Proposed Registration Decision PRD2020-17

Imazapyr, Habitat Aqua

(*publié aussi en français*)

18 December 2020

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

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ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2020-17E (print version)
H113-9/2020-17E-PDF (PDF version)

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Overview

Proposed registration decision for imazapyr

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act, is proposing registration for the sale and use of Imazapyr Technical Herbicide and Habitat Aqua, containing the technical grade active ingredient imazapyr, to control certain invasive plants that grow in and around aquatic sites.

Imazapyr is currently registered for control of weeds in non-cropland sites and in imazapyr tolerant canola and lentils crops.

For details on use in non-cropland sites, see Proposed Re-evaluation Decision PRVD2008-10, *Imazapyr* and Re-evaluation Decision RVD2008-17, *Imazapyr*.

For details on use in imazapyr tolerant canola and lentils, see Proposed Registration Decision PRD2011-12, *Imazapyr* and Registration Decision RD2012-10, *Imazapyr*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Imazapyr Technical Herbicide and Habitat Aqua Herbicide.

What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca website.

Before making a final registration decision on Imazapyr and Habitat Aqua, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on Imazapyr and Habitat Aqua Herbicide, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is imazapyr?

Imazapyr is currently registered in Canada, as a relatively non-selective herbicide used for the management of a broad range of weeds and brush in agricultural and non-agricultural, forestry or industrial settings. Imazapyr is applied postemergence to weeds and brush and is absorbed by the leaves and roots, and moves rapidly throughout the plant and inhibits activity of a necessary enzyme. Susceptible plants stop growing soon after treatment and die.

The proposed registration is for the sale and use of imazapyr in an aquatic setting in non-cropland areas, for the control of certain invasive plants that grow in and around aquatic sites.

Health considerations

Can approved uses of imazapyr affect human health?

Habitat Aqua, containing imazapyr, is unlikely to affect your health when used according to proposed label directions.

Imazapyr was previously assessed for terrestrial uses under PMRA Proposed Re-evaluation and Registration Decisions for imazapyr (PRVD2008-10, PRD2011-12), and the corresponding Regulatory Decisions (RVD2008-17, RD2012-10). A summary of previous human health assessments for imazapyr can be found in these documents.

Potential exposure to imazapyr may occur through the diet (food and drinking water), when handling and applying products containing imazapyr. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect

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

the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-fold (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient imazapyr was of low acute toxicity by the oral and dermal routes, and of slight toxicity via the inhalation route. Imazapyr was non-irritating to the skin and did not cause an allergic skin reaction, but was severely irritating to the eye. Consequently, the words “CAUTION POISON” and “DANGER – EYE IRRITANT” are required on the label.

The acute toxicity of the end-use product, Habitat Aqua, was low via the oral, dermal and inhalation routes of exposure. Habitat Aqua was non-irritating to the skin and minimally irritating to the eyes. It did not cause an allergic skin reaction. No acute hazard labelling is required.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of imazapyr to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive effect for risk assessment was a slight increase in mortality following long-term dosing at a high dose. There was no evidence that the young were more sensitive to imazapyr than the adult animal. The risk assessment protects against these effects and other potential effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in water and food

Dietary risks from food and drinking water are not of health concern.

The proposed use of imazapyr on undesirable vegetation in non-cropland sites, including areas in or around specified aquatic sites, is not expected to contribute to inadvertent residues in crops and livestock and therefore would not pose a heath risk of concern to any segment of the population, including infants, children, adults and seniors.

Imazapyr does not bio-accumulate in freshwater or marine organisms, and consumption of fish or waterfowl from a treated aquatic environment are not of concern.

Exposure to imazapyr in drinking water from the proposed uses is not expected to exceed the exposure to imazapyr in drinking water from the current registered uses for terrestrial, industrial and non-cropland areas. Therefore, risk due to exposure from drinking water is not of concern.

Risks in residential and other non-occupational environments are not of health concern

Residential postapplication exposure to imazapyr occurs while swimming in treated water. For exposures related to swimming in treated water, there are no health risks of concern for all subpopulations.

Occupational risks from handling Habitat Aqua

Occupational risks are not of concern when Habitat Aqua is used according to the proposed label directions, which include protective measures.

Applicators who mix, load or apply imazapyr as well as workers re-entering freshly treated areas can come in direct contact with imazapyr residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying imazapyr must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. The label also requires that workers do not enter treated areas until residues have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental considerations

What happens when imazapyr is introduced into the environment?

When imazapyr is used according to the proposed label directions, the risks to the environment have been determined to be acceptable.

Imazapyr was previously assessed for terrestrial uses under PMRA Proposed Re-evaluation and Registration Decisions for imazapyr (PRVD2008-10, PRD2011-12), and the corresponding Regulatory Decisions (RVD2008-17, RD2012-10) and special review (REV2014-03). A summary of the fate and toxicity of imazapyr can be found in these documents.

Imazapyr can enter the environment when it is used as a postemergence herbicide for control of invasive plants.

Imazapyr is currently registered as a commercial postemergence herbicide (applied on land) to control a number of weeds (including invasive Phragmites) in non-crop areas (industrial sites, non-irrigation ditches and rights-of-way areas), non-graze areas, and for forestry site preparations.

Habitat Aqua will be used in both terrestrial (applied on land) and aquatic sites, to control three invasive species (invasive Phragmites, *Butomus umbellatus* (flowering rush) and the salt-water *Spartina spp*. (cordgrass)). Application to aquatic sites will represent a new use pattern for imazapyr. Application to aquatic sites will be made directly to the emerged parts of the plants rather than to the water body.

To control invasive Phragmites and flowering rush, imazapyr will be applied to terrestrial sites (including industrial sites, non-irrigation ditches and rights-of-way areas which are already registered), as well as aquatic sites (including wetlands and transitional areas between terrestrial and aquatic sites). To control invasive emergent cordgrass, imazapyr will be applied in estuarine/marine tidal areas when the tide has receded.

When used to control invasive species in terrestrial sites, imazapyr may reach the soil surface where it is persistent and slowly broken down by bacteria. Following land applications, imazapyr can enter surface water from run-off, or leach to groundwater. The predominant use of Habitat Aqua Herbicide is for in and around aquatic sites, and non-crop terrestrial sites of intense plant growth. As such, the majority of spray for terrestrial invasive plants is expected to be intercepted by plant growth, and will not reach the soil surface and will not leach. Leaching to groundwater is not expected to be a relevant route of dissipation for applications in and around water given the shallow water table and the interactions between the groundwater and surface water systems on the periphery of the water body.

Imazapyr can enter water during, or following application to emergent plants in water or shorelines, or from surface run-off following terrestrial application. Once in water, imazapyr is expected to mainly remain in the water column where it is non-persistent and breaks down in the presence of light to form several transformation products, most of which are not persistent. Imazapyr is not expected to move into the air from water or moist soils, and not expected to accumulate in the tissues of organisms.

Imazapyr and its breakdown products pose an acceptable risk to most non-target organisms (birds, small wild mammals, bees, fish, algae, amphibians, and invertebrates such as earthworms and water fleas). Because of its herbicidal properties, imazapyr may affect non-target plants, and information will be provided on the label to protect desirable non-target plants. When used according to label directions, the use of Habitat Aqua will have the desired effect of controlling target invasive plant species that pose a risk to wetland habitats.

Value considerations

What is the value of Habitat Aqua?

Habitat Aqua is intended for use to control invasive plants that grow in and around certain aquatic sites.

A number of provinces have sought access to herbicides to control invasive plants in and around certain aquatic sites. Registered options are severely limited for this type of use in Canada. Following the application of Habitat Aqua for the control of invasive plants, native plants are able to re-establish. The registration of Habitat Aqua will provide a valuable tool to stakeholders including provincial authorities to help control and manage these invasive species in and around certain aquatic sites as part of a broader management strategy, for the long-term benefit of the environment.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Habitat Aqua to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

The personal protective equipment for mixers/loaders and applicators is a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Gloves are not required during application within a closed cab and/or cockpit.

Environment

- This product will be classified as restricted. The product can be used only by licensed pesticide applicators under appropriate federal or provincial authorizations. The nature of the restriction is as follows:
    - This is a restricted product that must be used in the manner authorized. This product is only to be used by individuals holding an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory authority where the pesticide application is to occur. This registration is granted under the *Pest Control Products Act* and does not exempt the user from any other legislative requirements. Use of this product in or immediately adjacent to water bodies must be appropriately authorized and must be used in accordance

with the *Aquatic Invasive Species Regulations under the Fisheries Act*. Use of this product must also be in accordance with any other required provincial authorizations. Consult with provincial regulatory authorities on any authorizations required prior to use of this product.

- The label will include precautionary statements indicating toxicity to terrestrial and aquatic vascular plants.

- Spray drift management measures are provided to inform users of potential zones of impact on non-target terrestrial and emergent aquatic plants resulting from downwind spray drift during either terrestrial or aquatic applications. These downwind distances are advisory, and for consideration in the context of protecting any desirable non-target terrestrial or aquatic plants at the application sites when controlling target invasive plant species.

Next steps

Before making a final registration decision on imazapyr and Habitat Aqua, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

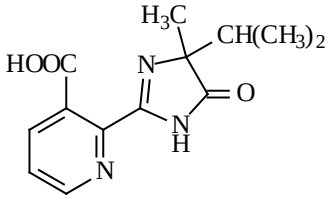
When the Health Canada makes its registration decision, it will publish a Registration Decision on Imazapyr and Habitat Aqua (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science evaluation

Imazapyr

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance	Imazapyr
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	*rac*-2-[(4*R*)-4-methyl-5-oxo-4-(propan-2-yl)-4,5-dihydro-1*H*-imidazol-2-yl]pyridine-3-carboxylic acid
2. Chemical Abstracts Service (CAS)	2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-3-pyridinecarboxylic acid
CAS number	81334-34-1
Molecular formula	$C_{13}H_{15}N_3O_3$
Molecular weight	261.3
Structural formula	
Purity of the active ingredient	98.5%

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product—Imazapyr Technical

Property	Result
Colour and physical state	White solid
Odour	Slight odour of acetic acid
Melting range	169–173°C
Boiling point or range	Not applicable
Density	1.03–1.08 kg/L

Property	Result
Vapour pressure at 60°C	< 0.013 mPa
Ultraviolet (UV)-visible spectrum	No absorbance at $\lambda > 300$ nm
Solubility in water	9.74 g/L at 15°C 11.3 g/L at 25°C
Solubility in organic solvents at 20°C (g/L)	Solvent — Solubility (g/L) Acetone — 33.9 Dimethyl sulfoxide — 471 Hexane — 0.0095 Methanol — 105 Dichloromethane — 87.2 Toluene — 1.80
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 0.11
Dissociation constant (pK_a)	pK_{a1} = 1.9 pK_{a2} = 3.6 pK_{a3} = 11
Stability (temperature, metal)	Stable for at least 2 years at 25°C, 1 year at 37°C and 3 months at 45°C. There is no reactive chemical hazard associated with exposure to common metals under normal conditions of storage.

End-use product - Habitat Aqua

Property	Result
Colour	Blue colour
Odour	Odourless
Physical state	Liquid
Formulation type	Solution
Guarantee	240 g/L
Container material and description	Non-fluorinated high-density polyethylene (HDPE) bottles with induction sealed caps, 1–1000 L.
Density	1.05–1.07 g/mL at 20ºC
pH of 1% dispersion in water	5.39 (1% solution) at 25ºC
Oxidizing or reducing action	The product is not considered to be an oxidizing or reducing agent
Storage stability	The product is stable when stored in commercial packaging (HDPE) for 12 months in a warehouse and at 5ºC.
Corrosion characteristics	The product is non-corrosive to the commercial packaging material (HDPE).
Explodability	The product is not potentially explosive.

1.3 Directions for use

Habitat Aqua is to be applied at different rates, depending on the target weed species. For labelled invasive cordgrasses (denseflower, salt-meadow, smooth and common) the rate is 4.68-7.0 L/ha (1.12–1.68 kg/ha) with higher rates being used for heavier weed pressure. For flowering

rush the rate is 3.0 L/ha (0.72 kg/ha), and for invasive Phragmites (European reed) it is 3.0–4.68 L/ha (0.72-1.12 kg/ha). In all cases Aquasurf Non-ionic Spray (NIS) Adjuvant must be added at 0.25–0.5% v/v, depending on the weed species. Application equipment is similar for application to all species and includes vehicle or boat-mounted high volume spray equipment such as high pressure handguns, conventional spray booms, low pressure equipment such as backpack and other pump type pressurized sprayers. Application to invasive Phragmites (European reed) may also be made by helicopter due to the exceedingly dense growth pattern and height of the plants (up to 15 m tall). In all cases application is directed to the foliage to maximize spray interception and minimize runoff.

1.4 Mode of action

Imazapyr belongs to the imidazolinone chemical family and is classified as a Herbicide Resistance Action Committee (HRAC) Group B or Weed Science Society of America (WSSA) Group 2. Imazapyr is a systemic herbicide that inhibits the activity of the enzyme acetolactate synthase which in turn prevents the synthesis of branched chain amino acids.

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of the active ingredient in Imazapyr Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for formulation analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for residue analysis

Please refer to Proposed Regulatory Decision PRD2011-12, *Imazapyr* for details on the methods for residue analysis.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of the toxicological database for imazapyr was conducted previously and is summarised in the Proposed Regulatory Decision, PRD2011-12, *Imazapyr*. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to imazapyr.

The end-use product, Habitat Aqua, was of low toxicity via the oral, dermal and inhalation routes of exposure in rats. It was minimally irritating to the eyes and non-irritating to the skin of rabbits, and was not a dermal sensitizer based on results from a Buehler study conducted in guinea pigs.

A summary of the toxicity profile of Habitat Aqua is available in Appendix I, Table 1 and a summary of the toxicology reference values for imazapyr is available in Appendix I, Table 2.

3.2 Toxicology reference values

Refer to Proposed Regulatory Decision PRD2011-12, *Imazapyr* for a full discussion. Toxicology Reference Values are summarized in Appendix I, Table 2.

3.3 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pest control products with a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for imazapyr. Imazapyr is an imidazolinone herbicide. Currently, there are six imidazolinone herbicides, four of which are registered for use in Canada, including imazapyr. Imazapyr was of low toxicity overall, with no targets of toxicity identified and often no effects up to the limit dose of testing. Furthermore, the toxicological effects following exposure to imidazolinone herbicides are considered to represent a more generalized toxicity, and a common mechanism of toxicity has not been identified. Therefore, a cumulative health risk assessment is not required at this time.

3.4 Occupational and residential risk assessment

Occupational exposure to Habitat Aqua Herbicide is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes

3.4.1 Toxicology reference values

Refer to Proposed Regulatory Decision PRD2011-12, *Imazapyr* for a full discussion. Toxicology reference values are summarized in Appendix I, Table 2.

3.4.1.1 Dermal absorption

Dermal absorption data were not submitted.

3.4.2 Occupational exposure and risk

3.4.2.1 Mixer/loader/applicator exposure and risk assessment

Individuals have potential for exposure to Habitat Aqua Herbicide during mixing, loading and application. Exposure to workers mixing, loading and applying imazapyr is expected to be short-to-intermediate term in duration and to occur primarily by the dermal and inhalation routes.

It was concluded in the toxicology assessment that a quantitative approach for dermal risk assessment was not required, thus, no dermal reference value was established for imazapyr. As such, a quantitative chemical handler risk assessment was conducted for inhalation exposure only.

Exposure estimates were derived for workers mixing, loading and applying Habitat Aqua Herbicide to non-cropland areas using groundboom, right-of-way, handheld and aerial application equipment. The exposure estimates are based on mixers/loaders/applicators wearing a long-sleeved shirt, long pants and chemical-resistant gloves.

As chemical-specific data for assessing human exposures during pesticide handling activities were not submitted, inhalation exposure estimates for workers were estimated using the Pesticide Handlers Exposure Database (PHED), version 1.1 (for closed mixing/loading, right-of-way sprayer application and handheld equipment application) and the Agricultural Handlers Exposure Task Force (AHETF) data (for open mixing/loading and closed cockpit aerial application).

Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 100.

Mixer/loader/applicator inhalation exposure estimates and MOE

Exposure Scenario	Unit exposure (µg/kg a.e. handled)	ATPD[1]	Rate (kg a.e./ha)	Daily inhalation exposure (mg/kg bw/day)[2]	Inhalation MOE[3]
PPE: Single layer + chemical-resistant gloves					
Groundboom application					
M/L/A	2.31	360 ha/day	1.68	1.75×10^{-2}	16 100
Handheld equipment application					
Manually-pressurized handwand M/L/A	45.2	150 L/day	1.68	1.42×10^{-3}	198 000
Backpack M/L/A	62.1	150 L/day	1.68	1.96×10^{-3}	144 000
Mechanically-pressurized handwand	151	3800 L/day	1.68	1.20×10^{-1}	2340

Exposure Scenario	Unit exposure (µg/kg a.e. handled)	ATPD[1]	Rate (kg a.e./ha)	Daily inhalation exposure (mg/kg bw/day)[2]	Inhalation MOE[3]
PPE: Single layer + chemical-resistant gloves					
M/L/A					
Right-of-way application					
M/L/A	5.63	3800 L/day	1.68	4.49×10^{-3}	62 800
Wicking/wiping and daubing application					
M/L/A	62.1[4]	150 L/day	1.12	1.30×10^{-3}	216 000
Aerial application					
M/L (open)	0.63	400 ha/day	1.12	3.53×10^{-3}	79 900
Applicator	0.00969	400 ha/day	1.12	5.43×10^{-5}	5 200 000
M/L (closed) + applicator	0.11969	400 ha/day	1.12	6.70×10^{-4}	421 000

ATPD = area treated per day, MOE = margin of exposure, M/L/A = Mixer/loader/applicator
[1] Default Area Treated per day values
[2] Daily exposure = (PHED/AHETF unit exposure × ATPD × Rate) / (80 kg bw × 1000 µg/mg)
[3] Margin of Exposure (MOE) = Daily Exposure / NOAEL
Based on NOAEL= 282 mg/kg bw/day, target MOE = 100
[4] PHED unit exposure for backpack M/L/A.

3.4.2.2 Exposure and risk assessment for workers entering treated areas

There is potential for exposure to workers re-entering areas treated with Habitat Aqua Herbicide to examine the efficacy of the herbicide and while mowing, rolling, burning and handling dead stalks. Given the nature of activities performed, the duration of exposure is considered to be short-to-intermediate term and the primary route of exposure for workers that enter treated areas would be dermal, through contact with residues on leaves.

As previously noted, it was concluded in the toxicology assessment that a quantitative approach for dermal risk assessment was not required. As such, a quantitative postapplication risk assessment was not conducted. Nevertheless, entry/re-entry to recently treated areas is restricted until sprays have dried, as has been specified on the label, which is the minimum restricted-entry interval (REI) for non-agricultural crops.

3.4.3 Residential exposure and risk assessment

Residential postapplication exposure to imazapyr occurs while swimming in treated water. Swimmers are expected to have short-to-intermediate term exposure to imazapyr while swimming in treated water.

Exposure estimates were based on the United States Environmental Protection Agency's (USEPA) Swimmer Exposure Model (SWIMODEL). The exposure equations used in SWIMODEL were originally conceived by the USEPA Office of Pesticide Programs Antimicrobials Division. These equations are used to develop screening exposure estimates tailored to swimmers exposed to pool chemicals and breakdown products in indoor pools and spas. The model uses well-accepted screening exposure assessment equations to calculate swimmers' total exposure expressed as a mass-based intake value (mg/day), or lifetime average daily dose (mg/kg/day). SWIMODEL focuses on potential chemical intakes only; it does not take into account metabolism or excretion of the chemical of concern.

Quantitative exposure estimates were based on the oral route of exposure. A risk assessment for dermal and inhalation exposure is not required since no dermal reference value has been established for imazapyr and imazapyr is not volatile. In addition, a determination was made that overall exposure will be appropriately addressed by SWIMODEL's screening-level oral exposure estimate.

Oral exposure was estimated by coupling the water concentration, ingestion rate and exposure time. Exposure was normalized to mg/kg bw/day by using default body weight values for each subpopulation.

Exposure estimates were compared to the toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 100.

Residential postapplication oral exposure estimates and MOE

Subpopulation	Water concentration (mg/L)[1]	Ingestion rate (L/hr)[2]	Exposure time (hr/day)[2]	Body weight (kg)[3]	Oral exposure (mg/kg bw/day)[4]	Oral MOE[5]
Adult	0.121	0.025	1	80	3.8×10^{-5}	7.5×10^{6}
Child 11 to <16	0.121	0.05	1	57	1.6×10^{-4}	2.7×10^{6}
Child 6 to <11	0.121	0.05	1	32	1.9×10^{-4}	1.5×10^{6}

[1] Estimated environmental concentration (EEC) for daily concentration of combined parent and metabolites M6, M7 and M8 in drinking water for an open-water use scenario
[2] Ingestion rate and exposure time from SWIMODEL (USEPA, 2003).
[3] Body weight from SPN2014-01.
[4] Daily exposure = (Water concentration × Ingestion rate × Exposure time) / (Body weight × 1000 µg/mg)
[5] Margin of Exposure (MOE) = Daily Exposure / NOAEL
Based on NOAEL= 282 mg/kg bw/day, target MOE = 100

3.4.3.1 Bystander exposure and risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to non-cropland areas only, and when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Health incident reports

As of 13 February 2020, 5 human and 15 domestic animal incident reports involving imazapyr had been submitted to the PMRA.

The human incidents were classified as major (1 report) and minor (4 reports). The major incident occurred in the United States. The individual applied a mixture of two pesticide products, one of which contained imazapyr. Clinical signs reported in the incident included respiratory symptoms, a partially collapsed lung and tongue swelling. The incident was considered to be possibly related to the pesticides. The role of imazapyr in the incident cannot be isolated, due to the presence of other active ingredients in the applied product. The 4 minor incidents occurred in Canada. The reported exposure scenarios included drift from an application site or exposure during activities associated with product application. In all four incidents, people were exposed to imazapyr along with other active ingredients (for example, glyphosate, imazamox). Only minor symptoms were reported in individuals including nausea, skin irritation and respiratory irritation, which could not be specifically attributed to imazapyr.

The domestic animal incidents were classified as death (14 reports) and minor (1 report). Most domestic animal deaths occurred in the United States (11 reports). In general, the animals reported in incidents included cows, horses, chickens, cats and dogs. Exposure of animals was mainly suspected to have occurred either via contact with a treated area, pesticide drift or after ingesting treated vegetation. The pesticides were applied to areas like utility right-of-ways or industrial sites. The symptoms reported in animals included diarrhea, weight loss or respiratory effects. The end-use product Habitat Aqua is proposed for use on non-crop land areas. Domestic animal access to these sites is expected to be limited, therefore, no additional mitigation measures are recommended based on the incident report review.

3.5 Food residues and drinking water exposure assessment

3.5.1 Residues in plant and animal foodstuffs

Please refer to Proposed Regulatory Decision PRD2011-12, *Imazapyr* for the complete review of residues of imazapyr in plants and animal foodstuffs.

3.5.2 Dietary risk assessment

Please refer to Proposed Regulatory Decision PRD2011-12, *Imazapyr* for the chronic (non-cancer) dietary risk assessment.

3.5.3 Exposure from drinking water

Concentrations in drinking water

Drinking water modelling was conducted only for uses in and around surface water bodies since modelling had previously been conducted for the land uses (in other words, terrestrial sites) of imazapyr (which included surface water and groundwater modelling). This modelling focused on estimating concentrations in surface water; leaching to groundwater sources of drinking water is not expected from applications in and around water bodies given the shallow water table and the interactions between the groundwater and surface water systems on the periphery of the water body.

For the current assessment, EECs were generated using a parent-daughter modelling approach. This approach models the parent and transformation products separately using the appropriate persistence and mobility data. In this case, the parent is imazapyr, and the daughter combines the most conservative properties of the transformation products of interest. The EECs for the parent and daughter were then added to calculate the combined residue EECs. See Table below for modelling inputs.

The use pattern modelled was a single application at the maximum yearly rate of 1.68 kg a.e./ha, applied directly to a water body and a small area of surrounding land where some of the invasive plant species may also be found. Resulting EECs are presented in the Table below.

EECs (in µg a.e./L) for the surface drinking-water risk assessment of imazapyr

Use pattern	Imazapyr (µg a.e./L)		Representative daughter (µg a.e./L)		Combined parent and daughter(µg a.e./L)	
	Daily[1]	Yearly[2]	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
1 application of 1.68 kg a.e./ha per year	69	39	52	40	121	79

[1] 90th percentile of the daily concentrations from each year.
[2] 90th percentile of yearly average concentrations.
[3] Sum of 90th percentile of the daily concentrations from each year of imazapyr and the representative daughter.
[4] Sum of 90th percentile of the yearly average concentrations from each year of imazapyr and the representative daughter. Note: 92 µg a.e./L was used in the risk assessment which is a conservative exposure estimate that did not impact risk conclusions.

Exposure to imazapyr in drinking water from the proposed uses is not expected to exceed the exposure to imazapyr in drinking water from the current registered uses for terrestrial, industrial and non-cropland areas. Therefore, risk due to exposure from drinking water is not of concern.

3.5.4 Aggregate exposure and risk

The aggregate risk for imazapyr consists of exposure from food and drinking water sources only; there are no residential uses.

3.5.5 Maximum residue limits

Maximum residue limits were not updated with the use in this non-food use.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

The fate and environmental behaviour of imazapyr have been previously assessed for use on non-crop areas (industrial sites, non-irrigation ditches and rights-of-way areas), non-graze areas, and for forestry site preparations. For further details see PMRA Proposed Re-evaluation and Registration Decisions for imazapyr (PRVD2008-10, PRD2011-12), the corresponding Regulatory Decisions (RVD2008-17, RD2012-10) and special review (REV2014-03). Additionally, the impact of two new fate studies (aquatic phototransformation and monitoring in tidal waters following application in British Columbia) were considered in the assessment. The fate data is summarized in Appendix I, Tables 4 and 5, and was used to assess the additional proposed application to aquatic sites.

Habitat Aqua Herbicide (containing imazapyr) will be used in terrestrial sites and aquatic sites as a foliar spray to control certain invasive plant species. Imazapyr is a systemic herbicide which is taken up by the plant foliage and roots.

Terrestrial sites include non-cropland areas and non-irrigation ditch banks. When foliar applications are made to control emergent invasive plants growing in terrestrial sites spray drift may reach non-target terrestrial areas. A minimal amount of imazapyr is expected to reach the ground owing to interception from dense growth of terrestrial invasive plants.

Aquatic sites include application to emergent aquatic plants in estuarine/marine tidal areas (when tide has receded), and also in and around still and slow-moving water, including wetlands, riparian areas, swamps, bogs, marshes, transitional areas between terrestrial and aquatic sites, seasonal wet areas, seeps, gravel bars, non-irrigation ditches, lakes, ponds, rivers and streams. The proposed aquatic use is to apply directly to the emergent plants rather than to the water body. It is applied as a spray solution to foliage of the target vegetation using care to avoid over-application or foliage run-off in order to minimize entry into water. However, following applications to aquatic emergent plants, some imazapyr may reach the water at the treatment site, or drift to adjacent aquatic and/or terrestrial habitats.

In soil, laboratory and field studies show that imazapyr is moderately persistent to persistent under aerobic and anaerobic conditions. In addition, imazapyr is mobile based on adsorption studies and very soluble in water. However, leaching to groundwater is not expected to be a relevant route of dissipation for applications in and around water given the shallow water table and the interactions between the groundwater and surface water systems on the periphery of the water body. In addition, intense emergent terrestrial plant growth is expected to intercept spray from reaching the soil surface and preclude its availability for leaching.

Imazapyr is expected to dissipate quickly in the aquatic environment. In water, laboratory studies have shown that imazapyr is persistent under anaerobic and aerobic aquatic conditions. However, photolysis is a significant route of transformation for imazapyr, and photolytic transformation products were found to be non-persistent. Aquatic field dissipation studies conducted in Florida, Louisiana and Missouri concluded that residues of imazapyr will not persist in water systems when applied directly to the water surface. In addition, field data from the use of imazapyr in tidal areas of British Columbia and Washington State reported that imazapyr declined to non-detectable levels in water (≤ 0.2 ppb) 48 hours after treatments of up to 224 ppb, which supports the conclusion that imazapyr is expected to dissipate quickly in the aquatic environment. Based on a BCF (bioconcentration factor) of <1 in a number of studies conducted with crayfish, fish, clam and shrimp, it is concluded that imazapyr does not bioaccumulate in marine or freshwater aquatic organisms.

4.2 Environmental risk characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1 for most species, 0.4 for acute risk to pollinators, and 2 for glass plate studies using the standard beneficial arthropod test species, *Typhlodromus pyri* and *Aphidius rhopalosiphi*; LOC = 1 is used for higher tier tests of the

standard arthropod test species and for other arthropod test species). If the screening level RQ is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The maximum rate of application for invasive cordgrasses (*Spartina spp*) applied to estuarine/marine tidal areas (when tide has receded) is 1680 g a.e./ha, which is the highest rate on the proposed label. The maximum rate for invasive Phragmites (*Phragmites australis subsp. australis*) applied to both terrestrial and aquatic areas (1123 g a.e./ha) is the same as currently registered rate for terrestrial sites on the Arsenal Powerline label (registration 30203); and the maximum rate of application for flowering rush (*Butomus umbellatus*) applied to both terrestrial and aquatic areas (720 g a.e/ha) is slightly lower.

4.2.1 Terrestrial site applications

The previous risk assessment for organisms that may be exposed from foliar use in terrestrial sites is considered relevant for the terrestrial uses of Habitat Aqua Herbicide (in other words, for control of invasive Phragmites and flowering rush in terrestrial sites). The risk assessment was based on a conservative application rate of 1690 g a.i./ha. For further details see PMRA Proposed Registration Decisions for imazapyr (PRVD2008-10, PRD2011-12), the corresponding Regulatory Decisions (RD2008-17, RD2012-10) and special review (REV2014-03).

4.2.2 Aquatic site applications

For the proposed new uses to aquatic sites, data in PRVD2008-10, PRD2011-12, RD2008-17, RD2012-10 and REV2014-03, are considered in the risk assessment.

4.2.2.1 Aquatic site applications: potential risks to non-target terrestrial organisms

Following application at aquatic sites, terrestrial organisms (such as honeybees, earthworms, birds, small wild mammals and terrestrial plants), could be exposed to imazapyr through contact with spray drift, contact with sprayed surfaces or from ingestion of contaminated food (including systemic transport into plants). However, the proposed use of the new end-use product, Habitat Aqua Herbicide, to control listed invasive species growing in or around aquatic sites is not expected to increase risk to non-target terrestrial organisms when compared to the previously registered use pattern for non-crop terrestrial uses.

The original screening level risk assessments for bees, birds, small wild mammals and terrestrial plants for terrestrial site applications (PRVD2008-10 and PRD2011-12) were conducted using a maximum foliar application rate of 1690 g a.e./ha with ground equipment. This rate is higher than proposed rates for terrestrial and aquatic sites for Habitat Aqua Herbicide. The rate (1690 g a.e./ha) is slightly higher than the proposed rate for invasive cordgrasses in estuarine/marine tidal areas (when tide has receded (1680 g a.e./ha), and higher (in other words, more conservative) for invasive Phragmites (1123 g a.e./ha) and bullrush (720 g a.e./ha) in terrestrial and aquatic sites. Habitat Aqua Herbicide will be applied by low-volume directed application techniques, or by broadcast using ground equipment or watercraft, for all three invasive weed species. In addition, aerial applications (by helicopter only) can be made for control of invasive Phragmites at aquatic sites.

Birds and mammals: Imazapyr poses an acceptable risk to birds and wild mammals. Based on the original screening level risk assessment with direct application to food items, the resulting RQs are all below the LOC (<1.0) (Appendix I, Table 6).

Soil dwelling organisms: Imazapyr poses an acceptable risk to soil dwelling organisms. Based on the original screening level risk assessment for earthworms with direct application to soil, the resulting RQs are all below the LOC (<1.0) (Appendix I, Table 6).

Honey bees: Imazapyr is considered non-toxic to bees. The original screening level risk assessments for pollinators for terrestrial site applications (PRVD2008-10 and PRD2011-12) were conducted using an older risk assessment method for pollinators. Based on that method, resulting RQs were below the LOC. Since that time, the PMRA has updated the pollinator risk assessment framework (see Guidance for Assessing Pesticide Risk to Bees). According to the new method of assessment, at the screening level, based on an application rate of 1680 g a.e./ha and acute contact and oral endpoint of >100 and >117 µg a.i./bee, respectively, there is no contact risk (RQ < 0.04). For oral exposure, the LOC was potentially very slightly exceeded (RQ <0.41; LOC 0.4), however, there were no effects at the highest dose tested, and the RQ is expected to be less than 0.41, therefore, no risk is expected. No risk was identified from an application rate of 1123 g a.e./ha (Appendix I, Table 6). Overall, the proposed new use of imazapyr poses an acceptable risk to pollinators.

Terrestrial plants: Imazapyr is considered toxic to plants. Resulting RQs in the original screening level risk assessments exceeded the LOC for seedling emergence (based on an EC_{25} of 2.7 g a.i./ha for sugarbeet) and vegetative vigour (based on an EC_{25} of 1.01 g a.i./ha for cucumber). Therefore, imazapyr may pose a risk of concern to non-target terrestrial plants.

In the current assessment, the risk to terrestrial vascular plants was further characterized by looking at off-field exposure from drift based on application rates of 1680 g a.e./ha (maximum rate for invasive cordgrasses for ground application) and 1123 g a.e./ha (rate applicable for both ground and aerial application) and 720 g a.e./ha (rate for flowering rush for ground application). For an ASAE (American Society of Agricultural Engineers) “medium” droplet size, the maximum spray drift deposition at one meter downwind from the point of application is 6% (ground application) and 23% (aerial application). Based on the risk quotients using the off-field

EECs from drift, the LOC for terrestrial vascular plants was exceeded for ground and aerial application (RQ = 1.12–255) (Appendix I, Table 7), and spray drift management measures were determined.

Mandatory spray buffer zones are not required for the proposed uses of controlling invasive plant species in sensitive habitats. Invasive plants pose a threat to the Canadian natural environment by posing a significant threat to biodiversity. They have an impact on species diversity and richness, and can destroy native habitat which may impact not only native plants, but also native animal species that rely on the native habitat. While it is recognized that some native plant species may also be present and affected by application of this product, the need to aggressively control invasive species outweighs the need for mandatory spray buffer zones. Although there are no mandatory spray buffer zones, downwind distances of possible impact, in addition to hazard statements, are presented on the label in order to inform users of the potential zone of impact for terrestrial and emergent aquatic non-target plants. It was determined that non-target terrestrial and emergent aquatic plants downwind of application (for both terrestrial and aquatic sites) may be affected within 20–40 m following ground application, and 450 m following aerial application. These distances can be considered when it is determined that there are desirable plants that need to be protected downwind of the application locations.

Overall conclusion about potential risks to non-target terrestrial organisms from application at aquatic sites

Overall, imazapyr poses an acceptable risk for earthworms, bees, birds and mammals. Imazapyr may pose a risk of concern to terrestrial plants. The PMRA recognizes that control of invasive species is necessary in order to help protect habitats for native species. This is taken into consideration in proposed preventative measures on the label. Downwind distances within which non-target terrestrial and emergent aquatic plants may be damaged are included on the label so that risk managers can take site-specific characteristics into consideration when determining if there are desirable plants that need to be protected downwind of the application locations.

4.2.2.2 Aquatic site applications: potential risks to non-target aquatic organisms

Following application at aquatic sites, aquatic organisms (such as fish, amphibians, invertebrates, algae and vascular plants), could be exposed to imazapyr through spray drift, or by entry into water during application to emergent invasive plants. Application to emerged invasive plants is to be directed onto the foliage, minimizing direct entry into water.

The original screening level risk assessments for use of imazapyr as a postemergent herbicide (applied on land) for fish, amphibians, invertebrates, algae and vascular plants for terrestrial site applications (PRVD2008-10 and PRD2011-12) were conducted using a maximum foliar application rate of 1690 g a.e./ha and conservatively assumed direct application to water. A summary of the toxicity can be found in Appendix I, Table 8. The original application rate is higher than the proposed rates for the new use pattern of Habitat Aqua Herbicide on both terrestrial and aquatic sites for the control of the three emergent invasive species, invasive Phragmites, flowering rush, and invasive cordgrasses. The original application rate (1690 g

a.e./ha) is slightly higher than the proposed rate for cordgrass in estuarine/marine tidal areas when the tide has receded (1680 g a.e./ha), and higher (in other words, more conservative) for invasive Phragmites (1123 g a.e./ha) and bullrush (720 g a.e./ha) in terrestrial and aquatic sites.

Freshwater invertebrates: Imazapyr poses an acceptable risk to freshwater aquatic invertebrates. Based on the conservative screening level risk assessment, the resulting RQs were all below the LOC (<1.0) (Appendix I, Table 9).

Fish and amphibians: Imazapyr poses an acceptable risk to fish and amphibians (considering fish as a surrogate for toxicity). Based on the conservative screening level risk assessment, the resulting RQs are all below the LOC (<1.0) (Appendix I, Table 9).

Algae and aquatic vascular plants: Based on the conservative screening level risk assessment, the resulting RQs for algae (green and blue-green algae) and diatoms (*Navicula pelliculosa* and *Skeletonema costatum*) are all below the LOC (<1.0) (Appendix I, Table 9). However, the RQ for the aquatic vascular plant (*Lemna gibba*) (RQ = 23) exceeded the LOC. Therefore, imazapyr may pose a risk of concern to non-target freshwater aquatic vascular plants.

Estuarine/marine species: Imazapyr poses an acceptable risk to marine aquatic invertebrates and fish. Based on the conservative screening level risk assessment, the resulting RQs are all below the LOC (<1.0) (Appendix I, Table 9).

Based on the mode of action, imazapyr is expected to be harmful to plants. Since none of the available endpoints for marine organisms included plants, the freshwater endpoint and risk assessment for *Lemna gibba* is considered as a surrogate for potential risk to marine plants (which is consistent with the previous assessments). Therefore, imazapyr may pose a risk of concern to non-target marine aquatic vascular plants.

Spray drift refinement

Similar to terrestrial plants, risk to aquatic vascular plants from spray drift from the treated sites is assessed by taking into consideration drift deposition of spray quality of ASAE medium droplet size for ground boom (6%), and aerial application (helicopter) (23%) at 1 m downwind from the site of application. Based on the risk quotients using the off-field EECs from drift, the LOC for aquatic vascular plants (*Lemna*) was exceeded for ground and aerial application at the 1680 g a.e./ha rate, and 1123 g a.e./ha for aerial applications (RQ = 1.4 to 3.6). No risk was identified for the ground application of 1123 g a.e./ha rate, or the 720 g a.e./ha rate (Appendix I, Table 10).

In addition, given that the intended application and mode of action of this product is for a foliar application to the emergent plant, the risk assessment considers a scenario for non-target emergent aquatic plants. Terrestrial plant endpoints are considered as a surrogate for non-target emergent aquatic plants, and the risk assessment is based on application rates and endpoints expressed in g a.e./ha (Appendix I, Table 7).

Overall conclusion about potential risks to aquatic organisms from application at aquatic sites

Overall, imazapyr poses an acceptable risk for freshwater and marine fish and invertebrates, as well as freshwater algae and diatoms. Imazapyr may pose a risk of concern to non-target freshwater and marine aquatic vascular plants. The PMRA recognizes that control of invasive species is necessary in order to help protect habitats for native species. This is taken into consideration in proposed risk prevention measures on the label. Downwind distances within which non-target terrestrial and emergent aquatic plants may be damaged are included on the label so that risk managers can take site-specific characteristics into consideration when determining if there are desirable plants that need to be protected downwind of the application locations.

4.2.3 Environmental incident reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found on the Report a Pesticide Incident page on Canada.ca

As of 13 February 2020, the database contained six environment incident reports. Only four of these were considered relevant to exposure to imazapyr. In these incidents, trees and/or plants (including conifers, blueberries and canola) were affected as a result of drift from an application of a pesticide containing imazapyr to gardens and industrial sites.

There were also 17 incident reports available in the USEPA's Ecological Incident Information System (EIIS) database, that were considered relevant to exposure to imazapyr. Plants were affected in 16 incidents, of which five reports were listed as probably related to imazapyr. The incidents involved damage to a wide variety of plants including wheat, potatoes, green beans, soybeans, grapes, tomatoes, corn, and hay. Exposure was reported to have occurred mainly via spray drift.

5.0 Value

Invasive alien species (IAS) are a growing problem around the world and may include plants, insects, mammals, fish, etc. The Government of Canada has addressed IAS in the publication: An Invasive Alien Species Strategy for Canada (2004). Herbicides to control and manage invasive plants can play an important role in this approach.

Invasive plants have many negative impacts including but not limited to the displacement of native species and degradation of natural habitats. Invasive plants may be terrestrial (occur only on land), aquatic (occur only in water) or semi-aquatic. Examples include invasive Phragmites (European reed) that often grows in ditches that contain water in the spring or after rainfall

events, and cordgrasses that grow in inter-tidal areas on the coast. Some cordgrasses have been introduced and are invasive on the west coast (denseflower, salt-meadow, smooth and common cordgrass). British Columbia has signed an agreement with the coastal American states to eradicate certain invasive cordgrasses on the west coast.

Many provinces have sought access to herbicides for the control or management of IAS in and around water, as only one herbicide, Reward Aquatic Herbicide, is presently registered. The provinces themselves are likely to be the major users of Habitat Aqua Herbicide. A lack of chemical control options has allowed certain species such as invasive Phragmites to spread.

The applicant provided scientific literature and use history information in support of the registration of Habitat Aqua Herbicide for the control of labelled invasive weeds. Imazapyr has been used in the United States for the management of vegetation around water since 2003 and the results of numerous published studies were provided for review. In Canada, imazapyr has received emergency registrations for use in British Columbia and Alberta where it has been used successfully for managing invasive cordgrasses, flowering rush and invasive Phragmites. Many American states have Best Management Practices publications that recommend the use of herbicides, including Habitat Aqua Herbicide for the management of these weed species.

The use of herbicides in the management of invasive plant species is adaptable and may be part of a Best Management Practices approach. For example, management of invasive Phragmites often involves applying a herbicide in the late summer or early fall. Once the plants die, large areas may then be mechanically rolled and burned as part of larger management plan.

The registration of Habitat Aqua Herbicide will provide stakeholders with an effective tool to manage cordgrasses, invasive Phragmites and flowering rush in and around certain aquatic sites. Although Habitat Aqua Herbicide application may impact non-target species, overall there is a long-term benefit to controlling or managing the invasive species as the continued presence of the IAS also impact the natural species.

6.0 Pest control product policy considerations

6.1 Assessment of the active ingredient under the toxic substances management policy

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, imazapyr and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that imazapyr and its transformation products do not meet all of the TSMP Track 1 criteria. Please refer to PRD2013-09 for further information on the TSMP assessment.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.[6] The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations, including the Toxic Substances Management Policy[1] and Formulants Policy,[8] and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999* (substances designated under the Montreal Protocol).

The PMRA has reached the conclusion that imazapyr and its end-use product, Habitat Aqua Herbicide, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act, is proposing registration for the sale and use of Imazapyr Technical Herbicide and Habitat Aqua, containing the technical grade active ingredient imazapyr, to control invasive plants that grow in and around certain aquatic sites.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

6 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

7 PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the Pest Control Products Act.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

List of abbreviations

µg	micrograms
a.i.	active ingredient
atm	atmosphere
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DFOC	double first order in parallel
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
g	gram
ha	hectare(s)
Hg	mercury
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOQ	limit of quantitation
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
NA	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PRD	Proposed Regulatory Decision
SFO	single first-order
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and figures

Table 1 Toxicity profile of habitat aqua containing imazapyr

Study Type/Animal/PMRA#	Study Results
Acute oral toxicity Wistar rats PMRA# 2584823	LD_{50} > 2000 mg/kg bw Low toxicity
Acute dermal toxicity Wistar rats PMRA# 2584824	LD_{50} >5000 mg/kg bw Low toxicity
Acute inhalation toxicity (head-only) Wistar rats PMRA# 2584825	LC_{50} > 5.3 mg/L Low toxicity
Dermal irritation NZW rabbits PMRA# 2584827	MAS = 0, MIS = 0 Non-irritating
Eye irritation NZW rabbits PMRA# 2584826	At 1 hour, slight conjunctival redness was observed. Eyes were normal at 48 hours. Minimally irritating
Dermal sensitization (Buehler test) Hartley guinea pigs PMRA# 2584828	Non-sensitizer

Table 2 Toxicology reference values for use in health risk assessment for imazapyr

Exposure Scenario	Study	Point of Departure and Effect	CAF[1] or Target MOE
Acute dietary	Not selected.		
	Acute Reference Dose = Not established as there were no acute endpoints of concern.		
Repeated dietary	24-month rat combined chronic/carcinogenicity	NOAEL = 253 mg/kg bw/day; based on early deaths and reduced survivorship in males at the lowest observed adverse effect level of 503 mg/kg bw/day	100
	Acceptable Daily Intake = 2.5 mg/kg bw/day		

Exposure Scenario	Study	Point of Departure and Effect	CAF[1] or Target MOE
Short and Intermediate-term dermal	Quantitative risk assessment is not required.		
Short and Intermediate-term inhalation[2]	12-month dog	NOAEL = 282 mg/kg bw/day (highest dose tested)	100
Non-dietary oral ingestion (short-term)	12-month dog	NOAEL = 282 mg/kg bw/day (highest dose tested)	100
Cancer	Overall, the weight of evidence supported the conclusion that carcinogenicity was not an endpoint of concern for risk assessment.		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments.
[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value)was used in route-to-route extrapolation.

Table 3 Major fate inputs for the modelling for parent-daughter modelling

Fate Parameter	Drinking Water
K_d (L/kg)	0.09
Water half-life (days at 25°C) (or whole system aerobic aquatic half-life)	57.4
Sediment half-life (days at 20°C) (or anaerobic half-life)	Stable
Photolysis half-life (days at 50° latitude)	81.4
Hydrolysis (days)	Stable
Soil half-life (days at 20°C)	Stable

Table 4 Fate and behaviour in the terrestrial and aquatic environments

Study type	Test material	Value[1]	Classification[2]/ Interpretation	Major transformation products[3]	Reference (PMRA#)
Abiotic transformation					
Hydrolysis	Imazapyr	30 d; 25ºC; pH 5, 7 and 9, and distilled water Stable	Not a route of transformation	NA	1168387
Phototransformation – soil	Imazapyr	Moist soil, continuous lightning Stable (> 4 weeks)	Not a major route of transformation	NA	1209132
Phototransformation – water	Imazapyr	pH 5 and 9, and distilled water, sterile, 12-h exposure cycle DT_{50}: 2.5-5.3 d	Major route of transformation	CL119060 (29.7%) CL9140 (22.7%) (23 minor photolytes)	1168388
	Imazapyr	Natural water, sterile, pH 7.9, 12-h exposure cycle DT_{50}: 0.54 d		CL119060 (29.7%) CL9140 (22.7%) M2, M7, M8 Half-lives ranges from 6.2 to 56.8 d.	1461250[4]
Phototransformation – air	Imazapyr is unlikely to volatilize based on its vapor pressure (< 10^{-7} mm Hg at 25ºC) and Henry's Law constant (< 7×10^{-17} atm*m^3/mol at 25ºC)				

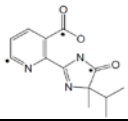
Study type	Test material	Value[1]	Classification[2]/ Interpretation	Major transformation products[3]	Reference (PMRA#)
Biotransformation					
Soil – aerobic	Imazapyr	121 d, pH 6.0, %OM 2.0, 25°C Sassafras Sandy Loam DT50: > 121 d (DFOP – extrapolated DT_{50} of 310 d, representative half-life of 368 d)	Persistent Not a major route of transformation	NA	1843078
	Formulated product	12 months, 25°C Sandy Loam DT_{50}: > 12 months (SFO – extrapolated DT_{50} of 16 months)	Persistent Not a major route of transformation	NA	1168391[5]
	Formulated product	12 months, 25°C Clay Loam Soil DT_{50}: > 12 months (DFOP – extrapolated DT_{50} of 776 d, representative half-life of 1310 d)	Persistent Not a major route of transformation	NA	1234174[5]
	Imazapyr	12 months, 25°C Princeton Sandy Loam Soil DT_{50}: > 12 months (Extrapolated DT_{50} of 5.9 years)	Persistent Not a major route of transformation	NA	USEPA RED
Soil – anaerobic	Imazapyr	120 d, four soils; pH 5.3–6.5, %OM 1.8 Loamy sand soil Stable	Persistent Not a route of transformation		1168392
Wate –-aerobic	Imazapyr	4 months, natural sediment:water, 25°C (DT_{50}: > 120 d; 1 % CO_2 produced in 120 d)	Persistent		1232294
	Photolytes (mixture of 25 substances)	4 months, sand sediment:water, 19–22°C Mineralization DT50: 0.7 weeks (DFOP, representative half-life: 8.2 weeks)	Non-persistent		1143626[6]
	CL119060 CL9140	14 days Total system CL119060 DT_{50}: > 4.9 d CL9140 DT_{50}: > 3.6 d Florida Pond water CL119060 DT_{50}: 2.45 d CL9140 DT_{50}: 0.7 d Missouri Pond water CL119060 DT_{50}: 1.3 d CL9140 DT_{50} ~ 1 d	Non-persistent		2584834
Water – anaerobic	Imazapyr	4 months, sand sediment:water, 19–22°C (< 2% transformation in 120 d)	Persistent Not a route of transformation		1209134
Mobility					
Adsorption/ desorption	Imazapyr	Two soils (pH 7.7–6.6, 0.47–0.64%OC) Florida Sand Imazapyr *K*oc = 20 CL119060 *K*oc = 120	Imazapyr: High to very high mobility CL119060 Low to high	NA	2584835

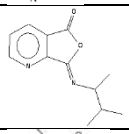
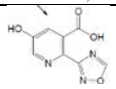
Study type	Test material	Value[1]	Classification[2]/ Interpretation	Major transformation products[3]	Reference (PMRA#)
		CL9140 *K*oc = 156 Missouri Silt Loam Imazapyr *K*oc = 84 CL119060 *K*oc = 302 CL9140 *K*oc = 5585	mobility CL9140 Immobile to moderately mobile		
		Five soils (pH 4.5–6.0, 0.28–3.93%OC) Arkansas Loamy Sand: *K*oc = 16 Indiana Silt Loam: *K*oc = 89 New Jersey Sandy Loam: *K*oc = 9 Wisconsin Loam: *K*oc = 16 Pond Sediment Loam: *K*oc = 93	Imazapyr: High to very high mobility	NA	2584836
Volatilization	Imazapyr is unlikely to volatilize based on its vapour pressure (< 10^{-7} mm Hg at 25ºC) and Henry's Law constant (< 7×10^{-17} atm*m^3/mol at 25ºC)				
Aquatic Field Study of dissipation	Formulated product	Study duration: 184 d Louisiana Pond DT_{50}: 1.9 d (water, SFO) DT_{50}: 1.01 d (sediment) (Representative sediment half-life : 14 d)	Non persistent		1858988[5]
		Florida Pond DT_{50}: 0.9 d (water, SFO) DT_{50}: 1.13 d (sediment) (Representative sediment half-life : 5.9 d)	Non persistent		1843082
		Florida Pond 11 Water DT_{50} < 1 d Florida Pond 21 Water phase DT_{50} = 3.95 d	Non persistent	M6 (CL 119060) M13 (CL 9140)	1888206
		Missouri Pond 11 Water DT_{50} = 12.9 d Missouri Pond 21 Water DT_{50} = 13.8 d	Non persistent	M6 (CL 119060) M13 (CL 9140)	1888208
Herbicidal residue trial in tidal water after *Spartina* Herbicide control in British Columbia and Washington State.	Formulated product, Habitat Aqua (at 1.7 kg a.e./ha). Application was made at low tide.	British Columbia and Washington state: 2013 48 hours after treatment, imazapyr was 0.029 µg/L and 1 week following treatment, it was not detectable (limit of detection: 0.02 µg/L). Washington state: 2006 Site 1: Immediately post treatment, imazapyr was 224, 40 and 2 ppb. Twenty four to 48	Residues declined rapidly	NA	2144498

Study type	Test material	Value[1]	Classification[2]/ Interpretation	Major transformation products[3]	Reference (PMRA#)
		hours after treatment, residues were not detectable. Site 2: Immediately post treatment, imazapyr was 3 and 2 ppb. Twenty four to 48 hours after treatment, residues were not detectable.			
Terrestrial field dissipation studies	In terrestrial field trials conducted in Alberta, at an application rate similar to the highest Canadian application rate, imazapyr dissipated to below the level of detection within two months and was not found below 10 cm. In addition, American field studies in Canadian relevant ecozones have demonstrated half-lives between 94 and 143 days. In four field trials in the northern United States, imazapyr had dissipated to concentrations below the level of detection within six months. In these field studies, imazapyr residues were restricted mainly to the top 15 cm of soil, with trace amounts being found between 15 and 30 cm. In a New Jersey (United States) field study, in which plants were treated with 14C-imazapyr, imazapyr persisted in the plants, and was added to the soil when the plants died; radioactive residues were found to a depth of 53 cm below the soil surface.		Moderately persistent Overall, the field studies indicated that imazapyr is detected in the 0-55 cm soil layer and the dissipation half-lives were less than the laboratory studies of persistence.	NA	REV2014-03
Bioconcentration/Bioaccumulation[7]					
Bioconcentration	Imazapyr	Species: seven fish, one crayfish BCF < 1	Not bioaccumulative	NA	234305
		Species: Oyster, shrimp BCF < 1			234306
		Species: bluegill sunfish BCF < 1			1204782[5]
		Species: bluegill sunfish BCF < 1			2584845[8]
		Species: freshwater clam BCF < 1			2343377[5]

[1] Kinetics models: SFO = single first-order; DFOP = double first order in parallel.
[2] USEPA classification, where applicable
[3] Major transformation products are those found at > 10% of the applied
[4] Study submitted under the incident report program
[5] Study submitted and reviewed in support of previous Registrations
[6] Test conducted with the mixture resulting of aquatic phototransformation test; contains 25 photolytes
[7] Bioconcentration factors (BCF)
[8] Additional study submitted in support of the current use expansion

Table 5 Imazapyr and its major transformation products formed in aqueous photolysis studies

Identification*	Structure	Maximum Detected	Level at study termination	Reference (PMRA#)
Imazapyr		98.6% (day 0) 100% (day 0)	 2.7% (day 10) < LOQ	1168388 1461250

Identification*	Structure	Maximum Detected	Level at study termination	Reference (PMRA#)
7-hydroxyfuro[3,4-b]pyridine-5(7H)-one (M6, CL 119060)		31.8% (day 9) 48.1% (day 2)	29.7% (day 10) 11.8% (day 14)	1168388 1461250
2,3-Pyridinedicarboxylic acid (M13, CL 9140)		22.8% (day 9) 16.1% (day 14)	22.7% (day 10) 16.1% (day 14)	1168388 1461250
Nicotinic Acid (M2)		12.1% (day 14)	12.1% (day 14)	1461250
(7Z)-7-[(1,2-dimethylpropyl)imino]furo[3,4-b]pyridin-5(7H)-one (M8)		39.0% (day 5)	29.0% (day 14)	1461250
5-hydroxy-2-(1,2,4-oxadiazol-3-yl)nicotinic acid (M7)		11.6% (day 1.5)	2.1% (day 14)	1461250

*All major transformation products are from phototransformation in aquatic systems.

Table 6 Toxicity of imazapyr to pollinators

Organism	LC50 Endpoint value (µg a.e./bee/day)	Application rate (g a.e./ha)	EEC[1] (µg a.e./bee/day)	RQ	LOC exceeded
Adult *Apis mellifera*	Contact: >100	1680	4.03	<0.04	No
	Oral: >117	1680	48.1	<0.41	**Yes** (based on no effects in study, no risk expected)
	Contact: >100	1123	2.69	<0.03	No
	Oral: >117	1123	32.1	<0.27	No

[1] For contact exposure, the exposure estimate = (2.4 µg a.i./bee)*(application rate in kg a.i./ha); dietary factors are 29 µg a.i./bee (adult).

Table 7 Risk quotients (RQs) for terrestrial and emergent aquatic plants

Species of plant	EC_{25} Endpoint value (g a.e./ha)	Screening EEC (g a.e/ha)	RQ	LOC exceeded	Off-field (% drift) EEC (g a.e/ha)	RQ	LOC exceeded
Vegetative vigour							
cucumber	1.01	1680	1663	Yes	100 (6%)	99	**Yes**
		1123	1112	Yes	258 (23%) 67.3 (6%)	255 66.6	**Yes**
		720	713	Yes	43 (6%)	43	**Yes**
sugarbeet	2.25	1680	747	Yes	100 (6%)	44.4	**Yes**
		1123	499	Yes	258 (23%) 67.3 (6%)	115 29.9	**Yes**
		720	320	Yes	43 (6%)	19	**Yes**
sunflower	6.07	1680	277	Yes	100 (6%)	16.5	**Yes**
		1123	185	Yes	258 (23%)	42.5	**Yes**

Species of plant	EC_{25} Endpoint value (g a.e./ha)	Screening EEC (g a.e/ha)	RQ	LOC exceeded	Off-field (% drift) EEC (g a.e/ha)	RQ	LOC exceeded
					67.3 (6%)	11.1	
		720	119	Yes	43 (6%)	7.1	**Yes**
wheat/onion	13.5	1680	124	Yes	100 (6%)	7.4	**Yes**
		1123	83.2	Yes	258 (23%) 67.3 (6%)	19.1 4.9	**Yes**
		720	53	Yes	43 (6%)	3.2	**Yes**
oat	14.6	1680	115	Yes	100 (6%)	6.8	**Yes**
		1123	76.9	Yes	258 (23%) 67.3 (6%)	17.7 4.61	**Yes**
		720	49	Yes	43 (6%)	2.9	**Yes**
tomato/corn	17.5	1680	96	Yes	100 (6%)	5.71	**Yes**
		1123	64	Yes	258 (23%) 67.3 (6%)	17.7 3.85	**Yes**
		720	41	Yes	43 (6%)	2.5	**Yes**
soybean	38.2	1680	44	Yes	100 (6%)	2.62	**Yes**
		1123	29.4	Yes	258 (23%) 67.3 (6%)	6.75 1.76	**Yes**
		720	18.8	Yes	43 (6%)	1.13	**Yes**
Seedling emergence							
sugarbeet	2.70	1680	622	Yes	100 (6%)	37	**Yes**
		1123	416	Yes	258 (23%) 67.3 (6%)	95.6 24.9	**Yes**
		720	267	Yes	43 (6%)	15.9	**Yes**
wheat	5.17	1680	325	Yes	100 (6%)	19.3	**Yes**
		1123	217	Yes	258 (23%) 67.3 (6%)	49.9 13	**Yes**
		720	139	Yes	43 (6%)	8.3	**Yes**
tomato	8.99	1680	187	Yes	100 (6%)	11.1	**Yes**
		1123	125	Yes	258 (23%) 67.3 (6%)	28.7 7.49	**Yes**
		720	80	Yes	43 (6%)	4.8	**Yes**
onion	38.2	1680	43.9	Yes	100 (6%)	2.62	**Yes**
		1123	29.4	Yes	258 (23%) 67.3 (6%)	6.75 1.76	**Yes**
		720	18.8	Yes	43 (6%)	1.12	**Yes**
oat	60.7	1680	27.7	Yes	100 (6%)	1.65	**Yes**
		1123	18.5	Yes	258 (23%) 67.3 (6%)	4.25 1.12	**Yes**
		720	11.8	Yes	43 (6%)	0.71	**No**

Note: Terrestrial plants are considered a surrogate for emergent plants in aquatic systems.

Table 8 Toxicity of imazapyr to non-target aquatic species (all endpoints from PRVD2008-10, PRD2011-12), the corresponding Regulatory Decisions (RVD2008-17, RD2012-10)

Species	Exposure	Value	Classification[1]
Freshwater			

Species	Exposure	Value	Classification[1]
Crustacean *(Daphnia magna)*	Acute	48-h EC_{50} > 100 $mg_{a.e.}$/L	Practically non-toxic
Crustacean *(Daphnia magna)*	Chronic	21-d NOEC = 97 $mg_{a.e.}$/L (no effects)	No classification
Green algae *(Selenastrum capricornutum)*	Acute	EC_{50} = 11.5 $mg_{a.e.}$/L	No classification
Blue-green algae *(Anabaena flos-aquae)*	Acute	EC_{50} = 12.2 $mg_{a.e.}$/L	No classification
Freshwater diatom (*Navicula pelliculosa*)	Chronic	NOEC = 41 $mg_{a.e.}$/L (no effects)	No classification
Duckweed (*Lemna gibba)*	Acute	EC_{50} = 0.018 $mg_{a.e.}$/L	No classification
Rainbow trout *(Oncorhynchus mykiss)*	Acute	96-h LC_{50} > 100 $mg_{a.e.}$/L	Practically non-toxic
Rainbow trout *(Oncorhynchus mykiss)*	Early Life Stage	NOEC = 43.1 $mg_{a.e.}$/L (no effects)	No classification
Bluegill sunfish (*Lepomis macrochirus*)	Acute	96-h LC_{50} > 100 $mg_{a.e.}$/L	Practically non-toxic
Channel catfish (*Ictalurus punctatus*)	Acute	96-h LC_{50} > 100 $mg_{a.e.}$/L	Practically non-toxic
Fathead Minnow (*Pimephales promelas*)	Early Life Stage	NOEC = 118 $mg_{a.e.}$/L (no effects)	No classification
Fathead Minnow (*Pimephales promelas*)	Chronic Full Life Cycle	NOEC = 120 $mg_{a.e.}$/L (no effects)	No classification
Marine			
Silverside minnow *(Menidia menidia)*	Acute	96-h LC_{50} > 184 $mg_{a.e.}$/L	Practically non-toxic
Eastern Oyster (*Crassostrea virginica*)	Acute	EC_{50} > 132 $mg_{a.e.}$/L	No classification
Pink shrimp *(Paneus duorarum)*	Acute	LC_{50} > 189 $mg_{a.e.}$/L	Practically non-toxic
Marine diatom (*Skeletonema costatum*)	Acute	EC_{50} = 92 $mg_{a.e.}$/L	No classification

[1] EPA classification, where applicable

Table 9 Screening level RQs for aquatic organisms in water bodies having a depth of 15 and 80 cm

Organism	Exposure	Endpoint value (mg a.i./L)	EEC (mg a.e./L)[1]	RQ[2]	LOC exceeded[3]
Freshwater					
Daphnia magna	Acute	EC_{50}/2 >50	0.21	<0.004	No
Daphnia magna	Chronic	NOEC = 97 (no effects)	0.21	0.002	No
Rainbow trout	Acute	LC_{50}/10 >10	0.21	<0.021	No
Rainbow trout	Chronic early-life stage	NOEC = 43 (no effects)	0.21	0.004	No
Bluegill sunfish	Acute	LC_{50}/10 >10	0.21	<0.021	No
Channel catfish	Acute	LC_{50}/10 >10	0.21	<0.021	No
Fathead minnow	Chronic early life stage	NOEC = 118 (no effects)	0.21	0.002	No
Fathead minnow	Chronic full life-cycle	NOEC = 120 (no effects)	0.21	0.002	No

Organism	Exposure	Endpoint value (mg a.i./L)	EEC (mg a.e./L)[1]	RQ[2]	LOC exceeded[3]
Amphibian[5] (considering fish endpoint as a surrogate)	Acute	LC_{50}/10 >10	1.12	<0.112	No
Amphibian (considering fish endpoint as a surrogate)	Chronic early life stage	NOEC = 43 (no effects)	1.12	0.026	No
Green algae (*Selenastrum capricornutum*)	Acute	EC_{50}/2 = 5.8	0.21	0.036	No
Blue-green algae	Acute	EC_{50}/2 = 6.1	0.21	0.03	No
Diatom (*Navicula pelliculosa*)	Chronic	NOEC = 41 (no effects)	0.21	<0.005	No
Aquatic vascular plants (*Lemna gibba*)	Acute	EC_{50}/2 = 0.009	0.21	23	**Yes**
Marine					
Easter Oyster	Acute	EC_{50}/2 >66	0.21	<0.003	No
Pink shrimp	Acute	EC_{50}/2 >94.5	0.21	<0.002	No
Silverside minnow	Acute	LC_{50}/10 >18	0.21	<0.011	No
Diatom (*Skeletonema costatum*)	Acute	EC_{50}/2 = 46	0.21	0.0045	No
Aquatic vascular plants (*Lemna gibba*) as a surrogate for a marine aquatic plant	Acute	EC_{50}/2 = 0.009	0.21	23	**Yes**

[1]EEC = Estimated Environmental Concentration. The EEC is calculated by assuming a direct overspray to water with the maximum application rate (1.69 kg a.i./ha).

[2]RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value).

[3]LOC = Level of concern. The RQ is compared to the LOC (LOC = 1.0). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

[4] Terrestrial plants used as a surrogate for emergent aquatic plants in the risk assesment

[5] Amphibian risk assessment considered fish endpoints as a surrogate and a water depth of 15 cm.

Note: All EECs based on 80 cm depth, except for amphibian RQ.

Table 10 Refined risk quotients (RQs) considering drift (from surrounding water and in water applications simultaneously) for aquatic organisms in water bodies having a depth of 80 cm

Organism	Exposure	Endpoint value (mg a.i./L)	% drift (rate)	EEC[1] (mg a.e./L)	RQ[2]	LOC exceeded[3]
Freshwater and Marine						
Aquatic vascular plants (*Lemna gibba*)	Acute	EC50/2 = 0.009	6% (1.68 kg a.e./ha)	0.0126	1.4	**Yes**
			6% (1.12 kg a.e./ha)	0.0084	0.007	**No**
			23% (1.12 kg a.e./ha)	0.032	3.6	**Yes**

Organism	Exposure	Endpoint value (mg a.i./L)	% drift (rate)	EEC[1] (mg a.e./L)	RQ[2]	LOC exceeded[3]
			6% (0.720 kg a.e./ha)	0.005	0.58	**No**

[1]EEC = Estimated Environmental Concentration. The EEC is calculated with an application rate 1.68 and 0.720 kg a.e./ha and 6% drift (ground); and 1.123 kg a.e./ha and 23% drift (aerial) and 6% drift (ground). EEC in 80 cm water at 1.68 kg a.e./ha = 0.21 mg/L, 1.12 kg a.e./ha = 0.14 mg/L and 0.720 kg a.e./ha = 0.0875 mg/L.
[2]RQ = Risk quotient. The RQ is calculated by dividing the EEC by the endpoint value (RQ = EEC/endpoint value).
[3]LOC = Level of concern. The RQ is compared to the LOC (LOC = 1.0). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary.

Table 11 Toxic substances management policy considerations-comparison to TSMP Track 1 criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Major Transformation Product Endpoints
Toxic or toxic equivalent as defined by the *Canadian Environmental Protection Act*[1]	Yes		**Yes** Toxic to vascular plants	**Yes** Unknown toxicity
Predominantly anthropogenic[2]	Yes		**Yes**	**Yes** for M6, M7 and M8 No for M2 and M13
Persistence[3]	Soil	Half-life ≥ 182 days	**Yes** DT_{50} > 12 months in soil	**Yes** Unknown transformation rates
	Water	Half-life ≥ 182 days	No Phototransformation DT_{50} 0.5 – 5.3 days Stable to biotransformation	No DT50 < 7 days
	Sediment	Half-life ≥ 365 days	Not expected to partition to sediments	Not expected to partition to sediments, except for M13 based on K_{OC} of 156 and 5 585
	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (< 10^{-7} mm Hg) and Henry's Law Constant (< 7×10^{-17} atm × m3/mol)	Not expected to be volatile based on observations during laboratory studies.
Bioaccumulation[4]	Log K_{OW} ≥ 5		No 0.22	EpiWeb4.1 predictions: -0.81 to 1.57
	BCF ≥ 5000		< 1	not available
	BAF ≥ 5000		not available	not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			**No, does not meet TSMP Track 1 criteria.**	**No, does not meet TSMP Track 1 criteria.**

[1]All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).
[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4]Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Table 12 List of supported uses

Items	Proposed label claims	PMRA supported use claims
Application rate	**Invasive Phragmites (European reed):** 3.0–4.68 L/ha (0.72–1.12 kg a.i./ha) Use the higher labeled rate where heavy or well established infestations occur **Invasive cordgrasses (denseflower, salt-meadow, smooth and common)**: 4.68 to 7.0 L/ha (1.12–1.68 kg ai/ha) Use higher labeled rates for heavy weed pressure **Flowering rush**: 3.0 L/ha (0.72 kg/ha)	As proposed.
Adjuvant	0.25–0.5% v/v Non Ionic surfactant or equivalent recommended for aquatic use	0.25-0.5% Aquasurf (Reg. No. 32152)
Application methods	Habitat Aqua Herbicide may be selectively applied by using low-volume directed application techniques or may be broadcast applied by using ground equipment, watercraft, or helicopter application equipment only for aerial application to aquatic sites. Aerial application is for invasive Phragmites only. One application per year.	As proposed.
Application timing	**Postemergence** **Invasive cordgrasses (denseflower, salt-meadow, smooth and common)**: apply to emergent green foliage. Schedule applications in order to allow 4 hours before treated plants are covered by tidewater **Invasive Phragmites**: Apply to green foliage after full leaf elongation. Ensure 100% coverage. For optimum results, treat in late summer or early fall when translocates are directed towards the roots of the plants. If stand has a substantial amount of old stem tissue, mow or burn, allow to regrow to approximately 1.5 m tall before treatment **Flowering rush**: apply to emergent green foliage.	As proposed.
Use methods	Habitat Aqua Herbicide must be applied to the emergent foliage of the target vegetation and does not control plants which are completely submerged or have a majority of their foliage under water. Habitat Aqua concentrations resulting from direct application to water are not expected to be of sufficient concentration nor duration to provide control of target vegetation. Application should be made in such a way as to maximize spray interception by the target vegetation while minimizing the amount of overspray that	As proposed.

Items	Proposed label claims	PMRA supported use claims
	enters the water. **Invasive cordgrasses (denseflower, salt-meadow, smooth and common)**: For control of invasive cordgrasses (denseflower, salt-meadow, smooth and common) in estuarine/marine tidal areas, apply Habitat Aqua Herbicide at least four hours before treated plants are covered by tidewater. Use higher labeled rates for heavy weed pressure. **Invasive Phragmites**: Due to the dense nature of invasive Phragmites, repeat treatments may be necessary to maintain control. Visual control symptoms will be slow to develop. For large monocultures of invasive Phragmites, work from the periphery inward in successive years to allow competing vegetation to establish in the treated area. A long-term control strategy should include measures to control both established plants and seedlings. Sprayed areas should be monitored to determine the appropriate follow-up management. Early detection and treatment of second and third generation seedlings is important to prevent re- infestation of invasive Phragmites. Desirable native plant communities will then have a chance to become re-established. Use the higher labelled rate where heavy or well established infestations of invasive Phragmites occur	

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