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Proposed Registration Decision

PRD2022-09

***Trichoderma asperellum* strain ICC 012, *Trichoderma gamsii* strain ICC 080, and Foretryx**

(publié aussi en français)

12 August 2022

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

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Canada 

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

Catalogue number: H113-9/2022-9E (print version)
H113-9/2022-9E-PDF (PDF version)

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Overview

Proposed registration decision for *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080

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 the microbial pest control agents (MCPAs) contained in *Trichoderma asperellum* ICC 012 Technical, *Trichoderma gamsii* ICC 080 Technical and Foretryx, containing the technical grade active ingredients *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080, for the suppression and partial suppression of certain fungal diseases on field and greenhouse fruiting vegetables, squash, lettuce, field and greenhouse strawberries, greenhouse ornamentals and cannabis produced commercially indoors.

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 *Trichoderma asperellum* strain ICC 012, *Trichoderma gamsii* strain ICC 080 and Foretryx.

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 acceptable¹ 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 value² 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 policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides.

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."

For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of the Canada.ca website.

Before making a final registration decision on *Trichoderma asperellum* strain ICC 012, *Trichoderma gamsii* strain ICC 080 and Foretryx, 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 Decision⁴ on *Trichoderma asperellum* strain ICC 012, *Trichoderma gamsii* strain ICC 080 and Foretryx, 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 are *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080?

Trichoderma is a genus of ubiquitous fungi that colonize rhizosphere soil and plant roots, rotting wood, and dead plant material. It is regarded as one of the most widely distributed of all soil fungi. It is found frequently in all types of natural or agricultural soils, including forest humus layers, and orchards. Some strains are able to parasitize plant pathogenic fungi.

Trichoderma asperellum strain ICC 012 and *Trichoderma gamsii* strain ICC 080 are new active ingredients for disease management on various field and greenhouse crops in Canada. These two active ingredients demonstrate fungicidal properties by competing with plant pathogens for space and nutrients on target crops and may also induce systemic resistance.

Health considerations

Can approved uses of *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080 and Foretryx affect human health?

***Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080 are unlikely to affect your health when Foretryx is used according to the label directions.**

Potential exposure to *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 may occur when handling and applying Foretryx. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic by-products);
- reports of any adverse incidents;

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*.

- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

The levels used to assess risks are established to protect 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 that are determined as having no health risks of concern are considered acceptable for registration.

Studies in laboratory animals describe potential health effects from large doses of exposure to a microorganism and identify any pathogenicity, infectivity and toxicity concerns.

When *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical were tested on laboratory animals, there was low toxicity following oral, pulmonary instillation and dermal exposures. Foretryx is minimally irritating to the skin and is non-irritating to the eyes. Furthermore, there was no sign that the microbial pest control agents, *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080, caused any disease.

Residues in water and food

Dietary risks from food and water are acceptable

Residues of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 on treated crops are possible at the time of harvest. Agricultural practices of washing these crops following harvest are expected to reduce the potential for dietary exposure to residues of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080. Furthermore, no signs of infectivity or toxicity were observed when *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 were tested on laboratory animals, and significant levels of secondary metabolites are not expected to occur on edible portions of the crops. In addition, the likelihood of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 contaminating drinking water is expected to be low as the label has the necessary mitigation measures to limit contamination of drinking water from the proposed uses of Foretryx. Consequently, dietary risks are acceptable.

Occupational risks from handling Foretryx

Occupational risks are acceptable when Foretryx is used according to label directions, which include protective measures

Workers handling Foretryx can come into direct contact with *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 on the skin, by inhalation, or in the eyes. To protect workers from exposure to Foretryx, the label states that workers must wear personal protective equipment, including waterproof gloves, long-sleeved shirt, long pants, a NIOSH-approved particulate filtering facepiece respirator, socks and shoes. The product label includes measures to restrict access to the treated area for 4 hours or until sprays have settled.

Risks in residential and other non-occupational environments

Estimated risk for non-occupational exposure is acceptable.

Foretryx is proposed for commercial use as a drip chemigation in greenhouses and diluted broadcast spray applications at planting to the soil surface in agricultural fields. The product label includes measures to prevent bystander exposure such as reducing spray drift. Residential and non-occupational exposure to Foretryx is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Environmental considerations

What happens when *Trichoderma asperellum* strain ICC 012, *Trichoderma gamsii* strain ICC 080 and Foretryx are introduced into the environment?

Environmental risks are acceptable.

Information on the environmental fate of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 suggests that, as a soil microorganism, they are likely to readily survive after applications of Foretryx to agricultural field crops, but that over time their populations should return to naturally sustainable levels.

There are no published reports of disease associated with natural populations of *Trichoderma gamsii* or *Trichoderma asperellum* in birds, wild mammals, fish, terrestrial and aquatic arthropods, terrestrial and aquatic non-arthropod invertebrates, or terrestrial and aquatic plants. Also, the applicant submitted studies designed to examine the effects of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 to bees, earthworms, soil microorganisms, fish, aquatic arthropods, and aquatic plants. No adverse effects were observed in bees, earthworms, soil microorganisms, or fish. There were toxic effects noted in daphnids including reproductive effects for *T. gamsii* strain ICC 080. There were toxic effects to duckweed from *T. gamsii* strain ICC 080 and growth inhibition to algae from both strains; however, these effects occurred at levels that exceed estimated exposure levels when Foretryx is used according to the label.

Based on a critical review of data and published scientific literature submitted by the applicant, no significant effects to birds, bees, arthropods, wild mammals, soil microorganisms, fish, or plants are expected when Foretryx is applied according to directions on the label.

Value considerations

What is the value of Foretryx?

Foretryx is a soil-applied fungicide containing two strains of live fungi for the control of soil –borne pathogens. The registration of Foretryx will provide Canadian growers with an alternative fungicide product for use to manage certain diseases on a variety of field and greenhouse crops.

Foretryx is applied to soil as a broadcast spray or via chemigation to suppress or partially suppress certain diseases on various field and greenhouse crop.

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 labels of Foretryx to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

All microorganisms, including *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080, contain substances that are potential sensitizers and thus, sensitivity may possibly develop in individuals exposed to potentially large quantities of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080. In turn, workers handling or applying Foretryx must wear waterproof gloves, a long-sleeved shirt, long pants, a NIOSH-approved particulate filtering facepiece respirator, socks and shoes. Furthermore, all unprotected workers are restricted from entering treated areas during application and for 4 hours following application or until sprays have settled.

Environment

The Foretryx label will include environmental precaution statements to prohibit aerial application, limit drift, and reduce the potential for contamination of aquatic systems.

Next steps

Before making a final registration decision on *Trichoderma asperellum* ICC 012 Technical, *Trichoderma gamsii* ICC 080 Technical and Foretryx, 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 *Trichoderma asperellum* ICC 012 Technical, *Trichoderma gamsii* ICC 080 Technical and Foretryx (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. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

Trichoderma asperellum ICC 012 Technical, Trichoderma gamsii ICC 080 Technical and Foretryx

1.0 The active ingredients, their properties and uses

1.1 Identity of the active ingredient

Active microorganism	<i>Trichoderma gamsii</i> strain ICC 080	<i>Trichoderma asperellum</i> strain ICC 012
Function	Fungicide – for the suppression and partial suppression of certain fungal diseases on field and greenhouse fruiting vegetables, squash, lettuce, field and greenhouse strawberries, greenhouse ornamentals and cannabis produced commercially indoors.	
Binomial	<i>Trichoderma gamsii</i> strain ICC 080	<i>Trichoderma asperellum</i> strain ICC 012
Taxonomic designation¹		
Kingdom	Fungi	
Phylum	Ascomycota	
Subphylum	Pezizomycotina	
Class	Sordariomycetes	
Order	Hypocreales	
Family	Hypocreaceae	
Genus	<i>Trichoderma</i>	
Species	<i>gamsii</i>	<i>asperellum</i>
Strain	ICC 080	ICC 012
Patent status information	None	
Minimum purity of active	Technical grade active ingredient: minimum of 1×10^9 colony forming units (CFU)/g	Technical grade active ingredient: minimum of 1×10^9 CFU/g
	Foretryx end-use product: minimum of 5×10^6 CFU/g <i>T. gamsii</i> strain ICC 080 and minimum of 5×10^6 CFU/g <i>T. asperellum</i> strain ICC 012	

Identity of relevant impurities of toxicological, and/or environmental significance	The technical grade active ingredients do not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. The products must meet microbiological contaminant release standards. The end-use product may contain antibiotic peptides collectively known as peptaibols. The absence of toxic effects in mammalian acute toxicity studies (see Section 3.0) suggests that the manufacturing process either does not favour the production of these potentially toxic metabolites or that the levels produced are too low to elicit an effect in animals administered a high dose of these fungi.
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¹ National Center for Biotechnology Information - Taxonomy Browser (<https://www.ncbi.nlm.nih.gov/taxonomy>)

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

Technical Product–*Trichoderma gamsii* ICC 080 Technical

Property	Result
Colour	grey-green
Physical State	solid powder
Odour	slight
pH	6.66
Tap density	0.200 g/mL

Technical product – *Trichoderma asperellum* ICC 012 Technical

Property	Result
Colour	grey-green
Physical State	solid powder
Odour	slight
pH	6.21
Tap density	0.195 g/mL

End-Use product – Foretryx

Property	Result
Colour	light grey to greenish
Physical State	fine powder
Odour	typical
pH	5.48
Density	0.60–0.62 g/mL

1.3 Directions for use

Foretryx is used to treat labelled field crops via a diluted broadcast spray application to the soil surface at planting at rates between 2.8-5.6 kg product/ha. Foretryx is used to treat labelled greenhouse crops via chemigation at a rate of 2.8 kg product/ha following a re-application interval of 14-21 days.

1.4 Mode of action

Trichoderma asperellum strain ICC 012 and *Trichoderma gamsii* strain ICC 080 compete with plant pathogens for space and nutrients, induce systemic resistance, secrete cell wall degrading enzymes, and cause mycoparasitism.

2.0 Methods of analysis

2.1 Methods for identification of the microorganisms

Acceptable methodologies for detection, isolation and enumeration of the active ingredients, *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012, were submitted by the applicant. The microbial pest control agents (MPCAs) have been fully characterized with respect to the origin of strain, natural occurrence and biological properties. *Trichoderma gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 have been confirmed to be members of their respective species using multi-locus sequence analysis of the ITS1 and tef1 sequences. Sequences of tef1 (for *T. gamsii* strain ICC 080) or ITS1 and tef1 in combination (for *T. asperellum* strain ICC 012) can be used to definitively identify the MPCAs to the strain level.

2.2 Method for establishment of purity of seed stock

Trichoderma gamsii strain ICC 080 has been deposited into the CABI IMI Culture Collection under number 392151. *Trichoderma asperellum* strain ICC 012 has been deposited into the CABI IMI Culture Collection under number 392716. The strains are maintained by the manufacturer in a manner sufficient to maintain purity and stability.

Acceptable methods for the establishment of the purity, viability and genetic stability of the banks were described.

2.3 Methods to define the content of the microorganism in the manufactured material used for the production of formulated products

The guarantees of the technical grade active ingredients and the end-use product are expressed in units of CFU/g. Representative data on five batches of each technical grade active ingredient and end-use product were submitted. The methods for determining CFU counts were adequately described.

2.4 Methods to determine and quantify residues (viable or non-viable) of the active microorganism and relevant metabolites

As noted above, acceptable methods are available to enumerate the microorganisms and to distinguish these MPCAs from other *Trichoderma* species.

2.5 Methods for determination of relevant impurities in the manufactured material

The quality assurance procedures used to limit contaminating microorganisms during the manufacture of *Trichoderma gamsii* ICC 080 Technical, *Trichoderma asperellum* ICC 012 Technical, and Foretryx are acceptable. These procedures include sterilization of all equipment and media as well as frequent sampling of the stock culture and production batches for purity and contamination.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of batches of Foretryx using standard microbiological methods for detecting and enumerating microbial contaminants of concern. All batches of Foretryx conform to the limits set out in the Organisation for Economic Co-operation and Development (OECD) issue paper on microbial contaminants for microbial pest control products [ENV/JM/MONO(2011)43].

2.6 Methods to determine storage stability, shelf-life of the microorganism

Storage stability data were provided for Foretryx. Results support a storage period of 15 months when the end-use product is stored unopened at 25°C.

3.0 Impact on human and animal health

3.1 Toxicity and infectivity summary

3.1.1 Testing

A detailed review of the submitted toxicological studies was conducted in support of the two technical grade active ingredients, *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical, and the associated end-use product, Foretryx.

Trichoderma asperellum ICC 012 Technical

To address the health hazard requirements for *Trichoderma asperellum* ICC 012 Technical, the applicant submitted acute oral toxicity, acute pulmonary toxicity/infectivity, and acute intraperitoneal pathogenicity studies. These studies were performed with *T. harzianum* strain ICC 012 which was equivalent to *Trichoderma asperellum* ICC 012 Technical.

In the acute oral toxicity study, young Sprague Dawley CD rats (5/sex) were given a single oral dose of at least 1.41×10^9 CFU of *T. harzianum* ICC 012 in 0.9% aqueous NaCl. Animals were observed for up to 14 days. There were no mortalities, treatment-related clinical signs, necropsy findings or changes in body weight.

In the acute pulmonary infectivity and toxicity study, young Sprague Dawley CD rats (15/sex) were given a single dose of 1.1×10^7 CFU of *T. harzianum* ICC 012 in 0.1% Tween20 by intratracheal instillation. Another group of rats (6/sex) was exposed to a similar suspension of inactivated spores. Animals were then observed for up to 21 days with interim scheduled sacrifices on Days 1, 4, 7, 14, and 21. There were no mortalities, treatment-related clinical signs, or changes in body weight. Necropsy findings in the lungs of both the active and inactive test item groups indicated a low level of irritation, likely due to the presence of spore components. A pattern of clearance was established, with levels of the MPCA declining over the course of the study period.

In the acute intraperitoneal pathogenicity study, young Sprague Dawley CD rats (3/sex) were injected with 1.2×10^8 CFU *T. harzianum* ICC 012 in 0.9% NaCl. Animals were then observed for 21 days. There were no mortalities, treatment-related clinical signs, necropsy findings or changes in body weight.

Trichoderma gamsii ICC 080 Technical

To address the health hazard requirements for Trichoderma gamsii ICC 080 Technical, the applicant submitted acute oral toxicity, acute pulmonary toxicity/infectivity, and acute intraperitoneal pathogenicity studies. These studies were performed with *T. viride* strain ICC 080 which was equivalent to Trichoderma gamsii ICC 080 Technical.

In the acute oral toxicity study, young Sprague Dawley CD rats (5/sex) were given a single oral dose of at least 2.76×10^8 viable spores of *T. viride* strain ICC 080 in 0.9% aqueous NaCl. Animals were observed for up to 14 days. There were no mortalities, treatment-related clinical signs, necropsy findings or changes in body weight.

In the acute pulmonary infectivity and toxicity study, young Sprague Dawley CD rats (15/sex) were given a single dose of 2.5×10^6 CFU *T. viride* strain ICC 080 in 0.1% Tween20 by intratracheal instillation. Another group of rats (6/sex) was exposed to a similar suspension of inactivated spores. Animals were then observed for up to 21 days with interim scheduled sacrifices on Days 1, 4, 7, 14, and 21. There were no mortalities, treatment-related clinical signs, or changes in body weight. Necropsy findings in the lungs of both the active and inactive test item groups indicated a low level of irritation, likely due to the presence of spore components. A pattern of clearance was established, with the MPCA having cleared completely by the end of the study period.

In the acute intraperitoneal pathogenicity study, young Sprague Dawley CD rats (3/sex) were injected with at least 8.37×10^6 CFU *T. viride* strain ICC 080 in 0.9% NaCl. Animals were then observed for 21 days. Treatment-related symptoms of slightly reduced motility, slight ataxia,

slightly reduced muscle tone, slight dyspnea, mydriasis and writhing were observed in all animals dosed with the test item immediately following treatment. All clinical signs completely resolved within 24 hours. There were no mortalities, treatment-related necropsy findings or changes in body weight.

Foretryx

To address the health hazard requirements for the end-use product, Foretryx, the applicant submitted acute oral toxicity, acute inhalation toxicity, acute dermal toxicity, dermal sensitization, eye irritation, and dermal irritation studies. These studies were performed with Remedier WP (7.8×10^7 CFU/g *T. viride* strain ICC 080 and 7.8×10^7 CFU/g *T. harzianum* strain ICC 012), which is equivalent to Foretryx.

In the acute oral toxicity study, young Sprague Dawley CD rats (5/sex) were given a single oral dose of 2000 mg/kg bodyweight (bw) Remedier WP in 0.9% aqueous NaCl. Animals were observed for up to 14 days. There were no mortalities, treatment-related clinical signs, necropsy findings or changes in body weight.

In the acute inhalation toxicity study, young Sprague Dawley CD rats (5/sex) were exposed by nose-only inhalation to Remedier WP for 4 hours at a concentration of 5.20 mg/L air. Animals were observed for 14 days. There were no mortalities, treatment-related clinical signs, necropsy findings or changes in body weight.

In the acute dermal toxicity study, young Sprague Dawley CD rats (5/sex) were dermally exposed to 2000 mg/kg bw Remedier WP for 24 hours to an area of approximately 10% of body surface area. The animals were observed for a period of 14 days. There were no mortalities and no treatment-related clinical signs, necropsy findings or changes in body weight.

In a skin sensitization study, one group of 10 young adult male Duncan-Hartley guinea pigs was tested with Remedier WP in 0.9% NaCl, using the method of Magnusson and Kligman. There were no mortalities, treatment-related changes in animal behaviour or body weight. In the induction stage, erythema (discrete/patchy, and moderate/confluent) was observed in all animals. In the challenge stage, no dermal reactions were observed.

In the primary eye irritation study, 100 mg of Remedier WP was instilled neat into the conjunctival sac of right eyes of three young adult male Himalayan rabbits for 8 hours. Animals then were observed for 72 hours. Irritation was scored by the method of Draize. Conjunctival redness (grade 1) was observed in the treated eyes of all animals 1 hour after instillation, but conjunctivae returned to normal (grade 0) by the 24-hour observation time-point. The cornea and iris were not affected by instillation of the test item. All animals were free of ocular irritation by 24 hours. The maximum irritation score (MIS) was 1/110 (at 1 h) and the maximum average score (MAS) was 0/110 (at 24, 48, 72 h).

In the primary dermal irritation study, three young male Himalayan rabbits were dermally exposed to 500 mg of Remedier WP to a 6 cm² site. The test area was covered with a gauze patch and non-irritating tape during the exposure period. After 4 hours, the dressings were removed. Following exposure, the animals were observed for a period of 6 days. Irritation was scored by the method of Draize. A very slight erythema (grade 1) was observed in all three animals 24 hours to 5 days after patch removal. A very slight edema (grade 1) was observed in one animal 72 hours and 4 days after patch removal. All animals were symptom-free by Day 6. The MIS was 1.33/8 (at 72 h) and the MAS was 1.11/8 (at 24, 48, 72 h).

Test results are summarized in Appendix I, Tables 1, 2, and 3.

3.1.2 Incident reports related to human and animal health

Trichoderma asperellum ICC 012 and *T. gamsii* ICC 080 are new active ingredients pending registration for use in Canada, and as of November 12, 2021, no incident reports had been submitted to the PMRA.

3.1.3 Hazard analysis

The data package submitted in support of registering *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical, and the associated end-use product, Foretryx, was reviewed from the viewpoint of human health and safety and was determined to be acceptable.

Trichoderma asperellum ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical are of low toxicity by the oral and pulmonary routes and not pathogenic or infective by the pulmonary route. *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 were not pathogenic by the intraperitoneal route. These MPCAs are considered to be potential sensitizers. Consequently, the hazard statements "POTENTIAL SENSITIZER" will appear on the principal display panel of the technical grade active ingredients. The statement, "May cause sensitization. Avoid contact with skin, eyes, and clothing. Avoid inhaling/breathing dust." is also required on the secondary panel of the labels under the "PRECAUTIONS" section.

The end-use product, Foretryx, is of low toxicity by the oral, dermal, and inhalation routes. Foretryx is non-irritating to the eyes and slightly irritating to the skin based on the MAS values. The dermal sensitization study indicated that Foretryx is not a dermal sensitizer; nevertheless, because all microorganisms contain substances that could elicit positive hypersensitivity reactions in humans, *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 are considered to be potential sensitizing agents. Thus, the hazard statement "POTENTIAL SENSITIZER" will appear on the principal display panel of the end-use product label. The statement, "May cause sensitization. Avoid contact with skin, eyes, and clothing. Avoid inhaling/breathing dust and spray mist." is also required on the secondary panel of the label under the "PRECAUTIONS" section.

Higher tier subchronic and chronic toxicity studies were not required because the Tier I studies: a) did not indicate the technical grade active ingredients or end-use product to be acutely toxic by the oral, pulmonary or dermal routes of administration; and b) there were no indications of any infectivity or pathogenicity in any test animals tested with these MPCAs.

Within the available scientific literature, there are no reports that suggest *T. gamsii* and *T. asperellum* have the potential to cause adverse effects on the endocrine system of animals. Based on the weight of evidence of available data, no adverse effects to the endocrine or immune systems are anticipated for these MPCAs.

3.2 Occupational, residential and bystander risk assessment

3.2.1 Occupational and post-application exposure and risk

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists. Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were cut, if the microbe was a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed.

Trichoderma gamsii and *T. asperellum* have not frequently been identified as dermal wound pathogens and there is no indication that they could penetrate intact skin of healthy individuals. Furthermore, testing with *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 showed low toxicity and no infectivity via the pulmonary route, and no toxicity via the oral route. Hazard testing with the end-use product showed that Foretryx is slightly irritating to the skin and non-irritating to the eyes.

Although *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 Technical were of low toxicity via the oral, pulmonary, and dermal routes, and the formulants in the end-use products are not expected to contribute additional toxicity, the PMRA assumes that all microorganisms contain substances that can elicit positive hypersensitivity reactions, regardless of the outcome of sensitization testing. Consequently, risk mitigation measures, such as personal protective equipment (PPE), including chemical-resistant gloves, a long-sleeved shirt, long pants, a NIOSH-approved particulate filtering facepiece respirator, socks and shoes are required to minimize exposure and protect applicators, mixer/loaders, and handlers that are likely to be exposed. Furthermore, for the dilute broadcast spray application to the soil surface, all unprotected workers are prohibited from entering treated areas where Foretryx has been applied for 4 hours or until sprays have settled.

Label warnings, restrictions and risk mitigation measures are adequate to protect users of Foretryx. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

3.2.2 Residential and bystander exposure and risk

The use of Foretryx as a broadcast spray application to the soil surface for outdoor field crops may result in bystander exposure due to drift. Bystander exposure will be mitigated by the inclusion of a spray drift statement on the label, advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment and sprayer settings. Also, *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical were of low toxicity and there were no signs that the MPCAs, *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080, caused any disease in studies on laboratory animals. Consequently, the health risks to bystanders and individuals in residential areas are acceptable.

3.3 Dietary exposure and risk assessment

3.3.1 Food

While Foretryx is applied to soil, indirect contact with edible portions of crops may result in possible residues on agricultural commodities. The risks from consuming food crops treated with Foretryx are acceptable because *T. asperellum* strain ICC 012, *T. gamsii* strain ICC 080, demonstrated no toxicity, pathogenicity, or infectivity, and Foretryx demonstrated no toxicity in Tier I studies. While *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 have the potential to produce the secondary metabolites peptaibols, the proposed uses are not expected to result in a significant level of residues of these secondary metabolites on food commodities at the time of harvest. In general, secondary metabolites are produced when the MPCAs come into contact with the target pathogens (in this case, following application to the soil). Translocation of peptaibols to edible portions of the crop is expected to be negligible due to their poor solubility in water. While *Trichoderma* are ubiquitous and abundant in the rhizosphere, only low levels are reported in the phyllosphere and, therefore, the MPCAs are not expected to produce significant amounts of peptaibols on edible portions of the treated crops. Furthermore, peptaibols are proteinaceous in nature and are expected to have a short residency time due to a rapid denaturation under environmental conditions; and the metabolite residues may be further removed by washing, peeling, or processing of commodities, further minimizing the potential for exposure.

When the end-use product is applied as directed by the label to cannabis produced commercially indoors, consumer exposure to Foretryx is low and therefore the health risk is acceptable.

Consequently, there is no health risk to the general population, including infants and children, or domestic animals.

3.3.2 Drinking water

Dietary exposure from drinking water is expected to be low as the labels have the necessary mitigation measures to limit contamination of drinking water from the proposed uses of Foretryx. The end-use product is used to treat growing medium in greenhouses and soil in the field, and the

labels will instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Municipal treatment of drinking water is also expected to further reduce the transfer of residues to drinking water. Furthermore, *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 demonstrated no pathogenicity or infectivity in Tier I studies. Health risks from residues of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 in drinking water are acceptable due to the low toxicity/pathogenicity profiles of *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical, and their limited exposure following application of the end-use product.

3.3.3 Acute and chronic dietary risks for sensitive subpopulations

Calculations of acute reference doses and acceptable daily intakes are not usually possible for predicting acute and long-term effects of microbial agents in the general population or to potentially sensitive subpopulations, particularly infants and children. The single (maximum hazard) dose approach to testing MPCAs is sufficient for conducting a reasonable general assessment of risk if no significant adverse effects (in other words, no acute toxicity, infectivity or pathogenicity endpoints of concern) are noted in acute toxicity and infectivity tests. Based on all the available information and hazard data, the PMRA concludes that *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 are of low toxicity, are not pathogenic or infective to mammals, and that infants and children are likely to be no more sensitive to these MPCAs than the general population. Thus there are no threshold effects of concern and, as a result, there is no need to require definitive (multiple dose) testing or apply uncertainty factors to account for intra- and interspecies variability, safety factors or margins of exposure. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of these MPCAs, including neurological effects from pre- or post-natal exposures, and cumulative effects on infants and children of the MPCAs and other registered microorganisms that have a common mechanism of toxicity, does not apply to these MPCAs. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 to human health.

3.3.4 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Foretryx is considered to be of low toxicity by the oral, pulmonary and dermal routes and the end-use product will not be applied near or to drinking water. When the end-use product is used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080.

3.3.5 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Residues of *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 on treated food crops are possible at the time of harvest. Dietary risk to humans from the proposed use of Foretryx is acceptable due to the low toxicity profile of *Trichoderma asperellum* ICC 012 Technical and *Trichoderma gamsii* ICC 080 Technical and that metabolites of toxicological significance (i.e., peptaibols) are not expected to be present on edible portions of the crops. In addition, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Therefore, the PMRA has determined that specification of an MRL under the *Pest Control Products Act* is not required for *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080.

3.4 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. In its assessment of common mechanism of toxicity, PMRA considers both the taxonomy of MPCAs and the production of any potentially toxic metabolites. For the current evaluation, the PMRA has determined that *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 share a common mechanism of toxicity with the MPCAs *T. asperellum* strain T34, *T. harzianum* Rifai strain T-22, *T. harzianum* Rifai strain KRL-AG2, *T. virens* strain G-41 and *Gliocladium catenulatum* strain J1466. The potential health risks from cumulative exposure of *T. asperellum* strain ICC 012, *T. gamsii* strain ICC 080 and these other MPCAs are acceptable when used as labelled given their low toxicity and pathogenicity and the anticipated absence of secondary metabolites of toxicological concern on the harvested portion of crops treated with the end-use product.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Environmental fate data are only triggered at Tier II/III if significant toxicological effects in non-target organisms are noted in Tier I testing.

Although significant toxicological effects were not noted in Tier I testing, scientific literature and test data was submitted by the applicant to address the environmental fate of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 in soil. Following application of Foretryx, populations of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 will initially increase in the area of application. This increase is expected to be temporary and localized, since studies characterizing

the mobility and persistence of other introduced *Trichoderma* species in soil over 6–18 weeks suggest that they decline over time. Mobility of *Trichoderma* spp. both vertically and horizontally in soil following application is limited, although watering of the soil contributes to movement to deeper soil layers. Overall, levels of these microorganisms are expected to eventually return to the natural background level.

While *Trichoderma* spp. have occasionally been isolated from air, this is not expected to be a significant environmental compartment for *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 given their natural occurrence in soil. Persistence and multiplication of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 in water is unlikely, given the absence of literature reports of these species in aquatic environments. While not generally recognized as an aquatic fungus, growth of *T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 could occur if sufficient nutrients were present in water (for example, in presence of decaying plant material).

Trichoderma spp. are common soil hyphomycetes found in all climate zones. *Trichoderma* species have been detected in various types of soil at concentrations ranging from 10^4 to 10^6 CFU/g. Based on the maximum application rate of Foretryx, the estimated environmental concentration (EEC) of both MPCAs in soil (to a depth of 15 cm) is 1.5×10^1 CFU/g soil (see Appendix II). Therefore, outdoor directed applications to soil are not expected to result in soil concentrations that are substantially above normal concentrations. Additionally, Foretryx is not proposed for applications to aquatic environments, and exposure in marine or estuarine environments resulting from runoff is expected to be similar to that which would occur as a result of naturally occurring background concentrations of *Trichoderma* species.

4.2 Effects on non-target species

The PMRA has a four-tiered approach to environmental testing of microbial pesticides. Tier I studies consist of acute studies on up to seven broad taxonomic groups of non-target organisms exposed to a maximum hazard or Maximum Challenge Concentration of the MPCA. The Maximum Challenge Concentration is generally derived from the amount of the MPCA, or its toxin, expected to be available following application at the maximum recommended label rate multiplied by a safety factor. Tier II studies consist of environmental fate (persistence and dispersal) studies as well as additional acute toxicity testing of MPCAs. Tier III studies consist of chronic toxicity studies (life cycle studies), as well as definitive toxicity testing (for example, LC₅₀, LD₅₀). Tier IV studies consist of experimental field studies on toxicity and fate, and are required to determine whether adverse effects are realized under actual use conditions.

The type of environmental risk assessment conducted on MPCAs varies depending on the tier level that was triggered during testing. For many MPCAs, Tier I studies are sufficient to conduct environmental risk assessments. Tier I studies are designed to represent “worst-case” scenarios where the exposure conditions greatly exceed the expected environmental concentrations. The absence of adverse effects in Tier I studies are interpreted as minimal risk to the group of non-target organisms. However, higher tiered studies will be triggered if significant adverse effects on non-target organisms are identified in Tier I studies.

These studies provide additional information that allows the PMRA to refine the environmental risk assessments. In the absence of adequate environmental fate and/or field studies, a screening level risk assessment can be performed to determine if the MPCA is likely to pose a risk to a group of non-target organisms.

The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value ($RQ = \text{exposure}/\text{toxicity}$), and the risk quotient is then compared to the level of concern (level of concern = 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*; level of concern = 1 is used for higher tier tests of the standard arthropod test species and for other arthropod test species).

If the screening level risk quotient 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 (environmental fate and/or field testing results). 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.

4.2.1 Effects on terrestrial organisms

A detailed review of the terrestrial non-target studies and other supporting information was conducted in support of the two technical grade active ingredients, Trichoderma gamsii ICC 080 Technical and Trichoderma asperellum ICC 012 Technical, and the associated end-use product, Foretryx.

Trichoderma gamsii ICC 080 Technical

Three studies were submitted to address the hazards of Trichoderma gamsii ICC 080 Technical to honey bees, earthworms, and soil microflora. These studies were performed with *T. viride* strain ICC 080, which is equivalent to Trichoderma gamsii ICC 080 Technical. Data submitted under human and animal health toxicity testing were considered to assess the risk of harm to wild mammals.

In a 48-hour contact and dietary toxicity study, 50 honeybees (*Apis mellifera*) were exposed to *T. viride* strain ICC 080 via contact at 50 µg/bee (8.5×10^4 CFU/bee) and 50 honeybees were exposed to *T. viride* strain ICC 080 via the diet at 112.1 µg/bee (1.9×10^5 CFU/bee). There were no treatment-related effects. Pathogenicity was not assessed.

In a 14-day acute toxicity study, earthworms (*Eisenia fetida*) were exposed to *T. viride* strain ICC 080 at 1.70×10^9 , 1.13×10^9 , 7.55×10^8 , 5.03×10^8 , and 3.37×10^8 CFU/kg soil dry weight (sdw). There were no treatment-related effects observed.

The effect of *T. viride* strain ICC 080 on soil microorganisms was investigated by testing nitrogen and carbon turnover in soil, metabolic indicators of microbial soil community activity. In this study, *T. viride* strain ICC 080 was incorporated in field soil at concentrations of 0.07 mg/kg sdw (1.19×10^5 CFU/kg sdw) and 0.67 mg/kg sdw (1.14×10^6 CFU/kg sdw) and then assessed for nitrogen and carbon turnover over 28 days. Nitrogen turnover was assessed by measuring nitrate production, and carbon turnover was assessed by measuring carbon dioxide production. There was no impact on either nitrogen turnover or carbon turnover at both test concentrations.

Test results are summarized in Appendix I, Table 4.

Trichoderma gamsii strain ICC 080 is not considered to be a mammalian pathogen, and the data submitted under Section 3.1.1 demonstrated that *Trichoderma gamsii* ICC 080 Technical showed no toxicity to laboratory test animals via the oral and pulmonary routes, no signs of pathogenicity via the intraperitoneal injection and pulmonary installation routes, and no infectivity via the pulmonary instillation route. No additional data or information to characterize the hazard to wild mammals are required.

Trichoderma asperellum ICC 012 Technical

Three studies were submitted to address the hazards of *Trichoderma asperellum* ICC 012 Technical to honey bees, earthworms, and soil microflora. These studies were performed with *T. harzianum* strain ICC 012, which is equivalent to *Trichoderma asperellum* ICC 012 Technical. Data submitted under human and animal health toxicity testing were considered to assess the risk of harm to wild mammals.

In a 48-hour contact and dietary toxicity study, 50 honeybees (*Apis mellifera*) were exposed to *T. harzianum* strain ICC 012 via contact at 50 µg/bee (2.1×10^5 CFU/bee) and 50 honeybees were exposed to *T. harzianum* strain ICC 012 via the diet at 111.5 µg/bee (4.7×10^5 CFU/bee). There were no treatment-related effects. Pathogenicity was not assessed.

In a 14-day acute toxicity study, earthworms (*Eisenia fetida*) were exposed to *T. harzianum* strain ICC 012 at 4.20×10^9 , 2.80×10^9 , 1.86×10^9 , 1.24×10^9 , and 8.32×10^8 CFU/kg sdw. There were no treatment-related effects observed.

The effect of *T. harzianum* strain ICC 012 on soil microorganisms was investigated by testing nitrogen and carbon turnover in soil, metabolic indicators of microbial soil community activity. In this study, *T. harzianum* strain ICC 012 was incorporated in field soil at concentrations of 0.07 mg/kg sdw (2.94×10^5 CFU/kg sdw) and 0.67 mg/kg sdw (2.81×10^6 CFU/kg sdw) and then assessed for nitrogen and carbon turnover over 28 days.

Nitrogen turnover was assessed by measuring nitrate production, and carbon turnover was assessed by measuring carbon dioxide production. There was no impact on either nitrogen turnover or carbon turnover at both test concentrations.

Test results are summarized in Appendix I, Table 5.

Trichoderma asperellum strain ICC 012 is not considered to be a mammalian pathogen, and the data submitted under Section 3.1.1 demonstrated that *Trichoderma asperellum* ICC 012 Technical showed no toxicity to laboratory test animals via the oral and pulmonary routes, no signs of pathogenicity via the intraperitoneal injection and pulmonary installation routes, and no infectivity via the pulmonary instillation route. No additional data or information to characterize the hazard to wild mammals are required.

Foretryx

Two studies were submitted to address the hazards of Foretryx to honey bees and predatory mites. These studies were performed with Remedier WP (containing 1.2×10^8 CFU/g *Trichoderma* conidia) or Tellus WP (9.3×10^7 CFU/g *T. viride* strain ICC 080 and 7.6×10^7 CFU/g *T. harzianum* strain ICC 012), which are both equivalent to Foretryx. Acceptable information and published scientific literature were also provided in support of requests to waive further testing on birds and terrestrial plants.

In a 10-day dietary toxicity study, honey bees (*A. mellifera*) were exposed to Tellus WP via the diet (50% w/w sucrose solution) for ten days at measured concentrations of 222 µg product/bee/day (6.95×10^3 CFU/bee/day *T. asperellum* strain ICC 012 and 1.08×10^4 CFU/bee/day *T. gamsii* strain ICC 080, or a total of 1.78×10^4 *Trichoderma* CFU/bee/day). Percent mortality in the test item, control and reference item (dimethoate) groups at Day 10 was 0%, 4% and 100%, respectively. There were no significant differences in feed consumption between the test item and control groups. There were no toxic or pathogenic effects observed.

In a 14-day non-guideline contact toxicity study, 60 (3 replicates of 20) predatory mite protonymphs (*Typhlodromus pyri*) were exposed to Remedier WP (1.2×10^8 CFU/g total *T. gamsii* ICC 080 and *T. asperellum* ICC 012) in a glass plate test at nominal concentrations of 61.8 g, 185 g, 556 g, 1.67 kg, and 5 kg/200L/ha. A toxic reference item (dimethoate) and a negative control (deionized water) were tested concurrently. There were no treatment-related effects on mortality. Although a dose-related response was not apparent from the reproductive indicators, there were statistically significant reductions in reproductive capacity at 61.8 g, 185 g, and 5 kg Remedier WP/ha relative to the untreated control. Soil-only applications of the end-use product will not result in sustained increased exposure to non-target arthropods in the phyllosphere and therefore the risk is acceptable.

The applicant provided a rationale to waive the requirement for avian toxicity/pathogenicity testing based on the fact that birds are frequently exposed to natural background levels of *Trichoderma* in the soil and that there were no relevant information found in the published scientific literature with respect to 'Trichoderma' and 'birds'. The use of the proposed end-use

product, Foretryx, is not expected to result in a sustained increase of *T. asperellum* ICC 012 and *T. gamsii* strain ICC 080 in treated soils. As well, an in vitro growth temperature study for the MPCAs demonstrated the inability of *T. asperellum* strain ICC 012 to grow at 37°C and *T. gamsii* strain ICC 080 to grow at 35°C. These temperatures are below the low end of the body temperature range of birds. This rationale is sufficient to warrant waiving the requirement for avian toxicity/pathogenicity testing for *T. asperellum* strain ICC 012 and *T. gamsii* strain ICC 080 for the use pattern of at-planting applications to soil for field crops.

Neither *T. asperellum* strain ICC 012 nor *T. gamsii* strain ICC 080 appear on authoritative lists of plant pathogens and pests. These MPCAs have been registered in the United States and in the European Union since 2010 and 2015, respectively, with no reports of adverse effects in plants. There were no reports of phytotoxicity or crop injury in any of the efficacy trials and Foretryx was observed to increase plant yield. Therefore, the proposed uses of Foretryx are not expected to result in adverse effects in non-target terrestrial plants. No additional data or information to characterize the hazard to non-target terrestrial plants are required.

Test results are summarized in Appendix I, Table 6.

Based on all the available data and information on the effects of *T. gamsii* strain ICC 080, *T. asperellum* strain ICC 012, and Foretryx to non-target terrestrial organisms, and the precautionary measures required on the Foretryx label, the risks to birds, wild mammals, arthropods (including honey bees), non-arthropod invertebrates, soil microorganisms and plants from the proposed use of Foretryx are acceptable.

4.2.2 Effects on aquatic organisms

A detailed review of the aquatic non-target studies and other supporting information was conducted in support of the two technical grade active ingredients, *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 Technical, and the associated end-use product, Foretryx.

Trichoderma gamsii ICC 080 Technical

Four studies were submitted to address the hazards of *Trichoderma gamsii* ICC 080 Technical to rainbow trout, daphnids, green algae, and aquatic plants. These studies were performed with *T. viride* strain ICC 080, which is equivalent to the technical grade active ingredient, *Trichoderma gamsii* ICC 080 Technical.

In a 30-day toxicity/pathogenicity study, 50 rainbow trout (*Oncorhynchus mykiss*) were aquatically exposed to *T. viride* strain ICC 080 at nominal concentrations of 100, 50, 25, 12.5, and 6.25 mg/L (8.7×10^7 , 4.4×10^7 , 2.2×10^7 , 1.1×10^7 , and 5.4×10^6 CFU/L) under static renewal test conditions. The test item was not incorporated into the diet. There were no treatment-related toxicity or pathogenicity effects observed.

In a 21-day toxicity study, 5 groups of 20 daphnids (*Daphnia magna*) were exposed to *T. viride* strain ICC 080 under static renewal conditions at nominal concentrations of 100, 50, 25, 12.5, and 6.25 mg/L (8.7×10^7 , 4.4×10^7 , 2.2×10^7 , 1.1×10^7 , and 5.4×10^6 CFU/L). The percent mortality in the negative control, sterile filtrate, 100, 50, 25, 12.5, and 6.25 mg/L test groups was 0, 20, 50, 25, 15, 10, and 5, respectively. Reproductive output was statistically significantly reduced in the 8.7×10^7 CFU/L test item concentration, relative to the untreated control. The no observed effects concentration (NOEC) for reproduction in this study (4.4×10^7 CFU/L) is three orders of magnitude greater than the EEC in water (refer to Appendix II for aquatic EEC calculation).

The effect of *T. viride* strain ICC 080 on green algae (*Desmodesmus subspicatus*) was studied for 72 hours at nominal concentrations of 6.25, 12.5, 25, 50, and 100 mg/L (5.8×10^7 , 1.2×10^8 , 2.3×10^8 , 4.7×10^8 , and 9.3×10^8 CFU/L) under static conditions. The algal growth rate and biomass were significantly reduced compared to the control in the 9.3×10^8 CFU/L test item group at 24, 48, and 72 hours. The NOEC for growth in this study (4.7×10^8 CFU/L) is four orders of magnitude greater than the EEC in water.

The effect of *T. viride* strain ICC 080 Technical on the freshwater floating aquatic vascular plant, duckweed (*Lemna gibba*), was studied for 14 days at nominal concentrations of 62.5, 125, 250, 500, and 1000 mg/L (5.4×10^7 , 1.1×10^8 , 2.2×10^8 , 4.4×10^8 , and 8.8×10^8 CFU/L) under static renewal conditions. Statistically significant reduction of frond numbers, inhibition of biomass gain, and inhibition of growth were observed in the 2.2×10^8 , 4.4×10^8 , and 8.8×10^8 CFU/L test group compared to the untreated control. The NOEC for growth in this study (1.1×10^8 CFU/L) is four orders of magnitude greater than the EEC in water.

Test results are summarized in Appendix I, Table 4.

Trichoderma asperellum ICC 012 Technical

Four studies were submitted to address the hazards of *Trichoderma asperellum* ICC 012 Technical to rainbow trout, daphnids, green algae, and aquatic plants. These studies were performed with *T. harzianum* strain ICC 012, which is equivalent to the technical grade active ingredient.

In a 30-day toxicity/pathogenicity study, 50 rainbow trout (*Oncorhynchus mykiss*) were aquatically exposed to *T. harzianum* strain ICC 012 at nominal concentrations of 100, 50, 25, 12.5, and 6.25 mg/L (1.2×10^8 , 6.0×10^7 , 3.0×10^7 , 1.5×10^7 , and 7.5×10^6 CFU/L) under static renewal test conditions. At 100 mg/L, there was a statistically significant decrease in body weight gain relative to the untreated control. The no observed effects concentration (NOEC) for body weight gain in this study (6.0×10^7 CFU/L) is three orders of magnitude greater than the EEC in water (refer to Appendix II for aquatic EEC calculation). There were no treatment-related mortality or pathogenicity effects observed.

In a 21-day toxicity/pathogenicity study, 5 groups of 20 female daphnids (*Daphnia magna*) were exposed aquatically to *T. harzianum* strain ICC 012 at nominal concentrations of 100, 50, 25, 12.5, and 6.25 mg/L (1.2×10^8 , 6.0×10^7 , 3.0×10^7 , 1.5×10^7 , and 7.5×10^6 CFU/L) under static renewal conditions. The percent mortality in the negative control, sterile filtrate, 100, 50, 25, 12.5, and 6.25 mg/L test groups was 0, 45, 35, 10, 25, 5, and 5, respectively. There were no statistically significant differences in offspring per surviving adult between any of the test item concentrations, the sterile filtrate, and the negative control. On Day 21, four daphnids from the 25 mg/L test group were reported to have spore agglomeration on the gills. The LC₅₀ in this study ($>1.2 \times 10^8$ CFU/L) is four orders of magnitude greater than the EEC in water.

The effect of *T. harzianum* strain ICC 012 on the freshwater aquatic vascular plant, duckweed (*Lemna gibba*), was studied at a concentration of 1000 mg/L (1.2×10^9 CFU/L nominal) under static renewal conditions over a period of 7 days. There were no significant differences in frond number, biomass gain, or growth rate observed between the test group, sterile filtrate control, or untreated control throughout the study.

The effect of *T. harzianum* strain ICC 012 on algae (*Desmodesmus subspicatus*), was studied at nominal concentrations of 100, 50, 25, 12.5, and 6.25 mg/L (1.3×10^9 , 6.5×10^8 , 3.3×10^8 , 1.6×10^8 , 8.1×10^7 CFU/L) under static conditions over a period of 72 hours. There were significant differences in growth rate and biomass gain observed between both the 100 mg/L test group and sterile filtrate group, and the untreated control. The NOEC for growth in this study (6.5×10^8 CFU/L) is four orders of magnitude greater than the EEC in water.

Test results are summarized in Appendix I, Table 5.

Foretryx

One study was submitted to address the hazards of Foretryx to daphnids. This study was performed with Remedier WP (7.8×10^7 CFU/g *T. viride* strain ICC 080 and 7.8×10^7 CFU/g *T. harzianum* strain ICC 012), which is equivalent to the end-use product, Foretryx.

In a 48-hour acute immobilization study, daphnids (*Daphnia magna*) were exposed to Remedier WP under static conditions at a concentration of 3.2×10^8 CFU/L. There were no treatment-related immobilization effects observed.

Based on all the available data and information on the effects of *T. gamsii* strain ICC 080, *T. asperellum* strain ICC 012, and Foretryx to non-target aquatic organisms and the precautionary measures required on the Foretryx label, the risks to fish, aquatic arthropods, aquatic plants, and algae from the proposed use of Foretryx are acceptable.

Test results are summarized in Appendix I, Table 6.

4.3 Incident reports related to the environment

Trichoderma asperellum ICC 012 and *T. gamsii* ICC 080 are new active ingredients pending registration for use in Canada, and as of November 12, 2021, no incident reports had been submitted to the PMRA.

5.0 Value

Trichoderma asperellum strain ICC 012 and *Trichoderma gamsii* strain ICC 080 are new biological active ingredients for disease management in Canada. Foretryx provides growers with a new biofungicide for use in an integrated pest management program to manage certain diseases on labelled field and greenhouse crops. Foretryx also provides a new product to manage verticillium wilt on strawberries (field and greenhouse) and cannabis (greenhouse or indoors), for which there are no alternatives registered. While alternatives are available for many other labelled diseases, the availability of Foretryx may reduce the risk of resistance development to conventional active ingredients and is acceptable for use in organic production.

The reports of 30 efficacy trials provided evidence that Foretryx suppresses or partially suppresses diseases on various field and greenhouse crops when applied at labelled rates. Based on the reports of these trials, phytotoxicity is not expected when Foretryx is applied according to the label.

The supported use claims are summarized in Appendix I, Table 7.

6.0 Pest control product policy considerations

6.1 Toxic substances management policy considerations

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 is given effect in evaluating the risks of a product.

During the review process, *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 Technical, and Foretryx were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 Technical, and Foretryx do not meet the Track 1 criteria because the active ingredients are

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

biological organisms and hence are not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the technicals as well as formulants and contaminants in the end-use product are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁶ The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations, including the Toxic Substances Management Policy and Formulants Policy⁸ and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade products *Trichoderma gamsii* ICC 080 Technical and *Trichoderma asperellum* ICC 012 Technical, and their end-use product, Foretryx, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants 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 PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of *Trichoderma asperellum* ICC 012 Technical, *Trichoderma gamsii* ICC 080 Technical and Foretryx, containing the technical grade active ingredients *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080, for the suppression and partial suppression of certain fungal diseases on field and greenhouse fruiting vegetables, squash, lettuce, field and greenhouse strawberries, greenhouse ornamentals and cannabis produced commercially indoors.

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.

⁶ SI/2005-114, last amended on 25 June 2008. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁷ PMRA's Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Product Act*.

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

List of abbreviations

°C	degree(s) Celsius
%	percent
µg	microgram
ADI	acceptable daily intake
ALS	acetolactate synthase
bw	body weight
CFU	colony forming units
cm	centimetre
DNA	deoxyribonucleic acid
EC ₅₀	effective concentration on 50% of the population
EEC	estimated environmental concentration
EP	End-use Product
g	gram
h	hour(s)
ha	hectare(s)
kg	kilogram
L	litre
LC ₅₀	median lethal concentration
LD ₅₀	median lethal dose
LOEC	low observed effect concentration
mg	milligram
mL	millilitre
MAS	maximum average score
MIS	Maximum Irritation Score
MPCA	microbial pest control agent
MRL	maximum residue limit
NaCl	sodium chloride
NIOSH	National Institute for Occupational Safety and Health
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
RQ	risk quotient
sdw	soil dry weight
TGAI	technical grade of the active ingredient
TSMP	Toxic Substances Management Policy
WP	wettable powder

Appendix I Tables and figures

Table 1 Toxicity profile of Trichoderma asperellum ICC 012 Technical

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA#	Study Results
14-day acute oral toxicity ¹ Sprague Dawley (CD) rat PMRA No. 3119363	Acute oral LD ₅₀ >1.41 × 10 ⁹ CFU/rat (Limit Test) Low Toxicity via oral gavage.
21-day acute pulmonary toxicity and infectivity ¹ Sprague Dawley (CD) rat PMRA No. 3119365	Acute pulmonary LD ₅₀ >1.1 × 10 ⁷ CFU/rat (Limit Test) Low Toxicity and not infective or pathogenic via intratracheal gavage.
21-day acute intraperitoneal pathogenicity ¹ Sprague Dawley (CD) rat PMRA No. 3119370	Acute intraperitoneal LD ₅₀ >1.2 × 10 ⁸ CFU/rat. Not pathogenic via intraperitoneal injection.

¹ The test substance was *T. harzianum* strain ICC 012 which is equivalent to Trichoderma asperellum ICC 012 Technical.

Table 2 Toxicity profile of Trichoderma gamsii ICC 080 Technical

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA#	Study Results
14-day acute oral toxicity ¹ Sprague Dawley (CD) rat PMRA No. 3118629	Acute oral LD ₅₀ >2.76 × 10 ⁸ spores/rat (Limit Test) Low Toxicity via oral gavage.
21-day acute pulmonary toxicity and infectivity ¹ Sprague Dawley (CD) rat PMRA No. 3118630	Acute pulmonary LD ₅₀ >2.5 × 10 ⁶ CFU/rat (Limit Test) Low Toxicity and not infective or pathogenic via intratracheal gavage.

Study Type/Animal/PMRA#	Study Results
21-day acute intraperitoneal pathogenicity ¹ Sprague Dawley (CD) rat PMRA No. 3118631	Acute intraperitoneal LD ₅₀ >8.37 × 10 ⁶ CFU/rat. Not pathogenic via intraperitoneal injection.

¹ The test substance was *T. viride* strain ICC 080 which is equivalent to *Trichoderma gamsii* ICC 080 Technical.

Table 3 Toxicity profile of Foretryx

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA#	Study Results
14-day acute oral toxicity ¹ Sprague Dawley (CD) rat PMRA No. 3118521	Acute oral LD ₅₀ >2000 mg/kg bw (Limit Test) Low Toxicity via oral gavage.
14-day acute dermal toxicity ¹ Sprague Dawley (CD) rat PMRA No. 3118523	Acute dermal LD ₅₀ >2000 mg/kg bw (Limit Test) Low Toxicity via dermal exposure.
14-day acute inhalation toxicity ¹ Sprague Dawley (CD) rat PMRA No. 3118522	Acute inhalation LC ₅₀ >5.20 mg/L air (Limit Test) Low Toxicity via inhalation.
72-hour dermal irritation ¹ Himalayan rabbit, male PMRA No. 3118524	Slightly irritating to the skin (MIS, 72h = 1.33/8; MAS=1.11/8).
72-hour eye irritation ¹ Himalayan rabbit, male PMRA No. 3118525	Non-irritating to the eyes (MIS, 1h = 1/110; MAS=0/110).
72-hour dermal sensitization ¹ Duncan-Hartley guinea pig, male PMRA No. 3118526	Not sensitizing via dermal exposure.

- 1 The test substance was Remedier WP, containing 7.8×10^7 CFU/g *T. viride* strain ICC 080 and 7.8×10^7 CFU/g *T. harzianum* strain ICC 012, which is equivalent to Foretryx.

Table 4 Toxicity/pathogenicity of *Trichoderma gamsii* ICC 080 Technical to non-target species

Organism Group	Exposure	Significant Effect, Comments	Reference
Terrestrial Organisms			
Invertebrates			
Arthropods			
Honeybee (<i>Apis mellifera</i>), adult worker ¹	48-hour – Contact exposure 48-hour – Dietary exposure	There were no treatment-related effects on mortality or behaviour. The 48-h contact LC ₅₀ was $>8.5 \times 10^4$ CFU/bee The 48-h dietary LC ₅₀ was $>1.9 \times 10^5$ CFU/bee LOW TOXICITY	3118643
Non-arthropods			
Earthworm (<i>Eisenia fetida</i>), adults ¹	14-day – Contact	No differences were observed between the control and treatment groups for mortality or body weight change. The 14-day LC ₅₀ was $>1.7 \times 10^9$ CFU/kg sdw LOW TOXICITY NOT PATHOGENIC	3118645
Microorganisms			
Soil microflora – metabolic activity ¹	28-day – Metabolic activity	No significant differences were observed in nitrogen turnover or carbon turnover between the treatment and the control.	3118646
Aquatic Organisms			
Vertebrates			
Rainbow trout (<i>Oncorhynchus mykiss</i>) ¹	30-day – Aquatic	There were no mortalities, behavioural abnormalities, no difference in mean body weight, and no difference in growth rate. The 30-day LC ₅₀ was $>8.70 \times 10^7$ CFU/L of media LOW TOXICITY NOT PATHOGENIC	3118642

Organism Group	Exposure	Significant Effect, Comments	Reference
Invertebrates			
Daphnids (<i>Daphnia magna</i>) ¹	21-day – Aquatic exposure	Mortality increased with test item concentration. Reproduction was reduced in the highest test concentration. 50% mortality was observed at 8.7×10^7 CFU/L The 21-day NOEC (reproduction) was 4.4×10^7 CFU/L TOXIC REPRODUCTIVE EFFECTS	3118644
Plants			
Green algae (<i>Desmodesmus subspicatus</i>) ¹	72-hour – Aquatic exposure	Growth rate and biomass were significantly reduced in the 9.3×10^8 CFU/L test group compared to the control. The 72-hour EC₅₀ was $> 9.3 \times 10^8$ CFU/L The 72-hour NOEC was 4.7×10^8 CFU/L GROWTH INHIBITION	3118647
Duckweed (<i>Lemna gibba</i>) ¹	14-day – Aquatic exposure	Significant reduction of frond numbers, inhibition of biomass gain, and inhibition of growth rate was observed in the 250, 500, and 1000 mg/L (2.2×10^8, 4.4×10^8, and 8.8×10^8 CFU/L) test groups compared to the untreated control. The 14-day EC₅₀ (frond number) was 451.4 mg/L (4.0×10^8 CFU/L) The 14-day EC₅₀ (biomass gain) was 669.7 mg/L (5.9×10^8 CFU/L) The 14-day EC₅₀ (growth rate) was 849.3 mg/L (7.5×10^8 CFU/L) The 14-day NOEC was 125 mg/L (1.1×10^8 CFU/L) The 14-day LOEC was 250 mg/L (2.2×10^8 CFU/L) GROWTH INHIBITION	3118649

¹ The test substance was *T. viride* strain ICC 080 which is equivalent to *Trichoderma gamsii* ICC 080 Technical.

Table 5 Toxicity/pathogenicity of trichoderma asperellum ICC 012 technical to non-target species

Organism Group	Exposure	Significant Effect, Comments	Reference
Terrestrial Organisms			
Invertebrates			
Arthropods			
Honeybee (<i>Apis mellifera</i>), adult worker ¹	48-hour – Contact exposure 48-hour – Dietary exposure	There were no treatment-related effects on mortality or behaviour. The 48-h contact LC ₅₀ was $>2.1 \times 10^5$ CFU/bee The 48-h dietary LC ₅₀ was $>4.7 \times 10^5$ CFU/bee LOW TOXICITY	3119396
Non-arthropods			
Earthworm (<i>Eisenia fetida</i>), adults ¹	14-day – Contact	No differences were observed between the control and treatment groups for mortality or body weight change. The 14-day LC ₅₀ was $>4.20 \times 10^9$ CFU/kg sdw LOW TOXICITY NOT PATHOGENIC	3119405
Microorganisms			
Soil microflora – metabolic activity ¹	28-day – Metabolic activity	No significant differences were observed in nitrogen turnover or carbon turnover between the treatment and the control.	3119409
Aquatic Organisms			
Vertebrates			
Rainbow trout (<i>Oncorhynchus mykiss</i>) ¹	30-day – Aquatic	Body weight gain was significantly reduced in the 100 mg/L test group compared to the untreated control. The 30-day NOEC (body weight gain) was 6.0×10^7 CFU/L of media The 30-day LC ₅₀ was $>1.2 \times 10^8$ CFU/L of media LOW TOXICITY NOT PATHOGENIC	3119392

Organism Group	Exposure	Significant Effect, Comments	Reference
Invertebrates			
Daphnids (<i>Daphnia magna</i>) ¹	21-day – Aquatic exposure	Mortality increased with test item concentration. The 21-day LC ₅₀ was $>1.2 \times 10^8$ CFU/L TOXIC	3119403
Plants			
Green algae (<i>Desmodesmus subspicatus</i>) ¹	72-hour – Aquatic exposure	Growth rate and biomass were significantly reduced in the 1.3×10^9 CFU/L test group compared to the control. The 72-hour EC ₅₀ was $> 1.3 \times 10^9$ CFU/L The 72-hour NOEC was 6.5×10^8 CFU/L GROWTH INHIBITION	3119413
Duckweed (<i>Lemna gibba</i>) ¹	7-day – Aquatic exposure	There were no significant differences in frond numbers, inhibition of biomass gain, or inhibition of growth rate observed. The 7-day EC ₅₀ was $> 1.2 \times 10^9$ CFU/L LOW TOXICITY	3119412

¹The test substance was *T. harzianum* strain ICC 012 which is equivalent to *Trichoderma asperellum* ICC 012 Technical.

Table 6 Toxicity/pathogenicity of Foretryx to non-target species

Organism Group	Exposure	Significant Effect, Comments	Reference
Terrestrial Organisms			
Invertebrates			
Arthropods			
Honeybee (<i>Apis mellifera</i>), adult worker	10-day – Dietary exposure	There were no treatment-related mortalities, abnormal behaviour, or differences in food consumption, compared to the untreated control. The 10-day dietary LD ₅₀ was $>222 \mu\text{g}/\text{bee}/\text{day}$ (6.95×10^3 CFU/bee/day <i>T. asperellum</i> strain ICC 012, and 1.08×10^4 CFU/bee/day <i>T. gamsii</i> strain ICC 080 or a total of 1.78×10^4 <i>Trichoderma</i> CFU/bee/day) LOW TOXICITY NOT PATHOGENIC	

Organism Group	Exposure	Significant Effect, Comments	Reference
Predatory mite (<i>Typhlodromus pyri</i>) ²	14-day – Surface contact	There were no treatment-related effects on mortality. There were reductions in reproduction of 32.7, 54.4, and 28.7% in the 61.8g, 185g, and 5 kg/ha test groups, respectively. REPRODUCTIVE EFFECTS	
Aquatic Organisms			
Invertebrates			
Daphnids (<i>Daphnia magna</i>)	48 hour – Aquatic exposure	There were no treatment-related immobilization effects observed. The 48-hour LC ₅₀ and EC ₅₀ were $>3.2 \times 10^8$ CFU/L LOW TOXICITY	

¹ The test substance was Tellus WP, containing 9.3×10^7 CFU/g *T. viride* strain ICC 080 and 7.6×10^7 CFU/g *T. harzianum* strain ICC 012, which is equivalent to Foretryx.

² The test substance was Remedier WP, containing 1.2×10^8 CFU/g *Trichoderma* conidia, which is equivalent to Foretryx.

Table 7 List of supported uses

Supported use claim for Foretryx
Crop: field and greenhouse fruiting vegetables (crop group 8) Disease: suppression of post-emergence damping-off (<i>Phytophthora capsici</i>) Application method: chemigation (greenhouse) or a diluted broadcast spray application to the soil surface at planting (field) Rate: 2.8 kg product/ha
Crop: greenhouse ornamentals Disease: partial suppression of post-emergence damping-off (<i>Phytophthora</i> spp.) Application method: chemigation Rate: 2.8 kg product/ha
Crop: field squash (summer and winter) Disease: suppression of phytophthora blight (<i>Phytophthora capsici</i>) Application method: a diluted broadcast spray application to the soil surface at planting Rate: 2.8-5.6 kg product/ha

Supported use claim for Foretryx
Crop: field and greenhouse strawberries Disease: partial suppression of post-emergence damping-off (<i>Phytophthora cactorum</i>) Application method: chemigation (greenhouse) or a diluted broadcast spray application to the soil surface at planting (field) Rate: 2.8 kg product/ha
Crop: greenhouse and indoor grown cannabis Disease: partial suppression of post-emergence damping-off (<i>Phytophthora</i> spp.) Application method: chemigation Rate: 2.8 kg product/ha
Crop: field lettuce Disease: partial suppression of sclerotinia drop/white mould (<i>Sclerotinia sclerotiorum</i>, <i>S. minor</i>) Application method: a diluted broadcast spray application to the soil surface at planting Rate: 2.8-3.4 kg product/ha
Crop: field and greenhouse fruiting vegetables (crop group 8) Disease: suppression of verticillium wilt (<i>Verticillium dahliae</i>) Application method: chemigation (greenhouse) or a diluted broadcast spray application to the soil surface at planting (field) Rate: 2.8 kg product/ha
Crop: field and greenhouse strawberries Disease: suppression of verticillium wilt (<i>Verticillium dahliae</i>) Application method: chemigation (greenhouse) or a diluted broadcast spray application to the soil surface at planting (field) Rate: 2.8 kg product/ha
Crop: greenhouse ornamentals Disease: suppression of verticillium wilt (<i>Verticillium dahliae</i>) Application method: chemigation Rate: 2.8 kg product/ha

Supported use claim for Foretryx**Crop:** greenhouse and indoor grown cannabis**Disease:** suppression of verticillium wilt (*Verticillium dahliae*)**Application method:** chemigation**Rate:** 2.8 kg product/ha

Appendix II Estimated environmental concentration

Aquatic

The maximum proposed application rate of Foretryx is 5.6 kg/ha or 5.6×10^{10} CFU (*T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 combined)/ha. There are 1.5×10^6 L of water in the top 15 cm of 1 ha. Therefore, assuming that the maximum application rate was applied to surface water, the EEC is 3.7×10^4 CFU/L in the top 15 cm of water.

Soil

The maximum proposed application rate of Foretryx is 5.6 kg/ha or 5.6×10^{10} CFU (*T. gamsii* strain ICC 080 and *T. asperellum* strain ICC 012 combined)/ha. There are 1.5×10^9 mL of soil in the top 15 cm of 1 ha. Therefore, assuming a specific gravity of 2.5 g/mL for soil, the EEC is 1.5×10^1 CFU/g in the top 15 cm of soil.

References

A. List of studies/information submitted by registrant

1.0 Product characterization and analysis

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- 3118617 2016, *Trichoderma gamsii* ICC 080 Document M-MA, Section 1 Identity OF the Micro-Organism, DACO: M2.1, M2.10.1, M2.10.2, M2.2, M2.4, M2.5, M2.7.1
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