelling did not exceed the LOC in the Prairies, Ontario and Quebec, but RQ was 4.4 in the Atlantic Region.

For chickpea seed treatments, the RQs did not exceed the LOC. For marine invertebrates, the RQs from modelling of field pea and fava bean seed treatments marginally exceeded the LOC, with maximum RQs of 2.6 in Quebec and 2.2 in the Atlantic Region, respectively.

Foliar applications are registered for legumes, except dry soybean (up to two applications of 48 g a.i./ha per year). When imidacloprid is used as a seed treatment, additional application via other methods like foliar application is prohibited within the same year. Modelling conducted for foliar applications on soybeans (3 applications of 49.9 g a.i./ha per year) was used to determine EECs in water from foliar use on legumes. For freshwater invertebrates, the estimated RQs for two foliar applications of 48 g a.i./ha on legumes, based on proportional adjustments of the modelling results for soybeans suggest that foliar use on legumes may exceed the LOC (estimated RQs up to 12). Estimated RQs for a single foliar application, adjusted proportionally based on three applications were approximately 6 in the Atlantic Region, and 3–4 in the Prairies, Ontario and Quebec.

For marine invertebrates, the estimated RQs for two foliar applications on legumes, adjusted proportionally based on three applications of 49.9 g a.i./ha on soybeans, suggest that foliar use on legumes may exceed the LOC (estimated RQs up to 5.5). Estimated RQs for a single foliar application, adjusted proportionally based on three applications, were up to approximately 3.

Targeted and non-targeted water monitoring data from the Prairie Region did not indicate a concern for chronic exposure. Monitoring data from other regions of Canada specific to use on legume crops (excluding soybeans) were not available to further characterize risks. The water monitoring data cannot distinguish between the contribution of different methods of application. However, the monitoring data from Prairie Region may not reflect a large contribution from foliar use of imidacloprid in the Prairies because use in that region is mainly as a seed treatment.

Based on the modelling, monitoring and crop information, risks to aquatic invertebrates from the seed treatment of legume crops are considered acceptable in the Prairie Region. Based on the modelling results for other regions of Canada, the LOC is exceeded for field peas in Ontario, Quebec and the Atlantic Region and for fava beans in the Atlantic Region (RQs ranged from 2.6–5.4). Field peas in Ontario and Quebec encompass only approximately 5700 ha and 3900 ha, respectively based on 2018 data (Statistics Canada, 2021d; PMRA# 3195976), and are grown as a rotation crop in areas where other major crops, such as corn and soybeans, are grown in the watersheds. No fava bean production was reported in the Atlantic Region in 2018 (Statistics Canada, 2021d; PMRA# 3195976). Taking into consideration the modelling, monitoring and crop information, the chronic risks from seed treatment use of imidacloprid on legumes (excluding soybeans, discussed with corn, above) are acceptable across Canada.

Based on modelling results, foliar application of imidacloprid on legumes poses risks and requires mitigation. To mitigate the potential risks to aquatic invertebrates, the maximum number of foliar applications for legumes (excluding soybeans) is reduced to one application of 48 g a.i./ha per season.

3.3.5.5 Vegetables (excluding potatoes)

Based on 2018 data, 85% of the 92 997 hectares of fresh vegetables planted in Canada were in Ontario and Quebec (Statistics Canada, 2021d; PMRA# 3195976).

Imidacloprid can be applied on vegetable crops using several application methods: seed treatment, soil drench, in-furrow or foliar applications. In a given year, imidacloprid can be applied on vegetables using only one method of application; additional applications of any neonicotinoid via other methods within the same year is prohibited.

Imidacloprid is registered as a seed treatment on a variety of vegetable crops at rates ranging from 0.012 to 0.3 g a.i./1000 seeds, equivalent to 0.2 to 140 g a.i./ha depending on the crop. The highest rate of application in grams of active ingredient per hectare is associated with lettuce (140 g a.i./ha).

The next highest rate is 93.2 g a.i/ha for carrots. Bunching onion seeds can be treated at a rate up to 58.8 g a.i./ha, while the rest of the vegetable seeds are treated at a rate of 50 g a.i./ha or less. Only one end-use product is registered for the treatment of vegetable seeds, Sepresto 75 WS (Registration Number 30972), which is a combination product with another neonicotinoid, clothianidin.

Modelling for spring wheat at a seed treatment rate of 52.47 g a.i./ha was used to estimate concentrations of imidacloprid from seed treatment use on vegetables. Based on regional scenarios for Ontario and Quebec, where most of the vegetables are grown in Canada, the estimated RQs for the highest seed treatment rate of 140 g a.i./ha for lettuce seeds, adjusted proportionally based on the modelling of 52.47 g a.i./ha slightly exceed the LOC for freshwater invertebrates (RQs of 3–4). For marine invertebrates, the estimated RQ for the highest seed treatment rate of 140 g a.i./ha was 1.9, based on the Quebec scenario.

Soil drench applications are registered on a variety of vegetables crop groups at rates of 80–520 g a.i/ha, depending on the crop. Modelling of soil drench application was conducted at rates of 86.6 g a.i./ha and 520 g a.i./ha for brassica vegetables as a representative crop. The RQs for soil drench uses exceeded the LOC for the highest rate of 520 g a.i./ha (RQs of 35–43 for freshwater invertebrates for Ontario and Quebec scenarios and RQ of 17 for marine invertebrates for the Quebec scenario). The RQs were less for the lower rate of application of 86.6 g a.i/ha (RQs of 5.9–7.5 for freshwater invertebrates and 2.9 for marine invertebrates).

In-furrow applications of imidacloprid are registered for various vegetable crop groups at rates of 86.6–520 g a.i/ha, depending on the crop. In-furrow application on vegetables was modelled at rates of 100 g a.i./ha and 408 g a.i./ha for root and tuber vegetables and rates of 86.6 g a.i./ha and 520 g a.i./ha for brassica vegetables. The RQs for the higher rates of 480 g a.i./ha and 520 g a.i./ha exceeded the LOC (RQs up to 31 for freshwater invertebrates for Ontario and Quebec scenarios and up to 12 for marine invertebrates for the Quebec scenario). The RQs were less for the lower rates of application of 86.6 g a.i./ha and 100 g a.i./ha (RQs up to 5.1 for freshwater invertebrates for Ontario and Quebec and up to 2.1 for marine invertebrates for Quebec).

Foliar applications are registered on various vegetable crop groups at up to two or three applications of 48–49 g a.i./ha per year depending on the crop. Modelling was conducted for one, two and three foliar applications of 49 g a.i./ha per year on tomatoes. For freshwater invertebrates, the RQs for three applications were 14 for both Ontario and Quebec scenarios, they were 9.4–11 for two applications and 3.4–4.8 for a single application per year. For marine invertebrates, the RQ for the Quebec scenario was 6.73 for three applications, 4.6 for two applications and 2.3 for one application per year.

Thirty-six site-years of monitoring data were available for waterbodies in areas where vegetables are grown in Quebec, Ontario and British Columbia. Seven of these site-years were from sites in two small watersheds in the Leamington area of Ontario where the tomato fields (representing 7%–11% of the watersheds) were treated with imidacloprid at planting. Three site-years in one of the Leamington area watersheds had maximum 28-day average concentrations of imidacloprid exceeding the chronic effects metric (maximum RQs of 1.7–4.0). The use of imidacloprid on tomato fields in these two watersheds likely contributed to levels of imidacloprid in water; however, the concentrations reflect the use pattern prior to the pollinator re-evaluation decision, RVD2019-06, where soil applications to tomatoes were still allowed. Maximum 28-day average concentrations of imidacloprid in one watershed in British Columbia where imidacloprid was used on a small number of hectares in 2017 and 2018 did not exceed the chronic effects metric.

In vegetable-growing areas, three other sites (five site-years) in Quebec and British Columbia showed maximum 28-day average imidacloprid concentrations exceeding the chronic effects metrics (RQs of 1.6–17). At these sites, vegetable crops were grown in the watershed and represent 18%–21% of the area; however, a large amount of the watersheds was represented by potatoes (21%), soybeans (12%–17%) corn (8%–17%), orchards (12%) and berries (44%), which can also be treated with imidacloprid.

The relative contribution of the use on vegetable crops to the levels of imidacloprid measured in the waterbodies cannot be determined based on monitoring data. It is possible that use on vegetables contributes to concentrations in water, but there is also likely input coming from use on the other crops in the watersheds, in particular major crops such as potatoes, and soybeans. The potential contribution of method of application on vegetable crops also cannot be determined based on the monitoring data because neonicotinoid use information on vegetables was only available for some sites in British Columbia and Ontario. For these reasons, modelling results were used to evaluate the relative contributions of the different application methods on vegetables to imidacloprid concentrations in water.

The risks to aquatic invertebrates from the seed treatment uses of imidacloprid are considered acceptable based on the modelling results. For in-furrow, soil drench 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 potential risks, the maximum soil drench application rate is limited to 86.6 g a.i./ha and the maximum in-furrow application rate is limited to 100 g a.i./ha. Foliar application is limited to a single application of 48 or 49 g a.i./ha per season, depending on the crop/rate combination.

The reductions in the rates of application for treated seeds, soil drench and in-furrow applications and the reduction in the number of foliar applications are expected to lower input from runoff of imidacloprid into waterbodies to acceptable levels in areas where vegetables are grown.

3.3.5.6 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).

Imidacloprid is registered for use on potato as a seed piece treatment (up to 9.4 g a.i./100 kg seed, equivalent to a maximum of 280 g a.i./ha), soil application (drench at up to 288 g a.i./ha or in-furrow at up to 480 g a.i./ha), or foliar application (up to 3 applications of 49 g a.i./ha per year). When imidacloprid is applied to potatoes using one method (seed piece, soil or foliar application), additional treatment of any other neonicotinoid via another application method is prohibited.

Modelling was conducted for seed piece application at 280 g a.i./ha, in-furrow application at 100 and 480 g a.i./ha and foliar application at one, two and three applications of 49 g a.i./ha per year. The modelling RQs for seed piece treatment did not exceed the LOC for freshwater or marine invertebrates (RQs <1). The RQs from in-furrow application at 480 g a.i./ha exceeded the LOC (RQs of up to 16 for freshwater invertebrates and up to 7.9 for marine invertebrates). The RQs for in-furrow application at 100 g a.i./ha exceeded the LOC but to a lesser extent (RQ of 3.4 for freshwater invertebrates and up to 1.7 for marine invertebrates). The RQs from three foliar applications exceeded the LOC (RQs up to 19 for freshwater invertebrates and up to 9.4 for marine invertebrates. Two foliar applications resulted in RQs of up to 14 for freshwater invertebrates and up to 7 for marine invertebrates, while RQs from a single foliar application were up to 7.5 for freshwater invertebrates and up to 3.6 for marine invertebrates.

Modelling for soil drench applications on brassica vegetables at 520 g a.i./ha was used to determine EECs in water from soil drench use on potatoes at 288 g a.i./ha. The estimated RQs for soil drench application (proportionally adjusted based on modelling of 520 g a.i./ha) exceed the LOC. For freshwater invertebrates, the estimated RQs were 18–28 for all scenarios except British Columbia, where the estimated RQ was 2.4). For marine invertebrates, the estimated RQs were up to 14.

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 imidacloprid did not exceed the chronic effects metric but use of imidacloprid was not confirmed. Outside the Prairies, there were 72 site-years of monitoring data from areas where potatoes were grown, of which 52 had potatoes as a main crop. At two sites in British Columbia where imidacloprid was reported to be applied to potato seed pieces in some of the fields in the watersheds in 2018, 28-day concentrations did not exceed the LOC. One site (three site-years) in Quebec showing a maximum 28-day concentration of imidacloprid exceeding the chronic effects metric had a significant portion of the watershed accounted for by potatoes (21%).

It also had other crops in the watershed, such as corn (17%), soybeans (17%) and vegetables (21%), which can also be treated with imidacloprid. The RQs based on monitoring for this site were 1.6–17.

In Prince Edward Island, where potatoes are the main crop grown, imidacloprid concentrations in waterbodies were low. However, the neonicotinoid clothianidin was detected more frequently and at higher concentrations than imidacloprid, suggesting that it was used more than imidacloprid on potatoes in that area. Clothianidin data were therefore used to estimate potential imidacloprid exposure if it were to be used more extensively in this region. Three site-years from two waterbodies in Prince Edward Island have maximum 28-day average concentrations of clothianidin exceeding the chronic effects metric for imidacloprid (0.275 and 0.433 µg/L in the Huntley River in 2017 and 2018 and 0.68 µg/L in the Wilmot River in 2017). Using these concentrations with the imidacloprid chronic effects metric, the resulting maximum RQs are 1,7, 2,7 and 4.3. The maximum registered rate of application of clothianidin on potatoes is 381 g a.i./ha, which is less than the maximum registered rate of imidacloprid on potatoes. Overall, the monitoring data in potato-growing areas indicate possible concern for exceedances of the chronic effects metric.

The highest concentrations of imidacloprid (and 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 imidacloprid 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). Application of imidacloprid on potatoes using soil drench or foliar spray was not reported. Aside from the above findings, monitoring data cannot distinguish the relative contribution of the four different application methods on potatoes to imidacloprid concentrations in water. Therefore, modelling results were used to evaluate the relative contributions.

The modelling results described above indicate that in-furrow, soil drench and foliar applications of imidacloprid on potatoes are expected to result in higher imidacloprid levels in water compared to seed piece treatment. Based on the modelling results and the available monitoring and crop use information, the risks from the use of imidacloprid on potatoes by seed piece treatment are considered acceptable. As mentioned above, available use information indicates soil drench and foliar spray are not common methods of application of imidacloprid on potatoes. Therefore, the water monitoring data may not reflect potential concentrations associated with runoff following use of these methods of application. Based on the magnitude of the modelling RQs and the large area of production nationally, in-furrow, soil drench and foliar applications may pose risks to freshwater and marine invertebrates and require mitigation. To mitigate these risks, the maximum rate of application for in-furrow use on potatoes is limited to 100 g a.i./ha, the number of foliar applications on potatoes is limited to one at up to 49 g a.i./ha per season and the application of imidacloprid on potatoes via soil drench is cancelled.

The reduction in the rate of application for in-furrow use, the reduction in the number of foliar applications and the cancellation of soil drench use are expected to reduce input of imidacloprid from runoff into waterbodies to acceptable levels in areas where potatoes are grown.

3.3.5.7 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).

Imidacloprid is registered for use on grapes as a sub-surface side dress or hill drench (at 1.8–2.88 g a.i./100 m of row, equivalent to 100–480 g a.i./ha) or as a foliar application (up to 2 applications of 48 g a.i./ha per season). In a given year, imidacloprid can be applied on grapes using only one method of application; additional applications of any neonicotinoid via other methods on grapes within the same year is prohibited.

Risk quotients from runoff modelling of soil application at 480 g a.i./ha marginally exceeded the LOC for freshwater invertebrates (RQs up to 1.1) and did not exceed the LOC for marine invertebrates (RQs < 1). The RQs for two foliar applications of 48 g a.i./ha per year were a maximum of 3.9 for freshwater invertebrates and a maximum of 1.7 for marine invertebrates.

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 imidacloprid exceeded the chronic effects metric at only two sites (four site-years) in Ontario and Quebec (maximum RQs of 1.2–4.4).

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, stone fruits and some tree nuts has been cancelled as a result of the pollinator re-evaluation decision for imidacloprid (RVD2019-06), the use of imidacloprid in these two watersheds is expected to decrease.

The risks to aquatic invertebrates from soil and 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.

3.3.5.8 Berries

Based on 2018 data, lowbush and highbush blueberries make up the majority (84%) of the total berry crop in Canada (approximately 91 500 ha). Lowbush blueberry production is almost exclusively in Quebec and the Atlantic provinces while highbush blueberry production is predominantly (92%) in British Columbia. Approximately 58% of the caneberries grown in Canada are in British Columbia (approximately 2200 ha nationally, based on raspberry and blackberry data). Of the remaining approximately 12 600 ha of other berry crops, the majority are grown in Ontario/Quebec (61%) and British Columbia (20%; Statistics Canada, 2021c; PMRA# 3195975).

The registered uses of imidacloprid on berries have changed as a result of the pollinator re-evaluation decision, RVD2019-06. Following this decision, imidacloprid is registered for use only as a foliar spray on Crop Groups 13A (cane berries), 13B (bush berries), 13F (small fruit vine excluding grape) and 13G (low growing berries). Up to two or three post-bloom applications at a rate of 42–112 g a.i./ha are currently allowed. For woody berries, post-bloom application is only allowed with renovation (cutting back of old growth after harvest is required).

Modelling for blueberries (one, two and three applications of 42 g a.i./ha per year) and raspberries (one, two and three applications of 112 g a.i./ha per year) was done to represent foliar use of imidacloprid on all berry crops. For freshwater invertebrates, the RQs based on modelling of three applications exceed the LOC, with higher RQs in regional scenarios from Eastern Canada and the Atlantic Regions (RQs of 26–31 for raspberries and 11–19 for blueberries). The RQs were lower in British Columbia where most caneberries and highbush blueberries are grown (RQ of 4.8 for raspberries and 1.8 for blueberries). The RQs for one application in Eastern Canada and the Atlantic Region were 11–12 for raspberries and 4–8.1 for blueberries but were lower in British Columbia (2.3 for raspberries and <1 for blueberries).

For marine invertebrates, the RQs for three applications were up to 15 for raspberries and up to 9.1 for blueberries in Eastern Canada and the Atlantic Region while in British Columbia, the RQs were 2.3 for raspberries and <1 for blueberries. The RQs for one application were up to 5.8 (1.1 in British Columbia) for raspberries and up to 3.9 (<1 in British Columbia) for blueberries.

Estimated RQs for two applications at 84 g a.i./ha for use on bushberries other than blueberries, proportionally adjusted based on modelling for two applications at 42 g a.i./ha, exceed the LOC for freshwater invertebrates in Eastern Canada and the Atlantic Region (estimated RQs 15–26) but were less in British Columbia (estimated RQ of 2.8). For marine invertebrates, the RQs were up to 12 (2.3 in British Columbia) for raspberries and up to 8.1 (<1 in British Columbia) for blueberries.

Water monitoring data in areas where berries represent a large portion of the watershed were available from British Columbia, but not from Quebec and Atlantic Canada. Imidacloprid was used on blueberries in watersheds from British Columbia sampled in 2017 and 2018 (PMRA# 2842180, 3168173). Three site-years (two sites) from one watershed where imidacloprid was used on blueberries had maximum 28-day average concentrations of imidacloprid exceeding the chronic effects metric (RQs of 1.7–2). The source of imidacloprid in this watershed is difficult to pinpoint because sampling at a site upstream of the imidacloprid-treated blueberry fields had higher concentrations. Other crops which can be treated with imidacloprid, like potatoes, vegetables, corn, ornamentals and nurseries, could have contributed to levels in water. Because the use on ornamentals has been restricted to outdoor coniferous evergreens and ornamental grasses as a result of the pollinator re-evaluation decision for imidacloprid (RVD2019-06), the use of imidacloprid on ornamentals and nurseries in this watershed is expected to decrease.

Based on runoff modelling results and monitoring information for British Columbia, where most of the highbush blueberries and cane berries are grown in Canada, the risks to aquatic invertebrates from post-bloom foliar application of imidacloprid on highbush blueberries and cane berries are acceptable.

Based on the modelling results for Atlantic provinces and Quebec, where most of the lowbush blueberries are grown in Canada, foliar application to lowbush blueberries poses a risk to aquatic invertebrates and requires mitigation. Lowbush blueberries are grown in highly intensive regions of Eastern Canada.

The normal production practices include a two-year production cycle, with application of imidacloprid allowed during the renovation year, which occurs every other year. Given this information, the magnitude of the modelled RQs, and the size of area grown, a localized risk has been identified, therefore, foliar application of imidacloprid on lowbush blueberries is cancelled.

While the modelled RQs are high, the area of production of low-growing berry crops and small fruit vine berries other than grapes is small across Canada (approximately 3900 ha reported for strawberries in 2018 (Statistics Canada, 2021c; PMRA# 3195975). The size of low-growing berry farms is likely small, based on the number of strawberry-growing producers in Ontario (675) and Quebec (507) (Greenhouse Canada, 2020; PMRA# 3196400, Government of Quebec, 2020; PMRA# 3196322, respectively). The risks to aquatic invertebrates from the foliar use of imidacloprid on low-growing berries and small fruit vine berries excluding grapes are considered acceptable.

3.3.5.9 Turf

Imidacloprid is registered for use as a foliar spray or a granular application on a variety of turf areas including golf courses and sod farms, but also home lawns, business and office complexes, shopping complexes, multi-family residential complexes, airports, cemeteries, parks, playgrounds and athletic fields. A single foliar application of 281.25 g a.i./ha or a single granular application of 280 g a.i./ha is allowed. For both methods of application, irrigation or rainfall (5–10 mm) is required after application. PRVD2016-20 recommended the timeframe for irrigation or rainfall following application to be reduced from 24 hours to 12 hours.

RQs based on runoff modelling of regional scenarios across Canada exceeded the LOC (RQs of 1.1 – 15, with RQs above 10 in scenarios from British Columbia, Ontario, Quebec and the Atlantic Region). There is insufficient water monitoring data linked to use on turf to characterize the risk using monitoring data.

The area of production for all turf uses of imidacloprid is unknown. However, 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 registered rate of 280–281.25 g a.i./ha and mitigation for foliar and granular application on turf is required. Because there is no other registered rate of application, the foliar and granular applications of imidacloprid on turf are cancelled.

3.3.5.10 Outdoor ornamentals

As a result of the pollinator re-evaluation, soil applications of imidacloprid to outdoor ornamentals have been limited to coniferous evergreens and ornamental grasses to mitigate risks to pollinators (RVD2019-06). A single application of 280 g a.i./ha per season is allowed.

Modelling of imidacloprid use on coniferous evergreens and ornamental grasses was not conducted due to high variability in the crop characteristics and the lack of modelling scenarios.

There is insufficient water monitoring data linked to use on ornamental evergreens and ornamental grasses to characterize the risk using monitoring data.

The relatively small scale (low intensity of production) of coniferous evergreens and ornamental grass production in a watershed is expected to limit the overall contributions of these sources to imidacloprid concentrations in water. Furthermore, it is unlikely that entire outdoor nurseries would be dedicated to evergreens and grasses. Based on these considerations, the risks associated with the soil application of imidacloprid on coniferous evergreens and ornamental grasses are considered acceptable.

3.3.5.11 Tree nuts

Imidacloprid is registered for use as a post-bloom foliar spray on beechnuts, brazil nuts, butternuts, cashews, filberts (hazelnuts), hickory nuts, macadamia nuts, pecans, pistachios, and walnuts at up to two airblast applications of 48–55.2 g a.i./ha, depending on the pest.

Tree nut production in Canada is limited, with a relatively small number of hectares grown.

Modelling for grapes (two applications of 48 g a.i./ha per year) was used as a surrogate for foliar application on tree nuts. The RQs for two foliar applications of 48 g a.i./ha were a maximum of 3.9 for freshwater invertebrates and a maximum of 1.7 for marine invertebrates.

Monitoring data (43 site-years) were available for watersheds where orchards represent an important portion of the watershed in Ontario, Quebec and British Columbia. Maximum 28-day average concentrations of imidacloprid exceeded the chronic effects metric at only two sites (four site-years) in Ontario and Quebec (maximum RQs of 1.2–4.4). The watersheds also contained vineyards, or other crops such as vegetables, soybeans and corn, which can also be treated with imidacloprid. Furthermore, the monitoring data from watersheds in areas with orchards would reflect use of imidacloprid prior to the pollinator re-evaluation decision (RVD2019-06) to cancel use on pome fruits, stone fruits and some tree nuts. As a result, the monitoring data may present conservative exposure estimates in some watersheds. The use of imidacloprid in these watersheds is expected to decrease.

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

3.3.5.12 Peanuts

Peanut production in Canada is limited, with only a few hundred tons of production per year (Peanut Bureau of Canada, 2020; PMRA# 3200793).

Imidacloprid is registered for use on peanuts as an in-furrow and transplant water soil drench application at a rate of 1.8 g a.i./100 of row (equivalent to 100–400 g a.i./ha). It is also registered as a foliar application at up to two applications of 48 g a.i./ha per year. When imidacloprid is applied to peanuts using one method (soil or foliar application), additional treatment via another application method is prohibited.

Modelling for root and tuber vegetables (at 100 and 408 g a.i./ha per year) was used as a surrogate for in-furrow application on peanuts. For freshwater invertebrates, the RQ for the Ontario and Atlantic Region scenarios were 9–25 for the higher rate of 480 g a.i./ha and were 2–5 for the lower rate of 100 g a.i./ha. For marine invertebrates, the RQ for the Atlantic Region was 12 for the rate of 480 g a.i./ha and 2.6 was for the rate of 100 g a.i./ha.

Modelling for brassica vegetables (at 86.6 and 520 g a.i./ha per year) was used as a surrogate for transplant water soil drench application on peanuts. For freshwater invertebrates, the RQ for the Ontario and Atlantic Region scenarios were 43–51 for the higher rate of 520 g a.i./ha and were 7.5–8.8 for the lower rate of 86.6 g a.i./ha. For freshwater invertebrates, estimated RQs for the rate of 400 g a.i./ha on brassica vegetables, proportionally adjusted based on modelling for the rate of 520 g a.i./ha, exceed the LOC for Ontario and the Atlantic Region (estimated RQs of 33–39). The RQs were 7.5–8.8 for the lower rate of 86.6 g a.i./ha. For marine invertebrates, the RQ for the Atlantic Region was 2.9 for 86.6 g a.i./ha and the was 14 RQ for 400 g a.i./ha (proportionally adjusted based on modelling of 520 g a.i./ha).

Modelling for tomatoes (one and two applications of 49 g a.i./ha per year) was used as a surrogate for foliar application on peanuts. For freshwater invertebrates, the RQs for the Ontario and Atlantic Region scenarios were 7–11 for two applications and 3.6–4.8 for a single application per year. For marine invertebrates, the RQ for the Atlantic Region scenario was 7 for two applications and 3.6 for a single application per year.

There is insufficient water monitoring data linked to use on peanuts to characterize the risk using monitoring data.

The modelled RQs for in-furrow, transplant water soil drench and foliar use of imidacloprid on peanuts exceed the LOC at the highest rate and maximum number of applications. However, the risks to aquatic invertebrates are considered acceptable given the very limited Canadian production.

3.3.5.13 Tobacco

Tobacco production in Canada has declined since the 1970s with less than 10 000 hectares being produced since 2014 (Tobacco Atlas, 2021; PMRA# 3200794).

Imidacloprid is registered for use on tobacco as an in-furrow application at 2.04 g a.i./100 m of row (equivalent to 113–453 g a.i./ha) and as a foliar spray at up to two applications of 48 g a.i./ha per year.

Modelling for root and tuber vegetables (at 100 and 408 g a.i./ha per year) was used as a surrogate for in-furrow application on tobacco. For freshwater invertebrates, the RQ for the Ontario scenario was 9 for the higher rate of 480 g a.i./ha and was 2 for the lower rate of 100 g a.i./ha. Exposure of marine invertebrates to imidacloprid use on tobacco is not expected because tobacco is grown in Ontario.

Modelling for tomatoes (one and two applications of 49 g a.i./ha per year) was used as a surrogate for foliar application on tobacco. For freshwater invertebrates, the RQ for the Ontario scenario was 11 for two applications and 4.8 for a single application per year.

There is insufficient water monitoring data linked to use on tobacco to characterize the risk using monitoring data.

Based on modelling results and the intensive area of production in southern Ontario, the risks to aquatic invertebrates are not acceptable at the registered rates of application and mitigation for in-furrow and foliar applications on tobacco is required. Because there is no other registered rate of application, the in-furrow application of imidacloprid on tobacco is cancelled. Foliar application is limited to a single application of 48 g a.i./ha per year.

The reduction in the number of foliar applications and the cancellation of in-furrow use are expected to reduce input of imidacloprid from runoff into waterbodies to acceptable levels in areas where tobacco is are grown.

3.3.5.14 Hops

Most of the 319 hectares of hops grown in Canada are in Ontario and Quebec (Statistics Canada, 2018; PMRA# 3200792).

Imidacloprid is registered for use as a foliar application on hops at up to two applications of 55.2 g a.i./ha per year. Modelling for grapes (two applications of 48 g a.i./ha per year) was used as a surrogate for foliar application on hops. The RQs for two foliar applications of 48 g a.i./ha were a maximum of 3.9 for freshwater invertebrates and a maximum of 1.7 for marine invertebrates.

There is insufficient water monitoring data linked to use on hops to characterize the risk using monitoring data.

Based on the modelling results and the small area of production, the risks to aquatic invertebrates from foliar applications of imidacloprid on hops are acceptable.

3.3.5.15 Herbs

Imidacloprid is registered for use on herbs as an in-furrow application at 1.44 g a.i/100 m of row (equivalent to 80–480 g a.i./ha) and as a foliar application at up to two applications of 48 g a.i./ha per year. When imidacloprid is applied to herbs using one method (soil or foliar application), additional treatment via another application method is prohibited.

Modelling of brassica vegetables was used to estimate risks from in-furrow application on herbs. For freshwater invertebrates, the RQs for a rate of 520 g a.i./ha were up to 36 and were up to 6.0 for a rate of 86.6 g a.i./ha. For marine invertebrates, the RQs for 520 g a.i./ha were up to 18 and were up to 2.9 for 86.6 g a.i./ha.

Modelling for tomatoes (one and two applications of 49 g a.i./ha per year) was used as a surrogate for foliar application on herbs. For freshwater invertebrates, the RQs for two applications were up to 14 and were up to 7.5 for a single application per year. For marine invertebrates, the RQ were up to 7.0 for two applications and up to 3.6 for one application per year.

There is insufficient water monitoring data linked to use on herbs to characterize the risk using monitoring data.

The estimated RQs based on modelling are high for the highest in-furrow rate of application and for foliar applications on herbs. However, the highest rate of application in grams of active ingredient per hectare for in-furrow use may not be used for all herb crops grown. It is unlikely that entire watersheds would be planted with herb crops. Given this, the risks to aquatic invertebrates from in-furrow and foliar applications of imidacloprid on herbs are acceptable.

3.3.5.16 Christmas trees

Christmas trees are produced over an area of approximately 24 000 hectares in Canada, from 1872 farms (Statistics Canada, 2021f; PMRA# 3200791).

Imidacloprid is registered as a foliar application on Christmas trees at up to two applications of 60 g a.i./ha per year. Modelling for grapes (two applications of 48 g a.i./ha) was used as a surrogate for foliar application on Christmas. The RQs for two foliar applications of 48 g a.i./ha were a maximum of 3.9 for freshwater invertebrates and a maximum of 1.7 for marine invertebrates.

There is insufficient water monitoring data linked to use on Christmas trees to characterize the risk using monitoring data.

Based on the modelling results and the limited scale of production, the risks to aquatic invertebrates from foliar applications of imidacloprid on Christmas trees are acceptable.

3.3.5.17 Greenhouses

Imidacloprid is registered for use in greenhouses as a soil drench or transplant tray plug drench Crop Group 5A (head and stem brassica crop sub-group) to be planted outdoors, lettuce to be transplanted outdoors, cucumbers, eggplant, pepper and tomato (mature plants), coniferous evergreens, ornamental grasses, cut flowers and indoor potted plants at 2.46–9.6 g /1000 plants for food crops and 0.002–0.003 g a.i./2.5 cm pot for non-food crops. The release of effluent containing imidacloprid into waterbodies is prohibited and is indicated on all imidacloprid product labels with greenhouse uses.

As described in Section 3.3.3.4.2.2, investigative monitoring data for neonicotinoids in the Leamington area of Ontario, where a large concentration of vegetable greenhouse operations are located, demonstrate that releases of high concentrations of imidacloprid from greenhouses are occurring.

In order to mitigate unintentional release of effluents, a third-party audit that will validate that measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds or other waters will be required for uses of imidacloprid in greenhouses.

3.3.6 Risk mitigation

3.3.6.1 Use restrictions

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

Crop	Method of application	Current rate	New requirement
All crops	Seed treatment	Not applicable	Prohibition of broadcast seeding Prohibition of disposal of treated seeds by over-seeding in headlands
Corn (field, seed, sweet)	Seed treatment	Field corn including seed production: 13 g a.i./80 000 seeds Field corn for seed production only: 48 g a.i./80 000 seeds Sweet corn: 67.2–250 g a.i./100 kg seed	Field corn (including field corn for seed production): 13 g a.i./80 000 seeds Sweet corn: 67.2 g a.i/100 kg seed
Soybeans	Seed treatment	62.5–125 g a.i./100 kg seed (equivalent to 35.6–157.5 g a.i./ha)	62.5 g a.i./100 kg seed
	Foliar	24.4–49 g a.i./ha, maximum three applications	24.4 g a.i./ha, one application only

Crop	Method of application	Current rate	New requirement
Oilseeds	Seed treatment	400–802 g a.i./100 kg seed (equivalent to 16–89.6 g a.i./ha, depending on crop)	No change to use pattern required
Cereals (excluding corn)	Seed treatment	10–30 g a.i./100 kg seed (equivalent to 5.38–52.47 g a.i./ha, depending on crop)	No change to use pattern required
Legumes/pulses (excluding soybean)	Seed treatment	62.5–125 g a.i./100 kg seed (equivalent to 18–246.25 g a.i./ha, depending on crop)	Excluding soybeans: No change to use pattern required
	Foliar	48 g a.i./ha, maximum two applications	Excluding soybeans: 48 g a.i./ha, only one application
Vegetables (tomato (transplant only), pepper (transplant only), carrot, leek, onion (bulb), onion (bunching), lettuce, broccoli, cabbage, cucumber, melon and squash)	Seed treatment	0.012–0.3 g a.i./1000 seeds (equivalent to 0.2–140 g a.i./ha, depending on crop)	Excluding brassica vegetables (such as broccoli and cabbage) and leafy vegetables (such as lettuce): No change to use pattern required Brassica vegetables (such as broccoli and cabbage) and leafy vegetables (such as lettuce): Continued registration for transplants only. Cancellation of direct seeding in field.
Crop Sub-Group 1B Root vegetables (except sugarbeet), Crop Sub-Group 1D Tuberous and corm vegetables (except potato), Crop Group 2 Leaves of root and tuber vegetables, Crop Group 4A Leafy greens (except Brassica), Crop Sub-Group 4B cardoon, celery, Chinese celery, celtuce, Florence fennel, rhubarb and Swiss chard, Crop Group 5 Brassica (cole) leafy vegetables	In-furrow	86.6–520 g a.i./ha (depending on crop)	Maximum of 100 g a.i./ha Cancellation of use. The use on these crops is cancelled due to the maximum application rate being reduced to 100 g a.i./ha or because the maximum allowable rate will be exceeded based on the row spacing for these crops.
Crop Sub-Group 1B Root vegetables (except sugarbeet), Crop Sub-Group 1D Tuberous and corm vegetables (except potato), Crop Group 2 Leaves of root and tuber vegetables, Crop Group 4A Leafy greens (except Brassica), Crop Sub-Group 4B cardoon, celery, Chinese celery, celtuce, Florence fennel, rhubarb and Swiss chard, Crop	Soil drench (post-plant soil drench)	80–520 g a.i./ha (depending on crop)	Maximum of 86.6 g a.i./ha Cancellation of use. The use on these crops is cancelled due to the maximum application rate being reduced to 86.6 g a.i./ha or because the maximum allowable rate

Crop	Method of application	Current rate	New requirement
Group 5 Brassica (cole) leafy vegetables			will be exceeded based on the row spacing for these crops
Crop Sub-Group 1B Root vegetables (except sugarbeet and ginseng), Crop Sub-Group 1D Tuberous and corm vegetables (except potato and sweet potato), Crop Group 2 Leaves of root and tuber vegetables, globe artichokes, Crop Group 4A Leafy greens (except Brassica, Crop Group 5 Brassica (cole) Leafy vegetables, Crop Group 8: Fruiting vegetables, eggplant and tomato	Foliar	48 g a.i./ha, maximum two applications	48 g a.i./ha, one application only
Tomato, Crop Group 5A Head and stem brassica crop sub-group	Foliar	49 g a.i./ha (with deltamethrin), maximum three applications	49 g a.i./ha (with deltamethrin), one application only
Potato	Seed piece treatment	6.2–9.4 g a.i./100 kg seed (equivalent to 72–280 g a.i./ha)	No change to use pattern required
	In-furrow	1.8–2.9 g a.i./100 m of row (equivalent to 100–480 g a.i./ha)	Maximum of 100 g a.i./ha Cancellation of use. The in-furrow use on potato is cancelled because the maximum allowable rate will be exceeded based on the row spacing for potato.
	Soil drench	288 g a.i./ha	Cancellation of soil drench uses
	Foliar	48 g a.i./ha, maximum two applications 49 g a.i./ha (with deltamethrin), maximum three applications	48 g a.i./ha, one application only 49 g a.i./ha (with deltamethrin), one application only
Grape	Soil drench (sub-surface side dress or hill drench)	1.8–2.88 g a.i./100 m of row (equivalent to 100–480 g a.i./ha)	No change to use pattern required
	Foliar	48 g a.i./ha, maximum two applications	No change to use pattern required
Crop Sub-Group 13A Caneberries	Foliar	42 g a.i./ha, maximum three applications, post-bloom Raspberries: 42–112 g a.i./ha, maximum three applications, post bloom For woody berries, post-	No change to use pattern required

Crop	Method of application	Current rate	New requirement
		bloom application is only allowed with renovation (cutting back of old growth after harvest is required).	
Crop Sub-Group 13B Bushberries (except lowbush blueberries)	Foliar	42–84 g a.i./ha, maximum two applications, post-bloom Highbush blueberries: 42 g a.i./ha (with deltamethrin), maximum three applications, post-bloom For woody berries, post-bloom application is only allowed with renovation (cutting back of old growth after harvest is required).	No change to use pattern required
Crop Sub-Group 13F Berry and small fruit vine excluding grapes	Foliar	48 g a.i./ha, maximum two applications, post-bloom For woody berries, post-bloom application is only allowed with renovation (cutting back of old growth after harvest is required).	No change to use pattern required
Crop Sub-Group 13G Berry and small fruit low growing berries	Foliar	42 g a.i./ha, maximum two applications, post-bloom For woody berries, post-bloom application is only allowed with renovation (cutting back of old growth after harvest is required).	No change to use pattern required
Lowbush blueberries	Foliar	42–84 g a.i./ha, maximum two applications, post-bloom 42 g a.i./ha (with deltamethrin), maximum three applications, post-bloom For woody berries, post-bloom application is only allowed with renovation (cutting back of old	Cancellation

Crop	Method of application	Current rate	New requirement
		growth after harvest is required).	
Beechnut, brazil nut, butternut, cashew, filbert (hazelnut), hickory nut, macadamia nut (bush nut), pecan, pistachio, walnut [black and English (Persian)]	Foliar	48–55.2 g a.i./ha, maximum two applications	No change to use pattern required
Peanut	In-furrow, transplant water soil drench	1.8 g a.i./100 m of row (equivalent to 100–400 g a.i./ha)	No change to use pattern required
	Foliar	48 g a.i./ha, maximum two applications	No change to use pattern required
Tobacco	In-furrow	2.04 g a.i./100 m of row (equivalent to 113–453 g a.i./ha)	Cancellation
	Foliar	48 g a.i./ha, maximum two applications	48 g a.i./ha, one application only
Hops	Foliar	55.2 g a.i./ha, maximum two applications	No change to use pattern required
Herbs	In-furrow	1.44 g a.i./100 m of row (equivalent to 80–480 g a.i./ha)	No change to use pattern required
	Foliar	48 g a.i./ha, maximum two applications	No change to use pattern required
Turf (home lawns, business and office complexes, shopping complexes, multi-family residential complexes, airports, cemeteries, parks, playgrounds, athletic fields, golf courses and sod farms)	Granular	280 g a.i./ha. one application only	Cancellation
	Foliar	281.25 g a.i./ha, one application only	Cancellation
Outdoor ornamentals (coniferous evergreens and ornamental grasses)	Soil drench	280 g a.i./ha	No change to use pattern required
Christmas trees	Foliar	60 g a.i./ha, maximum two applications	No change to use pattern required

Crop	Method of application	Current rate	New requirement
Greenhouse vegetables (transplant seedlings – brassica vegetables and mature plants – cucumber, eggplant, pepper and tomato) Greenhouse ornamentals (coniferous evergreens, ornamental grasses, greenhouse grown cut flowers and indoor potted plants)	Soil drench, transplant tray plug drench	Food crops: 2.46–9.6 g a.i./1000 plants Non-food crops: 0.002–0.003 g a.i./2.5 cm pot	Continued registration with additional measures to prevent the unintentional release of imidacloprid from greenhouses. In addition, there must be a third-party audit for greenhouses using closed recirculation system (for example, closed chemigation system) that validates the facility's closed recirculation systems and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

3.3.6.2 Spray buffer zones

Revised spray buffer zones based on the risks identified in this assessment will be required for the protection of freshwater and marine 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 imidacloprid products are provided in Appendix XI.

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.

4.0 Value assessment

Comments received in response to PRVD2016-20 did not result in a change in the value assessment. Therefore, the value assessment and conclusions are consistent with PRVD2016-20.

List of abbreviations

<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
µg	microgram(s)
a.i.	active ingredient
AAFC	Agriculture and Agri-Food Canada
ASAE	American Society of Agricultural and Biological Engineers
BBS	Breeding Bird Survey
B/S/S	Baggers/Sewers/Stacker
bw	body weight
CCME	Canadian Council of Ministers of the Environment
CETIS	Comprehensive Environmental Toxicology Information System
CI	confidence interval
cm	centimetre(s)
d	day(s)
DFOP	double first order in parallel
DMSO	dimethyl sulfoxide
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
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
EDE	estimated daily exposure
EEC	estimated environmental concentration
EFSA	European Food Safety Authority
EMWG	Environmental Monitoring Working Group
EP	end-use product
ERC	Evaluation Report
g	gram(s)
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
HCLA	High Contact Lawn Activities
HD_5	hazardous dose estimate that is assumed to be protective of 95% of species in a species sensitivity distribution
Hg	mercury
HTM	Hand-to-Mouth
IORE	Indeterminate Order Rate Equation model
IO	Incidental Oral
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_{25}	lethal concentration on 25% of the population
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LLFA	lower level fraction affected
$LLHC_5$	lower level HC_5
LOEC	lowest observed effect concentration
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantification
m	metre(s)
MASS	Macroinvertebrate Artificial Substrate Sampler
mg	milligram(s)
mL	millilitre(s)
M/L/A	Mixer/Loader/Applicators
mm	millimetre(s)
MOE	Margin of Exposure
N (n)	sample size
NA	not applicable
NC	not calculated
NI	no information
NOAEL	No Observable Adverse Effect Level
NOEC	no observed effect concentration
NOEL	no observed effect level
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OGVG	Ontario Greenhouse Vegetable Growers
OMAFRA	Ontario Ministry of Agriculture Food and Rural Affairs
PA	Post-application
PCP	Pest Control Product number
PCPA	Pest Control Products Act
PMRA	Pest Management Regulatory Agency
POCIS	polar organic chemical integrative samplers
PPE	Personal Protection Equipment
PRVD	Proposed Re-evaluation Decision
PSRD	Proposed Special Review Decision
PWC	Pesticides in Water Calculator
RD	Registration Decision
RIVM	Netherlands National Institute for Public Health and the Environment
RQ	risk quotient
RTI	Re-treatment interval
RVD	Re-evaluation Decision
SFO	single first order
sp.	species (singular)
spp.	species (plural)
SRD	Special Review Decision
SSD	species sensitivity distribution
SWCC	Surface Water Concentration Calculator

$t_{1/2}$	half-life
TFD	terrestrial field dissipation
TFSP	Task Force on Systemic Pesticides
TGAI	technical grade active ingredient
TTR	Turf Transferable Residue
TWA	time weighted average
ULFA	upper level fraction affected
$ULHC_5$	upper level HC_5
USEPA	United States Environmental Protection Agency
USEPA	EIIS USEPA's Ecological Incident Information System
w	weight
WIA	World Integrated Assessment
WSP	Wettable Power in Water Soluble Packaging

Appendix I Registered products containing imidacloprid in Canada

Table 1 Registered products containing imidacloprid in Canada[1] requiring label amendments[2]

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
28936	Technical grade active ingredient	Nufarm Agriculture Inc.	Nufarm Imidacloprid Technical	Solid	Imidacloprid 98%
32242	Manufacturing concentrate	Nufarm Agriculture Inc	Mallet 20 MC	Solution	Imidacloprid 20%
32243	Manufacturing concentrate	Nufarm Agriculture Inc	NUP-14001 MUP	Solution	Imidacloprid 19.19% Lambda-cyhalothrin 3.84%
32645	Technical grade active ingredient	Sharda Cropchem Limited	Imidacloprid Technical Insecticide	Solid	Imidacloprid 98.53%
24468	Technical grade active ingredient	Bayer CropScience Incorporated	Bay NTN 33893 Technical Insecticide	Solid	Imidacloprid 98%
25390	Manufacturing concentrate	Bayer CropScience Incorporated	Merit 75% Concentrate Insecticide	Wettable powder	Imidacloprid 75%
24094	Commercial	Bayer CropScience Incorporated	Admire 240 Flowable Systemic Insecticide	Suspension	Imidacloprid 240 g/L
25636	Commercial	Bayer CropScience Incorporated	Merit 60 WP Greenhouse And Nursery Insecticide	Wettable powder	Imidacloprid 60%
26124	Commercial	Bayer CropScience Incorporated	Gaucho 480 FL Insecticide	Suspension	Imidacloprid 480 g/L
27170	Commercial	Bayer CropScience Incorporated	Gaucho 600 FL Insecticide	Suspension	Imidacloprid 600 g/L
27357	Commercial	Bayer CropScience Incorporated	Intercept 60 WP Greenhouse Insecticide	Wettable powder	Imidacloprid 60%
29609	Commercial	Bayer CropScience Incorporated	Stress Shield For Cereals	Suspension	Imidacloprid 480 g/L
29610	Commercial	Bayer CropScience Incorporated	Stress Shield For Cereals and Soybeans	Suspension	Imidacloprid 480 g/L
29611	Commercial	Bayer CropScience Incorporated	Concept Liquid Insecticide	Suspension	Imidacloprid 75 g/L Deltamethrin 10 g/L
30513	Commercial	Bayer CropScience Incorporated	Maxforce Quantum Ant Bait	Paste	Imidacloprid 0.03%
30668	Commercial	Bayer CropScience Incorporated	Stress Shield 600	Suspension	Imidacloprid 600 g/L
30972	Commercial	Bayer CropScience Incorporated	Sepresto 75 WS	Wettable Powder	Imidacloprid 18.75% Clothianidin 56.25%
31068	Commercial	Bayer CropScience Incorporated	Acceleron IX-409 Insecticide Seed Treatment	Suspension	Imidacloprid 600 g/L

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
32234	Commercial	Bayer CropScience Incorporated	Quickbayt Granular Fly Bait	Granular	Imidacloprid 0.5% Muscalure 0.09%
32493	Commercial	Bayer CropScience Incorporated	Maxforce Fly Spot Bait	Granular	Imidacloprid 10% Muscalure 0.01%
32523	Commercial	Bayer CropScience Incorporated	Temprid Readyspray	Pressurized products	Imidacloprid 0.05% Beta-cyfluthrin 0.025%
32524	Commercial	Bayer CropScience Incorporated	Temprid SC	Suspension	Imidacloprid 21% Beta-cyfluthrin 10.5%
33014	Commercial	Bayer CropScience Incorporated	Credo SC Insecticide	Suspension	Imidacloprid 526 g/L
33305	Commercial	Bayer CropScience Incorporated	Quickbayt Spot Spray	Wettable granules	Imidacloprid 10% Muscalure 0.1%
29703	Commercial + Restricted	Bayer CropScience Incorporated	Confidor 200 SL	Solution	Imidacloprid 17.1%
30374	Technical grade active ingredient	Adama Agricultural Solutions Canada Limited	MANA Imidacloprid Technical	Solid	Imidacloprid 98.3%
28475	Commercial	Adama Agricultural Solutions Canada Limited	Alias 240 SC Systemic Insecticide	Suspension	Imidacloprid 240 g/L
30505	Commercial	Adama Agricultural Solutions Canada Limited	Sombrero 600 FS	Suspension	Imidacloprid 600 g/L
33562	Commercial	Sharda Cropchem Limited	Sofast Granular Fly Bait	Granular	Imidacloprid 0.5% Muscalure 0.1%
31375	Commercial + Restricted	Arborjet Incorporated	IMA- Jet	Solution	Imidacloprid 58.5 g/L
31479	Commercial + Restricted	Arborjet Incorporated	IMA-Jet 10	Solution	Imidacloprid 117 g/L
25127	Domestic	Elanco Canada Limited	Advantage 55 Flea and Lice Adulticide for Dogs 8 Weeks and Older Weighing between 11 and 25 Kg	Solution	Imidacloprid 9.1%
25128	Domestic	Elanco Canada Limited	Advantage 9 Flea Adulticide for Cats 8 Weeks and Older Weighing 4 Kg and Under	Solution	Imidacloprid 9.1%
25129	Domestic	Elanco Canada Limited	Advantage 18 Flea Adulticide for Cats 8 Weeks and Older Weighing Over 4 Kg	Solution	Imidacloprid 9.1%
25130	Domestic	Elanco Canada Limited	Advantage 10 Flea and Lice Adulticide for Dogs 8 Weeks and Older Weighing 4.5kg & Under	Solution	Imidacloprid 9.1%

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
25131	Domestic	Elanco Canada Limited	Advantage 100 Flea and Lice Adulticide for Dogs 8 Weeks and Older Weighing More Than 25 Kg	Solution	Imidacloprid 9.1%
25132	Domestic	Elanco Canada Limited	Advantage 20 Flea and Lice Adulticide for Dogs 8 Weeks and Older Weighing Between 4.6 and 11 Kg	Solution	Imidacloprid 9.1%
27581	Domestic	Elanco Canada Limited	Advantage II Small Dog	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27582	Domestic	Elanco Canada Limited	Advantage II Large Dog	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27583	Domestic	Elanco Canada Limited	Advantage II Medium Dog	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27584	Domestic	Elanco Canada Limited	Advantage II Extra Large Dog	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27585	Domestic	Elanco Canada Limited	Advantage II small Cat/Rabbit/Ferret	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27586	Domestic	Elanco Canada Limited.	Advantage II large Cat/Rabbit	Solution	Imidacloprid 9.1% Pyriproxifen 0.46%
27658	Domestic	Elanco Canada Limited	K9 Advantix 10 Flea, Tick, Mosquito, and Lice Adulticide	Liquid	Imidacloprid 8.8% Permethrin 44%
27659	Domestic	Elanco Canada Limited	K9 Advantix 100 Flea, Tick, Mosquito, and Lice Adulticide	Liquid	Imidacloprid 8.8% Permethrin 44%
27660	Domestic	Elanco Canada Limited	K9 Advantix 55 Flea, Tick, Mosquito, and Lice Adulticide	Liquid	Imidacloprid 8.8% Permethrin 44%
27661	Domestic	Elanco Canada Limited	K9 Advantix 20 Flea, Tick, Mosquito, and Lice Adulticide	Liquid	Imidacloprid 8.8% Permethrin 44%
29777	Domestic	Elanco Canada Limited	K9 Advantix II Small Dog	Solution	Imidacloprid 8.8% Pyriproxifen 0.44% Permethrin 44%
29778	Domestic	Elanco Canada Limited	K9 Advantix II Medium Dog	Solution	Imidacloprid 8.8% Pyriproxifen 0.44% Permethrin 44%
29779	Domestic	Elanco Canada Limited	K9 Advantix II Extra Large Dog	Solution	Imidacloprid 8.8% Pyriproxifen 0.44% Permethrin 44%
29780	Domestic	Elanco Canada Limited	K9 Advantix II Large Dog	Solution	Imidacloprid 8.8% Pyriproxifen 0.44% Permethrin 44%
31517	Domestic	Elanco Canada Limited.	Advantage II Kittens	Liquid	Imidacloprid 9.1% Pyriproxifen 0.46%
31307	Domestic	Fusion Animal Health Incorporated	Primidacide <4 Kg	Solution	Imidacloprid 9.1%
31308	Domestic	Fusion Animal Health Incorporated	Primidacide <4.5 Kg	Solution	Imidacloprid 9.1%
31309	Domestic	Fusion Animal Health Incorporated	Primidacide 4.6-11 Kg	Solution	Imidacloprid 9.1%

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
31310	Domestic	Fusion Animal Health Incorporated.	Primidacide >4 Kg	Solution	Imidacloprid 9.1%
31311	Domestic	Fusion Animal Health Incorporated	Primidacide >25 Kg	Solution	Imidacloprid 9.1%
31312	Domestic	Fusion Animal Health Incorporated	Primidacide 11-25 Kg	Solution	Imidacloprid 9.1%
33626	Domestic	Fusion Animal Health Incorporated	Primidacide Flea & Tick For Dogs Under 4.5KG	Liquid	Imidacloprid 8.8% Permethrin 44%
33627	Domestic	Fusion Animal Health Incorporated	Primidacide Flea & Tick For Dogs 4.6-11kg	Liquid	Imidacloprid 8.8% Permethrin 44%
33628	Domestic	Fusion Animal Health Incorporated	Primidacide Flea & Tick For Dogs 11-25kg	Liquid	Imidacloprid 8.8% Permethrin 44%
33629	Domestic	Fusion Animal Health Incorporated	Primidacide Flea & Tick For Dogs 25kg And Over	Liquid	Imidacloprid 8.8% Permethrin 44%
31507	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 9	Solution	Imidacloprid 9.1%
31508	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 10	Solution	Imidacloprid 9.1%
31509	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 18	Solution	Imidacloprid 9.1%
31510	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 55	Solution	Imidacloprid 9.1%
31511	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 100	Solution	Imidacloprid 9.1%
31512	Domestic	Brite Ridge Pharmaceuticals Incorporated	Barrier 20	Solution	Imidacloprid 9.1%
31980	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Cats 4 Kg and Under	Solution	Imidacloprid 9.1%
31982	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Dogs 4.5 Kg and Under	Solution	Imidacloprid 9.1%
31983	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Dogs Between 4.6 And 11 Kg	Solution	Imidacloprid 9.1%
31984	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Cats Over 4 Kg	Solution	Imidacloprid 9.1%
31985	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Dogs Over 25 Kg	Solution	Imidacloprid 9.1%
31986	Domestic	Wellmark International	Zodiac Infestop Topical Solution For Dogs Between 11 And 25 Kg	Solution	Imidacloprid 9.1%

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
32567	Domestic	Virbac Corporation	Preventic Topical Solution Extra Large Dog	Liquid	Imidacloprid 8.8% Permethrin 44%
32573	Domestic	Virbac Corporation	Ectoshield Topical Solution Medium And Large Cat	Solution	Imidacloprid 9.1%
32574	Domestic	Virbac Corporation	Ectoshield Topical Solution Small Cat	Solution	Imidacloprid 9.1%
32581	Domestic	Virbac Corporation	Ectoshield Topical Solution Small Dog	Solution	Imidacloprid 9.1%
32584	Domestic	Virbac Corporation	Ectoshield Topical Solution Extra Large Dog	Solution	Imidacloprid 9.1%
32585	Domestic	Virbac Corporation	Ectoshield Topical Solution Medium Dog	Solution	Imidacloprid 9.1%
32586	Domestic	Virbac Corporation	Preventic Topical Solution Large Dog	Liquid	Imidacloprid 8.8% Permethrin 44%
32588	Domestic	Virbac Corporation	Preventic Topical Solution Medium Dog	Liquid	Imidacloprid 8.8% Permethrin 44%
32589	Domestic	Virbac Corporation	Preventic Topical Solution Small Dog	Liquid	Imidacloprid 8.8% Permethrin 44%
32590	Domestic	Virbac Corporation	Ectoshield Topical Solution Large Dog	Solution	Imidacloprid 9.1%
33173	Domestic	Can-Vet Animal Health Supplies Limited	Bugwacker Flea Protector 9	Solution	Imidacloprid 9.1%
33738	Domestic	Evergreen Animal Health, LLC	Evergreen II Spot on For Extra Large Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33739	Domestic	Evergreen Animal Health, LLC	Evergreen II Spot on For on For Large Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33740	Domestic	Evergreen Animal Health, LLC	Evergreen II Spot On For Medium Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33741	Domestic	Evergreen Animal Health, LLC	Evergreen II Spot On For Small Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33789	Domestic	Evergreen Animal Health, LLC	Parapet K9 Praventa 360 for Extra Large Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
33790	Domestic	Evergreen Animal Health, LLC	Parapet K9 Praventa 360 for Large Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33791	Domestic	Evergreen Animal Health, LLC	Parapet K9 Praventa 360 for Medium Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%
33792	Domestic	Evergreen Animal Health, LLC	Parapet K9 Praventa 360 for Small Dogs	Solution	Imidacloprid 7.12% Permethrin 35.6% Pyriproxyfen 0.36%

1 as of 11 February 2021, excluding discontinued products or products with a submission for discontinuation

2 for products co-formulated with other active ingredients, the most restrictive label amendments apply

Table 2 Registered products containing imidacloprid in Canada[1] cancelled as a result of re-evaluation

Registration Number	Marketing Class	Registrant	Product Name	Formulation type	Guarantee
25932	Commercial	Bayer CropScience Incorporated	Merit Solupack Insecticide	Wettable powder	Imidacloprid 75%
25933	Commercial	Bayer CropScience Incorporated	Merit Granular	Granular	Imidacloprid 0.5%
29130	Commercial	Adama Agricultural Solutions Canada Limited	Quali-Pro Imidacloprid 75 WSP Insecticide	Wettable powder	Imidacloprid 75%
29185	Commercial	Adama Agricultural Solutions Canada Limited	Quali-Pro Imidacloprid 0.5 Granular Insecticide	Granular	Imidacloprid 0.5%
29738	Domestic	SBM Life Science Corporation	BioAdvanced Science-Based Solutions Season Long Grub Control	Granular	Imidacloprid 0.25%

1 as of 11 February 2021, excluding discontinued products or products with a submission for discontinuation

Appendix II Registered uses of imidacloprid in Canada

Table 1 Registered agricultural commercial and restricted class uses of imidacloprid in Canada as of 19 June 2020 (excluding structural products and spot on applications to domestic animals)

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Use-site Category 4 –Forests and Woodlots							
Christmas trees	Balsam twig aphid	Suspension	Ground application: airblast	60 g a.i./ha	2	7	
Use-site Category 5 – Greenhouse Food Crops							
Crop sub-group 5A (greenhouse seedling production) Head and Stem Brassica	Swede midge	Wettable powder	Transplant tray plug drench	2.46 g a.i./1000 seedlings	1 / crop cycle	Not applicable	
Greenhouse lettuce (transplant seedlings)	Aphids, and whiteflies						
Greenhouse cucumber, eggplant, pepper and tomato (mature plants)			Ground application: soil drench	9.6 g a.i./1000 plants			
Use-site Category 6 – Greenhouse Non-Food Crops							
Greenhouse coniferous evergreens, greenhouse ornamental grasses, greenhouse grown cut flowers and indoor potted plants	Aphids, and whiteflies	Wettable powder	Ground application: soil drench	0.002 g a.i./2.5 cm pot: 1-2 herbaceous plants/pot 0.003 g a.i./2.5 cm pot: 3+ herbaceous plants/pot or woody perennials	1 / crop cycle	Not applicable	
Use-site Category 10 – Seed and Plant Propagation Materials Food and Feed							
Broccoli and cabbage	Aphids, and flea beetle	Wettable powder	Commercial seed treatment equipment Seeds are not treated in Canada but are imported pre-treated with imidacloprid.	0.3 g a.i./1000 seeds 25.2 to 36.75 g a.i./ha	1	Not applicable	
Carrot	Carrot rust fly (suppression)			0.012 to 0.023 g a.i./1000 seed 10.8 to 93.2 g a.i./ha			
Bulb vegetables	Onion maggot, seedcorn maggot, and thrips			0.04 g a.i./1000 seed (onion - bulb, leek) 19.0 to 39.2 g a.i./ha 0.03 g a.i./1000 seeds (onion- bunching) 58.8 g a.i./ha			
Leafy vegetables	Aphids, and leafminer (suppression)			0.2 g a.i./1000 seeds 140 g a.i./ha (lettuce)			

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Fruiting vegetables	Aphids, leafminer (suppression on tomato), and thrips			0.0126 g a.i./ 1000 seeds (tomato) 0.2 to 4.9 g a.i./ha 0.083 g a.i./ 1000 seed (pepper) 2.5 g a.i./ha			
Cucurbit vegetables	Aphids, and thrips			0.25 g a.i./1000 seeds 4.6 to 6.9 g a.i./ha (cucumber) 0.8 to 1.6 g a.i./ha (melon) 0.6 to 6.2 g a.i./ha (squash)			
Potato	Colorado potato beetle, potato leafhopper, aphids, and potato flea beetle	Suspension	On farm seed treatment equipment	6.2 g a.i./100 kg seed pieces to 9.4 g a.i./100 kg seed pieces 72 to 280 g a.i./ha	1	Not applicable	
Crop sub-group 6A and C: Edible podded beans, Jackbean, dry shelled beans and broad bean (fava bean)	Potato leafhopper	Suspension	Commercial and on farm seed treatment equipment	62.5 g a.i./100 kg seed 18 to 103.13 g a.i./ha depending on crop	1	Not applicable	
	Wireworm		Commercial seed treatment equipment	62.5 g a.i./100 kg seed 18 to 103.13 g a.i./ha depending on crop			
Chickpea, lentil, and field pea			Commercial and on farm seed treatment equipment				
Faba bean	Pea leaf weevil and wireworm						
Field pea	Pea leaf weevil			62.5 to 125 g a.i./100 kg seed 80 to 246.25 g a.i./ha			
Soybean	Soybean aphid, bean leaf beetle, wireworm, seedcorn maggot European chafer, and Japanese beetle	Suspension	Commercial and on farm seed treatment equipment	62.5 to 125 g a.i./100 kg seed 35.63 to 157.5 g a.i./ha	1	Not applicable	
Barley, oats, and wheat	Wireworm	Suspension	Commercial and on farm seed treatment equipment	10 to 30 g a.i./100 kg seed 5.38 to 52.47 g a.i./ha depending on crop	1	Not applicable	

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Field corn (seed production only)	Corn flea beetle	Suspension	Commercial seed treatment equipment	48 g a.i./80 000 seeds 37.8 to 56.8 g a.i./ha	1	Not applicable	
Field corn (including seed production)	Wireworm		Commercial and on farm seed treatment equipment	13 g a.i./80 000 seeds 10.1 to 15.1 g a.i./ha			
Sweet corn (Ontario and Québec only)	Corn flea beetle			250 g a.i./100 kg seed 13.1 to 37.8 g a.i./ha			
	Wireworm			67.2g a.i./100 kg seed 3.5 to 10.3 g a.i./ha			
Canola, mustard (condiment type only), and rapeseed	Flea beetle	Wettable powder, suspension	Commercial seed treatment equipment	400-802 g a.i./ 100 kg seed 16 to 64.16 g a.i./ha	1	Not applicable	
Mustard (oilseed type)	Flea beetle	Suspension	Commercial seed treatment equipment	400 g a.i./100 kg seed or 800 g a.i./100 kg seed 18 to 89.6 g a.i./ha	1	Not applicable	
Use-site Category 13 – Terrestrial Feed Crops & Use-site Category 14 – Terrestrial Food Crops							
Potato	Colorado potato beetle, aphids, leafhoppers, and flea beetles	Suspension	Ground application: in-furrow	1.8 to 2.9 g a.i./100 m of row or 100 to 480 g a.i./ha	1	Not applicable	
	Reduction in numbers of larvae of the European chafer		Ground application: soil drench	288 g a.i./ha			
	Colorado potato beetle, aphids, and leafhoppers (suppression)		Ground application: foliar spray	48 g a.i./ha	2	7	
Potato	Colorado potato beetle, aphids, leafhopper, potato flea beetle, tarnished plant bug, and European corn borer (suppression)	Suspension	Ground and aerial application: foliar spray	49 g a.i./ha	3	5	
Soybean	Soybean aphid, bean leaf beetle (suppression), and Japanese beetle	Suspension	Ground and aerial application: foliar spray	24.4 to 49 g a.i./ha (with deltamethrin)	3	5	Do not apply during bloom or when bees are actively foraging.

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Use-site Category 14 Only – Terrestrial Food Crops							
Crop sub-group 1B: Root vegetables (except sugarbeet): Crop sub-group 1D: Tuberous and corm vegetables (except potatoes) Crop group 2: Leaves of root and tuber vegetables	Aphids, leafhoppers, and flea beetles	Suspension	Ground application: in-furrow	1.88 to 2.88 g a.i./100 m of row 100 to 408 g a.i./ha	1	Not applicable	
	Reduction in numbers of larvae of the European chafer		Ground application: soil drench	288 g a.i./ha			
	Aphids, and leafhoppers (suppression)		Ground application: foliar application	48 g a.i./ha	2	5	
Globe artichoke	Aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar application	48 g a.i./ha	2	7	
Crop group 4A: Leafy greens subgroup of leafy vegetables (except Brassica)	Aphids	Suspension	Ground application: transplant tray plug drench	2.45 g a.i./1000 plants (220 to 440 g a.i./ha)	1	Not applicable	
			Ground application: soil drench and in-furrow	1.44 g a.i./100m of row 80 to 480 g a.i./ha			
	Aphids, and leafhopper (suppression)		Ground application: foliar spray	48 g a.i./ha	2	5	
Crop sub-group 4B:cardoon, celery, Chinese celery, celtuce, florence fennel, rhubarb, and Swiss chard	Aphids	Suspension	Ground application: soil drench and in-furrow	1.44 g a.i./100m of row 80 to 480 g a.i./ha	1	Not applicable	
Crop group 5: Brassica (cole) leafy vegetables	Aphids	Suspension	Ground application: soil drench and in-furrow	1.56 g a.i./100 m of row 86.6 to 520 g a.i./ha	1	Not applicable	
			Ground application: side dress application	175.2 g a.i./ha			
	Aphids, and leafhoppers (suppression)		Ground application: foliar spray	48 g a.i./ha	2	7	
Head and stem brassica crop sub-group 5A	Imported cabbageworm diamondback moth, cabbage looper, crucifer flea beetle, and aphids	Suspension	Ground application: foliar spray	48.75 g a.i./ha (with deltamethrin)	3	5	

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Peanut	Aphids	Suspension	Ground applicationin-furrow	1.8 g a.i./100 m of row 100 to 400 g a.i./ha	1	Not applicable	
	Aphids, and leafhoppers (suppression)		Ground application: foliar spray	48 g a.i./ha	2	5	
Crop group 6: Legume vegetables (except dry soybean)	Aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar application	48 g a.i./ha	2	7	For broad beans/fava beans/ Vicia faba Apply postbloom only. For all other listed Crop Group 6 crops, excluding broad beans/ fava beans/ Vicia faba: Do not apply during bloom or when bees are actively foraging.
Crop group 8: Fruiting vegetables	Colorado potato beetle, aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar spray	48 g a.i./ha	2	5	Post-bloom only.
Eggplant and tomato	Colorado potato beetle						
Tomato	Colorado potato beetle, and tomato hornworm			49 g a.i./ha (with deltamethrin)	3	5	
Crop Sub-Group 13A: Cane berries	Aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar spray	42 g a.i./ha	3	7	Application is allowed only post-bloom with renovation after harvest
Raspberry	Rednecked and raspberry caneborer (suppression)			112 g a.i./ha	3	7	
Crop sub-group 13B: Bushberry	Aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar spray	42 g a.i./ha	2	7	
	Blueberry maggot			55.2 to 84 g a.i./ha			
	Japanese beetle adult			42 to 55 g a.i./ha			
Crop sub-group 13F: Berry and small fruit vine excluding grapes	Leafhoppers	Suspension	Ground application: foliar spray	48 g a.i./ha	2	14	Application is allowed only post-bloom with renovation after harvest.
Grape	Leafhoppers	Suspension	Ground application: foliar spray	48 g a.i./ha	2	14	Do not apply during bloom or when bees are actively foraging.
			Ground application: soil drench	1.8 to 2.88 g a.i/100 m of row 100 to 480 g a.i./ha	1	Not applicable	

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Blueberry (lowbush and highbush)	Blueberry aphid	Suspension	Ground application: foliar spray	42 g a.i./ha (with deltamethrin)	3	5	Application is allowed only post-bloom with renovation after harvest.
Crop sub-group 13G: Berry and small fruit low growing berries excluding strawberry	Aphids, and leafhoppers (suppression)	Suspension	Ground application: foliar spray	42 g a.i./ha	2	5	Application allowed only post-bloom with renovation after harvest.
Strawberry							Apply post-bloom only.
Tree nuts plus pistachio: beechnut, brazil nut, butternut, cashew, filbert (hazelnut), hickory nut, macadamia nut (bush nut), pecan, pistachio, walnut [black and English (Persian)].	Aphids (except woolly apple aphid)	Suspension	Ground application: airblast	55.2 g a.i./ha	2	6	Apply only during post-bloom period.
	leafhoppers (suppression)			48 g a.i./ha			
Herbs: Angelica, balm (lemon balm), basil (fresh and dried), borage, bumet, camomile, catnip, chervil (dried), Chinese chive, chive, clary, coriander (cilantro or chinese parsley leaves), costmary, culantro (leaf), curry (leaf), dillweed, horehound, hyssop, lemongrass, lovage (leaf), marigold, marjoram, nasturtium, parsley (dried), pennyroyal, rue, sage, savory (summer and winter), sweet bay (bay leaf), tansy, tarragon, thyme, wintergreen, woodruff, wormwood	Aphids	Suspension	Ground application: in-furrow	1.44 g a.i./100 m of row 80 to 480 g a.i./ha	1	Not applicable	Soil application is allowed only when herbs will be harvested prior to bloom.
	Aphids, and leafhoppers (suppression)		Ground application: foliar spray	48 g a.i./ha	2	5	Do not apply pre-bloom* or during bloom or when bees are actively foraging. Apply only during post-bloom period. *Exception: Pre-bloom application is allowed only when herbs will be harvested prior to bloom.
Hops	Aphids	Suspension	Ground application: foliar spray	55.2 g a.i./ha	2	28	
Tobacco	Aphids	Suspension	Ground application: foliar spray	48 g a.i./ha	2	7	
	Aphids, and flea beetles		Ground application: in-furrow	2.04 g a.i./100m of row 113 to 453 g a.i/ha	1	Not applicable	

Site(s)[1]	Pest(s)	Formulation type	Application methods and equipment	Single application rate	Maximum number of applications per year	Minimum application interval (days)	Change in application timing based on pollinator risk (RVD2019-06)[2]
Use-site Category 27 - Ornamentals Outdoor & Use-site Category 4 –Forests and Woodlots							
Albizia, ash, birch, box elder, buckeye, elm, hackberry, horse chestnut, maple, mountain ash, poplar, silk tree, sycamore/ London plane tree, and willow	Asian longhorned beetle (suppression)	Solution	Ground application: trunk injection	0.09 to 0.23 g a.i./cm DBH[3]	1	Not applicable	
Spruce	Brown spruce longhorn beetle (suppression)			0.23 g a.i./cm DBH			
Ash	Emerald ash borer (suppression)			0.09 to 0.23 g a.i./cm DBH			
	cottony ash psyllid			0.06 g a.i./cm DBH			
Birch	Bronze birch borer (suppression)						
Elm	European elm scale, elm leafminer						
Black locust	Locust leafminer						
Ornamental apple	Woolly apple aphid						
Hemlock including Eastern Hemlock	Hemlock woolly adelgid			0.05 to 0.19 g a.i./cm DBH			
Use-site Category 27 - Ornamentals Outdoor							
Container grown nursery ornamentals: coniferous evergreens (pine, fir, juniper, spruce, arborvitae, hemlock, cypress, yew, live Christmas trees) and ornamental grasses	European chafer (larvae), and Japanese beetle (larvae)	Wettable powder	Ground application: soil drench	280 g a.i./ha	1	Not applicable	
Use-site Category 30 – Turf							
Turf (home lawns, business and office complexes, shopping complexes, multi-family residential complexes, airports, cemeteries, parks, playgrounds, athletic fields, golf courses and sod farms)	European chafer (larvae), Japanese beetle (larvae), ataenius beetle (larvae) and European crane fly larvae (suppression)	Wettable powder (in water soluble bags)	Ground application: foliar	281.25 g a.i./ha	1	Not applicable	
		Granular	Ground application: granular spreader drop and rotary type	280 g a.i./ha			

1. 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
2. All foliar applications include a pollinator restriction of "Do not apply during bloom".

3. Diameter at breast height

Table 2 Registered domestic class uses of imidacloprid in Canada as of 19 June 2020

Site(s)	Pest(s)	Formulation type	Application methods and equipment	Single application rate (a.i.)[1]	Maximum number of applications per year	Minimum number of days between applications
Turf	Larval stages of: European chafer, Japanese beetle, black turfgrass ataenius beetle, and European crane fly	Granular	Granular broadcast spreaders	280 g/ha	1	Not applicable

Appendix III List of commenters to PRVD2016-20

List of commenters' affiliations for comments submitted in response to PRVD2016-20.

Category	Commenter
Agricultural	Agricultural Producers Association of Saskatchewan
	Aidra Farms Ltd.
	Alberta Barley Commission
	Alberta Canola Producers Commission
	Alberta Seed Processors
	Alberta Seed Producers
	Alberta Wheat Commission
	Almond Board of California
	American Peanut Council
	American Potato Trade Alliance
	American Seed Trade Organization
	Association des producteurs maraîchers du Québec
	BC Greenhouse Growers' Association
	BC Raspberry Industry Development Council
	Bootstrap Farms Inc.
	California Cherry Board
	California Table Grape Commission
	Canada Grains Council
	Canadian Canola Growers Association
	Canadian Horticultural Council
	Canadian Potato Council
	Canadian Seed Growers' Association
	Canadian Seed Trade Association
	Canola Council of Canada
	Cereals Canada
	Christian Farmers Federation of Ontario
	CropLife Canada
	Fédération québécoise des producteurs de fruits et légumes de transformation
	Glen Coulee Farm
	Grain Farmers of Ontario
	Grain Growers of Canada
	Ippolito Group
	Keystone Agricultural Producers of Manitoba
	Kowalchuck Farms
	L'Union des producteurs agricoles
	Manitoba Canola Growers

Category	Commenter
	Manitoba Corn Growers Association Inc.
	Mercer Seeds
	North American Blueberry Council
	Ontario Apple Growers
	Ontario Beekeepers Association
	Ontario Fruit and Vegetable Growers' Association
	Ontario Ginseng Growers Association
	Ontario Processing Vegetable Growers
	Ontario Tender Fruit Growers
	Park Lane Farms Ltd.
	Peak of the Market
	Potatoes New Brunswick
	Prince Edward Island Potato Board
	Producteurs de Grains du Quebec
	Pulse Canada
	SaskCanola
	Soy Canada
	Stoke Seeds Limited
	Suderman Bros. Ltd.
	US cranberry growers
	US Hop Industry Plant Protection Committee
	Waltview Farms Limited
	Washington Red Raspberry Commission
	Western Canadian Wheat Growers Association
	Woodside Farm Partnership
Aerial Services	Jonair (1988) Ltd. / Portage Aircraft Maintenance Ltd.
Golf Course Industry	Alberta Golf Superintendents Association
	Canadian Golf Superintendents Association
	Ontario Golf Superintendents' Association
Ornamental Plants Industry	Canadian Nursery Landscape Association
	Flowers Canada Growers
General Public	Individual growers
	Members of the public
Governmental	Alberta Agriculture and Forestry
	Aquaculture and Fisheries
	British Columbia Ministry of Agriculture
	Bureau des relations gouvernementales et municipales, Ville de Montréal
	Environment and Climate Change Canada
	Food & Rural Affairs

Category	Commenter
	New Brunswick Agriculture
	Ontario Ministry of Agriculture
Non-governmental	Beyond Pesticides
	Canadian Environmental Law Association
	Center for Food Safety
	David Suzuki Foundation
	Ducks Unlimited
	Environmental Defence
	Équiterre
	Friends of the Earth
	Prevent Cancer Now
	Saskatchewan Environmental Society
	Sierra Club Foundation Canada
	University of Guelph
	Xerces Society
Registrant	Bayer CropScience
	Dow AgroSciences
	DuPont Pioneer
	Monsanto
	Syngenta Canada
	Valent Canada
Turfgrass Industry	Western Canada Turfgrass Association

Appendix IV Comments and responses

A total of 46,000 comments were received during the consultation period of PRVD2016-20, *Imidacloprid*. To address all substantive comments, 99 responses were provided by Health Canada (8 Health + 85 Environment + 6 Value). Multiple points were made covering the human health, environmental and value assessments as well as risk mitigation. These points are addressed within this Appendix.

Because many of the substantive comments contained multiple comments on different 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.

1.0 Comments and responses related to the human health risk assessment

Comments related to human health were received from la Fédération québécoise des producteurs de fruits et légumes de transformation, L'Union des producteurs agricoles, Prevent Cancer Now, Beyond Pesticides, the David Suzuki Foundation, Équiterre, Stoke Seeds Limited, Environmental Defence and le Bureau des relations gouvernementales et municipales, Ville de Montréal.

In addition, comments related to maximum residue limits (MRLs) were received from the California Table Grape Commission, the US Hop Industry Plant Protection Committee, the Almond Board of California, the American Potato Trade Alliance, the American Peanut Council, Bryant Christie Inc. (US cranberry growers), the California Cherry Board, the North American Blueberry Council, and the Washington Red Raspberry Commission.

1.1 Comment: Agricultural producers are very concerned about the health risks posed by alternatives to imidacloprid

The mode of action of neonicotinoids involves binding to nicotinic acetylcholine receptors (nAChRs). They are selective for insect nAChRs, which are structurally different from those of mammals. Neonicotinoids, therefore, present low toxicity for operators and consumers, unlike other insecticide families such as organophosphates. The consultation document PRVD2016-20 indicates that it is unlikely that use of imidacloprid will affect human health when used according to the label directions.

In Quebec, the risks that pesticides pose to health and the environment are assessed by the Quebec Pesticide Risk Indicator (QPRI) (Samuel et al. 2012), which is a variable aggregation method that makes it possible to assign to a pesticide an indicator value concerning the potential risk associated with its use. It is composed of two separate components, namely the potential risk to the health of the pesticide user and the risk to the environment. When choosing a pesticide to control a pest, agricultural producers can compare the health and environmental risk indices of the pesticides registered for the same use by using the SAgE pesticide app (www.sagepesticides.qc.ca). Using this tool, we compared the risk indices of the phytosanitary treatments formulated based on imidacloprid and their alternative products, where they exist, for all the combinations of pests and crops or crop groups. Under most circumstances, the health risk index of the alternative products is much higher than the risk index of the phytosanitary treatments formulated based on imidacloprid, whose risk indices range from 6 to 57, depending on the combination of pests and crops or crop groups. For example, to control the leafhopper in raspberry plants, the health risk indices of the alternative products to imidacloprid range from 92 to 353, depending on the commercial product used, while the treatment formulated based on imidacloprid presents a risk index of 8. Agricultural producers, producers of processing vegetables as well as processors are extremely concerned about the proposal to phase out the agricultural uses of imidacloprid since they are the first to handle phytosanitary products and they advocate the use of products that entail the lowest risk to their health, such as the use of treated seeds.

Health Canada response

Part of Health Canada's mandate in regulating pesticides is to protect the health of Canadians. Health Canada acknowledges that each pesticide has a different hazard and risk profile. For this reason, all pesticides used, sold or imported into Canada undergo rigorous science-based assessments to determine if their use can be approved. Health Canada applies internationally accepted hazard and risk assessment methods and modern risk management approaches and policies to help ensure the safety of each pesticide. Any pesticides that could be used by farmers to replace imidacloprid would also have to undergo rigorous science-based assessments to help ensure they can be used safely before being approved for use in Canada.

1.2 Comment: Scientific review and human health

The scientific review of imidacloprid is lacking much of the relevant peer-reviewed literature. Beyond limitations of the ecological referencing noted above, a series of reports of human intoxication from the Japanese group led by Dr. Kumiko Taira (PMRA 2788275), are all missing from the consultation document. Health Canada, and Health Canada in particular, should carry out international best practices in systematic scientific review, so that the present claims of "weight of evidence" are transparently supported with the scientific evidence systematically presented along with meta-analyses when appropriate, grading of said evidence, and final weighing.

Health Canada response

Health Canada carefully considers published, peer-reviewed literature during the course of a re-evaluation which includes available human data such as case reports and epidemiological studies. As presented in the PRVD for imidacloprid, published case reports that explored the potential health effects of imidacloprid exposure (among other pesticides) in human populations were briefly discussed. Overall, the findings of all of the available human studies were often limited by small numbers of cases and lacked characterization of exposure conditions (such as the concentration of pesticide and the duration of exposure). Given the lack of specific details presented in these reports, Health

Canada concluded from a scientific perspective, that these reports were of limited quality and did not provide information to add to the weight-of-evidence for risk assessment purposes. On the other hand, the cited study by Taira was not included in the PRVD as it was unavailable at the time of the toxicology review. However, this study also has similar limitations including inadequate characterization of exposure conditions and failure to identify the specific neonicotinoid involved. The author refers to a collection of patients with a syndrome of adverse effects observed after the consumption of large amounts of domestic fruits/vegetables or tea beverages, but no analysis of these commodities was undertaken. The presence of 6-CNA (a non-specific metabolite of chloropyridinyl neonicotinoids) in 7/33 patients was the basis behind the authors speculation that effects were caused by neonicotinoid exposure. The only information specific to imidacloprid in this paper concerned an unspecified quantity of imidacloprid metabolites detected in the urine of two patients. Health Canada has concluded that the limited information presented in this study does not change the risk assessment conducted for imidacloprid.

1.3 Comment: Risks to human health

The Agency concludes that imidacloprid does not pose risks to human health. However, there are a growing number of studies beginning to investigate the impacts of chronic neonicotinoid exposure to human health. Many of these studies are reporting some association between neonicotinoid and neurological impairments. A 2016 study by Kimura-Kuroda et al. (PMRA 2788306) finds that “chronic neonicotinoid exposure alters the transcriptome of the developing mammalian brain in a similar way to nicotine exposure.” Neonicotinoids have been found to affect mammalian nAChRs in a way that is similar to the effects of nicotine. These receptors are of critical importance to human brain function, especially during development and for memory, cognition, and behavior. A review of the scientific evidence by Cimino et al., 2017 (PMRA 2788307) finds that there are reported associations between chronic neonicotinoid exposures and adverse developmental outcomes, including neurological effects, which support the reasonableness for these associations. We urge the Agency to monitor the science and update its human health risk assessment as studies document adverse health outcomes.

Health Canada response

As was indicated in the PRVD, Health Canada conducted a thorough search of all published, peer-reviewed literature for information relevant to the human health risk assessment of imidacloprid that was available at the time. The two papers cited by the commenter were published after completion of Health Canada’s human health risk assessment.

The study conducted by Kimura-Kuroda et al., 2016 (PMRA 2788306) was an in vitro study to examine the effects of 1 µM of imidacloprid on neonatal rat cerebellum. Immunocytochemistry revealed no differences in the number or morphology of immature neurons or glial cells in any group versus untreated control cultures. However, a slight disturbance in Purkinje cell dendritic arborization was observed. Results revealed alterations in the transcriptome of genes in the developing rodent brain with several genes found to be up or downregulated after exposure of cerebellar cultures to imidacloprid. Given that the study by Kimura-Kuroda was conducted in vitro, it is difficult to extrapolate these findings to relevant human in vivo exposure scenarios. Furthermore, the downstream consequences of these alterations in gene expression in an intact animal remain speculative. Notwithstanding these findings, Health Canada did have concerns for the potential neurotoxicity of imidacloprid. Specifically, Health Canada noted effects on the developing brain in the available developmental neurotoxicity study. These effects took the form of decreases in locomotor activity and in the thickness of the caudate/putamen as well as impaired learning on one trial in the water maze test in offspring at maternally toxic dose levels. The toxicological endpoints selected for risk assessment purposes were considered protective for potential alterations in the developing brain, and were based on a relevant route of human exposure.

In the literature review conducted by Cimino et al. 2017 (PMRA 2788307), human population studies published between 2005 and 2015 were searched in scientific databases. Eight studies investigating the human health effects of exposure to neonicotinoids were identified; four addressed acute exposures and four addressed chronic exposures. Of the acute exposure studies, one relied on questionnaire and biomonitoring data in a double-blind cross-over study of planters of treated conifer seedlings. In this study there was no correlation between symptoms and exposure to imidacloprid. The remaining three acute exposure studies consisted of one study considered by Health Canada in PRVD2016-20 and two studies examining poison control center data. More than half of the cases in the latter two studies involved accidental ingestion of imidacloprid and symptoms were consistent with those reported in PRVD2016-20. Cimino et al. assessed the four chronic exposure studies "as having probably to definitely high risk of bias as well as other factors reducing the level of confidence in their findings". The authors report that these studies "would be dropped as too weak for inclusion" except for the fact that they were exploring the knowledge base to date for human health effects to chronic neonicotinoid exposure. Associations were reported in these studies for developmental outcomes (tetralogy of Fallot, anencephaly and autism spectrum disorder) and neurological outcomes (memory loss and finger tremor). However, Cimino et al. cited numerous limitations to these studies related to the small sample sizes, weak methodology for characterizing exposure and poor control for environmental and genetic confounders. Overall, Health Canada concluded that these reports were not sufficiently robust for regulatory use and did not provide information to further the toxicological component of the risk assessment of imidacloprid.

1.4A Comment: Human population studies and experimental research on human cells

Health Canada evaluated health risks on the basis of human exposure estimates and levels at which no health effects occur in animal testing. The evaluation should have also taken into account the results of human population studies and experimental research on human cells. Researchers at the Tokyo Women's Medical University found patients continuously exposed to neonicotinoids, especially acetamiprid and thiamethoxam, display common symptoms. Subjective "neo-nicotinic symptoms" include headache, general fatigue, chest pain or palpitation, stomach ache, cough, muscle pain, weakness or spasms. Objective symptoms include postural tremor, short-term memory loss and fever. Chronic studies on neonicotinoids have shown associations with congenital heart defects, anencephaly and autism spectrum disorders.

New Canadian research not yet published shows that imidacloprid is also a potential endocrine disruptor. Approximately 70 per cent of diagnosed breast cancers are estrogen-dependent. In this type of cancer, there is overexpression of aromatase, the enzyme responsible for estrogen biosynthesis, in fibroblasts (preadipocyte cells), which stimulates the proliferation of cancer cells. In healthy breast tissue, aromatase expression is regulated by low activation of the promoter (region upstream of the gene) I.4. In the case of breast cancer, expression of the normally inactive promoters PII, I.3 and I.7 is increased, and the normal promoter I.4 is inhibited. In this research, exposing breast cancer cells to imidacloprid, at concentrations found in the environment, induced a change in the use of aromatase promoters similar to that observed in breast cancer, leading to a significant increase in expression and the activity of aromatase.

A recently published systematic review of the effects of neonicotinoid exposure on human health points to possible associations between chronic exposure and adverse developmental outcomes or symptom clusters including neurological effects. The review also reveals a paucity of data on neonicotinoid exposure and human health: only eight studies published in English between 2005 and 2015 were identified for inclusion in the review. The authors conclude that more studies on the human health effects of chronic neonicotinoid exposure are needed. A commentary published February 2017 in Environmental Health Perspectives reinforces the need for more human health studies on neonicotinoids. The toxicity of neonicotinoid degradates should also be re-examined as some may be more toxic than the parent compounds.

Specific requirements of section 19(2)(b)

In evaluating health risks, section 19(2)(b) of the *Pest Control Products Act* requires a number of specific considerations, including aggregate exposures; cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity; different sensitivities to health effects by subgroups such as pregnant women, infants, children, women and seniors; and threshold effects. In the case of products used in and around homes or schools, where a threshold effect can be demonstrated, the Act requires application of an extra margin of safety ("the PCPA factor") to take into account potential pre- and post-natal toxicity and uncertainties with respect to the vulnerability of infants and children. We are concerned that the health assessment for imidacloprid fails to consider cumulative effects and the PCPA factor was reduced to one-fold.

The commissioner of the environment and sustainable development recommended in 2015 that Health Canada finalize and apply a methodology for assessing cumulative effects. Health Canada agreed to this recommendation but is still working on finalizing methodology.

Consequently, cumulative effects have generally not been assessed to date. In the case of imidacloprid, Health Canada has indicated that it will determine whether a cumulative effects assessment is necessary after first completing the re-evaluation. We recommend Health Canada proceed with a cumulative effects assessment of all neonicotinoids.

Available evidence suggests cumulative effects are relevant as neonicotinoids share a common mode of action - they are nicotinic acetylcholine receptor (nAChR) agonists. There is now significant evidence from basic neuroscience research that the neonicotinoids have effects not only on invertebrate neurons, but on mammalian ones as well. In the context of human exposure to neonicotinoids, clinical studies demonstrated a connection between the nAChRs and the immune system. Kimura-Kuroda et al. (2012) conclude, based on effects observed in rats, that neonicotinoids may be harmful to human brain development. Exposure to several neonicotinoids could increase the risk of associated neurotoxic effects and other chronic health effects. As the Task Force on Systemic Pesticides concluded: all neonicotinoids bind to the same nAChRs in the nervous system such that cumulative toxicity is expected. At present, no studies have addressed the additive or synergistic effects of simultaneous exposure to multiple compounds of the neonicotinoid family, i.e. imidacloprid, clothianidin, thiamethoxam, dinotefuran, thiacloprid, acetamiprid, sulfoxaflor, nitenpyram, imidaclothiz, paichongding and cycloxaprid, into an aggregated dose of for example, “imidacloprid equivalents”. Currently, risk assessments are done for each chemical separately, while many non-target species, such as pollinators, are simultaneously being exposed to multiple neonicotinoids as well as other pesticides and stressors. As a consequence, the risks have been systematically underestimated. While quantifying the suite of co-occurring pesticides is largely an intractable problem, a single metric that incorporates all neonicotinoid exposures to representative taxa would be an invaluable starting point. Although *Pest Control Prroducts Act* does not mandate the assessment of synergistic effects, there is increasing evidence of synergy between different pesticides. P. Key et al. (2007) found that by mixing various products (fipronil, imidacloprid and atrazine), the LC_{50} of each product taken in isolation decreases.

Recommendation: Acknowledge that cumulative and synergistic effects have not yet been assessed, and that it is therefore premature to draw final conclusions about risks to human health associated with the use of imidacloprid.

The requirement for an extra margin of safety

We do not believe Health Canada is justified in reducing the PCPA factor to one, which is the same as applying no extra margin of safety. Domestic products containing imidacloprid are used in and around homes and schools - for example, products used on lawns, and cat and dog flea treatments - and multiple uncertainties are evident in the assessment of risks to the young. Under these circumstances, Section 19(b)(iii) of the Act generally requires a tenfold margin of safety “unless, on the basis of reliable scientific data, the Minister has determined that a different margin of safety would be appropriate.”

With respect to pre- and post-natal effects and the vulnerability of infants and children, potential harm to the developing brain is a particular concern given how neonicotinoids act on nicotinic receptors. Developmental neurotoxic effects such as decreased locomotor activity and caudate/putamen width, as well as impaired learning were observed in offspring at the highest dose level tested in the experimental studies considered in Health Canada health assessment. In the case of organophosphate insecticides, these types of neurotoxic effects have been observed at low doses in population studies although not in experimental studies. It is reasonable to suspect the same for imidacloprid. In addition, a "no observed adverse effects level" (NOAEL) was not established for the decrease in caudate/putamen width because morphometric assessments were not performed on offspring from the low- and intermediate-dose groups in the study conducted by the registrant. Health Canada concludes that the concern is low with respect to this missing data. We disagree.

Research underway at the University of Toronto is demonstrating neurodevelopmental effects in mice after in utero and early postnatal exposure to low doses of imidacloprid. Decreased body weight, increased motor activity, enhanced social dominance, decreased depressive-like behaviours, and decreased visible social aggression have been observed.

In human population studies, neonicotinoids have been associated with birth defects in the San Joaquin agricultural valley of California (data from 1997 to 2006, publication in 2016). Exposure to neonicotinoids enhanced the risks of: anotia/microtia (Adjusted Odds Ratio (AOR) = 3.0), craniosynostosis (AOR = 3.1) and transverse limb deficiency (AOR = 2.4). More specifically, imidacloprid was associated with anotia (AOR 3.0), transverse limb deficiency (AOR = 2.9) and craniosynostosis (AOR = 3.5). This was the first study to investigate the effect of neonicotinoids on birth defects (except the study quoted above concerning flea collars on household pets) (PMRA 2826010).

Potential low-dose endocrine disruption, at levels below the reference dose, is another source of uncertainty in the health assessment, given evidence of endocrine disruption in animal studies. Current risk assessments are based on unrealistically high chronic reference doses. Furthermore, dietary exposure estimates for contact pesticides are typically considered conservative, but this cannot be assumed in the case of systemic pesticides like imidacloprid. Systemic pesticide residues in food (including imidacloprid and other neonicotinoids) cannot be washed off and are directly ingested by consumers. Also, humans are in contact with a combination of herbicides, fungicides and insecticides daily, and we know little about the potential synergism between neonicotinoids and other substances during prenatal exposure. Recommendation: Apply a PCPA factor of at least five, if not 10, given the multiple uncertainties present in the assessment of imidacloprid.

1.4B Imidacloprid pet products and related human incident reports

We also encourage to ban indoor uses for lice, tick and flea treatment in dogs and cats as a precautionary measure due to case reports and research demonstrating potential harms to exposed children.

English, K., et al. *(2016). Unintentional insecticide poisoning by age: an analysis of Queensland Poisons Information Centre calls. Australian and New Zealand Journal of Public Health, 40(5): 457-461.*

Shaw GM, et al. *(1999). Maternal pesticide exposure from multiple sources and selected congenital anomalies. Epidemiology, 10: 60-66.*

Health Canada response

Human population studies and experimental research on human cells

During the review of the human health risk assessment, available toxicity studies and published journal articles were carefully reviewed for their relevance to the re-evaluation of imidacloprid. This included the consideration of the human data from toxicity studies, case reports and epidemiological studies that were available at the time of the review, as well as studies on human cells. Studies involving exposure of imidacloprid to human cells included assessments of genotoxicity and endocrine activity. Published case reports which explored the potential health effects of imidacloprid exposure (among other pesticides) in human populations were also discussed in the PRVD2016-20 as noted in the response to comments 1.1 and 1.2. The study that was conducted by researchers at the Tokyo Women's Medical University (PMRA 2788275), that was cited by the commenter, had several limitations including inadequate characterization of exposure conditions and failure to identify the specific neonicotinoid involved. The author referred to a collection of patients with a syndrome of adverse effects observed after the consumption of large amounts of domestic fruits/vegetables or tea beverages but no analysis of these commodities was undertaken. The presence of 6-CNA (a non-specific metabolite of chloropyridinyl neonicotinoids) in 7/33 patients was the basis behind the authors speculation that effects were caused by neonicotinoid exposure. The only information specific to imidacloprid in this paper concerned an unspecified quantity of imidacloprid metabolites detected in the urine of two patients. Health Canada has concluded that the limited information presented in this study does not impact the risk assessment conducted for imidacloprid.

As noted in response 1.3, the systematic review of the human health effects and neonicotinoid exposure conducted by Cimino et al. (PMRA 2788307), and cited by the commenter, was not included in the PRVD as it was not available at the time of the re-evaluation. This review assessed the available "chronic" exposure studies published between 2005 and 2015 that focused on exposure to pesticides and developmental health outcomes, including congenital heart defects (PMRA 2806309), neural tube defects (PMRA 2806310), and autism spectrum disorder (PMRA 2806311). Another more recently published study cited by the commenter, but not included in the review conducted by Cimino et al., examined the association between pesticide exposure and the development of five specific types of birth defects (PMRA 2826010). All studies were case-control studies. Three of these studies (PMRA 2806309, 2806310 and 2806311) examined mothers who had been exposed to commercial pesticides by residing within a 500 m radius of the pesticide application in the San Joaquin Valley in California. Pesticide exposure was estimated based on pesticide use records from the California Department of Pesticide Regulation, which described daily applications for the 461 pesticides representing various classes of pesticides studied between 1997 and 2006. In all of these studies, a window for pesticide exposure was assigned that corresponded to 1-month prior to conception to 2 months post-conception. Maternal interviews were conducted using a standardized, computer-based questionnaire administered primarily by telephone 6 weeks to 24 months after the infant's estimated date of delivery, with mothers reporting their residential history from 3 months before conception through delivery. Controls included non-malformed live-born infants randomly selected from birth hospitals to represent the population from which the cases arose. The first study investigated the presence of heart defects and examined 569 heart defect cases and 785 non-malformed controls that were born between October 1997 and December 2006. Findings that met the study criteria (adjusted odds ratio [AOR] ≥2 or ≤0.5 or having a confidence interval [CI] that excluded 1.0) included imidacloprid exposure and tetralogy of Fallot (AOR 2.4, 95% CI: 1.1- 5.4). The number of imidacloprid-exposed cases (9) was low. In the second study, early gestational exposures to pesticides and the risk of developing anencephaly, spina bifida, cleft lip with or without cleft palate, or cleft palate were investigated. The analyses included 73 cases with anencephaly, 123 with spina bifida, 277 with cleft lip and 177 with cleft palate in addition to 785 controls. While this study demonstrated a potential association between exposure to imidacloprid and the development of anencephaly (AOR 2.9, 95% CI: 1.0-8.2), the number of imidacloprid-exposed cases of anencephaly (6) was small. In the third study, the presence of five specific birth defects (anotia/microtia, anorectal atresia/stenosis, transverse limb deficiency, craniosynostosis and diaphragmatic hernia) was investigated following reported maternal exposure to pesticides. Exposure assignments were made for 366 cases (95 with anotia/microtia, 77 with anorectal atresia/stenosis, 60 with transverse limb deficiency, 79 with craniosynostosis and 62 with diaphragmatic hernia) and 779 controls. Findings that met the study criteria included imidacloprid exposure and the presence of anotia (AOR 3.0, 95% CI: 1.4-6.6), transverse limb deficiency (AOR 2.9, 95% CI: 1.1-7.4) and craniosynostosis (AOR 3.5, 95% CI: 1.5-8.3). The number of imidacloprid-exposed cases was low for all three of these birth defects with the number ranging from 6 to 10 for each birth defect. All three of these case control studies had similar limitations including a modest sample size for many comparisons which limited the precision of the estimates. None of these studies corrected the results for multiple comparisons, leading one of the authors to conclude that the associations may have emerged by chance alone, given the sizable number of comparisons. In addition, as noted by the authors, the exposure assessment did not take into account other factors that may have affected actual exposures (i.e. chemical half-lives and vapour pressure, wind patterns, an individual's ability to metabolize the chemicals) and other sources of pesticide exposure such as occupation or home use.

Another chronic case-control study (PMRA 2806311) examined the association between autism spectrum disorder and maternally-reported monthly application (1 application/month) of imidacloprid for flea and tick control in pets that contained ~9% imidacloprid. In this study, the exposure to a flea and tick product was reported from 3 months before conception, throughout pregnancy and during each year of the child's life up to age 2. In this study, there were 262 controls and 407 children with autism spectrum disorder. Compared with exposure among controls, the odds of prenatal imidacloprid exposure among children with autism spectrum disorder were slightly higher (OR = 1.3, 95% Credible Interval (CrI) 0.78-2.2). When the analysis was limited to frequent users of imidacloprid, the OR increased to 2.0 (95% CI, 1.0-3.9). The odds ratio for autism spectrum disorder was higher for imidacloprid exposures during the prenatal period versus during the first 3 years of life, although the finding was not significant. While this study suggests a potential association between exposure to imidacloprid and the development of autism spectrum disorder, there were numerous limitations with this study. Importantly, the usage of imidacloprid was determined through self-reporting of mothers up to 4 years after the reported pesticide exposure occurred. The frequency of application of the pesticide products to the household pets could have been misreported, exposure could have happened outside of the reported period and an independent assessment of the potential exposures was not undertaken. There was no information available for how much physical contact the mother had with the treated pet. The authors concluded that within plausible estimates of sensitivity and specificity, the association could result from exposure misclassification alone.

Although these case studies suggest an association between developmental outcomes and exposure to imidacloprid, they all had limitations which affected their usefulness for the risk assessment of imidacloprid. These limitations included a high risk of recall and interviewer bias from self-reporting, which was done often years after the exposure occurred, small sample sizes, weak methodology for characterizing exposure, potential influence of other pesticides/chemicals and poor control for environmental and genetic confounders. None of the study authors followed up with subjects individually or conducted biomonitoring. Cimino et al. (PMRA 2788307) even concluded that these studies definitely had a “high risk of bias as well as other factors reducing the level of confidence in their findings”. Overall, Health Canada concludes that these reports are not sufficiently robust for regulatory use and do not warrant revision of the risk assessment of imidacloprid.

The study commenter cited yet to be published data on aromatase expression in human breast cancer cells purporting imidacloprid as a potential endocrine disruptor. Health Canada is not able to consider information that is not yet accessible. That said, Health Canada reviewed and included the results of a number of studies in the human health risk assessment for imidacloprid that examined potential effects on androgen and estrogen activity (PMRA 2182445, 2182447, 2182448, 2182449, 2192450, 2182451 and 2182452). The results of these studies, performed for the United States Endocrine Disruptor Screening Program, along with other scientifically relevant information, including general toxicity data and open literature studies of sufficient quality, were all taken together to determine whether exposure to imidacloprid resulted in adverse effects that can occur from hormone perturbation. The results of this battery of studies conducted with imidacloprid found no evidence for potential interaction with any of the endocrine pathways, although, as noted in the PRVD, hormone levels were not directly measured in most in vivo studies. As presented in the PRVD, imidacloprid was evaluated for its effect on ovarian morphology, hormones and antioxidant enzymes in female rats following 90 days of oral (by gavage) exposure (PMRA 2418111). A NOAEL of 10 mg/kg bw/day was established for this study based on decreased ovarian weights, alterations in the levels of luteinizing hormone, follicle-stimulating hormone and progesterone, as well as changes in super oxide dismutase, catalase, glutathione peroxidase, glutathione s-transferase and lipid peroxidation at the next dosage level of 20 mg/kg bw/day. The results of this study were considered in the human health risk assessment. Since publication of the PRVD, Health Canada became aware of an additional published study (PMRA 2791517). In this study, groups of six male Wistar rats were exposed, by gavage, to imidacloprid of unknown purity at 0, 0.5, 2 or 8 mg/kg bw/day for 90 days. This study was considered supplemental for risk assessment purposes by Health Canada, since the number of animals examined per dose level was low and for some of the examined parameters individual animal data were not available, with results only presented in graphical format. Notwithstanding these limitations, decreased epididymal weights and serum testosterone levels were noted starting at a dose level of 0.5 mg/kg bw/day. At 2 and 8 mg/kg bw/day apoptosis and fragmentation of seminal DNA were increased. At 8 mg/kg bw/day, the rates of abnormal sperm, lipid peroxidation and fatty acid concentrations were increased while the concentration of epididymal sperm was significantly decreased. These results suggest that imidacloprid may have the potential to interfere with the male reproductive system; however, these studies were not considered sufficiently robust to affect the risk assessment.

Overall, it was concluded that there is a low level of concern for effects on hormones or endocrine organs following exposure to imidacloprid as the findings occurred at dose levels that produced other toxic effects which would have already been considered in the risk assessment, or the findings were noted in studies lacking sufficient scientific rigour.

Specific requirements of section 19(2) (b)

The *Pest Control Products Act* requires that Health Canada consider the cumulative effects of pest control products that have a common mechanism of toxicity. A cumulative health risk assessment framework has been developed by Health Canada and general methodology is available to undertake this task. As noted in PRVD2016-20, upon completion of the ongoing re-evaluations of other chemicals in the neonicotinoid class of pesticides (namely thiamethoxam and clothianidin), it will be determined whether a cumulative effects assessment is necessary, taking into account the ability of neonicotinoids to bind to nicotinic acetylcholine receptors. The cumulative effects assessment will be undertaken according to the process outlined in SPN2018-02. In the meantime, the current human health risk assessment of imidacloprid is considered complete.

The requirement for an extra margin of safety

As was stated in the PRVD for imidacloprid, the toxicological database was considered complete and consisted of the full array of toxicity studies currently required for the human health risk assessment. With respect to the completeness of the toxicity database as it pertains to the exposure of and toxicity to infants and children, the database contains the full complement of required studies including a multigeneration reproduction study in the rat, developmental toxicity studies in the rat and rabbit, and a developmental neurotoxicity study in the rat. With respect to identified concerns relevant to the assessment of risk to infants and children, there was no indication of increased susceptibility in the offspring compared to parental animals in the reproduction study. In the prenatal developmental toxicity studies in rats and rabbits, there was no indication of increased susceptibility of rat or rabbit fetuses following in utero exposure to imidacloprid. In the developmental neurotoxicity study, decreases in locomotor activity and thickness of caudate/putamen as well as impaired learning on one trial in the water maze test were noted in offspring at the highest dose level tested. A NOAEL for the reduced caudate/putamen width was not established as morphometric assessments were not performed on offspring from the low and mid dose groups. However, the concern regarding the missing measurements was low considering that i) no effects occurred in the young at lower dose levels (in particular there was no indication of adverse functional changes in the young at the low and mid dose levels); ii) the magnitude of the change in caudate/putamen width was small (2-5%); and iii) this effect occurred at a dose level that was toxic to maternal animals. The toxicological points of departure selected for risk assessment for repeat-exposure scenarios (5.7 to 8 mg/kg bw/day) were lower than the dose levels resulting in the offspring findings (55 to 58 mg/kg bw/day) and were thus considered protective. Consequently, the PCPA factor was reduced to 1-fold. The application of standard uncertainty factors for intraspecies variability and interspecies extrapolation were considered adequate to protect all populations. In the case of the Acceptable Daily Intake established by Health Canada, a margin of 1,000 exists between the ADI and the dose at which developmental neurotoxicity was observed in offspring.

One of the studies cited in this comment was a Master's thesis from the University of Toronto (PMRA 2791516). This thesis was undertaken to investigate the potential neurodevelopmental effects in mice following in utero and early postnatal exposure to low doses of imidacloprid. Imidacloprid, of unspecified purity, was administered by a subcutaneous pump, which is a route of exposure unrepresentative of how humans would be exposed to imidacloprid in Canada. The results were limited, presented in visual format (bar graphs) only and lacked individual animal data. Only one dosage level was examined, the number of dams treated was small and a thorough investigation of the maternal animals was not performed. Offspring effects reported included decreased body weight, increased motor activity, enhanced social dominance, decreased depressive-like behaviours and decreased visible social aggression. However, with only one dosage level examined, any treatment-related dose-response relationship for these reported findings could not be established. Given the limitations, this study was not suitable for risk assessment purposes.

The additional evidence (human population studies) cited by the commenter in support of an extra margin of safety was encumbered by numerous limitations, as discussed previously. Similarly, the concern for potential low-dose endocrine disruption was not supported by robust data. Also, the dietary exposure estimates for the general population and all subpopulations were generated using maximum residue limit values and field trial data, reflecting residues in food when imidacloprid is used according to label directions. Health Canada has taken all of the information into consideration and concluded that, at this time, no change is warranted to the PCPA factor established in the PRVD.

Imidacloprid pet products and related human incident reports

Residential exposure and health risk for imidacloprid pet treatment uses were assessed for all population groups including children. There are no risk concerns identified for any population groups. The assessments were conducted according the USEPA 2012 Residential Standard Operation Procedures and include protective assumptions such the use of lower body weight estimates for children and the consideration of child-specific activities such as hand-to-mouth exposure from petting treated dogs or cats. Results of the assessment can be found in Appendix VII and VIII of PRVD2016-20.

Since publication of PRVD2016-20, Health Canada has received six incidents involving five children and one teenager related to pet flea and tick products containing imidacloprid, and two incidents involving three children related to indoor structural products containing imidacloprid. In most cases involving a pet flea and tick product, the individuals were interacting with a treated pet up to 24 hours after product treatment, and developed minor skin or eye effects. Only one serious effect was reported in the U.S., which involved a pet collar product that is not registered for use in Canada and is co-formulated with another active ingredient, flumethrin. The two incidents involving an indoor structural product occurred after individuals re-entered a treated home, and minor to moderate symptoms were reported including headache, coughing, dizziness, nausea and difficulty breathing. In both incidents, the reported products contained other active ingredients in addition to imidacloprid. No incident reports involving congenital or developmental effects have been submitted to Health Canada for imidacloprid.

Additionally, labels for these Canadian pet and indoor products containing imidacloprid already contain precautionary statements to reduce the likelihood of child exposure to imidacloprid. In the case of indoor structural products, these statements require that the product to be kept out of reach of children, prohibit treatment of certain objects (such as clothing or toys), prohibit people from being present during and shortly after application and require ventilation of the home after application. For pet products containing imidacloprid, labels require that the product be kept out of reach of children and to avoid contact with the treated pet until dry.

Overall, the scientific data do not indicate any health concerns from exposure to imidacloprid when products are used according to label directions.

1.5 Comment: Worker exposure

Worker exposure to imidacloprid is low because: Seed is treated outside of Canada. Sepresto treated seed is typically shipped to customer in original packaging from the treater. Treated seed is coated with a binder or coating to seal the product and reduce dust off. Sepresto is used exclusively by professional growers most of whom have pesticide application training. Seed handlers and farmers fall under WHMIS and require protective clothing where any danger of exposure is detected. To compensate for the absence of imidacloprid, farmers will be required to handle more chemicals for field applications.

Health Canada response

Imidacloprid is registered for seed treatment use in Canada on a variety of seed types including barley, oats, wheat, canola, mustard, chickpea, lentils, beans, peas, corn (sweet and field), soybean and potato seed pieces. It is also registered for use on imported seeds that can be planted in Canada including leek, onion, carrot, lettuce, broccoli, cabbage, tomato, pepper, and cucurbits. For registered seed treatment uses in Canada, the exposure and health risks to mixers, loaders, and planters were assessed. For imported seed treatment uses, the exposure and health risks to planters were assessed. As indicated in the PRVD (2016-20) and Section 2.1, the health risks to seed treatment workers are shown to be acceptable provided that the appropriate personal protection equipment instructions and engineering controls are updated on labels. Any pesticides that could be used by farmers to replace imidacloprid would also have to undergo rigorous science-based assessments to help ensure they can be used safely before being approved for use in Canada.

1.6 Comment: Canadian maximum residue limits (MRLs)

Comments indicated that imidacloprid continues to be an important crop protection tool throughout U.S. agriculture, including for table grapes, hops, almond, potatoes, peanuts, cranberries, cherries, blueberries and raspberries, as it protects against a broad array of damaging insect pests. The comments noted that in the proposed re-evaluation decision, Health Canada is seeking to phase-out uses of imidacloprid in Canada. This decision is the result of concerns in the environmental assessment, with no human health concerns from dietary exposure.

Therefore, it was requested that, regardless of the final decision made on the registration of imidacloprid in Canada, that Health Canada maintain MRLs for imidacloprid on grapes, hops, almond, potatoes, peanuts, cranberries, cherries, blueberries and raspberries entering Canada so that trade may continue without interruption.

Health Canada response

Maximum residue limits (MRLs) for pesticides in/on food are specified by Health Canada's PMRA under the authority of the *Pest Control Products Act*. Canadian MRLs for imidacloprid are currently specified for a wide range of commodities, including grapes, hops (dried), almond nuts, potatoes, peanuts, cranberries, cherries, blueberries and raspberries. A complete list of MRLs specified in Canada can be found in PMRA's MRL Database, an online query application that allows users to search for specified MRLs, regulated under the *Pest Control Products Act*, for both pesticides and food commodities (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php).

As a result of imidacloprid re-evaluation, no dietary risks of concern were identified from exposure to imidacloprid through food and drinking water. Therefore, there will be no amendments to the currently established MRLs as part of the re-evaluation decision. That is, the current Canadian MRLs for imidacloprid will be maintained.

1.7 Comment: Low risk for humans and animals according to the PMRA

The City has some reservations regarding the uses of imidacloprid that will remain authorized. It appears incoherent to ban outdoor use (for example, for agriculture) when indoor use results in greater human exposure to the risks of imidacloprid-based pesticides. The PMRA intends to maintain the registration of 33 domestic class products for pets (cats and dogs) that target fleas and ticks. These products are applied directly to animals' fur and skin. It is very likely that humans are directly exposed to imidacloprid during physical contact with their pets. This route of exposure must therefore be accounted for in the PMRA's analysis of the substance. Although there are few studies on the topic, the precautionary principle should prevail. In addition, some studies have raised doubts regarding the safety of imidacloprid-based flea and tick treatments for human health (PMRA 2806311).

Health Canada response

As noted in the response to comment 1.4b, residential exposure and health risk for imidacloprid pet treatment uses were assessed for all population groups including children and are shown to be acceptable. The assessments were conducted according the USEPA 2012 Residential Standard Operation Procedures and included protective assumptions such the use of lower body weights for children and the consideration of child-specific activities such as hand-to-mouth exposure from petting treated dogs or cats. Results of the assessment can be found in Appendix VII and VIII of PRVD2016-20.

Potential applicator exposure and health risk as a result of imidacloprid tree injection use was also assessed. There were no health risk concerns identified for the use scenario. Results of the assessment can be found in Appendix VI, Table 2 of PRVD2016-20.

Health Canada considers all relevant incident reports, published studies, and registrant studies when conducting health risk assessments. Reports and studies that meet scientific criteria and guidelines and that are specific to the pesticide (in terms of chemical structure and usage) are considered most relevant to the assessment. Most human incidents for imidacloprid occurred following the application of a pet flea and tick control product or contact with pets following treatment with these products. In most cases involving a pet flea and tick product, the individuals were interacting with a treated pet up to 24 hours after product treatment, and developed minor skin or eye effects. Labels for these Canadian companion animal pesticide products containing imidacloprid already contain precautionary statements to reduce the likelihood of human exposure to imidacloprid, including statements requiring that the product be kept out of reach of children and to avoid contact with the treated pet until dry. In addition, the overall data do not indicate any serious health concerns from exposure to imidacloprid when it is used according to label directions.

2.0 Comments and responses related to the environmental assessment

Comments related to the environment were received from members of the public, Center for Food Safety, Canadian Environmental Law Association, Ontario Beekeepers Association, Canola Council of Canada, Canadian Seed Trade Association, Alberta Barley Commission, Keystone Agricultural Producers of Manitoba, Western Canadian Wheat Growers Association, Cereals Canada, Alberta Canola Producers Commission, Potatoes New Brunswick, Mercer Seeds Limited, Pulse Canada, Sierra Club Foundation Canada, Syngenta Canada, Soy Canada, Bayer CropScience, David Suzuki Foundation, Équiterre, Environmental Defence, Ville de Montréal, Ducks Unlimited, University of Guelph, Beyond Pesticides, Monsanto, Environment and Climate Change Canada, Saskatchewan Environmental Society, Xerces Society, Ontario Fruit and Vegetable Growers Association, DuPont Pioneer, Dow AgroSciences, Flowers Canada Growers, BC Greenhouse Growers Association, Canadian Potato Council, Grain Growers of Canada, Manitoba Corn Growers Association Incorporated, CropLife Canada, Canada Grains Council, Prince Edward Island Potato Board, British Columbia Ministry of Agriculture, SaskCanola, Alberta Wheat Commission, Alberta Seed Producers, Agricultural Producers Association of Saskatchewan, Valent Canada, Peak of the Market, Alberta Agriculture and Forestry, American Seed Trade Organization, Canadian Seed Growers' Association, American

Peanut Council, Union des producteurs agricoles, Manitoba Canola Growers, Friends of the Earth, Stoke Seeds Limited.

2.1 Comment: The phase-out period is too long

A three- to five-year delay in phasing out imidacloprid would needlessly prolong environmental risks. Imidacloprid contamination is likely to persist in aquatic and terrestrial ecosystems even after major uses have been phased out. The scientific literature does not support Health Canada's assumption that invertebrates from adjacent streams would recolonize impacted water bodies.

Health Canada response

A significant amount of new monitoring data with auxiliary information were submitted and are considered in the final decision. Additional toxicity information and comments received during the comment period have been used along with the new monitoring information to revise the risk assessment for imidacloprid. The final risk decisions, along with the proposed mitigation measures, are outlined in the science section of this document. The implementation of this final re-evaluation decision is in accordance with the process outlined Health Canada's Regulatory Directive DIR2018-01*, Policy on Cancellations and Amendments Following Re-evaluation and Special Review*. An imminent and serious risk to the environment was not identified; therefore, the implementation timelines for the phase-out period will follow those outlined in DIR2018-01.

2.2 Comment: Alternatives pose more risk

Without access to imidacloprid, farmers may have to rely on alternative products that could come with a new set of unintended consequences for the environment.

Health Canada response

Imidacloprid uses that are to be phased out will result in growers using alternative products. The *Pest Control Products Act* states that the health and environmental risks of a pest control product 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. All pesticides are subject to re-evaluation and the risks associated with their use are evaluated independently. The risks associated with alternative products have been assessed and will continue to be assessed through subsequent re-evaluations.

2.3 Comment: Imidacloprid does not pose human health concerns

Health Canada health assessment did not identify human health concerns from any exposure route when used according to current label standards. Potato growers strongly object to the proposal to discontinue an active ingredient with a demonstrated high margin of safety for human health in favour of a theoretical risk to aquatic insects.

Health Canada response

For product registrations and re-evaluations, a decision on the acceptability of continued use is determined by assessing the risks to both human health and the environment separately. In the case of imidacloprid, although the human health risk assessment has concluded the risks to human health are not a concern from the currently registered uses, the environmental risk assessment identified risks to aquatic organisms. As a result, PRVD2016-20 proposed the phase out of most uses of imidacloprid. Since the publication of the PRVD, additional data were used to refine the risk assessment. The results of the revised environmental risk assessment are presented in the science section of this document.

2.4 Comment: Accumulation in the environment over time

With a half-life of 457 days in some Prince Edward Island soils, the yearly use of imidacloprid will result in residues building up in the soil over time, reaching a plateau in 3 to 20 years.

Health Canada response

The persistence and potential accumulation of imidacloprid in soil was considered in the environmental risk assessment. Canadian terrestrial field dissipation (TFD) studies show that imidacloprid is slightly persistent to persistent in soil with first-order DT_{50} values ranging from 22 to 456 days. In some cases, there was high variability in soil dissipation between replicate treatment plots (for example, DT_{50} values of 45 to 426 days). A similar range of DT_{50} values is reported from studies conducted in the United States and Europe (44 days to >365 days). Carryover of imidacloprid residues to the next growing season is expected in Canadian soils based on the overall evidence from field studies (DT_{90} values of 457 to >1099 days). Imidacloprid residues increase in soil with each subsequent year of use until a plateau is reached (about 3 years).

2.5 Comment: Dry conditions in Western Canada

Request to allow Western Canadian farmers to continue to have access to imidacloprid given the much drier climate where surface water is not affected.

Health Canada response

The re-evaluation decision is based on available information and scientific principles. Water monitoring data from Western Canada have been submitted since the publication of PRVD2016-20 and the risk to aquatic invertebrates has been revised, taking into consideration the regional data.

2.6 Comment: Model using input parameters reflective of Western Canada

Predicted estimated environmental concentration (EEC) values calculated using the Surface Water Concentration Calculator (SWCC) are based on input parameters specific to Atlantic Canada and are not believed to be representative of the conditions found in Western Canada. This is considered to be an overly conservative assumption for Western Canada.

Health Canada response

Additional water modelling has been conducted with the Pesticide in Water Calculator (PWC) for the revised risk assessment. Modelling of soil and foliar spray applications as well as seed treatments has been conducted based on the registered use pattern following the pollinator re-evaluation decision (RVD2019-06). This includes modelling of crops and application rates with scenarios that are specific to Western Canadian conditions.

2.7 Comment: Leaching potential

Imidacloprid has a high potential of leaching into groundwater. Compared with 11 other popular pesticides imidacloprid moved more quickly through soil than any of the other pesticides tested including pesticides considered widespread water contaminants. It is classified by the United States Environmental Protection Agency (USEPA) in "Category I" - having the highest leaching potential.

Health Canada response

Health Canada agrees that imidacloprid has the potential to leach and has added precautionary label statements.

2.8 Comment: Well water and mosquitoes

A member of the public raised concerns regarding if the use of neonicotinoids in a near-by pond may be affecting the mosquito population.

Health Canada response

Insect populations are affected by many factors. Neonicotinoids are toxic to insects, however, without supporting evidence that the concentration in the pond would affect the mosquito population, it is not possible to comment on a causal relationship.

2.9 Comment: Evaluation of open literature studies

Syngenta Canada commented that studies considered to be of potential value for ecological risk assessment should first be evaluated to ascertain whether endpoints were derived using adequate scientific rigour and robustness before being used quantitatively to characterize potential risk. The USEPA outlines considerations about the quality of open literature studies and methods to account for study robustness in a risk assessment:

Depending on the measurement endpoint, the same evaluation criteria as those used in registrant-submitted guideline studies for similar endpoints should be used to gauge the utility of the open literature study.[6]

Rigorous quantitative approaches and systems have been developed to evaluate quality and relevance of scientific data for the purposes of risk assessment (for example, Klimisch et al., 1997 and Van Der Kraak et al., 2014, Hanson et al., 2016). A rigorous evaluation of all summaries and studies cited in the report was not included in the PRVD document.

Bayer CropScience commented that Health Canada has failed to appropriately evaluate the quality of the data, and inappropriately ascribed greater weight to the results of certain studies by counting their results multiple times. Specifically, Health Canada's reliance on foreign and open literature reviews for summarizing endpoints rather than on the original study report (i.e., original peer-reviewed article or registrant-submitted study report) has resulted in a carryover of errors from the non-original source, leading to findings being duplicated, incorrect reporting of test parameters, inclusion of invalid data, and errors when calculating endpoints. A single endpoint for each taxa tested should be derived from each study for consideration in the risk assessment.

Soy Canada commented that predictable, science-based decision making is supported as is the importance of including the latest research, innovation and data in the development of public policy and regulation. The quality and volume of data collected in the re-evaluation as well as methodology, transparency and predictability in arriving at its conclusion are a concern. The uncharacteristically broad and wide-ranging proposed phase out of imidacloprid blanketed across multiple crops and regions has triggered multiple questions on the tests and analysis used to determine risk.

Pulse Canada commented that Health Canada did not provide reasoning of their selection process for the inclusion or exclusion of toxicological studies. Additional information to support the toxicity study selection is requested.

Klimisch H.J. et al. *1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1–5.*

Van Der Kraak, G.J. et al. *2014. Effects of atrazine in fish, amphibians, and reptiles: An analysis based on quantitative weight of evidence. Critical Reviews in Toxicology. 44(S5):1-66.*

Hanson M.L. et al. *2016. How we can make ecotoxicology more valuable to environmental protection. Science of the Total Environment. 160.*

Health Canada response

Health Canada requires pesticide manufacturers to provide data to support new registrations. Through Health Canada's incident reporting program, pesticide manufacturers are required to submit new study data that could indicate increased risk as compared to the data submitted at the time of registration.

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[6] USEPA. 2011. "*Evaluation Guidelines for Ecological Toxicity Data in the Open Literature*" https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open

At the time of re-evaluation, pesticide manufacturers provide a list of available data to Health Canada from which studies that are required for the risk assessment are identified.

Health Canada relied on toxicity data from foreign reviews, open literature reviews, original open literature studies as well as registrant-submitted data. Care was taken to ensure that double counting of the same endpoints did not occur.

All open literature studies were fully reviewed by Health Canada in terms of their quality and acceptance for consideration in the risk assessment. In some cases, studies were deficient in some information that restricted how a study should be interpreted. In these cases, the uncertainties were considered when summarising all the data. Despite such limitations, these studies may have been considered acceptable for consideration in the risk assessment if the results were considered scientifically sound.

Documentation produced following review of the studies includes a discussion of the strength and limitations. Each study is classified as either acceptable or unacceptable for consideration in the risk assessment, including rationales to justify the classification. Although some studies were not conducted according to internationally acceptable guidelines, valuable information was still able to be obtained. The deficiencies and limitations of these studies were considered and taken into account when deriving the conclusion (i.e., if the studies were not a high enough quality to derive precise/accurate endpoints, qualitative conclusions were drawn).

Studies classified as acceptable in foreign reviews (for example, reviews conducted by European Food Safety Authority, United States Environmental Protection Agency) are considered acceptable by Health Canada. These studies are not always fully reviewed, nor is a listing of their strengths and limitations typically described. Regulatory agencies of Organization for Economic Cooperation and Development member states evaluate the quality of toxicity data following standards and guidelines that are deemed acceptable to Health Canada. If Health Canada determines that a foreign review of an environmental fate or toxicity study is inaccurate or has reason to believe that the study may be unacceptable, Health Canada will conduct a review of the original study.

2.10 Comment: Risks associated with tree injections

Due to imidacloprid’s ability to move through the tree’s vascular system from the injection site into the roots and leaves, the continued use of imidacloprid in commercial tree injections poses environmental risks by contaminating soil, exposing soil organisms to the pesticide, and threatening the health of aquatic ecosystems through runoff.

Canadian field and laboratory studies showed that autumn-shed leaves from imidacloprid-treated trees contain residues that pose risk of harm to aquatic and terrestrial decomposer organisms (Furlan and Kreutzweiser, 2015 (PMRA# 3158801)). Another study (Englert et al., 2016 (PMRA# 3158802)) indicated that the use of imidacloprid on trees generated concentrations in foliage that, as modelled, could contribute to concentrations in nearby streams that exceed the level of concern for aquatic organisms.

Health Canada response

The environmental risk of imidacloprid resulting from tree injection uses was previously assessed by Health Canada (ERC2011-03, PRD2016-16 and RD2016-28). An evaluation of available scientific information found that, under the approved conditions of use, tree injection uses of imidacloprid do not present an unacceptable risk to the environment.

The study review by Furlan and Kreutzweiser (2015, PMRA# 3158801) was not available at the time of Health Canada's initial assessment of tree injection uses. The studies cited and discussed by the authors that pertain to potential imidacloprid exposure to aquatic and terrestrial decomposers resulting from tree injection uses were considered in Health Canada's review: Kreutzweiser et al., 2008a (PMRA# 1908830), Kreutzweiser et al., 2008b (PMRA1908798), and Kreutzweiser et al., 2009 (PMRA# 1908803). These three studies, as well as two additional studies (Kreutzweiser et al., 2007 (PMRA# 2541841) and Kreutzweiser et al., 2008c (PMRA# 2544383) were also considered during the current re-evaluation of imidacloprid.

Englert et al., 2016 (PMRA# 3158802) was not considered in PRVD 2016-20. Health Canada has since conducted a cursory review and determined that this study agrees with the other available studies in that sublethal effects on aquatic leaf-shredding insects and litter-dwelling earthworms were demonstrated under laboratory conditions. Under field conditions, based on low mass loading of leaves into the environment and the reasonable expectation that leaves would be displaced by wind, the amount of imidacloprid residues from fallen leaves into soil or aquatic habitats at any location in the field is expected to be relatively low compared to those established under controlled laboratory exposure conditions. In an urban environment where leaf litter from injected trees may be collected in autumn, exposure to imidacloprid in fallen leaves is expected to be reduced. Therefore, the potential for effects on earthworms and decomposer organisms from tree injections under realistic conditions is expected to be limited.

2.11 Comment: Decisions made in the United States, Europe, Canadian provinces and municipalities

Health Canada environmental assessment reached a similar conclusion to the USEPA's preliminary aquatic risk assessment for imidacloprid. There is conclusive evidence that the persistent concentrations of these neonicotinoids are causing significant damage to a wide range of beneficial species, including aquatic insects. The European Union's highly commendable precautionary decision was promptly made in 2013 to restrict the use of clothianidin, imidacloprid and thiamethoxam, which led to the partial ban of these pesticides. France will ban all neonicotinoids in September 2018.

Two Canadian cities (Vancouver and Montreal) and two provinces (Ontario and Quebec) either have or are taking steps to restrict neonicotinoids. Soy Canada indicated the number of soybean acres seeded with neonicotinoids has declined (for example, a 22% reduction in soybean acres planted with neonicotinoids between 2014 and 2016). Provincial legislation aimed at reducing acreage planted with seed treatments are expected to further reduce the risk of pollution into waterways.

Expanding the re-evaluation decision to include more recent overall concentrations and frequency data will provide a more refined view of potential risk trends in specific areas and from specific uses.

Health Canada response

Health Canada works with national and international counterparts to closely monitor scientific information and other developments related to the potential impacts of pesticides on pollinators and the environment. Health Canada is aware of the risk assessments conducted by international regulatory authorities and considers this information in its risk assessments, however, regulatory decisions are made independently.

Risks to pollinators from imidacloprid were assessed through a separate process, with a proposed decision PRVD2018-12 and final decision RVD2019-06 having already been published. Pollinator assessments for two other neonicotinoids, clothianidin (PRVD2017-23, RVD2019-05) and thiamethoxam (PRVD2017-24, RVD2019-06), have also been published.

Risks to aquatic invertebrates for clothianidin and thiamethoxam were assessed and proposed special review decisions for clothianidin (PSRD2018-01) and thiamethoxam (PSRD2018-02) were published and subject to consultation. Final special review decisions have also been published for clothianidin (SRD2021-03) and thiamethoxam (SRD2021-04).

While Health Canada has the authority to register pesticides, municipalities and provinces have the authority to impose further restrictions on the use of these products.

2.12 Comment: Comments related to the task force on systemic pesticides

Ducks Unlimited, la Ville de Montréal, and a member of the public commented that in 2015, the Task Force on Systemic Pesticides (TFSP), an international group of independent scientists (van Lexmond et al., 2015; PMRA# 3166452), reviewed more than 1100 scientific peer-reviewed studies on neonicotinoids and found evidence of harm to honeybees and other pollinators, terrestrial invertebrates such as earthworms, aquatic invertebrates and birds and predicted "substantial impacts on biodiversity and ecosystem functioning" (van der Sluijs et al. 2015; PMRA# 3166451). Other recent reviews by Goulson, 2013 (PMRA# 3166450), Anderson et al., 2015 (PMRA# 3166453), Morrissey et al., 2015 (PMRA# 2538669), and Sánchez-Bayo et al., 2016 (PMRA# 2945923) examined the potential for neonicotinoids to have negative impacts on non-target aquatic invertebrates.

Health Canada response

The work done by the Task Force on Systemic Insecticides was considered in the risk assessment for the proposed re-evaluation decision, PRVD2016-20. Additional data published since the publication of the PRVD have also been considered in the revised risk assessment for the final re-evaluation decision which is presented in the science section of this document.

2.13 Comments: Risks to earthworms are understated

Wang et al., 2015 (PMRA# 3156536) demonstrated a lower LC_{50} for earthworms of 3.05 mg/kg and that exposure to 2.0 mg imidacloprid/kg caused an 84% decrease in fecundity and changes at the cellular level. Imidacloprid is also known to affect earthworm burrowing behaviour at concentrations as low as 0.1 mg/kg (Capowiez et al., 2009; PMRA# 2156538). Another study (Zaller et al., 2016; PMRA# 3156537) reported interactive effects between earthworms, collembolan, soil basal respiration and crop growth after a one-time application of a seed dressing containing imidacloprid.

Health Canada response

In PRVD2016-20, risk to earthworms was evaluated using the most sensitive endpoints, conservative scenarios and an examination of available higher-tier studies. Impacted populations were shown to recover in field studies. The studies highlighted by the commenters have been examined and they do not change the conclusion of the PRVD, that risks of concern are not expected for earthworms under field conditions of use.

2.14 Comments: Pollinator comments

Health Canada response

A number of comments were received as part of the consultation for PRVD2016-20 that relate to the re-evaluation of pollinator risks posed by imidacloprid; however, these comments are not relevant to the current assessment. Details on the imidacloprid pollinator re-evaluation can be found in the proposed decision (PRVD2018-12) and final decision (RVD2019-06) for pollinators.

2.15 Comment: Risks to beneficial arthropods is a concern

The University of Guelph commented that there is substantial consideration of beneficial arthropods in terrestrial systems and that the risk quotients exceed the LOC for beneficial arthropods at the lowest field application rate on-field and off-field. The results of several laboratory toxicity tests provide strong evidence for reducing usage or phasing out this insecticide from uses that could result in negative impacts on beneficial arthropods (on land) and aquatic invertebrates.

A member of the public commented that they have seen declines in the number of insects found in a local schoolyard following a shift in the cropping of nearby fields from pasture and a potato/grain/hay rotation to field crops (corn soybeans, canola, grain).

Health Canada response

The risk assessment identified potential risks to non-target terrestrial arthropods from the use of imidacloprid. Mitigation measures are required to minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site. These measures will protect off-field beneficial populations and promote recovery.

2.16 Comment: Risk to birds from treated seed

Precautionary label statements and proposed mitigation measures to incorporate or remove treated seed from the soil surface to reduce exposure are inadequate given research findings that ingestion of even a few treated seeds could cause mortality or reproductive impairment to sensitive bird species.

According to the Journal of Applied Ecology "although vertebrates are less susceptible than arthropods, consumption of small numbers of dressed seeds offers a route to direct mortality in birds and mammals."

Gibbons et al., 2014 (PMRA# 2545412) found, in a comprehensive review of 150 studies, that ingestion of even a few neonicotinoid-coated seeds could cause mortality or reproductive impairment to sensitive bird species. A Spanish study on partridges exposed to imidacloprid-coated seeds (Lopez-Antia et al., 2013 (PMRA# 2544545)) reported mortality at high doses and non-lethal effects at low doses (such as changes to blood parameters and reproductive effects) and changes in immune response of chicks.

Research has shown that a single corn kernel coated with a neonicotinoid can kill a songbird. Even a tiny grain of wheat or canola treated with imidacloprid can poison a bird. As little as 1/10th of a corn seed per day during egg-laying season is all that is needed to affect reproduction with any of the neonicotinoids registered to date.

Health Canada has proposed risk mitigation measures to reduce imidacloprid exposure for birds and wild mammals including requirements to incorporate or remove any spilled or exposed treated seed from the soil surface. It is worth noting that Smith, 2006 (PMRA# 2574059) reported that avian species have not been observed consuming soybean seeds and based on this evidence any treated soybean seed is not anticipated to be a risk to birds.

For birds and small animals, Health Canada proposes to conclude that the ingestion of seed treated with imidacloprid may pose a risk to their health. Health Canada notes that there is some uncertainty as to whether certain treated seeds would be an attractive food source and recommends risk mitigation measures directed at removing any spilled or exposed treated seed from the soil surface. This conclusion ignores data which show that imidacloprid has repellant properties stronger than some commercially available repellants. As a result, most birds and small animals will not choose imidacloprid coated seeds and will instead move on to other food sources.

Health Canada response

The risk to birds from the consumption of treated seed is discussed in the updated science section of this document.

2.17 Comment: Hummingbird risk

A study indicates that hummingbirds living near blueberry fields are exposed to neonicotinoid insecticides, including imidacloprid (Bishop et al., 2018 (PMRA# 2945928)).

Health Canada response

This study is discussed in the updated science section of this document.

2.18 Comment: Effect on goslings

Concerns were raised around Canada geese, including young goslings, grazing on young sprouted corn (3 inches high), growing from a treated seed near a pond.

Health Canada response

For birds, finding evidence of effects in the field is a recognized challenge. When evaluating risks to birds, Health Canada's goal is to protect birds at the population level. Risks to birds associated with treated seed are discussed in the updated science section of this document. In this instance described, young goslings were seen foraging on small corn plants that were growing near a pond. It is unclear if the birds would have consumed the entire plant (including roots) or simply eaten the green emergent portions of the plant. Risks to birds are associated with eating seeds, not with eating the growing plant, which would have much lower levels of neonicotinoids as compared to the coated seed. Flocks of geese will often move to other feeding locations, therefore, the disappearance of the flock from the field may have merely been related to foraging behaviour.

2.19 Comment: Birds affected by decline in insect populations

Concerns were raised about potential negative impacts on wetland ecosystem functionality and the aquatic invertebrate resources that are important to waterfowl and other wetland wildlife.

The Task Force on Systemic Pesticides concluded that the harmful effects of imidacloprid on aquatic invertebrates "have the potential to adversely alter the base of the aquatic food web" and processes central to freshwater ecosystem services. Health Canada should consider potential cascading effects of neonicotinoids on ecosystems in Canada.

Imidacloprid has been associated with insectivorous bird population declines in the Netherlands since the introduction of imidacloprid in the mid-1990s (Hallman et al., 2014 (PMRA# 2576352)). Studies and reports have linked insectivorous bird declines to neonicotinoid use, as bird reproductive success may be affected by food availability (Hallman et al., 2014 (PMRA# 2576352); Mineau and Palmer, 2013 (PMRA# 2526820)). Populations of aquatic insects can be affected by neonicotinoid water contamination. Herbivorous insects that are a key food source for birds can be exposed to neonicotinoids through their presence in leaves and other parts of plants. Both of these exposure routes, terrestrial and aquatic, can reduce invertebrate abundance and limit food resources for birds and other insectivorous wildlife.

Mean concentrations of imidacloprid in water samples taken during the summer months from wetlands that drain wheat and canola fields in Saskatchewan are far in excess of the concentrations known to have negative effects on aquatic life and on birds.

Health Canada response

Potential food chain effects are a concern and Health Canada has considered these in the environmental risk assessment. For the aquatic ecotoxicity assessment, all available and relevant toxicological information has been considered and the most relevant sensitive effects endpoints are used in the risk assessment. For the exposure assessment, water modelling exposure EECs calculated using available fate data are considered in conjunction with water monitoring data from across the country. In the revised environmental risk assessment for aquatic invertebrates, Health Canada used higher-tiered mesocosm data in the chronic risk assessment. Although this mesocosm endpoint does not include the total ecosystem community, the goal is to ensure that the invertebrate community is protected in areas at risk of exposure to imidacloprid. The required mitigation measures will protect the sensitive aquatic invertebrate community, and thereby protect aquatic ecosystems and mitigate potential food chain effects.

2.20 Comment: Other factors have more impact on bird populations

Regarding indirect effects on birds, the results of a recent field study conducted in the Netherlands (Hallman et al. 2014 (PMRA# 2576352)), shows evidence that suggests that a decline in insectivorous bird populations in farmlands is associated with imidacloprid use via indirect cascade level effects on the food chain.

As pointed out in PRVD2016-20, this is a correlational study of potential indirect effects of imidacloprid on birds and does not test causality. The authors acknowledge that direct effects may not be responsible for declines in bird population and focuses on a correlation of the presence of effects of imidacloprid in Dutch waters directly impacting bird population. The authors did not discuss other more complex factors that could be involved such as cropping practices, habitat alteration, or declines in long-distant migrants associated with wintering and migratory stop-over habitats, unrelated to their breeding locations (for example, neotropical migrants). Some of the species of birds showing significant negative correlations with imidacloprid use have a diet that would be dominated by invertebrates other than those with aquatic life stages (for example, skylarks (*Alauda*) predominantly feed on ground dwelling Coleoptera, spiders etc., Mistle thrush (*Turdus viscivorus*) on earthworms, snails etc., Starlings (Sturnidae) on leatherjackets, and other soil invertebrates).

When correlative statements are extrapolated from one landscape system to another, it is equally important to consider the findings and conditions within the second system. For instance, the population of many bird species in Canada, such as waterfowl (that consume aquatic insects during key periods of reproduction and development, which live in areas correlated with high use of imidacloprid and other neonicotinoids have increased over the past few decades. For those species where population declines have been noted, these trends have been occurring over a longer time period (some since the 1970s). These trends are due to macrochanges in the Canadian landscape, such as habitat loss, and other factors (for example, predation by non-native species, collisions, agricultural practices such as harvest, etc.). Health Canada should incorporate these factors if the correlative analysis between the occurrence of imidacloprid in aquatic systems and potential impact to higher trophic level organisms is to remain.

Health Canada response

The revised risk assessment, presented in the science section of this document, considers all available relevant information. It is agreed that other factors can have impacts on food chains and it is difficult to determine the relative contributions of all the different factors. The required mitigation measures for imidacloprid are expected to result in protection of aquatic invertebrate communities, which will in turn provide protection for food chains.

2.21 Comment: Correlation not drawn between impact on insects and birds

There has been no attempt to correlate concerns for aquatic invertebrates with fish and bird populations. Aquatic insects play an important role in the food chain as food for fish, and ultimately for birds. Local bird counts show a steady increase, especially fish-eating species. The only group showing decreases are the ones living on grassland insects. This is closely related to loss of habitat and food sources with ever-changing agricultural production.

Health Canada response

Evaluating impacts of potential imidacloprid-induced insect depletion on fish and bird populations in the real-world is challenging. Hallman et al., 2014 (PMRA# 2576352) reports significant negative correlations between imidacloprid surface water concentrations and insectivorous bird populations in the Netherlands. Such associations between specific pesticide use and bird populations, however, do not imply causality as the observed pattern may be explained by unknown factors not considered (for example, habitat loss, other pesticides, food supply during migration and during winter, predation). The risk mitigation measures required as a result of the revised environmental risk assessment will protect aquatic communities from the use of imidacloprid.

2.22 Comment: Immobility poorly reflects mortality

In several acute and chronic invertebrate toxicity tests, control immobilization was greater than control mortality (for example, 17% vs. 13% for *C. horaria* in Roessink et al., 2013 (PMRA# 2544385); 20% vs. 12% for *C. dipterum* in Van den Brink et al., 2016 (PMRA# 2712707)) showing that immobility poorly reflects mortality. The variation between the EC_{50} and LC_{50} values is indicative that the method for estimating immobility is an unreliable surrogate for mortality.

Health Canada response

Health Canada acknowledges that differences in control immobilization and control mortality are reported in some studies (for example, Roessink et al., 2013 (PMRA# 2544385) for *C. horaria*, Van den Brink et al., 2016 (PMRA# 2712707) for *C. dipterum*). These differences, however, are low and, in most cases, the level of control immobilization and mortality observed for invertebrate species is the same. For the control (i.e., the absence of any paralytic agent – imidacloprid), immobility is expected to be synonymous to mortality. In the context of the control groups, therefore, immobility is expected to be an accurate reflection of mortality rather than a poor one.

Immobility is considered ecologically relevant and appropriate for risk assessment purposes because organisms cannot feed, swim, or avoid predation. The large differences observed between EC_{50} (immobility) and LC_{50} (mortality) values (i.e., EC_{50}s < LC_{50}s) for most species are likely characteristic of the time-dependent nature of imidacloprid toxicity. For neurotoxic substances, such as imidacloprid, paralysis is the first visible symptom prior to mortality. The data of Rosessink et al*.,* 2013 (PMRA# 2544385) clearly demonstrates that a species-specific lag-time between immobility and mortality exists. Similar time-dependent toxicity responses and differences among aquatic invertebrate species are reported for imidacloprid (Sánchez-Bayo and Goka, 2006 (PMRA# 2574054), Van den Brink et al., 2016 (PMRA# 2712707)), other neonicotinoids (Beketov and Liess, 2008 (PMRA# 2544548), Tennekes, 2010 (PMRA# 2947465)) and for other pesticides (for example, chlorpyrifos - Rubach et al., 2011 (PMRA# 2947462)). In some cases, the lag time is short (i.e., as observed by the small or negligible difference between the immobility and mortality response - for example, *Chaoborus obscuripes* - 96-hr EC_{50} = 284 µg a.i./L and 96-hr LC_{50} = 294 µg a.i./L, respectively – Roessinks et al*.,* 2013 (PMRA# 2544385)). For other test species, a much longer lag time is observed (i.e., the difference between the immobility and mortality response is relatively large (for example, *Cloeon dipterum* 96-hr EC_{50} = 1.02 µg a.i./L and 96-hr LC_{50} = 26.3 µg a.i./L, respectively)). Moreover, a definitive time and concentration-dependent lag time is evident in the chronic data set of Roessink et al*.,* 2013 (PMRA# 2544385). Although the exposure concentrations used for the chronic toxicity tests were 100-fold lower than those used in acute toxicity tests, a low but detectable difference between the immobility and mortality response remained for some test species (for example, *C. horaria* 28-d EC_{50} and LC_{50} = 0.126 and 0.316 µg a.i./L, respectively); this would suggest that the lag time between the immobility and mortality response may not have been reached after 28 days.

If the effective insecticide exposure concentration causing paralysis is removed, recovery of an aquatic invertebrate may occur. However, an immobile organism is more likely to be outcompeted, undergo starvation and be subject to increased predation. The potential for aquatic invertebrates to remain immobilized long after imidacloprid exposure with no possibility of subsequent recovery is a valid concern due to imidacloprid's mode of action (i.e., virtually irreversible binding to nicotinic acetylcholine receptors in the central nervous system of insects) and the supportive observational evidence of delayed mortality in invertebrate species from laboratory studies. An apparent delay in mortality has also been observed in higher tier aquatic field studies that use a single pulse exposure: most of the organisms do not die immediately but start dying in large numbers after a week, and their populations disappear completely after a few weeks (for example, Hayasaka et al., 2012 (PMRA# 2541822) and Sánchez-Bayo and Goka 2006 (PMRA# 2541831)), as cited in Sánchez-Bayo et al., 2016 (PMRA# 2945923).

From a population standpoint, immobility is considered as relevant as mortality. For this reason, Health Canada feels that endpoints reported based on immobility (for example, Roessink et al., 2013 (PMRA# 2544385), Beketov and Liess, 2008 (PMRA# 2544548) and Van den Brink et al*.,* 2016 (PMRA# 2712707) are valid for consideration in the risk assessment.

Given that monitoring data show frequent detections of imidacloprid in Canadian surface waters that are above toxicity thresholds for aquatic invertebrates and that the lag time between acute immobility and mortality for invertebrate species may not be reached for most species after 96-hour exposures, toxicity endpoints based on a longer exposure period (chronic) may be a more relevant metric in the risk assessment.

2.23 Comment: Criteria for acceptable level of mortality in studies

Aquatic invertebrate control immobility/mortality above recommended standard guidelines (for example, >10% - OECD 202, 2004) is reported in some studies. Studies cited include:

- Sánchez-Bayo and Goka 2006 (PMRA# 2541831): In acute toxicity tests, control mortality of 9 and 11% is reported for *C. sphaericus* after 24 and 48 hours, respectively. Roessink et al., 2013 (PMRA# 2544385): Control mortality ranged from 0 to 20% for all aquatic invertebrate species tested (acute and chronic exposure tests) with only one exception (33% control mortality for *Gammarus pulex* for the acute toxicity test only).

- Van den Brink et al., 2016 (PMRA# 2712707): Control mortality ranged from 0 to 20% for all aquatic invertebrate species tested (acute and chronic exposure tests).

Health Canada response

The criterion for what constitutes an acceptable level of mortality in controls varies among standard guidelines for aquatic invertebrate toxicity tests. For acute toxicity tests with daphnia, the OECD and USEPA recommend that control immobility/mortality should not exceed 10% (OECD guideline 202 and USEPA guideline OCSPP850.1010). For chronic toxicity tests, the USEPA states control immobility exceeding 20% (USEPA - OCSPP850.1330) should not be considered acceptable, as does the 2007 Environment Canada guideline for *Ceriodaphnia dubia* (REPORT EPS1/RM/21). For acute toxicity tests with chironomid species, the OECD (OECD guideline 235) recommends that control immobility should not exceed 15%; for prolonged exposure tests, the OECD guideline (OECD guideline 219) recommends < 30% mortality based on emergence. Given the range of non-standard species tested with imidacloprid, Health Canada feels that there is some flexibility with other guidance with regard to acceptable control immobility/mortality. Toxicity tests with marginal exceedances in mortality/immobility above 10% but below 20% were considered acceptable.

Health Canada notes that the acute endpoint reported for *Gammarus pulex* in Roessink et al., 2013 (PMRA# 2544385) was considered in the initial aquatic invertebrate risk assessment. Based on the high control mortality reported for this test species (33%), the acute EC_{50} endpoint value should not have been considered acceptable and is not included in the updated acute aquatic invertebrate risk assessment.

The authors noted that the physicochemical variables showed no significant increase or decrease over the experimental period with the exception of the acute test for *G. pulex* (i.e., dissolved oxygen decreased drastically during the acute test performed with *G. pulex*). The elevated control mortality observed for *G. pulex*, therefore, may have been related to low dissolved oxygen conditions.

2.24 Comment: Natural behaviour of mayfly larvae

Mayflies are a non-standard invertebrate test species, the larval and nymph stages of which have been used in non-GLP laboratory toxicity studies. The natural behaviour of mayfly larvae is to remain still under test conditions; this behaviour precludes the use of standard methods of assessing immobility (for example, mechanical stimulation – swirling/agitation) as well as those employed by the study authors (visual observation for 20 seconds or mechanical stimulation) as it would lead to erroneous conclusions (i.e., false positives). Sánchez-Bayo and Goka, 2006 (PMRA# 2541831) and Roessink et al., 2013 (PMRA# 2544385) conducted toxicity tests for a number of aquatic invertebrate species that did not use stimuli, which is required for immobility assessment in standard regulatory guidelines (OCSPP and OECD guidelines). For some species the methodology employed in this study is not adequate for assessing adverse effects since the normal behaviour of the organism may be to cease movement in the presence of light or perceived predators (for example, human observer).

Health Canada response

Immobility (lack of movement) is used as a surrogate for lethality in standard toxicity testing guidelines for aquatic invertebrates. The methods recommended for measuring immobilization vary among standard guidelines as do the definitions as to what movement constitutes immobilization.

- The USEPA guideline for acute and chronic daphnid toxicity tests (OCSPP850.1010 and OCSPP850.1300, respectively), described mortality as "...unable to swim for 15 seconds after gentle agitation of the test vessel are considered to be immobilized even if they can still move their antennae".
- In OECD acute test guideline 235 (i.e., acute immobilization test for chironomids) immobility is also the standard measure of lethality since it can be difficult to determine mortality in first instar larvae; organisms are considered immobilized if unable to change position (crawling and swimming movements) within 15 seconds after mechanical stimulation (a gentle stream of water from a Pasteur pipette or gentle agitation of the test vessel).
- In other test guidelines, gentle prodding is recommended to assess immobility, but the period of observation is unspecified (OCSPP 850.1735: Spiked Whole Sediment 10-day Toxicity Test, Freshwater Invertebrates).

In Roessink et al., 2013 (PMRA# 2544385) and Van den Brink et al*.,* 2016 (PMRA# 2712707), all invertebrate test species were assessed by the same criteria: immobility (based on no observable movement over a 20-second period) and mortality (gentle stimulation using a Pasteur capillary pipette for 3 to 5 seconds). Although the methods differ slightly from recommended standard guidelines, the effects were assessed relative to control groups in which immobility/mortality was low. For observations, all test systems were treated the same (personal communication with study authors (PMRA# 2760347)). The study authors state that prior to inspection, the test systems were moved causing some external stimulus via movement of the water. The authors clarify that non-paralytic movements were observable in the two mayfly species over the 20-second period included gill and abdominal movement; for *C. dipterum*, crawling and swimming was also observed but for *C. horaria*, only crawling was observed sometimes.

Given that immobility/mortality in controls was observable and minor and Health Canada received clarification regarding observable movement from the study authors, the results from these toxicity studies are considered valid for the risk assessment. Additional advice and comments regarding the issue of detectable movements in mayfly larvae in laboratory toxicity studies were provided by Dr. Francisco Sánchez-Bayo (personal communication – 6 October 2017, PMRA# 2830131).

Health Canada notes that the USEPA also contacted the study authors during its 2016 Preliminary Aquatic Risk Assessment of Imidacloprid (PMRA# 3076605). The USEPA states:

> "…organisms were carefully observed for 20s for immobilization and communication with the study author (P. Van den Brink – 15 December 2016) indicated that mayflies did not recover after immobilization (i.e., immobilization led to death)."

In addition, the USEPA reports recalculated acute and chronic toxicity endpoints for some of the test species using raw data (provided by the study authors) and USEPA statistical methods. The USEPA's derived endpoint values are similar to those reported in Roessink et al., 2013 (PMRA# 2544385). It should be noted that the authors did not measure other chronic endpoints such as growth and reproduction, which conceivably could be more sensitive than survival or immobilization.

With respect to Sánchez-Bayo and Goka, 2006 (PMRA# 2541831), the toxicity of imidacloprid to mayfly was not assessed; the test species included three ostracods (*Ilyocypris dentifera* Sars, *Cypridopsis vidua* O.F. Mueller and *Cyretta seurati* Gauthier) and two cladoceran species (*Chydorus sphaericus* O.F. Mueller and *Daphnia magna*).

Based on the results reported in the study, a concentration response was demonstrated for all test organisms. Two endpoints were reported in the study: immobility and mortality. The number of immobile organisms and dead organisms was recorded after 24 and 48 hours of exposure. The distinction is described by the authors as follows:

> "Immobility, i.e., the inability to swim within 15 s after gentle agitation of the test container (OECD, 1993); and (ii) mortality. Both endpoints were checked after 24 and 48 h from the beginning of the tests. Immobility does not imply total paralysis, and in fact organisms usually spin helplessly at the bottom of the container – often upside down – while trying to lift themselves up, or in the case of ostracods use their limbs to crawl with difficulty. While immobility is a well established and easy to follow criterium for this kind of bioassays, mortality is by no means less clear: in addition to being

> motionless, dead crustaceans are usually colourless, have their carapaces fully opened, and sometimes they are ripped apart and have their guts spilled over. To avoid doubts about an organism being dead or fully paralysed, examination under a magnifying glass was done in all cases."

The methods employed by the authors are considered acceptable.

2.25 Comment: Control immobility/mortality not reported

Results for control immobility/mortality are not reported in some aquatic invertebrate toxicity studies. Studies cited include: Hayasaka et al., 2012 (PMRA# 2541822), Kungolos et al., 2009 (PMRA# 2544388), Daam et al., 2013 (PMRA# 2544387) and Beketov and Liess 2008 (PMRA# 2544548).

Health Canada response

In Hayasaka et al., 2012a (PMRA# 2544538), the acute toxicity of imidacloprid to five cladoceran species was investigated. The study authors report that OECD guideline 202 was followed (Acute Daphnia Immobilization Test, mentioned on page 423 of the study). Acceptable control mortality (immobilization) in OECD 202 is stated as "…not more than 10% of the daphnids should have been immobilized". Although control mortality (immobilization) is not reported in the study, the assumption is that immobilization was less than 10% for all species.

In Kungolos et al., 2009 (PMRA# 2544388) and Daam et al., 2013 (PMRA# 2544387), the acute toxicity of imidacloprid to *Daphnia magna* was investigated. A commercial *D. magna* toxicity test was used (MicroBioTests Inc.- Daphtoxkit F). The standard operating procedures of this toxicity test adhere to the following recognized and acceptable guidelines:

- ISO standard methods for *D. magna* (International Organisation for Standardisation, 2012. Water Quality – Determination of the Inhibition of the Mobility of *Daphnia magna* Straus (Cladocera, Crustacea) – Acute Toxicity Test. ISO p.6341
- OECD Guideline 202: *Daphni*a sp., Acute Immobilization Test.

These guidelines, as well as the test protocol for Daphtoxkit F –magna (MicroBioTests), stipulate that control mortality (the number of dead + immobile organisms) must not exceed 10%. Since the authors in either study make no mention of mortality exceeding 10% for *D. magna* within 48 hours, it can be assumed that control mortality was less than 10% for this species.

In Beketov and Liess, 2008 (PMRA# 2544548), the initial intended exposure duration of the acute toxicity tests was 96 hours for the three test species: an amphipod (*Gammarus pulex*), mayfly larvae (*Baetis rhodani*) and blackfly larvae (*Simulium latigonium).* Control mortality for *Baetis rhodani* was ≥ 10% mortality after 48 hours (referenced as a footnote in Table 2 of study). For this reason, the authors report a 48-hour LC_{50} for this species only, whereas for the other two test species (*Simulium latigonium* and *Gammarus pulex*), 96-hour LC_{50} values are reported.

Since the authors make no mention of mortality exceeding 10% for these two species within 96 hours (as was done for *B. rhodani* after 48 hours), it can be assumed that control mortality was less than 10% for these two species.

2.26 Comment: Exposure not analytically verified

In some aquatic invertebrate toxicity studies, the exposure concentrations were not analytically verified; the toxicity endpoints were determined based on the nominal test concentrations. Studies cited include: Hayasaka et al., 2012a (PMRA# 2544538), Kungolos et al., 2009 (PMRA# 2544388), Beketov and Liess 2008 (PMRA# 2544548), Sánchez-Bayo and Goka 2006 (PMRA# 2541831), Daam et al., 2013 (PMRA# 2544387).

Health Canada response

Health Canada recognizes the importance of testing exposure concentrations at appropriate intervals of all test concentration levels to verify that organisms were exposed to the selected target concentrations throughout the study period. This is particularly important for chemicals that may degrade quickly and/or may sorb to test materials (i.e., the walls of the test container). In such cases, the use of nominal test concentrations to determine acute toxicity endpoints can result in significant underestimation of toxicity. To offset this, semi-static or flow-through methods can be used.

Imidacloprid, however, is highly soluble in water and is not expected to sorb readily to surfaces. In addition, imidacloprid is shown to remain very close to nominal test concentrations in similar laboratory toxicity studies conducted over a 48-hour period without renewal (for example, Overmyer et al., 2005 (PMRA# 2541830)), and in toxicity studies that used longer renewal periods (for example, Pavlaki et al., 2011 (PMRA# 2541825), Roessink et al., 2013 (PMRA# 2544385), Agatz et al., 2013 (PMRA# 2541826)). In Hayasaka et al., 2012a (PMRA# 2544539), the acute immobilization tests were semi-static (i.e., test solutions were renewed daily), whereas static test conditions were employed in the other studies (Kungolos et al., 2009 (PMRA# 2544388), Beketov and Liess 2008 (PMRA# 2544548), Sánchez-Bayo and Goka 2006 (PMRA# 2541831), and Daam et al., 2013 (PMRA# 2544387)). Based on the relative stability of imidacloprid observed in other aquatic invertebrate toxicity studies, the use of toxicity endpoints based on the nominal test concentrations in the risk assessment is considered justified.

Health Canada notes that the endpoint values reported for each of the test species fall within the range of values reported for the same or similar species reported in other studies. The endpoint values from these studies are acceptable for use in the Health Canada risk assessment.

2.27 Comment: Real-world conditions not considered

Health Canada has derived its chronic toxicity endpoint for its aquatic invertebrate risk assessment (0.041 ppb) from Tier I and II data only. This approach assumes that the same exposure level observed in a laboratory occurs in all habitats, all of the time, across the country. It fails to consider the impact of real-world conditions such as geography, weather patterns, crop type and application. It also fails to consider that these real-world conditions vary regionally.

Health Canada response

Health Canada recognizes that real-world conditions vary based on many factors and has taken this into account to the extent possible. The revised assessment incorporates new information received since the proposed decision, considers differences in exposures across Canada as well as higher tier population effects information for aquatic invertebrate communities. Additional water modelling has been conducted for imidacloprid which better represents regional differences. New water monitoring data for the 2017 to 2019 growing seasons in waterbodies from nine provinces of Canada as well as ancillary information, such as precipitation and crops grown in the watersheds, were considered in a revised risk assessment. The toxicity endpoints used in the chronic toxicity assessment for aquatic invertebrates have been revised to better represent real-world population and community effects for aquatic invertebrates. While higher tier effects data indicates that population and community effects observed under field conditions are less pronounced than those determined for single species in the laboratory, there is much overlap between toxicity endpoints from the laboratory and the higher tier studies. Greater detail on all of these revisions is presented in the science section of this document.

2.28 Comment: Beketov and Liess 2008 (PMRA# 2544548)

In Beketov and Liess, 2008 (PMRA# 2544548), the purity of test compound is not reported and it is unclear if a negative control (i.e., no carrier solvent present) was used. In addition, a single replicate was used per treatment level.

Health Canada response

The purity of imidacloprid is not specifically reported but is described as analytical grade (i.e., Sigma-Aldrich). This is considered a minor deficiency.

The authors report the use of dimethyl sulfoxide (DMSO) for stock solutions with a maximum concentration of <1% DMSO in exposure solutions (equivalent to <0.6 mL/L); this level of solvent exceeded the solvent concentration of <0.1 mL/L recommended in standard toxicity guidelines (for example, OECD 235: *Chironomus* sp. Acute Immobilization test; OCSPP 850.1010: Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids). The authors provide a reference (Bowman et al., 1981 (PMRA# 3158804) to support that DMSO is not toxic to aquatic invertebrates at this concentration. Low acute and chronic toxicity of DMSO to aquatic invertebrates is also reported in other studies (for example, Barbosa et al., 2003 (PMRA# 2947458): 48-hour EC_{50} = 24.6 g/L for *Daphnia magna*; Barahona-Gomariz et al., 1994 (PMRA# 2947457): 6.7 g/L for *Artemia salina*). DMSO is typically used in toxicity studies to enhance the dissolution of insoluble, hydrophobic chemicals. Given that imidacloprid is readily soluble in water and that DMSO is shown to be relatively non-toxic to aquatic invertebrates, the presence of DMSO at slightly above the maximum concentration recommended in standard guidelines is not likely to have affected the study results. Therefore, although it is unclear whether a negative control (no DMSO) was used in the acute toxicity studies, this is considered a minor deficiency.

A total of 10 organisms were tested per treatment level (including control), with each placed "individually into 100-mL glass beakers each containing 60 mL of a test solution". A minimum of 10 organisms is recommended for acute studies with commonly tested species such as Daphnia (for example, EC 1990, EPS 1/RM/11). The test design used in terms of replication and total number of organisms is considered acceptable for the determination of acute toxicity endpoints. The acute toxicity endpoint values reported by Beketov and Liess, 2008 fall within range of other reported values for the same species or species belonging to the same family (Ephemeropterans).

2.29 Comment: Daam et al., 2013 (PMRA# 2545413)

In Daam et al., 2013 (PMRA# 2545413), acute toxicity tests with *D. magna* were performed in the dark.

Health Canada response

The light conditions during the toxicity tests are not reported. According to OECD 202, a 16-hour light and 8-hour dark cycle is recommended; however, complete darkness is also acceptable, especially for test substances unstable in light.

2.30 Comment: Kungolos et al., 2009 (PMRA# 2544388)

In Kungolos et al., 2009 (PMRA# 2544388), water quality data were not provided.

Health Canada response

The acute toxicity results for *D. magna* are the same as those reported in a previous publication (Kungolos et al., 2006; PMRA# 2541669). The reported endpoint falls within the range of 48-hour LC_{50} values reported for *D. magna*. The value can be used for risk assessment.

2.31 Comment: Pestana et al., 2010 (PMRA# 2541671)

In Pestana et al., 2010 (PMRA# 2541671), the evaluation of predatory cues was not conducted with guideline-validated methods and, therefore, introduces high uncertainty regarding robustness of the reported endpoint.

Health Canada response

Acute lethality experiments were conducted with *D. magna* in the absence and presence of predator chemical cues (water conditioned by fish for 24 h and macerated *Daphnia*) in order to determine if these altered the lethal sensitivity of *D. magna* to imidacloprid. The authors hypothesized that exposure to imidacloprid can affect *Daphnia*–fish interactions by causing alterations in the direction or magnitude of induced responses to fish perceived predation risk. The EC_{50} values of daphnids exposed to imidacloprid and predatory chemical cues were not significantly different compared to daphnids exposed to the pesticide alone revealing that for short term exposures perceived predation risk does not appear to increase the sensitivity of *D. magna* to imidacloprid. The imidacloprid 48-h LC_{50} (95% CI) for *D. magna* was 96.65 mg/L (95% CI: 87.83–105.60) with no predatory chemical cues and 90.68 mg/L (95% CI: 82.04–99.30) when simultaneously exposed to high concentration of predation chemical cues. *Daphnia* is shown to be the less sensitive to imidacloprid than other freshwater crustaceans and insects. The EC_{50} values are consistent with the range of acute toxicity values shown for *Daphnia* exposed to imidacloprid. Both LC_{50} values were included in the calculation of a geomean acute toxicity endpoint value for *D. magna* that was used in the species sensitivity distribution analysis; as the presence of chemical cues had no significant impact on toxicity, there is no reason to exclude the endpoint based on predatory cues. Although standard guideline methods were not used (i.e., evaluation of predatory cues), the study is considered scientifically sound and reliable.

2.32 Comment: Van Wijngaarden and Roessink 2013 (As reported in EFSA 2014, PMRA# 2545413)

A study by Van Wijngaarden and Roessink (2013), was not available to Health Canada for review, but the results of the study were considered by Health Canada based on those reported in EFSA’s 2014 environmental assessment of imidacloprid (PMRA# 2545413). The study tested the sensitivity of three different freshwater invertebrates to imidacloprid. While EFSA did not consider endpoints for two of the three tested species appropriate for risk assessment, Health Canada considered all three endpoints suitable despite not reviewing the study. In addition, the damselfly endpoint is not reported consistently by Health Canada. In the Proposed Decision, the endpoint is listed as 96-h EC_{50}=150 mg a.i./L but is presented as 150 µg a.i./L in the species sensitivity distribution (SSD) and hazard concentration 5 (HC_5) calculation and in the monograph.

Health Canada response

Studies classified as acceptable in foreign reviews of OECD member countries (for example, EFSA, USEPA) are considered acceptable by Health Canada. Such studies are not fully reviewed. OECD member regulatory agencies evaluate the quality of toxicity data following standards and guidelines that are deemed acceptable to Health Canada. If Health Canada feels that a foreign review of an environmental fate or toxicity study is inaccurate or has reason to believe that the study may be unacceptable, Health Canada will conduct a full review of the original study.

The study in question (Van Wijngaarden and Roessink, 2013) was not submitted to Health Canada for the re-evaluation of imidacloprid, nor was it submitted during the consultation period. Although Health Canada did not formally review the study, certain limitations that influence the study reliability/validity are addressed in the 2014 EFSA review. Specific concerns raised by EFSA included 1) high control mortality and 2) seasonal differences in sensitivity between Ephemeropteran species collected in summer and fall. Specific reasons for excluding the two Ephemeropteran endpoints in the risk assessment are not stated by EFSA.

<u>Control mortality:</u> EFSA reports that in the test with the univoltine mayfly (*Caenis* sp.), 30% mortality in the control occurred. The study authors assumed 20% control mortality as validity criterion. The high control mortality for this species was further discussed by the experts at the Pesticides Peer Review Experts Meeting 116 (EFSA, June 2014). The

experts considered that the standard validity criteria reported in the OECD guidelines for aquatic invertebrates cannot be applied to Ephemeroptera and that higher control mortality may not invalidate the results. Health Canada concurs; however, Health Canada feels that 30% control mortality is unacceptably high and warrants exclusion of the *Caenis horaria* endpoint. The EC_{50} endpoint value for this species should not have been considered in the initial aquatic invertebrate risk assessment and was not included in the updated risk assessment (i.e., recalculation of the acute SSD without the *C. horaria* endpoint). No concerns are raised by EFSA regarding control mortality for the other two test species.

<u>Seasonal sensitivity differences:</u> Notable differences in sensitivity are apparent between laboratory studies conducted with the multivoltine (*Cloeon*) and univoltine (*Caenis*) mayfly species collected in summer compared to fall (i.e., Roessink et al., 2013 (PMRA# 2544385) and Van Wijngaarden and Roessink, 2013. Greater sensitivity is observed with summer collected specimens. EFSA 2014 cites that the season of collection may be an important parameter influencing the response of Ephemeropterans. It is unclear whether EFSA's decision to exclude the endpoint for the *Cloeon sp.* reported in Van Wijngaarden and Roessinks 2013 is based on the noted difference observed in seasonal sensitivity.

In a more recent study, 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 generations 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*).

A comparison of higher tier aquatic toxicity studies also shows a seasonal difference in sensitivity for *C. dipterum.* In two outdoor microcosm experiments, the NOEC value for *C. dipterum* larval abundance in the summer (0.097 µg/L, Roessink et al., 2015 (PMRA# 2744281) is much more sensitive than that determined for this species in the fall (1.52 µg/L; Roessink and Hartger, 2014 as reported in EFSA, 2014 (PMRA# 2545413)). The study test designs were almost identical with the exception that one study was conducted in summer and the other in the fall. Temperature, however, may also have played a role in the difference observed between summer and fall toxicity (15.6 to 23.7ºC versus 5°C and 16°C, respectively). Temperature-enhanced toxicity in mayfly and other insect larvae exposed to imidacloprid is observed under laboratory conditions in studies by Camp and Buchwalter 2016 (PMRA# 2796398) and Van den Brink et al., 2016 (PMRA# 2712707).

The EFSA experts state that specimens used in the van Wijngaarden and Roessink (2013) were collected in October. In light of the evidence for seasonal differences in sensitivity of *C. dipterum* to imidacloprid, endpoints derived from specimens collected in summer (for example, Roessink et al., 2013 (PMRA# 2544385) should be considered over endpoints based on overwintering generations (e.g,. Van den Brink et al., 2016 (PMRA# 2712707).

The endpoint reported for *C. dipterum* by van Wijngaarden and Roessink 2013 (fall collected specimens), was not considered in the updated aquatic invertebrate risk assessment (i.e., the acute SSD was recalculated without the *C. dipterum* endpoint based on fall collected specimens).

Erratum — Coenagrionidae endpoint: The endpoint for Caenagrionidae in the proposed decision document PRVD2016-20 is reported incorrectly. The value cited in the monograph and used in SSD calculation for estimating the acute invertebrate HC_5 is correct (96-hour LC_{50} = 150 µg a.i./L).

2.33 Comment: Validity of studies

Toxicological studies by both Stoughton et al., 2008 (PMRA# 2541836) and Roessink et al., 2013 (PMRA# 2544385) are amongst the most conservative effect endpoints available and the European Food and Safety Authority (EFSA) review for imidacloprid has reported concern in the validity of these studies. An explanation from Health Canada on the use of these studies is requested.

Health Canada response

According to the 2014 EFSA Peer Review Report on Imidacloprid (PMRA# 2545413), the peer review experts requested and received raw data and other useful information not in the original publication for Roessink et al., 2013 (PMRA# 2544385). EFSA noted some inconsistencies between the raw data and the information reported in the published paper: for example, data on the control mortality in some chronic tests were slightly different; it was unclear how analytical measurements of imidacloprid in water were performed; information on sampling period was unclear (despite personal communication with authors). Overall, due to the lack of a detailed description of the study design, EFSA determined that it was not possible to rule out the identified shortcomings (i.e., further data would be needed to consider the study as fully reliable). Since this study indicated Ephemeroptera to be likely the most sensitive organisms to imidacloprid, Health Canada decided to use the endpoints for the SSD as a conservative approach (i.e., the study was considered reliable with restrictions). The authors did not measure other chronic endpoints, such as growth and reproduction, which conceivably could be more sensitive than survival or immobilization.

Health Canada agrees with the EFSA's assessment and, likewise, chose to include the Roessink et al., 2013 (PMRA# 2544385) data for SSD calculations. Data from Roessink et al., 2013 (PMRA# 2544385) was also considered in Bayer CropScience's aquatic risk assessment (PMRA# 2610253) and more recently in the USEPA's 2016 Preliminary Aquatic Risk Assessment of Imidacloprid (PMRA# 3076605). The USEPA reports recalculated acute and chronic toxicity endpoints for some of the test species using raw data (provided by the study authors) and USEPA statistical methods. The USEPA's derived endpoint values are similar to those reported in Roessink et al., 2013 (PMRA# 2544385).

EFSA notes that the number of replicates per time point was low (3-4 for *C. tentans*, 3 for *H. azteca*) and that the number of concentrations available for curve fitting should preferably have been higher. EFSA considered the overall quality of the study as reliable with restrictions and the data was used in EFSA's SSD analysis. Health Canada considers the study scientifically sound and ecologically relevant. The acute endpoint and chronic endpoint values (from 28-day constant exposure tests) were considered by Health Canada.

In the USEPA 2016 Preliminary Aquatic Risk Assessment of Imidacloprid (PMRA#3076605), the endpoints from Stoughton et al., 2008 (PMRA# 2541836) are reported as qualitative for the risk assessment; the nature of the classification is not provided. Bayer rated the study as "supplemental" (Knopper et al., 2015 (PMRA# 2530782)), however, the endpoint reported for *C. tentans* was used quantitatively in the SSD in Bayer's aquatic risk assessment (PMRA# 2610253). Bayer's classification of studies as supplemental includes those deemed ecologically relevant but with some uncertainties that may limit the reliability of the data (for example, study conditions or methods that deviate from preferred protocols or report insufficient detail to confirm use of acceptable methods). Bayer CropScience notes that supplemental data may be considered quantitatively in the absence of acceptable data and may also be considered qualitatively as part of a weight-of-evidence approach.

2.34 Comment: Include all toxicological data

Health Canada does not appear to have included all available toxicity studies in their evaluation of imidacloprid and, therefore, their derived acute and chronic toxicity reference values may have been either over or under conservative in their risk calculation.

Health Canada response

Health Canada has expanded its toxicological review to include environmental toxicity data that became available after completion of the initial environmental risk assessment and the publication of the Proposed Re-evaluation Decision for imidacloprid (PRVD2016-20). Additional toxicity data, referred to in the comments received during the public consultation period, has also been considered. Pulse Canada provided a comprehensive list of acute and chronic aquatic invertebrate toxicity data for imidacloprid during the consultation period for Health Canada's consideration. From this list, Health Canada identified fifteen studies that were not captured in the initial toxicological review (14 acute studies and 1 chronic toxicity study). The majority were either unsuitable or unacceptable for use in the risk assessment; one study was determined to be of acceptable quality for risk assessment consideration and was used to update the aquatic invertebrate risk assessment (Loureiro et al., 2010 (PMRA# 2945939)).

2.35 Comment: Laboratory-derived endpoints for most sensitive aquatic invertebrates

The endpoints used in the proposed re-evaluation decision were determined under ideal laboratory conditions, using the most sensitive species. Typically, risk assessment use standard test species, such as *Daphnia magna.* Health Canada does not indicate where and when these other more sensitive species are found in the environment or if they exist at all in Canada.

Health Canada response

All open literature studies are fully reviewed by Health Canada in terms of their quality and acceptance for consideration in the risk assessment. Although some studies may use a non-standard guideline species and are not conducted according to specific study guidelines, valuable information can still be obtained. In some cases, studies may be deficient in some area that may restrict how the results of a study should be employed. Despite such limitations, these studies may be considered reliable with restrictions (or acceptable with limitations). Non-Canadian species are not expected to be more sensitive than Canadian species, and non-Canadian species data were used as a surrogate to Canadian species toxicity information.

There is support for use of species in SSDs from different habitats and different geographic areas. An evaluation of toxicity data for insecticides shows that species assemblages used in SSDs from different habitats (for example, lentic vs. lotic) and from different geographical areas do not significantly influence HC_5 values (Maltby et al., 2005 – PMRA# 2947453) and Brock et al., 2008 (PMRA# 3161794).

The majority of the aquatic invertebrate species considered in Health Canada's revised aquatic invertebrate risk assessment are native to Canada; these data consist of both standard and non-standard test species. Health Canada's revised risk assessment also included a re-examination of aquatic invertebrate toxicity information from higher tier aquatic field studies considered for the initial risk assessment and consideration of additional higher tier aquatic studies published in the open literature since PRVD2016-20. Details of the revised aquatic risk assessment are provided in the science section of this document.

2.36 Comment: Similarity to situation in California

A report focusing on imidacloprid's impacts on aquatic invertebrates and current surface water contamination in the state of California (Xerces Society, Neonicotinoids in California's Surface Waters: A Preliminary Review of Potential Risk to Aquatic Invertebrates), agrees with Health Canada's conclusions that current surface water levels of imidacloprid may be harming sensitive aquatic species that serve important ecosystem functions.

Health Canada response

The Xerces Society report was not considered in PRVD2016-20, however the studies cited in the report that are relevant to acute and sublethal effects in aquatic invertebrates were considered in Health Canada's review.

2.37 Comment: Poor fit of the SSD curve

The software used by Health Canada to fit a species sensitivity distribution curve to the toxicity data and calculate a HC_5 is limited in its computing functions, with the result that the derived curve is wrong. The software assumes the aquatic invertebrate toxicity data are normally distributed (the "default normality assumption") where they are not in fact normally distributed. The model fit is assessed by the software, and the output for the fit analysis demonstrates that the results of the curve fit should be rejected. When the appropriate data are included, and the curve fit properly derived, the resulting acute endpoint is 1.5 µg a.i./L (PMRA# 2610253), a 5-fold difference from the value used by Health Canada in its risk assessment.

Health Canada response

The software used by Health Canada to estimate HC_5 values for use in risk assessments is E_TX 2.2, which is used by European jurisdictions for the same purpose. It was developed by RIVM (The Netherlands National Institute of Public Health and the Environment), and its underlying statistical methods have been peer reviewed and published (Aldenberg and Jaworska, 2000).

Health Canada acknowledges that E_TX 2.2 has some limitations including that only one distribution function is fit to the toxicity data (normal distribution fit to log transformed toxicity endpoints). Health Canada recognizes that in some cases alternative models could better describe the toxicity data. Recognizing that a number of other software packages are currently available to fit SSDs, Health Canada has undertaken an in-depth analysis of several available packages. Until a software package has been approved for use by Health Canada, it will not be implemented in regulatory risk assessments.

The acute SSD presented in PRVD2016-20 was acceptable at alpha = 0.025 based on the Kolmogorov-Smirnov test for normality, though it was not acceptable at alpha = 0.01 for either the Anderson-Darling nor the Cramer von Mises tests for normality. To date, Health Canada has accepted SSDs if at least one of the three named tests results leads to acceptance of normality at alpha = 0.01, and the fit seems adequate based on visual inspection.

With respect to the acute aquatic invertebrate dataset to which the SSD model was fit, this dataset has been updated since the PRVD. The revised dataset and analysis can be found in the Science Section of this document.

Health Canada reviewed the toxicity data presented in the registrant-commissioned aquatic invertebrate risk assessment (PMRA# 2610253). The decision criteria used by the registrant to determine acceptability of study endpoints was not submitted to Health Canada. There are considerable differences between Health Canada’s acute dataset and that of the registrants. Chiefly, Health Canada has included toxicity data for a number of species not included in the registrant’s SSD dataset (n = 10). Ultimately, Health Canada’s dataset consists of toxicity values for 48 species. All supporting studies were reviewed for acceptability and use in SSD development following Health Canada’s acceptability criteria (https://www.Canada.ca/en/health-Canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/determining-study-acceptability-pesticide-risk-assessments.html).

Aldenberg T, Jaworska JS. 2000. Uncertainty of the hazardous concentration and fraction affected for normal species sensitivity distributions. Ecotoxicol Environ Saf 46: 1-18.

2.38 Comment: Overly conservative HC5

The approach by Health Canada used the right breadth of species in the species sensitivity distribution (SSD) however, the use of an HC_5 seems to be overly conservative given the number of species used for the SSD. It is difficult to discern from Table 23 (PRVD2016-20) which values from the acute freshwater studies were chosen for the acute SSD. Clarification is requested.

Health Canada response

Health Canada recognizes that freshwater invertebrate endpoints chosen for the acute and chronic SSD were not identified in Table 23 of PRVD2016-20. This oversight is corrected in Appendix VII, Table 1 ("Effects of imidacloprid on aquatic invertebrates in laboratory tests"). Endpoints included in the acute and chronic SSD analysis are shown in bold in the table.

2.39 Comment: Endpoint selection

Health Canada's process for the selection of EC_{50} effect endpoints over those considered as preferential by the CCME (2007a) was not reported. The use of EC_{10} concentrations are themselves considered an overly conservative value for use when assessing population level effects. Clarification is requested.

Health Canada response

The assessment has been revised based on comments received and new information. Please refer to the science section of this document.

2.40 Comment: Acute and chronic endpoints

Health Canada derived an acute hazardous concentration (HC_5) threshold of 0.36 µg/L and a chronic threshold of 0.041 µg/L. A 2014 review of worldwide concentrations of neonicotinoids in surface waters and acute and chronic toxicity endpoints for aquatic invertebrates recommended an acute threshold below 0.2 µg/L and a chronic threshold below 0.035 µg/L (Morrissey et al., 2015 (PMRA# 2538669)). The authors further suggest the application of safety factors may be warranted to account for slow recovery, additive or synergistic effects and multiple stressors.

The Dutch short-term peak exposure (i.e., acute threshold) water quality standard for imidacloprid is 0.2 µg/L, and the Dutch National Institute for Public Health and the Environment (RIVM) is currently recommending lowering the long-term exposure standard (i.e., chronic threshold) from 0.067 µg/L to 0.0083 µg/L in response to recent research showing harmful effects on aquatic organisms and mayflies in particular (National Institute for Public Health and the Environment, 2014).

Health Canada response

Endpoint values that are used in Health Canada risk assessment for imidacloprid are based on studies and data that were available to Health Canada for review during the re-evaluation process and may differ from endpoints available to and used by other jurisdictions (based on study availability, quality criteria applied as well as slight differences in endpoint selection and data analysis). Health Canada considers data from submitted GLP studies as well as scientifically sound open literature studies. Environmental risk assessments that are conducted by other jurisdictions are reviewed and considered in the final determination of risk. As such, if lower endpoints are selected for use in other risk assessments from other national Agencies (for example, USEPA and EFSA) their data is thoroughly reviewed. The assessment has been revised using all currently available, relevant information. Please refer to the science section of this document.

2.41 Comment: Acute and chronic toxicity endpoint selection

Section 4.2.2 Screening Level Assessment makes no mention of an SSD HC_5 having been calculated in derivation of acute and chronic screening endpoints for aquatic invertebrates. Additionally, the application of uncertainty factor of 2 for aquatic invertebrates is not mentioned in the text. Clarification is requested.

Health Canada response

The Science Section of this decision document describes the revised risk assessment and the acute and chronic toxicity endpoints for imidacloprid used in the final decision.

2.42 Comment: Geometric mean calculation for *C. riparius*

Multiple EC_{50} endpoint values are provided for *Chironomus riparius* but were not included in the chronic endpoint calculation (values are not shown in bold in Appendix IX, Table 23, of PRVD2016-20). Clarification is requested.

Health Canada response

In the initial risk assessment, there were two chronic EC_{50} endpoint values for *C. riparius* that were used in the SSD analysis (0.0036 and 0.00311 mg a.i./L, shown in bold in Appendix IX, Table 23, of PRVD2016-20); all other EC_{50} endpoints listed are for transformation products of imidacloprid. The assessment has been revised based on comments received and new information. Please refer to the science section of this document.

2.43 Comment: Refinements and mitigation

Risk assessment refinement should be part of the standard approach, as should discussion on possible mitigation approaches for any areas of concern. This does not appear to have happened as part of the process to date. This is unfortunate and makes the process of re-evaluation reactive and more difficult for all parties.

Health Canada response

Risk assessment refinements are part of the standard tiered approach used by Health Canada. If the conservative screening level risk assessment fails, higher-tiered risk assessments are conducted to refine the risk assessment. For imidacloprid, water and drift modelling were conducted to estimate exposure concentrations for aquatic organisms. Further refinement was conducted using available water monitoring data. For toxicity endpoints, when applicable, laboratory data combined in a species sensitivity distribution and mesocosm studies are reviewed and used as appropriate in the refinement of the risk assessment.

Mitigation measures are also considered in the risk assessment. When risks associated with spray drift are identified, mitigation in the form of spray drift buffer zones is required. Other mitigation measures can include reducing application rates, reducing the number of applications, adjustments to application timing and changes to the crop/pest use pattern.

Proposed re-evaluation decisions are subject to consultation during which time stakeholders can submit information to refine the risk assessment and propose mitigation. All comments, new toxicity information, monitoring data and proposed mitigation measures to mitigate risks from imidacloprid use submitted to Health Canada following the publication of PSRD2016-20 were considered in the final re-evaluation decision. The risk assessment has been updated and is presented in the science section of this document.

2.44 Comment: Greenhouse mitigation

To address concerns cited in PRVD2016-20, Flowers Canada Growers would question if mitigation measures or use restrictions could be put in place to ensure the volume of imidacloprid applied to container grown ornamentals was minimized to the lowest effective rates and/or by ensuring that closed loop systems are in place for greenhouse generated water?

Health Canada response

Investigative monitoring for the 2017-2019 seasons has shown that leaks in greenhouse recirculation systems are the source of highest concentrations of imidacloprid measured in two Ontario watersheds. Measures to ensure that closed loop systems are in place for greenhouse generated water were initiated by stakeholders including the greenhouse growers and Crop Life Canada.

During the consultation period, the OGVG, in partnership with the Mitigation Working Group of Agriculture and Agri-food Canada's Multi-stakeholder Forum submitted a strategy to mitigate the risk of drench applied pesticides entering the environment through surface water discharges originating from greenhouse facilities (PMRA# 2907286).

Since then, the strategy to mitigate risks from releases of pesticides, including imidacloprid, from greenhouses was further developed by an industry-led Committee on Protected Agriculture Stewardship. Between November 2018 and December 2020, the committee developed national auditable standards for Phase I of the covered production systems, which focusses on greenhouses using closed chemigation systems (Protected Agriculture Stewardship, 2020; PMRA# 3202249). Details and additional guidance for implementation of these auditable standards are continuing to be developed through the Protected Agriculture Stewardship Committee. Members of the Committee included CropLife Canada, the Canadian Horticultural Council, Flowers Canada, the Canadian Nursery Landscape Association, Mushrooms Canada and the Cannabis Council of Canada, as well as registrant companies. Health Canada and Agriculture and Agri-Food Canada (AAFC) play an advisory role to this industry-led initiative. The auditable protocols would assist operators in identifying and mitigating risks to the environment associated with pesticide application.

A third-party audit that will validate that measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds or other waters will be required for uses of imidacloprid in greenhouses.

2.45 Comment: Rejection of mesocosm studies

Concerns were raised that the chronic toxicity endpoint of 0.041 ppb was not derived from the most environmentally relevant studies. Health Canada derived its acute and chronic toxicity endpoint from lower tier laboratory studies and failed to include in its chronic endpoint analysis the higher tier data from mesocosm studies which provide toxicity data from more environmentally realistic biological and exposure conditions. Had field study data been used, a more realistic chronic toxicity endpoint of 1.01 ppb would have been derived.

Health Canada rejected a large dataset from mesocosm studies that indicate minimal impact on aquatic invertebrates under field-realistic conditions. These mesocosm studies show 25 times lower toxicity levels than those calculated under pristine laboratory conditions and have well defined protocols. Consideration of this data, even if the studies are not identical to label uses in Canada, could provide meaningful information on the potential impacts of imidacloprid in the real-world environment. The mesocosm studies that were submitted by the registrant went through an independent scientific peer-review process and are available to the public in a scientific journal (Whitfield-Aslund et al., 2016 (PMRA# 3161801)). In addition, the assessment was evaluated by renowned, independent Canadian experts in the field of ecotoxicology (Giesy and Solomon, 2017 (PMRA# 2744283)) who concluded that the evaluation, methodologies, and conclusions of the assessment were appropriate.

Health Canada response

Health Canada routinely follows a weight-of-evidence approach in conducting its environmental risk assessments. The re-evaluation of imidacloprid considered results from several acute and chronic aquatic invertebrate toxicity studies as well as those from higher tier aquatic field studies (for example, mesocosms). The results of twenty-two higher tier studies considered in Health Canada’s initial aquatic risk assessment confirmed laboratory data showing that the most sensitive aquatic organisms are invertebrates and that certain components of the invertebrate community are particularly at risk.

Because of various deficiencies (and resulting uncertainties) identified, the higher tier data was considered supportive information only for the initial aquatic invertebrate risk assessment. The nature of the deficiencies was presented in PRVD2016-20.

Health Canada conducted a comprehensive re-examination of previously available higher tier aquatic invertebrate data, as well as review of additional data published since PRVD2016-20. Based on the review of toxicity endpoints from mesocosm studies investigating the effects of imidacloprid, a deterministic effects metric of 0.16 µg a.i./L 28-d TWA (time weighted average) was determined for use in the quantitative risk assessment. Details of the revised aquatic risk assessment are provided in the science section of this document.

2.46 Comment: Mesocosm guidance is needed

Health Canada, working with the USEPA, should collaborate with industry on mesocosm study guidelines and how to make the studies more useful for a risk assessment.

Health Canada response

Guidance on the design and interpretation of aquatic mesocosm studies is available from various sources. These include:

- OECD Series on Testing and Assessment Number 53 "Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosm and Mesocosms)", 2006
- Community-Level Aquatic System Studies Interpretation Criteria, SETAC, 2002
- EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)
- Aquatic Mesocosm Tests to Support Pesticide Registrations (USEPA, 1980, Leslie W. Touart)

In the case of imidacloprid, laboratory data suggested Ephemeroptera were most susceptible. As a result, Health Canada considered inclusion of Ephemeroptera in mesocosm studies important for the production of valid endpoints for the risk assessment.

2.47 Comment: Probabilistic risk assessment approach

Recently, a comprehensive higher tier probabilistic ecological risk assessment was conducted to evaluate the potential for acute and chronic effects to aquatic invertebrate communities from exposure to imidacloprid arising from labeled agricultural and non-agricultural uses (Whitfield-Aslund et al., 2016 (PMRA# 3161801)). This was not considered in Health Canada's risk assessment.

The results of this assessment demonstrated that aquatic invertebrate communities are not likely to be adversely affected by acute or chronic exposure to imidacloprid from currently registered uses.

Health Canada is asked to consider a probabilistic model assessing cumulative distributions of toxicity and exposure data (Monte Carlo simulation) in assessing overall risks to aquatic receptors.

Health Canada response

Health Canada does not routinely use or consider probabilistic methods for its environmental risk assessments. Bayer CropScience's probabilistic approach to refining EECs for aquatic habitats considers the US use pattern and is highly specific to agronomic conditions (for example, soil, weather) that exist at the regional scale in the United States. The results from Bayer CropScience's probabilistic risk assessment, therefore, are not considered directly applicable to and/or representative of the Canadian use pattern and agronomic conditions therein.

Given the potential for imidacloprid mobility in soil, persistence in water and the preponderance of surface water monitoring data with frequent detections well above concentration shown to elicit toxic effects to freshwater invertebrates, Health Canada does not feel that a probabilistic approach to the aquatic risk assessment for imidacloprid is warranted.

2.48 Comment: Recovery of invertebrates

Populations of sensitive invertebrate species, unlike many other taxa, have the capacity to quickly recover because of their high reproductive fecundity and rapid recolonization.

Health Canada response

Recovery is considered when mesocosm studies are reviewed. Depending on the severity, frequency and timing of the adverse effect, it may be wholly appropriate to consider significant effects as regulatory endpoints, even if they are transitory.

2.49 Comment: Bio-monitoring, no evidence of impact

Significant monitoring of the biota should be mandatory to be able to close the loop on the correlation (if any) between the residues found and potential effects that may be shown. Conversely, if no significant biota impairment is documented, it should allow more time to decide what may need to be done.

It is not immediately clear that detected levels of imidacloprid are causing harm to aquatic invertebrates. The proposed discontinuation of imidacloprid is based on rare, elevated detections of imidacloprid in water that may be harmful to a limited number of aquatic insects under laboratory conditions but have never been demonstrated in the real-world environment. As we do not see negative impacts on Mayfly populations in Canada, this would suggest, at least, further in field investigation prior to a regulatory phase out of a crop input product is important to the competitiveness and sustainability of modern grain production. In fact, there have been reports on the record emergence of Mayfly in Manitoba in 2016. The PRVD states multiple times that imidacloprid "may pose a risk" to aquatic insects, which is not an indication of certainty. More analysis is required to verify this assertion.

Health Canada response

Incident reports related to aquatic invertebrates are unlikely to be reported as the mortality or effects need to be observed and then reported. Biomonitoring of naturally occurring populations has not been conducted in a manner that would allow Health Canada to understand the effects of imidacloprid 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 this chemical. In the absence of such data, conservative assumptions must be made.

2.50 Comment: Overestimated EEC values

Health Canada risk assessment is potentially overestimating the EEC associated with maximum foliar application rate for raspberries based on the inclusion of an over-approximated whole-system representative half-live value. Health Canada should consider a modification of their aerobic aquatic whole-system representative half-live values and incorporate an aquatic field study dissipation time data into their model.

Health Canada response

Under section 19 of the *Pest Control Prroducts Act*, it is the registrant that has the burden of persuading Health Canada that the environmental risks are acceptable. The risk is acceptable if there is reasonable certainty that no harm to the environment will result from exposure to or use of the product, taking into account its conditions of registration. Half-lives for imidacloprid were calculated using standard Health Canada kinetic models and methodology. The aerobic aquatic whole-system half-life is a standard input to the model, along with other laboratory-based fate inputs. Field studies are not typical model inputs since they provide an overall dissipation rate, which considers all dissipation routes occurring simultaneously in the field. Therefore, field studies do not satisfy the model requirement for separate half-lives to represent each of the different routes of transformation. Specifically, for imidacloprid, it is noted that a very short half-life was used in the model to describe aqueous phototransformation. With a rapid aqueous phototransformation, the influence of the aquatic half-life on model results is relatively low.

2.51 Comment: Western Canada foliar and soil application rates

High end foliar application rate assumptions may not reflect the major crop species grown in Western Canada. The only major crop species currently listed to apply imidacloprid as a foliar application in Western Canada is the potato, and the estimated application rate after adjusting for downwind spray drift is approximately 5.28 g a.i./ha. Health Canada risk assessment utilized maximum EEC in surface water estimates based on spray drift assessments in raspberries (0.3% of crop acres in Alberta) at an assumed application rate of 242 g a.i./ha (which is 45 times the application rate for potatoes). Will Health Canada consider expanding its Surface Water Spray Drift model to better represent application rates for crops grown in Western Canada?

High-end soil application rate assumptions do not reflect the major crop species grown in Western Canada. In Alberta, the only crop currently listed to apply imidacloprid as a soil treatment is the potato and the estimated application rate is 311 g a.i./ha. In Health Canada risk assessment maximum EEC in surface waters were based on Crop Group 9 (which are less than 0.8% of the total crop production in Alberta) at an assumed application rate of 586.9 g a.i./ha from transplant water (which is 1.9 times the soil application rate for potatoes). Will Health Canada consider expanding its Surface Water runoff model to better represent application rates for crops grown throughout Canada including the Western Provinces?

Health Canada response

The risk assessment has been revised and details are found in the science section of this document. Buffer zones to mitigate spray drift are specific to each crop and application method. They are calculated using the maximum labelled rate for each crop and relevant application method. Additional water modelling was conducted for the revised assessment, which includes a broader range of use patterns and regions. The potato foliar use pattern was included in the revised modelling, using the standard set of modelling scenarios. Monitoring data from 2017 to 2019 from across Canada (including the western provinces) has also been considered in the revised assessment.

2.52a Comment: Long-term consequences to delicate aquatic ecosystems, changes to community structure, sub-lethal effects

Comments were received regarding exposure of aquatic invertebrates to low dose concentrations of insecticides leading to sublethal effects and population-level effects. The long-term consequences to delicate aquatic ecosystems as a result of prolonged, chronic exposure to imidacloprid at (or exceeding) levels of concern is currently unknown.

Health Canada response

Health Canada routinely considers both short-term acute high concentration exposures and long term chronic low concentration exposures for aquatic risk assessments. The revised imidacloprid aquatic invertebrate risk assessment considered results from several long-term exposure studies conducted with a variety of species, and that cover a broad range of exposure concentrations and durations (for example, pulse exposures, continuous exposures from 21 to 60 days). A myriad of apical sub-lethal effect parameters are reported in these studies (for example, mortality, immobilization, emergence, feeding activity, growth, reproduction, sex ratio).

The revised risk assessment also included a review of several higher tier aquatic studies consisting of a broad range of study designs (for example, artificial stream, microcosm, mesocosm) of varying scope, purpose, biological complexity and exposure conditions (for example, indoor versus outdoor conditions, pulsed or continuous exposure, single or multiple application, varying application intervals, study duration, temperature, etc.). A comprehensive comparison and analysis of statistically significant effects (the presence or absence thereof) of imidacloprid on aquatic invertebrate apical, population-, or community-level measurements was conducted.

Collectively, chronic toxicity data for imidacloprid (laboratory and higher tier) shows Ephemoropterans (i.e., *Cloeon dipterum*) as the most sensitive aquatic invertebrate species. The derivation of the chronic HC_5 metric for aquatic invertebrates includes this taxon. Based on the review of toxicity endpoints from mesocosm studies investigating the effects of imidacloprid, a deterministic effects metric of 0.16 µg a.i./L 28-d TWA was determined for use in the quantitative risk assessment; this effects metric is the NOEC established for *C. dipterum* abundance (larvae and emergent adults).

Details of Health Canada's revised aquatic risk assessment are provided in the science section of this document. Health Canada considers the chronic effect metrics determined for the chronic aquatic invertebrate risk assessment sufficiently conservative for the determination of long-term exposure risks to invertebrate populations and communities.

2.52b Comment: Long-term consequences to delicate aquatic ecosystems, changes to community structure, sub-lethal effects

Neurotoxic activity in aquatic invertebrates (such as aquatic insects, crustaceans, and worms) occurs when these chemicals get into waterways. Imidacloprid is very water soluble and breaks down in soil slowly, permitting it to move readily through runoff into surface water.

Experiments with both technical grade imidacloprid and formulated products containing imidacloprid have, in some cases, shown additional toxicity from formulations (Jemec et al., 2007 (PMRA# 2541824); Stoughton et al., 2008 (PMRA# 2541839); Tisler et al., 2009 (PMRA# 2541823)). There is wide variation in the sensitivity of different invertebrates between and within taxa. The commonly used test species for pesticide ecotoxicity studies, *Daphnia magna*, is orders of magnitude less sensitive to imidacloprid than many other invertebrates (Beketov and Liess, 2008 (PMRA# 2544548)), particularly Ephemeroptera and Trichoptera (mayflies and caddisflies) species (Roessink et al., 2013 (PMRA# 2544385)). Recent toxicological studies suggest that earlier research may have underestimated the toxicity of neonicotinoids on non-target invertebrates (for example, Cavallaro et al., 2017, PMRA# 2853622). In addition, older tests were not designed to look at sub-lethal impacts or long-term exposures. New information has shown that the effects of these insecticides are not short-term, but accumulate over time (Tennekes and Sánchez-Bayo, 2012). Low level exposures that do not cause immediate mortality may cause impaired feeding and other behaviours that contribute to mortality. Imidacloprid contamination can impact community structure in aquatic systems by triggering declines in sensitive species while leaving more tolerant species unaffected.

The range of concerning sublethal effects that have been identified could lead to mortality in individualsand lead to population-level impacts. Both lethal and sublethal effects impact the structure and ecological functions of aquatic invertebrate communities, with far-reaching consequences for other species that depend on healthy freshwater ecosystems (Hallman et al., 2014, (PMRA# 2576352)).

Health Canada response

The studies cited were reviewed by Health Canada with one exception; Tennekes and Sanchez-Bayo, 2012 was not directly reviewed. However, the information from this study (i.e., accumulated effect over time) was captured in the initial and revised risk assessment from the review of the World Integrated Assessment (WIA) on systemic pesticides (i.e., Pisa et al., 2014 and 2017 – PMRA# 2545410 and 2945936, respectively), as well as from results of other published studies. For neurotoxic substances, such as imidacloprid, paralysis is the first visible symptom prior to mortality. The data of Rosessink et al., 2013 (PMRA# 2544385) clearly demonstrates that a species-specific lag-time between immobility and mortality exists. Similar time dependent toxicity responses and differences among aquatic invertebrate species are reported for imidacloprid (for example, Sánchez-Bayo and Goka, 2006 – PMRA# 2541831, Van den Brink et al., 2016 – PMRA# 2712707, Tennekes, 2010 – PMRA# 2947465).

All available toxicological information has been considered in the revised risk assessment presented in the science section of this document. Laboratory and mesocosm studies both demonstrate higher sensitivity of Ephemeroptera. The endpoints chosen for the revised risk assessment are highly refined and are expected to be protective of aquatic invertebrate communities.

2.53 Comment: Water monitoring

Monitoring information, including a few published literature articles reporting concentrations of neonicotinoids in water were submitted for consideration during the consultation period for the proposed re-evaluation decision.

Health Canada response

Monitoring information submitted during the consultation period for PRVD2016-20 were included in the revised assessment if they reported concentrations of imidacloprid in Canadian surface water that were considered relevant to the aquatic risk assessment. Articles not considered included those reporting levels of neonicotinoids in playa wetlands in the United States (Anderson et al., 2013) or in wastewater treatment plants in San Francisco attributing imidacloprid concentrations measured in wastewater to pet flea control products (Sadaria et al., 2016). Canadian water monitoring data for wetlands and wastewater treatment plants were included in the revised aquatic risk assessment.

2.54 Comment: Aquatic invertebrate conclusions

Health Canada proposes to depart from its conclusion that imidacloprid poses an acceptable risk on the basis of its interpretation of the hazard from a limited subset of the available data, highly conservative extrapolation of anomalous surface water monitoring data to represent all Canadian surface waters, and establishment of a single level of concern to all aquatic systems regardless of the organisms and services the system can sustain under ideal conditions.

Health Canada response

Health Canada's revised risk assessment considers a wealth of aquatic invertebrate toxicity data, numerous microcosm/mesocosm studies and a large amount of new monitoring data from nine Canadian provinces that includes ancillary information (for example, site coordinates, type of waterbody, precipitation, crops grown in the watersheds).

The effects endpoints selected are considered protective of aquatic environments in general. All available information has been considered in the revised risk assessment which is presented in the science section of this document.

2.55 Comment: Availability of water monitoring data

Freshwater monitoring data from Ontario and Quebec confirmed exceedances of chronic risk thresholds, and in some cases also acute risk thresholds, in areas where imidacloprid is used extensively. It is reasonable to assume detection patterns would be similar in other areas of the country where robust monitoring data are currently lacking, especially considering that monitoring in other countries show concentrations of imidacloprid in water that exceed thresholds for effects in aquatic species.

Comments were received regarding the use of Eastern Canadian water monitoring data being extrapolated to reach a conclusion on imidacloprid use in other areas of the country with either limited or no surface water monitoring data existing. The commenters argue that it is not appropriate to extrapolate data from these sites to other regions in Canada that differ in many ways such as: rainfall, drainage (i.e., lack of tile drainage), crop and product use patterns, and soil types.

Health Canada response

Since the publication of the proposed re-evaluation decision, a large amount of monitoring data from 2017, 2018 and 2019 on imidacloprid concentrations in waterbodies representative of aquatic habitat in agricultural areas of Prince Edward Island, Nova Scotia, New Brunswick, Quebec, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia were submitted to Health Canada. Health Canada considered the new monitoring data and ancillary information in the revised aquatic invertebrate risk assessment for imidacloprid which is presented in the science section of this document.

2.56 Comment: Time is needed to generate new data and explore mitigation options

Comments were received regarding the aquatic toxicity endpoints and the length of time needed to collect water monitoring data for consideration in the final decision. Agriculture and Agri-Food Canada's Multi-Stakeholder Forum has set up a working group that is producing important water monitoring data that should inform the final decision. The re-evaluation decision should be expanded to include more recent overall concentrations and frequency data that will provide a more refined view of potential risk trends in specific areas and from specific uses.

Health Canada response

The toxicological endpoints used in the assessment came from registrant generated studies or from studies published in the public literature. All the studies used in determining endpoints were available to registrants prior to the publication of the proposed re-evaluation decision.

The risk assessment methods employed by Health Canada (use of the most sensitive species, calculation of species sensitivity distribution HC_5 values) are routine. The process followed by Health Canada to conduct a risk assessment and publish a proposed decision based on the available information has not changed.

Health Canada participated in the Agriculture and Agri-Food Canada (AAFC) Multi-Stakeholder Forum on Neonicotinoids and had a presence on the working groups for environmental monitoring, risk mitigation and alternatives. Health Canada has worked with stakeholders to provide guidance on the water monitoring data gaps, has provided guidance on the ancillary information required for proper analysis and has allowed additional time to generate new water monitoring data. National water monitoring data were generated for the 2017, 2018 and 2019 growing seasons and these data have informed the revised risk assessment. The Risk Mitigation Working Group submitted information on potential mitigation measures that has been considered in the risk assessment.

2.57 Comment: Need to identify sources of high detections

Comments were received regarding the difficulty in identifying sources of imidacloprid. Health Canada risk assessment indicates that the risk to freshwater insects cannot be attributed to a specific crop or application. In such cases, a proposal to withdraw all uses of imidacloprid without properly identifying uses that drive high concentrations in surface water is not acceptable. It indicates a need for a refined risk assessment which should incorporate data generated by AAFC's Multi-Stakeholder Forum. Environmental water sampling results can be used as an indicator that a pesticide residue has moved from the site of application.

The approach taken by Health Canada (limited sampling in high use area with light textured soil, representing the worst-case scenario) is not consistent with modern risk assessment approaches. Uses (by crop, geography, and application type) were not evaluated separately. We know from experience that growing conditions, use patterns and a range of other growing elements often differ from province-to-province and certainly between eastern and western Canada. Health Canada should assess the risk profile of all uses separately and consider focusing risk mitigation for those uses where detection above levels of concern appears most likely.

The limited water monitoring data available lacks ancillary information needed to better understand the source of the elevated levels of imidacloprid. The current proposal makes the sweeping proposal to cancel all uses without knowing what has led to the sampling numbers found to date.

AAFC's Multi-Stakeholder Forum has set up a working group (The Environmental Monitoring Working Group) which has developed a robust standardized protocol titled "Surface Water Monitoring for Neonicotinoids (Imidacloprid, Thiamethoxam and Clothianidin)" for addressing Health Canada's concerns related to the presence of neonicotinoids in surface water.

This program will generate scientifically robust data, Canada-wide, for use in this re-evaluation as well as the special reviews of clothianidin and thiamethoxam. This water monitoring data should be used to inform the final decision.

Health Canada response

Since the publication of PRVD2016-20, a large amount of monitoring data and associated ancillary information from across Canada for the 2017, 2018 and 2019 seasons was submitted to Health Canada, in large part by members of the Environmental Monitoring Working Group. The new information has significantly informed the revised risk assessment for aquatic invertebrates. In addition, the exposure assessment has been expanded using region- and crop-specific modelling of representative foliar, soil and seed treatment applications of imidacloprid in different regions of Canada. The revised assessment is found in the science section of this document.

2.58 Comment: Proposed decision is based on old data and grower practices have changed

Health Canada relied on limited, sometimes inappropriate and often old data. For example, Health Canada only reviewed water monitoring data generated up until 2014. Water monitoring studies conducted by an independent third party indicate that residues deriving from imidacloprid products used in Ontario have decreased considerably. Data collected through this report revealed much lower concentrations of imidacloprid in 2015 and 2016 in the areas with the highest detected levels of imidacloprid between the years of 2012-2014. The impact of changes to industry practices since then (for example, fluidity agents, dust deflectors, changes to greenhouse practices), would not be reflected in those data sets and do not appear to have been taken into account during Health Canada's review. Consideration of newer data would make it possible to refine the spatial and temporal trends to accurately determine the source(s) of potential risks and allow for the development of targeted risk mitigation strategies to reduce potential exposure.

Certain data used by the PMRA appear to be inappropriate or incomplete. First of all, the PMRA has established an acute freshwater estimated environmental concentration (EEC) of 11.9 µg/L. If we examine the document from which this data was taken (no. 2518467), we see that it is based on a single water sample of runoff collected in 2001 from a potato-growing area of Prince Edward Island. It is therefore reasonable to believe that the use of imidacloprid may have changed over time, particularly with the development of resistance to this insecticide by the Colorado potato beetle and since producers' practices regarding the handling and application of pesticides may have improved, not to mention the improvements in application equipment since then.

Secondly, the chronic freshwater EEC of 1.26 µg/L established by the PMRA is the average of the imidacloprid concentration of seven water samples collected by the Quebec Department of Sustainable Development, Environment and the Fight Against Climate Change in 2005 and 2006 in the Gibeault-Delisle Creek located in the organic soils of the Châteauguay River watershed in Quebec. Following the publication of this report in 2010, several initiatives were instituted to reduce pesticide concentrations in this creek. For example, the producers joined forces and, with the collaboration of local stakeholders, they funded the establishment of a centre of excellence in integrated pest management, which began operating in October 2012. The activities of this centre include the dissemination of information, particularly on best practices for pesticide use, and the training of agricultural producers. It is thus reasonable to believe that the best practices adopted by agricultural producers in the last few years have contributed to reducing imidacloprid levels in the Gibeault-Delisle Creek. Therefore, updating the imidacloprid concentration data based on a recent sampling of the creek would provide a more accurate assessment of the situation.

Health Canada response

For PRVD2016-20, the most recent water monitoring data available to Health Canada was used. Since the publication of the PRVD, additional water monitoring data up to and including the 2019 growing season have been submitted to Health Canada. These data are from nine provinces of Canada and include ancillary information to help in the analysis and refinement of the risk assessment. The revised assessment is found in the science section of this document.

2.59 Comment: Error in representing acute and chronic exposure

In their analysis of the water monitoring data, Health Canada compares single sample concentrations to the chronic endpoint of 0.041 µg/L when they should be comparing it to the acute endpoint of 0.36 µg/L. Single sample concentrations represent short exposure periods (acute exposure) while mean concentrations are intended to evaluate risk over a longer period (chronic exposure). This error results in a critical misrepresentation of the water monitoring data and an over-estimation of potential risk and is an issue that needs to be addressed before a final decision is reached.

For the risk assessment, Health Canada established a chronic freshwater EEC using the highest average concentration estimated from several individual imidacloprid monitoring data sets for Canadian freshwater bodies. The value used was based on 7 samples taken from one stream in a mixed vegetable/potato growing area, with the average concentration being 1.26 µg/L.

Given the limited dataset employed, derivation of a chronic concentration is not scientifically supportable.

Health Canada response

Since the publication of the PRVD, a large amount of 2017, 2018 and 2019 monitoring data on imidacloprid in waterbodies across Canada were submitted to Health Canada. While each monitoring program varied, sampling was typically weekly or biweekly (every two weeks) throughout the growing season, thereby allowing for an estimation of chronic exposure levels in water.

Single sample concentrations were compared to the acute effects metric and moving average concentrations of imidacloprid over 28 days were calculated and compared to the chronic effects metric in the revised assessment for imidacloprid. The revised assessment is found in the science section of this document.

2.60 Comment: Refinement of risk assessment based on water monitoring data

The imidacloprid data set allows for an assessment of differing natural systems with different aquatic invertebrate communities. Following this procedure, the level of concern (i.e., hazard endpoint) will change across different aquatic systems as well as the exposure (modelling or surface water monitoring) value. For example, surface water monitoring for ephemeral wetlands (Class I) and Class IV or V systems should not be used to assess risk for all aquatic species but rather the assessment should match up the proper hazard value for the communities that can live in those habitats.

Health Canada response

The risk assessment for aquatic invertebrates has been revised based on comments and new monitoring information received following the publication of PRVD2016-20. The type of waterbody sampled was considered in the assessment. The risk assessment is considered protective of aquatic invertebrate communities. Additional details can be found in the science section of this document.

2.61 Comment: Rare elevated detections and laboratory endpoints

The proposed discontinuation of imidacloprid is based on rare, elevated detections of imidacloprid in water that may be harmful to a limited number of aquatic insects under laboratory conditions but have never been demonstrated in the real-world environment.

Health Canada response

The aquatic invertebrate risk assessment has been revised using higher tier mesocosm toxicity studies which represent more realistic conditions than laboratory studies. In addition, a large amount of additional water monitoring data from waterbodies across Canada (2017-2019) has been considered. Please see the science section of this document for additional details.

2.62 Comment: Low frequency of detection and limit of detection

It is not scientifically valid to discount a study that indicates a low frequency of detection. Data from these studies are of value to inform the risk assessment and could indicate use profiles that may be acceptable. In addition, these data may validate earlier tier exposure model output and assumptions. It is also not valid to discount a study with a low limit of detection.

Health Canada response

Low detection frequencies are challenging to interpret if analytical detection limits are high and ancillary information is not provided. Low detection frequencies could be the result of many factors which cannot be determined unless sufficient supporting information is available. Such information could include analytical detection limits, pesticide use, precipitation, cropped area, and frequency of sampling.

2.63 Comment: Levels are extremely low

If the neonicotinoids are present at levels of a few parts per billion we should not view that as a cause for concern. The measurements of such extremely low levels are not necessarily indicative of a problem for aquatic life.

Health Canada response

Risk is assessed by comparing exposure concentrations to toxic effects metrics. Due to the high toxicity of imidacloprid to certain aquatic invertebrates, even very low concentrations in aquatic habitats have the potential to pose risks.

2.64 Comment: High levels being detected

A three-year investigation of neonicotinoid insecticide contamination in surface water sites across southern Ontario revealed three of the five neonicotinoids tested (imidacloprid, clothianidin, thiamethoxam), had more than 90 percent detection rates in over half of the sites. The Canadian government's threshold for imidacloprid residues in freshwater (0.23 ppb), was exceeded in 75 percent of the samples collected in two sampling sites. The data show a strong correlation between pesticide detection, precipitation, and stream discharge. Other studies of Canadian monitoring data revealed 91% detection (imidacloprid, thiamethoxam, clothianidin, acetamiprid) in wetlands sampled across the Prairie Pothole region. Health Canada reported imidacloprid at concentrations as high as 290 times greater than the level of acceptable risk. Across all studies, researchers noted neonicotinoids long-term persistence and highlighted specific concerns for wetlands in colder climates where the chemicals persist in soil and transport via snowmelt to nearby surface water.

Health Canada response

The assessment has been revised using new toxicity information, expanded water modelling and additional water monitoring from waterbodies across Canada. Additional details are available in the science section of this document.

2.65 Comment: Monitoring Peaks Underestimated

Monitoring data from areas of chemical-intensive agriculture in Ontario and Quebec show that imidacloprid is frequently detected at levels that may result in toxic effects to insects. The assessment also indicates that monitoring data probably underestimates real world exposures since sampling typically does not capture peak concentrations. In the case of modelled EECs, which are typically considered to be higher than actual environmental concentrations due to conservative assumptions in the model, Health Canada notes that imidacloprid monitoring data overlaps with the range of surface water concentrations predicted from modelling. Therefore, the estimated environmental concentrations cannot be considered conservative either.

Health Canada response

A large amount of additional monitoring data (2017 to 2019) was submitted to Health Canada since the publication of PRVD2016-20. The new monitoring data from across the country have informed the revised risk assessment for aquatic invertebrates.

While monitoring programs are typically not tailored to capture peak concentrations, some programs like the one of the Quebec provincial government involve sampling every two or three days, which has a higher likelihood of capturing peaks. Also, the sampling regimes in the targeted monitoring programs conducted between 2017 and 2019 by members of the AAFC Multi-Stakeholder Forum's Environmental Monitoring Working Group 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 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 assessment has been revised using new toxicity information, expanded water modelling and additional water monitoring from waterbodies across Canada. Additional details are available in the science section of this document.

2.66 Comment: Soybeans pose no risk to aquatic invertebrates

The re-evaluation decision did not identify any risk associated with the use of imidacloprid on soybeans, yet the soybean sector would still be subjected to a complete phase-out. This type of approach is certainly a deviation from the specific and tailored decisions made in previous Health Canada studies that ensure regulatory proposals match the specific risk they aim to mitigate.

Health Canada response

The acceptability of the use of imidacloprid on soybeans has been reassessed using new toxicity information, expanded water modelling done with crop- and region-specific scenarios and weather information and additional water monitoring data up to and including the 2019 growing season from waterbodies across Canada including areas where soybeans are grown. Additional details can be found in the science section of this document.

2.67 Comment: Concentrations in water in PEI

A summary of information from open source data in PEI on concentrations of imidacloprid in two streams was received and questions were asked about risks to aquatic invertebrates from the combined effects of multiple neonicotinoid pesticides.

Health Canada response

Available water monitoring data from rivers in Prince Edward Island for the years 2013 to 2018 have been included in the revised risk assessment for imidacloprid.

The risk to aquatic organisms was assessed using monitoring data for imidacloprid alone. Canadian water monitoring data show co-occurrence to varying degrees of the three most commonly used neonicotinoids – thiamethoxam, clothianidin and imidacloprid. When co-occurrence of residues occurs, the effects are expected to increase. 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.

Imidacloprid is not expected to partition to sediments, nor is it expected to accumulate in aquatic organisms based on its physico-chemical properties.

2.68 Comment: Monitoring in salt water

I live near agricultural fields planted with corn that are near a saltwater bay. I do not think pesticide monitoring has ever been done in the bay, but it would seem prudent, given that imidacloprid and clothianidin have been found in ground water in the watershed.

Health Canada response

As imidacloprid is very soluble in water, tides, currents and dilution are expected to play a large role in reducing concentrations in marine environments. Reducing the concentrations of imidacloprid in freshwater that runs off into the marine environment is expected to be protective of sensitive marine organisms.

2.69 Comment: Imidacloprid is being found in a variety of aquatic ecosystems

Recent advances in analytical techniques and increased water quality monitoring have found imidacloprid and other neonicotinoids in a variety of aquatic ecosystems, and sometimes at levels that are above thresholds for aquatic invertebrates. Starner and Goh, 2012 (PMRA# 2526148) found imidacloprid in 89% of water samples from three regions of California with high agricultural use. In a nationwide study in the United States, Hladik and Kolpin, 2016 (PMRA# 2559713) found at least one neonicotinoid in 53% of the stream samples collected, with imidacloprid detected most frequently (37%). Imidacloprid concentrations were positively related to the percentage of urban area within the basin. In Canada, Struger et al., 2017 (PMRA# 2703534) found imidacloprid in eight of 15 stream sites in southern Ontario. In contrast, Canadian surveys from 2000 to 2005 rarely detected imidacloprid. Imidacloprid has been found in prairie wetlands (Main et al., 2014 (PMRA# 2526133); Smalling et al., 2015 (PMRA 2526244)).

Health Canada response

Health Canada agrees that available information indicates that where imidacloprid is used, it is likely to be found in water. A large amount of Canadian water monitoring data from waterbodies across Canada including Prairie wetlands for the 2017 to 2019 growing seasons were submitted to Health Canada and included in a revised risk assessment for aquatic invertebrates.

2.70 Comment: National water monitoring program

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.

Commenters suggested a consistent, publicly funded, pan-Canadian water monitoring framework that includes other pesticides and urban contaminants of concern is needed. It was 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 and that there should be a commitment from federal and provincial governments to institute a long-term national Canada-wide monitoring program.

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 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.

2.71 Comment: Compliance program

When knowledge of imidacloprid detections in water became evident, Health Canada should have initiated a regulatory compliance program to target imidacloprid use in areas where elevated levels were being found. Such a program could have identified if the elevated detections were the result of label use of products or incidents of non-compliance with label directions.

Health Canada response

The development of a national water monitoring program framework will provide the foundation on which water monitoring programs in Canada can be strengthened.

2.72 Comment: Drift of dust from seed treatments

Exposure from drift is essentially eliminated with the use of seed treatments. Health Canada has implemented requirements that decrease exposure from dust-off when planting treated seeds as a mitigation that reduces pollinator exposure, but this measure will also reduce the potential for aquatic exposures from dust drift.

Health Canada response

Drift of dust from seed treatments has been reduced as a result of mitigation measures put in place to protect pollinators. There is evidence that dust generated during planting of seed may contribute to concentrations detected in surface water. Water monitoring data used in the revised risk assessment would account for any contributions from dust at the time of planting. Additional water modelling was conducted for the revised assessment, including comprehensive modelling of seed treatment uses.

2.73 Comment: Soybean seed treatment risks

For soybean seed treatments, the potential exposure of aquatic invertebrate communities to imidacloprid is negligible and below the level of concern. Seed is typically planted with incorporation rates exceeding 99% and at a depth of ≥1 inch (≥2.5 cm), so runoff of imidacloprid is not expected. In the PRVD, Health Canada did not present aquatic modelling results for soybean seed treatment scenarios, which would have shown no runoff to aquatic environments for treated soybean seeds.

Health Canada response

Additional water modelling was conducted for the revised assessment, including comprehensive modelling of the seed treatment uses. Water monitoring data from areas where soybeans are grown were also considered in the revised assessment. Please see the science section of this document for details.

2.74 Comment: Seed treatments have limited impact

Seed treatments that are used in small and sparing quantities in Western Canada are at risk of cancellation due to the intensive farming practices such as for potatoes which use far more insecticides and are far more likely to result in off-site impacts. Off-site impacts can be controlled without a ban.

Onion and carrot production present a relatively small environmental load as compared to other uses, resulting in low environmental exposure to imidacloprid. In addition, the seed is treated outside of Canada and is imported, so the treatment process presents no environmental load to Canada.

Health Canada response

Additional water modelling was conducted for the revised assessment, including a comprehensive modelling of the seed treatment uses of imidacloprid. The modelling generates estimated concentrations in a small generic pond located directly at the edge of the field, and therefore, does not provide insights into the contribution of the specific use pattern to the overall environmental load, for instance at a watershed scale.

The monitoring information complements the modelling by providing a better understanding of the overall exposure levels resulting from the sum of uses in a given area. In some cases, the ancillary information associated with the water monitoring data can allow for more in-depth analysis of the sources associated with high detections. However, while the monitoring information for imidacloprid is comprehensive, it is not always possible to isolate the contribution of specific use patterns. It is recognized that the smaller scale uses are less likely to contribute significantly to the overall exposure levels at a watershed scale.

2.75 Comment: Wetlands and seed treatments

Comments were received about the movement of neonicotinoids from treated seeds into wetland areas. When treated seeds are planted, only 1.6 to 20% of the insecticide is actually taken up by the seedling. The remaining material is retained in the soil. Neonicotinoids are persistent, meaning that they do not break down quickly. Half-life in soils is highly variable and ranges from 9 to 1250 days for imidacloprid. Long-term field studies have found that imidacloprid residues can carry over to the next growing season and increase in soil with each subsequent year of use until a plateau is reached after around three years. Due to their high solubility, neonicotinoids can move off site through surface or groundwater flow.

As wetlands are often at the lowest point of the regional topography, water flowing from treated fields will often end up in wetlands. Seed treatments are the mostly likely source of the neonicotinoids found in the prairie wetlands sampled by Main et al., 2014 (PMRA# 2526133, 2612760), as this is their primary use in Prairie Canada.

Health Canada response

The main use of neonicotinoids in the Prairie Region of Canada is as a seed treatment. Since the publication of the PRVD additional monitoring data on neonicotinoid concentrations in wetlands found in the Prairie Region of Canada for the 2017, 2018 and 2019 growing seasons were submitted to Health Canada. The additional monitoring data were considered in a revised assessment for aquatic invertebrates. The intensive sampling of many Prairie wetlands also allowed for the characterization of the dissipation of imidacloprid in these waterbodies. Please see the revised science section of this document for details.

2.76 Comment: Need for a cumulative effects assessment, potential for synergistic effects

Comments were received regarding cumulative risks of neonicotinoid pesticides to aquatic invertebrates. The Commissioner of the Environment and Sustainable Development recommended in 2015 that Health Canada finalize and apply a methodology for assessing cumulative effects. Health Canada agreed to this recommendation but is still working on finalizing methodology. Consequently, cumulative effects have generally not been assessed to date. In the case of imidacloprid, Health Canada has indicated that it will determine whether a cumulative effects assessment is necessary after first completing the re-evaluation. Health Canada should proceed with a cumulative effects assessment of all neonicotinoids.

When imidacloprid is detected in water, it is likely that other neonicotinoids are also present in the same environments, presenting cumulative risks to aquatic invertebrates. There has been little research done to identify the relative toxicity of various neonicotinoids, to assess the potential for synergistic effects in aquatic invertebrates or to identify the mechanisms behind synergistic interactions and their impact on aquatic invertebrates and ecosystems.

Health Canada response

Health Canada has not conducted a cumulative risk assessment for neonicotinoid mixtures in making its final regulatory decisions for imidacloprid, clothianidin and thiamethoxam. 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 stands by the general fact that given the similarity in the mode of action for the neonicotinoids, when co-occurrence of residues occurs, the effects are expected to be enhanced simply by the fact that the cumulative exposure concentration increases. 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 (PMRA# 3076589). Health Canada notes that the Canadian Council for the Ministers of the Environment (CCME) is proposing an additive approach for assessing cumulative neonicotinoid exposure by summing risk quotients for individual compounds.

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, this is an issue for older programs that have not done simultaneous sampling. 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.

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 (PMRA# 2873503) and 2018b (PMRA# 3076589), respectively). There was very little indication that chronic exposure to multiple neonicotinoids would produce a greater than additive effect. 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, while in the open water limnocorrals, mixture effects were categorized as directly additive only. Therefore, the potential for cumulative effects from both sub-lethal and lethal effects are expected to be adequately characterized by concentration addition.

2.77 Comment: Impact of other neonicotinoids

We strongly encourage Health Canada to take immediate action to curtail the use of all neonicotinoids, so as to ensure that the environmental benefits associated with an imidacloprid phase out are not suppressed by the increased use of similarly detrimental alternatives.

Further research into the aquatic toxicity of the other nitroguanidine neonicotinoids would inform regulation and ensure sufficient protection for aquatic species.

Health Canada response

The special reviews of clothianidin and thiamethoxam (effects on aquatic invertebrates) were conducted separately from the imidacloprid re-evaluation. All relevant available science for all three chemicals has been considered in the individual assessments (the final re-evaluation decision for imidacloprid and the final special review decisions on the risks to aquatic invertebrates for clothianidin (SRD2021-03) and thiamethoxam (SRD2021-04).

2.78 Comment: Explore mitigation measures

Growers are in favour of changing farm practices if warranted. This has been done over the years and includes moving to no-till or minimum till land management systems. Planting buffer zones, grassed waterways, and windbreaks are common practice across Ontario. Mitigation measures could be prescribed to further reduce soil movement into streams, if warranted. Consideration must be given to use of effective strategic mitigation practices to help resolve Health Canada concerns for certain use patterns in Canada.

Farmers are committed to implementing practices demonstrated to reduce risks to themselves, others and the environment. In order to reduce the risks, in this case to aquatic invertebrates, farmers must first understand the risks and they rely on Health Canada to conduct credible and thorough risk assessments to identify unacceptable risks.

Health Canada response

The willingness of growers to adopt mitigation measures is acknowledged by Health Canada as well as the fact that there is reliance on the regulator to identify and explain the risks. The revised risk assessment for imidacloprid considers mitigation options for all uses that exceed the level of concern. For crops with a range of registered rates, risk was examined for lower rates and number of applications and mitigation proposed, if appropriate.

2.79 Comment: New mitigation in place since water monitoring samples collected

As much of the water monitoring data relied on by Health Canada in their decision was collected prior to 2015, consideration should be given to risk mitigation measures that have been implemented since this time.

Health Canada response

Water monitoring data up to and including the 2019 growing season were considered in the revised imidacloprid risk assessment. It is recognized that the use pattern has been reduced as a result of the pollinator re-evaluation decision (RVD2019-06) and that this adds uncertainty to some of the water monitoring data that has been collected.

2.80 Comment: Best management practices not considered

Health Canada did not consider best management practices as a risk mitigation mechanism, despite the fact that this was a major factor in reducing risk to bees and leading to Health Canada and the US Environmental Protection Agency ultimately decided that imidacloprid poses no threat to pollinators.

Health Canada response

Risk to pollinators from imidacloprid was assessed separately and the final decision was published in RVD2019-06. Mitigation measures associated with RVD2019-06 provide protection for pollinators. Risk to other terrestrial and aquatic organisms were not assessed in RVD2019-06.

Best management practices and mitigation measures put in place to protect pollinators will not necessarily result in mitigation of risks for other organisms as exposure pathways may be different.

Health Canada agrees that best management practices can help reduce risks to the environment, however these practices are voluntary. The environmental risk assessment is conducted with conservative worst-case scenarios (refined when risks are identified) and includes mandatory mitigation measures only (such as spray buffer zones, burying and cleaning up spilled seeds).

2.81 Comment: Mitigation is not viable

Use-reduction strategies and precautionary label statements are not viable alternatives to mitigate the identified risks to aquatic insects. It is not possible to determine which uses must be reduced and how much of a reduction is needed in order to achieve levels of risk deemed "acceptable." Any use-reduction strategy could be undermined over time by shifting use patterns. Despite current label statements, levels of imidacloprid in waterbodies have been shown to pose risks to aquatic insects. The use of precautionary statements has proven to be inadequate.

Excerpts of PRVD2016-20 were cited regarding difficulties in mitigating risk through a use-reduction strategy. Phasing out imidacloprid, in consort with parallel action on other neonicotinoids, is the best approach to minimize risks to aquatic insects and the ecosystems they support.

Health Canada response

The statements quoted were in relation to the data available at the time of publication. Since the publication of PRVD2016-20, a wealth of robust water monitoring data has been collected from across the country over the course of three growing seasons. In addition, water modelling has been expanded and now includes seed treatments and spray applications to representative crops for all growing regions across the country. The additional monitoring data combined with the enhanced modelling allows for refinement of the risk assessment and identification of certain uses that are not expected to result in concentrations in water above the level of concern. The final decision on the acceptability of the uses of imidacloprid, presented in the science section of this document, is science-based and relies on the substantial amount of water monitoring information that has been collected by stakeholders in recent years.

2.82 Comment: Consideration of specific application methods to mitigate risk

Consideration of specific application methods is recommended as an alternative to the complete phase-out of imidacloprid: restriction on foliar spray application for select crops having a high application requirement in those regions where imidacloprid is already reported at elevated concentrations in surface water and implementation of a mandatory setback distance.

Health Canada response

The additional monitoring data combined with the enhanced modelling allows for refinement of the risk assessment and identification of certain uses that are not expected to result in concentrations in water above the level of concern. The risk assessment has been revised using new toxicity information, expanded water modelling and additional water monitoring data up to and including the 2019 growing season from waterbodies across Canada. Details are provided in the revised risk assessment section of this document.

2.83 Comment: Precautionary label statements for birds and beneficial arthropods not effective

Comments were received regarding how precautionary label statements cannot be relied on to protect against environmental risks to beneficial arthropods and birds. Limited research indicates that, in other contexts, precautionary statements on labels are selectively ignored by users who feel they do not need labels, marketing a product is seen as evidence of its safety, and many people view labels as information overload. For instance, very few people (6%) may actually read whole labels, and many (64%) only read part of food labels.

Health Canada response

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 Prrodu
cts 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.

Precautionary label statements inform the user of potential risks associated with use of a product and are typically linked to measures that reduce risk. For example, to protect beneficial arthropods in off-field habitats, spray drift is to be minimized in order to protect the population. Similarly, the requirement for users to clean up or cover spilled seed is there to protect birds and mammals. The protection goals established for birds, mammals and beneficial arthropods are at the population level. The possibility of some negative impacts on individuals within populations are a possibility, such as within the treated field.

2.84 Comment: Potential risks identified in 2001 review

Why were cascading broad based ecosystem effects not seen during original risk assessments for imidacloprid, either for the active ingredient or its many additional product formulations? Health Canada's Regulatory Note on Imidacloprid, September 7, 2001, was issued while the pesticide was under what was then called a Temporary Registration, granted in 1995 and indicated the potential to impact aquatic invertebrate indicator species in streams and ponds based on monitoring information and modelling. This is more than adequate time to consider alternatives, however Health Canada allowed aggressive growth for use in Canada.

Health Canada response

At the time of the initial registration of imidacloprid, potential risks were identified for aquatic organisms based on conservative water modelling estimates. The cyclical re-evaluation of pesticides by Health Canada (every 15 years) provides a means of re-examining decisions and refining risk assessments using new data and science. When potential risks of concern were identified with the cyclical re-evaluation of imidacloprid, special reviews of the potential risks to aquatic invertebrates were launched for two other neonicotinoids (thiamethoxam and clothianidin). For aquatic risks, water monitoring data plays an important role in refining risk assessment. Health Canada is working on a number of fronts to identify potential risk issues earlier.

3.0 Comments and responses related to the value assessment

Comments related to value were received from growers, grower groups, provincial governments, registrants, seed processors, seed trade associations and golf course/turf associations including:

Agricultural Producers Association of Saskatchewan, Aidra Farms Ltd., Alberta Agriculture and Forestry, Alberta Barley Commission, Alberta Canola Producers Commission, Alberta Golf Superintendents Association, Alberta Seed Processors, Alberta Wheat Commission, American Seed Trade Association, Association des producteurs maraîchers du Québec, Bayer CropScience, BC Greenhouse Growers' Association, BC Raspberry Industry Development Council, Bootstrap Farms Inc., British Columbia Ministry of Agriculture, Canada Grains Council, Canadian Canola Growers Association, Canadian Golf Superintendents Association, Canadian Horticultural Council, Canadian Nursery Landscape Association, Canadian Potato Council, Canadian Seed Growers' Association, Canadian Seed Trade Association, Canola Council of Canada, Cereals Canada, Christian Farmers Federation of Ontario, CropLife Canada, Dow AgroScience, Dupont Pioneer, Fédération québécoise des producteurs de fruits et légumes de transformation, Flowers Canada Growers, Glen Coulee Farm, Grain Farmers of Ontario, Grain Growers of Canada, individual growers, Ippolito Group, Jonair (1988) Ltd. / Portage Aircraft Maintenance Ltd., Keystone Agricultural Producers of Manitoba, Kowalchuck Farms, L'Union des producteurs agricoles, Manitoba Canola Growers, Manitoba Corn Growers Association Inc., Mercer Seeds, Monsanto Canada Inc., New Brunswick Agriculture, Aquaculture and Fisheries, Ontario Apple Growers, Ontario Bee Keepers Association, Ontario Fruit and Vegetable Growers' Association, Ontario Ginseng Growers Association, Ontario Golf Superintendents' Association, Ontario Ministry of Agriculture, Food & Rural Affairs, Ontario Processing Vegetable Growers, Ontario Tender Fruit Growers, Park Lane Farms Ltd., Peak of the Market, Potatoes New Brunswick, Prince Edward Island Potato Board, Producteurs de Grains du Quebec, Pulse Canada, SaskCanola, Soy Canada, Stoke Seeds Limited, Suderman Bros. Ltd., Valent Canada, Waltview Farms Limited, Western Canada Turfgrass Association, Western Canadian Wheat Growers Association, and Woodside Farm Partnership.

3.1 Comment: Limited or no alternatives to imidacloprid

A number of stakeholders emphasized that there are limited or no alternatives to imidacloprid and indicated challenges with the registered alternatives (for example, higher cost, lower effectiveness, may increase reliance on foliar sprays, pest resistance). For minor crops such as some of the fruits and vegetables, stakeholders feel that registrants will not finance the costs to register new pesticides on their crops.

Health Canada response

Health Canada acknowledges that there are few to no alternative active ingredients registered for certain imidacloprid uses. As a result of additional information received from stakeholders during the consultation period, Health Canada refined the risk assessments of imidacloprid, and risks were shown to be acceptable for certain uses with additional risk mitigation measures. Risk mitigation measures are presented in Section 3.3.6 of the Science Evaluation Assessment.

Risk concerns remain for some uses and these will be cancelled. Health Canada acknowledges that the loss of imidacloprid will leave gaps in pest control programs for some growers. Health Canada encourages grower groups to contact the registrants of potential alternative products, Agriculture and AgriFood Canada (AAFC), and their provincial minor use coordinator to discuss the possibility of pursuing new registrations to address their crop-specific needs.

3.2 Comment: Loss of imidacloprid will negatively affect the domestic and international competitiveness of Canadian producers

Imidacloprid is a critical tool in pest management strategies for many crops, and its loss will negatively affect the domestic and international competitiveness of Canadian producers. Producers need access to the best cost-effective pest management tools.

Health Canada response

Health Canada acknowledges the importance of producers being competitive in the domestic and international marketplace and recognizes the need for effective pest control products. As a result of additional information received from stakeholders during the consultation period, Health Canada refined the risk assessments of imidacloprid, and risks were shown to be acceptable for certain uses with additional risk mitigation measures. Growers will have the option of using imidacloprid with other currently registered alternative insecticides for pest management.

3.3 Comment: Imidacloprid is important as a seed/potato seed piece treatment

Imidacloprid is important as a seed/potato seed piece treatment based on its systemic activity, effectiveness against soil insects, and early season foliar pests. Imidacloprid seed treatment is a critical tool in precision agriculture.

Health Canada response

Health Canada acknowledges that seed treatments contribute to the pest management of soil insects and early season foliar pests, and that neonicotinoid seed treatments complement current crop production practices. Based on the additional information received during consultation, Health Canada refined the risk assessment, and most seed treatment uses of imidacloprid are retained with risk mitigation measures (lower rate of application). As a consequence of the reduction of the maximum rate for some seed treatment uses, some pest claims will be removed from the label. Growers will still have the option of using imidacloprid as a seed treatment for barley, oats, wheat, canola, mustard, corn, legumes (including soybean), potato, tomato, pepper, carrot, leek, bulb onion, broccoli and cabbage, cucumber, melon and squash.

3.4 Comment: Availability of untreated seed

Canada does not have a vegetable seed production industry. Most varieties grown commercially in Canada are sourced from the United States. This makes harmonization with their regulations important for providing a reliable source of varieties suitable for growing in Canada.

Health Canada response

Health Canada acknowledges that growers may have limited access to untreated seeds for certain crops. Health Canada encourages grower groups to contact their seed associations, and AAFC to raise their concerns regarding access to untreated vegetable seed.

3.5 Comment: Imidacloprid is important to produce certified seed

The Canadian Seed Growers' Association commented that Health Canada needs to consider the important role higher generation seed (foundation and registered seed) has to the Canadian seed production system. Seed for multiplication is essential to the delivery of innovative plant genetics to Canadian crop producers and supports competitiveness and success of the Canadian agriculture industry.

Health Canada response

Health Canada acknowledges that imidacloprid has value for the production of higher generation seed to the Canadian seed production system. Health Canada encourages grower groups to contact the registrants of potential alternative seed treatment products, AAFC, and their provincial minor use coordinator to discuss the possibility of pursuing new registrations to address their crop-specific needs.

3.6 Comment: Importance of imidacloprid for control of regulated pests.

Imidacloprid is an extremely important use against Canadian Food Inspection regulated pests that threaten the ability of some Canadian farmers to export their crops, including Japanese beetle on ornamentals and Swede midge on brassica vegetable crops.At present, there is only one additional registered product (Acelepryn, PCP# 28980) that is effective, not known to cause phytotoxicity and is registered for use to control Japanese beetle on ornamentals. There are no alternatives to the imidacloprid tray drench applied on brassica transplant seedlings to prevent or control the spread of swede midge from greenhouses to field grown brassica crops.

Health Canada response

Health Canada acknowledges the importance of imidacloprid for the control of Japanese beetle larvae in ornamentals and swede midge in brassica crops. During consultation, Health Canada received additional information. This additional information was used to refine the assessment of imidacloprid and risks were shown to be acceptable for greenhouse tray drench application on brassica transplant seedlings and foliar application for Japanese beetle on coniferous evergreens, and ornamental grasses.

Appendix V Revised occupational, residential, and aggregate exposure and risk estimates

Table 1 Imidacloprid commercial seed treatment unit exposure values

Study – Crop	Seeds assessed	Engineer control, PPE[1,2]	Tasks	Unit exposure (µg/kg ai)	
				Dermal	Inhalation
Previous Assessment					
2006 Study (Wheat)	Lentil, chickpea, bean, corn, pea, wheat, barley, oats, soybean, canola, mustard	Open M/L, Baseline PPE	M/L/A	265.7	2.47
Updated Assessment					
2010 Study (Corn)	Corn	Closed M/L, Baseline PPE	Application	256	3.72
			B/S/S	114	18.7
Comparison of Corn and Canola Unit Exposure Data[3]					
2010 Study (Corn)	-	Closed M/L, Mid-level PPE	Application	170	3.72
			B/S/S	54.5	18.7
2010 Study (Canola)	-	Closed M/L, Mid-level PPE	Application	53.5	1.12
			B/S/S	7.33	1.50

PPE = Personal protective equipment, M/L/A = mix/loading/apply, B/S/S = bag/sew/stack

1 Baseline PPE = long sleeved shirt and pants and chemical resistant gloves.

2 Mid-Level PPE = coveralls over long sleeved shirt and pants and chemical resistant gloves. Canola data was not available for baseline PPE scenarios.

3 Mid-Level PPE data was compared instead of baseline PPE because there are no baseline PPE data for canola.

Table 2 Short-term corn seed treatment exposure and risk assessment for M/L/A and B/S/S

Crop	Formulation[1]	Activity	Seed treated (kg seed/day)[2]	Rate (g ai/kg seed)	Unit exposure (ug/kg ai)		MOE (Target = 100)[4,5]		
					Dermal	Inhalation	Dermal	Inhalation	Combined
Previous Estimate. PMRA#1335563 (Wheat Seed Treatment Study, 2006). Long-sleeved shirt, pants, chemical-resistant gloves, Open mix/load.									
Corn	Liquid	M/L/A	60000	4.8[3]	265.7	2.47	170	900	140
Updated Estimate. PMRA #1885209 (Corn Seed Treatment Study, 2010). Long-sleeved shirt, pants, chemical-resistant gloves, Closed mix/load.									
Corn	Liquid	Application	60000	0.488[6]	256	3.72	1700	5900	1300
		B/S/S	60000	0.488[6]	114	18.7	3800	1200	900

M/L/A = Mixer/Loader/Applicators, B/S/S = Bagger/Sewer/Stackers, MOE = Margin of Exposure

1 Liquid formulation includes suspensions.

2 It was estimated that 60,000 kg of seed could be treated in an 8 hour shift based on commercial equipment capacity.

3 Maximum label rate.

4 Exposure (mg/kg bw/day) = Amount handled * Unit Exposure (µg/kg ai) /body weight (80 kg for adults). A 5% dermal absorption factor was applied to the dermal exposure estimates. Amount handled = seed treated/day * rate * 0.001 (g to kg).

5 MOE = NOAEL/Exposure. NOAEL is based on oral NOAEL of 8 mg/kg bw/day for short-intermediate term scenarios. Target MOE = 100. Combined MOE = 1/(1/dermal MOE + 1/inhalation MOE). Shaded cell indicates a MOE that is below the target.

6 The application rate is based on a lower rate used in the environment assessment.

Table 3 Imidacloprid peak TTR summary

Location	Rate (kg a.i./ha)	Spray volume (L/ha)	Peak TTR (% Application Rate)	Peak sampling time (hour)
2016 Study: Non Irrigated Plots				
Georgia	0.5826	485	2.6%	1
Kansas	**0.5666**	**235**	**9.0%**	**1**
California	0.5693	327	12.3%	1
2016 Study: Irrigated Plots				
Georgia	0.5744	479	0.2%	1
Kansas	**0.5706**	**237**	**0.2%**	**24**
California	0.5616	323	0.4%	24
2020 Study: Non-Irrigated Plots, Medium Droplet Size				
Georgia	0.453	826	1.6%	23
Pennsylvania	**0.427**	**779**	**1.3%**	11
California	0.448	817	0.7%	1
2020 Study: Non-Irrigated Plots, Coarse Droplet Size				
Georgia	0.453	827	1.7%	23
Pennsylvania	**0.436**	**796**	**1.3%**	**11**
California	0.450	822	0.4%	1

TTR = Turf Transferable Residue, **Bold values were selected for the risk assessment**

Table 4 Residential post-application dermal exposure for turf

Formulation[1]	Scenario	Life stage	Peak TTR[1] (µg/cm²)	TC[2] (cm²/hr)	Exposure time[2] (hr)	Dermal exposure (mg/kg bw/day)[3]	Dermal MOE[4]
No Irrigation, Low Spray Volume Scenario (Peak TTR = 9% of Rate)							
Wettable Powder in Water Soluble Packaging	HCLA	Adult	0.25	180000	1.5	0.0427	200
		Youth 11 <16 yrs	0.25	148000	1.3	0.0427	200
		Children 1 to <2 yrs	0.25	49000	1.5	0.0846	90
	Mowing	Adult	0.25	5500	1	0.0009	9000
		Youth 11 <16 yrs	0.25	4500	1	0.0010	8000
	Golfing	Adult	0.25	5300	4	0.0034	2000
		Youth 11 <16 yrs	0.25	4400	4	0.0039	2000
		Children 6 to <11 yrs	0.25	2900	4	0.0046	2000
No Irrigation, High Spray Volume Scenario (Peak TTR = 1.3% of Rate)							
Wettable Powder in Water Soluble Packaging	HCLA	Adult	0.04	180000	1.5	0.0062	1300
		Youth 11 <16 yrs	0.04	148000	1.3	0.0062	1300
		Children 1 to <2 yrs	0.04	49000	1.5	0.0122	650
	Mowing	Adult	0.04	5500	1	0.0001	64000
		Youth 11 <16 yrs	0.04	4500	1	0.0001	55000
	Golfing	Adult	0.04	5300	4	0.0005	17000
		Youth 11 <16 yrs	0.04	4400	4	0.0006	14000
		Children 6 to <11 yrs	0.04	2900	4	0.0007	12000
Irrigation, Low Spray Volume Scenario (Peak TTR = 0.2% of Rate)							
Wettable Powder in Water Soluble Packaging	HCLA	Adult	0.01	180000	1.5	0.0009	8400
		Youth 11 <16 yrs	0.01	148000	1.3	0.0009	8400
		Children 1 to <2 yrs	0.01	49000	1.5	0.0019	4260
	Mowing	Adult	0.01	5500	1	0.00002	414000
		Youth 11 <16 yrs	0.01	4500	1	0.00002	360000
	Golfing	Adult	0.01	5300	4	0.0001	107000
		Youth 11 <16 yrs	0.01	4400	4	0.0001	92000
		Children 6 to <11 yrs	0.01	2900	4	0.0001	78000

TTT = turf transferable residue, TC = transfer coefficient, MOE = margin of exposure, HCLA = high contact lawn activities

1 TTRs based on chemical-specific peak TTR data and the maximum application rate (0.281 kg a.i./ha).

2 Default values from USEPA Residential SOPs 2012.

3 Exposure (mg/kg bw/day) = TTR on day 0 (µg/cm²) × Conversion Factor 0.001 (mg/µg) × TC (cm²/hr) × Exposure Time (hrs/day) × Dermal Absorption (5%)/Body Weight. Body weight for adults 80 kg, youth 57 kg, children 6 to <11 years 32 kg, and children 1 to <2 years 11 kg.

4 Dermal MOE = NOAEL/Exposure. Short-intermediate term oral NOAEL of 8 mg/kg bw/day was used. Target MOE = 100. Shaded cells indicate MOEs that are below the target.

Table 5 Residential post-application surface-to-hand-to-mouth incidental oral exposure and risk for turf

Formulation	Lifestage[1]	Hand residue[2] (mg/cm²)	Oral exposure[3] (mg/kg bw/day)	Incidental oral MOE[4]
No Irrigation, Low Spray Volume Scenario (Peak TTR = 9% of Rate)				
WSP	Children 1 to <2 year	0.0037	0.0347	200
No Irrigation, High Spray Volume Scenario (Peak TTR = 1.3% of Rate)				
WSP	Children 1 to <2 year	0.0005	0.0050	1600
Irrigation, Low Spray Volume Scenario (Peak TTR = 0.2% of Rate)				
WSP	Children 1 to <2 year	0.0001	0.0008	10400

MOE = Margin of Exposure, WSP = Wettable Powder in Water Soluble Packaging

1 Children 1 to < 2 years has been chosen as the index lifestage to assess based on their behavioral characteristics (likelihood of putting hand in mouth following potential dermal imidacloprid exposure) and the strengths and limitations of the available data.

2 Hand residue loading (mg/cm^2) = Fraction ai on hands compared to total surface residue (0.06) × Dermal Exposure (mg/day, using an application rate of 0.281 kg ai/ha)/Typical Surface Area of one hand (cm^2) × 2

3 Exposure (mg/kg bw/day) = Hand Residue Loading (mg/cm^2) × Fraction Hand Surface Area Mouthed/event (0.127/event) × Typical Surface Area of one hand (150 cm^2) × Exposure Time (1.5 hrs/day) × Number of replenishment intervals per hour (4 intervals/hour) × [1-(1-Saliva Extraction Factor, 0.48)^(Number of hand-to-mouth contact events per hour (13.9 events/hour)/Number of replenishment intervals per hour (4 intervals/hour))]/ body weight (11 kg for children 1 to <2 years). Calculated according to the USEPA Residential SOPs 2012.

4 Incidental Oral MOE = NOAEL/Exposure. Short-Intermediate Term Oral NOAEL of 8 mg/kg bw/day was used. Target MOE = 100.

Table 6 Aggregate residential and chronic dietary exposure and risk for turf

Formulation	Life stage	Residential scenario		Exposure (mg/kg bw/day)[1]					Aggregate MOE[4]
		Application	PA	Applicator	PA Dermal	PA IO	Dietary[2]	Total[3]	
No Irrigation, Low Spray Volume Scenario (Peak TTR = 9% of Rate)									
Wettable Powder in Water Soluble Packaging	Adult	-	HCLA[5]	-	0.04271	-	0.0025	0.0452	180
	Youth 11 to <16 yr	-	HCLA[5]	-	0.04272	-	0.0026	0.0453	180
	Children 6 to <11 yr	-	Golfing	-	0.00459	-	0.0046	0.0092	870
	Children 1 to <2 yr	-	HCLA + HTM[6]	-	0.08457	0.03468	0.0107	0.1299	62
No Irrigation, High Spray Volume Scenario (Peak TTR = 1.3% of Rate)									
Wettable Powder in Water Soluble Packaging	Adult	-	HCLA[5]	-	0.00617	-	0.0025	0.0087	920
	Youth 11 to <16 yr	-	HCLA[5]	-	0.00617	-	0.0026	0.0088	910
	Children 6 to <11 yr	-	Golfing	-	0.00066	-	0.0046	0.0053	1500
	Children 1 to <2 yr	-	HCLA + HTM[6]	-	0.01222	0.00501	0.0107	0.0279	290
Irrigation, Low Spray Volume Scenario (Peak TTR = 0.2% of Rate)									
Wettable	Adult	-	HCLA[5]	-	0.00095	-	0.0025	0.0034	2300

Formulation	Life stage	Residential scenario		Exposure (mg/kg bw/day)[1]					Aggregate MOE[4]
		Application	PA	Applicator	PA Dermal	PA IO	Dietary[2]	Total[3]	
Powder in Water Soluble Packaging	Youth 11 to <16 yr	-	HCLA[5]	-	0.00095	-	0.0026	0.0035	2300
	Children 6 to <11 yr	-	Golfing	-	0.00010	-	0.0046	0.0047	1700
	Children 1 to <2 yr	-	HCLA + HTM[6]	-	0.00188	0.00077	0.0107	0.0133	600

PA = post-application, IO = incidental oral, MOE = margin of exposure, HCLA = high contact lawn activities, HTM = hand-to-mouth

1 Residential exposure estimates for application and post-application activities are based on estimates from Appendix V, Tables 4 and 5.

2 Chronic food and drinking water exposure estimates for adults, youth 11 to < 16 years, children 6 to <11 years, children 1 to <2 years.

3 Total Exposure = Applicator + PA Dermal Route + PA Incidental Oral Route + Chronic Dietary.

4 Aggregate MOE = Aggregate NOAEL (8 mg/kg bw/day) for short-intermediate term / Total Exposure. Target MOE = 100. Shaded cell indicates a MOE that is below the target.

5 The post-application dermal exposure estimate for high contact lawn activities was used as it has the highest post-application exposure and addresses other post-application activities such as mowing and golfing.

6 Incidental soil and granule ingestion and object-to-mouth exposure are not included in the aggregate risk assessment because these exposures are considered to be inter-related with hand-to-mouth exposure and would result in an overly conservative aggregate risk assessment.

Appendix VI Revised quantitative acute avian risk assessment

Table 1 Revised acute screening-level risk quotients for birds potentially exposed via diet to imidacloprid from the highest foliar application rate on turf (281.25 g a.i./ha)

Bird mass (g)	Feeding guild (food item)	EDE (mg a.i./kg bw)	RQ[1]
20	Insectivore	22.9	7.4
100	Insectivore	17.9	5.8
1000	Herbivore (short grass)	11.5	3.7

[1] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).

Table 2 Revised acute avian risk quotients using maximum and mean imidacloprid residue values based on the maximum cumulative agricultural foliar rate (raspberry – 112.88 g a.i./ha × 3 at 7-day intervals – 223.4 g a.i./ha) and the highest application rate for turf use (281.25 g a.i./ha)

Use	Bird mass (g)	Food guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off field		On-field		Off field	
			EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]
Raspberry – 112.88 g a.i./ha × 3 at 7-day intervals[2]	20	Insectivore	18	5.9	13	4.3	13	4.1	9.3	3.0
		Frugivore (fruit)	5.6	1.8	4.2	1.3	2.7	0.9	2.0	0.6
	100	Insectivore	14	4.6	11	3.4	9.8	3.2	7.3	2.3
		Frugivore (fruit)	4.4	1.4	3.3	1.1	2.1	0.7	1.6	0.5
	1000	Insectivore	4.1	1.3	3.1	0.9	2.9	0.9	2.1	0.7
		Herbivore (short grass)	9.2	3.0	6.8	2.2	3.3	1.1	2.4	0.8
		Herbivore (long grass)	5.6	1.8	4.1	1.3	1.8	0.6	1.4	0.4
		Herbivore (Broadleaf plants)	8.5	2.7	6.3	2.0	2.8	0.9	2.1	0.7

Use	Bird mass (g)	Food guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off field		On-field		Off field	
			EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]
Turf use – 281.25 g a.i./ha	20	Insectivore	23	7.4	2.5	0.3	16	5.1	1.7	0.2
	100	Insectivore	18	5.8	2.0	0.2	12	4.0	1.4	0.2
	1000	Insectivore	5.2	1.7	0.6	0.2	3.6	1.2	0.4	0.1
		Herbivore (short grass)	12	1.4	1.3	0.2	4.1	0.5	0.5	<0.1
		Herbivore (long grass)	7.1	2.3	0.8	0.3	2.3	0.7	0.3	<0.1
		Herbivore (Broadleaf plants)	11	1.3	1.2	0.2	3.5	0.4	0.4	<0.1

[1] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).
[2] The cumulative application rate for raspberry is based on a default half-life of 10 days for foliar dissipation. This value is based on the foliar dissipation of a variety of active ingredients reported by Willis and McDowell (1987); with 93% of the foliar dissipation half-life less than 10 days, this value is considered to be a reasonable conservative estimate of typical foliar half-lives.

Table 3 Revised acute avian risk quotients for insectivores using maximum and mean imidacloprid residue values based on the maximum cumulative agricultural rate (raspberry – 112 g a.i./ha × 3 at 7-day intervals – 112.88 g a.i./ha) and an arthropod DT_{50} of 1 day (Wolf 2004, PMRA# 2142783).

Bird mass (g)	Maximum nomogram residues				Mean nomogram residues			
	On-field		Off field		On-field		Off field	
	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]	EDE (mg ai/kg bw)	RQ[1]
20	9.2	3.0	6.8	2.2	6.3	2.1	4.7	1.5
100	7.2	2.3	5.3	1.7	5.0	1.6	3.7	1.2

[1] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).

Table 4 The number of imidacloprid-containing granules required to reach the revised acute avian effects metric by ingestion

Bird mass (g)	Number of granules to reach effects metric[1]	
	PCP 25933 (Merit Granular)	PCP 29185 (Quali-pro Imidacloprid 0.5 Granular)
20	10	0.6
100	49	3.1
1000	488	31

[1] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).

Table 5 Revised acute screening level risk quotients for birds potentially consuming treated granules

Bird mass (g)	PCP 25933 (Merit Granular) RQ[1]	PCP 29185 (Quali-pro Imidacloprid 0.5 Granular) RQ[a]
20	402	425
100	320	321
1000	94	94

[1] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).

Table 6 Revised acute avian risk quotients for granivorous birds potentially consuming imidacloprid treated seeds based on LD_{50}/10

Crop (EEC: mg a.i./kg seed)[1]	Bird mass (g)	EDE (mg a.i./kg bw/day)	RQ[2]
Canola, mustard (condiment type only) and rapeseed seed; Mustard (oilseed type) (4000 – 8020)[3]	20	1016 – 2037	328 – 657
	100	798 – 1600	257 – 516
	1000	233 – 466	75 – 150
Sweet corn (675[4] – wireworm, 2500 – flea beetle)	20	171 – 635	55 – 205
	100	135 – 499	43 – 161
	1000	39 – 145	13 – 47
Field corn (487 – including seed production) (1800 – seed production)	20	124 – 457	40 – 147
	100	97 – 359	31 – 116
	1000	28 – 105	9.1 – 34
Field pea, soybean (625 – 1250)	20	159 – 317	51 – 102
	100	125 – 249	40 – 80
	1000	36 – 73	12 – 23

Crop (EEC: mg a.i./kg seed)[1]	Bird mass (g)	EDE (mg a.i./kg bw/day)	RQ[2]
Chickpea (desi and kabuli), dry beans, snap beans, white bean, lima bean, faba bean, lentils, coloured beans (625)	20	159	51
	100	125	40
	1000	36	12
Lettuce (140000)	20	35551	11468
	100	27926	9008
	1000	8141	2626
Barley, wheat, oats (100 – 300)	20	25 – 76	8.2 – 25
	100	20 – 60	6.4 – 19
	1000	6 – 17	1.9 – 5.6
Broccoli and cabbage (93333)	20	237001	7646
	100	18617	6006
	1000	5428	1751
Summer squash (2500), cucumber (pickles; 10000), melon (2500), pumpkin (1000)	20	254 – 2539	82 – 819
	100	199 – 1995	64 – 644
	1000	58 – 582	19 – 188
Tomato (4410)[5]	20	1120	361
	100	880	284
	1000	256	83
Pepper (12450)[5]	20	3162	1020
	100	2483	801
	1000	724	234
Carrot (4600 – 20700)	20	1168 – 5257	388 – 1696
	100	918 – 4129	296 – 1332
	1000	268 – 1204	86 - 388
Green onion (8400) Dry onion (11200) Leek (14000)	20	2133 – 3555	264 – 1147
	100	1676 – 2793	208 – 900
	1000	488 – 814	61 – 262

[1] For seed treatments registered with a range of rates the full range of EDEs and RQs are shown.
[2] Acute risk quotients for birds use the revised acute avian effects metric: 3.1 mg/kg bw (LD_{50} of 31 mg/kg bw for Japanese quail divided by an uncertainty factor of 10).
[3] Canola, mustard (condiment type only) and rapeseed seed was modeled with seeding parameters for canola-mustard, with an assumption of 1.9 g/1000 seeds. Mustard (oilseed type) was modeled with the seeding parameters for mustard – brown and oriental with and assumption of 2.7 g/1000 seeds. The EDEs for the highest rate for Canola, mustard (condiment type only and rapeseed, and mustard (oilseed type) (8000 versus 8020 mg a.i./kg seed) differ slightly (2032 versus 2037 mg a.i./kg bw/day, respectively). The EDE value shown here is representative of the slightly higher rate for Canola, mustard (condiment type only and rapeseed; the RQs nevertheless are the same for both crops.
[4] The rate on sweet corn for wireworm is 672 mg a.i/kg seed; 675 mg a.i./kg seed was modeled in error, but the difference does not impact conclusions of the risk assessment.
[5] Currently, tomatoes and peppers are generally either grown in greenhouses or transplanted from greenhouses in Canada. They are not generally directly seeded into fields.

Table 7 The number of seeds treated with imidacloprid required to be ingested for birds to reach the acute avian effects metric (LD_{50}/10) and the corresponding estimated percentage of daily food intake rate and foraging area based on LD_{50}/10

Crop (EEC: mg a.i./kg seed)	Bird mass (g)	Number of seeds to reach the effects metric (min to max.)[1]	Percent of estimated daily food intake	Area required (m^2)[2]
Canola, mustard (condiment type only) and rapeseed seed (High rate – 8020)	20	4	0.2	0.2 – 0.5
	100	20	0.2	1.1 – 2.6
	1000	205	0.7	10 – 26
Canola, mustard (condiment type only) and rapeseed seed (Low rate – 4000)	20	8.2	0.3	0.4 – 1.0
	100	41	0.4	2.1 – 5.2
	1000	410	1.3	21 – 52
Mustard (oilseed type) (High rate – 8000)	20	2.9	0.2	0.2 – 0.5
	100	14	0.2	1.1 – 2.6
	1000	143	0.7	10 – 26
Mustard (oilseed type) (Low rate – 4000)	20	5.8	0.3	0.4 – 1.0
	100	29	0.4	2.1 – 5.2
	1000	286	1.3	21 – 52
Field corn (487 – including seed production)	20	0.4	2.6	8.1 – 12
	100	1.9	3.2	40 – 61
	1000	19	11	403 – 606
Field corn (1800 – seed production only)	20	0.1	0.7	2.2 – 3.3
	100	0.5	0.8	11 – 16
	1000	5	2.8	109 - 164
Sweet corn (2500 – flea beetle)	20	0.1 – 0.2	0.5	1.6 – 19
	100	0.5 – 1.0	0.6	16 – 47
	1000	5.0 – 10	1.5	164 – 472
Sweet corn[3] (675 – wireworm)	20	0.4 – 0.7	1.7	6.1 – 70
	100	1.8 – 3.7	2.3	61 – 175
	1000	18 – 37	2.2	111 – 321
Field pea (1250)	20	0.2 – 0.4	1.3	0.03 -0.3
	100	0.7 – 2.0	1.2	0.4 – 0.6
	1000	7.4 – 20	4.2	3.8 – 5.9
Field pea (625)	20	0.3 – 0.8	2.0	0.06 – 0.6
	100	1.5 – 4.0	2.5	0.8 – 1.2
	1000	15 – 40	8.6	7.6 – 12

Crop (EEC: mg a.i./kg seed)	Bird mass (g)	Number of seeds to reach the effects metric (min to max.)[1]	Percent of estimated daily food intake	Area required (m^2) [2]
Soybean (625)	20	0.6 – 0.7	1.9	0.2 – 0.7
	100	2.7 – 3.7	2.5	1.2 – 2.6
	1000	27 – 37	8.6	12 – 26
Soybean (1250)	20	0.3 – 0.4	1.1	0.1 – 0.4
	100	1.4 – 1.8	1.3	0.6 – 1.3
	1000	14 – 18	4.4	6.0 – 13
Chickpea – desi and kabuli (625)	20	0.3	1.2 – 2.0	0.2
	100	1.5	1.5 – 2.5	1.0 – 1.1
	1000	15	5.2 – 8.6	9.7 – 11
Dry beans (625)	20	0.3 – 0.5	2.0	0.2 – 1.6
	100	1.5 – 2.5	2.5	1.8 – 4.7
	1000	15 – 25	8.6	18 – 47
Snap beans (625)	20	0.2 – 0.3	2.0	0.1 – 0.6
	100	1.0 – 1.5	2.5	0.9 – 1.9
	1000	10 - 15	8.6	9 – 19
White bean (625)	20	0.3 – 0.5	2.0	0.2 – 1.6
	100	1.5 – 2.5	2.5	1.8 – 4.7
	1000	15 – 25	8.6	18 – 47
Lima bean (625)	20	0.1 – 0.2	2.0 – 2.6	0.2 – 1.6
	100	0.5 – 0.7	2.3 – 2.5	1.7 – 5.2
	1000	5.0 – 7.4	8.5 – 8.6	17 – 52
Faba bean (625)	20	0.1 – 0.2	2.0	0.04 – 0.2
	100	0.5 – 1.0	2.5	0.4 – 0.6
	1000	5.0 – 10	8.6	4.0 – 5.7
Lentils (625)	20	1.2 – 3.3	2.0	0.1 – 1.8
	100	6.0 – 16	2.4 – 2.5	1.7 – 3.3
	1000	60 – 164	8.6	17 – 33
Coloured beans (625)	20	0.3 – 0.5	2.0	0.3 – 1.6
	100	1.5 – 2.5	2.5	2.4 – 4.7
	1000	15 - 25	8.6	24 – 47
Lettuce (140000)	20	0.3	0.008	0.07 – 0.1
	100	1.6	0.011	0.3 – 0.7
	1000	15	0.04	3.4 – 6.7
Barley, wheat, oats[4] (High rate – 300)	20	4.6 – 6.8	4.1	0.3 – 1.8
	100	23 – 34	3.2	1.8 – 8.7
	1000	227 – 341	17	18 – 87

Crop (EEC: mg a.i./kg seed)	Bird mass (g)	Number of seeds to reach the effects metric (min to max.)[1]	Percent of estimated daily food intake	Area required (m^2) [2]
Barley, wheat, oats[4] (Low rate – 100)	20	14 – 20	12	1.1 – 5.2
	100	68 – 102	5.2	5.5 – 26
	1000	682 – 1023	53	55 – 262
Broccoli and cabbage (93 333)	20	0.2	0.01	0.6 – 0.8
	100	1.0	0.02	2.9 – 3.7
	1000	10	0.06	29 – 37
Cucumber (pickles, 10 000)	20	0.3	0.2	2.7 – 4.1
	100	1.2	0.2	14 – 20
	1000	12	0.5	136 – 204
Summer squash (2500)	20	0.3	0.6	6.8 – 34
	100	1.2	0.6	34 – 171
	1000	12	2.1	341 – 1708
Pumpkin (1000)	20	0.3	0.03 – 0.04	6.7 – 34
	100	1.2	0.03 – 0.04	34 – 168
	1000	12	0.10 – 0.14	336 – 1677
Melon (2500)	20	0.3	0.6	12 – 23
	100	1.2	0.6	61 – 114
	1000	12	2.1	606 – 1139
Tomato (4410)	20	4.9	0.3	3.9 – 95
	100	25	0.4	19 – 473
	1000	246	1.2	194 – 4734
Peppers (12 450)	20	0.8	0.1	7.6
	100	3.7	0.1	38
	1000	38	0.4	377
Carrots (20 700)	20	2.7	0.06	0.2 – 0.9
	100	14	0.08	1.0 – 4.5
	1000	135	0.3	10 – 45
Green onion (8400)	20	2.1	0.2	0.3
	100	10	0.2	1.6
	1000	103	0.6	16
Dry onion, bulb (11 200)	20	1.6	0.1	0.3 – 0.4
	100	7.8	0.1	1.9 – 2.1
	1000	78	0.5	19 – 21
Leeks (14 000)	20	1.6	0.09	0.6 – 1.2
	100	7.8	0.1	3.1 – 6.1
	1000	78	0.4	31 – 61

[1] Minimum to maximum number of seeds to reach effects metric based on seed size range (maximum to minimum). The effects metric is the regulatory LD_{50} of 31 mg/kg bw (Japanese quail) divided by an

uncertainty factor of 10 (the acute avian effects metric is thus, 3.1 mg/kg bw).
[2] Minimum and maximum area required based on minimum and maximum seeding rate.
[3] The rate on sweet corn for wireworm is 672 mg a.i/kg seed; 675 mg a.i./kg seed was modeled in error, but the difference does not impact conclusions of the risk assessment.
[4] The number of seeds to reach the endpoint and foraging distance required to achieve the endpoint is based on oats; wheat, barley and oats have been grouped together as the seed size and seeding rate range for each are very similar. The number seeds to reach the endpoints, and the required foraging distance to achieve the endpoint, are expected to be similar for each of these three seed crops.

Table 8 Comparison of the estimated number of treated seeds to reach the revised acute effects metric for birds to the number of seeds observed consumed from bait stations field based on $LD_{50}/10$

Crop (EEC: mg a.i./kg seed)	Bird mass (g)	# Seeds to reach the acute effects metric[1]	Bait station data[2]		
			Mean # seeds consumed per visit	Max. # seeds consumed per visit	# Species (% dehusking)
Canola, mustard (condiment type only) and rapeseed seed (8020)	20	4	36 – 104	85 – 240	3 (43 – 100)
	100	20	NI		
	1000	205	214 – 2201	361 – 4887	2
Canola, mustard (condiment type only) and rapeseed seed (4000)	20	8.2	36 – 104	85 – 240	3 (43 – 100)
	100	41	NI		
	1000	410	214 - 2201	361 – 4887	2
Sweet corn (2500 – flea beetle)	20	0.1 – 0.2	3 – 4	4 - 11	3
	100	0.5 – 1.0	5 – 10	15 - 20	2
	1000	5.0 – 10	5 – 92	12 – 266	5
Sweet corn[3] (675 – wireworm)	20	0.4 – 0.7	3 – 4	10 – 11	3
	100	1.8 – 3.7	5 – 10	15 – 20	2
	1000	3.4 – 6.7	5 – 92	12 – 266	5
Field pea (1250)	20	0.2 – 0.4	1	2	1
	100	0.7 – 2.0	1	1	1
	1000	7.4 – 20	3 – 31	4 – 113	4
Field pea (625)	20	0.3 – 0.8	1	2	1
	100	1.5 – 4.0	1	1	1
	1000	15 – 40	3 – 31	4 – 113	4
Barley (spring) (300)	20	4.6 – 6.8	1 – 18	1 – 53	12 (0 – 100)
	100	23 – 34	2 – 20	2 – 37	4
	1000	227 – 341	4 – 144	10 – 328	6
Barley (spring) (100)	20	14 – 20	1 – 18	1 – 53	12 (0 – 100)
	100	68 – 102	2 – 20	2 – 37	4
	1000	682 – 1023	4 – 144	10 – 328	6
Wheat (300)	20	4.6 – 6.8	2 – 19	4 – 74	11 (0 – 100)
	100	23 – 34	1 – 45	1 – 90	6
	1000	227 – 341	28 – 126	128 – 392	4

Crop (EEC: mg a.i./kg seed)	Bird mass (g)	# Seeds to reach the acute effects metric[1]	Bait station data[2]		
			Mean # seeds consumed per visit	Max. # seeds consumed per visit	# Species (% dehusking)
Wheat (100)	20	14 – 20	2 – 19	4 – 74	11 (0 – 100)
	100	68 – 102	1 – 45	1 – 90	6
	1000	682 – 1023	28 – 126	128 – 392	4
Oat (300)	20	4.6 – 6.8	6 – 11	10 – 46	3
	100	23 – 34	2 – 13	3 – 67	3
	1000	227 – 341	NI		
Oat (100)	20	14 – 20	6 – 11	10 – 46	3
	100	68 – 102	2 – 13	3 – 67	3
	1000	682 – 1023	NI		

[1] Minimum to maximum number of seeds to reach effects metric based on seed size range (maximum to minimum). The effects metric is the regulatory LD_{50} of 31 mg/kg bw (Japanese quail) divided by an uncertainty factor of 10 (the acute avian effects metric is thus, 3.1 mg/kg bw). The number of seeds to reach the endpoint for barley and wheat was determined based on the seed size for oats; as the seed size for barley, wheat and oat are very similar, the number of seeds to reach the endpoint for oats is considered representative of that for barley and wheat.

[2] The seed consumption data (i.e., mean and max # seeds consumed per visit) is representative of bird species ranging in weight from 18 to 30g (small sized birds), 80 to 125g (medium birds) and 450 to >1000g (large birds), for the 20, 100 and 1000 bird size categories, respectively (data from Prosser and Hart 2005 and Smith 2006 PMRA# 2574060 and 2574059, respectively); NI = no information.

[3] The rate on sweet corn for wireworm is 672 mg a.i/kg seed; 675 mg a.i./kg seed was modeled in error, but the difference does not impact conclusions of the risk assessment.

Appendix VII Toxicity to aquatic invertebrates

Table 1 Effects of imidacloprid on aquatic invertebrates in laboratory tests

Organism	Exposure	Test substance	Endpoint value (μg a.i./L)	Comments	Reference
Freshwater Acute					
D. magna	Acute 48-h	Imidacloprid (>95% purity)	48-h LC_{50} = **10400**	From Song et al. 1997 (PMRA# 2541668)	USDA 2005 (PMRA# 2334762)
		Imidacloprid (Admire Flowable)	48-h LC_{50} = **43300**		Hayasaka et al. 2012 (PMRA# 2541822)
		Imidacloprid (95.9% purity)	48-h LC_{50} = **85200**		USDA 2005 (PMRA# 2334762); (original study PMRA# 1155861)
		Imidacloprid (97.3%)	48-h LC_{50} = **88100**		PMRA# 1504639
		Imidacloprid (Confidor 200SL)	48-h LC_{50} = **96700** (no predatory cues) 48-h LC_{50} = **90700** (predatory cues)	Acute lethality experiments were conducted in the presence of predator kairomones (brown trout) and alarm cues (macerated Daphnia). EFSA 2014 (PMRA# 2545413) aquatic risk assessment used predatory cues LC_{50} in SSD.	Pestana et al. 2010 (PMRA# 2541671)
		Imidacloprid (Confidor, guarantee not reported)	48-h LC_{50} = **64600**		Kungolos et al. 2009, (PMRA# 2544388)
		Imidacloprid (technical)	48-h LC_{50} = **56600**		Tisler et al. 2009 (PMRA# 2541823)
		Imidacloprid (Confidor SL200; 200 g a.i./L)	48-h LC_{50} = **30000**		
		Imidacloprid (Confidor 200 SC)	48-h EC_{50} = **84000** (immobility)		Daam et al. 2013 (PMRA# 2544387); EFSA 2014 (PMRA# 2545413)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
		Imidacloprid (>99.5%)	48-h LC_{50} = 64900 48-h EC_{50} = **6000** (immobility)	Note: Acute toxicity test using *D. magna* was conducted under light exposure conditions only (not tested under dark conditions as the other four test species in the study were).	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)
		Technical (purity not reported)	48-h LC_{50} = **97000**		Loureiro et al. 2010 (PMRA# 2945939)
D.magna Strauss	Acute 48-h	Imidacloprid (10% SC)	48-h EC_{50} = **998**		Li et al. 2013 (PMRA# 2712665)
Caecidotea sp.	Acute 96-h	Imidacloprid (98.6% purity)	96-h LC_{50} = >15600 (mortality) 96-h EC_{50} = **321** (immobility)		Raby et al., 2018 (PMRA# 2842540)
Cypretta seuratti	Acute 48-h	Imidacloprid (>99.5%)	<u>16 h:8 h light:dark cycle</u> 48-h LC_{50} = 301 48-h EC_{50} = **16** (immobility) <u>Dark</u> 48-h LC_{50} = not reported 48-h EC_{50} = **1** (immobility)	Acute toxicity tests were conducted under light (16-h:8-h light dark cycle) and dark conditions.	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)
Cypridopsis vidua			<u>16-h:8-h light:dark cycle</u> 48-h LC_{50} = 715 48-h EC_{50} = **3** (immobility) <u>Dark</u> 48-h LC_{50} = 273 48-h EC_{50} = **10** (immobility)		
Ilyocypris dentifera			<u>16-h:8-h light:dark cycle</u> 48-h LC_{50} = 517 48-h EC_{50} = **3** (immobility) <u>Dark</u> 48-h LC_{50} = 214 48-h EC_{50} = **3** (immobility)		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Chydorus sphaericus			16-h:8-h light:dark cycle 48-h LC_{50} = 132700 48-h EC_{50} = **2210** (immobility) Dark 48-h LC_{50} =not reported 48-h EC_{50} = **832** (immobility)		
Ceriodaphnia dubia		Imidacloprid (Admire Flowable)	48-h LC_{50} = **572**		Hayasaka et al. 2012 (PMRA# 2541822)
		Imidacloprid (Admire Pro)	48-h LC_{50} = **2.07**		Chen et al. 2010 (PMRA# 2541670)
		Imidacloprid (98.6% purity)	48-h LC_{50} = 72100[a]		Raby et al. 2018 (PMRA# 2842540)
Ceriodaphnia reticulata		Imidacloprid (Admire Flowable)	48-h EC_{50} = **5550**		Hayasaka et al. 2012 (PMRA# 2541822)
Daphnia pulex		Imidacloprid (Admire Flowable)	48-h EC_{50} = **36900**		Hayasaka et al. 2012 (PMRA# 2541822)
Moina macrocopa		Imidacloprid (Admire Flowable)	48-h EC_{50} = **45300**		Hayasaka et al. 2012 (PMRA# 2541822)
Isopod *Asellus aquaticus*	Acute 96-h	Imidacloprid (formulated product – 200 g a.i./L)	96-h LC_{50} = 20000 (mortality) 96-h EC_{50} = **78** (immobilization)	Slightly greater sensitivity was observed for fall collected specimens over those collected in spring (i.e., May - EC_{50} = 120 µg a.i./L; also reported in Roessink et al., 2013; PMRA# 2544385). The more sensitive of the two endpoints (fall) was considered.	Van den Brink et al. 2016 (PMRA# 2712707)
Amphipod *Gammarus pulex*	Acute 96-h	Imidacloprid (technical)	96-h LC_{50} = **270**		EFSA 2014 (PMRA# 2545413)/Beketov and Liess 2008 (PMRA# 2544548)
	Acute 48 and 96-h	Imidacloprid (>97%)	48-h LC_{50} = 110 96-h LC_{50} = **130**		Ashauer et al. 2011 (PMRA# 2541673)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
	Acute 96-h	Imidacloprid (formulated product – 200 g a.i./L)	96-h LC_{50} = 386 (mortality) 96-h EC_{50} = **49** (immobilization)	Greater sensitivity was observed for spring-collected specimens over those collected in fall (i.e., spring - EC_{50} = 18 µg a.i./L; also reported in Roessink et al., 2013; PMRA# 2544385). As control mortality was unacceptable for experiments conducted with spring collected specimens (33% mortality), the spring endpoint was not considered.	Van den Brink et al. 2016 (PMRA# 2712707)
Amphipod *Gammarus roeseli*	Acute 96-h	Imidacloprid (purity not reported)	96-h EC_{50} = **14.2** (immobilization)		Böttger et al. 2012 (PMRA# 2541837); EFSA 2014 (PMRA# 2541453)
Mayfly larvae *Baetis rhodani*	Acute 48-h	Imidacloprid (technical)	48-h LC_{50} = **8.49**		EFSA 2014 (PMRA# 2545413)/Beketov and Liess 2008 (PMRA# 2544548)
Blackfly larvae *Simulium latigonium*	Acute 96-h	Imidacloprid (technical)	96-h LC_{50} = **3.73**		
Midge larvae *Chaoborus obscuripes*	Acute 96-h	Imidacloprid (formulated product – 200 g a.i./L)	96-h LC_{50} = 294 (mortality) 96-h EC_{50} = **284** (immobilization)	Greater sensitivity was observed for spring/summer collected specimens over those collected in fall. A comparison of endpoints between spring/summer and fall collected specimens is provided in Van den Brink et al., 2016 (PMRA# 2712707); spring/ summer specimen based endpoints are reported in Roessink et al, 2013 only. The same experimental procedures were followed in both studies. The more sensitive spring/summer based endpoints was considered.	EFSA 2014 (PMRA# 2545413); Roessink et al. 2013 (PMRA# 2544385)
Alderfly larvae *Sialis lutaria*	Acute 96-h		96-h LC_{50} > 10000 (mortality) 96-h EC_{50} = **50.6** (immobilization)		

Organism	Exposure	Test substance	Endpoint value (μg a.i./L)	Comments	Reference
Pygmy backswimmer larvae *Plea minutissima*	Acute 96-h		96-h LC_{50} = 37.5 (mortality) 96-h EC_{50} = **35.9** (immobilization)	Greater sensitivity was observed for spring/summer collected specimens over those collected in fall. A comparison of endpoints between spring/summer and fall collected specimens is provided in Van den Brink et al., 2016 (PMRA# 2712707); spring/ summer specimen based endpoints are reported in Roessink et al., 2013 only. The same experimental procedures were followed in both studies. The more sensitive spring/summer based endpoints was considered.	
Backswimmer *Notonecta* spp.	Acute 96-h		96-h LC_{50} > 10000 (mortality) 96-h EC_{50} = **18.2** (immobilization)		
Water boatman *Micronecta* spp.	Acute 96-h		96-h LC_{50} = 28.2 (mortality) 96-h EC_{50} = **10.8** (immobilization)		
Caddisfly larvae Limnephilidae	Acute 96-h		96-h LC_{50} = 25.7 (mortality) 96-h EC_{50} = **1.79** (immobilization)		
Mayfly larvae *Caenis horaria*	Acute 96-h		96-h LC_{50} = 6.68 (mortality) 96-h EC_{50} = **1.77** (immobilization)	Greater sensitivity was observed for spring/summer collected specimens over those collected in fall. A comparison of endpoints between spring/summer and fall collected specimens is provided in Van den Brink et al., 2016 (PMRA# 2712707); spring/ summer specimen based endpoints are reported in Roessink et al, 2013 only. The same experimental procedures were followed in both studies. The more sensitive spring/summer based endpoints was considered.	

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Mayfly larvae *Cloeon dipterum*	Acute 96-h		96-h LC_{50} = 26.3 (mortality) 96-h EC_{50} = **1.02** (immobilization)	Greater sensitivity was observed for spring/summer collected specimens over those collected in fall. A comparison of endpoints between spring/summer and fall collected specimens is provided in Van den Brink et al., 2016 (PMRA# 2712707); spring/ summer specimen based endpoints are reported in Roessink et al, 2013 only. The same experimental procedures were followed in both studies. The more sensitive spring/summer based endpoints was considered.	
Mayfly larvae *Cloeon* sp.	Acute 96-h	Imidacloprid (98.6% purity)	96-h LC_{50} = 1152 (mortality) 96-h EC_{50} = **23** (immobilization)		Raby et al., 2018 (PMRA# 2842540)
Mayfly larvae *Ephemerella* sp.			96-h LC_{50} = 68 (mortality) 96-h EC_{50} = **11** (immobilization)		
Mayfly larvae *McCaffertium* sp.			96-h LC_{50} = 1810 (mortality) 96-h EC_{50} = **11** (immobilization)		
Mayfly larvae *Neocloeon triangulifer*			96-h LC_{50} = 5 (mortality) 96-h EC_{50} = **3** (immobilization)		
Hemiptera *Trichocorixa* sp.	Acute 48-h		48-h LC_{50} = 450 (mortality) 48-h EC_{50} = **63** (immobilization)		
Coleoptera *Gyrinus* sp.	Acute 96-h		96-h LC_{50} = 132 (mortality) 96-h EC_{50} = **58** (immobilization)		
Coleoptera *Stenelmis* sp.			96-h LC_{50} = 366 (mortality) 96-h EC_{50} = **99** (immobilization)		
Micrasema sp.			96-h LC_{50} = 14.6 (mortality) 96-h EC_{50} **< 6.4** (immobilization)		
Cheumatopsyche sp.			96-h LC_{50} = 325 (mortality) 96-h EC_{50} = **176** (immobilization)		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Coenagrion sp.			96-h LC_{50} = 3462 (mortality) 96-h EC_{50} <5437 (immobilization)	The 96-h LC_{50} value is reported as 3463 µg a.i./L (C.I.: -2047 to 8972). The endpoint is considered unreliable: 1) the LC_{50} value is lower than the unbound EC_{50} value, 2) the LC_{50} lower bound confidence interval is reported as a negative value.	
Mayfly larvae *Isonychia bicolor*			96-h EC_{50} = **60** (immobilization)		
	Acute 96-h	Imidacloprid (99.9% purity)	96-h LC_{50} = 18.8 (mortality) 96-h EC_{50} = **5.8** (immobilization)		Camp and Buchwalter 2016 (PMRA# 2796398)
Damselfly Coenagrionidae (Zygoptera)	Acute 96-h		96-h EC_{50} = **150** (immobilization)		van Wijngaarden and Roessink 2013, as reported in EFSA 2014 (PMRA# 2545413)
Amphipod *Gammarus fossarum*	Acute 24-h	Imidacloprid (Confidor 200SL – 200 g a.i./L)	24-h NOEC = 205 (mortality)	Mortality was significant at the two highest test concentrations – 40 and 46% at 256 and 511 µg a.i./L.	Malev et al. 2012, (PMRA# 2541840)
Diptera *Aedes* sp.	Acute 48-h	Imidacloprid (98.6% purity)	72-h LC_{50} = 40.8[a]		Raby et al. 2018 (PMRA# 2842540)
Diptera *Aedes aegypti*	Acute 48-h	Imidacloprid (>95% purity)	48-h LC_{50} = **44**	From Song et al. 1997 (PMRA# 2541668)	USDA 2005 (PMRA# 2334762)
Diptera *Aedes aegypti*	Acute 72-h	Imidacloprid (99.2% purity)	72-h LC_{50} = **210**		Uragayla et al., 2015 (PMRA# 2841146)
Diptera *Anopheles stephensi* (SS strain – Nadiad)			72-h LC_{50} = **49**		
Diptera *A. stephensi* (RR strain – Goa)			72-h LC_{50} = **66**		
Diptera *Culex quinquefasciatus*			72-h LC_{50} = **20**		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Ostracod *Heterocypris incongruens*	Acute 6-d	Imidacloprid (Confidor 200 SC)	6-d EC_{50} = 10 – 15 (growth inhibition) 6-d LC_{50} > 15 (mortality)	Acute mortality is reported as unbound (greater than the highest test concentration). In view of limited method details reported, and endpoint uncertainty, the results for this species are not considered amenable for use in the risk assessment.	Daam et al. 2013 (PMRA# 2544387); EFSA 2014 (PMRA# 2545413)
Mayfly larvae *Epeorus longinanus* Eaton	Acute 24-h	Imidacloprid (Admire, 240 g a.i./L)	24-h LC_{50} = 2.1		Alexander et al. 2007 (PMRA# 2541832); EFSA 2014 (PMRA# 2545413)
	Acute 96-h		96-h LC_{50} = **0.65**		
	Acute 24-h pulse		NOEC = 0.1 (reduced feeding rate)	The experiment consisted of a 24-h pulse exposure followed by a 4-day post-exposure period. The NOEC is based on reduced feeding rate measured at the end of the post-exposure period (day 5).	
Black fly larvae *Similium vittatum*	Acute 48-h	Imidacloprid (>98% purity)	48-h LC_{50} = **8.18**	This endpoint value is the mean of three LC_{50} values reported from three separate tests); EFSA 2014 used the lowest LC_{50} of the three tests (6.75 µg a.i./L)	Overmyer et al. 2005 (PMRA# 2541830) EFSA 2014 (PMRA# 2545413)
Amphipod *Hyalella azteca*	Acute 96-h	Imidacloprid (purity not reported)	96-h LC_{50} = 526 96-h EC_{50} = **55**	Also listed in the 2016 USEPA Preliminary Aquatic Risk Assessment of Imidacloprid (PMRA# 3076605).	USDA 2005 (PMRA# 2334762); (original study PMRA# 1155859)
	Acute 96-h	Imidacloprid-guanidine (NTN 33823, 96.9%)	96-h LC_{50} = 51800		USDA 2005 (PMRA# 2334762); (original study PMRA# 1167316, 1166100)
	Acute 96-h	Imidacloprid-urea (NTN 33519)	96-h LC_{50} > 94830		USDA 2005 (PMRA# 2334762); (original study PMRA# 1166103)
	Acute 96-h	Imidacloprid technical	96-h LC_{50} = **65**		Stoughton et al. 2008 (PMRA# 2541839); EFSA 2014 (PMRA# 2545413)
	Acute 96-h	Admire (240 g a.i./L)	96-h LC_{50} = **17.4**		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
	Acute 96-h	Imidacloprid (98.6% purity)	96-h LC_{50} = 363 (mortality) 96-h EC_{50} = **177** (immobilization)		Raby et al., 2018 (PMRA# 2842540)
	Acute 168-h (7- day)	Imidacloprid (98.6% purity)	168-h EC_{50} = 199 (immobilization)	Published in 2019 as: Bartlett et al., 2019(PMRA# 2975959).	Environment and Climate Change Canada 2017 (PMRA# 2753706)
Hexagenia spp.	Acute 96-h		96-h LC_{50} = 900 96-h EC_{50} = **10**	Published in 2018 as: Bartlett, et al., 2018 (PMRA# 2861091). 96-h EC_{50} is based on behavioural endpoint (measured as number of surviving animals inside artificial burrows). The EC_{50} is considered representative of mobility impairment response that would potentially impact survival.	
		Imidacloprid (98.6% purity)	96-h LC_{50} = 9321 96-h EC_{50} = not calculated		Raby et al., 2018 (PMRA# 2842540)
Midge larvae *Chironomus dilitus* (formerly known as *tentans*)	Acute 96-h	Imidacloprid (95% purity)	96-h LC_{50} = **10.5** 96-h NOEC = 1.24	In the 2016 USEPA Preliminary Aquatic Risk Assessment of Imidacloprid (PMRA# 3076605), the 48-h LC_{50} is listed from this study (68.9 µg a.i./L).	USDA 2005 (PMRA# 2334762); original study Gagliano 1991 (PMRA# 1155863)
	Acute 96-h	Imidacloprid (Admire 240F)	96-h LC_{50} = **2.65** 96-h NOEC = 1.39		Leblanc et al. 2012 (PMRA# 2544384)
	Acute 96-h	Imidacloprid-guanidine (NTN 33823, 96.9%)	96-h LC_{50} > 82800		USDA 2005 (PMRA# 2334762); EFSA 2014 (PMRA# 2545413); (original study PMRA# 1167315, 1166101)
	Acute 96-h	Imidacloprid-urea (NTN 33519)	96-h LC_{50} > 99800		USDA 2005 (PMRA# 2334762); EFSA 2014 (PMRA# 2545413)
	Acute 96-h	6-chloronicotinic acid (97% a.i.)	96-h LC_{50} > 1000		USDA 2005 (PMRA# 2334762); EFSA 2014 (PMRA# 2545413); (original study PMRA# 1182985, 1181128)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
	Acute 96-h	Imidacloprid technical	96-h LC_{50} = **5.75**		Stoughton et al. 2008 (PMRA# 2541839); EFSA 2014 (PMRA# 2545413)
	Acute 96-h	Admire (240 g a.i./L)	96-h LC_{50} = **5.40**		
	Acute 96-h	Imidacloprid (98.6% purity)	96-h LC_{50} = 11.8 (mortality) 96-h EC_{50} = **2.5** (immobilization)		Raby et al., 2018 (PMRA# 2842540)
	Acute 96-h	Imidacloprid (98.8% purity)	96-h LC_{50} = **4.63**		Maloney et al., 2017 (PMRA# 2818524)
Midge larvae *Chironomus riparius*	Acute 24 – 48-h	Imidacloprid (Confidor 200SL)	48-h LC_{50} = **19.9**		Azevedo-Pereira et al. 2011a (PMRA# 2541835)
		Imidacloprid-5-hydroxy	24-h LC_{50} = 668		EFSA 2008 (PMRA# 2332663)
		Imidacloprid-nitroso	24-h LC_{50} = 283		
	Acute 48 – 96-h	Imidacloprid (Confidor 200SL)	96-h NOEC = 0.55 (reduced locomotion)	The experiments consisted of exposure followed by a 48-hour recovery period. Reduced ventilation and AChE activity were observed at all test concentrations (i.e., NOEC below the lowest test concentration of 0.55 µg/L).	Azevedo-Pereira et al. 2011b (PMRA# 2544386); EFSA 2014 (PMRA# 2545413)
Caddisfly larvae *Seristocoma vittatum*	Acute 96-h	Imidacloprid (Confidor 200SL; 200 g a.i./L)	96-h LC_{50} = **13** (no predatory cues) 96-h LC_{50} = **14** (predatory cues)	Acute lethality experiments were conducted in the presence and absence of predator kairomones (brown trout) and alarm cues (macerated *C. riparius* or *S. vittatum*, depending on the test).	Pestana et al. 2009b (PMRA# 2544390)
			96-h LC_{50} = **47** (no predatory cues) 96-h LC_{50} = **36** (predatory cues)		
Caddisfly larvae *Cheumatopsyche brevilineata*	Acute 48-h	Imidacloprid (≥ 98.0%)	48-h EC_{50} = **4.22**		Yokoyama et al. 2009 (PMRA# 2722291)
Oligochaete *Lumbriculus variegatus*	Acute 96-h	Imidacloprid (Admire, 240 g a.i./L)	96-h LC_{50} = **6.2**		Alexander et al. 2007 (PMRA# 2541832); EFSA 2014 (PMRA# 2545413)
	Acute 24-h pulse		NOEC = 1 (reduced egestion rate)	The experiment consisted of a 24-h pulse exposure followed by a 4-day post-exposure period. The NOEC is based on reduced egestion rate measured at the end of the post-exposure period (day 5).	

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
	Acute 96-h	Imidacloprid (98.6% purity)	96-h LC_{50} = 45.4 (mortality) 96-h EC_{50} = **32.4** (immobilization)		Raby et al., 2018 (PMRA# 2842540)
Parasitic nematode *Agamerimis unka*	Acute 24-h	Imidacloprid (97% purity)	24-h LC_{50} = 1580	Choo et al. 1998 as reported in 2016 USEPA Preliminary Aquatic Risk Assessment of for Imidacloprid (PMRA# 3076605). Listed as qualitative. No other details are provided.	Choo et al. 1998, as reported in USEPA 2016 (PMRA# 3076605)
Stonefly larvae *Pteronarcys dorsata*	Acute 14-d	Imidacloprid (Confidor 200SL; 200 g a.i./L)	14-d LC_{50} = 70	Results are for higher tier laboratory microcosm experiments containing both species; imidacloprid was applied directly to microcosms. By the end of the 14-day experimental period, concentrations in water were reduced by 53%–55%.	Kreutzweiser et al. 2008c (PMRA# 2544383)
Crane fly *Tipula sp.*			14-d LC_{50} = 139		
Wavy-rayed lampmussel *Lampsilis fasciola* (glochidia)	Acute 48-h	TGAI	48-h LC_{50} **> 688**	<10% reduction in viability at highest test concentration	Prosser et al., 2016 (PMRA# 2712688)
Ramshorn snail *Planorbella pilsbryi*	Acute 7-d	TGAI	7-d LC_{50} = 3980		
Freshwater Chronic					
D. magna	21-d Chronic Static renewal	Imidacloprid (purity not reported)	EC_{50} > 7300 (immobilization) 21-d NOEC = **1800** 21-d LOEC = 3600	Mean measured. LOEC: Significantly reduced adult daphnid length in comparison with pooled controls.	EFED 2008 (PMRA# 2334663); (original study PMRA# 1155875)
	21-d Chronic Static renewal	Imidacloprid (purity not reported)	21-d NOEC = **2000** (cumulative offspring/live daphnia) 21-d EC_{50} = 5500	Static renewal (every 2 days). Endpoint are based on nominal concentrations. Measured imidacloprid concentrations reported as less than 5% of the nominal concentrations. Based on reduced cumulative number of offspring/live daphnia after exposure. Adult bodylength was also significantly affected at ≥ 6000 µg a.i./L (NOEC = 4000 µg a.i./L)	Pavlaki et al. 2011 (PMRA# 2541825)
	21-d Chronic Static renewal	Imidacloprid technical	21-d NOEC = **1250** (number of neonates/adult) 21-d NOEC = 20000 (mortality)	Static renewal (every two days). The concentration of test substance was not verified. However, the stability of imidacloprid over 2	Jemec et al. 2007 (PMRA# 2541824)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
		Imidacloprid (Confidor 200 SL)	21-d NOEC = 2500 (number of neonates/adult, brood size and days to first brood) 21-d NOEC = 5000 (mortality)	days under study conditions was tested prior. Measured concentrations (in experiments using the technical and Confidor SL 200) did not differ by more than 20% from the nominal or initial concentrations; the results reported are based on nominal concentrations.	
	21-d Chronic Static renewal	Imidacloprid (97.7%)	21-d NOEC = **2000** (reproduction, growth rate of parent) 21-d NOEC = 2000 (mortality; based on visual inspection of data)	Static renewal (every three days). Mean measured. The effect of imidacloprid at a range of nutritional levels (defined as algae C:P ratios) on *D. magna* was investigated; juveniles were supplied with 4 different food quality levels and exposed to a range of imidacloprid concentrations for 21 days under semi-static conditions. Survival, growth rates, and reproduction were monitored.	Ieromina et al. 2014, (PMRA# 2541828)
	34-d Chronic	Imidacloprid (99%)	NOEC = 1300 (reproduction: reduced number offspring/brood) NOEC< 150, LOEC = 150 (growth)	Exposure phase was 7 days after which organisms transferred to clean media. Test conditions reported as quasistatic – i.e., exposure media was changed once during the seven-day exposure phase. The exposure duration is insufficient to be categorized as chronic exposure. Effects were observed under low food density conditions but not under high food density conditions. Therefore, food ration may have influenced results rather than imidacloprid toxicity.	Agatz et al. 2013 (PMRA# 2541826)
	21-d Chronic, Static renewal	Imidacloprid (99.8%)	21-d EC_{10} = **2690** 21-d EC_{50} = 4590 21-d NOEC = 6130	Endpoints based on number of neonates produces per adult.	Raby et al., 2018 (PMRA# 2912491)
C. dubia	~7-d Chronic, Static renewal	Imidacloprid (99.8%)	7-d EC_{10} = **1360** 7-d EC_{50} = 2980 7-d NOEC = 3060	Endpoints based on number of neonates produces per adult.	
Isopod *Asellus aquaticus*	28-d Chronic	Imidacloprid (Confidor 200SL – 200 g a.i./L)	28-d LC_{50} = 20.3 28-d EC_{50} = 12 28-d EC_{10} = **1.71**	Static renewal (weekly). Concentrations verified at test initiation and end of each week prior to renewal. Concentrations of imidacloprid measured at the beginning of the tests were 95.5% ± 4.3% of the nominal concentrations. During the 4-week test period of the chronic tests, the time-weighted average imidacloprid concentrations were 91.9 ± 4.6% of nominal concentrations; chronic effect endpoints reported	EFSA 2014 (PMRA# 2545413)/Roessink et al. 2013 (PMRA# 2544385)
Amphipod *Gammarus pulex*			28-d LC_{50} = 33.8 28-d EC_{50} = 15 28-d EC_{10} = **2.95**		
Midge larvae *Chaoborus obscuripes*			28-d LC_{50} = 12.6 28-d EC_{50} = 12 28-d EC_{10} = **4.57**		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Alderfly larvae *Sialis lutaria*			28-d LC_{50} = 32.5 28-d EC_{50} = 3.5 28-d EC_{10} = **1.28**	are based on nominal test concentrations. Note: The endpoints for *C. dipterum* are also reported in Van den Brink et al., 2016 (PMRA# 2712707). Endpoints based on emergence.	
Pygmy backswimmer larvae *Plea minutissima*			28-d LC_{50} = 9.8 28-d EC_{50} = 6.5 28-d EC_{10} = **2.03**		
Mayfly larvae *Caenis horaria*			28-d LC_{50} = 0.316 28-d EC_{50} = 0.13 28-d EC_{10} = **0.033**		
Mayfly larvae *Cloeon dipterum*			28-d LC_{50} = 0.195 28-d EC_{50} = 0.12 28-d EC_{10} = **0.024**		
Midge larvae *Chironomus dilitus* (formerly known as *tentans*)	10-d Chronic, Static renewal	Imidacloprid (95% a.i.)	10-d LC_{50} = 3.17 10-d NOEC = 1.24 (survival) 10-d NOEC = 0.67 (growth)	The chronic results of this study are listed as invalid in the 2016 USEPA Preliminary Risk Assessment of Imidacloprid (PMRA# 3076605; no details are provided). The study duration (10 days) is insufficient to be categorized as chronic exposure.	USDA 2005 (PMRA# 2334762); (original study PMRA# 1155863)
	28-d Chronic, Static renewal	Imidacloprid (98.8%)	28-d EC_{20} = **0.14** (emergence) 28-d EC_{50} = 0.5 (emergence)		Maloney et al., 2018 (PMRA# 2873503)
	14-d and 40-d Chronic	TGAI	14-d LC_{50} = 1.52 (larval mortality) 40-d EC_{20} = **0.06** (emergence) 40-d EC_{50} = 0.39 (emergence) 40-d NOEC <0.1 (emergence)	Static renewal (60% treatment water every third day). All endpoints based on mean measured concentrations corrected for recoveries. The NOEC for emergence was not established (i.e., NOEC < the lowest concentration tested). The 40-d EC_{20} emergence endpoints were considered in place of the NOEC for chronic sublethal and lethal effects.	Cavallaro et al. 2017 (PMRA# 2712687)
	56-d Chronic, Static renewal	TGAI	56-d EC_{10} = **0.15** (emergence) 56-d EC_{50} = 0.24 (emergence) 56-d NOEC = 0.18 (emergence)	Static renewal (three times per week). Water samples were collected to verify concentrations prior to solution renewal from 3 replicates per treatment, for 2 – 3 treatments per test, 2 – 3 times throughout the test duration. Mean percent differences between nominal and measured neonicotinoid concentrations were within 13%.	Raby et al. 2018 (PMRA# 2912490)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
	28-d Chronic, Static renewal	Imidacloprid (Admire; 240 g a.i./L)	Constant exposure 28-d LC_{50} = 0.91 (survival; equivalent to 28 d EC_{50} for emergence)* 28-d NOEC = **1.14** (survival, dry weight) Pulse exposure** 28-d NOEC = 3.47 (survival, dry weight)	Static renewal (partially renewed every two days). Test concentrations verified after water changes (new water) and again two days later, prior to the next water change (old water). Mean imidacloprid concentration calculated over the entire 28-day test for the constant treatment and for the first four days of exposure to the pulse treatment. *LC_{50} is equivalent to EC_{50} (emergence) because survival was measured as emerged adults. **Pulse exposure experiments consisted of 4 days of exposure followed by 24 days in clean substrate and culture media. The pulse exposure experiments are not considered representative of a chronic exposure.	Stoughton et al. 2008 (PMRA# 2541839); EFSA 2014 (PMRA# 2545413)
Amphipod *Hyallela azteca*	28-d Chronic, Static renewal	Imidacloprid (Admire; 240 g a.i./L)	Constant exposure 28-d LC_{50} = 7.08 (survival) 28-d NOEC = 3.44 (survival) 28-d NOEC = **11.5** (dry weight) Pulse exposure* 28-d NOEC = 3.53 (survival) 28-d NOEC = 11.9 (dry weight)		
	28-d Chronic	TGAI	EC_{10} = **0.69** (growth – wet weight) LC_{10} = 10.2 (mortality)	Static renewal (weekly). Concentrations were verified at the beginning and end of each renewal period. Mean measured values ranged from 75.4 – 104% of nominal values for all six neonicotinoids. Results were based on nominal concentrations.	Bartlett et al., 2019 (PMRA# 2975959)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Midge larvae *Chironomus riparius*	28-d Chronic	Imidacloprid (Confidor 200SL)	EC_{50} = 3.6 NOEC = 2.7 (emergence)	Limited details are provided in EFSA 2008 report. Although the study endpoint was considered in the 2008 review, the following information is noted by EFSA in 2014 (PMRA# 2545413): The chronic endpoint for *C. riparius* included in the dossier from the applicant supporting the EU Annex I inclusion was not included in the data set for the construction of the SSD curve, while that endpoint was considered valid during the peer review. This endpoint has been left out deliberately, because the study was performed in the presence of artificial sediment and the endpoint refers to nominal initial concentrations in the water phase. Static test conditions were used (no water renewal). Actual concentrations have most likely been lower, due to sorption and degradation, but were not measured. The PMRA agrees that the endpoint should not be considered because the study followed a static test design and test concentrations were not verified.	EFSA 2008 (PMRA# 2332663)
		Imidacloprid (98.4%)	EC_{50} = 3.11 EC_{10} = 2.09 (emergence)	This study employed a static exposure design (no test solution renewal) and test solutions were not verified during the study.	EFSA 2008 (PMRA# 2332663); (original study PMRA# 2523501)
	10-d Chronic	Imidacloprid (Confidor 200SL; 200g a.i./L)	10-d NOEC = 0.74 (decreased growth, reduced locomotion and ventilation frequencies)	Note: The study also included a 4-day pulse exposure followed by a 6-day recovery period; growth relative to control group recovered 6 days following exposure at the highest test concentration. Behavioural observations (reduced locomotion and ventilation frequencies), however, did not fully recover after the 6-day recovery period. Not considered a chronic exposure.	Azevedo-Pereira et al. 2011[1] (PMRA# 2541835)
			10-d NOEC = 0.4 (decreased growth, emergence)	Note: A NOEC for developmental rate could not be determined (i.e., NOEC below the lowest test concentration). Not considered a chronic exposure.	Pestana et al. 2009 (PMRA# 2544390)
	28-d Chronic	Imidacloprid-desnitro	EC_{50} = 46000 (emergence)		EFSA 2008 (PMRA# 2332663)
		Imidacloprid-urea	EC_{50} = 249000 (emergence)		

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
		Imidacloprid-AMCP (1-(6-chloropyridin-3-yl)methanamine)	EC_{50} > 105000 (emergence)		
		Imidacloprid-desnitro-olefin (96%)	EC_{50} = 21300 (emergence)		EFSA 2008 (PMRA# 2332663); original study PMRA# 2523502)
		Imidacloprid (SC 350H G, 30.0 %)	Emergence EC_{50} = 1.11 NOEC = **0.96** Developmental rate EC_{50} > 1.81 NOEC = 1.81	Endpoints recalculated based on time weighted average concentration (overlying water).	Brun 2010 (PMRA# 2693971)
		Imidacloprid (OD 200A G, 19.6%)	Emergence EC_{50} = 1.14 NOEC = **0.66** Developmental rate EC_{50} > 1.39 NOEC = 1.39		Brun 2009 (PMRA# 2693972)
Ramshorn snail *Planorbella pilsbryi*	28-d Chronic	TGAI	LC_{50} = 645.6 (mortality) LC_{10} = **45.7** (mortality) NOEC < 10 (growth) NOEC <10 (biomass production)	Static renewal (every 7 days). Results were based on nominal concentrations; measured values showed test material was relatively stable over 7-day exposure period (mean difference of 3.7 ± 0.02% of initial measured values). This study is scientifically sound with limitations. Variability in adult snail weights preclude the use of growth data quantitatively; however, the mortality endpoints can be used in an aquatic risk assessment.	Prosser et al., 2016 (PMRA# 2712688)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Mayfly *N. triangulifer*	32-d Chronic, Static renewal	TGAI	32-d EC_{10} = **1.12** (emergence) 32-d EC_{50} = 1.75 (emergence) 32-d NOEC =1.05 (emergence)	Static renewal (three times per week). Water samples were collected to verify concentrations prior to solution renewal from 3 replicates per treatment, for 2 – 3 treatments per test, 2 – 3 times throughout the test duration. Mean percent differences between nominal and measured neonicotinoid concentrations were within 20%.	Raby et al., 2018 (PMRA# 2912490)
Freshwater mussel *Lampsilis siliquoidea*	28-d Chronic	TGAI	28-d NOEC ≥ 9121 (survival)	No effect at juvenile or adult stages up to the highest test concentration (mean measured).	Salerno et al., 2018 (PMRA# 2912493)
			Marine/estuarine – Acute		
Artemia sp., and Mosquito (*Aedes taeniorhynchus*)	Acute 48-h, Static	Imidacloprid (>95%)	*Artemia* sp.: 48h LC_{50} = 361230 (307830 – 498090) *Aedes taeniorhynchus:* 48h LC_{50} = **13** (10 – 16)	Increasing salinity increased sensitivity to imidacloprid. The endpoint for *A. taeniorhynchus* is cited incorrectly by the USDA as 130 µg a.i/L (USDA 2005; PMRA# 2334762).	Song et al. 1997 (PMRA# 2541668)
Marine mysid *Mysidopsis bahia*	Acute 96-h, Flow-through	Imidacloprid (96.2%)	96h LC_{50} = 37.7 (1st test) 96h LC_{50} = 34.1 (2nd test) NOEC = 13.3	1st test: NOEC was not determined within the test concentration range.	USDA 2005 (PMRA# 2334762); (original study PMRA# 1155858)
		Imidacloprid (240 FS, 22.7%)	96h LC_{50} = 36 NOEC = 21		USDA 2005 (PMRA# 2334762); (original study PMRA# 1155860)
Eastern Oyster *Crassostrea virginica*	Acute 96-h, Flow-through	Imidacloprid (95.8 – 96.2%)	96h EC_{50} > 23300 (1st test) EC_{50} > 145000 (2nd test – limit test)	100% survival; no effects on shell growth in first test. New shell growth of exposed was 22% less than controls in 2nd test - limit test. EFSA states that the second test is not valid due to increase in shell thickness of the controls below the 2mm (1.52 – 1.72mm).	USDA 2005 (PMRA# 2334762); EFSA 2014 (PMRA# 2545413)

Organism	Exposure	Test substance	Endpoint value (µg a.i./L)	Comments	Reference
Blue crab *Callinectes sapidus*	Acute 24-h, Static	Imidacloprid (99.5%) Trimax® Pro (40.8%)	Imidacloprid Megalopae (post larval stage) 24-h LC_{50} = 10 Juvenile 24-h LC_{50} = 1112 Trimax® Pro Megalopae (post larval stage) 24-h LC_{50} = 313 Juvenile 24-h LC_{50} = 817		Osterberg et al. 2012, (PMRA# 2544541)
Grass shrimp *Palaemonestes pugio*	Acute 96-h, Static renewal	Imidacloprid (99.5%)	Larvae (2-d old): 96-h LC_{50} = 309 Adult: 96-h LC_{50} = 564		Key et al. 2007 (PMRA# 2544540)
Marine/estuarine – Chronic					
Marine mysid *Mysidopsis bahia*	28-d Chronic, Flow-through	Imidacloprid (96.2%)	NOEC = 0.56 (1st test; based on reduced number of offspring/female reproductive day) NOEC = **0. 326** (2nd test; based on reduced growth of first generation as length and as dry weight)	**First Test**: At 5 µg/L and higher: significantly reduced growth of first-generation mysids as total length and as dry weight. At 10 µg/L: statistically increased mortality in comparison with pooled controls for first generation. No effects on mortality in second generation. **Second test:** At 0.6 µg/L: statistically increased mortality in comparison with pooled controls for first generation. No effects on mortality in second generation. No real explanation for discrepancy between first and second tests with regard to growth.	USDA 2005 (PMRA# 2334762); (original study PMRA# 1155862)

Bolded values indicate that the endpoint was used in HC_5 estimation (the 5th percentile of the species sensitivity distribution of the EC_{50} values); geomean values were used for species with multiple endpoint values. The acute and chronic HC_5 = 0.54 and 0.011 µg a.i./L, respectively. A summary of the SSD analysis is provided in Appendix VIII.

[1] These endpoints were mistakenly not included in the acute SSD. This omission is not expected to have any impact on the conclusions of the risk assessment given that other data were available for these taxa (i.e., they were represented in the SSD), and the species sensitivity distribution dataset is relatively large (n = 48).

Table 2 Summary of apical endpoints from mesocosm studies of effects of imidacloprid on aquatic invertebrates

Order	Family	Taxon Assessed	Measurement Endpoint	Imidacloprid Concentration (µg a.i./L)[1]						PMRA No. (Study Grouping)[3]
				Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
				NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
Diptera	Tipulidae	*Tipula sp.*	Larval mortality	12	120	6.51	73.6	--	--	2541841 (G)
Diptera	Tipulidae	*Tipula sp.*	Larval mortality	≥96	>96	≥64	>64	--	--	2544383 (G)
Ephemeroptera	Baetidae	*Baetis spp.*	Female head length	≥1	>1	≥0.8	>0.8	--	--	2545402 (A)
Ephemeroptera	Baetidae	*Baetis spp.*	Female head length	≥10	>10	--	--	--	--	2545402 (B)
Ephemeroptera	Baetidae	*Baetis spp.*	Male head length	<0.1	0.1	<0.1	0.1	--	--	2545402 (A)
Ephemeroptera	Baetidae	*Baetis spp.*	Male head length	<0.1	0.1	--	--	--	--	2545402 (B)

Order	Family	Taxon Assessed	Measurement Endpoint	Imidacloprid Concentration (µg a.i./L)[1]						PMRA No. (Study Grouping)[3]
				Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
				NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
Ephemeroptera	Heptageniidae	*Epeorus spp.*	Female thorax length	≥1	>1	≥0.8	>0.8	--	--	2545402 (A)
Ephemeroptera	Heptageniidae	*Epeorus spp.*	Female thorax length	≥10	>10	--	--	--	--	2545402 (B)
Ephemeroptera	Heptageniidae	*Epeorus spp.*	Male thorax length	≥0.1	>0.1	≥0.1	>0.1	--	--	2545402 (A)
Ephemeroptera	Heptageniidae	*Epeorus spp.*	Male thorax length	<0.1	0.1	--	--	--	--	2545402 (B)
Odonata	Libellulidae	*Sympetrum infuscatum*	Emergence/survival	<52.8	52.8	<32.0	32.0	<21.3	21.3	2544392 (F)
Odonata	Libellulidae	*Sympetrum infuscatum*	Larval mortality	<52.8	52.8	<32.0	32.0	<21.3	21.3	2544392 (F)
Pleocoptera	Pteronarcyidae	*Pteronarcys dorsata*	Larval mortality	48	96	33	64	--	--	2544383 (G)
Pleocoptera	Pteronarcyidae	*Pteronarcys dorsata*	Larval mortality	12	120	6.51	73.6	--	--	2541841 (G)

[1] Endpoints presented are the lowest of all sampling intervals. TWA = time-weighted average.
[2] Nominal concentrations, unless nominal was not provided.
[3] + indicates a study that provided raw data, presented measures of effects prior to treatment and presented sufficient analytical data for robust characterization of dissipation in the test systems.

Table 3 Summary of abundance endpoints for taxa of order classification or lower from mesocosm studies examining effects of imidacloprid

Phylum	Class	Order	Family	Taxon Assessed (number of NOEC/LOEC pairs)	Low/ High	Imidacloprid Concentration (µg a.i./L)[1]						PMRA Nos. (Study Category)[3]
						Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
						NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
Annelida	Clitellata	Haplotaxida	Tubificidae	Tubificidae (4)	Low	0.6	0.8	0.37	0.49	0.34	0.45	2545413 (C)
					High	<39	39	<28	28	<21	21	2544539 (F)
		Rhynchobdellida	Glossiphoniidae	*Helobdella stagnalis* (2)	--	3.8	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Arthropoda	Arachnida	Trombidiformes	--	Hydracarina (2)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
	Branchiopoda	Anomopoda	Moinidae	*Moina rectirostris*		≥39	>39	≥28	>28	≥21	>21	2544539 (F)
		Cladocera	Daphniidae	*Daphnia magna*	--	9.4	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
				Daphnia pulex and Daphnia longispina	--	1.5	3.8	0.84	2.27	0.89	2.44	2142729+ (C)
			--	Cladocera	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
		Diplostraca	Chydoridae	*Alona rustica*	--	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
				Chydorus sphaericus	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Pleuroxus laevis	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
			Macrotrichidae	*Macrothrix spinosa*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
			Sididae	*Diaphanosoma brachyurum*	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Latonopsis occidentalis	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
	Hexanauplia	Calanoida	--	Calanoid copepods	--	0.6	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
		Cyclopoida	--	Cyclopoid copepods	--	9.4	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
			--	Copepodites	--	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
	Insecta	Coleoptera	Dryopidae	Dryopidae (Helichus) (Adult)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Dytiscidae	*Guignotus japonicus*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)

Phylum	Class	Order	Family	Taxon Assessed (number of NOEC/LOEC pairs)	Low/ High	Imidacloprid Concentration (µg a.i./L)[1]						PMRA Nos. (Study Category)[3]
						Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
						NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
			Hydrophilidae	*Enochrus japonicus*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
				Hydrobius fuscipes	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
				Hydrophilidae (Barosus)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			--	Coleoptera	--	≥20	>20	--	--	--	--	2544389 (E)
		Diptera	Ceratopogonidae	Ceratopogonidae (2)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Chaoboridae	Chaoboridae (2)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Chaoborus crystallinus	Low	0.6	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
					High	1.1	3.3	0.67	2.02	0.62	1.86	2545413 (C)
				Chaoborus spp.	Low	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C)
					High	3.8	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
			Chironomidae	*Ablabesmyia spp.*	--	17.3	40	6.17	14.26	3.89	9.00	2544391 (D)
				Chironominae (7)	Low	0.2	2	0.11	1.43	0.09	1.05	3119449 (D)
					High	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E), 2545413 (C), 2142729+ (C)
				Chironomini (3)	Low	0.6	0.8	0.37	0.49	0.34	0.45	2545413 (C)
					High	20	60	2.87	7.28	2.73	8.18	1155896+ (E)
				Chironomus spp.	--	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C)
				Cladopelma spp.	--	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C)
				Cricotopus spp.	--	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C)
				Dicrotendipes spp.	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
				Orthocladiinae (5)	Low	1.5	3.8	0.84	2.27	0.89	2.44	2142729+ (C), 2544391 (D), 2545400 (B). 3119449 (D)
					High	≥20	>20	≥9.82	>9.82	≥7.46	>7.46	3119449 (D)
				Psectrocladius spp.	--	3.8	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
				Psectrotanypus spp.	--	23.5	23.5	19.00	19.00	17.12	17.12	2142729+ (C)
				Tanypodinae (8)	Low	3.8	9.4	2.27	6.91	2.44	6.40	2142729+ (C), 1155896+ (E), 2545400 (B), 3119449 (D)
					High	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	
				Tanypus spp.	--	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C)
				Tanytarsini (4)	Low	0.6	0.8	0.37	0.49	0.34	0.45	2545413 (C), 1155896+ (E), 2545400 (B)
					High	60	180	7.28	25.77	8.18	25.27	
				Chironomidae (8)	Low	0.2	2	0.11	1.43	0.09	1.05	2544391 (D), 2142729+ (C), 3119449 (D), 2544539 (F)
					High	≥40	>40	≥14.26	>14.26	≥9.00	>9.00	
			--	Diptera	Low	≥12	>12	--	--	--	--	2545400 (B), 2544389
					High	≥20	>20	--	--	--	--	
			Culicidae	Culcidae sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
			Ephydridae	Ephydridae sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)

Phylum	Class	Order	Family	Taxon Assessed (number of NOEC/LOEC pairs)	Low/ High	Imidacloprid Concentration (µg a.i./L)[1] Nominal or Peak Measured[2] NOEC	Nominal or Peak Measured[2] LOEC	14-d TWA NOEC	14-d TWA LOEC	28-d TWA NOEC	28-d TWA LOEC	PMRA Nos. (Study Category)[3]
			--	Ephydridae, Canacidae and Muscidae ("hard-bodied" insects)	--	≥0.5	>0.5	NC	NC	NC	NC	2912492 (H)
		Ephemeroptera	Baetidae	Baetidae (3)	Low	<0.6	0.6	<0.33	0.33	<0.36	0.36	2142729+ (C), 1155896+ (E)
					High	2	6	0.27	0.62	0.23	0.64	
				Baetis spp. (6)	Low	0.5	1	0.30	0.80	--	--	2545402 (A, B)
					High	≥10	>10	≥9.10	>9.10	--	--	
				Baetiella japonica	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
				Cloeon dipterum (4)	Low	0.243	0.608	0.15	0.38	**0.16**	0.38	2744281+ (C), 2744280+ (C)
					High	≥3.8	>3.8	2.87	2.87	3.09	3.09	
			Caenidae	Caenidae	Low	2	6	0.27	0.62	0.23	0.64	1155896+ (E)
					High	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	
				Caenis spp.	Low	1.4	3.2	0.50	1.14	0.32	0.72	2544391 (D)
					High	7.5	17.3	2.68	6.17	1.69	3.89	
			Heptageniidae	*Epeorus spp.* (6)	Low	0.5	1	0.30	0.80	--	--	2545402 (A, B)
					High	5	10	3.90	9.10	--	--	
			--	Ephemeroptera (3)	Low	2	20	--	--	--	--	2544389 (B), 2545400 (B)
					High	≥12	>12	--	--	--	--	
		Hemiptera	Gerridae	*Gerris latiabdominis*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
		Lepidoptera	Pyralidae	Pyralidae sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
		Odonata	Aeschnidae	Aeschnidae sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
			Coenagrionidae	*Ischnura senegalensis*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
				Coenagrionidae	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Libellulidae	Libellulidae	--	2	6	0.27	0.62	0.23	0.64	1155896+ (E)
				Crocothemis servilia mariannae	--	<39	39	<28	28	<21	21	2544539 (F)
				Orthetrum albistylum speciosum	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
		Plecoptera	--	Plecoptera	--	≥20	>20	--	--	--	--	2544389 (B)
		Trichoptera	Hydroptilidae	Hydrophilidae (Berosus) (larvae)	--	2	6	0.27	0.62	0.23	0.64	1155896+ (E)
				Hydroptilidae	--	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
				Hydroptilidae (Orthotrichia)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Hydroptilidae (Oxyethira)	--	2	6	0.27	0.62	0.23	0.64	1155896+ (E)
			Polycentropodidae	*Neureclipsis sp.*	--	<12	12	--	--	--	--	2545400 (B)
			--	Trichoptera	Low	≥12	>12	--	--	--	--	2545400 (B), 2544389 (B)
					High	≥20	>20	--	--	--	--	
		--	--	Insects (taxa not specified)*	--	<0.05	0.05	--	--	--	--	2545413 (C)
	Malacostraca	Amphipoda	Gammaridae	*Gammarus roeseli* (4)	Low	<12	12	--	--	--	--	2545404 (B)
					High	≥12	>12	--	--	--	--	2545404 (B)

Phylum	Class	Order	Family	Taxon Assessed (number of NOEC/LOEC pairs)	Low/ High	Imidacloprid Concentration (µg a.i./L)[1]						PMRA Nos. (Study Category)[3]
						Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
						NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
				Gammarus sp.	--	≥12	>12	--	--	--	--	2545400 (B)
				Large gammarids	--	<12	12	--	--	--	--	2545400 (B)
			Hyalellidae	*Hyalella azteca*	--	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
			--	Amphipoda (3)	Low	<2	2	<0.27	0.27	<0.23	0.23	1155896+ (E)
					High	2	6	0.27	0.62	0.23	0.64	
	Ostracoda	Podocopida	Cyprididae	*Heterocypris sp.*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
				Ilyocypris sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
				Stenocypris sp.	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
Mollusca	Bivalvia	Sphaeriidae	Sphaeriidae	*Pisidium spp.*	--	9.4	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
	Gastropoda	--	Planorbidae	*Gyraulus albus*	Low	0.6	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
					High	9.4	23.5	6.91	19.00	6.40	17.12	
				Planorbidae	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Physidae	Physidae (2)	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Lymnaeoidae	*Radix sp.*	--	≥40	>40	≥14.26	>14.26	≥9.00	>9.00	2544391 (D)
			Viviparidae	*Sinotaia quadrata histrica*	--	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
Rotifera	Monogonta	Collothecaceae	Collothecidae	*Collotheca mutabilis*	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
		Flosculariaceae	Hexarthridae	*Hexarthra mira* and *Hexarthra intermedia*	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
		Ploima	Brachionidae	*Brachionus spp.*	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
				Brachionus urceolaris and *Brachionus variabilis*	--	0.6	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
				Lepadella patella	Low	9.4	23.5	6.91	19.00	6.40	17.12	2142729+ (C), 1155896+ (E)
					High	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	
			Notommatidae	*Cephalodella spp.*	--	1.5	3.8	0.84	2.27	0.89	2.44	2142729+ (C)
			Lecanidae	*Lecane luna*	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Lecane spp.	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
				Monostyla closterocarca	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Monostyla quandridentata	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
			Synchaetidae	*Polyarthra remata*	--	20	60	2.87	7.28	2.73	8.18	1155896+ (E)
				Synchaeta spp.	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
			Trichoceridae	*Trichocerca pusilla*	--	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
				Trichocerca spp.	--	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)

Study categories: (A) artificial stream with continuous exposure, (B) artificial streams with pulse exposures, (C) outdoor mesocosms with 2 applications 21-day RTI, (D) Outdoor mesocosms with 3 applications and 7-day RTI, (E) Outdoor mesocosm with 4 applications 14-day RTI, (F) Rice paddy mesocosms, (G) single application to small pond mesocosms, (H) limnocorral

Bold value indicates toxicity endpoint used as effects metric

[1] Endpoints presented are the lowest of all sampling intervals. TWA = time-weighted average.

[2] Nominal concentrations, unless nominal was not provided.

[3] + indicates a study that provided raw data, presented measures of effects prior to treatment and presented sufficient analytical data for robust characterization of dissipation in the test systems.

Study categories: (A) artificial stream with continuous exposure, (B) artificial streams with pulse exposures, (C) outdoor mesocosms with 2 applications 21-day RTI, (D) Outdoor mesocosms with 3 applications and 7-day RTI, (E) Outdoor mesocosm with 4 applications 14-day RTI, (F) Rice paddy mesocosms, (G) single application to small pond mesocosms, (H) limnocorral

Table 4 Summary of community-level endpoints from mesocosm studies investigating effects of imidacloprid on aquatic invertebrates

Taxon Assessed	Measurement Endpoint	Imidacloprid Concentration (µg a.i./L)[1]						PMRA No. (Study Category)[3]
		Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
		NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
Oligochaeta	Abundance	2	20	NC	NC	NC	NC	2544389 (B)
Oligochaeta	Abundance (Ekman grab samples)	60	180	7.28	25.77	8.18	25.27	1155896+ (E)
Oligochaeta	Abundance (MASS)	60	180	7.28	25.77	8.18	25.27	1155896+ (E)
Acarina	MASS abundance	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Copepoda	Nauplii abundance	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Copepoda	Abundance	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
Chironomidae	Richness	7.50	17.3	2.68	6.17	1.69	3.89	2544391 (D)
Orthocladiinae	Richness	17.30	40	6.17	14.26	3.89	9.00	2544391 (D)
Ephemeroptera, Plecoptera, Trichoptera	Abundance	2	20	--	--	--	--	2544389 (B)
Ephemeroptera, Plecoptera, Trichoptera	Richness	≥20	>20	--	--	--	--	2544389 (B)
Hirudinea	Abundance	≥39	>39	≥28	>28	≥21	>21	2544539 (F)
Insecta	Emergent PRC composition	<12	12	--	--	--	--	2545400 (B)
Insecta	Abundance	2	20	--	--	--	--	2544389 (B)
Insecta	Emergence	1.10	3.3	0.67	2.02	0.62	1.86	2545413 (C)
Insecta	Emergent richness	1.50	3.8	0.84	2.27	0.89	2.44	2142729+ (C)
Insecta	Emergent diversity (Shannon Index)	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Insecta	Emergent evenness	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Insecta	Emergent similarity (Steinhaus Index)	0.60	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
Insecta	Emergent similarity (Stander's Index)	0.60	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
Insecta	Emergent PRC	0.60	1.5	0.33	0.84	0.36	0.89	2142729+ (C)
Ostracoda	Abundance	≥23.5	23.5	≥19.00	19.00	≥17.12	17.12	2142729+ (C)
Arthropoda	Abundance	<240	240	<90.18	90.18	<49.08	49.08	2574054 (F)
Arthropoda	Abundance on crops and bunds	≥240	240	≥90.18	90.18	≥49.08	49.08	2574054 (F)
Arthropoda (found on crops)	Abundance	≥49	>49	≥26	>26	≥16	>16	2544538 (F)
Crustacean	Abundance, nauplii	6	20	0.62	2.87	0.64	2.73	1155896+ (E)
Macroarthropod	Diversity (Shannon Index)	<240	240	<90.18	90.18	<49.08	49.08	2574054 (F)
Nematoda	Abundance (Ekman grab samples)	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Turbellaria	Abundance (MASS)	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Rotifera	Abundance	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Benthic invertebrate	Abundance	2	20	--	--	--	--	2544389 (B)
Benthic organisms	Abundance	<49	49	--	--	--	--	2544538 (F)
Benthic organisms	Abundance	<49	49	--	--	--	--	2544538 (F)
Insecta	Emergence (not clear what level of organisation within Insecta)[b]	<0.50	0.5	--	--	--	--	2545413 (C)
Invertebrate	MASS PRC composition	1.10	3.3	0.67	2.02	0.62	1.86	2545413 (C)
Invertebrate larvae	Abundance	1.10	3.3	0.67	2.02	0.62	1.86	2545413 (C)
Invertebrates	Diversity (Shannon Index)	≥49	>49	≥26	>26	≥16	>16	2544538 (F)
Invertebrates	PRC composition	≥49	>49	≥26	>26	≥16	>16	2544538 (F)
Invertebrates	PRC composition	<39	39	<28	28	<21	21	2544539 (F)
Macroinvertebrates	Emergent richness	2	6	0.27	0.62	0.23	0.64	1155896+ (E)

Taxon Assessed	Measurement Endpoint	Imidacloprid Concentration (µg a.i./L)[1]						PMRA No. (Study Category)[3]
		Nominal or Peak Measured[2]		14-d TWA		28-d TWA		
		NOEC	LOEC	NOEC	LOEC	NOEC	LOEC	
Macroinvertebrates	Emergent abundance	2	6	0.27	0.62	0.23	0.64	1155896+ (E)
Macroinvertebrates	Community loss index	2	20	--	--	--	--	2544389 (B)
Macroinvertebrates	Richness	≥20	20	--	--	--	--	2544389 (B)
Macroinvertebrates	Diversity (Simpson's)	≥20	20	--	--	--	--	2544389 (B)
Macroinvertebrates	Family biotic index	≥20	20	--	--	--	--	2544389 (B)
Macroinvertebrates	Richness	≥12	12	--	--	--	--	2545400 (B)
Macroinvertebrates	PRC composition	≥12	12	--	--	--	--	2545400 (B)
Macroinvertebrates	MASS richness	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Macroinvertebrates	MASS diversity (Shannon Index)	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Macroinvertebrates	MASS similarity (Steinhaus Index)	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Macroinvertebrates	MASS similarity (Stander's Index)	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Macroinvertebrates	MASS PRC	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Macroinvertebrates	Sediment sample similarity (Steinhaus Index)	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Macroinvertebrates	Sediment sample similarity (Stander's Index)	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Macroinvertebrates	Sediment sample PRC	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Macroinvertebrates	MASS evenness	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Macroinvertebrates	Sediment sample richness	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Macroinvertebrates	Sediment sample diversity (Shannon Index)	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Macroinvertebrates	Sediment sample evenness	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Macroinvertebrates	Richness (MASS)	20	60	2.87	7.28	2.73	8.18	1155896+ (E)
Macroinvertebrates	MASS abundance	20	60	2.87	7.28	2.73	8.18	1155896+ (E)
Macroinvertebrates	Richness (Ekman grab samples)	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Macroinvertebrates	Abundance (Ekman grab samples)	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Nekton organisms (aquatic)	Abundance	<49	49	<26	26	<16	16	2544538 (F)
Nekton organisms (aquatic)	Abundance	<240	240	<90.18	90.18	<49.08	49.08	2574054 (F)
Neuston organisms (floaters)	Abundance	<49	49	<26	26	<16	16	2544538 (F)
Neuston organisms (floaters)	Abundance	<240	240	<90.18	90.18	<49.08	49.08	2574054 (F)
Zooplankton	Abundance	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Zooplankton	Similarity (Steinhaus Index)	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Zooplankton	Similarity (Stander's Index)	3.80	9.4	2.27	6.91	2.44	6.40	2142729+ (C)
Zooplankton	PRC	9.40	23.5	6.91	19.00	6.40	17.12	2142729+ (C)
Zooplankton	Richness	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Zooplankton	Diversity (Shannon Index)	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Zooplankton	Evenness	≥23.5	>23.5	≥19.00	>19.00	≥17.12	>17.12	2142729+ (C)
Zooplankton	Richness	≥180	>180	≥25.77	>25.77	≥25.27	>25.27	1155896+ (E)
Zooplankton	Abundance	≥49	>49	≥26	>26	≥16	>16	2544538 (F)
Zooplankton crustaceans	Abundance	<240	240	<90.18	90.18	<49.08	49.08	2574054 (F)

[1] Endpoints presented are the lowest of all sampling intervals. TWA = time-weighted average.
[2] Nominal concentrations, unless nominal was not provided.
[3] + indicates a study that provided raw data, presented measures of effects prior to treatment and presented sufficient analytical data for robust characterization of dissipation in the test systems.
Study categories: (A) artificial stream with continuous exposure, (B) artificial streams with pulse exposures, (C) outdoor mesocosms with 2 applications 21-day RTI, (D) Outdoor mesocosms with 3 applications and 7-day RTI, (E) Outdoor mesocosm with 4 applications 14-day RTI, (F) Rice paddy mesocosms, (G) single application to small pond mesocosms, (H) limnocorral

Table 5 Revised screening level risk of imidacloprid to aquatic invertebrates exposed at the highest seasonal application rate for soil application on crop group 5 (Brassica (cole) leafy vegetables - 520 g a.i./ha)

Organism	Exposure	Species	Effects metric[1] (µg a.i./L)	EEC[2](µg a.i./L)	RQ	LOC exceeded
Freshwater organisms						
Invertebrates	Acute	48 invertebrate species	HC_5 = 0.54	65	**120**	**Yes**
Invertebrate community	Chronic	*Cloeon dipterum* (mesocosm study)	28-d TWA NOEC = 0.16 (effects on adult and larvae abundance)	65	**406**	**Yes**
Marine/Estuarine organisms						
Invertebrates	Acute	Mosquito (*Aedes taeniorhynchus*)	48-h LC_{50} ÷ 2 = 6.5	65	**10**	**Yes**
	Chronic	Marine mysid *Mysidopsis bahia*	28-d NOEC growth = 0.33	65	**197**	**Yes**

[1] The HC_5 is the 5th percentile of the species sensitivity distribution for 48 – 96-h LC_{50} or EC_{50} endpoints from laboratory studies (acute exposures)
[2] Estimated Environmental Concentration (EEC) based on an 80 cm water depth.
Bolded values indicate an exceedance of the level of concern (LOC) (RQ = 1).

Table 6 Revised refined risk assessment of imidacloprid for aquatic invertebrates from predicted levels of spray drift

Organism	Exposure	Species	Effects metric[1] (µg a.i./L)	EEC[2] (µg a.i./L)	RQ	LOC exceeded
Freshwater organisms						
Invertebrates	Acute	48 invertebrate species	HC_5 = 0.54	2.0 (field sprayer)	**3.7**	**Yes**
				24.2 (airblast sprayer)	**45**	**Yes**
				4.7 (aerial sprayer)	**8.7**	**Yes**
Invertebrate community	Chronic	*Cloeon dipterum* (mesocosm study)	28-d TWA NOEC = 0.16 (effects on adult and larvae abundance)	2.0 (field sprayer)	**12**	**Yes**
				24.2 (airblast sprayer)	**151**	**Yes**
				4.7 (aerial sprayer)	**29.3**	**Yes**
Marine/Estuarine organisms						
Invertebrates	Acute	Mosquito (*Aedes taeniorhynchus*)	48-h LC_{50} ÷ 2 = 6.5	2.0 (field sprayer)[3]	0.3	No
				8.3 (airblast sprayer)[3]	**1.3**	**Yes**
				6.1 (aerial sprayer)[3]	0.9	No

[1] 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). The 28-day time-weighted average NOEC is based on significant effects on *Cloeon dipterum* abundance (adult and larvae) observed at 0.38 µg/L (LOEC) in a mesocosm study with freshwater invertebrates.
[2] 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 × 49 g a.i./ha (potatoes, soybeans) with 5-d application interval and 80th percentile $t_{1/2}$ = 191 days, EEC = 18 µg a.i./L; airblast = 3 × 112 g a.i./ha (raspberries, post-bloom) with 7-d application interval and 80th percentile $t_{1/2}$ = 191 days, EEC = 41 µg a.i./L; field sprayer = 1 × 281.3 g a.i./ha (turf), EEC = 35 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 = 59% (late season, as only post-bloom application is allowed).

[3] Marine EECs are 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 7 Revised refined risk assessment of imidacloprid for aquatic invertebrates from predicted levels of pesticide runoff

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
Freshwater organisms										
Invertebrates	Acute	48 invertebrate species	HC_5 = 0.54[1]	Foliar	Blueberry	3 × 42 g a.i./ha at 5-d intervals	BC	0.64	**1.2**	**Yes**
							ON	3.7	**6.9**	**Yes**
							QC	3.4	**6.3**	**Yes**
							Atlantic	5.2	**9.6**	**Yes**
						2 × 42 g a.i./ha at a 5-d interval	BC	0.52	**1.0**	**Yes**
							ON	2.5	**4.6**	**Yes**
							QC	2.3	**4.3**	**Yes**
							Atlantic	3.7	**6.9**	**Yes**
						1 × 42 g a.i./ha	BC	0.28	0.5	No
							ON	1.4	**2.6**	**Yes**
							QC	1.2	**2.2**	**Yes**
							Atlantic	2.7	**5.0**	**Yes**
					Raspberry	3 × 112 g a.i./ha at 7-d intervals	BC	1.7	**3.2**	**Yes**
							ON	9.5	**18**	**Yes**
							QC	10	**19**	**Yes**
							Atlantic	8.4	**16**	**Yes**
						2 × 112 g a.i./ha at a 7-d interval	BC	1.4	**2.6**	**Yes**
							ON	6.7	**12**	**Yes**
							QC	7.2	**13**	**Yes**
							Atlantic	6.9	**13**	**Yes**
						1 × 112 g a.i./ha	BC	0.75	**1.4**	**Yes**
							ON	3.7	**6.9**	**Yes**
							QC	3.6	**6.7**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Atlantic	4.1	**7.6**	**Yes**
					Grape	2 × 48 g a.i./ha at a 14-d interval	BC	0.077	0.1	No
							ON	1.3	**2.4**	**Yes**
							QC	0.79	**1.5**	**Yes**
							Atlantic	1.3	**2.4**	**Yes**
						1 × 48 g a.i./ha	BC	0.042	< 0.1	No
							ON	0.66	**1.2**	**Yes**
							QC	0.47	0.9	No
							Atlantic	0.77	**1.4**	**Yes**
					Tomato	3 × 49 g a.i./ha at 5-d intervals	BC	0.82	**1.5**	**Yes**
							Prairie	3.4	**6.3**	**Yes**
							ON	4.4	**8.2**	**Yes**
							QC	4.3	**8.0**	**Yes**
							Atlantic	5.9	**11**	**Yes**
						2 × 49 g a.i./ha at a 5-d interval	BC	0.58	**1.1**	**Yes**
							Prairie	2.4	**4.4**	**Yes**
							ON	3.2	**5.9**	**Yes**
							QC	2.7	**5.0**	**Yes**
							Atlantic	4.8	**8.9**	**Yes**
						1 × 49 g a.i./ha	BC	0.33	0.6	No
							Prairie	1.2	**2.2**	**Yes**
							ON	1.6	**3.0**	**Yes**
							QC	1.4	**2.6**	**Yes**
							Atlantic	2.5	**4.6**	**Yes**
					Soybean	3 × 24.4 g a.i./ha at 5-d intervals	BC	0.20	0.4	No
							Prairie	1.7	**3.2**	**Yes**
							ON	2.3	**4.3**	**Yes**
							QC	1.9	**3.5**	**Yes**
							Atlantic	2.2	**4.1**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
						3 × 49.9 g a.i./ha at 5-d intervals	BC	0.41	0.8	No
							Prairie	3.6	**6.7**	**Yes**
							ON	4.7	**8.7**	**Yes**
							QC	3.8	**7.0**	**Yes**
							Atlantic	4.4	**8.2**	**Yes**
					Potato	3 × 49 g a.i./ha at 5-d intervals	BC	0.36	0.7	No
							Prairie	3.5	**6.5**	**Yes**
							ON	4.6	**8.5**	**Yes**
							QC	3.1	**5.7**	**Yes**
							Atlantic	5.9	**11**	**Yes**
						2 × 49 g a.i./ha at a 5-d interval	BC	0.26	0.5	No
							Prairie	2.3	**4.3**	**Yes**
							ON	3.0	**5.6**	**Yes**
							QC	2.2	**4.1**	**Yes**
							Atlantic	4.8	**8.9**	**Yes**
						1 × 49 g a.i./ha	BC	0.14	0.3	No
							Prairie	1.2	**2.2**	**Yes**
							ON	1.7	**3.2**	**Yes**
							QC	1.2	**2.2**	**Yes**
							Atlantic	2.5	**4.6**	**Yes**
					Turf	1 × 281 g a.i./ha	BC-Okanagan	0.40	0.7	No
							BC-Vancouver	4.5	**8.3**	**Yes**
							Prairie-AB south	4.1	**7.6**	**Yes**
							Prairie-AB north	1.8	**3.3**	**Yes**
							Prairie-SK	2.9	**5.4**	**Yes**
							Prairie-MB	2.6	**4.8**	**Yes**
							ON-east	4.0	**7.4**	**Yes**
							ON-west	3.3	**6.1**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							QC	3.0	**5.6**	**Yes**
							Atlantic-NS	3.4	**6.3**	**Yes**
							Atlantic-PEI	3.6	**6.7**	**Yes**
				Soil: drench	Grape[4]	1 × 100 g a.i./ha	BC	0.006	< 0.1	No
							ON	0.066	0.1	No
							QC	0.027	< 0.1	No
							Atlantic	0.036	< 0.1	No
						1 × 480 g a.i./ha	BC	0.028	< 0.1	No
							ON	0.32	0.6	No
							QC	0.13	0.2	No
							Atlantic	0.18	0.3	No
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.25	0.5	No
							Prairie	1.6	**3.0**	**Yes**
							ON	2.5	**4.6**	**Yes**
							QC	1.8	**3.3**	**Yes**
							Atlantic	2.9	**5.4**	**Yes**
						1 × 520 g a.i./ha	BC	1.5	**2.8**	**Yes**
							Prairie	9.8	**18**	**Yes**
							ON	15	**28**	**Yes**
							QC	11	**20**	**Yes**
							Atlantic	17	**31**	**Yes**
				Soil: in-furrow[4]	Potato	1 × 100 g a.i./ha	BC	0.026	< 0.1	No
							Prairie	0.26	0.5	No
							ON	0.41	0.8	No
							QC	0.43	0.8	No
							Atlantic	1.0	**1.9**	**Yes**
						1 × 480 g a.i./ha	BC	0.13	0.2	No
							Prairie	1.2	**2.2**	**Yes**
							ON	2.0	**3.7**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							QC	2.0	**3.7**	**Yes**
							Atlantic	5.0	**9.3**	**Yes**
					Other root/tuber vegetables	1 × 100 g a.i./ha	BC	0.16	0.3	No
							Prairie	0.77	**1.4**	**Yes**
							ON	0.64	**1.2**	**Yes**
							QC	0.68	**1.3**	**Yes**
							Atlantic	1.7	**3.2**	**Yes**
						1 × 480 g a.i./ha	BC	0.77	**1.4**	**Yes**
							Prairie	3.7	**6.9**	**Yes**
							ON	3.1	**5.7**	**Yes**
							QC	3.1	**5.7**	**Yes**
							Atlantic	7.7	**14**	**Yes**
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.17	0.3	No
							Prairie	1.2	**2.2**	**Yes**
							ON	1.7	**3.2**	**Yes**
							QC	1.2	**2.2**	**Yes**
							Atlantic	2.1	**3.9**	**Yes**
						1 × 520 g a.i./ha	BC	1.0	**1.9**	**Yes**
							Prairie	6.9	**13**	**Yes**
							ON	10	**19**	**Yes**
							QC	7.3	**14**	**Yes**
							Atlantic	13	**24**	**Yes**
				Seed treatment	Barley	1 × 36.33 g a.i./ha	BC	0.018	< 0.1	No
							Prairie-SK	0.19	0.4	No
							ON	0.16	0.3	No
							QC	0.21	0.4	No
							Atlantic	0.54	**1.0**	**Yes**
					Canola	1 × 64.16 g	BC	0.23	0.4	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
						a.i./ha	Prairie-SK	0.33	0.6	No
							Prairie-MB	0.36	0.7	No
							ON	5.4	**10**	**Yes**
							QC	7.6	**14**	**Yes**
							Atlantic	1.3	**2.4**	**Yes**
					Field corn[4]	1 × 150 g a.i./ha	BC	0.27	0.5	No
							Prairie-SK	0.28	0.5	No
							Prairie-MB	0.38	0.7	No
							ON	0.29	0.5	No
							QC	0.37	0.7	No
							Atlantic	1.30	**2.4**	**Yes**
					Pea, dry	1 × 246.25 g a.i./ha	BC	0.083	0.2	No
							Prairie	0.92	**1.7**	**Yes**
							ON	0.86	**1.6**	**Yes**
							QC	1.1	**2.0**	**Yes**
							Atlantic	0.36	0.7	No
					Potato	1 × 280 g a.i./ha	BC	0	0	No
							Praire	0.002	< 0.1	No
							ON	0.024	< 0.1	No
							QC	0.033	< 0.1	No
							Atlantic	0.078	0.1	No
					Soybean[4]	1 × 157.5 g a.i./ha	BC	1.2	**2.2**	**Yes**
							Prairie-SK	1.3	**2.4**	**Yes**
							Prairie-MB	1.2	**2.2**	**Yes**
							ON	1.6	**3.0**	**Yes**
							QC	1.3	**2.4**	**Yes**
							Atlantic	3.0	**5.6**	**Yes**
					Wheat, spring	1 × 52.47 g a.i./ha	BC	0.43	0.8	No
							Prairie-SK	0.39	0.7	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Prairie-MB	0.23	0.4	No
							ON	0.24	0.4	No
							QC	0.30	0.6	No
							Atlantic	0.91	**1.7**	**Yes**
					Chickpea	1 × 96.88 g a.i./ha	Not grown in BC, ON, QC or Atlantic Region			
							Prairie	0.11	0.2	No
					Faba bean	1 × 232.5 g a.i./ha	Not grown in BC			
							Prairie	0.19	0.4	No
							ON	0.020	< 0.1	No
							QC	0.017	< 0.1	No
							Atlantic	1.3	**2.4**	**Yes**
Invertebrates	Chronic	*Cloeon dipterum* (mesocosm study)	28-d TWA NOEC = 0.16 (adult and larvae abundance)	Foliar	Blueberry	3 × 42 g a.i./ha at 5-d intervals	BC	0.29	**1.8**	**Yes**
							ON	1.9	**12**	**Yes**
							QC	1.8	**11**	**Yes**
							Atlantic	3.0	**19**	**Yes**
						2 × 42 g a.i./ha at a 5-d interval	BC	0.23	**1.4**	**Yes**
							ON	1.4	**8.8**	**Yes**
							QC	1.2	**7.5**	**Yes**
							Atlantic	2.1	**13**	**Yes**
						1 × 42 g a.i./ha	BC	0.14	0.9	No
							ON	0.73	**4.6**	**Yes**
							QC	0.64	**4.0**	**Yes**
							Atlantic	1.3	**8.1**	**Yes**
					Raspberry	3 × 112 g a.i./ha at 7-d intervals	BC	0.77	**4.8**	**Yes**
							ON	5.0	**31**	**Yes**
							QC	4.8	**30**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Atlantic	4.2	**26**	**Yes**
						2 × 112 g a.i./ha at a 7-d interval	BC	0.62	**3.9**	**Yes**
							ON	3.7	**23**	**Yes**
							QC	3.4	**21**	**Yes**
							Atlantic	3.6	**23**	**Yes**
						1 × 112 g a.i./ha	BC	0.37	**2.3**	**Yes**
							ON	1.8	**11**	**Yes**
							QC	1.8	**11**	**Yes**
							Atlantic	1.9	**12**	**Yes**
					Grape	2 × 48 g a.i./ha at a 14-d interval	BC	0.038	0.2	No
							ON	0.63	**3.9**	**Yes**
							QC	0.37	**2.3**	**Yes**
							Atlantic	0.57	**3.6**	**Yes**
						1 × 48 g a.i./ha	BC	0.018	0.1	No
							ON	0.35	**2.2**	**Yes**
							QC	0.21	**1.3**	**Yes**
							Atlantic	0.34	**2.1**	**Yes**
					Tomato	3 × 49 g a.i./ha at 5-d intervals	BC	0.37	**2.3**	**Yes**
							Prairie	1.6	**10**	**Yes**
							ON	2.3	**14**	**Yes**
							QC	2.2	**14**	**Yes**
							Atlantic	3.1	**19**	**Yes**
						2 × 49 g a.i./ha at a 5-d interval	BC	0.26	**1.6**	**Yes**
							Prairie	1.1	**6.9**	**Yes**
							ON	1.7	**11**	**Yes**
							QC	1.5	**9.4**	**Yes**
							Atlantic	2.3	**14**	**Yes**
						1 × 49 g a.i./ha	BC	0.16	**1.0**	**Yes**
							Prairie	0.55	**3.4**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							ON	0.77	**4.8**	**Yes**
							QC	0.75	**4.7**	**Yes**
							Atlantic	1.2	**7.5**	**Yes**
					Soybean	3 × 24.4 g a.i./ha at 5-d intervals	BC	0.097	0.6	No
							Prairie	0.79	**4.9**	**Yes**
							ON	1.1	**6.9**	**Yes**
							QC	0.92	**5.8**	**Yes**
							Atlantic	1.4	**8.8**	**Yes**
						3 × 49.9 g a.i./ha at 5-d intervals	BC	0.20	**1.3**	**Yes**
							Prairie	1.6	**10**	**Yes**
							ON	2.2	**14**	**Yes**
							QC	1.9	**12**	**Yes**
							Atlantic	2.8	**18**	**Yes**
					Potato	3 × 49 g a.i./ha at 5-d intervals	BC	0.17	**1.1**	**Yes**
							Prairie	1.6	**10**	**Yes**
							ON	2.0	**13**	**Yes**
							QC	1.5	**9.4**	**Yes**
							Atlantic	3.1	**19**	**Yes**
						2 × 49 g a.i./ha at a 5-d interval	BC	0.12	0.8	No
							Prairie	1.1	**6.9**	**Yes**
							ON	1.3	**8.1**	**Yes**
							QC	1.2	**7.5**	**Yes**
							Atlantic	2.3	**14**	**Yes**
						1 × 49 g a.i./ha	BC	0.063	0.4	No
							Prairie	0.56	**3.5**	**Yes**
							ON	0.78	**4.9**	**Yes**
							QC	0.65	**4.1**	**Yes**
							Atlantic	1.2	**7.5**	**Yes**
							BC-Okanagan	0.17	**1.1**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
					Turf	1 × 281 g a.i./ha	BC-Vancouver	2.4	**15**	**Yes**
							Prairie-AB south	1.9	**12**	**Yes**
							Prairie-AB north	0.83	**5.2**	**Yes**
							Prairie-SK	1.3	**8.1**	**Yes**
							Prairie-MB	1.1	**6.9**	**Yes**
							ON-east	1.8	**11**	**Yes**
							ON-west	1.5	**9.4**	**Yes**
							QC	1.7	**11**	**Yes**
							Atlantic-NS	1.5	**9.4**	**Yes**
							Atlantic-PEI	2.0	**13**	**Yes**
				Soil: drench	Grape[4]	1 × 100 g a.i./ha	BC	0.003	< 0.1	No
							ON	0.035	0.2	No
							QC	0.013	< 0.1	No
							Atlantic	0.017	0.1	No
						1 × 480 g a.i./ha	BC	0.012	< 0.1	No
							ON	0.17	**1.1**	**Yes**
							QC	0.063	0.4	No
							Atlantic	0.080	0.5	No
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.11	0.7	No
							Prairie	0.85	**5.3**	**Yes**
							ON	1.2	**7.5**	**Yes**
							QC	0.94	**5.9**	**Yes**
							Atlantic	1.4	**8.8**	**Yes**
						1 × 520 g a.i./ha	BC	0.68	**4.3**	**Yes**
							Prairie	5.1	**32**	**Yes**
							ON	6.9	**43**	**Yes**
							QC	5.6	**35**	**Yes**
							Atlantic	8.1	**51**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
				Soil: in-furrow[4]	Potato	1 × 100 g a.i./ha	BC	0.012	< 0.1	No
							Prairie	0.21	**1.3**	**Yes**
							ON	0.21	**1.3**	**Yes**
							QC	0.26	**1.6**	**Yes**
							Atlantic	0.55	**3.4**	**Yes**
						1 × 480 g a.i./ha	BC	0.058	0.4	No
							Prairie	1.0	**6.3**	**Yes**
							ON	0.99	**6.2**	**Yes**
							QC	1.2	**7.5**	**Yes**
							Atlantic	2.6	**16**	**Yes**
					Other root/tuber vegetables	1 × 100 g a.i./ha	BC	0.073	0.5	No
							Prairie	0.62	**3.9**	**Yes**
							ON	0.32	**2.0**	**Yes**
							QC	0.39	**2.4**	**Yes**
							Atlantic	0.84	**5.3**	**Yes**
						1 × 480 g a.i./ha	BC	0.35	**2.2**	**Yes**
							Prairie	3.0	**19**	**Yes**
							ON	1.5	**9.4**	**Yes**
							QC	1.9	**12**	**Yes**
							Atlantic	4.0	**25**	**Yes**
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.076	0.5	No
							Prairie	0.56	**3.5**	**Yes**
							ON	0.81	**5.1**	**Yes**
							QC	0.68	**4.3**	**Yes**
							Atlantic	0.96	**6.0**	**Yes**
						1 × 520 g a.i./ha	BC	0.45	**2.8**	**Yes**
							Prairie	3.4	**21**	**Yes**
							ON	4.9	**31**	**Yes**
							QC	4.1	**26**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Atlantic	5.8	**36**	**Yes**
				Seed treatment	Barley	1 × 36.33 g a.i./ha	BC	0.008	0.05	No
							Prairie-SK	0.12	0.75	No
							ON	0.13	0.81	No
							QC	0.17	**1.1**	**Yes**
							Atlantic	0.27	**1.7**	**Yes**
					Canola	1 × 64.16 g a.i./ha	BC	0.18	**1.1**	**Yes**
							Prairie-SK	0.21	**1.3**	**Yes**
							Prairie-MB	0.18	**1.1**	**Yes**
							ON	2.7	**17**	**Yes**
							QC	5.8	**36**	**Yes**
							Atlantic	0.63	**3.9**	**Yes**
					Field corn[4]	1 × 56.8 g a.i./ha	BC	0.14	0.9	No
							Prairie-SK	0.23	**1.4**	**Yes**
							Prairie-MB	0.14	0.9	No
							ON	0.15	0.9	No
							QC	0.21	**1.3**	**Yes**
							Atlantic	0.70	**4.4**	**Yes**
					Pea, dry	1 × 246.25 g a.i./ha	BC	0.037	0.2	No
							Prairie	0.73	**4.6**	**Yes**
							ON	0.43	**2.7**	**Yes**
							QC	0.86	**5.4**	**Yes**
							Atlantic	0.20	**1.3**	**Yes**
					Potato	1 × 280 g a.i./ha	BC	0	0	No
							Prairie	0.002	< 0.1	No
							ON	0.013	< 0.1	No
							QC	0.017	0.1	No
							Atlantic	0.061	0.4	No
					Soybean[4]	1 × 157.5 g	BC	0.6	**3.8**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
						a.i./ha	Prairie-SK	0.58	**3.6**	**Yes**
							Prairie-MB	0.55	**3.4**	**Yes**
							ON	0.84	**5.3**	**Yes**
							QC	0.67	**4.2**	**Yes**
							Atlantic	1.5	**9.4**	**Yes**
					Wheat, spring	1 × 52.47 g a.i./ha	BC	0.22	**1.4**	**Yes**
							Prairie-SK	0.14	0.9	No
							Prairie-MB	0.31	**1.9**	No
							ON	0.19	**1.2**	**Yes**
							QC	0.24	**1.5**	**Yes**
							Atlantic	0.61	**3.8**	**Yes**
					Chickpea	1 × 96.88 g a.i./ha	Not grown in BC, ON, QC or Atlantic Region			
							Prairie	0.083	0.52	No
					Faba bean	1 × 232.5 g a.i./ha	Not grown in BC			
							Prairie	0.15	0.9	No
							ON	0.011	< 0.1	No
							QC	0.009	< 0.1	No
							Atlantic	0.71	**4.4**	**Yes**
Marine/estuarine organisms										
Invertebrates	Acute	Mosquito (*Aedes taeniorhynchus*)	48h LC_{50} ÷ 2 = 6.5	Foliar	Blueberry	3 × 42 g a.i./ha at 5-d intervals	BC	0.64	0.1	No
							QC	3.4	0.5	No
							Atlantic	5.2	0.8	No
						2 × 42 g a.i./ha at a 5-d interval	BC	0.52	< 0.1	No
							QC	2.3	0.4	No
							Atlantic	3.7	0.6	No
						1 × 42 g a.i./ha	BC	0.28	< 0.1	No
							QC	1.2	0.2	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Atlantic	2.7	0.4	No
					Raspberry	3 × 112 g a.i./ha at 7-d intervals	BC	1.7	0.3	No
							QC	10	**1.5**	**Yes**
							Atlantic	8.4	**1.3**	**Yes**
						2 × 112 g a.i./ha at a 7-d interval	BC	1.4	0.2	No
							QC	7.2	**1.1**	**Yes**
							Atlantic	6.9	**1.1**	**Yes**
						1 × 112 g a.i./ha	BC	0.75	0.1	No
							QC	3.6	0.6	No
							Atlantic	4.1	0.6	No
					Grape	2 × 48 g a.i./ha at a 14-d interval	BC	0.077	< 0.1	No
							QC	0.79	0.1	No
							Atlantic	1.3	0.2	No
						1 × 48 g a.i./ha	BC	0.042	< 0.1	No
							QC	0.47	< 0.1	No
							Atlantic	0.77	0.1	No
					Tomato	3 × 49 g a.i./ha at 5-d intervals	BC	0.82	0.1	No
							QC	4.3	0.7	No
							Atlantic	5.9	0.9	No
						2 × 49 g a.i./ha at a 5-d interval	BC	0.58	< 0.1	No
							QC	2.7	0.4	No
							Atlantic	4.8	0.7	No
						1 × 49 g a.i./ha	BC	0.33	< 0.1	No
							QC	1.4	0.2	No
							Atlantic	2.5	0.4	No
					Soybean	3 × 24.4 g a.i./ha at 5-d intervals	BC	0.20	< 0.1	No
							QC	1.9	0.3	No
							Atlantic	2.2	0.3	No
						3 × 49.9 g a.i./ha at 5-d intervals	BC	0.41	< 0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							QC	3.8	0.6	No
							Atlantic	4.4	0.7	No
					Potato	3 × 49 g a.i./ha at 5-d intervals	BC	0.36	< 0.1	No
							QC	3.1	0.5	No
							Atlantic	5.9	0.9	No
						2 × 49 g a.i./ha at a 5-d interval	BC	0.26	< 0.1	No
							QC	2.2	0.3	No
							Atlantic	4.8	0.7	No
						1 × 49 g a.i./ha	BC	0.14	< 0.1	No
							QC	1.2	0.2	No
							Atlantic	2.5	0.4	No
					Turf	1 × 281 g a.i./ha	BC-Okanagan	0.40	< 0.1	No
							BC-Vancouver	4.5	0.7	No
							QC	3.0	0.5	No
							Atlantic-NS	3.4	0.5	No
							Atlantic-PEI	3.6	0.6	No
				Soil: drench	Grape[4]	1 × 100 g a.i./ha	BC	0.006	< 0.1	No
							QC	0.027	< 0.1	No
							Atlantic	0.036	< 0.1	No
						1 × 480 g a.i./ha	BC	0.028	< 0.1	No
							QC	0.13	< 0.1	No
							Atlantic	0.18	< 0.1	No
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.25	< 0.1	No
							QC	1.8	0.3	No
							Atlantic	2.9	0.5	No
						1 × 520 g a.i./ha	BC	1.5	0.2	No
							QC	11	**1.7**	**Yes**
							Atlantic	17	**2.6**	**Yes**
				Soil: in-	Potato	1 × 100 g a.i./ha	BC	0.026	< 0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
				furrow[4]			QC	0.43	< 0.1	No
							Atlantic	1.0	0.2	No
						1 × 480 g a.i./ha	BC	0.13	< 0.1	No
							QC	2.0	0.3	No
							Atlantic	5.0	0.8	No
					Other root/tuber vegetables	1 × 100 g a.i./ha	BC	0.16	< 0.1	No
							QC	0.65	0.1	No
							Atlantic	1.6	0.3	No
						1 × 480 g a.i./ha	BC	0.77	0.1	No
							QC	3.1	0.5	No
							Atlantic	7.7	**1.2**	**Yes**
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.17	< 0.1	No
							QC	1.2	0.2	No
							Atlantic	2.1	0.3	No
						1 × 520 g a.i./ha	BC	1.0	0.2	No
							QC	7.3	**1.1**	**Yes**
							Atlantic	13	**2.0**	**Yes**
				Seed treatment	Barley	1 × 36.33 g a.i./ha	BC	0.018	< 0.1	No
							QC	0.21	< 0.1	No
							Atlantic	0.54	< 0.1	No
					Canola	1 × 64.16 g a.i./ha	BC	0.23	< 0.1	No
							QC	7.6	**1.2**	**Yes**
							Atlantic	1.3	0.2	No
					Field corn[4]	1 × 56.8 g a.i./ha	BC	0.27	< 0.1	No
							QC	0.37	< 0.1	No
							Atlantic	1.3	0.2	No
					Pea, dry	1 × 246.25 g a.i./ha	BC	0.083	< 0.1	No
							QC	1.1	0.17	No
							Atlantic	0.36	< 0.1	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
					Potato	1 × 280 g a.i./ha	BC	0	0	No
							QC	0.033	< 0.1	No
							Atlantic	0.078	< 0.1	No
					Soybean[4]	1 × 157.5 g a.i./ha	BC	1.2	0.2	No
							QC	1.3	0.2	No
							Atlantic	3.0	0.5	No
					Wheat, spring	1 × 52.47 g a.i./ha	BC	0.43	< 0.1	No
							QC	0.30	< 0.1	No
							Atlantic	0.91	0.1	No
					Chickpea	1 × 96.88 g a.i./ha	Not grown in BC, QC or Atlantic Region			
					Faba bean	1 × 232.5 g a.i./ha	Not grown in BC			
							QC	0.017	< 0.1	No
							Atlantic	1.3	0.2	No
	Chronic	Marine mysid (*Mysidopsis bahia*)	28-d NOEC growth = 0.33	Foliar	Blueberry	3 × 42 g a.i./ha at 5-d intervals	BC	0.29	0.9	No
							QC	1.8	**5.5**	**Yes**
							Atlantic	3.0	**9.1**	**Yes**
						2 × 42 g a.i./ha at a 5-d interval	BC	0.23	0.7	No
							QC	1.2	**3.6**	**Yes**
							Atlantic	2.1	**6.4**	**Yes**
						1 × 42 g a.i./ha	BC	0.14	0.4	No
							QC	0.64	**1.9**	**Yes**
							Atlantic	1.3	**3.9**	**Yes**
					Raspberry	3 × 112 g a.i./ha at 7-d intervals	BC	0.77	**2.3**	**Yes**
							QC	4.8	**15**	**Yes**
							Atlantic	4.2	**13**	**Yes**
						2 × 112 g a.i./ha at a 7-d interval	BC	0.62	**1.9**	**Yes**
							QC	3.4	**10**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
							Atlantic	3.6	**11**	**Yes**
						1 × 112 g a.i./ha	BC	0.37	**1.1**	**Yes**
							QC	1.8	**5.5**	**Yes**
							Atlantic	1.9	**5.8**	**Yes**
					Grape	2 × 48 g a.i./ha at a 14-d interval	BC	0.038	0.1	No
							QC	0.37	**1.1**	**Yes**
							Atlantic	0.57	**1.7**	**Yes**
						1 × 48 g a.i./ha	BC	0.018	< 0.1	No
							QC	0.21	0.6	No
							Atlantic	0.34	**1.0**	**Yes**
					Tomato	3 × 49 g a.i./ha at 5-d intervals	BC	0.37	**1.1**	**Yes**
							QC	2.2	**6.7**	**Yes**
							Atlantic	3.1	**9.4**	**Yes**
						2 × 49 g a.i./ha at a 5-d interval	BC	0.26	**0.8**	**Yes**
							QC	1.5	**4.6**	**Yes**
							Atlantic	2.3	**7.0**	**Yes**
						1× 49 g a.i./ha	BC	0.16	0.5	No
							QC	0.75	**2.3**	**Yes**
							Atlantic	1.2	**3.6**	**Yes**
					Soybean	3 × 24.4 g a.i./ha at 5-d intervals	BC	0.097	0.3	No
							QC	0.92	**2.8**	**Yes**
							Atlantic	1.4	**4.2**	**Yes**
						3 × 49.9 g a.i./ha at 5-d intervals	BC	0.20	0.6	No
							QC	1.9	**5.8**	**Yes**
							Atlantic	2.8	**8.5**	**Yes**
					Potato	3 × 49 g a.i./ha at 5-d intervals	BC	0.17	0.5	No
							QC	1.5	**4.6**	**Yes**
							Atlantic	3.1	**9.4**	**Yes**
						2 × 49 g a.i./ha	BC	0.12	0.4	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
						at a 5-d interval	QC	1.2	**3.6**	**Yes**
							Atlantic	2.3	**7.0**	**Yes**
						1 × 49 g a.i./ha	BC	0.063	0.2	No
							QC	0.65	**2.0**	**Yes**
							Atlantic	1.2	**3.6**	**Yes**
					Turf	1 × 281 g a.i./ha	BC-Okanagan	0.17	0.5	No
							BC-Vancouver	2.4	**7.3**	**Yes**
							QC	1.7	**5.2**	**Yes**
							Atlantic-NS	1.5	**4.6**	**Yes**
							Atlantic-PEI	2.0	**6.1**	**Yes**
				Soil: drench	Grape[4]	1 × 100 g a.i./ha	BC	0.003	< 0.1	No
							QC	0.013	< 0.1	No
							Atlantic	0.017	< 0.1	No
						1 × 480 g a.i./ha	BC	0.012	< 0.1	No
							QC	0.063	0.2	No
							Atlantic	0.080	0.2	No
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.11	0.3	No
							QC	0.94	**2.9**	**Yes**
							Atlantic	1.4	**4.2**	**Yes**
						1 × 520 g a.i./ha	BC	0.68	**2.1**	**Yes**
							QC	5.6	**17**	**Yes**
							Atlantic	8.1	**25**	**Yes**
				Soil: In-furrow[4]	Potato	1 × 100 g a.i./ha	BC	0.012	< 0.1	No
							QC	0.26	0.8	No
							Atlantic	0.55	**1.7**	**Yes**
						1 × 480 g a.i./ha	BC	0.058	0.2	No
							QC	1.2	**3.6**	**Yes**
							Atlantic	2.6	**7.9**	**Yes**
					Other	1 × 100 g a.i./ha	BC	0.073	0.2	No

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
					root/tuber vegetables		QC	0.39	**1.2**	**Yes**
							Atlantic	0.84	**2.6**	**Yes**
						1 × 480 g a.i./ha	BC	0.35	**1.1**	**Yes**
							QC	1.9	**5.8**	**Yes**
							Atlantic	4.0	**12**	**Yes**
					Brassica vegetables	1 × 86.6 g a.i./ha	BC	0.076	0.2	No
							QC	0.68	**2.1**	**Yes**
							Atlantic	0.96	**2.9**	**Yes**
						1 × 520 g a.i./ha	BC	0.45	**1.4**	**Yes**
							QC	4.1	**12**	**Yes**
							Atlantic	5.8	**18**	**Yes**
				Seed treatment	Barley	1 × 36.33 g a.i./ha	BC	0.008	< 0.1	No
							QC	0.17	0.5	No
							Atlantic	0.27	0.8	No
					Canola	1 × 64.16g a.i./ha	BC	0.18	0.6	No
							QC	5.8	**18**	**Yes**
							Atlantic	0.63	**1.9**	**Yes**
					Field corn[4]	1 × 56.8 g a.i./ha	BC	0.14	0.4	No
							QC	0.21	0.6	No
							Atlantic	0.70	**2.1**	**Yes**
					Pea, dry	1 × 246.25 g a.i./ha	BC	0.037	0.1	No
							QC	0.86	**2.6**	**Yes**
							Atlantic	0.20	0.6	No
					Potato	1 × 280 g a.i./ha	BC	0	0	No
							QC	0.017	< 0.1	No
							Atlantic	0.061	0.2	No
					Soybean[4]	1 × 157.5 g a.i./ha	BC	0.23	0.7	No
							QC	0.18	0.6	No
							Atlantic	0.41	**1.2**	**Yes**

Organism	Exposure	Representative species	Effects metric (µg a.i./L)	Use scenario	Crop	Use rate[2]	Region	EEC[3] (µg a.i./L)	RQ	LOC exceeded
					Wheat, spring	1 × 52.47 g a.i./ha	BC	0.22	0.7	No
							QC	0.24	0.7	No
							Atlantic	0.61	**1.8**	**Yes**
					Chickpea	1 × 96.88 g a.i./ha	Not grown in BC, QC or Atlantic Region			
					Faba bean	1 × 232.5 g a.i./ha	Not grown in BC			
							QC	0.009	< 0.1	No
							Atlantic	0.71	**2.2**	**Yes**

[1] 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 endpoints (acute exposures).
[2] Use rate represents the maximum number of applications and rate (g a.i./ha) for a crop.
[3] EECs based on an 80 cm water depth. For comparison against acute invertebrate effects metrics based on data with 48 – 96-h, 24-hour EECs were used to derive RQs. For comparison against chronic invertebrate effects metrics based on data with 28-d TWA mesocosm NOEC, 21-day EECs were used to derive RQs. EECs for seed treatments were adjusted for 20% removal by uptake from plants.
[4] EECs for in-furrow uses, soil drench application for grapes (hill drench) and corn and soybean seed treatments are those from modelling using the "increasing with depth" scenario.
Bolded values indicate an exceedance of the level of concern (RQ = 1).

Appendix VIII Species sensitivity distribution (SSD)

1.1 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 2.2 is used to generate SSDs, which was developed by RIVM (Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands).

1.2 SSD Toxicity data analysis for imidacloprid

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 SSDs. 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.

1.3 Results of SSD analysis for imidacloprid insecticide

For PRVD2016-20, 32 acute and 10 chronic endpoints were available for aquatic invertebrate species. The resulting HC_5 values were 0.36 µg a.i./L for acute and 0.041 µg a.i./L for chronic.

The SSDs for aquatic invertebrates were revised based on comments received during the consultation period, new data published since the completion of the initial aquatic invertebrate risk assessment, as well as data that were not captured during the initial risk assessment.

Updates to the acute SSD include:

- Addition of the wavy-rayed lampmussel (*Lampsilis fasciola*) glochidia 48-h LC_{50} of > 688 µg a.i./L (Prosser et al. 2016; PMRA# 2712688).
- Addition of the *Chironomus dilutus* 96-h LC_{50} of 4.63 µg a.i./L (Maloney et al., 2017; PMRA# 2818524).
- Addition of the *Chironomus dilutus* 96-h immobilization EC_{50} of 2.5 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Lumbriculus variegates* 96-h immobilization EC_{50} of 32.4 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Hyalella azteca* 96-h immobilization EC_{50} of 177 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Caecidotea* sp. 96-h immobilization EC_{50} of 321 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Cheumatopsyche* sp. 96-h immobilization EC_{50} of 176 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Stenelmis* sp. 96-h immobilization EC_{50} of 99.2 µg a.i./L (Raby et al. 2018; PMRA# 2842540).

- Addition of the *Trichocorixa* sp. 48-h immobilization EC_{50} of 63 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Gyrinus* sp. 96-h immobilization EC_{50} of 58 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Cloeon* sp. 96-h immobilization EC_{50} of 23 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Ephemerella* sp. 96-h immobilization LC_{50} of 10.6 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *McCaffertium* sp.96-h immobilization LC_{50} of 10.6 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Neocloeon triangulifer* 96-h EC_{50} of 3.1 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Isonychia bicolor* 96-h immobilization EC_{50} of 60.4 µg a.i./L (Raby et al. 2018; PMRA# 2842540).
- Addition of the *Isonychia bicolor* 96-h immobilization EC_{50} of 5.8 µg a.i./L (Camp and Buchwalter, 2016; PMRA# 2796398).
- Addition of the *Culex quinquefasciatus* 72-h LC_{50} of 20 µg a.i./L (Uragayla et al. 2015; PMRA# 2841146).
- Addition of the *Anopheles stephensi* 72-h LC_{50}s of 49 and 66 µg a.i./L for SS strain - Nadiad and RR strain – Goa, respectively (Uragayla et al. 2015; PMRA# 2841146),
- Addition of the *Aedes aegypti* the 72-h LC_{50} of 210 µg a.i./L (Uragayla et al. 2015; PMRA# 2841146).
- Addition of the *Hexagenia* spp. 96-h EC_{50} of 10 µg a.i./L (Based on number of surviving animals inside artificial burrows, which was considered representative of mobility impairment; ECCC 2017, PMRA# 2753706).
- Addition of the *Cheumatopsyche brevilineata* 48-h EC_{50} of 4.22 µg a.i./L (Yokoyama et al. 2009; PMRA# 2722291).
- Addition of the *Daphnia magna* 48-h LC_{50} of 97000 µg a.i./L (Loureiro et al. 2010; PMRA# 2945939).
- Addition of the *Daphnia magna* 48-h EC_{50} of 998 µg a.i./L (Li et al. 2013; PMRA# 2712665).
- Addition of the *Gammarus pulex* 96-h immobilization EC_{50} of 49 µg a.i./L (fall; Van den Brink et al. 2016; PMRA# 2712707), and associated removal of the spring endpoint from Roessink et al. (2013, PMRA# 2544385; 96-h immobilization EC_{50} of 18.3 µg a.i./L) due to unacceptably high control mortality (33%; these studies followed the same procedure and were conducted by the same laboratory).
- Addition of the *Asellus aquaticus* fall 96-h immobilization EC_{50} of 78 µg a.i./L (Van den Brink et al. 2016; PMRA# 2712707), and the associated removal of the less sensitive spring endpoint from Roessink et al. (2013; PMRA# 2544385; 96-h immobilization EC_{50} of 119 µg a.i./L; these studies followed the same procedure and were conducted by the same laboratory).
- Addition of the *Chydorus sphaericus* dark 48-h immobilization EC_{50} of 832 µg a.i./L (this value was geomeaned with the 16-h:8-h light:dark 48-h immobilization EC_{50} of 2210 µg a.i./L; Sánchez-Bayo and Goka 2006; PMRA# 2541831).

- Addition of the *Cypretta seuratti* dark 48-h immobilization EC_{50} of 1 µg a.i./L (this value was geomeaned with the 16-h:8-h light:dark 48-h immobilization EC_{50} of 16 µg a.i./L; Sánchez-Bayo and Goka 2006; PMRA# 2541831).
- Addition of the *Cypridopsis vidua* dark 48-h immobilization EC_{50} of 3 µg a.i./L (this value was the same as the16-h:8-h light:dark 48-h immobilization EC_{50}, such that the SSD input remained the same; Sánchez-Bayo and Goka 2006; PMRA# 2541831).
- Addition of the *Hyalella azteca* 96-h immobilization EC_{50} of 55 µg a.i./L (this value replaced the 96-h LC_{50} of 526 µg a.i./L from the same study (Unpublished report, 1991; PMRA# 1155859).
- Removal of the midge 48-h LC_{50} of 69 µg a.i./L that was reported from EFED (2008; PMRA# 2332665). It was determined that this value originated from Gagliano (1991; PMRA# 1155863). The species was determined to be *Chironomus dilutus* (formerly *tentans*). The original study reports a 96-h LC_{50} of 10.5 µg a.i./L. This value was included in the geomean of acute endpoints for *C. dilutus* that was used in the acute SSD instead of the less sensitive 48-h endpoint.
- Removal of the *Caenis horaria* 72-h EC_{50} of 17 µg a.i./L (Wijngaarden and Roessink 2013 as reported in EFSA 2014; PMRA# 2545413) in favour of the more sensitive spring/summer endpoint reported by Roessink et al. (2013, PMRA# 2544385; 96-h immobilization EC_{50} of 1.77 µg a.i./L).
- Removal of the *Cloeon dipterum* 96-h immobilization EC_{50} of 12 µg a.i./L(Wijngaarden and Roessink 2013 as reported in EFSA 2014; PMRA# 2545413) in favour of the more sensitive spring/summer endpoint reported by Roessink et al. (2013, PMRA# 2544385; 96-h immobilization EC_{50} of 1.02 µg a.i./L).

In PRVD2016-20, EC_{50} values were used in the chronic SSD. This was because most of these studies were shown to be chronic exposures, while most of the NOEC values were found to be of an unacceptable exposure duration or type (i.e., pulsed exposures) or were not a standard laboratory study. Based on the availability of additional chronic exposure data (i.e., from newly published studies or studies not captured for the initial assessment), a sufficient number of “no effect” level values (for example, NOEC, EC_{10}) from reliable studies of acceptable exposure duration were available for SSD analysis.

Updates to the chronic SSD include:

- Addition of the *Daphnia magna* 21-d reproduction (number of neonates per adult) EC_{10} of 2690 µg a.i./L from Raby et al. (2018; PMRA# 2912491).
- Addition of the *Daphnia magna* 21-d growth NOEC of 1800 µg a.i./L from an unpublished study (1990; PMRA# 1155875).
- Addition of the *Daphnia magna* 21-d reproductive (meonates/adult) NOEC of 1250 µg a.i./L from Jemec et al. (2007; PMRA# 2541824).
- Addition of the *Daphnia magna* 21-d growth and reproduction NOEC of 2000 µg a.i./L from Ieromina et al. (2014; PMRA# 2541828).
- Addition of the *Ceriodaphnia dubia* 7-d reproduction (number of neonantes per adult) EC_{10} of 1360 µg a.i./L from Raby et al. (2018; PMRA# 2912491).
- Addition of the *Chironomus dilutus* 28-d EC_{20} of 0.14 µg a.i./L from Maloney et al. (2018; PMRA# 28723503).

- Addition of the *Chironomus dilutus* 40-d emergence EC_{20} of 0.06 µg a.i./L from Cavallaro et al. (PMRA# 2712678).
- Addition of the *Chironomus dilutus* 56-d EC_{10} of 0.15 µg a.i./L from Raby et al. (2018; PMRA# 2912490; data re-analysed by Health Canada).
- Addition of the *Chironomus dilutus* 28-d survival and dryweight NOEC of 1.14 µg a.i./L from Stoughton et al. (2008; PMRA# 2541839), and the associated removal of the 28-d LC_{50} of 0.91 µg a.i./L from the same study.
- Addition of the *Hyalella azteca* 28-d growth (wet weight) EC_{10} of 0.69 µg a.i./L from Bartlett et al. (2019; PMRA# 2975959).
- Addition of the *Chironomus riparius* 28-d emergence NOEC of 0.96 µg a.i./L from Brun 2010 (PMRA# 2693971).
- Addition of the *Chironomus riparius* 28-d emergence NOEC of 0.66 µg a.i./L from Brun 2009 (PMRA# 2693972).
- Addition of the *Planorbella pilsbryi* 28-d LC_{10} of 45.7 µg a.i./L from Prosser et al. (2016; PMRA# 2712688).
- Addition of the *Neocloeon triangulifer* 32-d emergence EC_{10} of 1.12 µg a.i./L from Raby et al. (2018; PMRA# 2912490; data re-analysed by Health Canada).
- Addition of the *Asellus aquaticus* 28-d immobilization EC_{10} of 1.71 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 12 µg a.i./L from the same study.
- Addition of the *Caenis horaria* 28-d immobilization EC_{10} of 0.033 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 0.13 µg a.i./L from the same study.
- Addition of the *Chaoborus obscuripes* 28-d immobilization EC_{10} of 4.57 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 12 µg a.i./L from the same study.
- Addition of the *Cloeon dipterum* 28-d immobilization EC_{10} of 0.024 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 0.12 µg a.i./L from the same study.
- Addition of the *Sialis lutaria* 28-d immobilization EC_{10} of 1.28 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 3.5 µg a.i./L from the same study.
- Addition of the *Plea minutissima* 28-d immobilization EC_{10} of 2.03 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC50 of 6.5 µg a.i./L from the same study.
- Addition of the *Hyalella azteca* 28-d dry weight NOEC of 11.5 µg a.i./L from Stoughton et al. (2008; PMRA# 2541839), and the associated removal of the 28-d LC_{50} of 7.08 µg a.i./L from the same study.
- Addition of the *Gammarus pulex* 28-d immobilization EC_{10} of 2.95 µg a.i./L from Roessink et al. (2013; PMRA# 2544385), and the associated removal of the 28-d immobilization EC_{50} of 15 µg a.i./L from the same study.
- Addition of the *Daphnia magna* 21-d reproduction (cumulative offspring/live daphnia) NOEC of 2000 µg a.i./L from Pavalaki et al. (2011; PMRA# 2541825), and the associated removal of the 21-d EC_{50} of 5500 µg a.i./L from the same study.
- Removal of the *Chironomus riparius* 28-d emergence EC_{50} of 3.6 µg a.i./L from EFSA (2008; PMRA# 2332663).

- Removal of the *Chironomus riparius* 28-d emergence EC_{50} of 3.11 µg a.i./L from an unpublished study (2001; PMRA# 2523501).

A summary of the revised SSD results is shown in Table 1. A list of the endpoint values (and the study references) used in the SSD analysis are provided in Tables 2 and 3. The updated freshwater invertebrates acute SSD includes 48 species and the chronic SSD includes 14 species. The acute HC_5 for freshwater invertebrates is 0.54 µg a.i./L. The chronic HC_5 for freshwater invertebrates is 0.0113 µg a.i./L.

Table 1 Summary of Species Sensitivity Distribution (SSD) analysis for acute and chronic effects of imidacloprid on freshwater invertebrates

Exposure	Test material	Endpoint type	Freshwater invertebrates (µg a.i./L)
Acute	TGAI or EPs, expressed as a.i./L	EC_{50}/LC_{50}	HC_5: 0.54 Species count: 48 LLHC5: 0.180 ULHC5: 1.27 LLFA: 2.18 ULFA: 8.12
Chronic		NOEC/EC_{10}	HC_5: 0.0113 Species count: 14 $LLHC_5$: 5.2E-4 $ULHC_5$: 7.7E-2 LLFA: 0.92 ULFA: 16.63

TGAI = technical grade active ingredient; EP = end-use product; HC_5 = Hazardous concentration (or dose) to 5% of species; $LLHC_5$ = lower level HC_5; $ULHC_5$ = upper level HC_5; LLFA = lower level fraction affected; ULFA = upper level fraction affected

Table 2 Toxicity data used in the Species Sensitivity Distribution (SSD) for acute effects of imidacloprid on freshwater invertebrates

Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	References
Moina macrocopa	45300.0		Hayasaka et al., 2012 (PMRA# 2541822)
Daphnia pulex	36900.0		Hayasaka et al., 2012 (PMRA# 2541822)
Daphnia magna	35811.5	Geomean of 13 endpoint values	USDA 2005 (PMRA# 2334762), Hayasaka et al., 2012 (PMRA# 2541822), Young and Hicks 1990 (PMRA# 1155861), PMRA# 1504639, Pestana et al. 2010 (PMRA# 2541671), Kungolos et al. 2009 (PMRA# 2544388), Tisler et al. 2009 (PMRA# 2541823), Daam et al. 2013 (PMRA# 2544387), Sánchez-Bayo and Goka, 2006 (PMRA# 2541831), Loureiro et al. 2010 (PMRA# 2945939), Li et al. 2013 (PMRA# 2712665)
Ceriodaphnia reticulata	5550.0		Hayasaka et al., 2012 (PMRA# 2541822)

Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	References
Chydorus sphaericus	1356.0	Geomean of 2 endpoint values	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)
Wavy-rayed lampmussel, *Lampsilis fasciola* glochidia	>688.0	Uncensored value	Prosser et al., 2016 (PMRA# 2712688)
Caecidotea sp.	321.0		Raby et al., 2018 (PMRA# 2842540)
Midge larvae, *Chaoborus obscuripes*	284.0		Van den Brink et al. 2016 (PMRA# 2712707), EFSA 2014 (PMRA# 2545413), Roessink et al. 2013 (PMRA# 2544385)
Cheumatopsyche sp.	176.4		Raby et al., 2018 (PMRA# 2842540)
Damselfly, Coenagrionidae (Zygoptera)	150.0		van Wijngaarden and Roessink. 2013 as reported in EFSA 2014 (PMRA# 2545413)
Amphipod, *Gammarus pulex*	119.8	Geomean of 3 endpoint values	Ashauer et al. 2011 (PMRA# 2541673), EFSA 2014 (PMRA# 2541453), Beketov and Liess 2008 (PMRA# 2544548), Van den Brink et al. 2016 (PMRA# 2712707)
Coleoptera, *Stenelmis* sp.	99.2		Raby et al., 2018 (PMRA# 2842540)
Mosquito larvae, *Aedes aegypti*	96.1	Geomean of 2 endpoint values	Song et al. 1997 (PMRA# 2541668), Uragayla et al., 2015 (PMRA# 2841146)
Isopod, *Asellus aquaticus*	78.0		Van den Brink et al. 2016 (PMRA# 2712707)
Diptera, An. stephensi (RR strain – Goa)	66.0		Uragayla et al., 2015 (PMRA# 2841146)
Hemiptera, *Trichocorixa* sp.	63.1		Raby et al., 2018 (PMRA# 2842540)
Amphipod, *Hyalella azteca*	57.6	Geomean of 4 endpoint values	Stoughton et al. 2008 (PMRA# 2541839), USEPA 2016 (PMRA# 3076605), Raby et al., 2018 (PMRA# 2842540)
Coleoptera *Gyrinus* sp.	57.5		Raby et al., 2018 (PMRA# 2842540)
Alderfly larvae - *Sialis lutaria*	50.6		EFSA 2014 (PMRA# 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Diptera, *Anopheles stephensi,* (SS strain – Nadiad)	49.0		Uragayla et al., 2015 (PMRA# 2841146)
Caddisfly larvae, *Seristocoma vittatum*	41.1	Geomean of 2 endpoint values	Pestana et al. 2009b (PMRA# 2544390)
Pygmy backswimmer larvae, *Plea minutissima*	35.9		EFSA 2014 (PMRA 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Ceriodaphnia dubia	34.4	Geomean of 2 endpoint values	Hayasaka et al. 2012, PMRA# 2541822, Chen et al. 2010 (PMRA# 2541670)
Ephemeroptera, *Cloeon* sp.	23.1		Raby et al., 2018 (PMRA# 2842540)

Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	References
Diptera, *Culex quinquefasciatus*	20.0		Uragayla et al., 2015 (PMRA# 2841146)
Mayfly, *Isonychia bicolor*	18.7	Geomean of 2 endpoint values	Camp and Buchwalter 2016 (PMRA# 2796398), Raby et al., 2018 (PMRA# 2842540)
Backswimmer, *Notonecta* spp.	18.2		EFSA 2014 (PMRA# 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Midge larvae, *Chironomus riparius*	15.4	Geomean of 3 endpoint values	Azevedo-Pereira et al. 2011a (PMRA# 2541835), Pestana et al. 2009b (PMRA# 2544390)
Amphipod, *Gammarus roeseli*	14.2		EFSA 2014 (PMRA# 2541453) - Böttger et al. 2012 (PMRA# 2541837)
Oligochaete, *Lumbriculus variegatus*	14.2	Geomean of 2 endpoint values	EFSA 2014 (PMRA# 2545413) - Alexander et al. 2007 (PMRA# 2541832), Raby et al., 2018 (PMRA# 2842540)
Water boatman, *Micronecta* spp.	10.8		EFSA 2014 (PMRA# 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Ephemeroptera, *Ephemerella* sp.	10.6		Raby et al., 2018 (PMRA# 2842540)
Ephemeroptera, *McCaffertium* sp.	10.6		Raby et al., 2018 (PMRA# 2842540)
Hexagenia spp.	10.0		Environment and Climate Change Canada 2017 (PMRA# 2753706)
Mayfly larvae, *Baetis rhodani*	8.49		EFSA 2014 (PMRA# 2541453) - Beketov and Liess 2008 (PMRA# 2544548)
Black fly larvae, *Similium vittatum*	8.18		EFSA 2014 (PMRA# 2545413) - Overmyer et al. 2005 (PMRA# 2541830)
Micrasema sp.	<6.4		Raby et al., 2018 (PMRA# 2842540)
Cypridopsis vidua	5.48	Geomean of 2 endpoint values	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)
Midge larvae, *Chironomus dilutus*	4.64	Geomean of 6 endpoint values	USDA 2005 (PMRA# 2334762) – USEPA 2016 (PMRA# 3076605), Leblanc et al. 2012 (PMRA# 2544384), EFSA 2014 (PMRA# 2545413) - Stoughton et al. 2008 (PMRA# 2541839), Raby et al., 2018 (PMRA# 2842540), Maloney et al., 2017 (PMRA# 2818524)
Caddisfly larvae, *Cheumatopsyche brevilineata*	4.22		Yokoyama et al. 2009 (PMRA# 2722291)
Cypretta seuratti	4.00	Geomean of 2 endpoint values	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)

Species name	EC_{50}/LC_{50} (µg a.i./L)	Notes	References
Blackfly larvae, *Simulium latigonium*	3.73		EFSA 2014 (PMRA# 2541453) – Beketov and Liess 2008, (PMRA# 2544548)
Ephemeroptera, *Neocloeon triangulifer*	3.10		Raby et al., 2018 (PMRA# 2842540)
Ilyocypris dentifera	3.00	Geomean of 2 endpoint values	Sánchez-Bayo and Goka, 2006 (PMRA# 2541831)
Caddisfly larvae, Limnephilidae	1.79		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Mayfly larvae, *Caenis horaria*	1.77		Van den Brink et al. 2016 (PMRA# 2712707) - EFSA 2014 (PMRA# 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Mayfly larvae, *Cloeon dipterum*	1.02		Van den Brink et al. 2016 (PMRA# 2712707) - EFSA 2014 (PMRA# 2545413) - Roessink et al. 2013 (PMRA# 2544385)
Mayfly larvae, *Epeorus longinanus Eaton*	0.65		EFSA 2014 (PMRA# 2545413) – Alexander et al. 2007 (PMRA# 2541832)

Table 3 Toxicity data used in the Species Sensitivity Distribution (SSD) for chronic effects of imidacloprid on freshwater invertebrates

Species name	$NOEC/EC_{10}$ (µg a.i./L)	Notes	References endpoints cited
Daphnia magna	1891	Geomean of 5 endpoint values	EFED 2008 (PMRA# 2332665) – Young and Blackmore 1990 (PMRA# 1155875), Pavlaki et al. 2011 (PMRA# 2541825), Jemec et al. 2007 (PMRA# 2541824), Ieromina et al. 2014, (PMRA# 2541828), Raby et al. 2018 (PMRA# 2912491)
Ceriodaphnia dubia	1360		Raby et al. 2018 (PMRA# 2912491)
ramshorn snail, *Planorbella pilsbryi*	45.7		Prosser et al., 2016 (PMRA# 2712688)
Midge larvae, *Chaoborus obscribes*	4.57		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Amphipod, *Gammarus pulex*	2.95		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Amphipod, *Hyalella azteca*	2.82	Geomean of 2 endpoint value	Environment and Climate Change Canada 2017 (PMRA# 2753706), Stoughton et al. 2008 (PMRA# 2541839)
Pygmy backswimmer larvae, *Plea minutissima*	2.03		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)

Species name	NOEC/EC10 (µg a.i./L)	Notes	References endpoints cited
Isopod, *Asellus aquaticus*	1.71		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Alderfly larvae, *Sialis lutaria*	1.28		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Mayfly larvae, *N. triangulifer*	1.12		Raby et al. 2018 (PMRA# 2912490)
Midge larvae, *Chironomus riparius*	0.796	Geomean of 2 endpoint values	Brun 2009 (PMRA# 2693972), Brun 2010 (PMRA# 2693971)
Midge larvae, *Chironomus dilutus*	0.195	Geomean of 4 endpoint values. Includes an estimated EC_{20} value from Cavallaro et al., 2017 and Maloney et al., 2018.	Raby et al. 2018 (PMRA# 2912490), EFSA 2014 (PMRA# 2545413) – Stoughton et al. 2008 (PMRA# 2541839), Cavallaro et al. 2017 (PMRA# 2712687) and Maloney et al. 2018 (PMRA# 2873503)
Mayfly larvae, *Caenis horaria*	0.033		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)
Mayfly larvae, *Cloeon dipterum*	0.024		EFSA 2014 (PMRA# 2545413) – Roessink et al. 2013 (PMRA# 2544385)

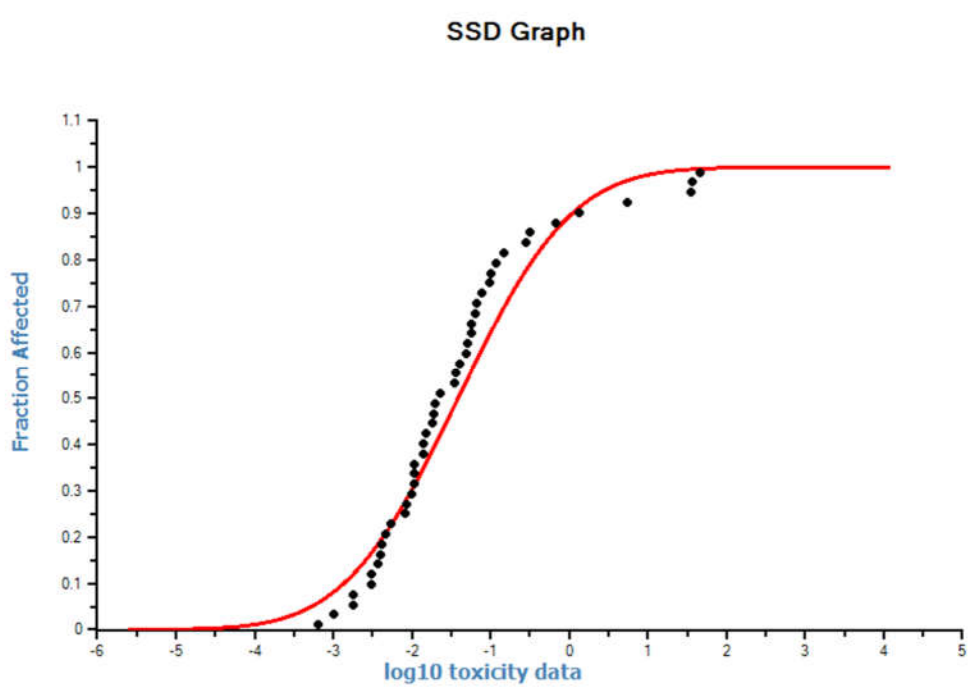


Figure 1 Species Sensitivity Distribution for acute toxicity of imidacloprid insecticide to freshwater invertebrates

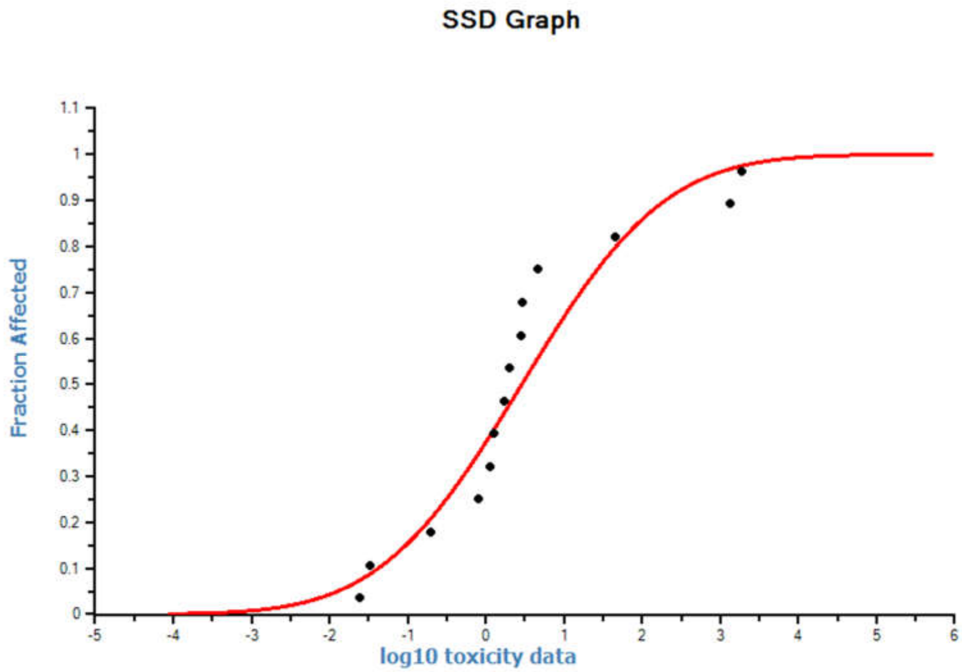


Figure 2 Species Sensitivity Distribution for chronic toxicity of imidacloprid insecticide to freshwater invertebrates

1.4 Comments on data used in 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 the taxonomic sub-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 24-hour modelled EEC (i.e., excluding > 96-h endpoints) as well as to account for latent effects of imidacloprid on aquatic invertebrates (i.e., excluding < 48-h endpoints).
- Toxicity data having no effects at the highest test concentration were excluded (for example, EC_{50} > X) if there were other results to represent the species or similar taxa (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).
- All toxicity values were based on studies with the TGAI or an EP, and concentration units being µg a.i./L.
- For freshwater acute invertebrate data, EC_{50} values were used in the SSD when they were available, otherwise LC_{50} values were used.
- For freshwater chronic invertebrate data, chronic toxicity endpoints were represented by NOEC and EC_{10} values which represent a “no effect” level as well as an EC_{20} value, used as a surrogate for a NOEC.

Appendix IX Summary of revised ecoscenario water modelling

For the revised risk assessment for aquatic invertebrates, the EECs of imidacloprid from runoff into a receiving waterbody were simulated using the Pesticide in Water Calculator (PWC, version 1.5.2). The PWC model simulates pesticide runoff from a treated field into an adjacent body of water and the fate of a pesticide within it. Spray drift is not considered for this modelling. The waterbody used in the modelling is a 1-ha wetland with an average depth of 0.8 m and a drainage area of 10 ha.

Various initial application dates were modelled, depending on the use patterns and application windows, with several representative scenarios to cover all use patterns listed in Table 1. For seed treatments where a range of seeding depths was available, the shallowest was selected for the modelling. Models were run for 50 years for all scenarios.

For each year of the simulation, PWC reports peak (or daily maximum), and time-averaged concentrations calculated by averaging the peak concentrations over different time periods (24-hour, 96-hour, 21-day, 60-day and 90-day). The 90th percentiles over each averaging period are reported as the EECs for that period. The EECs were generated for all selected crops using runoff extraction parameters recommended in Young and Fry (2017). These parameters include a runoff interaction fraction of 0.19, a maximum runoff interaction depth of 8 cm and an exponential decline coefficient of 1.4 cm^{-1}.

Specifically for seed treatments, PWC allows for different modelling approaches to determine pesticide concentrations in water. For the revised modelling, two of these scenarios were selected: “at depth” and “increasing with depth”. The “at depth” scenario assumes that, at the time of application, the pesticide is present in soil only at the depth the seed is planted. This scenario was used for all the seed treatments selected for modelling. The “increasing with depth” scenario assumes that the pesticide concentration in soil at the time of application linearly increases with depth form the soil surface to the seeding depth. This scenario was used for corn and soybeans, as these are larger seeds which are typically sown using pneumatic equipment. With this type of seeding method, as the seed penetrates the soil, there is deposition of seeding dust close to the surface and up to the final depth of the seed.

For applications on soil, while most use patterns were modelled using default soil distribution parameters, for “hill drench in sufficient water to ensure in incorporation into the root-zone following irrigation” use on grapes, the distribution of the pesticide within the soil profile at the time of application was assumed to be linearly increasing with depth, up to a depth of 10 cm.

Table 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	Barley	1 × 36.33 g a.i./ha	Seed treatment	2	April 10–June 30
	Canola	1 × 64.16 g a.i./ha	Seed treatment	1.25	April 20–June 30
	Corn	1 × 56.8 g a.i./ha	Seed treatment[1]	3	May 1–May 31
	Pea (dry)	1 × 246.25 g a.i./ha	Seed treatment	2	April 1–June 20
	Wheat	1 × 52.47 g a.i./ha	Seed treatment	1.25	April 20–June 21
	Potato	1 × 280 g a.i./ha	Seed piece treatment	7.9	February 15–June 15

Region	Crop	Use pattern	Application method	Seed depth (cm)	Timing of application
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	5–10	February 11–June 20
		1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground foliar	NA	May 1–August 30
	Soybean	1 × 157.5 g a.i./ha	Seed treatment[1]		
		3 × 24.4 g a.i./ha, 3 × 49.9 g a.i./ha	Ground foliar	NA	July 1–September 20
	Root and tuber vegetables other than potato	1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	4	February 11–June 20
	Brassica vegetables	1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	In-furrow[1]	2	May 11–August 20
		1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	Soil drench	4	May 11–August 20
	Blueberry	1 × 42 g a.i./ha, 2 × 42 g a.i./ha, 3 × 42 g a.i./ha	Ground foliar	NA	May 1–September 10
	Raspberry	1 × 112 g a.i./ha, 2 × 112 g a.i./ha, 3 × 112 g a.i./ha	Ground foliar	NA	May 1–September 10
	Grape	1 × 48 g a.i./ha, 2 × 48 g a.i./ha	Ground foliar	NA	June 11–August 20
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (hill drench and irrigation)[1]	10 (assumed)	April 1–July 31
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (subsurface side-dress shanked into the root-zone followed by irrigation)[2]	10 (assumed)	April 1–July 31
	Tomato	1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground foliar	NA	May 11–September 30
	Turf	1 × 281 g a.i./ha	Ground foliar	NA	May 21–October 20
Prairie	Barley	1 × 36.33 g a.i./ha	Seed treatment	2	April 2–June 20
	Canola	1 × 64.16 g a.i./ha	Seed treatment	2	April 17–June 23
	Corn	1 × 56.8 g a.i./ha	Seed treatment[1]	3	April 20–May 31
	Pea (dry)	1 × 246.25 g a.i./ha	Seed treatment	2.54	April 10–May15
	Wheat	1 × 52.47 g a.i./ha	Seed treatment	2.05	April 15–July 20
	Chickpea	1 × 96.88 g a.i./ha	Seed treatment	3.5	April 15–May 25
	Faba bean	1 × 232.5 g a.i./ha	Seed treatment	3.8	April 10–May 31
	Potato	1 × 280 g a.i./ha	Seed piece treatment	7	April 20–June 1
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	5–10	April 11–May 31
		1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground and aerial foliar	NA	May 1–September 10
	Soybean	1 × 157.5 g a.i./ha	Seed treatment[1]	1.9	May 15–June 1
		3 × 24.4 g a.i./ha, 3 × 49.9 g a.i./ha	Ground foliar	NA	July 1–September 10
	Root and tuber vegetables other than potato	1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	4	April 11–May 31
	Brassica vegetables	1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	In-furrow[1]	2	May 11–July 31
		1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	Soil drench	4	May 11–July 31
	Tomato	1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground foliar	NA	May 21–September 30

Region	Crop	Use pattern	Application method	Seed depth (cm)	Timing of application
	Turf	1 × 281 g a.i./ha	Ground foliar	NA	April 20–October 20
ON/QC	Barley	1 × 36.33 g a.i./ha	Seed treatment	2.5	March 3–June 1
	Canola	1 × 64.16 g a.i./ha	Seed treatment	0	April 1–June 10
	Corn	1 × 56.8 g a.i./ha	Seed treatment[1]	3.8	April 14–June 15
	Pea (dry)	1 × 246.25 g a.i./ha	Seed treatment	2.5	April 1–August 1
	Wheat	1 × 52.47 g a.i./ha	Seed treatment	2.5	March 1–June 6
	Faba bean	1 × 232.5 g a.i./ha	Seed treatment	5	May 1–June 10
	Potato	1 × 280 g a.i./ha	Seed piece treatment	5	April 15–June 25
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	5–10	April 11–June 30
		1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground and aerial foliar	NA	May 10–August 20
	Soybean	1 × 157.5 g a.i./ha	Seed treatment[1]	2.5	May 1–June 15
		3 × 24.4 g a.i./ha, 3 × 49.9 g a.i./ha	Ground foliar	NA	June 21–September 10
	Root and tuber vegetables other than potato	1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	4	April 11–June 30
	Brassica vegetables	1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	In-furrow[1]	2	April 21–August 20
		1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	Soil drench	4	April 21–August 20
	Blueberry	1 × 42 g a.i./ha, 2 × 42 g a.i./ha, 3 × 42 g a.i./ha	Ground foliar	NA	May 1–October 10
	Raspberry	1 × 112 g a.i./ha, 2 × 112 g a.i./ha, 3 × 112 g a.i./ha	Ground foliar	NA	May 1–October 10
	Grape	1 × 48 g a.i./ha, 2 × 48 g a.i./ha	Ground foliar	NA	April 1–October 20
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (hill drench and irrigation)[1]	10 (assumed)	May 1–July 31
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (subsurface side-dress shanked into the root-zone followed by irrigation)[2]	10 (assumed)	May 1–July 31
	Tomato	1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground foliar	NA	May 11–September 30
	Turf	1 × 281 g a.i./ha	Ground foliar	NA	April 1–October 20
Atlantic	Barley	1 × 36.33 g a.i./ha	Seed treatment	2	April 20–June 8
	Canola	1 × 64.16 g a.i./ha	Seed treatment	1	May 21–June 30
	Corn	1 × 56.8 g a.i./ha	Seed treatment[1]	2.5	May 1–June 15
	Pea (dry)	1 × 246.25 g a.i./ha	Seed treatment	3.5	May 7–June 15
	Wheat	1 × 52.47 g a.i./ha	Seed treatment	2	March 20–June 6
	Faba bean	1 × 232.5 g a.i./ha	Seed treatment	2.5	May 1–June 10
	Potato	1 × 280 g a.i./ha	Seed piece treatment	5	March 20–June 15
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	5–10	April 21–June 20
		1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground and aerial foliar	NA	June 21–September 20
	Soybean	1 × 157.5 g a.i./ha	Seed treatment[1]	2.5	May 10–June 7
		3 × 24.4 g a.i./ha, 3 × 49.9 g a.i./ha	Ground foliar	NA	June 21–September 10

Region	Crop	Use pattern	Application method	Seed depth (cm)	Timing of application
	Root and tuber vegetables other than potato	1 × 100 g a.i./ha, 1 × 480 g a.i/ha	In-furrow[1]	4	April 21–June 20
	Brassica vegetables	1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	In-furrow[1]	2	May 11–August 20
		1 × 86.6 g a.i./ha, 1 × 520 g a.i/ha	Soil drench	4	May 11–August 20
	Blueberry	1 × 42 g a.i./ha, 2 × 42 g a.i./ha, 3 × 42 g a.i./ha	Ground foliar	NA	May 1–September 30
	Raspberry	1 × 112 g a.i./ha, 2 × 112 g a.i./ha, 3 × 112 g a.i./ha	Ground foliar	NA	May 1–September 30
	Grape	1 × 48 g a.i./ha, 2 × 48 g a.i./ha	Ground foliar	NA	May 11–June 20
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (hill drench and irrigation)[1]	10 (assumed)	May 1–July 31
		1 × 100 g a.i./ha, 1 × 480 g a.i/ha	Soil drench (subsurface side-dress shanked into the root-zone followed by irrigation)[2]	10 (assumed)	May 1–July 31
	Tomato	1 × 49 g a.i./ha, 2 × 49 g a.i./ha, 3 × 49 g a.i./ha	Ground foliar	NA	June 21–September 20
	Turf	1 × 281 g a.i./ha	Ground foliar	NA	April 1–October 20

NA = not applicable
[1] EECs for in-furrow uses, soil drench application for grapes (hill drench) and corn and soybean seed treatments are those from modelling using the "increasing with depth" scenario.
[2] Subsurface side-dress shanked into the root-zone on both sides of the plants followed by irrigation was modelled for grapes assuming that all the pesticide was found at root depth (estimated at 10 cm) at the time of application.

The main environmental fate parameters used in the models are summarized in Table 2. For details on the fate information, refer to PRVD2016-20.

Table 2 Major surface water model inputs for the revised ecoscenario runoff modelling of imidacloprid

Parameter[1]	Value	Comment
Molecular weight (g/mole)	255.67	
Vapour pressure (mm Hg) at 20°C	1.5×10^{-9}	
Solubility (mg/L) in water	510	
Henry's law constant (unitless)	4.0×10^{-11}	
Photolysis half-life (days, adjusted to 35° latitude)	0.175	Single value
Hydrolysis (days, at pH 7)	Stable	
K_{OC} (L/kg)	85	20th percentile of 27 values
Soil half-life (days, adjusted to 25°C)	1159	90th percentile confidence bound on the mean of 4 values
Aerobic aquatic half-life (days, adjusted to 25°C)	191	Whole system; 80th percentile of 4 values
Anaerobic aquatic half-life (days, adjusted to 25°C)	27	Anaerobic soil; single value
Application efficiency	0.99; 1.0	Ground foliar; in-furrow, soil-drench and seed treatment
Diffusion coefficient in air (cm^2/day)	4250	
Heat of Henry (J/mole)	59000	Default in PWC

[1] Refer to PRVD2016-20 for details on the fate of imidacloprid.

Appendix X Summary of monitoring analysis

Table 1 Water monitoring programs excluded from the revised assessment but which had been previously considered in the proposed re-evaluation decision for imidacloprid, PVRD2016-20

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Total number of samples
Environment Canada, 2011 (PMRA# 2525751); Environment Canada, 2006 (PMRA# 1403269); Environment Canada, 2007 (PMPRA# 2424839)	New Brunswick, Prince Edward Island, Nova Scotia	surface water	0.1–0.3	2003–2005	14	187
	Reason for exclusion: The analytical detection limit is high relative to other more recent monitoring programs. Only the number of detections were reported (2 out of a total of 187); concentrations were not reported. The non-detections are difficult to interpret because the analytical detection limit is high. Data are more than 15 years old and may not reflect current use practices.					
Environment Canada, 2001 (PMRA# 1401896, 1401897)	Ontario	urban creeks and rivers	0.25–2.5	2000, 2001	19	194
	Reason for exclusion: The analytical detection limit is high relative to other more recent monitoring programs. There was only one detection, indicated as less than 1 µg/L. The non-detects are difficult to interpret because the analytical detection limit is high. Data are more than 15 years old and may not reflect current use practices. More recent datasets from many of the same waterbodies are available.					
Environment Canada, 2006 (PMRA# 1403269)	Ontario	inland lakes	Not reported	2003–2005	10	168
	Reason for exclusion: No detections but the analytical detection limit is not reported. Site information was not provided. Data are more than 15 years old and may not reflect current use practices. The inland lakes were considered pristine and therefore would not represent areas of use of imidacloprid.					
Environment Canada, as cited in Mineau and Palmer, 2013 (PMRA# 2526820)	Ontario	mainly streams	0.00128	2011	16	17
	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 (2012 to 2016) in most of the waterbodies were available.					
Murphy et al., 2006, as cited in CCME, 2007 (PMRA# 2526803)	New Brunswick	streams	0.2	2003–2005	Not reported	57
	Reason for exclusion: Only 2 detections out of 57 samples were reported. No concentrations were provided. The analytical detection limit is high relative to other more recent monitoring programs. Site information was not provided. Data are more than 15 years old and may not reflect current use practices.					
Health Canada Hive Monitoring Program, unpublished (PMRA# 2548876)	British Columbia, Manitoba, Ontario, Quebec, Nova Scotia	streams, culverts, ditches	0.0011	2014	13	13
	Reason for exclusion: Sampling occurred near beehives; the program was not designed to monitor aquatic habitats near areas of imidacloprid use.					

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Total number of samples
Main et al., 2014 (PMRA# 2526133, 2612760)	Saskatchewan	wetlands	0.0011	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. Site locations were not provided. Crop in the fields where the wetlands were sampled were provided; however, site locations were not identified. 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. Results were within the range of those for more recent wetland datasets that have season-long sampling and large amounts of ancillary info available.					
Main et al., 2015 (PMRA# 2608629, 2612762)	Saskatchewan	wetlands	0.0011	2013	144	166
	Reason for exclusion: A total of 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 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	0.0023	2014	16	75
	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.					
Denning et al., 2004 (PMRA# 2518467)	Prince Edward Island	agricultural runoff	0.5	2001–2002	11	62
	Reason for excluding: The study looked at the effectiveness of vegetative strips at reducing pesticide runoff. The samples are from agricultural runoff in a collector at the edge of potato fields or 10 metres in the vegetative zone; this is not representative of aquatic habitat. The analytical detection limit is high relative to other more recent monitoring programs. Data are more than 15 years old and may not reflect current use practices.					
Julien et al., 1996 (PMRA# 2518490)	Prince Edward Island	agricultural runoff and stream water	0.003	1995	2	11
	Reason for excluding: The samples are from agricultural runoff from potato fields, which is not representative of aquatic habitat. The concentrations were only reported as > 0.1 and > 0.5 µg/L. Data are 25 years old and may not reflect current use practices.					
Hewitt, 2006 as cited in CCME, 2007 (PMRA# 2526803)	New Brunswick	runoff, streams	0.2	2003–2005	Not reported	Not reported
	Reason for excluding: Some of the samples are from agricultural runoff, which is not representative of aquatic habitat. The number of samples and individual concentrations were not reported, aside from an approximate maximum concentration of 0.3 µg/L. The detection limit is high relative to other more recent monitoring programs. Data are more than 15 years old and may not reflect current use practices.					

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Total number of samples
Ontario Ministry of the Environment and Ontario Ministry of Agriculture and Food, 2013 (PMRA# 2523836)	Ontario	Streams	0.126	2012–2013	20	198
	Reason for exclusion: The analytical detection limit is high compared to other monitoring datasets available, making non-detects more difficult to interpret. The detection frequency (2%) was low compared to other programs. More useful and more recent monitoring data for these sites were available for 2015–2018, which had a much lower analytical detection limit.					
Byrtus et al., 2002 (PMRA# 1311124)	Alberta	surface water (irrigation return flows and dry-land farming streams)	0.02–1	1999–2000	12	42
	Reason for excluding: The samples may not be from locations representative of aquatic habitat. The analytical detection limit is high relative to other more recent monitoring programs. Data are 20 years old and may not reflect current use practices.					
Health Canada Bee Mortality Incident Monitoring, unpublished (PMRA# 2548877)	Ontario, Manitoba	pond, creek, stream, culvert	Not reported	2013	68	68
		pond, creek, marsh	0.0011	2014	23	23
	Reason for exclusion: Sampling occurred in areas where bee mortality incidents occurred; the program was not designed to monitor aquatic habitats near areas of imidacloprid use.					
Schaafsma et al., 2015 (PMRA# 2526184)	Ontario	ditches and drainage tile outlets within 0 to 100 metres from the perimeter of corn fields	Not reported	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. The analytical detection limit was not reported. There were few detections of imidacloprid (2 detections out of 22 ditch samples and 1 detection out of 8 drainage tile outlet samples, and maximum concentrations measured were also low (0.065 µg/L in ditches and 0.023 µg/L in drainage tile outlets). In the study, imidacloprid was only detected in 2 out of 90 samples taken from puddles (not considered aquatic habitat to be protected in this assessment) within or outside corn fields; the low detection frequency is contrary to what would be expected if imidacloprid had been used on corn seeds planted in the fields sampled. The study authors did not include imidacloprid results in total neonicotinoid concentrations reported in the study; the total neonicotinoid concentrations were the sum of clothianidin and thiamethoxam concentrations. The results of this study will be considered in a general sense in the assessment of the use of imidacloprid on corn, but will not be used quantitatively.					
Xing et al., 2013 (PMRA# 2526162)	New Brunswick	streams	0.0066	2003–2005	Not reported	Not reported
	Reason for excluding: The number of samples and individual concentrations were not reported, aside from an average concentration and a detection frequency. Data are more than 15 years old and may not reflect current use practices.					

<table>
<tr><th>Program (PMRA#)</th><th>Province</th><th>Type of waterbody</th><th>Limit of detection or reporting limit (µg/L)</th><th>Year</th><th>Number of sites</th><th>Total number of samples</th></tr>
<tr><td rowspan="2">Department of Communities, Land and Environment (PMRA# 2468268)</td><td>Prince Edward Island</td><td>streams</td><td>0.1</td><td>2009–2012</td><td>9</td><td>48</td></tr>
<tr><td colspan="6">Reason for excluding: The data for sampling years 2009 to 2012 were excluded from the analytical detection limit was much higher compared to subsequent years of sampling. There were only 2 detections out of 48 samples. The non-detects are difficult to interpret. Monitoring data from 2013 to 2018 are available for the same sites, with a lower analytical detection limit.</td></tr>
</table>

Table 2 Summary of water monitoring programs considered in the final re-evaluation decision of imidacloprid. New monitoring data not previously considered in the proposed re-evaluation decision are shaded and highlighted in bold

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[1]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Environment and Climate Change Canada (PMRA# 2834289)	New Brunswick, Nova Scotia, Prince Edward Island	Rivers, brooks	0.00128	**2015**	**May 21–Sep 12**	**3**	**19**	**6–7**	**1–42**
				2016	**Aug 17–Sep 14**	**6**	**8**	**1–3**	**1–15**
Department of Communities, Land and Environment (PMRA# 2745506, 2468268, 2845169, 3169038)	Prince Edward Island	Streams	0.02	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**
			0.0032–0.02	**2018**	**May 29–Oct 1**	**9**	**54**	**6**	**19–29**
Ministère de l'Environnement et de la Lutte contre les changements climatiques (PMRA# 2035772, 2523837, 2544468, 2561884, 2821394, 2840206, 2895037, 2929764, 2965069)	Quebec	Rivers, streams	0.001–0.004	2005	Aug 31	1	1	1	NA
				2006	Jun 7–Aug 16	1	6	6	7–21
				2010	May 9–Aug 23	4	113	27–30	2–9
				2011	May 5–Aug 31	2	58	27–31	1–9
				2012	May 23–Aug 30	7	122	10–28	1–14
				2013	May 16–Aug 27	6	95	10–28	2–15
				2014	May 15–Aug 25	2	60	30	2–5
				2015	**May 14–Aug 23**	**5**	**65**	**1–29**	**2–14**
				2016	**May 15–Aug 25**	**2**	**60**	**30**	**2–5**
				2017	**May 23–Aug 31**	**17**	**217**	**6–26**	**1–21**
				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	0.0007–0.00128	**2007**	**May 22–Oct 22**	**16**	**103**	**2–9**	**6–56**
				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**

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[1]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Ministry of Environment, Conservation and Parks (PMRA# 3032989) (Stream Monitoring Program)	Ontario	Streams	0.005	**2015**	**Apr 10–Nov 11**	**5**	**95[2]**	**17–23[2]**	**1–35[3]**
				2016	**Apr 25–Oct 22**	**5**	**86[2]**	**15–19[2]**	**1–30[3]**
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	0.0006	**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) (Investigative monitoring to identify the source of high concentrations in two watersheds)	Ontario	Creeks, drainage ditches in the Leamington area	0.002–0.005	**2017**	**May 4–Oct 19**	**15**	**164[4]**	**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	0.0006	**2019**	**Apr 16–Oct 09**	**10[e]**	**209[5]**	**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, rivers	0.00025	**2015**	**Jun 10–Jul 10**	**16**	**32**	**2**	**28**
			0.00004	**2016**	**Jun 15–Jul 15**	**16**	**32**	**2**	**28**

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[1]	Number of samples per site (min–max)	Sampling interval (min–max, days)
Ontario Ministry of Environment and Climate Change (PMRA# 2170505)	Ontario	Municipal waste water treatment plant influent[6]	0.005	**2016**	**Jun 7–Jun 23**	**7**	**19**	**1–3**	**1**
		Municipal waste water treatment plant effluent[6]	0.005	**2016**	**Jun 7–Jun 23**	**7**	**19**	**1–3**	**1**
Environment and Climate Change Canada (PMRA# 2745819)	Manitoba, Saskatchewan, Alberta	Rivers	0.00128	**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**
Ducks Unlimited Canada (PMRA# 2847073, 2847083, 3167980)	Manitoba, Saskatchewan, Alberta	Wetlands	0.005	**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	0.0032	**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[7]**	**19–22**	**7–59**
Ministry of Agriculture and Water Security Agency (PMRA# 2849265, 2849266, 3167960, 3169037)	Saskatchewan	Streams	0.0032	**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	0.0006	**2018**	**May 14–Oct 2**	**56**	**790**	**5–17**	**4–44**

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Sampling season (initial–final)	Number of sites	Total number of samples[1]	Number of samples per site (min–max)	Sampling interval (min–max, days)
	Manitoba, Saskatchewan, Alberta	Wetlands in fields planted with thiamethoxam-treated seeds	0.0006	**2019**	**Apr 30–Oct 6**	**58**	**834**	**2–19**	**3–67**
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	Wetlands	0.0012	2014	Jun 24–Jul 5	46[8]	46[8]	1	NA
Canadian Canola Growers Association (PMRA# 3169611)	Saskatchewan, Alberta	Wetlands	0.0032	**2019**	**May 13–Jul 12**	**17**	**135**	**4–9**	**3–22**
Ministry of Agriculture and Forestry (PMRA# 2842307, 2842433, 3167974)	Alberta	Rivers	0.0032	**2017**	**Jun 1–Sep 21**	**28**	**110**	**3–4**	**12–59**
				2018	**Mar 12–Sep 19**	**23**	**148**	**5–7**	**12–57**
		Streams	0.0032	**2017**	**May 16–Jul 21**	**29**	**66**	**1–3**	**1–13**
				2018	**Mar 27–Sep 28**	**26**	**183**	**20–61**	**1–63**
		Wetlands	0.0032	**2018**	**Apr 24–Sep 27**	**18**	**49**	**1–9**	**6–83**
		Reservoirs	0.0032	**2018**	**Jun 14–Aug 30**	**8**	**15**	**1–2**	**70–75**
		Irrigation canals[9]	0.0032	**2017**	**May 29–Aug 28**	**50**	**194**	**3–4**	**25–35**
				2018	**Apr 4–Sep 24**	**21**	**119**	**5–7**	**13–62**
		Tile drains[9]	0.0032	**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	0.00128	**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[10]**	**120**	**8**	**12–16**
				2018	**May 8–Sep 26**	**15[10]**	**120**	**7–10**	**13–28**

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

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

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

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

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

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

[6] Municipal waste water treatment plant influent and effluent may not be representative of aquatic habitat.

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

[8] 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.

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

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

Table 3 Summary of the number of samples collected, sampling sites, and site-years of monitoring data considered in the final re-evaluation decision for imidacloprid

	Samples	Sites	Site-years[1]
Data previously considered in PRVD2016-20			
Prairie Provinces	46	46	46
Rivers, creeks, lakes, reservoirs	1	1	1
Wetlands	45	45	45
Irrigation canals	0	0	0
Tile drains	0	0	0
Other Regions of Canada	790	35	60
Streams, rivers, creeks, brooks, sloughs, lakes	790	35	60
Drainage ditches	0	0	0
Municipal waste water treatment plant influent and effluent	0	0	0
New data not previously considered			
Prairie Provinces	4671	442	599
Rivers, creeks, lakes, reservoirs	1308	129	244
Wetlands	3005	253	275
Irrigation canals	313	53	71
Tile drains	45	7	9
Other Regions of Canada[3]	3455	281	464
Streams, rivers, creeks, brooks, sloughs, lakes	3067	224	400
Drainage ditches	350	43	50
Municipal waste water treatment plant influent and effluent	38	14[2]	14[2]
Total Prairie Provinces	**4717**	**488**	**645**
Total Other Regions of Canada[3]	**4245**	**291**	**524**
Grand Total	**8962**	**779**	**1169**

[1] One site monitored in one given year is equivalent to one monitoring site-year.
[2] Municipal waste water treatment plant influent and effluent samples from the same plant were treated as coming from different sites.
[3] Numbers include those for sites in two Ontario watersheds shown through investigative sampling as receiving inputs from greenhouses; these are excluded from analyses of field and urban uses of imidacloprid (743 samples from 18 sites, and a total of 49 site-years).

Table 4 Number and percentage of sampling sites in Canada, grouped according to the number of years (1–8) of monitoring 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=291)[1]	190 (65%)	48 (17%)	21 (7%)	22 (8%)	3 (1%)	3 (1%)	2 (< 1%)	2 (< 1%)
Overall (n=779)[1]	**537 (69%)**	**173 (22%)**	**37 (5%)**	**22 (3%)**	**3 (< 1%)**	**3 (< 1%)**	**2 (< 1%)**	**2 (< 1%)**

[1] Numbers include those for 18 sites (monitored between one and eight years; 49 site-years) in two Ontario watersheds shown through investigative sampling as receiving inputs from greenhouses; these were excluded from analyses of field and urban uses of imidacloprid.

Table 5 Summary of imidacloprid concentrations measured in Canadian waterbodies between 2005 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 the analytical limit of detection

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
Environment and Climate Change Canada (PMRA# 2834289)	New Brunswick, Nova Scotia, Prince Edward Island	Rivers, brooks	0.00128	2015	3	3 (100%)	0.0626	0 (0%)	0 (0%)
				2016	6	5 (83%)	0.0561	0 (0%)	0 (0%)
Department of Communities, Land and Environment (PMRA# 2745506, 2468268, 2845169, 3169038)	Prince Edward Island	Streams	0.02	2013	3	0 (0%)	0.01	0 (0%)	0 (0%)
				2014	3	1 (33%)	0.03	0 (0%)	0 (0%)
				2015	3	3 (100%)	0.18	1 (33%)	0 (0%)
				2017	9	0 (0%)	0.01	0 (0%)	0 (0%)
			0.0032–0.02	2018	9	3 (33%)	0.094	0 (0%)	0 (0%)
Ministère de l’Environnement et de la Lutte contre les changements climatiques (PMRA# 2035772, 2523837, 2544468, 2561884, 2821394, 2840206, 2895037, 2929764, 2965069)	Quebec	Rivers, streams	0.001–0.004	2005	1	1 (100%)	0.26	1 (100%)	0 (0%)
				2006	1	1 (100%)	7.77	1 (100%)	1 (100%)
				2010	4	4 (100%)	0.27	1 (25%)	0 (0%)
				2011	2	2 (100%)	0.31	1 (50%)	0 (0%)
				2012	7	7 (100%)	0.2	1 (14%)	0 (0%)
				2013	6	5 (83%)	4	1 (17%)	1 (17%)
				2014	2	2 (100%)	0.118	1 (50%)	0 (0%)
				2015	5	4 (80%)	4.3	1 (20%)	1 (20%)
				2016	2	2 (100%)	0.13	0 (0%)	0 (0%)
				2017	17	9 (53%)	0.23	1 (6%)	0 (0%)
				2018	17	13 (76%)	0.57	6 (35%)	1 (6%)
Montiel-León et al., 2019 (PMRA# 2991134)	Quebec	St. Lawrence River and tributaries	0.001	2017	68	7[4] (10%)	0.011	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	Ontario	Streams	0.0007–0.00128	2007	16	6 (38%)	0.1106	0 (0%)	0 (0%)
				2012	12	11 (92%)	5.47 Excluding Lebo Drain and Sturgeon Creek: 0.247	2 (17%) Excluding Lebo Drain and Sturgeon Creek: 1 (9%)	1 (8%) Excluding Lebo Drain and Sturgeon Creek: 0 (0%)
				2013	18	14 (78%)	5.03	3 (17%)	2 (11%)

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
							Excluding Lebo Drain and Sturgeon Creek: 0.367	Excluding Lebo Drain and Sturgeon Creek: 1 (6%)	Excluding Lebo Drain and Sturgeon Creek: 0 (0%)
				2014	9	8 (89%)	10.4 Excluding Lebo Drain and Sturgeon Creek: 0.486	3 (33%) Excluding Lebo Drain and Sturgeon Creek: 1 (14%)	2 (22%) Excluding Lebo Drain and Sturgeon Creek: 0 (0%)
				2015	11	10 (91%)	3.32 Excluding Lebo Drain and Sturgeon Creek: 0.19	5 (45%) Excluding Lebo Drain and Sturgeon Creek: 3 (33%)	2 (18%) Excluding Lebo Drain and Sturgeon Creek: 0 (0%)
				2016	11	10 (91%)	2.59 Excluding Lebo Drain and Sturgeon Creek: 0.136	2 (18%) Excluding Lebo Drain and Sturgeon Creek: 0 (0%)	2 (18%) Excluding Lebo Drain and Sturgeon Creek: 0 (0%)
Ministry of Environment, Conservation and Parks (PMRA# 2712893, 3032989) (Stream Monitoring Program)	Ontario	Streams	0.005	2015	5	5 (100%)	2.3	1 (20%)	1 (20%)
				2016	5	5 (100%)	5.1	2 (40%)	2 (40%)
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	0.0006	2015	17	16 (94%)	4.6 Excluding Lebo Drain: 0.24	2 (12%) Excluding Lebo Drain: 1 (6%)	1 (6%) Excluding Lebo Drain: 0 (0%)
				2016	17	13 (76%)	0.52 Excluding Lebo Drain: 0.08	1 (6%) Excluding Lebo Drain: 0 (0%)	0 (0%)
				2017	18	16 (89%)	0.5 Excluding Lebo	2 (11%) Excluding	0 (0%)

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
							Drain: 0.33	Lebo Drain: 1 (6%)	
				2018	19	18 (95%)	0.37 Excluding Lebo Drain: 0.28	2 (11%) Excluding Lebo Drain: 1 (6%)	0 (0%)
Bayer CropScience Canada (PMRA# 2818733, 2936038, 3050884)	Ontario	Creeks, drainage ditches in the Leamington area	0.002–0.005	2017	**Sites within 2 km downstream of greenhouses**				
					10	10 (100%)	29.65	10 (100%)	10 (100%)
					Sites with no greenhouses within 2 km upstream				
					5	5 (100%)	1.086	3 (60%)	2 (40%)
				2018	**Sites within 2 km downstream of greenhouses**				
					12	12 (100%)	8.98	11 (92%)	7 (58%)
					Sites with no greenhouses within 2 km upstream				
					3	3 (100%)	0.107	0 (0%)	0 (0%)
				2019	**Sites within 2 km downstream of greenhouses**				
					13	13 (100%)	12.2	11 (85%)	11 (85%)
					Sites with no greenhouses within 2 km upstream				
					2	2 (100%)	0.121	0 (0%)	0 (0%)
Syngenta Canada (PMRA# 3070837)	Ontario	Rivers, creeks	0.0006	2019	10[e]	7 (70%)	0.13	0 (0%)	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: 16 (89%)	Grab sampling: 1.195 Excluding Lebo Drain: 0.0841 POCIS: 0.9934 Excluding Lebo Drain: 0.0231	Grab sampling: 1 (17%) Excluding Lebo Drain: 0 (0%) POCIS: 1 (6%) Excluding Lebo Drain: 0 (0%)	Grab sampling: 1 (17%) Excluding Lebo Drain: 0 (0%) POCIS: NC[6]
Environment and Climate Change Canada (PMRA# 2785041)	Ontario, Quebec (one site)	Drainage ditches in the Ottawa area (one site in Quebec)	0.00025	2014	31	17 (55%)	0.0115	0 (0%)	0 (0%)

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
		Streams, rivers	0.00025	2015	16	11 (69%)	0.012	0 (0%)	0 (0%)
			0.00004	2016	16	4 (25%)	0.014	0 (0%)	0 (0%)
Ontario Ministry of Environment and Climate Change (PMRA# 2710505)	Ontario	Municipal waste water treatment plant influent[7]	0.005	2016	7	19 (100%)	0.5	0 (0%)	0 (0%)
		Municipal waste water treatment plant effluent[7]	0.005	2016	7	19 (100%)	0.13	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2745819)	Manitoba, Saskatchewan, Alberta	Rivers	0.00128	2014	4	3 (75%)	0.0184	0 (0%)	0 (0%)
				2015	4	1 (25%)	0.0113	0 (0%)	0 (0%)
				2016	2	1 (50%)	0.0026	0 (0%)	0 (0%)
Ducks Unlimited Canada (PMRA# 2847073, 2847083, 3167980)	Manitoba, Saskatchewan, Alberta	Wetlands	0.005	2017–2018	60	4 (7%)	0.0365	0 (0%)	0 (0%)
Ministry of Agriculture (PMRA# 2849359, 2849370, 3167930)	Manitoba	Rivers, creeks	0.0032	2017	33	10 (30%)	0.1144	0 (0%)	0 (0%)
				2018	33	7 (21%)	0.0751	0 (0%)	0 (0%)
Challis et al., 2018 (PMRA# 2879350)	Manitoba	Rivers	Not reported	2014–2015	6	6 (100%)	0.0141[8] (7 days)	0 (0%)	NC[6]
Ministry of Agriculture and Water Security Agency (PMRA# 2849265, 2849266, 3167960, 3169037)	Saskatchewan	Streams	0.0032	2017	15	6 (40%)	0.0425	0 (0%)	0 (0%)
				2018	17	6 (35%)	0.0453	0 (0%)	0 (0%)
				2019	16	7 (44%)	0.0759	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	4 (67%)	0.0929	0 (0%)	0 (0%)
			0.002	2018	6	6 (100%)	0.023	0 (0%)	0 (0%)
			0.002	2019	6	6 (100%)	0.1924	1 (17%)	0 (0%)
		Wetlands in fields planted with clothianidin-treated seeds	0.002	2018	25	24 (96%)	0.0212	0 (0%)	0 (0%)
			0.002	2019	23	12 (52%)	0.0588	0 (0%)	0 (0%)

Program (PMRA#)	Province	Type of waterbody	Limit of detection or reporting limit (µg/L)	Year	Number of sites	Number (percentage) of sites with detections	Maximum concentration (µg/L)	Number (percentage) of sites with detections exceeding the chronic effects metric[2]	Number (percentage) of sites with detections exceeding the acute effects metric[3]
Syngenta Canada (PMRA# 2947434, 3070838)	Saskatchewan	Wetlands in fields planted with thiamethoxam-treated seeds	0.0006	2018	56	1 (2%)	0.0057	0 (0%)	0 (0%)
	Manitoba, Saskatchewan, Alberta	Wetlands in fields planted with thiamethoxam-treated seeds	0.0006	2019	58	2 (3%)	0.0092	0 (0%)	0 (0%)
Morrissey, 2016 (unpublished; PMRA# 2712896)	Saskatchewan	Wetlands	0.0012	2014	46[9]	14 (30%)	0.198	7 (15%)	0 (0%)
Canadian Canola Growers Association (PMRA# 3169611)	Saskatchewan, Alberta	Wetlands	0.0032	2019	17	3 (18%)	0.0262	0 (0%)	0 (0%)
Ministry of Agriculture and Forestry (PMRA# 2842307, 2842433, 3167974)	Alberta	Rivers	0.0032	2017	28	3 (11%)	0.0632	0 (0%)	0 (0%)
				2018	23	2 (9%)	0.0447	0 (0%)	0 (0%)
		Streams	0.0032	2017	29	3 (10%)	0.0546	0 (0%)	0 (0%)
				2018	26	6 (23%)	0.0368	0 (0%)	0 (0%)
		Wetlands	0.0032	2018	18	3 (17%)	0.122	0 (0%)	0 (0%)
		Reservoirs	0.0032	2018	8	0 (0%)	0.0016	0 (0%)	0 (0%)
		Irrigation canals[10]	0.0032	2017	50	2 (4%)	0.0702	0 (0%)	0 (0%)
				2018	21	6 (29%)	0.0366	0 (0%)	0 (0%)
		Tile drains[10]	0.0032	2017	3	0 (0%)	0.0016	0 (0%)	0 (0%)
				2018	6	0 (0%)	0.0016	0 (0%)	0 (0%)
Environment and Climate Change Canada (PMRA# 2707947, 2889992)	British Columbia	Rivers, creeks, sloughs	0.00128	2014	5	3 (60%)	0.0125	0 (0%)	0 (0%)
				2015	7	3 (43%)	0.0332	0 (0%)	0 (0%)
				2016	6	6 (100%)	0.0459	0 (0%)	0 (0%)
Ministry of Agriculture (PMRA# 2842180, 3168173)	British Columbia	Rivers, streams	0.005	2017	15[11]	6 (40%)	0.74	1 (7%)	1 (7%)
				2018	15[11]	5 (33%)	0.574	2 (13%)	2 (13%)

NC = not calculated

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

[2] The chronic effects metric is a 28-day time-weighted average mesocosm NOEC of 0.16 µg/L based on significant effects on *Cloeon dipterum* abundance (adult and larvae; see Section 3.3.3.1 Revisions to Imidacloprid Effects Metrics)

[3] The acute effects metric is an HC_5 of 0.54 µg/L from an acute aquatic invertebrate species sensitivity distribution; see Section 3.3.3.1 Revisions to Imidacloprid Effects Metrics)
[4] Number of detections was calculated by the reviewer based on the provided sample size and detection frequency.
[5] Includes additional sampling on two occasions at three sites on the Nottawasaga Creek.
[6] 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).
[7] Municipal waste water treatment plant influent and effluent may not be representative of aquatic habitat.
[8] Concentrations in this study are time-weighted averages over timeframes of 7 to 59 days. 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).
[9] Only results from a subset of the sites from this data set (46 out of 115 sites) were considered relevant for an aquatic risk assessment and are included here.
[10] Irrigation canals and tile drains may not be representative of aquatic habitat.
[11] Excludes results from a site with no pesticide use in the watershed (No-Pesticide Check).

Table 6 Dissipation of imidacloprid in intensively sampled Prairie wetlands, which were within or adjacent to fields planted with neonicotinoid-treated seeds

Site	Year	DT_{50} (days)	Representative half-life (days)	Kinetics[1]	Data Set (PMRA#)
MENT0015-05	2017–2018	7	7	SFO	Bayer CropScience (PMRA# 2921988)
CENT0001-C0406	2018	18.8	18.8	SFO	Bayer CropScience (PMRA# 2921990)
CENT0002-01	2019	10.9	10.9	SFO	Bayer CropScience (PMRA# 3050880)
CENT0002-01	2019	12.6	12.6	SFO	Bayer CropScience (PMRA# 3050880)
CENT0002-02	2019	9.8	9.8	SFO	Bayer CropScience (PMRA# 3050880)
CENT0002-05	2019	9.9	9.9	SFO	Bayer CropScience (PMRA# 3050880)
CENT0002-06	2019	12.2	12.2	SFO	Bayer CropScience (PMRA# 3050880)
CETI0004-02	2019	4.8	4.8	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-04	2019	6.8	6.8	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-06	2019	5.5	5.5	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-20	2019	7.9	7.9	SFO	Bayer CropScience (PMRA# 3050882)
CETI0004-21	2019	9.4	9.4	SFO	Bayer CropScience (PMRA# 3050882)
Overall	***N***	***12***			
	Average	***9.6***			

[1] 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 7 Concentrations of imidacloprid at the main Lebo Drain and Sturgeon Creek sites in Ontario between 2012 and 2019

Year	Main Lebo Drain site			Main Sturgeon Creek site			PMRA#
	Samples	Average[1] (µg/L)	Maximum (µg/L)	Samples	Average[1] (µg/L)	Maximum (µg/L)	
2012	NS	NS	NS	12	2.126	5.47	2523839, 2703534, 2834287
2013	12	1.092	4.03	12	0.801	5.03	2523839, 2703534, 2834287
2014	14	0.76	2.5	14	1.342	10.4	2532563, 2703534, 2834287
2015	13	1.06	3.32	13	0.307	1.18	2681876, 2834287
	6	1.975	4.6	0	NS	NS	3070884
2016	6	0.559	2.59	6	0.263	0.796	2834287
	7	0.314	0.52	NS	NS	NS	3070884
	POCIS: 2 Grab sampling: 3	POCIS: NC Grab sampling: 1.064	POCIS: 0.9334[2] Grab sampling: 1.195	NS	NS	NS	2945668
2017	13	1.967	18.978	13	0.379	0.985	2818733
	7	0.228	0.5	NS	NS	NS	3157906
2018	22	0.171	0.683	22	0.189	0.476	2936038
	8	0.155	0.37	NS	NS	NS	3157906
2019	20	0.170	0.625	20	0.319	2.5	3050884

NS = not sampled; NC = not calculated; POCIS = polar organic chemical integrative samplers

[1] Average concentrations presented here are those for all the samples collected in a given year.

[2] Concentrations measured using POCIS represent time-weighted average exposures for deployment periods of 14 days.

Table 8 Summary of investigative monitoring conducted by Bayer CropScience in the Lebo Drain watershed of Ontario between 2017 and 2019

Year	Site	Type of waterbody	Samples	Average[1] (Standard Deviation) (µg/L)	Median (µg/L)	Maximum (µg/L)
2017	**Sites within 2 km downstream of greenhouses**					
	Main Lebo Drain site[2]	Creek	13	1.964 (5.125)	0.419	18.978
	LD2	Creek	13	1.24 (2.226)	0.471	8.112
	LD5	Drainage ditch	13	1.777 (3.061)	0.421	10.153
	LD7	Creek	10	0.791 (0.559)	0.572	2.028
	LD8	Creek	10	1.061 (0.64)	0.969	2.076
	LD9	Creek	9	4.01 (9.64)	0.567	29.65
	LD10	Drainage ditch	9	1.3 (2.204)	0.355	6.984
	Sites not within 2 km downstream of greenhouses					
	LD3	Creek	8	0.153 (0.113)	0.122	0.333
	LD4	Drainage ditch	13	0.221 (0.305)	0.121	1.086
	LD6	Drainage ditch	10	0.313 (0.216)	0.308	0.733
2018	**Sites within 2 km downstream of greenhouses**					
	Main Lebo Drain site[2]	Creek	22	0.171 (0.154)	0.118	0.683
	LD2	Creek	22	0.118 (0.079)	0.094	0.26
	LD5	Drainage ditch	22	0.885 (2.124)	0.057	8.98
	LD7	Creek	22	0.137 (0.079)	0.133	0.312
	LD8	Creek	22	0.182 (0.186)	0.138	0.819
	LD11	Drainage ditch	13	0.226 (0.294)	0.097	1.07
	LD12	Drainage ditch	22	0.129 (0.12)	0.081	0.462
	Sites not within 2 km downstream of greenhouses					
	LD4	Drainage ditch	8	0.021 (0.009)	0.018	0.036
	LD6	Drainage ditch	22	0.026 (0.023)	0.021	0.107
2019	**Sites within 2 km downstream of greenhouses**					
	Main Lebo Drain site[2]	Creek	20	0.17 (0.157)	0.147	0.625
	LD2	Creek	20	0.221 (0.437)	0.09	1.92

Year	Site	Type of waterbody	Samples	Average[1] (Standard Deviation) (µg/L)	Median (µg/L)	Maximum (µg/L)
	LD5	Drainage ditch	20	0.214 (0.356)	0.058	1.34
	LD7	Creek	20	0.208 (0.179)	0.148	0.67
	LD8	Creek	20	0.256 (0.27)	0.181	1.11
	LD14	Drainage ditch	20	0.751 (2.71)	0.023	12.2
	RR1[3]	Drainage ditch	19	0.041 (0.088)	0.012	0.39
	Sites not within 2 km downstream of greenhouses					
	LD13[3]	Creek	19	0.027 (0.024)	0.022	0.121

[1] Average concentrations presented here are those for all the samples collected in a given year.
[2] The main Lebo Drain site is the same location used in the monitoring program by Environment and Climate Change Canada in 2012–2016, in the program of the Ministry of Environment, Conservation and Parks in collaboration with the Ontario Ministry of Agriculture and Rural Affairs in 2015–2018 and in the monitoring conducted by Metcalfe et al., 2018 in 2016.
[3] Sampling site is outside the watershed boundary.

Table 9 Summary of investigative monitoring conducted by Bayer CropSciences in the Sturgeon Creek watershed of Ontario between 2017 and 2019

Year	Site	Type of waterbody	Number of Samples	Average[1] (Standard Deviation) (µg/L)	Median (µg/L)	Maximum (µg/L)
2017	**Sites within 2 km downstream of greenhouses**					
	Main Sturgeon Creek site[2]	Creek	13	0.379 (0.319)	0.257	0.985
	SC3	Creek	13	0.685 (1.03)	0.222	3.04
	SC4	Creek	9	0.433 (0.425)	0.21	1.28
	Sites not within 2 km downstream of greenhouses					
	SC2	Drainage ditch	8	0.01 (0.009)	0.009	0.03
	LE1[3]	Drainage ditch	13	0.062 (0.04)	0.049	0.154
2018	**Sites within 2 km downstream of greenhouses**					
	Main Sturgeon Creek site[2]	Creek	22	0.189 (0.14)	0.142	0.476
	SC3	Creek	22	0.213 (0.254)	0.146	1.19
	SC4	Creek	19	0.19 (0.227)	0.082	0.888
	SC5	Creek	21	0.273 (0.389)	0.105	1.7
	SC6	Drainage ditch	9	0.007 (0.004)	0.006	0.015
	Sites not within 2 km downstream of greenhouses					
	LE1[3]	Drainage ditch	13	0.016 (0.014)	0.012	0.062
2019	**Sites within 2 km downstream of greenhouses**					
	Main Sturgeon Creek site[2]	Creek	20	0.319 (0.681)	0.062	2.5
	SC3	Creek	20	0.111 (0.104)	0.089	0.387
	SC4	Creek	20	0.152 (0.433)	0.039	1.98
	SC6	Drainage ditch	20	0.003 (0.004)	0.001	0.018
	SC8	Creek	20	0.219 (0.732)	0.009	3.19
	SC9	Drainage ditch	19	0.012 (0.008)	0.011	0.03
	Sites not within 2 km downstream of greenhouses					
	LE1[3]	Drainage ditch	19	0.014 (0.007)	0.013	0.028

[1] Average concentrations presented here are those for all the samples collected in a given year.

[2] The main Sturgeon Creek site is the same location used in the monitoring program by Environment and Climate Change Canada in 2012–2016.
[3] Sampling site is outside the watershed boundary.

Table 10 Summary of the 11 site-years from 8 sites (7 watersheds) with peak concentrations of imidacloprid exceeding the acute HC_5 of 0.54 µg/L in the Atlantic Region, Quebec, Ontario and British Columbia, excluding the sites in the Lebo Drain and Sturgeon Creek watersheds influenced by releases of imidacloprid from greenhouses

Waterbody	Watershed size in km^2 (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Number of samples exceeding the acute effects metric of 0.54 µg/L	Maximum concentration, in µg/L	Maximum risk quotient[1] calculated using acute effects metric of 0.54 µg/L[2]	Comments
Big Creek, Ontario (PMRA# 2523839, 2703534, 2712893, 2834287, 3032989)	55 (90%)	Corn (15%), soybean (60%)	1 out of 3 2016	9	Range from the samples exceeding the endpoint: 0.67–5.1	Range from the samples exceeding the endpoint: 1.2–9.4	Nine samples collected between mid-June and mid-October 2016 exceeded the endpoint. Two of the nine samples exceeding the endpoint are maximums observed during wet events.
North Creek, Ontario (PMRA# 2712893, 3032989, 3070837)	36.5 (70%)	Soybean (40%), corn (10%)	2 out of 3 2015, 2016	2015: 1 2016: 1	2015: 2.3 2016: 1.4	2015: 4.3 2016: 2.6	The concentrations exceeded the acute effects metric in one sample collected in May 2015 and one sample collected in October 2016. For all three years of sampling, an increase in concentration is observed in October, likely post-harvest.
Gibeault-Delisle Creek, Quebec (PMRA# 2035772, 2821394)	12 (85%)	Potato (21%), vegetable (21%), corn (17%), soybean (17%)	2 out of 4 2006, 2013	2006: 1 2013: 2	2006: 7.77 2013: Range from the samples exceeding the endpoint: 0.54–4	2006: 14 2013: Range from the samples exceeding the endpoint: 1.0–7.4	In 2013, two non-consecutive samples collected within seven days in May had concentrations equal to or exceeding the acute effects metric.

Waterbody	Watershed size in km^2 (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Number of samples exceeding the acute effects metric of 0.54 µg/L	Maximum concentration, in µg/L	Maximum risk quotient[1] calculated using acute effects metric of 0.54 µg/L[2]	Comments
Rousse Creek, Quebec (PMRA# 2523837, 2544468, 2821394, 2840206, 2929764)	18 (60%)	Vegetable (18%), orchard (12%), corn (12%), soybean (12%)	1 out of 5 2015	1	4.3	8	Only one out of 129 samples collected every two to three days between May and August over five years exceeded the acute 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%) [These sites were not receiving input from greenhouses.]	LD4 1 out of 2 2017	2	Range from the samples exceeding the endpoint: 0.609–1.086	Range from the samples exceeding the endpoint: 1.1–2.0	Available use and rate information for imidacloprid on tomatoes, soybeans and wheat in this watershed suggest that use on tomatoes may be a greater contributor to the concentrations measured in water than use on wheat or soybeans.
			LD6 1 out of 2 2017	1	0.733	1.4	
Nicomekl River, British Columbia (PMRA# 2842180, 3168173) Upstream site	Total agricultural land in the sampled area of the watershed: 30.2	Grass, alfalfa and forage (78%), berries (13%), nursery (4%)	2 out of 2 2017, 2018	2017: 1 2018: 1	2017: 0.74 2018: 0.574	2017: 1.4 2018: 1.1	Concentrations of imidacloprid at the downstream site were lower than at the upstream site, suggesting that there is a source of imidacloprid upstream of the upstream site.
Saint-Pierre Lake (station 4) (PMRA# 2929764)	The entire watershed is 990,000, but the area of the portion in Quebec was not determined.	Corn, soybean, wheat, potato, urban (percentages not determined)	1 out of 2 2018	1	0.57	1.1	Input would likely be from the southern shore of the Lake as the channel separates the sources of water from the North and South shore. Southern shore tributaries include Richelieu River, Yamaska Rivers, Saint-François and Nicolet Rivers (PMRA# 3200092).

[1] Risk Quotient = maximum concentration for the site-year ÷ acute effects metric
[2] The acute effects metric for freshwater invertebrates is an HC_5 of 0.54 µg/L from an acute freshwater invertebrate species sensitivity distribution; see Section 3.3.3.1 Revisions to Imidacloprid Effects Metrics)

Table 11 Summary of the 17 site-years from 11 sites (8 watersheds) with 28-day moving average concentrations of imidacloprid exceeding the mesocosm NOEC of 0.16 µg/L in the Atlantic Region, Quebec, Ontario and British Columbia, excluding the sites in the Lebo Drain and Sturgeon Creek watersheds influenced by releases of imidacloprid from greenhouses

Waterbody	Watershed size in km^2 (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-d (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[1] calculated using mesocosm NOEC of 0.16 µg/L and LOEC of 0.38 µg/L[2]	Comments
Lebo Drain, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2818733, 2834287, 2936038, 2945668, 3050884, 3070884, 3157906) [4 sites with minimal or no potential for input from greenhouses; 6 site-years]	25.9 (86%)	Soybean (40%), corn (20%), cereals (9%), tomato (11%), greenhouse (3%) [These sites had minimal or no potential to receive input from greenhouses.]	LD3 1 out of 1 2017	0.2758	28 d (3)	NOEC: 1.7 LOEC: 0.7	
			LD4 1 out of 2 2017	0.6456	28 d (3)	NOEC: 4.0 LOEC: 1.7	
			LD6 1 out of 2 2017	0.5264	29 d (3)	NOEC: 3.3 LOEC: 1.4	
Big Creek, Ontario (PMRA# 2523839, 2703534, 2712893, 2834287, 3032989)	55 (90%)	Corn (15%), soybean (60%)	1 out of 3 2016	2.685	22 d (2)	NOEC: 17 LOEC: 7.1	In 2016, all 13 bi-weekly samples collected between June and October had concentrations well above the chronic effects metric. All samples collected in 2012 and 2015 had concentrations well

Waterbody	Watershed size in km^2 (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-d (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[1] calculated using mesocosm NOEC of 0.16 µg/L and LOEC of 0.38 µg/L[2]	Comments
							below the chronic effects metric.
McKillop Drain, Ontario (PMRA# 2945668, 3070884, 3157906)	45 (66%)	Corn (28%), soybean (33%)	1 out of 4 2017	0.196	29 d (2)	NOEC: 1.2 LOEC: 0.5	In 2017, only one of the eight monthly samples collected between April and November had concentrations exceeding the chronic effects metric. Only one other sample in the four years of sampling had concentrations above the chronic effects metric, in 2015.
North Creek, Ontario (PMRA# 2712893, 3032989, 3070837)	36.5 (70%)	Soybean (40%), corn (10%)	2 out of 3 2015, 2016	2015: 0.8253 2016: 0.4683	2015: 24 d (3) 2016: 31 d (3)	2015: NOEC:5.2 LOEC: 2.2 2016: NOEC: 2.9 LOEC: 1.2	In 2015, the maximum 28-day average is influenced by one sample with a high concentration, in May. For all three years of sampling, an increase in concentration is observed in October, likely post-harvest.
Gibeault-Delisle Creek, Quebec (PMRA# 2035772, 2821394)	12 (85%)	Potato (21%), vegetable (21%), corn (17%), soybean (17%)	3 out of 4 2006, 2013, 2014	2006: 2.768 2013: 0.597 2014:0.2523	2006: 28 d (3) 2013: 28 d (7) 2014: 29 d (9)	2006: NOEC: 17 LOEC: 7.3 2013: NOEC: 3.7 LOEC: 1.6 2014: NOEC: 1.6	In 2006, four out of six samples collected between May and August had imidacloprid concentrations near or exceeding the chronic effects metric. In 2013, the maximum average is influenced by

Waterbody	Watershed size in km² (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-d (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[1] calculated using mesocosm NOEC of 0.16 µg/L and LOEC of 0.38 µg/L[2]	Comments
						LOEC: 0.7	two non-consecutive samples collected within seven days in May. In 2014, five consecutive samples collected within 14 days had concentrations exceeding the chronic effects metric. The maximum average is influenced by 2 non-consecutive samples collected within 7 days; only 1 other sample in 2013 was above the chronic effects metric.
Rousse Creek, Quebec (PMRA# 2523837, 2544468, 2821394, 2840206, 2929764)	18 (60%)	Vegetable (18%), orchard (12%), corn (12%), soybean (12%)	1 out of 5 2015	0.7102	28 d (9)	NOEC: 4.4 LOEC: 1.9	In 2015, ten out of 13 samples collected between May 19 and June 30 had concentrations equal to or exceeding the chronic effects metric. Out of the 100 samples collected during the other four years of sampling, only one sample in 2011 and one sample in 2018 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-d (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[1] calculated using mesocosm NOEC of 0.16 µg/L and LOEC of 0.38 µg/L[2]	Comments
Two Mile Creek, Ontario (PMRA# 2523839, 2532563, 2681876, 2703534, 2834287)	24.4 (65%)	Orchard/vineyard (59%)	3 out of 5 2012, 2013, 2014	2012: 0.1997 2013: 0.1951 2014: 0.262	2012: 28 d (3) 2013: 28 d (2) 2014: 29 d (3)	2012: NOEC: 1.2 LOEC: 0.5 2013: NOEC: 1.2 LOEC: 0.5 2014: NOEC: 1.6 LOEC: 0.7	In 2012, three consecutive bi-weekly samples collected between April 18 and May 16 had concentrations near or exceeding the chronic effects metric. In 2013, only one out of 14 samples had imidacloprid concentrations exceeding the chronic effects metric, in November. In 2014, two consecutive bi-weekly samples in May had concentrations above the chronic effects metric; one sample in July, November and December also had concentrations exceeding the chronic effects metric. No 28-day averages exceeded the chronic effects metric in 2015 or 2016.
Nicomekl River, British Columbia (PMRA# 2842180, 3168173) [2 sites; 4 site-years]	**Upstream site**						In 2017, two consecutive bi-weekly samples in June, and also in September were above the chronic effects metric, leading to 28-day
	Total agricultural land in the sampled area of the	Grass/alfalfa/forage (78%), berries (13%), nursery (4%)	2 out of 2 2017, 2018	2017: 0.3267 2018: 0.2969	2017: 27 d (3) 2018: 29 d (3)	2017: NOEC: 2.0 LOEC: 0.9 2018: NOEC:	

Waterbody	Watershed size in km^2 (Percent cropped)	Main crops	Years exceeding compared to years of monitoring	Maximum 28-d (approx.) moving average, in µg/L	Timeframe (Number of values used to calculate the moving average)	Maximum risk quotient[1] calculated using mesocosm NOEC of 0.16 µg/L and LOEC of 0.38 µg/L[2]	Comments
	watershed: 30.2					1.9 LOEC: 0.8	averages above the chronic effects metric at the upstream site (but not the downstream site). In 2018, two or three consecutive samples in May were above the chronic effects metric, leading to 28-day averages above the chronic effects metric at both the upstream and downstream sites. The upstream site had higher concentrations than the downstream site, indicating a likely source of imidacloprid near or upstream of the upstream site.
	Downstream site						
	Total agricultural land in the sampled area of the watershed: 16.3	Berries (44%), potato and vegetable (26%), grass/alfalfa/forage (19%), corn (8%)	1 out of 2 2018	0.2773	29 d (3)	NOEC: 1.7 LOEC: 0.7	

NOEC = no observable effect concentration; LOEC = lowest obsersable effect concentration; ECCC = Environment and Climate Change Canada; POCIS = polar organic chemical integrative samplers; MECP = Ministry of the Environment, Conservation and Parks; OMAFRA = Ontario Ministry of Agriculture, Food and Rural Affairs

[1] Risk Quotient = maximum 28-day average concentration for the site-year ÷ chronic effects metric

[2] The chronic effects metric for freshwater invertebrates is a 28-day time-weighted average mesocosm NOEC of 0.16 µg/L based on significant effects on *Cloeon dipterum* abundance (adult and larvae) observed at 0.38 µg/L (LOEC); see Section 3.3.3.1 Revisions to Imidacloprid Effects Metrics).

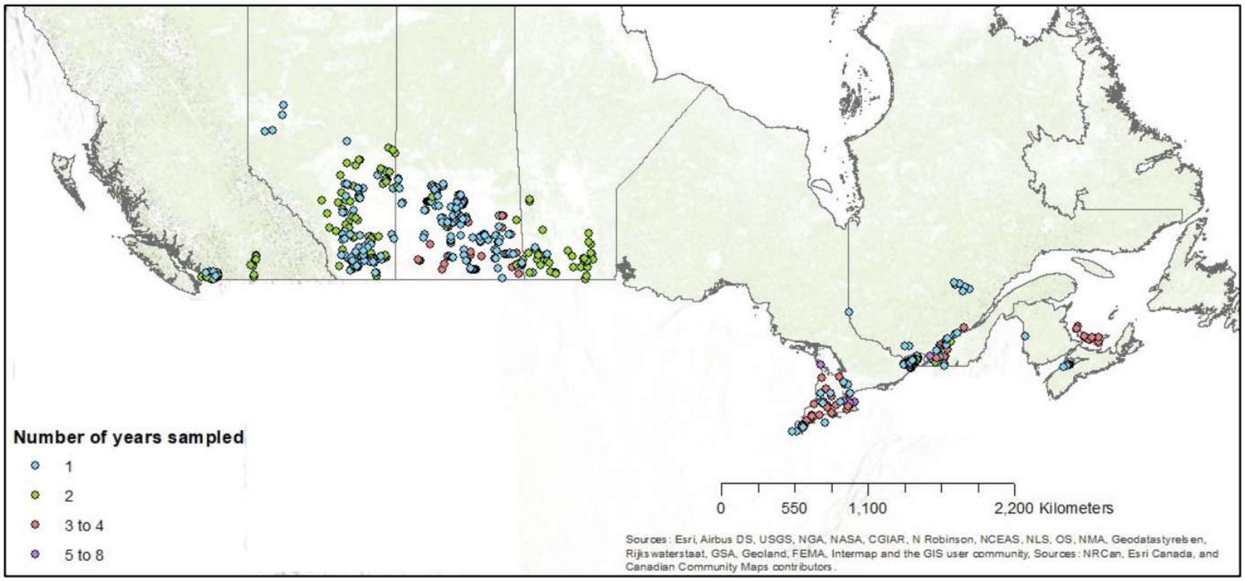


Figure 1 Location of imidacloprid water monitoring sites in Canada between 2005 and 2019, identified based on the number of years of sampling conducted at each site

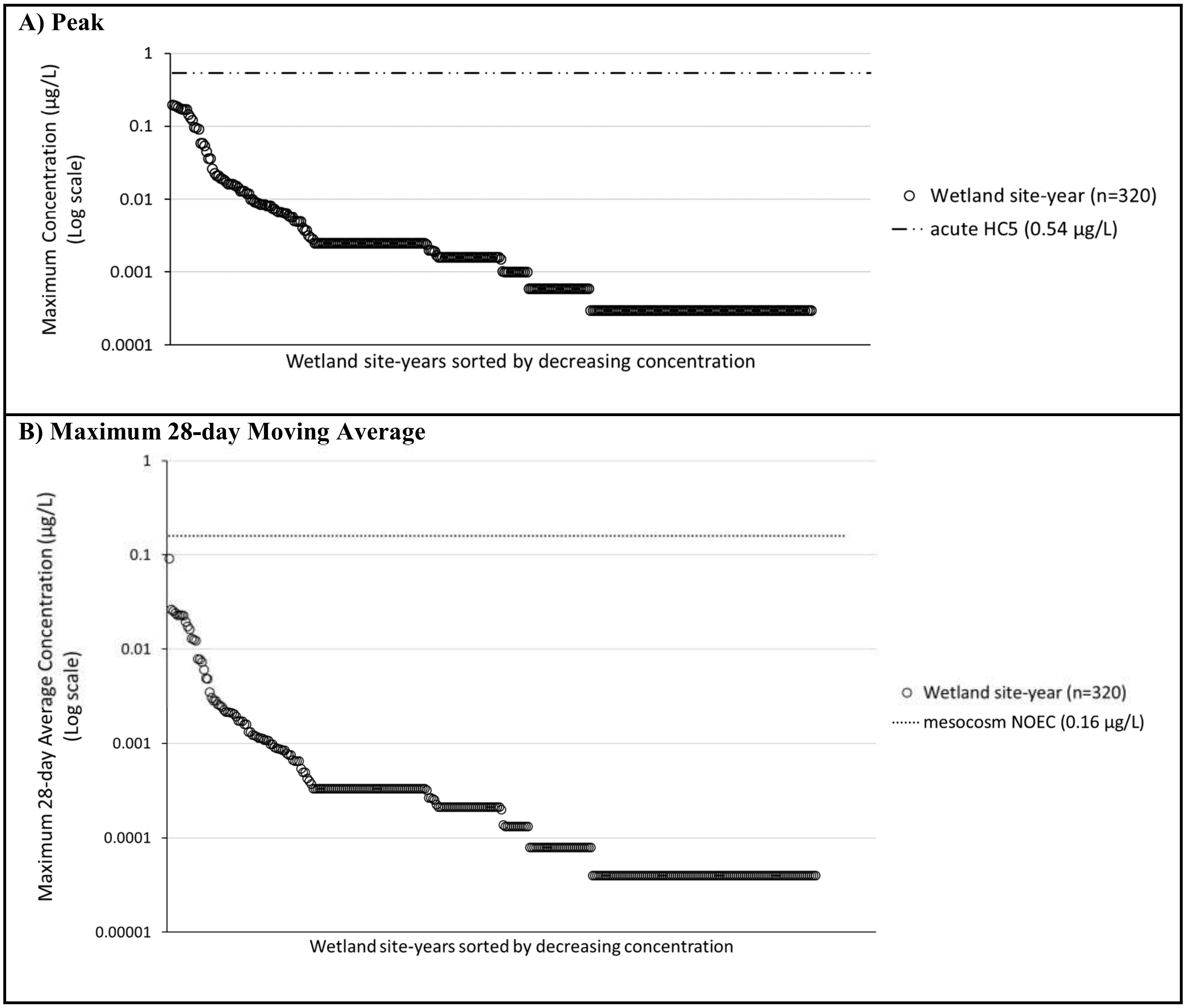
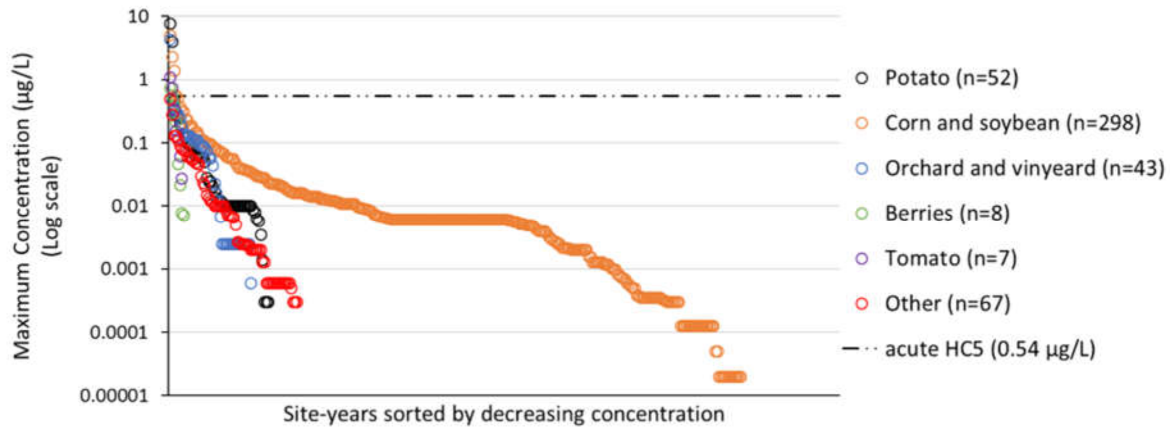


Figure 2 A) Peak and B) maximum 28-day moving average concentrations (µg/L) of imidaloprid measured in Prairie wetlands between 2014 and 2019 and comparison with acute and chronic effects metrics for aquatic invertebrates. The black circles represent the concentrations for each of 320 site-years of monitoring, sorted by decreasing concentration. The 28-day average concentrations were calculated using observed data only in wetlands with peak concentrations exceeding the chronic effects metric; for the other sites, the 28-day average concentration was estimated using the peak concentration and an average DT_{50} of 9.6 days assuming dissipation followed single first-order kinetics

A) Peak



B) Expanded view

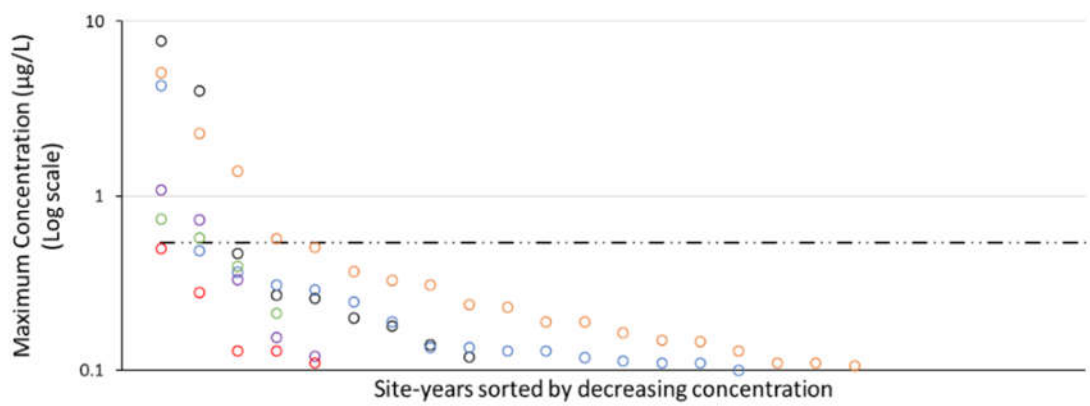
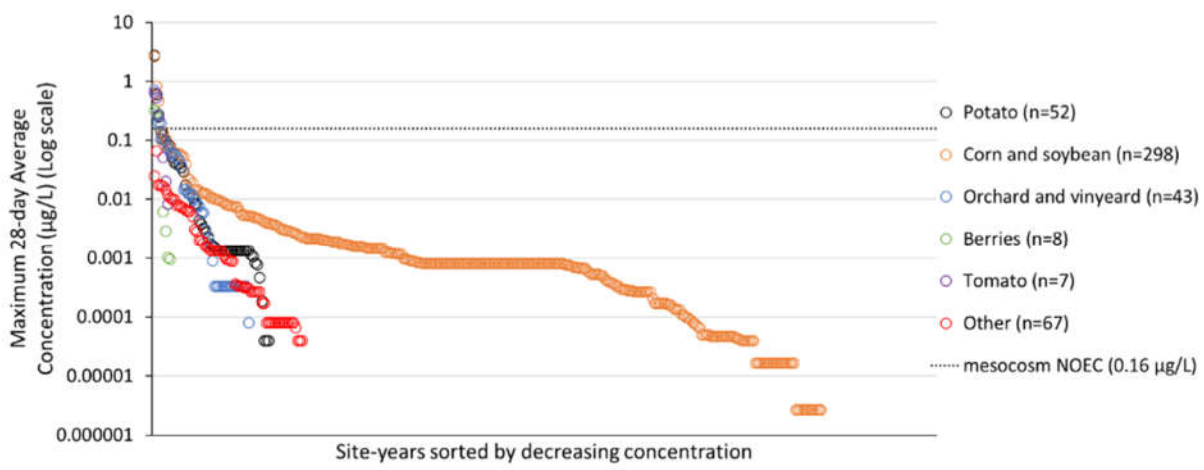


Figure 3 A) Peak concentrations (µg/L) of imidacloprid measured in 273 sites (total of 475 site-years of monitoring) in the Atlantic Region, Quebec, Ontario and British Columbia sampled between 2005 and 2019, by main crops grown in the watershed, and comparison with the acute effects metric for aquatic invertebrates. Panel B) shows the expanded view of site-years with peak concentrations above 0.1 µg/L. These results exclude 18 sites (49 site-years) from the Lebo Drain and Sturgeon Creek watersheds influenced by the release of imidacloprid from greenhouses. Each circle represents a site-year of monitoring, and they are sorted by decreasing concentration

A) Maximum 28-day Moving Average



B) Expanded view

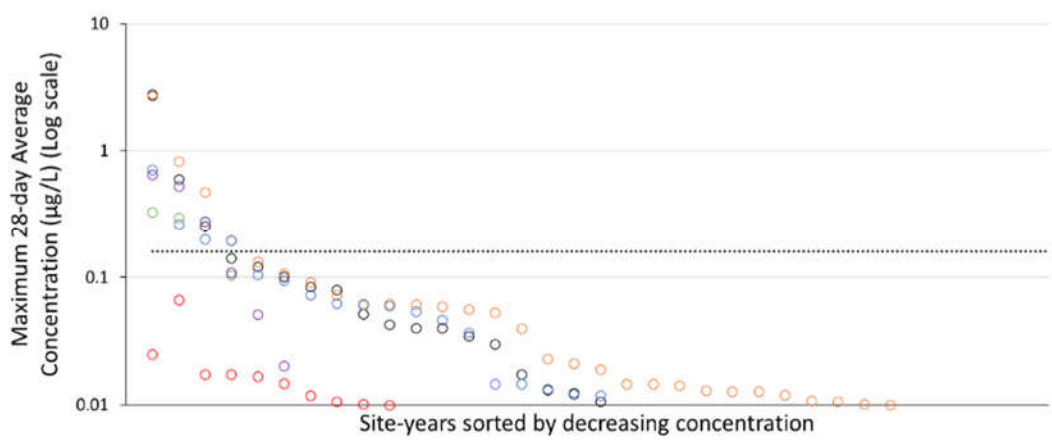


Figure 4 A) Maximum 28-day moving average concentrations (µg/L) of imidacloprid measured in 273 sites (total of 475 site-years of monitoring) in the Atlantic Region, Quebec, Ontario and British Columbia sampled between 2005 and 2019, by main crops grown in the watershed, and comparison with the chronic effects metric for aquatic invertebrates. Panel B) shows the expanded view of site-years with maximum 28-day moving concentrations above 0.01 µg/L. These results exclude 18 sites (49 site-years) from the Lebo Drain and Sturgeon Creek watersheds influenced by the release of imidacloprid from greenhouses. 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 in sites with peak concentrations exceeding the chronic effects metric; for the other sites, the 28-day average concentration was estimated using the peak concentration and an average DT_{50} of 9.6 days assuming dissipation followed single first-order kinetics

Appendix XI Label amendments for products containing imidacloprid

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements given below.

Remove any instructions and/or references from the label for all uses being cancelled, and update the directions for use instructions for any uses with mitigation requirements, as outlined in this re-evaluation decision. This includes but is not limited to application rates, maximum number of applications per year, and re-application intervals.

CANCELLED USES and associated instructions TO BE REMOVED FROM PRODUCT LABELS:

- Seed treatment for corn flea beetle on field and sweet corn.
- Seed treatment: direct field seeding of brassica vegetables (such as broccoli and cabbage) and leafy vegetables (such as lettuce) and listed pests.
- In-furrow application on brassica, leafy, and root and tuber vegetables (including potato) and listed pests.
- In-furrow application on tobacco and listed pests.
- Soil drench application (except European chafer on ginseng) on brassica, leafy, and root and tuber vegetables (including potato, excluding sugar beet) and listed pests.
- Field application of tray plug drench application on leafy vegetables and listed pests.
- Foliar and granular application on turf and listed pests.
- Foliar application on lowbush blueberry and listed pests.

Cancelled uses with an extended phase out schedule:

The following table must be added to the PRINCIPAL DISPLAY PANEL on the label:

Cancellation date for cancelled uses with and extended phase out period

Crop	Pest(s)	Last Date of Use
Ginseng (soil drench)	European chafer	19 May 2025

REQUIRED LABEL AMENDMENTS FOR ALL PRODUCTS, WHERE APPLICABLE:

- Labels are to state the product rates. Any label changes that are required to convert active ingredient rates to product rates must be made by the registrants, and must factor in any formulation-specific calculations, such as specific gravity.
- Labels with structural uses must be amended to adopt the revised definitions for application types outlined in the 2020 PMRA publication PMRA Guidance Document, *Structural Pest Control Products: Label Updates*.

Label amendments related to the human health risk assessment

For products with uses for continued registration, the following label amendments are required:

Label amendments for technical class products containing imidacloprid

The hazard statement on the primary display panel of the technical product for PCP Registration Number 28936 must be revised from WARNING ‑ POISON to DANGER ‑ POISON.

Label amendments for commercial class products containing imidacloprid

1. Personal protective equipment and engineering controls
Label statements must be amended (or added) to include the following directions to the appropriate labels, unless the current label mitigation is more restrictive:

Commercial seed treatment for canola, mustard:
"For use in commercial seed treatment facilities (and by mobile treaters) with closed-transfer, including closed mixing, loading, calibrating, and closed-treatment equipment only. No open transfer is permitted."

"During mixing, loading, application, bagging, sewing and stacking, wear coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear."

Commercial seed treatment for corn:
"For use in commercial seed treatment facilities (and by mobile treaters) with closed-transfer, including closed mixing, loading, calibrating, and closed-treatment equipment only. No open transfer is permitted."
"During mixing, loading, application, bagging, sewing and stacking, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear."

All other seed treatment and potato seed piece uses:
"When treating seeds, handling and planting treated seeds, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear."

Commercial seed treatment for all seed types:
"When cleaning seed treatment equipment, wear chemical-resistant coveralls over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides."

Planting of commercially treated seed:
Treated seed bags must be labelled or tagged with the following instructions for workers planting treated seed.

"Closed cabs must be used for planting commercially treated and bagged seeds."
"Do not plant treated seeds by hand."

2. Restricted-entry intervals:

The following label wording must be added to commercial end-use products with crop uses other than seed or potato seed piece treatment, if not already specified:

"DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours."

3. Use precautions

The following label wording must be added to commercial end-use products with crop uses other than seed or potato seed piece treatment:

"Apply only when the potential for drift to areas of human habitation and human activity (other than golf courses) such as parks, school grounds, and playing fields, is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

The following Label Amendment is required for Temprid SC (Registration Number 32524):
In the product label, under PRECAUTIONS, replace:

"Ventilate treated areas either by opening windows and doors or through use of air exchange/ventilation systems confirmed to be operational. Use fans where required to aid in the circulation of air."

With:

"Ventilate treated areas during and after application either by opening windows and doors or using fans, where required, to aid in the circulation of air. Air exchange/ventilation systems confirmed to be operational may also be used. Ensure ventilation during application does not result in spray drifting onto non-target surfaces."

4. Direction for use

For commercial products that are not registered for use under Use Site Category 5 and 6 (greenhouse food and non-food crops) and that include crops that may be found in greenhouses (for example: cucumber, tomato), add the following statement:

"For outdoor use only."

Label amendments for domestic class products containing imidacloprid
The product labels for four spot-on companion animal products containing imidacloprid (PCP Registration Numbers 33626, 33627, 33628, 33629) are required to be updated according to the label amendments outlined in the 2019 PMRA Guidance Document, Label Improvements for Spot-on Pesticides Used on Companion Animals.

Label amendments related to the environmental risk assessment

1. **Label amendments for technical class products containing imidacloprid**

The following statements are to be added to the "ENVIRONMENTAL PRECAUTIONS" section of the labels:

Toxic to aquatic organisms.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

The following statements are required under the "Disposal" Section of the labels:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer and the provincial regulatory agency.

2. **Label amendments for commercial class products containing imidacloprid**

a. **Directions for use:**

The maximum application rates, maximum number of applications and application timing on the label must be updated to match the information specified in Table 1 for each crop currently registered on the label and granted continued registration.

Table 1 Use directions changes required for imidacloprid.

Crop	Method of application	Current rate	New requirement
All crops	Seed treatment	Not applicable	Prohibition of broadcast seeding Prohibition of disposal of treated seeds by over-seeding in headlands
Corn (field, seed, sweet)	Seed treatment	Field corn including seed production: 13–48 g a.i./80 000 seeds Field corn for seed production only: 48 g a.i./80 000 seeds Sweet corn: 67.2–250 g a.i./100 kg seed	Field corn (including field corn for seed production): 13 g a.i./80 000 seeds Sweet corn: 67.2 g a.i/100 kg seed
Soybeans	Seed treatment	62.5–125 g a.i./100 kg seed (equivalent to 35.6–157.5 g a.i./ha)	62.5 g a.i./100 kg seed

Crop	Method of application	Current rate	New requirement
	Foliar	24.4–49 g a.i./ha, maximum three applications	24.4 g a.i./ha, one application only
Legumes/pulses (excluding soybean)	Foliar	48 g a.i./ha, maximum two applications	Excluding soybeans: 48 g a.i./ha, only one application
Brassica vegetables (such as broccoli and cabbage) and Leafy vegetables (such as lettuce)	Seed treatment	0.2–0.3 g a.i./1000 seeds (equivalent to 36.75–140 g a.i./ha, depending on crop)	Cancellation of direct seeding in field (Continued registration for transplants only)
Crop Sub-Group 1B Root vegetables (except sugarbeet), Crop Sub-Group 1D Tuberous and corm vegetables (except potato), Crop Group 2 Leaves of root and tuber vegetables, Crop Group 4A Leafy greens (except Brassica), Crop Sub-Group 4B cardoon, celery, Chinese celery, celtuce, Florence fennel, rhubarb and Swiss chard, Crop Group 5 Brassica (cole) leafy vegetables	In-furrow	86.6–520 g a.i./ha (depending on crop)	Maximum of 100 g a.i./ha Cancellation of use. The use on these crops is cancelled due to the maximum application rate being reduced to 100 g a.i./ha or because the maximum allowable rate will be exceeded based on the row spacing for these crops.
Crop Sub-Group 1B Root vegetables (except sugarbeet), Crop Sub-Group 1D Tuberous and corm vegetables (except potato), Crop Group 2 Leaves of root and tuber vegetables, Crop Group 4A Leafy greens (except Brassica), Crop Sub-Group 4B cardoon, celery, Chinese celery, celtuce, Florence fennel, rhubarb and Swiss chard, Crop Group 5 Brassica (cole) leafy vegetables	Soil drench (post-plant soil drench)	80–520 g a.i./ha (depending on crop)	Maximum of 86.6 g a.i./ha Cancellation of use. The use on these crops is cancelled due to the maximum application rate being reduced to 86.6 g a.i./ha or because the maximum allowable rate will be exceeded based on the row spacing for these crops.
Crop Sub-Group 1B Root vegetables (except sugarbeet and ginseng), Crop Sub-Group 1D Tuberous and corm vegetables (except potato and sweet potato), Crop Group 2 Leaves of root and tuber vegetables, globe artichokes, Crop Group 4A Leafy greens (except Brassica, Crop Group 5 Brassica (cole) Leafy vegetables, Crop Group 8: Fruiting vegetables, eggplant and tomato	Foliar	48 g a.i./ha, maximum two applications	48 g a.i./ha, one application only
Tomato, Crop Sub-Group 5A Head and stem brassica crop sub-group	Foliar	49 g a.i./ha (with deltamethrin), maximum three applications	49 g a.i./ha (with deltamethrin), one application only
Potato	In-furrow	1.8–2.9 g a.i./100 m of row (equivalent to 100–480 g a.i./ha)	Maximum of 100 g a.i./ha Cancellation of use. The in-furrow use on potato is cancelled because the maximum allowable rate will be exceeded based on the row spacing for potato.
	Soil drench	288 g a.i./ha	Cancellation of soil drench uses

Crop	Method of application	Current rate	New requirement
	Foliar	48 g a.i./ha, maximum two applications 49 g a.i./ha (with deltamethrin), maximum three applications	48 g a.i./ha, one application only 49 g a.i./ha (with deltamethrin), one application only
Lowbush blueberries	Foliar	42–84 g a.i./ha, maximum two applications, post-bloom 42 g a.i./ha (with deltamethrin), maximum three applications, post-bloom For woody berries, post-bloom application is only allowed with renovation (cutting back of old growth after harvest is required).	Cancellation
Tobacco	In-furrow	2.04 g a.i./100 m of row (equivalent to 113–453 g a.i./ha)	Cancellation
	Foliar	48 g a.i./ha, maximum two applications	48 g a.i./ha, one application only
Turf (home lawns, business and office complexes, shopping complexes, multi-family residential complexes, airports, cemeteries, parks, playgrounds, athletic fields, golf courses and sod farms	Granular	280 g a.i./ha. one application only	Cancellation
	Foliar	281.25 g a.i./ha, one application only	Cancellation

The following statements are to be added to the DIRECTIONS FOR USE section of all product labels:

> 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.

b. Spray buffer zone related label statements required for all applicable end-use products except PCP Reg. No. 29611:

Add to ENVIRONMENTAL PRECAUTIONS:

Toxic to aquatic organisms. Observe spray buffer zones specified under DIRECTIONS FOR USE.

Add to DIRECTIONS FOR USE:

Field sprayer application: 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.

DO NOT apply by air.

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) and estuarine/marine habitats.

Method of application	Crop	Spray Buffer Zones (metres) Required for the Protection of:			
		Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer	Crop Sub-Group 1B: Root vegetables (except sugarbeet), Crop sub-group 1D: Tuberous and corm vegetables (except potatoes) Crop group 2: Leaves of root and tuber vegetables, globe artichoke Crop group 4A: Leafy greens subgroup of leafy vegetables (except Brassica), Crop group 5: Brassica (cole) leafy vegetables, Crop group 6: Legume vegetables (except dry soybean), Crop group 8: Fruiting vegetables, eggplant, tomato, potato, tobacco	5	3	0	0
	Crop sub-group 13G: Berry and small fruit low growing berries, strawberry, peanut, herbs, grapes	10	5	0	0
	Hops	10	5	1	0
	Crop sub-group 13B: Bushberry (except lowbush blueberries)	15	10	1	0

Method of application	Crop		Spray Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Airblast	Crop sub-group 13F: Berry and small fruit vine excluding grapes	Early growth stage	30	20	0	0
		Late growth stage	20	15	0	0
	Blueberry: highbush, Crop Sub-Group 13A: Cane berries	Early growth stage	35	25	0	0
		Late growth stage	25	15	0	0
	Tree nuts plus pistachio: beechnut, brazil nut, butternut, cashew, filbert (hazelnut), hickory nut, macadamia nut (bush nut), pecan, pistachio, walnut [black and English (Persian)], hops	Early growth stage	30	25	1	0
		Late growth stage	25	15	1	0
	Christmas trees (USC 4)	Early growth stage	35	25	1	0
		Late growth stage	25	15	1	0
	Raspberry	Early growth stage	45	35	2	0
		Late growth stage	35	25	1	0

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 web site.

c. Spray buffer zone related label statements required for PCP Reg. No. 29611:

Add to ENVIRONMENTAL PRECAUTIONS:

Toxic to aquatic organisms and non-target terrestrial plants. Observe spray buffer zones specified under DIRECTIONS FOR USE.

Add to DIRECTIONS FOR USE:

Field sprayer 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 8 km/h at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Air-induction nozzles must be used for the ground application of this product. 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 8 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) medium-coarse classification. DO NOT apply under weather conditions of less than 50% relative humidity and temperatures greater than 20°C. 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 has 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 differ from the label recommendations for the ground application. 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 1-888-283-6847 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 50 litres per hectare.

Spray buffer zones

A spray buffer zone is NOT required for uses with hand-held application equipment permitted on this label.

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Spray Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:		Terrestrial Habitat:
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Soybean		1	1	10	5	0
	Potato, tomato, Crop sub-group 5A: head and stem brassica		1	1	20	10	0
Airblast	Highbush blueberry	Early growth stage	35	25	75	65	1
		Late growth stage	25	15	65	55	1
Aerial	Soybean, potato	Fixed wing	10	5	800	800	0
		Rotary wing	10	5	800	600	0

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 airblast application of 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 web site. Spray buffer zones for field sprayer or aerial applications CANNOT be modified using the Spray Buffer Zone Calculator.

d. Greenhouse use

The following statement is to be added in the DIRECTIONS FOR USE section of all product labels with greenhouse use:

DO NOT allow releases, effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Additional requirement for greenhouses using closed recirculation system (for example, closed chemigation): Only to be used in greenhouse facilities that have undergone a third-party audit that validates the facility’s closed recirculation systems and other measures are sufficient to prevent releases, effluent or runoff containing this product from entering lakes, streams, ponds, or other waters.

e. Environmental precautions

The following statements are to be added to the ENVIRONMENTAL PRECAUTIONS section of all product labels:

Toxic to small wild mammals.

Toxic to birds.

Toxic to certain beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). Minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site such as hedgerows and woodland.

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.

This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

For all product labels that are not exclusively seed treatments, the following statement is also to be added under ENVIRONMENTAL PRECAUTIONS:

Imidacloprid is persistent and may carry over. It is recommended that this product not be used in areas treated with any products containing imidacloprid during the previous season.

Greenhouse use

The following statement is to be added in the ENVIRONMENTAL PRECAUTIONS section of all product labels with greenhouse use:

> Greenhouse use: Toxic to bees and other beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). May harm bees and other beneficial arthropods, including those used in greenhouse production. Avoid application when bees or other beneficial arthropods are in the treatment area.

For seed treatment labels

Under ENVIRONMENTAL PRECAUTIONS, after hazard statements for birds and small wild mammals, add:

> Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.

Under labeling of treated seed

Delete:

> Dispose of all excess treated seed. Leftover treated seed may be double-sown around the headland or buried away from water sources in accordance with local requirements.

Add:

> Toxic to small wild mammals. Toxic to birds. Any spilled or exposed seeds must be incorporated into the soil or otherwise cleaned-up from the soil surface.
>
> Dispose of all excess treated seed. Leftover treated seed may be buried away from water sources in accordance with local requirements. Do not dispose of seed by double-sowing in headlands. Broadcast seeding is prohibited.

Appendix XII References considered following publication of PRVD2016-20

A. Information considered in the toxicology assessment

A.1 Additional information considered

Published information

PMRA Document Number	Reference
2788275	Human Neonicotinoids Exposure in Japan. Japanese Journal of Clinical Ecology, 23 (1): 14-24. 2014. DACO 4.8.
2788306	Neonicotinoid Insecticides Alter the Gene Expression Profile of Neuron-Enriched Cultures from Neonatal Rat Cerebellum. International Journal of Environmental Research and Public Health, 13 (10): 987-1014. 2016. DACO 4.8.
2788307	Effects of Neonicotinoid Pesticide Exposure on Human Health: A Systematic Review. Environmental Health Perspectives, 125 (2): 155-162. 2017. DACO 4.8.
2806309	Residential agricultural pesticide exposures and risk of selected congenital heart defects among offspring in the San Joaquin Valley of California. Environmental Research, 135: 133-138. 2014. DACO 4.8.
2806310	Residential Agricultural Pesticide Exposures and Risk of Neural Tube Defects and Orofacial Clefts Among Offspring in the San Joaquin Valley of California. American Journal of Epidemiology, 179 (6): 740-748. 2014. DACO 4.8.
2806311	Autism spectrum disorder, flea and tick medication, and adjustments for exposure misclassification: the CHARGE (Childhood Autism Risks from Genetics and Environment) case-control study. Environmental Health, 13 (1): 3. 2014. DACO 4.8.
2791516	Neurodevelopmental and Behavioural Study of Mice Following In Utero and Early Postnatal Exposure to Imidacloprid, a Neonicotinoid Pesticide. Leslie Dan Faculty of Pharmacy, University of Toronto. Presented at the 10th Annual Canadian Association for Neuroscience Meeting, Toronto. 2016. DACO 4.8.
2791517	Insecticide imidacloprid induces morphological and DNA damage through oxidative toxicity on the reproductive organs of developing male rats. Cell Biochemistry and Function, 30(6): 492-499. 2012. DACO 4.8.
2826010	Residential agricultural pesticide exposures and risks of selected birth defects among offspring in the San Joaquin Valley of California. Birth Defects Research (Part A) Clinical and Molecular Teratology, 106(1): 27-35. 2016. DACO 4.8.

B. Information considered in the updated occupational and non-occupational assessment

B.1 Registrant submitted studies/information

Unpublished information

PMRA Document Number	Reference
3129235	2020. Determination of Imidacloprid Transferable Residue from Turf Transferable Residue from Turf after Application of Merit 2F ® (240 g/L imidacloprid) in North America. Unpublished, DACO 5.9b
2638509	2016. Imidacloprid-Determination of Transferable Residues from Turf, DACO 5.9b

B.2 Additional information considered

Unpublished information

PMRA Document Number	Reference
3116354	2020. RE: Comment to the Imidacloprid Proposed Interim Registration Review Decision, Case Number 7605. EPA-HQ-OPP-2008-0844-1608, DACO 5.14

C. Information considered in the updated environmental assessment

C.1 Registrant submitted studies/information

C.1.1 Environmental fate and effects assessment

Published information

PMRA Document Number	Reference
2712665	Li, D., Z. Lan, Z. Yanning, H. Weizhi, F. Lei and J. Hongyun, 2013, Acute immobilization of four neonicotinoid insecticides to *Daphnia magna* Straus, Pesticide Science and Administration 34(6): 23–25, DACO: 9.3.2
2712687	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, Environmental Toxicology and Chemistry 36(2): 372–382, DACO: 9.3.4
2712688	Prosser, R.S., S.R. de Solla, E.A.M. Holman, R. Osborne, S.A. Robinson, A.J. Bartlett, F.J. Maisonneuve and P.L. Gillis, 2016, Sensitivity of the early-life stages of freshwater mollusks to neonicotinoid and butenolide insecticides, Environmental Pollution 218: 428–435, DACO: 9.3.4

PMRA Document Number	Reference
2712707	Van den Brink, P.J., J.M. Van Smeden, R.S. Bekele, W. Dierick, D.M. De Gelder, M. Noteboom and I. Roessink, 2016, Acute and chronic toxicity of neonicotinoids to nymphs of a mayfly species and some notes on seasonal differences, Environmental Toxicology and Chemistry 35: 128–133, DACO: 9.3.5

Unpublished information

PMRA Document Number	Reference
1155859	1991, Acute Toxicity of NTN 33893 to *Hyalella azteca* (101960;39442) (Imidacloprid/Admire), DACO: 9.3.1
1155896	1992, Assessment of the potential ecological and biological effects of NTN 33893 on aquatic ecosystems as measured in fiberglass pond systems (102600) (Imidacloprid/Admire), DACO: 9.5.3.1
1191040	1999, Field Monitoring of Birds, Mammals and Soil Invertebrates on Fields with Imidacloprid - Dressed Cereal Seeds in Great Britain, DACO: 9.9
1191041	1997, Field Monitoring for Evaluating Possible Risks to Wildlife Arising from the Use of Gaucho as a Seed Treatment for Winter Cereals, DACO: 9.9
2142729	2009, Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds, DACO: 8.6
2142783	2009, Residues in arthropod prey of birds and mammals after the application of Confidor SL 200 (active substance imidacloprid) in a german pome fruit orchard, DACO: 9.9
2523501	2001, Influence of imidacloprid (tech.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system, DACO: 9.3.4
2530782	2015, Criteria for evaluating mesocosm studies of aquatic invertebrates exposed to imidacloprid, DACO: 9.9
2610253	2016, Aquatic Invertebrate Assessment of Imidacloprid - Final Report, DACO: 8.6
2693971	2010, *Chironomus riparius* 28-day chronic toxicity test with imidacloprid SC 350H G in a water-sediment system using spiked water, DACO: 9.3.4
2693972	2009, *Chironomus riparius* 28-day chronic toxicity test with imidacloprid OD 200 A G in a water-sediment system using spiked water, DACO: 9.3.4
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
2744282	2016, Avian effects data summary and screening level risk characterization for imidacloprid and clothianidin seed treatment uses, DACO: 9.9

PMRA Document Number	Reference
2744286	2017, Population trends in guilds of birds across North America, Phase 2, Objective 1, DACO: 9.9

C.1.2 Water monitoring assessment

Unpublished information

PMRA Document Number	Reference
2818731	2017, Additional Ancillary Data for Ontario Water Monitoring Studies Conducted from 2012 to 2016, DACO: 8.6.1,8.6.2
2818733	2017, Additional Ancillary Data for Ontario Water Monitoring Studies Conducted from 2012 to 2016, DACO: 8.6.1,8.6.2
2818734	2017, Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2818735	2017, Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada, DACO: 8.6.1,8.6.2
2870577	2018, Relevancy of Monitoring Sites for Aquatic Invertebrate Risk Assessment Classification of 2014 Water Sampling Locations (Morrissey), DACO: 8.6
2870578	2018, Relevancy of Monitoring Sites for Aquatic Invertebrate Risk Assessment Classification of 2014 Water Sampling Locations (Morrissey), DACO: 8.6
2921987	2018, Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada - Spring 2018 Update, 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
2921989	2018, 2018 Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada, 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
2935271	2018, Syngenta Canada Response to PMRA PSRD2018-02 – Thiamethoxam, DACO: 8.1
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
2936037	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

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
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
3025394	2019, Thiamethoxam Interim Data – 2019 Prairie Wetland and Ontario Watersheds Water Monitoring Studies, DACO: 8.1
3050879	2019, 2019 Imidacloprid Surface Water Monitoring Study in Saskatchewan, Canada - Final Report, DACO: 8.6
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
3050883	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
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
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

C.2 Additional information considered

C.2.1 Environmental fate and effects assessment

Published information

PMRA Document Number	Reference
2541668	Song, M.Y., J.D. Stark and J.J. Brown, 1997, Comparative toxicity of four insecticides, including imidacloprid and tebufenozide, to four aquatic arthropods. Environmental Toxicology and Chemistry 16(12): 2494–2500, DACO: 9.3.2

PMRA Document Number	Reference
2541826	Agatz, A., T.A. Cole, T.G. Preuss, E. Zimmer and C.D. Brown, 2013, Feeding inhibition explains effects of imidacloprid on the growth, maturation, reproduction, and survival of *Daphnia magna*. Environmental Science and Technology 47: 2909–2917, DACO: 9.3.3
2541831	Sánchez-Bayo, F. and K. Goka, 2006, Influence of light in acute toxicity bioassays of imidacloprid and zinc pyrithione to zooplankton crustaceans. Aquatic Toxicology 78: 262–271, DACO: 9.3.4
2541841	Kreutzweiser, D., K. Good, D. Chartrand, T. Scarr and D. Thompson, 2007, Non-target effects on aquatic decomposer organisms of imidacloprid as a systemic insecticide to control emerald ash borer in riparian trees. Ecotoxicology and Environmental Safety 68: 315–325, DACO: 9.3.5
2544383	Kreutzweiser, D.P., K.P. Good, D.T. Chartrand, T.A. Scarr and D.G. Thompson, 2008, Toxicity of the systemic insecticide, imidacloprid, to forest stream insects and microbial communities. Bulletin of Environmental Contamination and Toxicology 80: 211–214, DACO: 9.3.5
2544385	Roessink, I., L.B. Merga, H.J. Zweers and P.J. Van den Brink, 2013, The neonicotinoid imidacloprid shows high chronic toxicity to mayfly nymphs. Environmental Toxicology and Chemistry 32(5): 1096–1100, DACO: 9.3.5
2544389	Pestana, J.L.T., A.C. Alexander, J.M. Culp, D.J. Baird, A.J. Cessna and A.M.V.M. Soares, 2009, Structural and functional responses of benthic invertebrates to imidacloprid in outdoor stream mesocosms. Environmental Pollution 157: 2328–2334, DACO: 9.3.6
2544391	Colombo, V., S. Mohr, R. Berghahn and V.J. Pettigrove, 2013, Structural changes in a macrozoobenthos assemblage after imidacloprid pulses in aquatic field-based microcosms. Archives of Environmental Contamination and Toxicology 65: 683–692, DACO: 9.3.6
2544392	Jinguji, H., D. Quoc Thuyet, T. Uéda and H. Watanabe, 2013, Effect of imidacloprid and fipronil pesticide application on *Sympetrum infuscatum* (Libellulidae: Odonata) larvae and adults. Paddy Water and Environment 11: 277–284, DACO: 9.3.6
2544539	Hayasaka, D., T. Korenaga, K. Suzuki, F. Saito, F. Sánchez-Bayo and K. Goka, 2012, Cumulative ecological impacts of two successive annual treatments of imidacloprid and fipronil on aquatic communities of paddy mesocosms. Ecotoxicology and Environmental Safety 80: 355–362, DACO: 9.3.6,9.5.5
2544541	Osterberg, J.S., K.M. Darnell, T.M. Blickley, J.A. Romano and D. Rittschof, 2012, Acute toxicity and sub-lethal effects of common pesticides in post-larval and juvenile blue crabs, *Callinectes sapidus*. Journal of Experimental Marine Biology and Ecology 424–425: 5–14, DACO: 9.4.2,9.4.6

PMRA Document Number	Reference
2545400	Mohr, S., R. Berghahn, R. Schmiediche, V. Hübner, S. Loth, M. Feibicke, W. Mailahn and J. Wogram, 2012, Macroinvertebrate community response to repeated short-term pulses of the insecticide imidacloprid. Aquatic Toxicology 110–111: 25–36, DACO: 9.9
2545402	Alexander, A.C., K.S. Heard and J.M. Culp, 2008, Emergent body size of mayfly survivors. Freshwater Biology 53: 171–180, DACO: 9.9
2545404	Böttger, R., M. Feibicke, J. Schaller and G. Dudel, 2013, Effects of low-dosed imidacloprid pulses on the functional role of the caged amphipod *Gammarus roeseli* in stream mesocosms. Ecotoxicology and Environmental Safety 93: 93–100, DACO: 9.9
2545413	European Food Safety Authority, 2014, Peer Review Report on Imidacloprid (Art. 21), DACO: 12.5.9
2574054	Sánchez-Bayo, F. and K. Goka, 2006, Ecological effects of the insecticide imidacloprid and a pollutant from antidandruff shampoo in experimental rice fields. Environmental Toxicology and Chemistry 25(6): 1677–1687, DACO: 9.3.6
2574059	Smith, G.K., 2006, Risks to Birds from Pesticide-treated Seed and the Possible Role of Ultraviolet Reflection in Seed Colour Preferences and Repellent Strategies. Masters thesis, Department of Biology, Carleton University, Ottawa, Ontario, Canada, DACO: 9.6.6
2681691	Avery M.L., D.G. Decker and D.L. Fischer, 1994, Crop protection, cage and flight pen evaluation of avian repellency and hazard associated with imidacloprid-treated rice seed. Crop Protection 13(7): 535–540, DACO: 9.9
2722291	Yokoyama, A., K. Ohtsu, T. Iwafune, T. Nagai, S. Ishihara, Y. Kobara, T. Horio and S. Endo, 2009, A useful new insecticide bioassay using first-instar larvae of a net-spinning caddisfly, *Cheumatopsyche brevilineata* (Trichoptera: Hydropsychidae), Journal of Pesticide Science 34(1): 13–20, 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. Aquatic Toxicology 178: 49–57, DACO: 9.3.4
2818524	Maloney, E.M., C.A. Morrissey, J.V. Headley, K.M. Peru and K. Liber, 2017, Cumulative toxicity of neonicotinoid insecticide mixtures to *Chironomus dilutus* under acute exposure scenarios, Environmental Toxicology and Chemistry 36 (11): 3091–3101, DACO: 9.9
2841146	Uragayala S., V. Verma, E. Natarajan, P.S. Velamuri and R. Kamaraju, 2015, Adulticidal and larvicidal efficacy of three neonicotinoids against insecticide susceptible and resistant mosquito strains. Indian J. Med. Res. 142(Supplement): 64–70, DACO: 9.3.4,9.9
2842540	Raby, M., M. Nowierski, D. Perlov, X. Zhao, C. Hao, D.G. Poirier and P.K. Sibley, 2018, Acute toxicity of six neonicotinoid insecticides to freshwater invertebrates. Environmental Toxicology and Chemistry, Accepted Article, DOI: 10.1002/etc.4088., DACO: 9.3.4,9.9

PMRA Document Number	Reference
2861091	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, 2018, Lethal and sublethal toxicity of neonicotinoid and butenolide insecticides to the mayfly, *Hexagenia* spp., Environmental Pollution 238: 63–75, DACO: 9.3.4,9.9
2873503	Maloney, E.M., C.A. Morrissey, J.V. Headley, K.M. Perua and K. Liber, 2018, Can chronic exposure to imidacloprid, clothianidin, and thiamethoxam mixtures exert greater than additive toxicity to *Chironomus dilutus*?, Ecotoxicology and Environmental Safety 156: 354–365, DACO: 9.3.4,9.9
2912490	Raby, M., X. Zhao, C. Hao, D.G. Poirer, P.K. Sibley, 2018, 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. Poirer, P.K. Sibley, 2018, 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
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 two 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
2945923	Sánchez-Bayo, F., K. Goka and D. Hayasaka, 2016, Contamination of the aquatic environment with neonicotinoids and its implication for ecosystems. Frontiers in Environmental Science 4: 1–14, DACO: 9.9
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