Proposed Registration Decision

Santé

Canada

PRD2020-03

Trichoderma asperellum strain T34, Asperello **T34 Biocontrol**

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Overview

Proposed Registration Decision for *Trichoderma asperellum* strain T34.

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u>, is proposing registration for the sale and use of T34 Biocontrol Technical, and Asperello T34 Biocontrol, containing the technical grade active ingredient *Trichoderma asperellum* strain T34 to be used against certain fungal diseases on greenhouse ornamentals, cannabis produced commercially indoors and greenhouse vegetables.

Trichoderma asperellum strain T34 is currently registered to suppress fusarium wilt on greenhouse ornamentals. For details, see Proposed Registration Decision PRD2011-21, *Trichoderma asperellum* strain T34, and Registration Decision RD2013-19, *Trichoderma asperellum* strain T34.

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 T34 and Asperello T34 Biocontrol.

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.

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[&]quot;Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[&]quot;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 Canada.ca.

Before making a final registration decision on *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol, 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 T34 and Asperello T34 Biocontrol, 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 Trichoderma asperellum strain T34?

Trichoderma asperellum strain T34 is the active ingredient in the product Asperello T34 Biocontrol, a biological fungicide to be used against certain fungal diseases on greenhouse ornamentals, cannabis produced commercially indoors and greenhouse vegetables. It has multiple modes of action to protect plants from disease infection.

Health Considerations

Can Approved Uses of Trichoderma asperellum strain T34 Affect Human Health?

Trichoderma asperellum strain T34 is unlikely to affect your health when Asperello T34 Biocontrol is used according to the label directions.

Potential exposure to *Trichoderma asperellum* strain T34 may occur through the diet (food and water) or when handling and applying Asperello T34 Biocontrol. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, infection cycle);
- reports of any adverse incidents;
- 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.

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[&]quot;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 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.

Toxicology 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 Asperello T34 Biocontrol was tested on laboratory animals, there was low toxicity following oral, inhalation, and pulmonary exposures, there was no toxicity or irritation following dermal exposure, and there were no signs that it caused any disease.

Residues in Water and Food

Dietary risks from food and water are acceptable

Residues of *Trichoderma asperellum* strain T34 on treated food crops are possible at the time of harvest. However, populations of *Trichoderma* spp. on crops measured after application of the end-use product are low and decline over time. As well, no secondary metabolites of toxicological significance are detectable in the formulated product or in the edible parts of crops treated with the end use product. While *Trichoderma asperellum* and other related *Trichoderma* species are abundant in nature, no cases involving foodborne illness have been reported. Moreover, no signs of infectivity and low toxicity were observed when Asperello T34 Biocontrol was tested on laboratory animals. In addition, the likelihood of residues of *Trichoderma asperellum* strain T34 contaminating drinking water supplies from the proposed application of Asperello T34 Biocontrol on greenhouse food crops and cannabis grown commercially indoors is low. Consequently, dietary risks are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is acceptable.

Asperello T34 Biocontrol is proposed for use in greenhouses only. Consequently, it is unlikely that the general public will be exposed to *Trichoderma asperellum* strain T34. Even in the event of exposure, risk to residents and the general population is acceptable since Asperello T34 Biocontrol is of low toxicity and there were no signs that it caused any disease in studies on laboratory animals.

Occupational Risks From Handling Asperello T34 Biocontrol

Occupational risks are not of concern when Asperello T34 Biocontrol is used according to label directions, which include protective measures.

Workers handling Asperello T34 Biocontrol can come into direct contact with *Trichoderma* asperellum strain T34 on the skin, by inhalation, or in the eyes. To protect workers from exposure to Asperello T34 Biocontrol, the label states that mixers, loaders, and applicators must wear personal protective equipment, including waterproof gloves, long-sleeved shirt, long pants,

goggles, socks with shoes, and NIOSH-approved particulate filtering facepiece respirator. A restricted-entry interval of 4 hours, or until dusts have settled or sprays have dried is required. If re-entry into treated areas is necessary during the restricted-entry interval, workers must wear waterproof gloves, long-sleeved shirt, long pants, goggles, socks with shoes, and NIOSH-approved particulate filtering facepiece respirator.

Environmental Considerations

What Happens When *Trichoderma asperellum* strain T34 Is Introduced Into the Environment?

Environmental risks are acceptable.

Asperello T34 Biocontrol is an end use product that is currently registered for use on greenhouse ornamentals and is not registered for outdoor uses. The proposed use expansions of Asperello T34 Biocontrol to greenhouse food crops and cannabis grown commercially indoors are not expected to result in sustained increases of *Trichoderma asperellum* strain T34 in terrestrial and aquatic environments beyond natural background levels.

Based on a critical review of data provided and information from public sources conducted during the initial registration of Asperello T34 Biocontrol, no significant effects to birds, wild mammals, fish, aquatic insects, earthworms, soil microorganisms, mushrooms, or horticultural crops are expected when Asperello T34 Biocontrol is applied according to directions on the label. Also, minimal exposure to non-target organisms is anticipated from the proposed use of Asperello T34 Biocontrol in greenhouses.

Value Considerations

What Is the Value of Asperello T34 Biocontrol?

Trichoderma asperellum strain T34 suppresses or partially suppresses listed diseases on greenhouse ornamentals, cannabis produced commercially indoors and greenhouse vegetable crops.

Asperello T34 Biocontrol is a biological fungicide that will provide an alternative disease management product for use on these crops. This product may contribute to resistance reduction for conventional fungicides as well as provide organic growers with an additional tool for disease management.

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 T34 Biocontrol Technical and Asperello T34 Biocontrol to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

All microorganisms, including *Trichoderma asperellum* strain T34, contain substances that are potential sensitizers and thus, sensitivity may possibly develop in individuals exposed to potentially large quantities of *Trichoderma asperellum* strain T34. In turn, workers handling or applying Asperello T34 Biocontrol must wear waterproof gloves, long-sleeved shirt, long pants, socks with shoes, and a NIOSH-approved particulate filtering facepiece respirator.

A restricted-entry interval of 4 hours or until sprays have dried or dusts have settled is required for Asperello T34 Biocontrol. If re-entry into treated areas is required during the restricted-entry interval, workers must waterproof gloves, long-sleeved shirt, long pants, goggles, socks with shoes, and NIOSH-approved particulate filtering facepiece respirator.

Environment

The end use product label includes environmental precaution statements that reduce contamination of aquatic systems from the use of Asperello T34 Biocontrol.

Next Steps

Before making a final registration decision on *Trichoderma asperellum* strain T34 and Asperello T34 Biocontrol, 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* strain T34 and Asperello T34 Biocontrol (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

Trichoderma asperellum strain T34

1.0 The Active Substance, Its Properties And Uses

1.1 Physical and Chemical Properties of the Technical Grade Active Ingredient and the End-use Product

Refer to PRD2011-21, Trichoderma asperellum strain T34, for details.

1.2 Directions for Use

Asperello T34 Biocontrol is to be used on greenhouse crops for suppression of fusarium wilt or partial suppression of certain diseases. Asperello T34 Biocontrol is to be applied preventively by incorporation in the growing media, spray or drench application to seedtrays, multipots, and other types of seedling containers, chemigation after planting, or foliar applications.

1.3 Mode of Action

Trichoderma asperellum strain T34, classified as a Group BM02 fungicide by the Fungicide Resistance Action Committee (FRAC), has multiple modes of action to protect plants from disease, including the colonization of growing media and plant roots leading to competition with fungal pathogens, a physical barrier protecting the roots from pathogens, direct parasitism, and inducing systemic resistance in the host plant.

2.0 Methods of Analysis

2.1 Methods for Identification of the Microorganisms

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

2.2 Methods for Establishment of Purity of Seed Stock

Refer to PRD2011-21, Trichoderma asperellum strain T34, for details.

2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

Refer to PRD2011-21, Trichoderma asperellum strain T34, for details.

2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of batches of Asperello T34 Biocontrol and T34 Biocontrol Technical for the initial registration decision using standard methods for detecting and enumerating microbial contaminants of concern. In addition, all batches of T34 Biocontrol Technical must 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

Refer to PRD2011-21, Trichoderma asperellum strain T34, for details.

3.0 Impact on Human and Animal Health

3.1 Toxicity and Infectivity Summary

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

3.1.1 Incident Reports Related to Human and Animal Health

As of 8 July 2019, no human or domestic animal incident reports involving *Trichoderma* asperellum strain T34, nor its related strains, have been reported to the PMRA.

3.1.2 Hazard Analysis

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Occupational Exposure and Risk

While the proposed expanded uses of Asperello T34 Biocontrol to include greenhouse food crops and cannabis grown commercially indoors could result in workers handling the product more frequently or for longer periods, the maximum application rates are unchanged from registered applications. Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details. The addition of the foliar spray application method may alter the occupational exposure slightly, but this application method is similar to the currently registered spray applications to growing medium, and the label already includes appropriate personal protective equipment and

precautionary statements for spray applications. Therefore, the proposed addition of greenhouse food uses and cannabis grown indoors is not expected to increase the potential for occupational exposure if the product is applied according to label directions.

Risk mitigation measures such as personal protective equipment (PPE), including waterproof gloves, long-sleeved shirt, long pants, socks with shoes, and a NIOSH-approved particulate filtering facepiece respirator are required to minimize exposure and protect applicators, mixer/loaders and handlers that are likely to be exposed. Based on the results from the eye irritation study, eye protection is not required, however, goggles are already prescribed on the product label.

Label warnings, restrictions and risk mitigation measures are adequate to protect users of Asperello T34 Biocontrol when applied to greenhouse food crops and cannabis grown commercially indoors. Overall, occupational risks to workers are acceptable when the precautionary statements on the label are followed which include PPE.

3.2.2 Residential and Bystander Exposure and Risk

Refer to PRD2011-21, Trichoderma asperellum strain T34, for details.

3.3 Dietary Exposure and Risk Assessment

3.3.1 Food

While dietary exposure to *Trichoderma asperellum* strain T34 may occur through consumption of treated crops, the risk from consuming food crops treated with Asperello T34 Biocontrol is acceptable since the end use product demonstrated low toxicity in acute oral, inhalation, and dermal studies, and no pathogenicity or infectivity in the Tier I acute oral, pulmonary, and intraperitoneal studies.

The likelihood of dietary exposure to toxic secondary metabolites such as trichothecenes as a result of the proposed food uses of Asperello T34 Biocontrol is negligible. Studies provided with the original registration of T34 Biocontrol demonstrated that if trichodermin is present in the formulated product, it is at levels much lower than in known producer strains, and that T2 toxin and harzianum A are undetectable in the formulated product. To support the use expansion, additional studies were provided which demonstrated that T2 toxin, trichodermin, and harzianum A are not detectable in the edible portion of crops treated with *Trichoderma asperellum* strain T34 or Asperello T34 Biocontrol at rates exceeding the maximum proposed label rate, both by foliar spray and soil application, and in the presence and absence of a pathogenic fungus. The absence of detectable trichothecenes in the formulated product and in crops treated with Asperello T34 Biocontrol indicate that dietary exposure to secondary metabolites of toxicity concern as a result of the proposed food uses will be negligible.

As well, studies of crops treated with Asperello T34 Biocontrol indicated that the populations of *Trichoderma* spp. on leaves and fruits of plants are low, decrease and/or are nearly undetectable 10–50 days after treatment. In the soil, *Trichoderma* spp. populations can remain slightly higher than on leaves and fruit after 50 days. However, even if dietary exposure to the MPCA is slightly

higher from consumption of bulb vegetables, the hazard to human health remains low, as demonstrated by the low oral toxicity and infectivity of Asperello T34 Biocontrol in the Tier I toxicity/infectivity studies. Therefore, the health risks for the general population and sensitive subpopulations such as infants and children, or to animals are acceptable.

3.3.2 Drinking Water

Dietary exposure from drinking water is expected to be negligible as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of Asperello T34 Biocontrol. The proposed use expansion is limited to greenhouses and the label 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. Health risks from residues of *Trichoderma asperellum* strain T34 in drinking water are acceptable due to the low toxicity/pathogenicity profile of Asperello T34 Biocontrol and 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 (ARfDs) and acceptable daily intakes (ADIs) 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 Trichoderma asperellum strain T34 is of low toxicity, is not pathogenic or infective to mammals, and that infants and children are likely to be no more sensitive to the MPCA 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 the MPCA, including neurological effects from pre- or postnatal exposures, and cumulative effects on infants and children of the MPCA and other registered microorganisms that have a common mechanism of toxicity, does not apply to this MPCA. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of *Trichoderma asperellum* strain T34 to human health.

3.3.4 Aggregate Exposure and Risk

Based on the toxicity and infectivity test data submitted and other relevant information in the PMRA's files, there is reasonable certainty that no harm will result from aggregate exposure of residues of *Trichoderma asperellum* strain T34 to the general Canadian population, including infants and children, when the end use product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information. Dermal and inhalation exposure to the

general public will be low since the product is not allowed for use on turf, residential or recreational areas. Furthermore, adverse effects from exposure to other *Trichoderma asperellum* strains encountered in the environment have not been reported. Even if there is an increase in exposure to *Trichoderma asperellum* strain T34 from the use of Asperello T34 Biocontrol, there should not be any increase in potential human health risk.

3.3.5 Maximum Residue Limits (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that 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 an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Residues of *Trichoderma asperellum* strain T34 on treated food crops at the time of harvest are anticipated following foliar applications to agricultural crops. Consequently, the PMRA has applied a hazard-based approach for determining whether an MRL is required for this microorganism. The risks anticipated for dietary exposure are considered low as no adverse effects from dietary exposure have been attributed to natural populations of *Trichoderma asperellum* and no adverse effects were observed in Tier I acute oral and acute inhalation toxicity studies. Secondary metabolites of toxicological concern are not detectable on crops treated with the end-use product, and populations of *Trichoderma* spp. on crops after treatment are low and/or decrease following treatment. In addition, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Therefore, the PMRA has determined that the specification of an MRL, under the *Pest Control Products Act*, will not be required for *Trichoderma asperellum* strain T34.

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. Accordingly, a cumulative health assessment was undertaken. In its assessment of common mechanism of toxicity, the PMRA considers both the taxonomy of MPCAs and the production of any potentially toxic metabolites. For the current evaluation, the PMRA has determined that *Trichoderma asperellum* strain T34 shares a common mechanism of toxicity with the MPCAs *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 *Trichoderma asperellum* strain T34 and these other MPCAs are acceptable when used as labelled given the inherent low toxicity profile of *Trichoderma asperellum* strain T34 and the demonstrated absence of trichothecene toxins in the formulated product and on crops treated with Asperello T34 Biocontrol.

4.0 Impact on the Environment

Since the site and maximum rate of application are unchanged from the currently registered uses for this active ingredient and there are no changes to the formulation of T34 Biocontrol Technical or Asperello T34 Biocontrol, the environmental fate and behaviour and the environmental toxicological databases for these products are considered acceptable. As such, no additional environmental fate and behaviour or non-target organism studies were required. Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

As a precaution, the label already contains statements prohibiting the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The label also directs growers to not allow effluent or run-off from greenhouses containing this product to enter lakes, streams, ponds or other waters and to avoid contaminating surface water by disposal of wastes.

4.1 Incident Reports related to the Environment

As of 8 July 2019, no environment incidents involving *Trichoderma asperellum* strain T34, nor its related strains, were reported to the PMRA.

5.0 Value

Asperello T34 Biocontrol represents an alternative product for use preventively in an integrated pest management program. It may also provide an alternative product for organic growers to utilize for disease management by reducing infection levels of economically important diseases. Data from efficacy trials, published literature and scientific rationales supported the listed disease claims. Extrapolations from the provided trials to certain greenhouse crops and transplants were supported based on their susceptibility to the disease and causal pathogen.

There was no phytotoxicity or other adverse effects observed in the trial studies. The supported use claims are summarized in Appendix I, Table 1.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

6.2 Formulants and Contaminants of Health or Environmental Concern

Refer to PRD2011-21, *Trichoderma asperellum* strain T34, for details.

7.0 Summary

7.1 Methods for Analysis of the Microorganism as Manufactured

The product characterization data previously submitted for the initial registration of T34 Biocontrol Technical and Asperello T34 Biocontrol were adequate to assess their potential human health and environmental risks for the proposed major new uses. T34 Biocontrol Technical was fully characterized and the specifications of the end-use product were supported by the analyses of a sufficient number of batches. All batches of T34 Biocontrol Technical must conform to the limits set out in the OECD issue paper on microbial contaminants for microbial pest control products [ENV/JM/MONO(2011)43]. Storage stability data were sufficient to support a shelf life of one year when stored between 4°C–15°C. For additional information, refer to PRD2011-21 *Trichoderma asperellum* strain T34.

7.2 Human Health and Safety

The previously-submitted acute toxicity/infectivity studies and newly-submitted secondary metabolite studies and *Trichoderma* population studies in support of the use expansion for T34 Biocontrol Technical and Asperello T34 Biocontrol were determined to be acceptable to permit a decision on registration for the proposed major new uses for greenhouse food crops and cannabis grown commercially indoors. Based on all the available information, the end-use product was of low toxicity in the rat when administered via oral, pulmonary and dermal routes and was not infective via the oral, pulmonary and intraperitoneal routes of exposure with a pattern of clearance established by Day 21. The end-use product was not irritating to the skin and was minimally irritating to the eyes. The MPCA is considered to be a potential sensitizer.

As previously determined during the initial registration of *Trichoderma asperellum* strain T34, when handled according to the label instructions, the potential for dermal, inhalation and eye exposure for applicators, mixer/loaders, and handlers exist, with the primary source of exposure to workers being exposure to the skin or inhalation of dusts and mists. The existing precautionary statements on the Asperello T34 Biocontrol label and the wearing of PPE by workers will adequately mitigate the risks from exposure. Furthermore, precautionary labelling will alert users of the potential sensitization hazard of the product.

The health risk to the general population, including infants and children, as a result of residential and bystander exposures and/or chronic dietary exposure is acceptable due to the low toxicity/pathogenicity profile for Asperello T34 Biocontrol, the absence of detectable trichothecene toxins on aerial portions of crops after treatment with the end-use product, the low and/or decreasing levels of *Trichoderma* spp. on crops following treatment with the end-use product, as well as the absence of sustained increases in exposure to bystanders beyond natural levels. The specification of an MRL under the *Pest Control Products Act* is not required for *Trichoderma asperellum* strain T34.

7.3 Environmental Risk

The previously-submitted scientific studies and rationales in support of T34 Biocontrol Technical and its associated end-use product, Asperello T34 Biocontrol, were determined to be acceptable. The greenhouse use of Asperello T34 Biocontrol containing *Trichoderma asperellum* strain T34 is not expected to pose a risk to non-target organisms when the directions for use on the label are followed. Environmental exposure to *Trichoderma asperellum* strain T34 is expected to continue to be minimal given that the proposed major new uses of Asperello T34 Biocontrol are limited to greenhouses, consistent with the registered uses. Therefore, the greenhouse use of Asperello T34 Biocontrol on food crops and cannabis grown commercially indoors is not expected to result in sustained increases of *Trichoderma asperellum* strain T34 in terrestrial and aquatic environments.

As a general precaution, the Asperello T34 Biocontrol label prohibits the direct application of Asperello T34 Biocontrol to aquatic habitats (such as lakes, streams and ponds) and the release of greenhouse effluent and run-off to natural aquatic systems. The label also directs users to avoid contaminating surface water by disposal of equipment wash waters.

7.4 Value

The information submitted to add major new uses to the Asperello T34 Biocontrol label supports the claims outlined in Appendix I, Table 1. It will provide growers, especially organic growers, with an alternative product to manage diseases on greenhouse crops and potentially contribute to a reduction in resistance development for conventional fungicides.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u>, is proposing registration for the sale and use of T34 Biocontrol Technical, and Asperello T34 Biocontrol, containing the technical grade active ingredient *Trichoderma asperellum* strain T34 to be used against certain fungal diseases on greenhouse ornamentals, cannabis produced commercially indoors and greenhouse vegetables.

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.

List of Abbreviations

μg micrograms

1/n exponent for the Freundlich isotherm

a.i. active ingredientADI acceptable daily intakeALS acetolactate synthaseARfD acute reference dose

atm atmosphere bw body weight

CAS Chemical Abstracts Service

cm centimetres
DF dry flowable

DNA deoxyribonucleic acid

DT₅₀ dissipation time 50% (the dose required to observe a 50% decline in

concentration)

DT₉₀ dissipation time 90% (the dose required to observe a 90% decline in

concentration)

EC₂₅ effective concentration on 25% of the population EC₅₀ effective concentration on 50% of the population

ER₂₅ effective rate for 25% of the population

g gram ha hectare(s)

HDT highest dose tested

Hg mercury

HPLC high performance liquid chromatography

IUPAC International Union of Pure and Applied Chemistry

kg kilogram

K_d soil-water partition coefficientK_F Freundlich adsorption coefficient

km kilometre

 K_{oc} organic-carbon partition coefficient K_{ow} *n*-octanol-water partition coefficient

L litre

LC₅₀ lethal concentration 50%

LD₅₀ lethal dose 50%

LOAEL lowest observed adverse effect level LOEC low observed effect concentration

 $\begin{array}{ccc} LOQ & limit of quantitation \\ LR_{50} & lethal \ rate \ 50\% \\ mg & milligram \\ mL & millilitre \\ \end{array}$

MAS maximum average score
MOE margin of exposure
MRL maximum residue limit
MS mass spectrometry
N/A not applicable

NOAEL no observed adverse effect level NOEC no observed effect concentration

NOEL no observed effect level NOER no observed effect rate

N/R not required

NZW New Zealand white
OC organic carbon content
OM organic matter content
PBI plantback interval
PHI preharvest interval
pKa dissociation constant

PMRA Pest Management Regulatory Agency

ppm parts per million

RSD relative standard deviation

SC soluble concentrate

 $t_{1/2}$ half-life

T3 tri-iodothyronine

T4 thyroxine

TRR total radioactive residue

TSMP Toxic Substances Management Policy

UAN urea ammonium nitrate UF uncertainty factor

USEPA United States Environmental Protection Agency

UV ultraviolet

v/v volume per volume dilution

Appendix I

Table 1 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

List of Supported Uses

Supported use claim

Crop: greenhouse ornamentals

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse cucurbit vegetables (CG9)

Disease: suppression of fusarium wilt (Fusarium oxysporum)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse cucurbit vegetables (CG9)

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*, *Phytophthora capsici*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse cucurbit vegetables (CG9)

Disease: partial suppression of gummy stem blight (*Didymella bryoniae*)

Application method: foliar application

Rate: 0.6–1.0 kg/ha

Crop: tomato and pepper

Disease: suppression of fusarium wilt (Fusarium oxysporum)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse fruiting vegetables (CG8-09)

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: tomato, pepper, and eggplant

Disease: partial suppression of postemergence damping off and crown rot (*Phytophthora capsici*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse strawberries

Disease: suppression of fusarium wilt (*Fusarium oxysporum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse strawberries

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse strawberries

Disease: partial suppression of crown rot (*Phytophthora cactorum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: cannabis produced commercially indoors

Disease: suppression of fusarium wilt (*Fusarium oxysporum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: cannabis produced commercially indoors

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse vegetable transplants of: cucurbit vegetables (CG9), lettuce, spinach, swiss chard, celery, bean, pea, onion, garlic, brassica leafy vegetables (CG5), tomato, pepper, and strawberry

Disease: suppression of fusarium wilt (*Fusarium oxysporum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse vegetable transplants of: cucurbit vegetables (CG9), lettuce, spinach, swiss chard, pea, brassica leafy vegetables (CG5), fruiting vegetables (CG8-09), and strawberry

Disease: partial suppression of postemergence damping off and crown rot (*Pythium aphanidermatum*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

Crop: greenhouse vegetable transplants of: cucurbit vegetables (CG9), bean, tomato, pepper, and eggplant

Disease: partial suppression of postemergence damping off and crown rot (*Phytophthora capsici*)

Application method: incorporation in the growing media, spray/drench, or chemigation after planting

Rate: 10⁴ CFU/mL of substrate/growing media

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1.0 Product Characterization and Analysis

None.

2.0 Human And Animal Health

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3.0 Environment

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