Proposed Registration Decision PRD2015-29

Difenoconazole

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Overview

Proposed Registration Decision for Difenoconazole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Difenoconazole Technical Fungicide and Inspire Fungicide, containing the technical grade active ingredient difenoconazole, to control or suppress fungal diseases on a variety of fruit and vegetable crops.

Difenoconazole Technical Fungicide (Registration Number 25631) and Inspire Fungicide (Registration Number 30004) are conditionally registered in Canada for foliar application on a variety of terrestrial food crops. The detailed review for the foliar use of Difenoconazole Technical Fungicide and Inspire Fungicide can be found in Evaluation Report ERC2011-06, *Difenoconazole*. The current applications were submitted to convert Difenoconazole Technical Fungicide and Inspire Fungicide from conditional registration to full registration for the foliar use.

In addition, Difenoconazole Technical Fungicide has full registration as a seed treatment on a variety of cereal crops as well as for use on turf. The detailed review for the seed treatment use can be found in the Proposed Regulatory Decision Document PRDD99-01, *Difenoconazole* as well as in the Regulatory Decision Document RDD2001-04, *Difenoconazole Fungicide*. The detailed review for the turf use can be found in the Proposed Registration Decision PRD2015-10, *Difenoconazole*.

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 provides detailed technical information on the human health, environmental and value assessments of Difenoconazole Technical Fungicide and Inspire 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 acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and 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 Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on difenoconazole, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on difenoconazole, 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 of this consultation document.

What Is Difenoconazole?

Difenoconazole is a Group 3 fungicide active ingredient that inhibits mycelial growth, which slows or stops the growth of the fungus and effectively prevents further infection or invasion of host tissues.

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

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

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 Difenoconazole Affect Human Health?

Difenoconazole is unlikely to affect your health when used according to label directions.

Potential exposure to difenoconazole may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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

In laboratory animals, the technical grade active ingredient difenoconazole was of slight acute toxicity by the oral route; consequently, the hazard signal words “CAUTION – POISON” are required on the Difenoconazole Technical Fungicide label. It was of low acute toxicity dermally and through inhalation exposure. Difenoconazole was mildly irritating to the eyes, minimally irritating to the skin and did not cause an allergic skin reaction. The hazard signal words

“CAUTION – EYE IRRITANT” are required on the Difenoconazole Technical Fungicide label.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of difenoconazole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included fetal loss and effects on the liver, body weight and food consumption. Longer-term dosing with difenoconazole resulted in liver tumors in mice at very high doses, but not in rats. The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

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

Chronic dietary intake estimates (food plus drinking water) revealed that the general population and children between the age of one and two years old, the subpopulation which would ingest the most difenoconazole relative to body weight, are expected to be exposed to less than 61% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from difenoconazole is not of health concern for all population subgroups. There are no lifetime cancer risks of concern from the use of difenoconazole.

The acute dietary (food plus drinking water) intake estimate for the population subgroup of women aged between 13 and 49 years old was less than 14% of the acute reference dose. Estimates for all other subpopulations, including the highest exposed subpopulation of children between the age of one and two years old, were also less than 14%. Hence, none are of health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The confined crop rotational trial study provided to the Agency in support of the conversion from conditional to full registration for foliar use, as well as the cherry tomato field trial study submitted in support of removing the restriction on small diameter size tomatoes on the label of the end-use product Inspire Fungicide, are both considered acceptable.

Information concerning the MRLs for difenoconazole on various crop commodities can be found in the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website.

Occupational Risks From Handling Inspire Fungicide

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

Farmers and custom applicators who mix, load or apply Inspire Fungicide as well as field workers entering treated fields and orchards can come in direct contact with difenoconazole residues on the skin or through inhalation of spray mists. Therefore, the label specifies that anyone mixing, loading and applying Inspire Fungicide, or involved in equipment clean-up or repairs, must wear chemical-resistant gloves, protective eyewear, long-sleeved shirt, long pants, socks and shoes. The label also requires that workers do not enter treated fields or other treated sites for 1–10 days after application for specific activities in some crops. For all other uses, a restricted entry interval of 12 hours is specified. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risk to workers handling Inspire Fungicide is not of concern.

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

For the general population involved in pick-your-own activities in pome fruit orchards, health risks are also not of concern.

Environmental Considerations

What Happens When Difenoconazole Is Introduced Into the Environment?

When used according to label directions, difenoconazole is not expected to pose an unacceptable risk to the environment.

Difenoconazole has the potential to persist in soil. In the terrestrial environment, difenoconazole breaks down very slowly and has the potential to carryover from one growing season to the next with repeated yearly applications and could eventually move to lower soil depths. Difenoconazole is not volatile and is not expected to bioaccumulate.

Amphibians would be at the highest potential risk through exposure from off-target spray drift and runoff entering aquatic systems resulting from the application of difenoconazole. There is also a potential risk to freshwater and marine/estuarine invertebrates and fish, beneficial terrestrial arthropods and non-target terrestrial plants.

Value Considerations

What Is the Value of Inspire Fungicide?

Difenoconazole, the active ingredient in Inspire Fungicide, controls or suppresses a range of economically important pathogens on fruit and vegetable crops.

Inspire Fungicide is a product formulated as a foliar treatment against various fungal diseases on fruit and vegetable crops. Inspire Fungicide is a broad spectrum fungicide with systemic and curative properties which offers a new fungicide chemistry to Canadian growers and may be applied as a foliar spray in alternating spray programs. Inspire Fungicide may also be applied in tank mixes with other crop protection products for pest resistance management, or to increase the disease spectrum on crops that are registered on both product labels.

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 Inspire Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As there is a concern with users coming into direct contact with Inspire Fungicide on the skin, anyone mixing, loading and applying Inspire Fungicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and protective eyewear. The label also requires restricted-entry

intervals of ten (10) days for cane-turning and vine girdling in grapes, three (3) days for hand harvesting and irrigation in brassica vegetables, two (2) days for all other postapplication activities in grapes, and one (1) day for scouting in brassica vegetables. A 12-hour restricted-entry interval is required for all other re-entry activities. In addition, standard label statements to protect against drift during application appear on the Inspire Fungicide label.

Environment

The following label statements are required to mitigate exposure to non-target aquatic and terrestrial habitats:

- Label statements to mitigate spray drift entering aquatic and terrestrial habitats
- Label statements to mitigate contamination of irrigation or drinking water supplies and aquatic habitats
- Buffer zones to mitigate the risk of spray drift entering aquatic and terrestrial habitats
- Label statements to mitigate the risk of surface runoff from treated fields
- Label statement to mitigate accumulation in soil from repeated seasonal applications
- Label statement to mitigate the risk to beneficial arthropods

Next Steps

Before making a final registration decision on difenoconazole, 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 difenoconazole (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

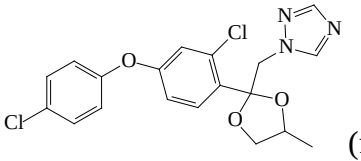
Difenoconazole

An evaluation report, ERC2011-06, *Difenoconazole*, provides a summary of data reviewed for the foliar use of difenoconazole. The information capture herein relates to new information provided to the PMRA in support of a conversion from conditional to full registration for the foliar use of difenoconazole.

Additional information for difenoconazole is available in the review of the seed treatment and turf uses: Proposed Regulatory Decision Document PRDD99-01, *Difenoconazole*, Regulatory Decision Document RDD2001-04, *Difenoconazole Fungicide*, and Proposed Registration Decision PRD2015-10, *Difenoconazole*.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Difenoconazole
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-chloro-4-[(2*RS*,4*RS*;2*RS*,4*SR*)-4-methyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether
2. Chemical Abstracts Service (CAS)	1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole
CAS number	119446-68-3
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$
Molecular weight	406.3
Structural formula	 (four stereoisomers)
Purity of the active ingredient	95.0 %

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

Technical Product – Difenoconazole Technical Fungicide

Please refer to PRDD99-01 for the chemistry review of Difenoconazole Technical Fungicide.

End-Use Product – Inspire Fungicide

Property	Result
Colour	Clear yellow to brown
Odour	Penetrating odour
Physical state	Liquid at 25°C
Formulation type	Emulsifiable concentrate
Guarantee	250 g/L
Container material and description	Fluorinated PE, HDPE, and stainless steel containers, 10 L to 1000 L
Density	1.070 g/cm^3 at 20°C
pH of 1% dispersion in water	5–7 at 25°C
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable for 1 year at 20°C in fluorinated HDPE
Corrosion characteristics	Not corrosive to fluorinated HDPE after one year storage at 20°C
Explodability	Not explosive

Please refer to ERC2011-06 for the directions for use for Inspire Fungicide and the mode of action for difenoconazole.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

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

2.3 Methods for Residue Analysis

For environmental media, high-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in soil, water and animal biota. Methods for residue analysis are summarized in Appendix I, Table 1.

Please refer to ERC2011-06 and PRDD99-01 for residue analytical methods used for data generation and enforcement purposes in food.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Please refer to ERC2011-06 for the complete toxicological review for difenoconazole, as well as the details on the *Pest Control Products Act* hazard characterization, acute reference dose, acceptable daily intake, and cancer assessment.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to Canadian health or the environment. The database was searched for incident reports involving difenoconazole. As of 25 September 2015, the PMRA had received ten human and ten domestic animal incident reports. These incident reports also involved other registered active ingredients.

The symptoms reported in eight human incidents (mainly minor or moderate in severity) were determined to have some degree of association with the reported exposure scenario. Overall, minor effects like headache, vomiting, dizziness or eye irritation were reported. In most incidents, exposure occurred as a result of application activities associated with treated seeds. Equipment failure was noted in one report.

In four domestic animal incidents, the effects experienced by the animal were considered to be related to the reported pesticide exposure. The severity of effects was classified as minor or moderate in three cases and major in one case. In all four cases, a dog accidentally ingested seed treated with difenoconazole and other active ingredients. The symptoms vomiting, diarrhea, tremors, lethargy or dehydration were reported.

Overall, no significant health risks from the use of products containing difenoconazole have been identified from this review of incident reporting data, as most incidents involved minor symptoms or generalized effects that may have been caused by other factors and current label statements address the potential hazards.

3.2 Occupational and Residential Risk Assessment

3.2.1 Toxicological Endpoints

Please refer to ERC2011-06 for the short- and intermediate-term dermal and inhalation endpoints of concern for difenoconazole.

3.2.1.1 Dermal Absorption

Please refer to ERC2011-06 for a summary of the dermal absorption data on file for difenoconazole.

3.2.2 Occupational Exposure and Risk

3.2.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Please refer to ERC2011-06 for the most recent exposure and risk assessment conducted for workers exposed to difenoconazole while handling Inspire Fungicide.

3.2.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

Since the risk assessment presented in ERC 2011-06, the default transfer coefficient used to estimate workers' exposure during hand thinning activities in pome fruit has decreased from 8000 cm^2/hr to 3000 cm^2/hr. As such, a new postapplication risk assessment was warranted to update the restricted entry interval.

Given the nature of the activity (hand thinning in pome fruit) the duration of exposure is considered to be short- to intermediate-term and the primary route of exposure for workers that enter treated orchards would be dermal, through contact with residues on leaves. Inhalation exposure is not considered to be a significant route of exposure for workers entering treated areas compared to the dermal route since the active ingredient difenoconazole is relatively non-volatile according to NAFTA criteria for outdoor use, and as such, a risk assessment was not required.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients and the dermal absorption factor (DA) for difenoconazole. Activity-specific transfer coefficients are based on reviewed Agricultural Re-Entry Task Force (ARTF) data, of which Syngenta is a member. Chemical-specific DFR data were not submitted. As such, a default DFR value of 25% of the application rate on the day of application and a default daily dissipation rate of 10% were used in the exposure assessment. Exposure was adjusted using a dermal absorption of 51% and normalized by using 80 kg adult body weight. Exposure estimates were compared to the No Observed Adverse Effect Level (NOAEL) of 25 mg/kg bw/day to obtain the Margin of Exposure (MOE); the target MOE is 300.

Table 3.2.2.2.1 Postapplication Exposure and Risk Estimate for Hand Thinning in Pome Fruit on the Day of Last Application (Day 0) of Inspire Fungicide

Crop	Max. App. Rate (g a.i./ha)	No. of App./Year (RTI)	Peak DFR ($\mu g/cm^2$)[1]	Re-Entry Activity	Transfer Coefficient (cm^2/hr)[2]	Dermal Exposure (mg/kg bw/day)[3]	Calculated MOE[4]
Pome fruit	72	5 (7 days)	0.3364	Hand thinning	3000	0.0515	**486**

[1] Dislodgeable foliar residues (DFR) were calculated using 25% dislodgeable on Day 0 and 10% dissipation per day; peak DFR is the DFR on Day 0.
[2] The transfer coefficient (TC) was obtained from the PMRA Agricultural TC Table (2015-02-26) based on ARTF data.
[3] Dermal exposure = (Peak DFR [$\mu g/cm^2$] × TC [cm^2/hr] × 8 hours) × 51% / (80 kg bw × 1000 µg/mg).
[4] MOE = NOAEL / Dermal Exposure; based on a short- to intermediate-term dermal NOAEL of 25 mg/kg bw/day and a dermal target MOE of 300.

Given that the calculated MOE on the day of last application is above the target MOE of 300 for hand thinning activities in pome fruit, the restricted-entry interval of 12 hours is considered acceptable and protective of re-entry workers.

Please refer to ERC2011-06 for the most recent exposure and risk assessment for all other postapplication re-entry scenarios.

3.2.3 Residential Exposure and Risk Assessment

3.2.3.1 Postapplication Exposure and Risk (Pick-Your-Own)

Please refer to ERC2011-06 for the most recent aggregate exposure and risk assessment conducted for the general population, including children (0–9 years), youth (10–18 years), adults (19+ years) and females (13–49 years), exposed to difenoconazole through pick-your-own activities in pome fruit orchards previously treated with Inspire Fungicide.

3.2.3.2 Bystander Exposure and Risk

Please refer to ERC2011-06 for bystander exposure and risk to difenoconazole.

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant and Animal Foodstuffs

Please refer to ERC2011-06 and PRDD99-01 for a summary of the previously reviewed residue data for difenoconazole in/on animal and plant matrices.

The confined crop rotational trial data requirements identified in ERC2011-06 were submitted and deemed to be scientifically acceptable. As required, the study was conducted with the maximum potential seasonal application rate in rotated crops of ~512 g a.i./ha using a phenyl-labelled difenoconazole and adequately characterized the nature of the residue in rotational crops following foliar applications. No separate residue definition is required for rotational crops, and in combination with a previously reviewed field rotational crop study, the plant-back interval of 60 days is now fully supported for all crops not registered for use with difenoconazole.

The crop field trial data on small diameter size tomatoes, as required by DIR2010-01 in order to remove the label restriction on tomatoes with a diameter size smaller than 5 cm, were submitted and deemed to be scientifically acceptable. The study included two trials conducted with four foliar applications of an emulsifiable concentrate formulation of difenoconazole on cherry tomatoes. The highest average field trial (HAFT) value measured in mature cherry tomatoes harvested on the day of the last application was 0.49 ppm, hence below the currently established maximum residue limit (MRL) of 0.60 ppm for residues of difenoconazole in/on commodities of Crop Group 8-09, fruiting vegetables. As such, an update to this MRL value is not required.

The submitted confined crop rotational data, as well as the submitted field trial data conducted in cherry tomatoes, are both summarized in Appendix I, Table 2.

3.3.2 Dietary Risk Assessment

Following the review of the required confined crop rotational trial study, no changes in the dietary exposure to difenoconazole are expected.

Moreover, given that the highest difenoconazole residues (HAFT of 0.49 ppm) generated during the cherry tomato field trials were not higher than the currently established MRL of 0.60 ppm in/on fruiting vegetables, the dietary exposure to difenoconazole from the use of Inspire Fungicide on all sizes of tomatoes, including small and regular sizes, is not expected to increase the dietary exposure to this active ingredient from the currently registered use pattern (regular size only). As such, an update to the dietary exposure assessment of difenoconazole was not conducted.

Please refer to PRD2015-10 for details about the most recent comprehensive dietary exposure assessment for difenoconazole.

3.3.3 Aggregate Exposure and Risk

The aggregate risk for difenoconazole consists of exposure from food and drinking water sources, as well as residential uses (golfing). Please refer to PRD2015-10 for further details.

3.3.4 Maximum Residue Limits

As no new MRLs are proposed for promulgation with the current applications, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the currently established MRLs for difenoconazole.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Please refer to ERC2011-06 and PRD2015-10 for a summary of the fate and behaviour of difenoconazole in the environment.

4.2 Environmental Risk Characterization

Please refer to ERC2011-06 and PRD2015-10 for a summary of the risk of difenoconazole to terrestrial and aquatic non-target organisms in the environment.

The terrestrial plant toxicity studies that were identified as an outstanding data requirement in ERC2011-06 have subsequently been submitted and reviewed. The new data satisfy the environmental assessment requirements for difenoconazole.

There were no adverse effects on the vegetative vigour of the ten species tested up to the highest test concentration of 140 g. The EC_{25} was therefore estimated to be > 140 g a.i./ha. For seedling emergence, only lettuce showed a significant reduction in biomass of 27% at the highest test concentration of 140 g a.i./ha. The EC_{25} was therefore approximated to be 140 g a.i./ha (Appendix 1, Table 2).

The risk to terrestrial habitats was determined on the basis of the approximated EC_{25} of 140 kg a.i./ha and the maximum cumulative application rate of difenoconazole. As the screening level risk exceeds the level of concern, a precautionary label statement and terrestrial buffer zones are required.

4.3 Incident Reports

The PMRA database was searched for all environment incidents or scientific studies involving the active ingredient difenoconazole as of 10 July 2015. There were two environmental incidents and two scientific studies reported for the active ingredient difenoconazole.

Environmental Incidents

Since 25 April 2007, the Incident Reporting Program has received two environment incidents related to difenoconazole. Both of these incidents also reported a number of other active ingredients, had a severity level of minor and involved the death of honeybees. In these cases, the causality was assessed as part of a broader re-evaluation of the neonicotinoids and their impact on bee health. Difenoconazole was reported because it was a component of a seed treatment to which the bees may have been exposed. Difenoconazole is relatively non-toxic to bees and it was not considered to have contributed to these bee deaths.

No incident reports for difenoconazole were located in the United States Environmental Protection Agency's Ecological Incident Information System database.

5.0 Value

5.1 Consideration of Benefits

Inspire Fungicide can be used in rotation with other products and is compatible with existing integrated pest management practices. Inspire Fungicide may also be applied in tank mixes with other crop protection products for resistance management, or to increase the disease spectrum on crops that are registered on both product labels.

While numerous conventional and non-conventional fungicide alternatives are registered to control the supported disease claims, this product will provide another rotational alternative. It is noted that only one alternative is registered for management of powdery mildew in brassica crops.

5.2 Effectiveness Against Pests

Efficacy data from 30 trials were reviewed to confirm the value of 16 disease claims that were conditionally supported after the initial product assessment. The trials were conducted at different fields in various Canadian provinces and in other countries including the United States. Based on the available value information, the conditional claims were fully supported at the suppression or control level.

5.3 Non-Safety Adverse Effects

Please refer to ERC2011-06 for non-safety adverse effects.

5.4 Supported Uses

Based on information provided, all conditionally supported disease claims were supported at the control or suppression level. A complete list of supported uses is provided in Appendix 1, Table 4.

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: in other words, 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*].

During the review process, difenoconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions (Appendix I, Table 5):

- Difenoconazole does not meet all the Track 1 criteria
- Difenoconazole does meet the Track 1 criterion for persistence because the half-life values in soil (103-1600 days) and water (307-494 days), do exceed the Track 1 criterion for soil and water.

- Difenoconazole does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 4.4) is below the Track 1 criterion and the highest bioconcentration factor in fish was 570.

[5] 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 product 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 NOI2005-01[7] 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:

> Technical grade difenoconazole may contain traces of TSMP Track 1 polychlorinated dibenzodioxins and furans generated during the manufacturing process. Analysis of the technical grade active ingredient material has shown no polychlorinated dibenzodioxins and furans were detected at the level of detection of 1-44 parts per trillion;
>
> Inspire Fungicide contains a List 2 aromatic petroleum distillate (which has been indicated on the product label).

7.0 Summary

7.1 Human Health and Safety

Mixers, loaders, applicators and workers entering treated fields and orchards are not expected to be exposed to levels of difenoconazole that will result in unacceptable risk when Inspire Fungicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Health risk to workers entering treated areas is not of concern as long as the specified restricted entry intervals are observed. Health risk to the general population, including children, youth, adults and females, at pick-your-own orchards is not of concern.

No separate residue definition is required for rotational crops following foliar applications of difenoconazole and the plant-back interval of 60 days is fully supported for all crops not registered for use on the label of the end-use product Inspire Fungicide.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (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 1 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 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

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

Moreover, the use of difenoconazole on small diameter size tomatoes (diameter < 5 cm) through Inspire Fungicide is not expected to constitute a health risk of concern for any segment of the population, including infants, children, adults and seniors.

Please refer to ERC2011-06 and PRDD99-01 for a summary of all other registered uses of difenoconazole.

7.2 Environmental Risk

The terrestrial plant toxicity studies that were identified as an outstanding data requirement in ERC2011-06 have been submitted, reviewed, and satisfies the environmental assessment requirements for difenoconazole.

The EC_{25} for vegetative vigour and seedling emergence was estimated to be > 140 g a.i./ha and 140 g a.i./ha, respectively. The screening level risk to terrestrial habitats exceeds the level of concern, as such, a precautionary label statement and terrestrial buffer zones are required.

Please refer to ERC2011-06 and PRD2015-10 for a summary of the risk of difenoconazole to all other terrestrial and aquatic non-target organisms in the environment.

7.3 Value

The value information submitted was sufficient to support the full registration of the 16 disease claims for Inspire Fungicide. This will continue to provide Canadian growers with a product to effectively manage economically important diseases in various fruit and vegetable crops. It also can be used as a rotational alternative, which contributes to resistance management. The use of Inspire Fungicide is compatible with current integrated pest management and production practices.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Difenoconazole Technical Fungicide and Inspire Fungicide, containing the technical grade active ingredient difenoconazole, to control or suppress fungal diseases on a variety of fruit and vegetable crops.

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

<	less-than
>	greater-than
≥	greater-than or equal to
˚C	degrees Celsius
µg	microgram(s)
a.i.	active ingredient
App.	application
ARTF	Agricultural Re-entry Task Force
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimeter(s)
cm^2	centimetre(s) squared
cm^3	centimetre(s) cubed
DA	dermal absorption
DACO	data-code
DEA	dietary exposure assessment
DFR	dislodgeable foliar residue
DIR	Regulatory Directive
EC	emulsifiable concentrate
EC_{25}	effective concentration on 25% of the population
EIIS	USEPA Ecological Incident Information System
ERC	Evaluation Report
g	gram(s)
ha	hectare(s)
HAFT	highest average field trial
HDPE	high density polyethylene (plastic)
HPLC-MS-MS	high performance liquid chromatography with Tandem mass spectrometry
hr	hour(s)
ID	identification
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LAFT	lowest average field trial
LOQ	limit of quantitation
m^2	meter(s) square
mg	milligram(s)
min.	minute(s)
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
n	number of independent field trials

NAFTA	North American Free Trade Agreement
ng	nanogram(s)
No.	number
NOAEL	no observed adverse effect level
NOI	Notice of Intent
PBI	plantback interval
PE	Polyethylene (plastic)
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
ppm	parts per million
ppt	parts per trillion
PRD	Proposed Registration Decision
PRDD	Proposed Regulatory Decision Document
RDD	Regulatory Decision Document
REI	restricted entry interval
RTI	retreatment interval
Std. Dev.	standard deviation
TC	transfer coefficient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis for Environmental Media

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil	T013656-05	difenoconazole	HPLC-MS-MS	1.0 ng/g	1757693, 1757695
		CGA-205375		1.0 ng/g	
		CGA-71019		1.0 ng/g	
Water	GRM066.01A	difenoconazole	HPLC-MS-MS	0.1 µg/L	2450970, 2450971
		CGA-205375		0.1 µg/L	
		CGA-142856		0.1 µg/L	
		CGA-71019		0.1 µg/L	
Biota (animal)	REM147.07	difenoconazole	HPLC-MS-MS	10 ng/g	2279975, 2279976, 2279977
		CGA-205375		10 ng/g	

Table 2 Integrated Food Residue Chemistry Summary

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Lettuce, radish, sorghum/ wheat		**Reference: 1928975**
Radiolabel Position	^{14}C-difenoconazole ([4-chlorophenyl-UL]-labelled)	
Test site	Wooden boxes of 152 cm × 91 cm × 46 cm (1.39 m^2), plastic lined with no drain holes, each filled with soil and located outdoors.	
Formulation	Inspire, formulated as an emulsifiable concentrate (EC)	
Application rate and timing	Bare soil was treated with a single application of ^{14}C-difenoconazole ([4-chlorophenyl-UL]-labelled) at a rate of approximately 516 g a.i./ha. Rotational crops (lettuce, radish, sorghum/wheat) were sown at four different plant-back intervals (PBIs): 30, 60, 120 and 270 days.	
Total Radioactive Residues (TRRs)		
Matrices	**PBI (days)**	**^{14}C-difenoconazole ([4-chlorophenyl-UL]-labelled) (ppm)**
Immature lettuce leaves	30	0.052
	60	0.020
	120	0.017
	270	0.012
Mature lettuce leaves	30	0.095
	60	0.008
	120	0.017
	270	0.005
Radish leaves	30	0.026
	60	0.021
	120	0.088
	270	0.026
Radish roots	30	0.028
	60	0.022
	120	0.029
	270	0.019

Sorghum forage	30	0.015	
Sorghum stover	30	0.066	
Sorghum grain	30	0.009	
Wheat forage	60	0.008	
	120	0.012	
	270	0.011	
Wheat hay	60	0.018	
	120	0.020	
	270	0.015	
Wheat straw	60	0.055	
	120	0.051	
	270	0.030	
Wheat grain	60	0.004	
	120	0.007	
	270	0.006	
Metabolites Identified		**Major Metabolites (>10% of the TRRs)**	**Minor Metabolites (<10% of the TRRs)**
Matrices	**PBI (days)**	**^{14}C-difenoconazole ([4-chlorophenyl-UL]-labelled)**	
Immature lettuce leaves	30	Difenoconazole	Unknown compound eluting at 26.80 min., two unknown compounds eluting at 8.07 min., CGA 205375, CGA 189138
	60	CGA 205375, difenoconazole	None detected
	120	Difenoconazole	CGA 205375
	270	Difenoconazole , CGA 189138	CGA 205375
Mature lettuce leaves	30	CGA 189138, difenoconazole	Unknown compound eluting at 3.87 min., unknown compound eluting at 28.07 min., CGA 205375
	60	Matrix was not analyzed	Matrix was not analyzed
	120	Difenoconazole	CGA 205375
	270	Matrix was not analyzed	Matrix was not analyzed
Radish leaves	30	CGA 205375, difenoconazole	Unknown compound eluting at 3.67 min., unknown compound eluting at 27.93 min., unknown compound eluting at 29.33 min., unknown compound eluting at 32.13 min., unknown compound eluting at 32.8 min.
	60	CGA 205375, difenoconazole	None detected
	120	Difenoconazole	CGA 205375
	270	CGA 205375, difenoconazole	None detected
Radish roots	30	Unknown compound eluting at 17.93 min., difenoconazole	Unknown compound eluting at 17.00 min., unknown compound eluting at 25.53 min., unknown compound eluting at 26.40 min., unknown compound eluting at 27.93 min., unknown compound eluting at 29.33 min., CGA 205375, unknown compound eluting at 32.13 min., unknown compound eluting at 32.8 min.

	60	CGA 205375, difenoconazole	CGA 205374, CGA 189138
	120	CGA 205375, difenoconazole	Unknown compound eluting at 23.47 min.
	270	CGA 205375, difenoconazole	Unknown compound eluting at 29.87 min., CGA 205374
Sorghum forage	30	Unknown compound eluting at 3.73 min., unknown compound eluting at 26.93 min.	CGA 205375, difenoconazole
Sorghum stover	30	Unknown compound eluting at 18.47 min., unknown compound eluting at 21.00 min., unknown compound eluting at 26.93 min.	Unknown compound eluting at 17.80 min.
Sorghum grain	30	Matrix was not analyzed	Matrix was not analyzed
Wheat forage	60	Matrix was not analyzed	Matrix was not analyzed
	120	Matrix was not analyzed	Matrix was not analyzed
	270	Matrix was not analyzed	Matrix was not analyzed
Wheat hay	60	Matrix was not analyzed	Matrix was not analyzed
	120	Matrix was not analyzed	Matrix was not analyzed
	270	Matrix was not analyzed	Matrix was not analyzed
Wheat straw	60	Unknown compound eluting at 20.40 min., CGA 205375	Difenoconazole
	120	CGA 205375, difenoconazole	Unknown compound eluting at 3.40 min., unknown compound eluting at 20.47 min.
	270	Unknown compound eluting at 20.33 min., CGA 205375	Difenoconazole
Wheat grain	60	Matrix was not analyzed	Matrix was not analyzed
	120	Matrix was not analyzed	Matrix was not analyzed
	270	Matrix was not analyzed	Matrix was not analyzed

The proposed metabolic pathway for difenoconazole is the degradation of dioxolane ring to CGA 205374 followed by reduction to CGA 205375. Alternatively, oxidative cleavage of CGA 205374 would lead to CGA 189138.

CROP FIELD TRIALS ON CHERRY TOMATOES | **Reference : 2451231**

Two field trials for difenoconazole on cherry tomatoes (diameter size less than 5 cm or 2 inches) were conducted in 2008 and 2009 in the United States, in the NAFTA Growing Zone 3 (Florida). Difenoconazole 250 EC (emulsifiable concentrate, 250 g a.i./L) was applied four times as foliar broadcast sprays at a rate of 127–133 g a.i./ha/application for a seasonal application rate of 512–524 g a.i./ha. The applications were made at 7–9 day intervals with the last application occurring on the day of harvest (PHI = 0 days). A non-ionic surfactant (~ 0.125 % v/v) was included in all spray mixtures.

Commodity	Total Application Rate (g a.i./ha)[1]	PHI (days)	Difenoconazole Residue Levels (ppm)[2]					
			n[3]	LAFT[4]	HAFT[4]	Median	Mean	Std. Dev.
Cherry tomato fruit	512–524	0	2	0.17	0.49	0.33	0.33	0.19

[1] A non-ionic surfactant (~ 0.125% v/v) was added to the spray mixture of all applications.
[2] Values reflect per trial averages.
[3] n = number of independent field trials (with duplicate samples analyzed)
[4] LAFT = lowest average field trial; HAFT = highest average field trial.

Table 3 Toxicity of Difenoconazole to Non-Target Terrestrial Plants

Organism	Exposure	Test substance	Endpoint Value	Reference
Vascular plants (10 species)	Seedling emergence	Difenoconazole formulation	EC_{25} = 140 g a.i./ha	2142303 2142305
	Vegetative vigour	Difenoconazole formulation	EC_{25} > 140 g a.i./ha	2142300

Table 4 List of Supported Uses

Summary of supported label claims
Control of alternaria blight (*Alternaria brassicae)* in brassica (cole) leafy vegetables at the rate of 91-128 g a.i./ha
Control of powdery mildew (*Erysiphe polygoni*) in brassica (cole) leafy vegetables at the rate of 91-128 g a.i./ha
Control of purple blotch (*Alternaria porri*) in bulb vegetables at the rate of 91-128 g a.i./ha
Control of powdery mildew *(Sphaerotheca fuliginea)* in cucurbit vegetables at the rate of 91-128 g a.i./ha
Suppression of gummy stem blight (*Didymella bryoniae*) in cucurbit vegetables at the rate of 128 g a.i./ha
Control of powdery mildew (*Uncinula necator*) in grapes at the rate of 73 g a.i./ha
Control of anthracnose (*Colletotrichum coccodes, Colletotrichum acutatum*) in fruiting vegetables at the rate of 73-128 g a.i./ha
Control of scab (*Venturia inaequalis, Venturia pirina*) in pome fruit at the rate of 73 g a.i./ha
Suppression for powdery mildew (*Podosphaera leucotricha*) on pome fruit at the rate of 73 g a.i./ha
Control of *altenaria* black spot (*Alternaria brassicae*) in canola at the rate of 73-125 g a.i./ha

Table 5 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
Toxic or toxic equivalent as defined by the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Half-life = 103-1600
	Water	Half-life ≥ 182 days	Half-life = 307-494
	Sediment	Half-life ≥ 365 days	Half-life = 411

	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure and Henry's Law Constant.
Bioaccumulation[4]	Log $K_{OW} \geq 5$		4.4
	BCF ≥ 5000		170-570
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (for example, bioaccumulation factors) are preferred over laboratory data (such as bioconcentration factors), which, in turn, are preferred over chemical properties (for example, log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1757960	2009, Inspire Fungicide Identification, DACO: 3.1.1, 3.1.3, 3.1.4 CBI
1757961	2009, Inspire Fungicide Identification, DACO: 3.1.2 CBI
1757962	2009, Inspire Fungicide Starting Materials, DACO: 3.2.1 CBI
1757963	2009, Inspire Fungicide Description of Formulation Process, DACO: 3.2.2 CBI
1757964	2009, Inspire Fungicide Discussion of Formation of Impurities, DACO: 3.2.3 CBI
1757965	2009, Inspire Fungicide Certification of Limits, DACO: 3.3.1 CBI
1757966	1992, CGA 169374 in Formulation, DACO: 3.4.1 CBI
1757967	2009, Inspire Fungicide Chemical and Physical Properties, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
1797351	2009, Description of Starting Materials - Clarification details, DACO: 3.2.1 CBI
1797352	2009, Description of Starting Materials - Confidential Statement of Ingredients, DACO: 3.2.1 CBI
1820382	2009, Enforcement Method Inspire Clarification, DACO: 3.4.1 CBI
1826418	2009, Enforcement Method Inspire Clarification, DACO: 3.4.1
1936096	2010, 3.4.1-1 - Analytical Method - 10432308, DACO: 3.4.1 CBI
1757693	2005, Determination of Difenoconazole and its Metabolites CGA-205375, CGA-142856 and CGA-71019 in Soil, Using Liquid Chromatography-Electrospray Ionization Tandem Mass Spectrometry, DACO: 8.2.2.1, 8.2.2.2
1757695	2006, Determination of Difenoconazole and its Metabolites CGA-205375, CGA-142856 and CGA-71019 in Soil, Using Liquid Chromatography-Electrospray Ionization Tandem Mass Spectrometry, DACO: 8.2.2.1, 8.2.2.2
2450970	2014, Difenoconazole - Residue Method for the Determination of Difenoconazole, CGA205375, CGA142856 and CGA71019 in Water, DACO: 8.2.2.3
2450971	2014, Difenoconazole - Independent Laboratory Validation of Residue Method (GRM066.01A) For the Determination of Difenoconazole, CGA205375, CGA142856 and CGA71019 in Water by LC-MS/MS, DACO: 8.2.2.3
2279975	2008, Residue Method for the Determination of Residues of Difenoconazole (CGA169374) and CGA205375 in Animal Products. Final Determination by LC-MS/MS, DACO: 8.2.2.4

2279976	2004, Difenoconazole (CGA169374) and CGA205375 - Validation of Residue Analytical Method REM 147.07 for the Determination of Residues in Animal Products, DACO: 8.2.2.4
2279977	2004, Independent Laboratory Validation of Residue Method REM 147.07 for the Determination of Difenoconazole and CGA 205375 in Animal Products, DACO: 8.2.2.4

2.0 Human and Animal Health

PMRA Document Number	Reference
2451229	2012, Inspire Fungicide – Refinement of Restricted Entry Intervals for Pome Fruit, DACO: 5.2
2451231	2010, Difenoconazole - Magnitude of the Residues in or on Cherry Tomato, DACO: 7.4.1
1928975	2010, 14C- Difenoconazole: Uptake and Metabolism in Confined Rotational Crops, DACO: 7.4.3

3.0 Environment

PMRA Document Number	Reference
2142300	2011, Difenoconazole - Toxicity Effects on the Vegetative Vigour of Ten Species of Plants, DACO: 9.8.4, 9.8.6
2142303	2011, Difenoconazole - Toxicity Effects on the Seedling Emergence of Ten Species of Plants, DACO: 9.8.4, 9.8.6
2142305	2011, Difenoconazole - Toxicity Effects on the Seedling Emergence of Two Species of Plants, DACO: 9.8.4, 9.8.6

4.0 Value

PMRA Document Number	Reference
2451212	2010, Evaluation of A7402T for Control of Anthracnose in Pepper and Tomato, DACO: 10.2.3.3
2451214	2008, Evaluation of the Efficacy of SYN545192 for the Control of *Colletotrichum* spp. on Peppers/Cucurbits, DACO: 10.2.3.3
2451222	2011, Isopyrazam (A15149W) Registration Trials in Brassicae, DACO: 10.2.3.3
2328626	2013, Value Summary, DACO: 10.1,10.2.3.1,10.3.1,10.3.2

B. Additional Information Considered

i) Published Information

1.0 Value

PMRA Document Number	Reference
2533975	Rideout, S.L, C.M. Waldenmaier, G. Gu, S.K. Pollard, K.D. Fiedler and J.T. Custis, Jr. 2012. Evaluation of selected fungicides for the management of gummy stem blight in watermelon, 2012. Plant Disease Management Reports 7:V037.