Proposed Registration Decision PRD2011-07

Prothioconazole

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Overview

Proposed Registration Decision for Prothioconazole

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 Prothioconazole Technical Fungicide and JAU6476 100FS Seed Treatment Fungicide, containing the technical grade active ingredient prothioconazole, and L1397 Seed Treatment Fungicide, containing the technical grade active ingredients prothioconazole, metalaxyl and tebuconazole, to control seed and seedling diseases of various crops.

Prothioconazole Technical Fungicide (Registration Number 28358) was originally granted conditional registered in Canada in 2006. The detailed review for Prothioconazole can be found in Regulatory Note REG2007-03, *Prothioconazole*. Subsequent to the original applications, an application to convert Prothioconazole to full registration was reviewed and approved (Proposed Registration Decision PRD2010-08, *Prothioconazole*, Registration Decision RD2010-13, *Prothioconazole*). The current applications were submitted to register a major new use for Prothioconazole.

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 Prothioconazole Technical Fungicide, JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment 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.

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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."

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 (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). 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 PMRA's website at healthcanada.gc.ca/pmra.

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

The active ingredient prothioconazole and the associated end-use product JAU6476 100FS Seed Treatment belong to a major class of sterol biosynthesis inhibitor (SBI) fungicides called demethylation inhibitors (DMI). Demethylation inhibitor fungicides are classified as Group 3 Fungicides. JAU6476 100FS Seed Treatment is a seed treatment fungicide for use on corn, small-grain cereals, large-seeded pulse crops and soybean.

L1397 Seed Treatment Fungicide is a seed treatment fungicide formulation containing prothioconazole, tebuconazole and metalaxyl. Prothioconazole and tebuconazole are DMI fungicides. Metalaxyl belongs to the phenylamide class of fungicides and is classified as a Group 4 Fungicide. L1397 Seed Treatment Fungicide is for use on small-grain cereals.

Health Considerations

Can Approved Uses of Prothioconazole Affect Human Health?

Potential exposure to prothioconazole and its prothioconazole-desthio metabolite may occur through the diet (food and water) or when handling and applying the product.

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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*.

Prothioconazole and prothioconazole-desthio have a similar toxicological profile with prothioconazole-desthio effects occurring at lower doses. Therefore, the endpoints used for this risk assessment were those of the metabolite. 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 (e.g., 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 prothioconazole (with prothioconazole-desthio) products are used according to label directions.

Prothioconazole and prothioconazole-desthio were considered to be of low acute toxicity by the oral, dermal and inhalation routes in Wistar rats. These compounds were non-irritating when applied to the skin of rabbits. Prothioconazole was considered slightly irritating to the eyes of rabbits while prothioconazole-desthio was non-irritating. The results of skin sensitization testing were negative for both compounds, as such, no signal words are required on the label.

The end-use product JAU6476 100FS Seed Treatment Fungicide is of low acute toxicity to rats via the oral, dermal, and inhalation routes. It is non-irritating to the eye and slightly irritating to the skin of rabbits. JAU6476 100FS Seed Treatment Fungicide caused an allergic skin reaction.

The end-use product L1397 Seed Treatment Fungicide is of low toxicity to rats via the oral, dermal, and inhalation routes. It is moderately irritating to the eye and non-irritating to the skin of rabbits. It did not cause an allergic skin reaction.

Prothioconazole and prothioconazole-desthio did not cause cancer in animals and were not genotoxic. Decreased motor and locomotor activity were observed following dosing with these compounds. Numerous reproductive effects were also observed. The first signs of toxicity in animals given daily doses of these compounds over longer periods of time were liver, kidney, thyroid and ovary effects. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When prothioconazole was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to this compound than the adult animal. When prothioconazole-desthio was given to pregnant animals, effects on the developing fetus were observed at doses that were not toxic to the mother, indicating that the fetus is more sensitive to this compound than the adult animal. Because of this observation, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to prothioconazole-desthio.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that females 13-49 years old, the most sensitive population group to prothioconazole, are expected to be exposed to less than 33% of the acceptable daily intake, and all infants (<1 year), the population group that would ingest the most prothioconazole relative to body weight, are expected to be exposed to ≤20% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from prothioconazole is not of concern for all segments of the population. There is no evidence that prothioconazole is carcinogenic; therefore, a cancer dietary exposure assessment was not required.

A single dose of prothioconazole is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary intake estimate for females 13-49 years old was less than 84% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act (FDA)* 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 FDA purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA).* Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using prothioconazole on various crops were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this consultation document.

Occupational Risks From Handling JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide

Occupational risks are not of concern when JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide are used according to the proposed label directions, which include protective measures.

Seed treatment workers in commercial seed treatment facilities or on-farm, who treat seeds with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide, as well as workers planting treated seed, can come in direct contact with prothioconazole residues on the skin. Therefore, the label specifies that during seed treatment, workers must wear long pants, a long-sleeved shirt and chemical resistant gloves. In addition, workers bagging treated seed, handling bagged seed or transferring treated seed to a storage bin must also wear a dust mask. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for seed treatment workers and planters, the risks to these individuals are 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.

Environmental Considerations

What Happens When Prothioconazole Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide are used according to label directions, which include a precautionary label statement.

Prothioconazole and the transformation products prothioconazole-desthio and prothioconazole-*S*-methyl have been considered together in a total toxic residue approach. Total toxic residues of prothioconazole are not expected to persist in soil, nor are they expected to carryover to the next growing season. These compounds have low potential to leach through the soil profile and enter groundwater. Total toxic residues of prothioconazole are not expected to persist in aquatic environments under aerobic conditions, but they are expected to be persistent under anaerobic conditions. Residues of prothioconazole are not expected to be present in air due to its low volatility.

JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide, when used according to label directions, do not present a risk to earthworms, bees, beneficial arthropods and other insects, terrestrial plants and aquatic organisms. The overall risk to birds and mammals from the consumption of seeds treated with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide is considered to be low. No mitigation measures are required, other than a precautionary label statement to clean up spilled seeds, and an advisory statement to identify the leaching potential of metalaxyl, one of the active ingredients in L1397 Seed Treatment Fungicide.

Value Considerations

What Is the Value of JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide

JAU6476 100FS Seed Treatment Fungicide is a broad-spectrum systemic fungicide that contains prothioconazole, a new seed treatment active ingredient that can be used in an integrated pest management program for seed and seedling diseases of small-grain cereals, corn, soybean, dry pea, lentil, and chickpea. This will contribute to reduce resistance development in fungal populations which is already considered low for seed treatment.

L1397 Seed Treatment Fungicide contains prothioconazole as well as metalaxyl and tebuconazole. This seed treatment is for use on small-grain cereals.

As seed treatments, the rate per hectare of both of these products is low and application to the seed reduces exposure to non-target organisms compared to foliar pesticide applications. In addition to reducing resistance development and exposure to non-target organisms, these two end-use products will provide an additional tool to growers for control and suppression of a wide range of seed and seedling diseases on important Canadian crops.

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 JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide on the skin or through inhalation, anyone treating seed, or handling seed treated with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide must wear long pants, a long-sleeved shirt and chemical resistant gloves. In addition, workers bagging treated seed, handling bagged seed or transferring treated seed to a storage bin must also wear a dust-mask. Workers planting treated seed must wear a long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.

Environment

Precautionary label statements to clean up spilled seeds are included on the labels. An advisory label statement is required on the label for L1397 Seed Treatment Fungicide to reduce potential leaching to groundwater of metalaxyl, one of the active ingredients in this end-use product.

Next Steps

Before making a final registration decision on prothioconazole, the PMRA will consider all 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 note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. 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

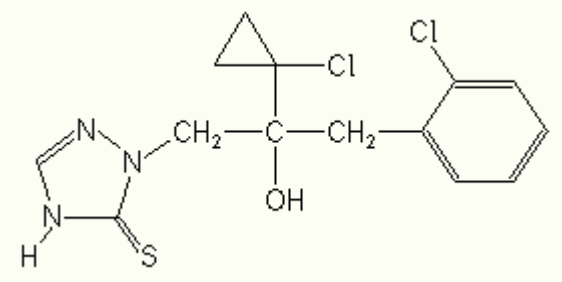
When the PMRA makes its registration decision, it will publish a Registration Decision on prothioconazole (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application,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

Science Evaluation

Prothioconazole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Prothioconazole
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
2. Chemical Abstracts Service (CAS)	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione
CAS number	178928-70-6
Molecular formula	$C_{14}H_{15}Cl_2N_3OS$
Molecular weight	344.2640
Structural formula	
Purity of the active ingredient	98.4 %

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

Technical Product— Prothioconazole Technical Fungicide

Property	Result
Colour and physical state	Colourless to faint beige solid powder
Odour	Faint, uncharacteristic odour
Melting range	139.1 – 144.5°C
Boiling point or range	N/A
Density	1.36 g/mL
Vapour pressure at 20°C	< 4 x 10^{-7} Pa
Henry's law constant at 20°C	4.5 × 10^{-12} atm × m^3/mol
Ultraviolet (UV)-visible spectrum	Peak maxima at 275 nm. No absorption at > 300 nm.
Solubility in water at 20°C	pH: Solubility (g/L) 4: 0.005 8: 0.3 9: 2.0
Solubility in organic solvents at 20°C (g/100 mL)	Solvent: Solubility (g/100 mL) Acetone: > 25 Acetonitrile: 6.9 Dichloromethane: 8.8 Dimethylsulfoxide: 12.6 Ethylacetate: > 25 n-Heptane: < 0.01 1-Octanol: 5.8 Polyethyleneglycol (MW400): >25 2-Propanol: 8.7 Xylene: 0.8
n-Octanol-water partition coefficient (K_{ow})	pH: log K_{ow} water: 4.05 4: 4.16 7: 3.82 9: 2.0
Dissociation constant (pKa)	pKa = 6.9
Stability (temperature, metal)	Thermally stable at room temperature under air. Stable to most metals. Colour changes observed in the presence of copper materials.

End-Use Product—Prothioconazole in JAU6476 100FS Seed Treatment Fungicide

Property	Result
Colour	Red
Odour	Bitter, almond-like odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	Prothioconazole…….……..……..100 g/L 1,2-benzisothiazolin-3-one…….0.0386 % (as preservative) 5-chloro-2-methyl-4-isothiazolin-3-one…….0.00113 % (as preservative) 2-methyl-4-isothiazolin-3-one ……...0.00037 % (as preservative).
Container material and description	HDPE bottles or drums, Plastic jug, tote; 0.5 L to 1000 L
Density	1.16 g/mL
pH of 1% dispersion in water	5.4
Oxidizing or reducing action	N/A
Storage stability	Stable for more than 24 months at ambient temperature.
Corrosion characteristics	Not corrosive to commercial packaging.
Explodability	N/A

End-Use Product—Prothioconazole in L1397 Seed Treatment Fungicide

Property	Result
Colour	Red
Odour	White glue-like odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	Tebuconazole…… 3.0 g/L Prothioconazole……. 15.4 g/L Metalaxyl……... 6.2 g/L
Container material and description	Plastic jug or tote 0.947 L to 1000 L
Density	1.0458 g/mL
pH of suspension	5.90 (undiluted)
Oxidizing or reducing action	None
Storage stability	Storage stability study will be submitted upon completion
Corrosion characteristics	Corrosion characteristics study will be submitted upon completion
Explodability	N/A

1.3 Directions for Use

JAU6476 100FS Seed Treatment Fungicide is a broad-spectrum, systemic fungicide seed treatment and is formulated as a flowable concentrate containing 100 g of prothioconazole per litre of product. JAU6476 100FS Seed Treatment Fungicide is for use in commercial seed treatment operations and for on-farm treatment with conventional seed treating equipment which can accurately meter, mix and apply flowable seed treatment formulations. JAU6476 100FS Seed Treatment Fungicide should be applied to seed at a rate of 50 mL per 100 kg seed for control and suppression of various seed and seedling diseases of small-grain cereals, corn, soybean, dry pea, lentil, and chickpea.

L1397 Seed Treatment Fungicide is a seed treatment fungicide containing prothioconazole, tebuconazole and metalaxyl. The product is formulated as a flowable microdispersion containing 15.4 g of prothioconazole, 3.1 g of tebuconazole, and 6.2 g of metalaxyl per litre. L1397 Seed Treatment Fungicide is a ready-to-use formulation designed for commercial or on-farm seed treatment with conventional equipment that accurately controls application rates and provides good distribution of the chemical onto the seed in the mixing chamber. L1397 Seed Treatment Fungicide should be applied to seed at a rate of 325 mL per 100 kg seed for control and suppression of various barley, oats, and wheat diseases.

1.4 Mode of Action

Prothioconazole belongs to the Group 3 Fungicides. It is a triazole, which falls into the demethylation inhibitor (DMI) class of sterol biosynthesis inhibitors (SBI: Class 1). There are 24 other fungicidal active ingredients within the same class as prothioconazole. The mode of action of this active ingredient is to inhibit the demethylation process at position C14 of the lanosterol or 2,4-methylene dihydrolano-sterol, both of which are precursors of sterols in fungi.

2.0 Methods of Analysis

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Registration Decision PRD2010-08, *Prothioconazole*, for a detailed assessment of the methods for active ingredient, formulation and residue analysis.

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole* for details on technical prothioconazole.

The end-use product JAU6476 100FS Seed Treatment Fungicide is of low acute toxicity to rats via the oral (LD_{50} > 2000 mg/kg bw), dermal (LD_{50} > 4000 mg/kg bw), and inhalation routes (LC_{50} > 2.735 mg/L). It is non-irritating to the eye of rabbits based on an MAS (24-72 hours) of 0/110 and slightly irritating to the skin of rabbits based on an MAS (24-72 hours) of 1/8. It is a dermal sensitizer in guinea pigs.

The end-use product L1397 Seed Treatment Fungicide is of low toxicity to Sprague-Dawley derived albino rats via the oral (LD_{50} > 2000 mg/kg bw), dermal (LD_{50} > 5000 mg/kg bw), and inhalation routes (LC_{50} > 2.55 mg/L). It is moderately irritating to the eye of New Zealand albino rabbits based on a MAS (24-72 hours) of 23.8/110 with irritation persisting at 7 days. L1397 Seed Treatment Fungicide is non-irritating to the skin of New Zealand albino rabbits based on a MAS of 0/8. It is not a dermal sensitizer in Hartley albino guinea pigs.

3.1.1 PCPA Hazard Characterization

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole*.

3.2 Determination of Acute Reference Dose

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole*.

3.3 Determination of Acceptable Daily Intake

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole*.

3.4 Occupational and Residential Risk Assessment

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole*.

3.4.1 Toxicological Endpoints

Occupational exposure to JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes.

3.4.1.1 Dermal Absorption

Dermal absorption data were not required since an occupational endpoint from a dermal toxicity study was used for prothioconazole.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Commercial Treater Exposure and Risk Assessment

Individuals can potentially be exposured to JAU6476 100FS Seed Treatment Fungicide while treating cereal, legume and corn seed, and to L1397 Seed Treatment Fungicide while treating cereal seed on farm and in commercial seed treatment facilities. The use of L1397 Seed Treatment Fungicide on cereals fits within the registered use pattern for tebuconazole and metalaxyl; therefore, these two active ingredients will not be further discussed in the occupational exposure and risk section. However, a risk assessment for prothioconazole was conducted.

Exposure to workers treating seed with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide at commercial seed treatment facilities is expected to be intermediate- term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for commercial treaters applying JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide to seeds using typical commercial seed treatment equipment. The exposure estimates are based on workers wearing a single layer of clothing plus chemical resistant gloves.

Dermal and inhalation exposure estimates for workers were generated from surrogate seed treatment passive dosimetry studies. Chemical-specific dust-off data were submitted to bridge the proposed use pattern to the use pattern in the surrogate exposure studies used in the risk assessment for prothioconazole.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (no observed adverse effects levels, NOAELs) to obtain the margin of exposure (MOE); the target MOE is 300 for dermal exposure and 1000 for inhalation exposure.

For cereal seed, the 2006 passive dosimetry study, conducted on wheat, where bagging of cereal grain seed was not done, was considered to be appropriate to estimate exposure to workers treating cereal seeds at commercial seed treatment facilities.

Only four commercial replicates were measured in this study, and the amount of seed handled and the amount of active ingredient handled in the study are significantly lower than the expected use pattern for JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide. As such, it was considered appropriate to use the 90th percentile unit exposure values from the study to estimate exposure to commercial treatment workers.

The submitted 2009 dust-off study demonstrated similar dust-off potential for wheat and barley, with the dust-off values for oats being lower. For untreated seed, barley was dustier than wheat, but for seeds treated with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide, wheat seed was dustier than barley seed. Although, the dust-off potential for oats was reported to be lower than that for wheat in this study; in another dust-off study it was shown to be higher. Given the results of the submitted dust-off study, the surrogate study on wheat is not expected to underestimate exposure for barley or oats.

Calculated MOEs were above the target MOEs for all workers in commercial seed treatment facilities for cereal seeds (Table 3-1). No dust-off data were provided for rye, triticale, or millet and, as such, it cannot be determined whether the calculated exposure estimate based on the data for wheat will underestimate exposure to these crops, thus, confirmatory dust-off data are required.

Table 3-1. Exposure and risk estimates for workers treating cereals in commercial seed treatment facilities

Scenario	Unit exposure (µg/kg a.i. handled)[1]		kg seed treated per day[2]	App rate (kg a.i./kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		MOE [5]	
	Dermal	Inhalation				Dermal	Inhalation	Dermal	Inhalation
Cereals	265.70	2.47	325 700	0.00005	16.3	0.0619	0.000575	485	3477

[1] Unit exposure values are 90th percentile values from the commercial wheat seed treatment study (2006).
[2] Default amount of seed treated per day for cereals.
[3] kg a.i. handled per day = kg seed treated per day × application rate (kg a.i./kg seed)
[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{\text{70 kg bw} \times \text{1000 µg/mg}}$
[5]Dermal NOAEL = 30 mg/kg bw/day, target MOE= 300; inhalation NOAEL = 2 mg/kg bw/day, target MOE = 1000

To estimate exposure to workers treating legume and corn seeds with JAU6476 100FS Seed Treatment Fungicide, the 1989 passive dosimetry study was considered appropriate since workers were monitored while treating canola seeds, and bagging treated seeds. The dust-off potential of canola seeds was not measured in the submitted 2009 dust-off study, but in another dust-off study submitted by the applicant the dust-off potential of untreated and treated canola was similar to that for dry beans and peas, and slightly lower than that for corn. As such, the 1989 study is considered to be a suitable surrogate study to estimate the exposure of commercial treatment facilities that bag the treated legume and corn seed.

Calculated MOEs were above the target MOEs for all workers in commercial seed treatment facilities treating legume and corn seed with JAU6476 100FS Seed Treatment Fungicide (Table 3-2). No dust-off data were provided for chickpeas or lentils, but the dust-off potential for these crops is expected to be similar to dried beans and peas and no further confirmatory data are required.

Table 3-2. Exposure and risk estimates for workers treating legumes and corn in commercial seed treatment facilities

Scenario	Unit exposure (µg/kg a.i. handled)[1]		kg seed treated per day[2]	App rate (kg a.i./kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		MOE [5]	
	Dermal	Inhalation				Dermal	Inhalation	Dermal	Inhalation
Legumes									
Mixer/loader	187.8	1.49	216 000	0.00005	10.8	0.0290	0.000230	1035	8700
Coater	32.33	0.96	216 000	0.00005	10.8	0.00499	0.000148	6014	13503
Bagger/sewer	20.43	0.11	216 000	0.00005	10.8	0.00315	0.0000170	9518	117845
Foreman	97.52	0.50	216 000	0.00005	10.8	0.0150	0.0000771	1994	25926
Corn									
Mixer/loader	187.8	1.49	60 000	0.00005	3.0	0.00805	0.0000639	3727	31320
Coater	32.33	0.96	60 000	0.00005	3.0	0.00139	0.0000411	21652	48611
Bagger/sewer	20.43	0.11	60 000	0.00005	3.0	0.000876	0.00000471	34263	424242
Foreman	97.52	0.50	60 000	0.00005	3.0	0.00418	0.0000214	7178	93333

[1] Unit exposure values for mixer/loaders, coaters, bagger/sewers and foremen in commercial treatment facilities are from the commercial canola seed treatment study (1989).
[2] Default seed treated per day data for legumes and corn at commercial facilities.
[3] kg a.i. handled per day = kg seed treated per day × application rate (kg a.i./kg seed)
[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{\text{70 kg bw} \times \text{1000 µg/mg}}$
[5] Dermal NOAEL = 30 mg/kg bw/day, target MOE= 300; inhalation NOAEL = 2 mg/kg bw/day, target MOE = 1000

3.4.2.2 On-farm Treater Exposure and Risk Assessment

Individuals have potential for exposure to JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide while treating seed on-farm.

Exposure to workers treating seed with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for on-farm treaters applying JAU6476 100FS Seed Treatment Fungicide to cereal, legume and corn seeds ,and L1397 Seed Treatment Fungicide to cereals seeds using typical on-farm seed treatment equipment. The exposure estimates are based on workers wearing a single layer of clothing plus chemical resistant gloves.

Dermal and inhalation exposure estimates for workers were generated from surrogate seed treatment passive dosimetry studies. Chemical-specific dust-off data were submitted to bridge the proposed use pattern to the use pattern in the surrogate exposure studies used in the risk assessment for prothioconazole.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (NOAELs) to obtain the MOE; the target MOE is 300 for dermal exposure and 1000 for inhalation exposure.

For on-farm seed treatment and planting, the 2006 passive dosimetry study was considered appropriate to address exposure to all proposed crops. The study measured exposure to workers treating and planting wheat seed on-farm. In the submitted 2009, dust-off study treated wheat seed was shown to be dustier than treated barley, oats, soybeans, dry beans, field peas and corn seed. As such, exposure data from the 2006 study are not expected to underestimate exposure to workers treating cereals, legumes and corn on farm.

Information was not available on whether planting was done in open or closed cab tractors in the 2006 study. As such, it is assumed that the workers used closed cab equipment during planting.

Table 3-3 summarizes the exposure and risk estimates for prothioconazole when workers treat cereals, soybean and corn seed on-farm with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide. Calculated MOEs were above the target MOEs for all workers and planters. No dust-off data were provided for rye, triticale, or millet, and, as such it cannot be determined whether the calculated exposure estimate based on the data for wheat will underestimate exposure to these crops, thus, confirmatory dust-off data are required.

Table 3-3. Exposure and risk estimates for JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide for workers treating cereals, legumes and corn in on-farm seed treatment facilities

Scenario	Unit exposure (µg/kg a.i. handled)[1]		kg seed treated per day[2]	App rate (kg a.i./kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		MOE [5]	
	Dermal	Inhalation				Dermal	Inhalation	Dermal	Inhalation
Cereal	145.22	7.61	13600	0.00005	0.68	0.00141	0.0000739	21266	27054
Legumes	145.22	7.61	20000	0.00005	1.0	0.00207	0.000109	14461	18397
Corn	145.22	7.61	1350	0.00005	0.068	0.000141	0.00000739	212659	270542

[1] Unit exposure values are from the on-farm wheat seed treatment study (2006).
[2] Default amount of seed treated per day for cereals, legumes and corn.
[3] kg a.i. handled per day = kg seed treated per day × application rate (kg a.i./kg seed)
[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{\text{70 kg bw} \times \text{1000 µg/mg}}$
[5] Dermal NOAEL = 30 mg/kg bw/day, target MOE= 300; inhalation NOAEL = 2 mg/kg bw/day, target MOE = 1000

3.4.2.3 Planter Exposure and Risk Assessment

Individuals can potentially be exposured to JAU6476 100FS Seed Treatment Fungicide while planting treated cereal, legume and corn seed, and to L1397 Seed Treatment Fungicide while planting treated cereal seed on-farm.

Exposure to workers planting seed is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for workers planting treated seed using typical on-farm seed treatment equipment. The exposure estimates are based on workers wearing a single layer of clothing plus chemical resistant gloves. Dermal and inhalation exposure estimates for workers were generated from surrogate seed planting passive dosimetry studies. Chemical-specific dust-off data were submitted to bridge the proposed use pattern to the use pattern in the surrogate exposure studies used in the risk assessment.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (NOAELs) to obtain the MOE; the target MOE is 300 for dermal exposure and 1000 for inhalation exposure.

For cereal seed, the estimates of on-farm treating and planting from the 2006 passive dosimetry study are not expected to underestimate exposure from planting of commercially treated seed. However, legumes and corn are usually bagged at commercial facilities, and as such, the 2006 study is not representative of exposure to workers loading and planting bagged seed. To address this exposure scenario, there are two studies available to which the applicant has access: the 1990 study conducted with canola seed and the 2007 study conducted with corn seed.

Both the 1990 and 2007 passive dosimetry studies monitored exposure from workers planting treated seeds from bags, which is the similar exposure scenario as workers who plant legume and corn seeds treated with JAU6476 100FS Seed Treatment Fungicide in commercial facilities. The limitation of using these two studies as surrogates to estimate planter exposure is that neither study assesses exposure from planting using an open cab tractor.

The 1990 study is considered more suitable to estimate planter exposure from the proposed use on legumes, as the seed type is more similar to canola than to corn. The submitted 2009 dust-off study did not measure the dust-off potential of canola; however, in a dust-off study submitted by the applicant in support of another application the dust-off potential of untreated and treated canola was similar to that for dry beans and peas. The 2007 study is a better surrogate to estimate planter exposure from the proposed use on corn since the 2007 study is conducted on corn.

MOEs for workers planting legume and corn seed treated with JAU6476 100FS Seed Treatment Fungicide are well above the target MOEs (Table 3-4). Even though it was assumed that closed cab tractors were used to generate the planting data in the 2006 study, and closed cabs were used in the 1990 and 2007 studies, the calculated MOEs are considered high enough to cover off this uncertainty and closed cab tractors will not be required for planting seed treated with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide.

Table 3-4. Exposure and risk estimates for JAU6476 100FS Seed Treatment Fungicide for workers planting treating legumes and corn from bags

Scenario	Unit exposure (µg/kg a.i. handled)[1]		kg seed planted per day[2]	App rate (kg a.i./kg seed)	kg a.i. handled per day [3]	Exposure [4] (mg/kg bw/day)		MOE [5]	
	Dermal	Inhalation				Dermal	Inhalation	Dermal	Inhalation
Legumes	424.17	1.11	20000	0.00005	1.0	0.00606	0.0000159	4951	126126
Corn	1803	82.83	1350	0.00005	0.068	0.00175	0.0000805	17128	24856

[1] Unit exposure values for planters of treated legume seed are from the canola seed planting study (1990). Unit exposure values for planters of treated corn seed are from the corn seed planting study (2007).
[2] Default values for legumes and corn seed for seed planted per day, based on planting capacity of on-farm equipment.
[3] kg a.i. handled per day = kg seed treated per day × application rate (kg a.i./kg seed)
[4] Exposure (mg/kg bw/day) = $\frac{\text{Unit exposure (µg/kg a.i. handled per day)} \times \text{kg a.i. handled per day}}{\text{70 kg bw} \times \text{1000 µg/mg}}$
[5] Dermal NOAEL = 30 mg/kg bw/day, target MOE= 300; inhalation NOAEL = 2 mg/kg bw/day, target MOE = 1000

3.4.3 Residential Exposure and Risk Assessment

There are no residential uses for JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide, and as such, a residential risk assessment was not required.

3.4.3.3 Bystander Exposure and Risk

Bystander exposure is expected to be negligible since the potential for drift is expected to be minimal when planting seed.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Registration Decision PRD2010-08, *Prothioconazole,* for the residue definition for risk and enforcement purpose, the field trial data on various crops resulting from foliar application, and the frozen storage stability of prothioconazole in plant and animal foodstuffs. The information captured herein relates to the bridging field trial data resulting from the seed treatment use of prothioconazole provided to the PMRA in support of the registration of a major new use for prothioconazole.

The bridging data submitted for comparison of foliar and seed treatment uses on wheat and peanut confirmed that residues of prothioconazole resulting from the proposed seed treatment are not expected to be greater than those from foliar application. The proposed maximum residue limits can be supported.

3.5.2 Dietary Risk Assessment

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Registration Decision PRD2010-08, *Prothioconazole*, for a detailed assessment of the dietary exposure and characterization.

3.5.3 Aggregate Exposure and Risk

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

3.5.4 Maximum Residue Limits

Table 3.5.4 Proposed Maximum Residue Limit

Commodity	Recommended MRL (ppm)
Crop Subgroup 6C (dried shelled pea and bean, except soybean)	0.9

For additional information on Maximum Residue Limits (MRL) in terms of the international situation and trade implications, refer to Appendix II.

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Registration Decision PRD2010-08, *Prothioconazole*, for the proposed maximum residue limits, the nature of the residues in animal and plant matrices, analytical methodology, field trial data, and the acute and chronic dietary risk estimates.

4.0 Impact on the Environment

Refer to Regulatory Note REG2007-03, *Prothioconazole* for a detailed assessment of the environmental impacts of prothioconazole.

Metalaxyl and tebuconazole, the active ingredients combined with prothioconazole in L1397 Seed Treatment Fungicide, are already registered for use as seed treatments at similar rates of application. Thus, an assessment of the environmental impacts of these two active ingredients was not required.

No environmental incident reports were found for prothioconazole since the conditional registration was granted in 2006. Specific information regarding the mandatory reporting system regulations that came into on force April 26 2007 under the *Pest Control Products Act* can be found at http://canadagazette.gc.ca/partII/2006/20061115/html/sor260-e.html.

4.1 Fate and Behaviour in the Environment

The properties and environmental fate characterization of prothioconazole have been previously reviewed and reported in Regulatory Note REG2007-03, *Prothioconazole*.

4.2 Environmental Risk Characterization

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

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). 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 (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

The effects of prothioconazole residues on terrestrial organisms have been previously reviewed and reported in Regulatory Note REG2007-03, *Prothioconazole*. However, a new risk assessment was conducted to determine whether treated seed presented unacceptable risk to birds and mammals that may eat the treated seed in the field after planting.

The screening level risk quotients do not exceed the level of concern for birds, but they exceed the level of concern for mammals of all sizes on a developmental toxicity basis (Appendix I, Table 7). The endpoint for developmental neurotoxicity to rabbits (2 mg/kg bw/day) was chosen at the screening level because it was the most conservative but it may not be the most relevant to the environment due to the dosing regime (gavage rather than dietary exposure).

Considering that (i) the screening level risk quotients observed for mammals only slightly exceeds the level of concern (ii) the conservative assumptions made at the screening level relative to the feeding pattern of mammals (assumed that 100% of the diet is comprised of treated seed), and (iii) the conservative assumption that 100% of applied prothioconazole remains as toxic residue either as untransformed or as a toxic transformation product (prothioconazole-desthio or prothioconazole-S-methyl), the overall risk to mammals is considered to be low.

Nonetheless, the developmental risk of total toxic residues of prothioconazole to mammals was further characterized. Risk quotients were calculated using the lowest observed effect level (LOEL) from the developmental neurotoxicity study in rabbits (10 mg/kg bw/day), a level at which ecologically relevant effects [arthrogryposis (permanently contracted joint), multiple malformations] were observed. The risk quotients calculated using the LOEL are below the level of concern for all sizes of mammals (Appendix I, Table 8).

Similar conclusions are drawn when the second most sensitive no observed effect level (NOEL) was used (3.6 mg/kg bw/day from a developmental study in rats using prothioconazole-desthio) (Appendix I, Table 8). Using this NOEL, the level of concern is slightly exceeded for small and medium sized mammals. A further characterization of risk by calculating risk quotients using the LOEL from that study (15.1 mg/kg bw/day) indicates all risk quotients are less than one. Furthermore, the level of concern is not exceeded for any mammal size when the most sensitive NOEL from multi-generation reproduction studies is used (NOEL of 9.5 mg/kg bw/day from a study in rats using prothioconazole-desthio) (Appendix I, Table 8). These two studies are considered more relevant to the environmental risk assessment than the developmental neurotoxicity study in rabbits used in the initial assessment because the test compound was administered through the diet rather than by gavage.

The results of the long term studies taken together suggest that mammals are not expected to be exposed to levels of total toxic prothioconazole residues demonstrated to result in observable adverse effects in laboratory studies. The overall risk to mammals from total toxic residues of prothioconazole from the proposed seed treatment uses of prothioconazole is considered to be low.

Please refer to the Regulatory Note REG2007-03, *Prothioconazole* for the risk assessment of prothioconazole residues on organisms other than birds and mammals.

4.2.2 Risks to Aquatic Organisms

The effects of prothioconazole residues on aquatic organisms have been previously reviewed and reported in Regulatory Note REG2007-03, *Prothioconazole*.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

For JAU6476 100FS Seed Treatment Fungicide, the data from 35 trials were used to support a use rate of 50 mL per 100 kg of seed (5 g a.i./100 kg seed) for JAU6476 100FS Seed Treatment Fungicide on corn, small-grain cereals, large-seeded pulse crops and soybean against a range of seed and seedling diseases. The efficacy data contained in 47 small-scale field trial reports and 28 laboratory study reports were used to evaluate the efficacy of JAU6476 100FS Seed Treatment Fungicide against seed and seedling diseases caused by seed-borne and soil-borne pathogens of wheat, barley, oats, corn, large-seeded pulses including chickpea, field pea and lentil, and soybean. Based on the efficacy data and scientific rationales submitted, all proposed disease claims are supported. The data also demonstrated that JAU6476 100FS Seed Treatment Fungicide applied at the proposed rate was safe to use on wheat (spring, winter and durum), barley (spring and winter), oats, soybean, field pea, lentil and corn.

Please refer to Appendix I, Table 10 for a full listing of the diseases that JAU6476 100FS Seed Treatment Fungicide, applied at a rate of 50 mL per 100 kg of seed, will control/suppress.

The scientific rationales provided were considered acceptable to support the following tank mixtures with JAU6476 100FS Seed Treatment Fungicide at a rate of 50 mL per 100 kg of seed:

- Trilex AL Fungicide on pea (dried and field), chickpea, lentil, soybean.
- Allegiance FL; Poncho 600 FS Insecticide; Poncho 600 FS Insecticide + Allegiance FL on corn (field, sweet, popcorn)
- Allegiance FL on wheat, barley, oats & rye for export only.

For L1397 Seed Treatment Fungicide, efficacy data generated from 62 field trials and nine laboratory seed bioassays and inoculated soil screens were used to demonstrate the efficacy of L1397 Seed Treatment Fungicide against seed and seedling diseases of wheat, barley and oats. L1397 Seed Treatment Fungicide was shown to provide a level of performance that was greater to that of currently registered tebuconazole-containing seed treatment products against key fungal pests that included seed-borne *Fusarium* spp. and *Cochliobolus sativus* while still controlling all of the seed-borne smuts and bunts that are labelled on the tebuconazole-containing product labels. Based on the information and data submitted in this report, all proposed disease claims are supported. Please refer to Appendix I, Table 11, for a full listing of the diseases that L1397 Seed Treatment Fungicide, applied at a rate of 325 mL per 100 kg seed, will control/suppress.

The scientific rationales provided were considered acceptable to support the tank mix of L1397 Seed Treatment Fungicide at the rate of 325 mL per 100 kg seed with the insecticide Stress Shield For Cereals (Registration number 29609).

5.2 Economics (Sections 5.2 and 5.2.1 are taken directly from the applicant's value summary reports)

In terms of land use and production (and excluding hay crops), wheat is Canada's most important field crop, followed by canola and barley. In addition, wheat is Canada's largest Agri-food export. According to Statistics Canada, in 2005, 2006 and 2007, Canada exported about $2.697, $3.609 and $4.637 billion (CDN), respectively, on a balance-of-payments basis. These wheat exports accounted for about 9.8%, 13.1%, and 15.6% of the total Canadian Agri-food and fishing products exports in these three years, respectively.

5.2.1 Crop Losses and Economic Impact

Soil-borne *Fusarium* species can cause seedling blight, damping-off, common root rot, crown rot, and foot rot in wheat, barley and oat. The loss of crown roots and crown tissues can result in yield losses up to 20% (Mikkelson et al., 2002). In the Prairies, losses of about 10% are believed to occur each year in barley. Infection of the roots and crown causes lesions on the roots, coleoptiles and leaves, which leads to stunting and seedling death. Seedling diseases in wheat caused by *Fusarium* and *Cochliobolos sativus*, another important fungal pathogen of seedlings, are thought to cause annual losses of 6% – 7% in wheat grown on the Prairies. Take-all and *Pythium* root rot have been known to reduce wheat yields by 10-25% in local areas in Idaho (NSF Center for Integrated Pest Management, 2000).

In years when smut diseases have been severe in West Virginia, especially in drier areas, more than 50% the oat panicles in individual fields have been smutted, and losses over larger areas have averaged as much as 20% (West Virginia University Extension Service, no date). Smut diseases in barley and oat are easily controlled with the use of resistant cultivars and seed treatment fungicides. Where susceptible cultivars have been grown without a seed treatment, losses could be quite high. Losses attributable to loose smut in barley average less than 1%, but losses up to 40% have been recorded (Agriculture, Food and Rural Development, Government of Alberta, 2005). Losses are related to reductions in yield as well as reduction in seed quality.

In field trials across western Canada, application of seed treatment fungicides to pulses increased seedling emergence by 10-30% when pathogen populations were high (Agriculture and Agri-Food Canada, 2001). Seed rot and seedling blight caused by *Pythium, Fusarium* and *Rhizoctonia* can reduce plant stands and yield by 10-15% (PAN, 2003). Ascochyta blight, caused by the fungus *Ascochyta rabiei*, is the most damaging disease of chickpea in western Canada. Complete yield losses to Ascochyta blight have been recorded. This disease can reduce seed quality significantly as well (NDSU Extension Service, 2008). Under favourable conditions, even the most resistant varieties can experience yield losses exceeding of 70% (Saskatchewan Agriculture and Food, 2007).

In Canada, 100% of the corn seeded is treated with a fungicide. The importance of a seed treatment in corn, against fungi and insects, cannot be overstated. Corn is a weak competitor early in the growing season. Yield losses attributable to seed rot and damping-off caused by *Fusarium* in corn are poorly documented. However, if losses caused by *Fusarium* are comparable to those caused by *Pythium*, another corn seedling pathogen, then losses probably range from 3% to 10% or 20% annually, depending on the severity of the disease.

Fungicide seed treatments are an economical way to protect a crop against seed and seedling diseases. The addition of JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide to the market will provide additional tools and increase choices a grower has to control seed and seedling diseases.

5.3 Sustainability

5.3.1 Survey of Alternatives

There are several options available for suppressing or controlling seed and seedling diseases of corn, cereal grains, oilseeds and pulse crops. Resistant varieties and hybrids are available for some diseases. Since varieties and hybrids differ in their tolerance to diseases, cultivar choice is an important component in disease management. Several seed treatment fungicides are available, Refer to Appendix I, Table 9 for a summary of the active ingredients currently registered for the uses supported with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Due to their spectrum of activity, JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide may be used with non-chemical components of Integrated Pest Management to control the major seed and seedling diseases of the listed crops. Seed treatment fungicides should be used in rotation with other registered seed treatment and foliar fungicides to prevent and manage fungicide resistance.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

According to the Fungicide Resistance Action Committee (FRAC), there are great differences in the activity spectra of the different DMI fungicides, and resistance is known in various strains of fungi. It is accepted that cross resistance is present between fungicides active against the same fungus. However, it is also believed that the SBI Class 1 DMI fungicides show no cross resistance to other classes of SBI fungicides. Prothioconazole is rated as having a medium risk for resistance developing in a fungal population, in general. However, the selection pressure and risk of resistance development are considered low for seed treatment. According to FRAC, the proposed diseases and pathogens are classified as having a low risk of resistance development to fungicides.

5.3.4 Contribution to Risk Reduction and Sustainability

Application of prothioconazole as a seed treatment will contribute to risk reduction in several ways. Use of seed treatments delivers a low dosage of active on a per hectare basis. The delivery of the active ingredient on the seed reduces the potential impact to non-target organisms relative to foliar applied fungicides. Seed treatment is an effective application method to reduce the risk of a pesticide having any harmful effect on the surrounding ecosystem.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

Refer to Regulatory Note REG2007-03, *Prothioconazole*, Proposed Re-evaluation Decision PRVD2007-10, *Metalaxyl and Metalaxyl-M* and Regulatory Note REG2006-11, *Tebuconazole* for information on the Pest Control Product Policy considerations of prothioconazole, metalaxyl and tebuconazole, respectively.

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*[5]. The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[7], 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 prothioconazole and the end-use products JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

- The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-0002[8].

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5 *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.*

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

7 DIR2006-02, PMRA Formulants Policy.

8 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

Refer to Regulatory Note REG2007-03, *Prothioconazole* and Proposed Regulatory Decision PRD2010-08, *Prothioconazole.*

Workers treating seed with JAU6476 100FS Seed Treatment Fungicide or L1397 Seed Treatment Fungicide and planting treated seed are not expected to be exposed to levels of prothioconazole that will result in an unacceptable risk when the JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide are used according to label directions. The personal protective equipment on the product label is adequate to protect workers treating seed in commercial or on-farm seed treatment facilities and workers planting treated seeds.Based on the submitted field trial data, the PMRA recommends that the maximum residue limit of 0.9 ppm be established for residues of prothioconazole in/on Crop Subgroup 6C (dried shelled pea and bean, except soybean).

7.2 Environmental Risk

JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide, when used according to label directions, do not present a risk to earthworms, bees, beneficial arthropods and other insects, terrestrial plants and aquatic organisms. The overall risk to birds and mammals from the consumption of seeds treated with JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide is considered to be low. No mitigation measures are required, other than a precautionary label statement to clean up spilled seeds, and an advisory statement to identify the leaching potential of metalaxyl, one of the active ingredients in L1397 Seed Treatment Fungicide.

7.3 Value

The efficacy data and scientific rationale submitted to register JAU6476 100FS Seed Treatment Fungicide and L1397 Seed Treatment Fungicide were adequate to demonstrate efficacy for use on all proposed diseases and crops claims. In addition, the proposed tank mixes are supported. Refer to Appendix I, Table 10 and 11.

8.0 Proposed Regulatory Decision

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 Prothioconazole Technical Fungicide and JAU6476 100FS Seed Treatment Fungicide, containing the technical grade active ingredient prothioconazole, and L1397 Seed Treatment Fungicide, containing the technical grade active ingredients prothioconazole, metalaxyl and tebuconazole, to control seed and seedling diseases of various 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

µg	micrograms
a.i.	active ingredient
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
CBI	confidential business information
CDN	Canadian
d	day(s)
DACO	data code
DMI	Demethylation Inhibitor
dw	dry weight
EEC	estimated environmental concentration
F_1	first generation
F_2	second generation
FDA	*Food and Drugs Act*
FIR	food ingestion rate
FRAC	Fungicide Resistance Action Committee
g	gram
ha	hectare(s)
HAFT	highest average field trial
HDPE	high density polyethylene
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LOEC	low observed effect concentration
LOEL	lowest observed effect level
LOQ	limit of quantitation
m	metre
mg	milligram
mL	millilitre
MAS	maximum average score
MIS	maximum irritation score
MOE	margin of exposure
MRL	maximum residue limit
n	sample size
N/A	not applicable
NDSU	North Dakota Statue University
NIS	non-ionic surfactant
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
NSF	National Science Foundation
nm	nanometre(s)
NZW	New Zealand white
OECD	Organisation for Economic and Cooperative Development
Pa	pascals
PCPA	*Pest Control Products Act*
PHI	pre-harvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RQ	risk quotient
SBI	sterol biosynthesis inhibitor
STMdR	standard median residue
STMR	standard mean residue
U.S.	United States
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of End-use Product(s) Containing Prothioconazole
(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
JAU6476 100FS Seed Treatment Fungicide	
Acute oral toxicity Wistar rats PMRA #1733593	LD_{50} > 2000 mg/kg bw Low toxicity
Acute dermal toxicity Wistar rats PMRA #1733595	LD_{50} > 4000 mg/kg bw Low toxicity
Acute inhalation toxicity (nose-only) Wistar rats PMRA #1733597	LC_{50} > 2.735 mg/L Low toxicity
Dermal irritation Himalayan rabbits PMRA #1733601	MAS[a] = 1/8 Slightly irritating
Eye irritation Himalayan rabbits PMRA #1733599	MAS[a] = 0/110 , MIS = 0/110 Non-irritating
Dermal Sensitization Hsd Poc:DH Guinea Pig (Maximization) PMRA# 1733603	Dermal sensitizer
L1397 Seed Treatment Fungicide	
Acute oral toxicity Sprauge-Dawley rats PMRA # 1733668	LD_{50} > 2000 mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rats	LD_{50} > 5000 mg/kg bw Low toxicity

Study Type/Animal/PMRA #	Study Results
PMRA # 1733670	
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA # 133672	LC_{50} > 2.55 mg/L Low toxicity
Dermal irritation NZW rabbits PMRA # 133676	MAS[a] = 0/8 Non-irritating
Eye irritation NZW rabbits PMRA # 133674	MAS[a] = 23.8/110 , MIS = 26/110 Moderately irritating and persisting at 7days
Dermal Sensitization Hartley Guinea Pig (Maximization) PMRA# 133678	Not a dermal sensitizer.

[a] (24, 48 and 72 hours)

Table 2 Integrated Food Residue Chemistry Summary

CROP FIELD TRIALS ON WHEAT	PMRA# 1733620
Field trials were conducted at three locations to evaluate the magnitude of the total residues of prothioconazole and prothioconazole-desthio in wheat forage, hay, grain, and straw following the use of JAU6476 480 SC (a suspension concentrate containing 480 g prothioconazole/litre of formulation) in various new use patterns as compared with the previously established foliar application use pattern. The previously registered use pattern for prothioconazole on wheat is two foliar spray applications of JAU6476 480 SC made 14 days apart at a target rate of 130 g a.i./ha for the first application and 200 g a.i./ha for the second application. In this study, the previously registered use pattern was repeated in plots TDF1 (sampled for forage) and TDF2 (sampled for hay, grain, and straw). In addition, plot TDS, sampled for all commodities, was planted with wheat seeds treated at the maximum seed treatment rate of 10 g a.i./100 kg seed with no further applications. Plots TDSF1 and TDSF2 were planted with treated seeds and also received the foliar applications. Finally, plots TDFA1 and TDFA2 received the foliar applications but with a non-ionic surfactant (NIS). A total of seven treated plots were evaluated in each field trial. No prothioconazole residues greater than the limit of quantitation (LOQ, 0.05 ppm) were observed in any of the wheat commodities harvested from the TDS plot. No prothioconazole residues greater than the LOQ (0.01 ppm) were observed in wheat grain from any of the treated plots. The total prothioconazole residues were similar in the respective matrices in all of the application patterns investigated.	

CROP FIELD TRIALS ON WHEAT											PMRA# 1733620
Commodity	Treatment	Total Applic. Rate (g a.i./ha)	PHI (days)	Total Prothioconazole Residues (ppm)							
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.	
Wheat Forage	TDS	10 g a.i./ 100 kg seed	53-174	3	<0.10	<0.10	<0.10	<0.10	<0.10	0	
	TDSF1	333-338	5-7		0.89	6.05	6.05	3.20	3.38	1.5	
	TDF1	324-326	5-7		2.01	4.73	4.73	3.26	3.33	0.78	
	TDFA1	324-326	5-7		2.42	6.64	6.64	3.50	4.19	1.3	
Wheat Hay	TDS	10 g a.i./ 100 kg seed	152-232	3	<0.10	<0.10	<0.10	<0.10	<0.10	0	
	TDSF2	332-339	14		0.55	0.96	0.96	0.81	0.77	0.12	
	TDF2	323-330	14		0.48	1.47	1.47	0.83	0.93	0.29	
	TDFA2	326-329	14		0.64	1.37	1.37	0.97	0.99	0.21	
Wheat Grain	TDS	10 g a.i./ 100 kg seed	178-266	3	<0.02	<0.02	<0.02	<0.02	<0.02	0	
	TDSF2	332-339	40-48		<0.02	<0.02	<0.02	<0.02	<0.02	0	
	TDF2	323-330	40-48		<0.02	<0.02	<0.02	<0.02	<0.02	0	
	TDFA2	326-329	40-48		<0.02	<0.02	<0.02	<0.02	<0.02	0	
Wheat Straw	TDS	10 g a.i./ 100 kg seed	178-266	3	<0.10	<0.10	<0.10	<0.10	<0.10	0	
	TDSF2	332-339	40-48		<0.10	0.40	0.40	0.22	0.23	0.10	
	TDF2	323-330	40-48		<0.11	0.37	0.37	0.37	0.27	0.10	
	TDFA2	326-329	40-48		<0.12	0.75	0.75	0.46	0.44	0.19	

CROP FIELD TRIALS ON Peanut **PMRA# 1733615**

Field trials were conducted at three locations to evaluate the magnitude of the total residues of prothioconazole and prothioconazole-desthio in peanut meat and hay following the use of JAU6476 480 SC (a suspension concentrate containing 480 g prothioconazole/litre of formulation) in a seed treatment, in-furrow treatment and foliar application. There were two plots in each trial. The first plot (seed treatment/in-furrow/foliar pattern, TDSFF) was planted with peanut seeds treated at 10 g prothioconazole/100 kg seed and planted at seeding rates ranging from 11.6 to 13.2 g/m^2 for application rates ranging from 12 to 13 g a.i./ha. This plot also received an in-furrow directed spray of JAU6476 480 SC at planting rates ranging from 192 to 200 g a.i./ha, followed by four broadcast foliar spray applications of JAU6476 480 SC at rates ranging from 96 to 105 g a.i./ha/application with a 13-14 days interval between applications. Total treatment rates for the TDSFF plot ranged from 609 to 613 g a.i./ha. The second plot (foliar only pattern, TDF), planted with untreated seed, received four broadcast foliar spray applications of JAU6476 480 SC at rates ranging from 190 to 205 g a.i./ha/application with a 13-14 days interval between applications. The total treatment rates for the TDF plots ranged from 774 to 814 g a.i./ha. For both plots, peanut samples were harvested with PHIs (pre-harvest interval) of 8-14 days.

No prothioconazole residues greater than the LOQ of 0.01 ppm were observed in peanut nutmeat samples treated with either application pattern from any of the field trials.

Commodity	Treatment	Total Applic. Rate (g a.i./ha)	PHI (days)	Total Prothioconazole Residues (ppm)						
				n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Peanut nutmeat	TDSFF	609-613	8-14	3	<0.02	<0.02	<0.02	<0.02	<0.02	0
	TDF	774-814	8-14	3	<0.02	<0.02	<0.02	<0.02	<0.02	0
Peanut hay	TDSFF	609-613	8-14	3	0.73	2.38	2.38	1.12	1.41	0.50
	TDF	774-814	8-14	3	2.37	6.08	6.08	3.63	4.03	1.09

Table 3 Fate and Behaviour in the Environment

Please refer to Regulatory Note REG2007-03, *Prothioconazole*.

Table 4 Toxicity to Non-Target Species

Please refer to the Regulatory Note REG2007-03, *Prothioconazole*.

Table 5 Estimated Exposure to Generic Birds and Mammals Through the Consumption of Seed Treated With Prothioconazole

Crop	# seeds/ g seed	Generic body weight of organism (g)	FIR[a] (g dw diet/day)	Estimated exposure[b] (# seeds/day)
Birds				
Millet (pearl, proso)	333.33	20	5.08	1693
		100	19.9	6649
		1000	58.1	19,384
Chickpeas	2	20	5.08	10
		100	19.9	40
		1000	58.1	116
Mammals				
Millet (pearl, proso)	333.33	15	2.18	726
		35	4.37	1456
		1000	68.7	22,906
Chickpeas	2	15	2.18	4
		35	4.37	9
		1000	68.7	137

[a] Food Ingestion Rate; is based on equations from Nagy (1987):

For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used: FIR (g dry weight/day) = $0.398(\text{bw in g})^{0.850}$

For generic birds with body weight greater than 200 g, the "all birds" equation was used:
FIR (g dry weight/day) = $0.648(\text{bw in g})^{0.651}$

For mammals, the "all mammals" equation was used:

FIR (g dry weight/day) = $0.235(\text{bw in g})^{0.822}$

Food ingestion is calculated in terms of g dry weight of food per day. As a conservative estimate, treated seed is assumed to be equivalent to dry weight of food as minimal moisture is expected to be present in treated seeds ready for planting.

[b] Estimated exposure calculated as # seeds/g x FIR. Assumes that 100% of the diet is comprised of treated seeds.

Table 6 Toxicity of Total Toxic Residues of Prothioconazole to Birds and Mammals Expressed as a Daily Dose

Study Type (compound)[a]	Test species[a]	Study results[a]	Daily dose[a, b]	Most sensitive endpoint applying uncertainty factor [c]
Birds				
Acute oral (prothioconazole)	Bobwhite	LD_{50} >2000 mg/kg bw NOEL= 2000 mg/kg bw (mortality) NOEL = 200 mg/kg bw (diarrhea)	No conversion required	LD_{50}/10 = 200 mg/kg bw
Acute oral (prothioconazole-desthio)	Bobwhite	LD_{50} >2000 mg/kg bw NOEL = 1000 mg/kg bw (mortality) NOEL = 500 mg/kg bw (clinical signs of toxicity, weight reduction, reduced food consumption)	No conversion required	
5-d dietary (prothioconazole-desthio)	Bobwhite	LC_{50} = 4252 mg/kg diet[d] NOEC = 1243 mg/kg diet (mortality, clinical signs of toxicity, weight loss, reduced food consumption)	LC_{50} not converted to an LD_{50} due to effects on food consumption at the two highest concentrations. An initial conservative assessment can be done using the NOEL. NOEL = 391 mg/kg bw/d[e]	As an LD_{50} for the most sensitive species was not determined, an initial conservative assessment will be done using the NOEL. NOEL = 391 mg/kg bw/d
Reproduction (prothioconazole-desthio)	Bobwhite	NOEC = 506.7 mg/kg diet (no effects)	NOEL = 43.9 mg/kg bw/d[f]	NOEL = 43.9 mg/kg bw/d
Mammals				
Acute (prothioconazole-*S*-methyl)	Rat	LD_{50} >2000 mg/kg bw NOEL = 2000 mg/kg bw (no mortality)	No conversion required	LD_{50}/10 = 200 mg/kg bw

Study Type (compound)[a]	Test species[a]	Study results[a]	Daily dose[a, b]	Most sensitive endpoint applying uncertainty factor [c]
Multi-generational reproduction, dietary exposure (prothioconazole-desthio)	Rat	NOEC = 160 mg/kg diet LOEC = 640 mg/kg diet (parents and F_1 adults: dam deaths due to dystocia; F_1 and F_2 pups: decreased body weight, decreased viability index)	NOEL = 9.5 mg/kg bw/d LOEL = 39.6 mg/kg bw/d	NOEL = 2 mg/kg bw/d
Developmental neurotoxicity, dietary (prothioconazole-desthio)	Rat	NOEC = 40 mg/kg diet LOEC = 160 mg/kg diet (increased number of stillborn pups, progressive malocclusion and deviated snout)	NOEL = 3.6 mg/kg bw/d LOEL = 15.1 mg/kg bw/d	
Developmental toxicity, gavage (prothioconazole-desthio)	Rabbit	NOEC = 66.7 mg/kg diet[g] LOEC = 333 mg/kg diet[g] (arthrogryposis (permanently contracted joint), multiple malformations)	NOEL = 2 mg/kg bw/d LOEL = 10 mg/kg bw/d	

[a] From Regulatory Note REG2007-03, *Prothioconazole*.

[b] Endpoints reported as a concentration are converted to a daily dose: Toxicity Dose = Concentration x (FIR/bw). FIR and bw are drawn from original studies. No conversion required for acute oral endpoints due to the nature of the test (is already a dose). Mammal endpoints typically reported as doses by study authors; mammal doses were reported in original prothioconazole review (REG2007-03).

[c] The most conservative endpoint (from studies with prothioconazole, prothioconazole-desthio or prothioconazole-S-methyl) for each study type for birds and mammals was used for the risk assessment. In addition, the acute oral and acute dietary endpoints were divided by an uncertainty factor of 10 to account for potential differences in species sensitivity as well as varying protection levels (population, community, individual).

[d] The LC_{50} reported as greater than 4252 mg/kg diet in REG2007-03 should have been reported as equal to 4252 mg/kg diet.

[e] Daily dose reported in the original study. Reviewer-calculated mean (0-5 day) FIR and bw for the birds in the 1243 mg/kg diet concentration (the NOEC concentration, as food consumption was affected at the two highest concentrations) were 6.8 g/bird/d and 26.7 g, respectively. The reviewer-calculated daily dose was 315 mg a.i./kg bw/d; the daily dose reported by the authors (391 mg a.i./kg bw/d) was used in the risk assessment.

[f] Endpoint converted to a daily dose using FIR and bw drawn from the original study, for the entire study period in birds fed the 506.7 mg/kg diet concentration: FIR = 17.9 g/bird/d; bw = 206.6 g.

[g] NOEC and LOEC in mg/kg diet estimated by the reviewer using the NOEL and LOEL and assuming a food consumption of 0.06 kg diet/day and an average body weight of 2 kg (10 mg a.i./kg bw/day x 2 kg x 1/0.06 kg diet/day = 66.7 mg a.i./kg diet; 50 mg a.i./kg bw/day x 2 kg x 1/0.06 kg diet/day = 333 mg a.i./kg diet)

Table 7 Screening Level Risk Quotients for Birds and Mammals. Exposure and Toxicity Information Presented for the Largest (Chickpea) and Smallest (millet) Seeds

Generic body weight of organism	Exposure (# seeds/d)	Toxicity; number of seeds to reach toxicity endpoint(# seeds/d)[a]	RQ
Birds			
20g	Chickpea: 10; Millet: 1693	**Acute** Chickpea: 160; Millet: 26,666	0.06
		Dietary Chickpea: 31; Millet: 5213	0.32
		Reproduction Chickpea: 35; Millet: 5853	0.29
100g	Chickpea: 40; Millet: 6649	**Acute** Chickpea: 800; Millet: 133,332	0.05
		Dietary Chickpea: 156; Millet: 26,066	0.26
		Reproduction Chickpea: 176; Millet: 29,266	0.23
1000g	Chickpea: 116; Millet: 19,384	**Acute** Chickpea: 8000; Millet: 1,333,320	0.01
		Dietary Chickpea: 1564; Millet: 260,664	0.07
		Reproduction Chickpea: 1756; Millet: 292,664	0.07
Mammals			
15g	Chickpea: 4; Millet: 726	**Acute** Chickpea: 120; Millet: 20,000	0.04
		Developmental neurotoxicity in rabbits Chickpea: 1; Millet: 200	3.63
35g	Chickpea: 9; Millet: 1456	**Acute** Chickpea: 280; Millet: 46,666	0.03
		Developmental neurotoxicity in rabbits Chickpea: 3; Millet: 467	3.12
1000g	Chickpea: 137; Millet: 22,906	**Acute** Chickpea: 8000; Millet: 1,333,320	0.02
		Developmental neurotoxicity in rabbits Chickpea: 80; Millet: 13,333	1.72

[a] Number of seeds to reach the toxicity endpoint calculated as: daily dose (mg a.i./kg bw or mg a.i./kg bw/day) x generic body weight of organism (kg) ÷ amount of active ingredient per seed (mg a.i./seed). For daily doses refer to Appendix I, Table 6 of this document.

Amount of active ingredient per seed (mg a.i./seed) calculated as: proposed rate of application (g a.i./100 kg seed) ÷ number of seeds per 100 kg seed x 1000; proposed rate of application is 5 g a.i./100 kg seed; number of seeds per 100 kg seed is 33,333,000 for millet and 200,000 for chickpeas, as provided by the applicant.

Risk quotient (RQ) = exposure/toxicity

Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)

Table 8 Refined Risk Assessment on Mammals. Exposure and Toxicity Information Presented for the Largest (Chickpea) and Smallest (millet) Seeds

Generic body weight of mammal	Exposure (# seeds/d)	Daily dose with uncertainty factor (mg a.i./kg bw/d)	Toxicity; number of seeds to reach toxicity endpoint (# seeds/d)[a]	RQ
Developmental neurotoxicity study in rabbits with prothioconazole-desthio				
15g	Chickpea: 4; Millet: 726	LOEL = 10	Chickpea: 6; Millet: 1000	0.73
35g	Chickpea: 9; Millet: 1456	LOEL = 10	Chickpea: 14; Millet: 2333	0.62
1000g	Chickpea: 137; Millet: 22,906	LOEL = 10	Chickpea: 400; Millet: 66,666	0.34
Developmental toxicity study in rats with prothioconazole-desthio				
15g	Chickpea: 4; Millet: 726	NOEL = 3.6	Chickpea: 2; Millet: 360	2.02
		LOEL = 15.1	Chickpea: 9; Millet: 840	0.48
35g	Chickpea: 9; Millet: 1456	NOEL = 3.6	Chickpea: 5; Millet: 24,000	1.73
		LOEL = 15.1	Chickpea: 21; Millet: 1510	0.41
1000g	Chickpea: 137; Millet: 22,906	NOEL = 3.6	Chickpea: 144; Millet: 3523	0.95
		LOEL = 15.1	Chickpea: 604; Millet: 100,666	0.23
Multi-generation reproduction study in rats with prothioconazole-desthio				
15g	Chickpea: 4; Millet: 726	NOEL = 9.5	Chickpea: 6; Millet: 950	0.76
35g	Chickpea: 9; Millet: 1456	NOEL = 9.5	Chickpea: 13; Millet: 2217	0.66
1000g	Chickpea: 137; Millet: 22,906	NOEL = 9.5	Chickpea: 380; Millet: 63,333	0.36

[a] Number of seeds to reach the toxicity endpoint calculated as: daily dose (mg a.i./kg bw or mg a.i./kg bw/day) x generic body weight of organism (kg) ÷ amount of active ingredient per seed (mg a.i./seed).

Amount of active ingredient per seed (mg a.i./seed) calculated as: proposed rate of application (g a.i./100 kg seed) ÷ number of seeds per 100 kg seed x 1000; proposed rate of application is 5 g a.i./100 kg seed; number of seeds per 100 kg seed is 33,333,000 for millet and 200,000 for chickpeas, as provided by the applicant.

Risk quotient (RQ) = exposure/toxicity
Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)

Table 9 Alternative Seed Treatment Fungicides Registered to Control or Suppress the Supported Pests and Crops Combinations

Product	Reg. No.	Active Ingredient	FRAC Fungicide Group	Crops
Agrox B-2	26956	captan + diazinon	M	corn, peas, soybeans, beans.
Agrox CD	26957	captan + diazinon	M	corn, peas, soybeans, beans.
Apron Maxx RTA	27577	fludioxonil + metalaxyl-M	12, 4	chickpea, lentil, dry bean, dry pea, soybean.
Apron Maxx RFC	28817	fludioxonil + metalaxyl-M	12, 4	chickpea, lentil, dry bean, dry pea, soybean.
Apron XL LS	25585	metalaxyl-M	4	wheat, barley, oats, corn, chickpea, lentil, pea, field beans, soybean.

Product	Reg. No.	Active Ingredient	FRAC Fungicide Group	Crops
Baytan 30	24677	triadimenol	3	wheat, barley.
Agrox FL	12028	captan	M	beans, chickpea, lentil, pea, soybean, corn.
Captan 400	22819	captan	M	beans, corn, pea, soybean.
Charter	26455	triticonazole	3	wheat, barley, oats.
Charter RTU	29400	triticonazole	3	wheat, barley, oats.
Crown	23430	thiabendazole + carbathiin	1, 7	lentil, chickpea.
DB-Red L	27144	maneb	M	wheat, barley, oats.
Dividend XL RTA	25777	difenoconazole + metalaxyl-M	3, 4	wheat, barley, oats, corn.
Dividend XL	25778	difenoconazole + metalaxyl-M	3, 4	wheat, barley, oats, corn.
Dividend Extreme	29490	difenoconazole + metalaxyl-M	3, 4	wheat, barley, oats, corn.
Gemini	27826	triticonazole + thiram	3, M	wheat, barley, oats.
Maxim 480FS	27001	fludioxonil	12	wheat, barley, oats, corn, bean, pea, soybean, chickpea, lentil.
Maxim XL	27071	fludioxonil + metalaxyl-M and S-isomer	4, 12	field corn, sweet corn and popcorn
Raxil 250FL	26138	tebuconazole	3	wheat, barley, oats.
Raxil SP	26137	tebuconazole	3	wheat, barley, oats.
Raxil 312 FS	25762	tebuconazole	3	wheat, barley, oats.
Raxil T	27566	tebuconazole + thiram	3, M	wheat, barley, oats.
Raxil MD	27692	tebuconazole + metalaxyl	3, 4	wheat, barley, oats.
Thiram 75WP	27556	thiram	M	dry bean, soybean, pea, field corn
Vitaflo 280	11423	carbathiin + thiram	7, M	wheat, barley, oats, dry beans, corn, lentil, pea, soybean,
Vitaflo 220	21174	carbathiin + thiram	7, M	wheat, barley, oats, dry beans, corn, lentil, pea, soybean,
Vitavax Flowable Fungicide	27550	carbathiin	7	wheat, barley, oats
Vitavax 200	27555	carbathiin + thiram	7, M	wheat, barley, soybean for export only.
Vitavax Powder	27595	carbathiin + thiram	7, M	wheat, barley, oats.
Allegiance FL	26674	metalaxyl	4	beans, chickpea, corn, lentil, pea, soybean, for export only: wheat, barley, oats.
Dynasty 100FS	28394	azoxystrobin	11	corn

Product	Reg. No.	Active Ingredient	FRAC Fungicide Group	Crops
A14379B	29113	metalaxyl-M + fludioxonil + thiamethoxam (insecticide)	4, 12	soybean
Anchor Planter Box	18788	carbathiin + thiram	7, M	peas, lentils, soybean.
Trilex AL	29160	trifloxystrobin + metalaxyl	11, 4	beans, chickpea, lentils, soybean.
Trilex FS	29161	trifloxystrobin	11	beans, chickpea, peas, lentils, soybean, corn.
Armour	29296	triticonazole	3	wheat, barley, oats.
Caption CT	26987	captan + thiophanate-methyl	1, M	sweet corn.
Cruiser Maxx Beans	28821	metalaxyl-M + fludioxonil + thiamethoxam (insecticide)	4, 12	beans, peas, soybean.
Cruiser Maxx Cereals	29127	difenoconazole + metalaxyl-M + thiamethoxam (insecticide)	4, 12	cereals including: wheat, barley, oats.
DCT Dual	14986	captan + thiophanate-methyl + diazinon (insecticide)	M, 1	sweet corn
Proseed	29814	fludioxonil	12	wheat, barley, oats, corn

Table 10 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported for JAU6476 100FS Seed Treatment Fungicide

Crop	Rate	Disease Claim	Supported/ Unsupported
Cereal grains (wheat, barley, oat, rye, triticale, millet, pearl millet, proso millet)	Apply 50 mL per 100 kg of seed	<u>*Diseases Controlled:*</u> Seed rot / pre-emergence damping-off caused by seed- and soil-borne *Fusarium* spp. and *Cochliobolus sativus* Seedling blight caused by seed-borne *Fusarium* spp. and *Cochliobolus sativus* Post-emergence damping-off caused by soil-borne *Fusarium* spp. Seed rot / pre-emergence damping-off, and post-emergence damping-off and seedling blight caused by seed-borne *Aspergillus* spp. Common bunt (*Tilletia foetida*)	Supported

Crop	Rate	Disease Claim	Supported/ Unsupported
		False loose smut and covered smut of barley (*Ustilago nigra* and *U. hordei*); Barley leaf stripe (*Pyrenophora graminea*) Loose smut and covered smut of oat (*Ustilago avenae* and *U. kolleri*) *Diseases Suppressed:* Loose smut of wheat (*Ustilago tritici*) Root rot caused by seed-borne and soilborne *Fusarium* spp. Root rot caused by soil-borne *Cochliobolus sativus* Crown rot of small-grain cereals caused by seed-borne *Fusarium* spp. Seedling blight caused by seed-borne *Penicillium* spp.	
Corn (field, sweet, popcorn)	Apply 50 mL per 100 kg of seed	*Diseases Controlled:* Seed rot and pre-emergence damping-off caused by seed-borne and soil-borne *Fusarium* spp. Post-emergence damping-off caused by soil-borne *Fusarium* spp. Seed rot and pre-emergence damping-off caused by seed-borne *Cladosporium* spp. and *Aspergillus* spp. *Diseases Suppressed:* Seed rot and pre-emergence damping-off caused by *Penicillium* spp.	Supported
Dry bean, dried and field pea, chickpea, lentil and soybean, immature soybean seed	Apply 50 mL per 100 kg of seed	*Diseases Controlled:* Seed rot / pre-emergence damping-off and post-emergence damping-off caused by soil-borne *Fusarium* spp. Seed rot and pre-emergence damping-off of soybean caused by seed-borne *Phomopsis longicolla* Seed rot and pre-emergence damping-off of chickpea caused by *Ascochyta rabiei* Seed infection on soybean caused by *Penicillium* spp.	Supported

Crop	Rate	Disease Claim	Supported/ Unsupported
Dry Bean Pea (dried and field) Chickpea Lentil Soybean Soybean (immature seed)	Tank-mix with Trilex AL		Supported
Corn (field, sweet, popcorn)	Tank-mix with: Allegiance FL Poncho 600 Poncho 600 + Allegiance FL		Supported
Wheat, barley, oats & rye for export only	Tank-mix with Allegiance FL		Supported

Table 11 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported for L1397 Seed Treatment Fungicide

Crop	Rate	Disease Claim	Supported/ Unsupported
Barley	Apply 325 mL per 100 kg of seed	<u>*Diseases Controlled:*</u> Seed rot, pre-emergent damping-off caused by seed- and soil-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne *Pythium* spp. Seedling blight caused by seed-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne, *Fusarium* spp. and *Pythium* spp. Post-emergent damping-off caused by seedand soil-borne *Fusarium* spp. and *Cochliobolus sativus* True loose smut & Covered smut False loose smut Barley leaf stripe Seed rot, pre-emergent damping-off, postemergent damping-off and seedling blight caused by seed-borne *Aspergillus* spp. <u>*Diseases Suppressed:*</u> Root and Crown rot caused by seed- and soil-borne *Fusarium* spp.	Supported

Crop	Rate	Disease Claim	Supported/ Unsupported
		Common root rot caused by seed- and soilborne *Cochliobolus sativus* Seedling blight caused by seed-borne *Penicillium* spp.	
Oats	Apply 325 mL per 100 kg of seed	<u>*Diseases Controlled:*</u> Seed rot, pre-emergent damping-off caused by seed- and soil-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne *Pythium* spp. Seedling blight caused by seed-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne, *Fusarium* spp. and *Pythium* spp. Post-emergent damping-off caused by seedand soil-borne *Fusarium* spp. and *Cochliobolus sativus* Loose smut & Covered smut Seed rot, pre-emergent damping-off, postemergent damping-off and seedling blight caused by seed-borne *Aspergillus* spp. <u>*Diseases Suppressed:*</u> Root and crown rot caused by seed- and soil-borne *Fusarium* spp. Common root rot caused by seed- and soilborne *Cochliobolus sativus* Seedling blight caused by seed-borne *Penicillium* spp.	Supported
Wheat	Apply 325 mL per 100 kg of seed	<u>*Diseases Controlled:*</u> Seed rot, pre-emergent damping-off caused by seed- and soil-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne *Pythium* spp. Seedling blight caused by seed-borne *Fusarium* spp., *Cochliobolus sativus* and soil-borne, *Fusarium* spp. and *Pythium* spp. Post-emergent damping-off caused by seedand soil-borne *Fusarium* spp. and *Cochliobolus sativus* Seed rot, pre-emergent damping-off, postemergent damping-off and seedling blight caused by seed-borne *Aspergillus* spp.	Supported

Crop	Rate	Disease Claim	Supported/ Unsupported
		Loose smut Common bunt *Diseases Suppressed:* Root and Crown rot caused by seed- and soil-borne *Fusarium* spp. Common root rot caused by seed- and soilborne *Cochliobolus sativus* Seedling blight caused by seed-borne *Penicillium* spp.	
Barley, oats, and wheat	Tank-mix with Stress Shield for Cereals		Supported

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Table 1 Differences Between MRLs in Canada and in Other Jurisdictions

Commodity	Canada (ppm)	U.S. (ppm)	Codex* (ppm)
Crop Subgroup 6C (Dried shelled pea and bean (except soybean) subgroup)	0.9	0.9	Not established by Codex

* Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices.

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