



Proposed Registration Decision

PRD2018-09

***Trichoderma harzianum* Rifai
strain KRL-AG2;
Trichoderma virens strain G-41;
BW240 WP Biological
Fungicide;
RootShield Plus WP Biological
Fungicide;
TurfShield Plus WP Biological
Fungicide**

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Overview

Proposed Registration Decision for *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of RootShield Technical Biological Fungicide, containing *Trichoderma harzianum* Rifai strain KRL-AG2, and G-41 Technical, containing *Trichoderma virens* strain G-41, and the end-use products BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, containing both microbial pest control agents (MPCAs), to control root diseases in ginseng, greenhouse food crops and greenhouse ornamentals, outdoor ornamentals and certain foliar diseases in turf.

Trichoderma harzianum Rifai strain KRL-AG2 is currently registered for the suppression of root and foliar diseases on greenhouse crops, outdoor nursery plants and agricultural field crops. For details, please see the Regulatory Note REG2002-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, the Proposed Registration Decision PRD2009-13, *RootShield Biological Fungicide, Trichoderma harzianum* Rifai strain KRL-AG2, the Registration Decision RD2010-02, *RootShield Biological Fungicide, Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum* Rifai strain KRL-AG2 and Its Associated End-use Products.

Trichoderma virens strain G-41 is currently registered on outdoor container-grown nursery plants. For details, please see the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41 and the Registration Decision RD2012-24, *Trichoderma virens* strain G-41.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide.

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

Before making a final registration decision on *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, the PMRA will consider any comments received from the public in response to this consultation document.³ The PMRA will then publish a Registration Decision⁴ on *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

What Are *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41?

Trichoderma harzianum Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are beneficial fungi that outcompete plant pathogenic fungi for space and nutrients, colonizing the plant roots before soil pathogens can become established. They also produce enzymes that break down the hyphae of the plant pathogenic fungi. They are used preventatively for the suppression or partial suppression of soil-borne pathogens that cause root diseases in ginseng, greenhouse food crop groups and greenhouse ornamentals, outdoor ornamentals and certain foliar diseases in turf.

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.”

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*.

Health Considerations

Can Approved Uses of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 Affect Human Health?

***Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are unlikely to affect your health when BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are used according to the label directions.**

Potential exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 may occur when handling and applying BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide and from potential residues in water and food. 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.

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 exposure to large doses of a microorganism and identify any pathogenicity, infectivity and toxicity concerns. When *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 were tested on laboratory animals, there was no sign that they caused any significant toxicity or disease. However, *Trichoderma virens* strain G-41 produces a secondary metabolite known as gliotoxin. While gliotoxin is present in G-41 Technical and in the end-use products, no adverse effects attributed to gliotoxin were noted in studies conducted on laboratory animals.

G-41 Technical, RootShield Technical Biological Fungicide and, consequently, their associated end-use products contain the allergen wheat. The end-use products also contain the allergen sulphites.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Residues of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 on the treated crops, at the time of harvest, are possible following applications to agricultural crops. *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 produced no adverse effects (disease or toxicity) when administered orally to rats. Although *Trichoderma virens* strain G-41 is known to produce gliotoxin, this metabolite is not taken up into the edible portions of plants when the end-use products are applied directly to soil. In addition, natural populations of *Trichoderma virens* strains that produce gliotoxin are commonly found in the environment, and outdoor uses of the end-use products are not expected to cause a sustained increase in the level of gliotoxin in the environment, including water bodies used for drinking water, beyond what is naturally occurring.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

In addition to indoor greenhouse uses, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are proposed for directed outdoor applications to ginseng, nursery plants and turf (for example, sports fields and golf courses). There are no residential uses for these end-use products. Applications to outdoor crops and nursery plants or turf are not of concern to bystanders, as *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 will colonize the thatch and root zones of turf, and the product labels include measures to prevent bystander exposure. Even in the event of exposure, risk to the general population is not a concern since no signs of disease or toxicity were noted in animal studies conducted with *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 and their associated end-use products.

Occupational Risks From Handling BW240 WP Biological Fungicide, Rootshield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide

Occupational risks are not of concern when BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are used according to label directions, which include protective measures.

Workers handling BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide can come into direct contact with *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 on the skin, in the eyes, or by inhalation. For this reason, the product labels for the end-use products will specify that workers must wear waterproof gloves, long-sleeved shirts, long pants, a mist and dust filtering mask or respirator, eye goggles and shoes with socks. To further reduce exposure to gliotoxin, the end-use product labels will advise users to avoid skin contact with treated soil or potting mix. In addition, to minimize postapplication exposure, unprotected workers are restricted from entering areas treated with BW240 WP Biological Fungicide, RootShield Plus WP Biological

Fungicide or TurfShield Plus WP Biological Fungicide for 4 hours following application or until sprays have dried.

Environmental Considerations

What Happens When *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 Are Introduced Into the Environment?

Environmental risks are not of concern.

Trichoderma harzianum and *Trichoderma virens* are commonly isolated from soils throughout North America. Published scientific literature on the environmental fate of these fungi suggests that, as soil microorganisms, *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are able to survive in various climates and environmental conditions. Survival depends on the type of soil, moisture, acidity levels and temperature. Over time, however, the elevated populations of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 that immediately follow operational applications are expected to return to naturally sustainable levels.

BW240 WP Biological Fungicide is for use on greenhouse grown food crops and ornamentals, field food crops and ornamentals, and turf. RootShield Plus WP Biological Fungicide is for use on greenhouse and field grown food crops, and greenhouse and nursery ornamentals. TurfShield Plus WP Biological Fungicide is a new product proposed for turf uses only. The products are applied to the growing media.

The end-use products are not intended for aquatic uses and exposure to aquatic environments is limited to spray drift, leaching and runoff (following a rain event) following field or turf applications. Neither *Trichoderma harzianum* Rifai strain KRL-AG2 nor *Trichoderma virens* strain G-41 are aquatic species, and they are unlikely to persist in aquatic environments.

Based on a critical review of the available information, no significant effects to birds, wild mammals, fish, terrestrial and aquatic non-target arthropods, and plants are expected when BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are applied according to directions on the label.

Value Considerations

What Is the Value of BW240 WP Biological Fungicide, Rootshield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide?

BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide will provide growers with the first fungicide products registered for the management of root rot on greenhouse strawberries.

BW240 WP Biological Fungicide and TurfShield Plus WP Biological Fungicide also provide users with the first biological products to manage pythium damping off in turf.

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 RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are considered eye irritants. In addition, all microorganisms, including *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41, contain substances that are potential sensitizers and thus, respiratory and dermal sensitivity may develop in individuals exposed repeatedly to large quantities of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41. In turn, workers handling or applying the end-use products must wear waterproof gloves, long-sleeved shirts, long pants, eye goggles, a dust and mist filtering mask or respirator, and shoes with socks. In addition, to minimize postapplication exposure, unprotected workers are restricted from entering treated areas for 4 hours following application or until sprays have dried. These measures will also minimize any potential exposure to gliotoxin.

A standard statement is required on the end-use product labels to minimize the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas as well as statements to limit contamination of water supplies through cleaning, waste disposal, effluent or runoff.

Environment

End-use product labels will include environmental precaution statements to limit drift, minimize runoff (including from greenhouse effluent) and contamination of aquatic systems from the use of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide.

Next Steps

Before making a final registration decision on *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA 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). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide (based on the Science Evaluation section 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 harzianum* Rifai strain KRL-AG2**

***Trichoderma virens* strain G-41**

BW240 WP Biological Fungicide

RootShield Plus WP Biological Fungicide

TurfShield Plus WP Biological Fungicide

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredients

Active microorganisms	<i>Trichoderma harzianum</i> Rifai strain KRL-AG2	<i>Trichoderma virens</i> strain G-41
Function	To provide suppression of root rot in greenhouse and outdoor food or ornamental crops and turf.	
Binomial names	<i>Trichoderma harzianum</i> Rifai strain KRL-AG2	<i>Trichoderma virens</i> strain G-41
Taxonomic designation		
	Kingdom Fungi	Fungi
	Phylum Dueteromycontina	Dueteromycontina
	Class Hyphomycetes	Hyphomycetes
	Order Hyprocreales	Hyprocreales
	Genus <i>Trichoderma</i>	<i>Trichoderma</i>
	Species <i>harzianum</i>	<i>virens</i>
	Strain KRL-AG2	G-41
Patent Status information	<i>T. harzianum</i> Rifai strain KRL-AG2: None <i>T. virens</i> strain G-41: US Patent and Trademark Office (Patent number US 2010/0028303)	
Nominal purity of active	RootShield Technical Biological Fungicide technical grade active ingredient: $\geq 5 \times 10^8$ viable spores of <i>T. harzianum</i> Rifai strain KRL-AG2/g dry weight.	

G-41 Technical: $\geq 1 \times 10^8$ viable spores of *T. virens* strain G-41/g dry weight.

BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide: $\geq 1.0 \times 10^7$ CFU of *T. harzianum* Rifai strain KRL AG2/g dry weight $\geq 5.3 \times 10^6$ CFU *T. virens* strain G-41/g dry weight.

Identity of relevant impurities of toxicological, environmental and/or significance.

The technical grade active ingredients do not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. Each technical grade active ingredients must meet microbiological contaminant release standards.

Trichoderma harzianum Rifai strain KRL-AG2 can produce 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 for RootShield Technical Biological Fungicide 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 this fungus.

Trichoderma virens strain G-41 is a known producer of gliotoxin, a secondary metabolite of toxicological significance. Presence of Gliotoxin has been confirmed in the technical grade active ingredients and end-use products, however its presence is not expected to pose a health risk of concern when used according to label directions.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

RootShield Technical Biological Fungicide and G-41 Technical exist only transiently and are not packaged. Therefore, physical and chemical properties for the technical grade active ingredients have not been provided.

End-use Products – BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide

Property	Result
Colour	Gray green
Physical State	Solid
Odour	Slightly musty

1.3 Directions for Use

BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide are used preventatively in solution for the suppression of soil-borne pathogens that cause root diseases. These products are used in greenhouse ornamentals, greenhouse vegetable transplants, certain greenhouse vegetables, greenhouse strawberries, greenhouse wasabi, cannabis (marijuana) produced commercially indoors, outdoor nursery crops and ginseng. Products are applied at a concentration of 30–60 g/100 L water to the soil or potting mix at planting. BW240 WP Biological Fungicide and TurfShield Plus WP Biological Fungicide can be used in turf for the suppression or partial suppression of certain foliar diseases.

1.4 Mode of Action

Trichoderma harzianum Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are beneficial fungi that outcompete plant pathogenic fungi for space and nutrients, colonizing the plant roots ahead of the pathogens. They also act as a mycoparasite by producing enzymes, which break down the hyphae of the plant pathogenic fungi. Species of *Trichoderma* have recently been assigned to the Group BM 02 Fungicides by the Fungicide Resistance Action Committee (FRAC).

2.0 Methods of Analysis

2.1 Methods for Identification of the Microorganisms

Acceptable methods for detection, isolation and enumeration of both microorganisms were fully described for the MPCAs in support of previous registration decisions. For information on these methods, see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

2.2 Methods for Establishment of Purity of Seed Stock

Acceptable methods for establishment of purity of seed stock were fully described for both MPCAs in support of the initial registration decisions. There have been minor changes to these methods that have resulted in more consistent and very similar production methods for both active ingredients, resulting in improved quality assurance. For information on these methods, see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

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

Acceptable methods to define the content of the microorganisms in the manufactured material were fully described for both MPCAs in support of previous registration decisions. For information on these methods, see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

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

Acceptable methods are available to enumerate viable spores and to distinguish these MPCAs from each other and other *Trichoderma* species, as well other strains of *Trichoderma virens* and *Trichoderma harzianum*. The presence of gliotoxin, a secondary metabolite of *Trichoderma virens* strain G-41 has been confirmed in G-41 Technical and is expected in the end-use products. Appropriate methods are available to detect and quantify gliotoxin in food matrices. No methodologies were required to quantify peptaibol residues in previous registration decisions. For further information, see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

Acceptable methods for the determination of relevant impurities in the manufactured material have been fully described in previous registration decisions. For information on these methods, see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of batches of end-use products using standard methods for detecting and enumerating microbial contaminants of concern. In addition, all batches of RootShield Technical Biological Fungicide and G-41 Technical must conform to the limits set out in the Organization 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 RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide. For RootShield Technical Biological Fungicide, the storage stability data support a storage period of 12 months at $\leq 5^{\circ}\text{C}$. For G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, the storage stability data support a storage period of 10 months at $\leq 5^{\circ}\text{C}$.

3.0 Impact on Human and Animal Health

3.1 Toxicology and Infectivity Summary

3.1.1 Testing

No new human health and safety data were submitted or required for the proposed major new uses. Instead, the applicant cited human health and safety studies and waiver rationales submitted in support of the original registrations of RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide. These studies were previously assessed and found to be acceptable. Information relevant to BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide are applicable to TurfShield Plus WP Biological Fungicide. Toxicity and infectivity information related to *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 can be found in the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum* Rifai strain KRL-AG2 and Its Associated End-use Products, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens* strain G-41.

3.1.2 Additional Information

Trichoderma virens strain G-41 is a known producer of the secondary metabolite gliotoxin which may pose a health concern with the liver appearing to be the target organ. A single oral administration of gliotoxin to hamsters at doses of 15, 25 or 35 mg/kg bw resulted in mortality in 4/5, 5/8 and 7/8 animals, respectively. The LD₅₀ values in mice exposed to gliotoxin via the intraperitoneal and intravenous routes were found to be 25 mg/kg bw and 7.8 mg/kg bw, respectively. In rats, the LD₅₀ value for intraperitoneal exposure was 50–65 mg/kg bw. No information was available on the potential toxicity of gliotoxin via the dermal route and no chronic studies were available in the published literature. Gliotoxin is known to be an immunosuppressive agent.

Trichoderma harzianum Rifai strain KRL-AG2 produces linear hydrophobic polypeptides called peptaibols. Peptaibols function as antibiotics and contain a high proportion of α,α -dimethylisobutyric acid. Many peptaibols, such as the trichorzianines, trichokindins, trichorzins, trichorozins and harzianins, exhibit a broad range of bioactivities related to cell membrane perturbation. These activities include such in vitro effects as hemolysis, uncoupling of oxidative phosphorylation in rat liver mitochondria, inhibition of multiplication of different types of cells, acting as channel agonists in bullfrog cardiac myocytes and enhancing secretion of catecholamine from adrenal chromaffin cells. In a previously submitted study, strain KRL-AG2's potential to produce these peptaibols was studied under conditions that favoured their production. The results of this study clearly showed that strain KRL-AG2 produced four peptaibols, namely trichorzins HA II and HA V, and harzianins HB I and HC XIII. However, no new peptaibols were isolated and no significant adverse effects were reported in Tier I acute toxicity/pathogenicity studies (see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2).

3.1.3 Incident Reports Related to Human and Animal Health

As of 23 November 2017, no human or domestic animal incident reports involving *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 have been submitted to the PMRA.

3.1.4 Hazard Analysis

The database submitted previously in support of registering RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide was reviewed from the viewpoint of human health and safety and was determined to be complete.

Based on a review of all available data and information, RootShield Technical Biological Fungicide is considered to be of low toxicity via the oral, pulmonary (intratracheal) and dermal exposure routes, and *Trichoderma harzianum* Rifai strain KRL-AG2 is not pathogenic or infective via the pulmonary (intratracheal) and intravenous injection routes. Furthermore, RootShield Technical Biological Fungicide is minimally irritating to the eyes and skin. As is the case for all microorganisms, *Trichoderma harzianum* strain KRL-AG2 is considered to be a potential sensitizer and, therefore, the hazard statement “POTENTIAL SENSITIZER” must appear on the principal display panel of the RootShield Technical Biological Fungicide label; and on the label’s secondary display panel, the following PRECAUTIONS statement must be included: “May cause sensitization. Avoid contact with eyes, skin and clothing. Avoid breathing dust.”

Similarly, G-41 Technical is of low toxicity by the oral and pulmonary routes of exposure. *Trichoderma virens* strain G-41 is also not infective or pathogenic by the oral, pulmonary (intratracheal), intraperitoneal and intravenous routes of exposure. The technical grade active ingredient, G-41 Technical, is not irritating to the skin, but it is considered to be mildly irritating to the eye. Also, the active ingredient, *Trichoderma virens* strain G-41, is considered to be a potential sensitizer. Consequently, the hazard statements “POTENTIAL SENSITIZER” and “CAUTION EYE IRRITANT” must appear on the principal display panel of the label for G-41 Technical. The following statement must also be included under the PRECAUTIONS section on the technical grade active ingredient label’s secondary display panel: “May cause sensitization. May irritate eyes. Avoid contact with eyes, skin and clothing. Avoid breathing dust.”

Testing was performed using an alternative formulation to support the registration of the end-use products. Based on these tests, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are considered to be of low toxicity via the oral, inhalation and dermal routes of exposure and are not considered to be irritating to the skin but are mild ocular irritants. Like the technical grade active ingredients, these end-use products are considered to be potential sensitizers. Therefore, the standard precautionary statements “POTENTIAL SENSITIZER” and “CAUTION EYE IRRITANT” must be included on the principal display panel of the end-use product labels and the following statement must appear under the PRECAUTIONS section on each end-use products label’s

secondary display panel: “May cause sensitization. May irritate eyes. Avoid contact with eyes, skin and clothing. Avoid breathing dust and spray mist.”

G-41 Technical and the end-use products contain detectable levels of gliotoxin and it is expected that additional gliotoxin will be produced by *Trichoderma virens* strain G-41 after application of the end-use products to soil. Similarly, RootShield Technical Biological Fungicide and the end-use products may also contain peptaibols. The concerns associated with the presence of gliotoxin are addressed in the occupational/bystander exposure and dietary exposure and risk assessments below. The health concerns associated with peptaibols were addressed in previous registration decisions on *Trichoderma harzianum* Rifai strain KRL-AG2 (see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum* Rifai strain KRL-AG2, and the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum* Rifai strain KRL-AG2 and Its Associated End-use Products).

Higher tier subchronic and chronic toxicity studies were not required by PMRA because there are no indications of infectivity, toxicity or pathogenicity in the test animals treated in the Tier I acute oral, pulmonary and intravenous toxicity/infectivity tests.

Within the available scientific literature, there are no reports that suggest *Trichoderma harzianum* Rifai strain KRL-AG2 or *Trichoderma virens* strain G-41 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 system is anticipated for *Trichoderma virens* strain G-41 or *Trichoderma harzianum* Rifai strain KRL-AG2. Gliotoxin, however, is a known immunosuppressive agent.

3.2 Occupational, Residential and Bystander Risk Assessment

3.2.1 Occupational Exposure and Risk

When the end-use products, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, are handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, with primary exposure routes being dermal and inhalation. Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption can occur only if the skin were cut or if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin. Neither *Trichoderma harzianum* Rifai strain KRL-AG2 nor *Trichoderma virens* strain G-41 has been identified as dermal wound pathogens; there is no indication that they can penetrate intact skin of healthy individuals. Furthermore, toxicity testing showed the end-use products were unlikely to be toxic via the oral, inhalation and dermal routes, and were non-irritating to the skin, but likely mildly irritating to the eye. Also, testing with the technical grade active ingredients, G-41 Technical and RootShield Technical Biological Fungicide, showed no signs of infectivity or pathogenicity via the oral, pulmonary, intraperitoneal and/or intravenous injection routes. However, the PMRA assumes that all microorganisms contain substances that can elicit positive hypersensitivity reactions, regardless of the outcome of sensitization testing.

Risk mitigation measures, such as personal protective equipment, including waterproof gloves, long-sleeved shirts, long pants, eye goggles, a NIOSH-approved dust or mist filtering respirator or NIOSH-approved dust or mist filtering mask, and shoes with socks are required to minimize exposure and protect commercial applicators, mixer/loaders, and handlers that are likely to be exposed. In addition, to minimize postapplication exposure, unprotected workers are prohibited from entering treated areas where the end-use products have been applied for 4 hours or until the sprays have dried.

Occupational exposure to gliotoxin is not expected to pose a health concern based on the results of human health and safety studies on the technical grade active ingredients and end-use products, and the requirement for personal protective equipment, particularly the dust/mist filtering respirator/mask. To further reduce exposure to gliotoxin, the end-use product labels will advise workers to avoid skin contact with treated soil or potting mix.

Label warnings, restrictions and risk mitigation measures are adequate to protect users of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, and no significant occupational risks are anticipated for these products.

3.2.2 Residential and Bystander Exposure and Risk

There is a potential for bystander exposure to spray drift from applications to outdoor field crops, outdoor nursery plants and turf. For bystanders, inhalation exposure is expected to be much less than that of handlers and mixer/loaders. Although golf course and sports field users may come into contact with turf treated with BW240 WP Biological Fungicide or TurfShield Plus WP Biological Fungicide, exposure will be low given that *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are expected to colonize the thatch and root zones of the turf following application.

Overall, the PMRA does not expect that residential and bystander exposures will pose a health risk of concern on the basis of the low toxicity profiles for BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, the low infectivity/pathogenicity profiles for *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41, and the expectation that precautionary label statements will be followed by commercial applicators in the use of the end-use products. As well, *Trichoderma harzianum* and *Trichoderma virens* are species that are common in the environment, and the use of the end-use products is not expected to cause sustained increases in exposure to bystanders beyond natural levels. Consequently, the health risk to infants and children is expected to be low.

3.3 Dietary Exposure and Risk Assessment

3.3.1 Food

While the proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities, dietary risk is expected to be low and not of concern for the general population and sensitive subpopulations such as infants and children because *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 demonstrated low toxicity

in the acute oral studies and no pathogenicity or infectivity in the Tier I acute oral, pulmonary, intravenous and/or intraperitoneal injection studies.

Although gliotoxin is present in the end-use products, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, and is expected to increase after application to soil, an acceptable study was provided demonstrating that gliotoxin is not translocated to the edible portions of food crops when the end-use products are applied directly to soil. This finding is applicable to all edible portions of the plant, including roots, leaves and fruit.

Higher tier subchronic and chronic dietary exposure studies were not required because of the anticipated low toxicity and lack of infectivity or pathogenicity associated with the active ingredients *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41.

3.3.2 Drinking Water

Health risks are not expected from exposure to *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 via drinking water because exposure will be low from operational applications and because there were no harmful effects observed in Tier I acute oral toxicity testing and infectivity testing. The end-use products labels instruct users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Users are also to minimize effluent or runoff from greenhouses and outdoor applications to enter lakes, streams, ponds or other waters. Furthermore, municipal treatment of drinking water is expected to reduce the transfer of residues to drinking water.

Trichoderma virens strain G-41 is a known producer of gliotoxin. Gliotoxin does not adsorb strongly to soils and is considered to have very high mobility through soil. Also, gliotoxin is soluble in water at environmentally relevant temperatures (25°C and 30°C). Based on these properties, gliotoxin may leach into ground water as a result of outdoor applications of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide. Natural populations of *Trichoderma virens* strains that produce gliotoxin, however, are also commonly found in the environment, including agricultural soils. Outdoor uses of the end-use products are, therefore, not expected to cause a sustained increase in the level of gliotoxin in the environment, including water sources used for drinking water, beyond what is naturally occurring.

Peptaibols are linear hydrophobic peptides that are likely to possess limited mobility through soils. Furthermore, the level of peptaibols produced by *Trichoderma harzianum* Rifai strain KRL-AG2 is not expected to be greater than the level produced by naturally occurring *Trichoderma* strains, for which there have been no reports of adverse effects to humans. Due to the proteinaceous nature of these polypeptides, they are expected to be short-lived in the environment once produced as they are susceptible to denaturing by ultraviolet light, high temperatures and various microbial processes in the environment. On this basis, the potential presence of peptaibols in drinking water is not expected to pose a concern for human health.

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 the MPCAs are of low toxicity, are not pathogenic or infective to mammals, and that infants and children are likely to be no more sensitive to the 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 postnatal exposures, and cumulative effects on infants and children of these MPCAs and other registered microorganisms that have a common mechanism of toxicity, do not apply to these MPCAs. As a result, the Agency has not used a margin of exposure (safety) approach to assess the risks of these MPCAs 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 harzianum* Rifai strain KRL-AG2 and *Trichoderma reesei* strain G-41 to the general Canadian population, including infants and children, when BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are 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 in residential areas. Applications to outdoor crops and nursery plants or turf is expected to result in only low dermal and inhalation exposure to the general public given that the MPCAs are expected to colonize the thatch and root zones of the turf and that the label will include mitigation measures to reduce spray drift. Even if there is an increase in exposure to these microorganisms from the use of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide or TurfShield Plus WP Biological Fungicide, there should not be any increase in potential human health risk.

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 *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 on treated food crops, at the time of harvest, may be present following applications to soil surfaces growing agricultural crops. Consequently, the PMRA has applied a hazard-based approach for determining whether MRLs are required for these microorganisms. The risks anticipated for dietary exposure are considered low, based on the lack of toxicity and pathogenicity effects observed in the acute toxicity and infectivity studies. Although gliotoxin is present in the end-use products and its level is expected to increase after application to soil, it is not taken up into the edible portions of food crops. In addition, the risks to human health associated with any residues of *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41 or their associated metabolites transferring to drinking water are low. Therefore, the PMRA has determined that specification of MRLs under the *Pest Control Products Act* are not required for *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41.

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 *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 share a common mechanism of toxicity with each other and with the registered MPCAs *Trichoderma harzianum* Rifai strain T-22, *Trichoderma asperellum* strain T34 and *Gliocladium catenulatum* strain J1466. The potential health risks from cumulative exposure of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 and these other registered MPCAs are not of concern given their low toxicity and pathogenicity.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

No studies were submitted to address the environmental fate and behaviour of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41. Environmental fate data (Tier II/III) are not normally required at Tier I, and are only triggered if significant toxicological effects in non-target organisms are noted in Tier I testing.

Fungal species belonging to the genus *Trichoderma* are common in soils from all climate zones. *Trichoderma harzianum* and *Trichoderma virens* are naturally occurring in North America and can be found in soils, on decaying wood and vegetable matter but are not expected to persist in the phyllosphere of growing plants or proliferate in aquatic environments. These fungi produce copious conidia held together in mucoid spore balls, which can be disseminated by water and by

soil fauna such as insects and earthworms. Outdoor applications of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide are not expected to result in soil concentrations of these fungi that are substantially above background concentrations.

Although there is potential for surface water exposure resulting from spray drift from field applications or runoff events following rain, the concentrations of *Trichoderma. harzianum* Rifai strain KRL-AG2 or *Trichoderma virens* strain G-41, which are deposited in surface water bodies, are expected to be at or below naturally-occurring levels. Recovery of *Trichoderma* from fresh or salt water environments is rare, suggesting that *Trichoderma. harzianum* and *Trichoderma virens* are unable to establish themselves in aquatic environments.

The use of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide is not expected to result in a sustained increase in levels of *Trichoderma harzianum* Rifai strain KRL-AG2 and its associated metabolites (for example, peptaibols) beyond the naturally occurring levels of those produced by native *Trichoderma harzianum* strains. Peptaibols are not expected to persist in the environment, as they are easily denatured by ultraviolet light, heat and various microbial processes in the environment.

Trichoderma virens strain G-41 is a known producer of gliotoxin, a secondary metabolite of toxicological significance. G-41 Technical and the EPs are expected to contain gliotoxin. Based on its physicochemical properties, gliotoxin may leach in to water bodies as a result of outdoor applications of the end-use products. Natural populations of *Trichoderma virens* strains that produce gliotoxin, however, are commonly found in the environment. The use of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide is not expected to result in a significant increase in levels of gliotoxin beyond naturally occurring levels produced by native *Trichoderma virens* strains.

4.2 Effects on Non-Target Species

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 (MCC) of the MPCA. The MCC 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 (i.e., 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 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 (LOC).

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 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

Acceptable scientific rationales were previously submitted to waive Tier I testing requirements for both *Trichoderma* strains based on the results of an extensive search and review of the published scientific literature (see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum Rifai strain KRL-AG2*, the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum Rifai strain KRL-AG2 and Its Associated End-use Products*, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens strain G-41*).

The rationales were based on the common occurrence of *Trichoderma* spp. in the environment and the high likelihood that non-target terrestrial organisms are frequently exposed with apparent lack of adverse effects as supported by the results of the literature searches. In addition, neither strain is expected to grow well at avian and mammalian body temperatures and nor are they reported as entomopathogens as they do not cause insect epizootics.

While honey bees and other insects may come in contact with residues in soil treated with the end-use products, they primarily associate with foliar surfaces of plants. Therefore, since the end-use products are intended for soil directed use only, exposure to these non-target organisms will likely be limited.

Trichoderma harzianum Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 are common soil fungi and are not related to any known plant pathogens; therefore, adverse effects to non-target terrestrial plants are not expected to result from the directed application to the soil of turf or field crops.

Based on all the available information on the biological properties of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 and their anticipated effects on non-target terrestrial organisms, there is reasonable certainty that no harm will be caused to birds, wild mammals, terrestrial non-target arthropod invertebrates, non-arthropod invertebrates, and terrestrial plants from the proposed greenhouse, agricultural and turf uses of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide. Furthermore, the formulants are not expected to contribute to potential toxicity of the products.

4.2.2 Effects on Aquatic Organisms

Acceptable scientific rationales were previously submitted to waive Tier I testing requirements for both *Trichoderma* strains based on the results of an extensive search and review of the published scientific literature (see the Proposed Regulatory Decision Document PRDD2007-01, *RootShield Biological Fungicide Trichoderma harzianum Rifai strain KRL-AG2*, the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum Rifai strain KRL-AG2 and Its Associated End-use Products*, and the Proposed Registration Decision PRD2012-06, *Trichoderma virens strain G-41*). The rationales were based on minimal exposure to aquatic environments due to the products' proposed use patterns, the ubiquitous nature of both strains, lack of reported adverse effects in the literature and the inability of either strain to become established in aquatic environments.

Based on all the available information on the effects of *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 to non-target aquatic organisms, there is reasonable certainty that no harm will be caused to fish, aquatic arthropod and non-arthropod invertebrates, and aquatic plants from the proposed greenhouse, agricultural and turf uses of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide. As a general precaution, no aerial application is permitted. The label will also prohibit the direct application of these products to aquatic habitats, estuaries or marine habitats, and direct handlers to not contaminate surface water by disposal of equipment wash waters. The product labels also instruct users how to minimize drift during application and to reduce runoff to aquatic environments.

4.3 Incident Reports Related to the Environment

As of 23 November 2017, no environment incident reports involving *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41 have been submitted to the PMRA.

5.0 Value

BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, containing *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41, were demonstrated to have value when used against the listed diseases on the crops specified on these product labels, based on a combination of efficacy data and scientific rationales.

In support of the label expansion of BW240 WP Biological Fungicide, a combination of scientific rationales and efficacy data were provided. Supported claims are shown in Appendix I, Table 1.

The risk for resistance development for the active ingredients is low with these types of products. Damping off in greenhouse transplant lettuce was established as a low priority at the 2015 Grower Priority Setting Meeting.

For the greenhouse and field crops, there are few conventional products registered to manage root rot. There are several non-conventional products registered, although not for every crop-disease claim. There are no alternatives for the management of root rot on greenhouse strawberries. These products will provide growers with a useful tool for this crop. For the management of dollar spot on turf, there are several conventional and non-conventional products of available. For the claim of pythium damping off in turf, there are currently four conventional active ingredients registered for this claim, but there are no non-conventional products. This registration will provide users with the first non-conventional active ingredients to manage pythium damping off in turf.

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 [those that meet all four criteria outlined in the policy, i.e. 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*].

RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide were assessed in accordance with the PMRA Regulatory Directive DIR99-03.⁵

- RootShield Technical Biological Fungicide does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.
- G-41 Technical does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products.
- There are also no formulants, contaminants or impurities present in the end-use products that would meet the TSMP Track 1 criteria.

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

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*⁶. The list is used as described in the PMRA Notice of Intent NOI2005-01⁷ and is based on existing policies and regulations including DIR99-03 and DIR2006-02,⁸ 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:

- The technical grade active ingredients, RootShield Technical Biological Fungicide and G-41 Technical contain wheat which is identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641-2643: *List of Pest Control Product Formulants of Health or Environmental Concern* as an allergen known to cause anaphylactic-type reactions. Therefore, the labels for both RootShield Technical Biological Fungicide and G-41 Technical and their associated end-use products must include the warning statement “Warning: this product contains the allergen wheat” on the principal display panel.
- The end-use products, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, contain a formulant which is a mixture containing sulphites. Sulphites are identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641-2643: *List of Pest Control Product Formulants of Health or Environmental Concern* as an allergen known to cause anaphylactic-type reactions. Therefore, the labels for the end-use products must contain the precautionary statement “Warning: this product contains the allergen sulphites” on the principal display panel.

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

⁶ *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-11-30) pages 2641-2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613: *Part I Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern*.

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

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

7.0 Summary

7.1 Methods for Analysis of the Microorganism as Manufactured

The product characterization data for RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide were adequate to assess their potential human health and environmental risks. The technical materials were fully characterized and the specifications of the end-use products were supported by the analyses of a sufficient number of batches. All batches of RootShield Technical Biological Fungicide and G-41 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 submitted were sufficient to support a shelf life for the end-use products and G-41 Technical of 10 months at $\leq 5^{\circ}\text{C}$. Storage stability data support a storage period of 12 months for RootShield Technical Biological Fungicide at $\leq 5^{\circ}\text{C}$.

7.2 Human Health and Safety

The acute toxicity and infectivity studies and scientific waiver rationales previously submitted in support of RootShield Technical Biological Fungicide, G-41 Technical, BW240 WP Biological Fungicide and RootShield Biological Fungicide were determined to be sufficiently complete to permit a decision on registrations for their expanded uses and for TurfShield Plus WP Biological Fungicide.

Based on data submitted by the applicant and publicly available information from the scientific literature, RootShield Technical Biological Fungicide is considered to be of low toxicity via pulmonary (intratracheal) and dermal exposure routes, and *Trichoderma harzianum* Rifai strain KRL-AG2 is not pathogenic or infective via the pulmonary (intratracheal) and intravenous injection exposure routes. Furthermore, RootShield Technical Biological Fungicide is minimally irritating to the eyes and skin, and is considered to be a potential sensitizer. Therefore, the hazard statement "POTENTIAL SENSITIZER" must appear on the label's principal display panel and the following precautionary statements must appear on the secondary display panel: "May cause sensitization. Avoid contact with eyes, skin and clothing. Avoid breathing dust."

Similarly, G-41 Technical is of low toxicity by the oral and pulmonary routes of exposure, and *Trichormia virens* strain G-41 is not infective or pathogenic by the oral, pulmonary (intratracheal), intraperitoneal and intravenous routes of exposure. G-41 Technical is not irritating to the skin but it is considered to be mildly irritating to the eye and is also considered to be a potential sensitizer. Consequently, the hazard statements "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT" must appear on the principal display panel of the G-41 Technical label, and the following precautionary statement is required on the secondary panel: "May cause sensitization. May irritate eyes. Avoid contact with eyes, skin and clothing. Avoid breathing dust."

The alternative formulation used to support the registration of the end-use products is considered to be of low toxicity via the oral, inhalation and dermal routes of exposure; it is not considered to be irritating to the skin but was mildly irritating to the eye, and the technical grade active ingredients are considered to be potential sensitizers. Therefore, the standard precautionary statements “POTENTIAL SENSITIZER” and “CAUTION EYE IRRITANT” must be included on the principal display panel of the end-use product labels and the following precautionary statements must be included on their secondary panels: “May cause sensitization. May irritate eyes. Avoid contact with eyes, skin and clothing. Avoid breathing dust and spray mist.”

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, with primary exposure routes being dermal and inhalation. Respiratory and dermal sensitivity is possible upon repeated exposure to the products since all microorganisms, including *Trichoderma harzianum* Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41, contain substances that are potential sensitizers. Therefore, anyone handling or applying BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide must wear waterproof gloves, eye goggles, a long-sleeved shirt, long pants, a NIOSH approved dust or mist filtering mask or respirator, and shoes with socks. To reduce exposure to gliotoxin, the end-use product labels will advise workers to avoid skin contact with treated soil or potting mix. In addition, to minimize postapplication exposure, unprotected workers are restricted from entering areas treated with these end-use products for 4 hours following application or until sprays have dried.

The health risk to the general population, including infants and children, as a result of bystander exposure and/or chronic dietary exposure is low and not of concern due to the low toxicity/pathogenicity profile for *Trichoderma harzianum* Rifai strain KRL-AG2, *Trichoderma virens* strain G-41, RootShield Technical Biological Fungicide, G-41 Technical, and the associated end-use products. Furthermore, the use of the end-use products will not result in a significant increase in exposure to *Trichoderma harzianum*, *Trichoderma virens*, or their associated metabolites beyond natural levels and no metabolites of concern are translocated to the edible portions of treated crops when the end-use products are applied directly to soil. The specification of an MRL under the *Pest Control Products Act* is not required for *Trichoderma harzianum* Rifai strain KRL-AG2 or *Trichoderma virens* strain G-41.

7.3 Environmental Risk

The scientific rationales and supporting published scientific literature previously submitted in support of RootShield Technical Biological Fungicide and G-41 Technical and their associated end-use products (BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide) were determined to be complete to permit a decision on registration. The greenhouse, agricultural and turf uses of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide containing *Trichoderma harzianum* Rifai strain KRL-AG2 or *Trichoderma virens* strain G-41 are not expected to pose a risk to non-target organisms when the directions for use on the label are followed. The proposed use of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide is not expected to result in sustained increases of *Trichoderma harzianum* Rifai strain KRL-AG2 or *Trichoderma virens*

strain G-41 in terrestrial and aquatic environments. The production of metabolites such as gliotoxin or peptaibols by these strains is not an environmental risk of concern because outdoor uses of the end-use products are not expected to cause a significant increase in the level of these metabolites beyond that of natural populations of *Trichoderma*.

As a general precaution, the product labels will prohibit aerial application or the direct application of BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), estuaries or marine habitats. Handlers will be instructed to not contaminate surface water by disposal of equipment wash waters or greenhouse effluent and to limit runoff from treated areas.

7.4 Value

Trichoderma harzianum Rifai strain KRL-AG2 and *Trichoderma virens* strain G-41, the active ingredients in BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide have been shown to be effective at providing suppression of soil-borne pathogens that cause root diseases in ginseng, greenhouse food crop groups, greenhouse ornamentals and outdoor ornamentals. These active ingredients also provide suppression or partial suppression of labeled diseases in turf.

BW240 WP Biological Fungicide and RootShield Plus WP Biological Fungicide will provide growers with the first fungicide products registered for the management of root rot on greenhouse strawberries.

BW240 WP Biological Fungicide and TurfShield Plus WP Biological Fungicide also provide users with the first biological products to manage pythium damping off in turf.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of RootShield Technical Biological Fungicide, containing *Trichoderma harzianum* Rifai strain KRL-AG2, and G-41 Technical, containing *Trichoderma virens* strain G-41, and the end-use products BW240 WP Biological Fungicide, RootShield Plus WP Biological Fungicide and TurfShield Plus WP Biological Fungicide, containing both MPCAs, to control root diseases in ginseng, greenhouse food crops and greenhouse ornamentals, outdoor ornamentals and certain foliar diseases in turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

°C	degrees Celsius
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CBI	confidential business information
CFU	colony forming unit
DACO	data code
DIR	Regulatory Directive
EP	end-use product
FRAC	Fungicide Resistance Action Committee
g	gram(s)
kg	kilogram(s)
L	litre(s)
LC ₅₀	median lethal concentration
LD ₅₀	median lethal dose
LOC	level of concern
m	metre(s)
mg	milligram(s)
MCC	Maximum Challenge Concentration
MPCA	microbial pest control agent
MRL	maximum residue limit
NIOSH	The National Institute for Occupational Safety and Health
OECD	Organisation for Economic Co-operation and Development
PCPA	<i>Pest Control Products Act</i>
PMRA	Pest Management Regulatory Agency
PRD	Proposed Registration Decision
PRDD	Proposed Regulatory Decision Document
PRVD	Proposed Re-evaluation Decision
RD	Registration Decision
REG	Regulatory Note
RQ	risk quotient
TSMP	Toxic Substances Management Policy
US	United States
WP	wettable powder

Appendix I Tables and Figures

Table 1 List of Supported Uses

Supported use claims
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse ornamentals at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse vegetable transplants at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse fruiting vegetables at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse cucurbit vegetables at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse brassica vegetables at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse leafy vegetables at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse strawberries at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on greenhouse wasabi at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp. and <i>Phytophthora</i> spp. on cannabis (marijuana) produced commercially indoors at a rate of 30–60 g/100 L of water applied to 10 m ² of soil/potting mixture surface.
Suppression of root rot and damping off caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp. and <i>Fusarium</i> spp. on ginseng at a rate of 3–4 kg/ha applied in a minimum of 1000 L of water.
Partial suppression of dollar spot (<i>Sclerotinia sclerotiorum</i>) and suppression of Pythium damping off (<i>Pythium</i> spp.) on turf at a rate of 45 g/100 m ² in 4–20 L of water.
Application methods: ground equipment and chemigation

References

A. List of Studies/Information Submitted by Registrant

1.0 The Active Substance, Its Properties and Uses

PMRA Document Number	Reference
2636428	2016, Manufacturing Process for <i>Trichoderma virens</i> (G-41), DACO: M2.8, M2.9 CBI
2669982	2009, Five Batch Analysis CFU Results G-41, T-22, BW240, DACO: M2.10.1, M2.10.3 CBI
2669983	2009, Analysis for T-22 Technical, DACO: M2.10.2, M2.10.3 CBI
2669984	2016, Response to Deficiencies for Rootshield Technical Biological Fungicide, DACO: M2.10.2, M2.10.3
2636364	2014, Explanation of Liquid Inoculum for <i>Trichoderma harzianum</i> strain KRL-AG2, DACO: M2.8, M2.9, M2.9.1, M2.9.2, M2.9.3 CBI
2636365	2014, Total Ingredient List Liquid Inoculum for <i>Trichoderma harzianum</i> strain KRL-AG2, DACO: M2.8, M2.9 CBI
2636366	2016, Manufacturing Process for <i>Trichoderma harzianum</i> strain KRL-AG2 (T-22), DACO: M2.8, M2.9 CBI
2636367	2009, Media for Inoculum SOP, DACO: M2.8, M2.9 CBI
2670000	2009, Five Batch Analysis CFU Results G-41, T-22, BW240, DACO: M2.10.1, M2.10.3 CBI
2670001	2009, Analysis for T-22 Technical, DACO: M2.10.2, M2.10.3 CBI

2.0 Impact on Human and Animal Health

PMRA Document Number	Reference
2628178	2016, Exposure Assessment for New Uses for BW240 WP Biological Fungicide (Reg. No. 31989), DACO: M5.0
2628179	2016, Scientific Rationale to Demonstrate that Gliotoxin is not Translocated Through the Plant, or Accumulated in Edible Plant Parts from the Use of G-41 Technical, containing <i>Trichoderma virens</i> strain G-41, DACO: M7.0
2664216	2016, Cross Reference for BW240 WP Biological Fungicide, DACO: M7.0
2820305	2017, Magnitude of Gliotoxin Residues Following Application of RootShield Plus WP Biological Fungicide to Greenhouse Tomatoes, DACO: M7.0
2664380	Jefferys, E. G. (1952). The Stability of Antibiotics in Soils. <i>J Gen Microbiol</i> , 7: 295-312, DACO: M7.0
2664381	Lumsden, R. D., Locke, J. C., Adkins, S. T., Walter, J. F., and Ridout, C. J. (1992). Isolation and Localization of the Antibiotic Gliotoxin Produced by <i>Gliocladium virens</i> from Alginate Prill in Soil and Soilless Media. <i>Phytopathology</i> , 82: 230-235, DACO: M7.0

PMRA Document Number	Reference
2664382	Mobius, N., and Hertweck, C. (2009). Fungal phytotoxins as mediators of virulence. <i>Current Opinion in Plant Biology</i> , 12: 390-398, DACO: M7.0
2664383	Wilhite, S.E, and Straney, D. C. (1996). Timing of gliotoxin biosynthesis in the fungal biological control agent <i>Gliocladium virens</i> (<i>Trichoderma virens</i>). <i>Appl Microbiol Biotechnol</i> , 45: 513-518, DACO: M7.0
2664384	Wright, J. M. (1951). Phytotoxic effects of some antibiotics. <i>Annals of Botany</i> , 15: 493-499, DACO: M7.0

4.0 Value

PMRA Document Number	Reference
2628143	2013, Optimizing Pythium Blight Control on a Perennial Ryegrass Turf: Rutgers University 2013- Test 2 (Pyth-2-13), DACO: M10.2.2
2628144	2015, Fall \$-Spot Control with Selected Fungicides and Biological Products: Rutgers University 2015, DACO: M10.2.2
2628145	2015, Efficacy of Rootshield Plus WP for the control of Phytophthora Root Rot and Blight of Pepper (Field), DACO: M10.2.2
2628146	2015, Efficacy of Rootshield Plus WP for the control of Phytophthora Root Rot and Blight of Squash, DACO: M10.2.2
2628147	2015, Efficacy of Rootshield Plus WP for the control of Phytophthora Root Rot and Blight of Squash, DACO: M10.2.2
2628149	2011, Efficacy of BW240, RootMate, and RootShield against Phytophthora root rots <i>Phytophthora parasitica</i> infesting Petunia under greenhouse conditions., DACO: M10.2.2
2628150	2011, Efficacy of BW240, RootMate, and RootShield against Phytophthora root rots <i>Phytophthora parasitica</i> infesting Azalea under greenhouse conditions., DACO: M10.2.2
2628151	2010, Efficacy of BW240 against Pythium root rot <i>Pythium ultimum</i> infesting Hibiscus <i>Rhododendron obtusam</i> under greenhouse conditions, DACO: M10.2.2
2628152	2010, Efficacy of BW240 against Phytophthora root rot <i>Phytophthora cinnamomi</i> infesting Boxwood <i>Buxus japonica</i> under greenhouse conditions, DACO: M10.2.2
2628155	2015, Efficacy of selected biofungicides against Fusarium Wilt <i>Fusarium oxysporum f.sp. lycopersici</i> infesting Tomato <i>Lycopersicon esculentum</i> under greenhouse conditions, DACO: M10.2.2
2628158	2011, Efficacy of RootShield Plus WP against Phytophthora root rot <i>Phytophthora parasitica</i> infesting Tomato under greenhouse conditions, DACO: M10.2.2
2628163	2015, Efficacy of selected biofungicides against Phytophthora Root rot <i>Phytophthora parasitica</i> infesting Azalea under greenhouse conditions, DACO: M10.2.2

PMRA Document Number	Reference
2628164	2015, Efficacy of selected biofungicides against Phytophthora Root rot <i>Phytophthora parasitica</i> infesting Petunia spp. under greenhouse conditions, DACO: M10.2.2
2628165	2015, Efficacy of RootShield - based products against Phytophthora root rot <i>Phytophthora parasitica</i> infesting Strawberry under greenhouse conditions, DACO: M10.2.2
2628166	2015, Efficacy of RootShield - based products against Phytophthora root rot <i>Phytophthora parasitica</i> infesting Tomato under greenhouse conditions, DACO: M10.2.2
2628168	2015, Efficacy of RootShield - based products against Rhizoctonia root rot <i>Rhizoctonia solani</i> infesting Strawberry under greenhouse conditions, DACO: M10.2.2
2628170	2016, Value Summary for BW240 WP Biological Fungicide, containing <i>Trichoderma harzianum</i> Rifai strain KRL-AG2 and <i>Trichoderma virens</i> strain G-41, for Root Rot caused by <i>Pythium</i> spp., <i>Rhizoctonia</i> spp., <i>Fusarium</i> spp., and <i>Phytophthora</i> spp. in Greenhouse Crops, Greenhouse Vegetable Transplants, Cannabis (marijuana) produced commercially indoors, Outdoor Nursery Plants, Ginseng and Dollar spot and Pythium in Turf, DACO: M10.1, M10.2.1, M10.2.2, M10.3.1, M10.3.2, M10.4.1, M10.4.2, M10.4.3, M10.4.4
2628173	2016, History of Use from United States Grower - Greenhouse Ornamentals, DACO: M10.5
2628174	2016, History of Use from United States Grower - Greenhouse Ornamentals, DACO: M10.5
2628175	2016, History of Use from United States Grower - Greenhouse Ornamentals, DACO: M10.5
2628176	2016, History of Use from United States Grower - Greenhouse Ornamentals and Nursery Crops, DACO: M10.5