PRD2009-02

Proposed Registration Decision

Trifloxystrobin

Trilex AL Seed Treatment Fungicide
Trilex FL Seed Treatment Fungicide
Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment
Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment

(publié aussi en français)

26 February 2009

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

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

HC Pub: 8016

ISBN: 978-1-100-11729-4 (978-1-100-11730-0)
Catalogue number: H113-9/2009-2E (H113-9/2009-2E-PDF)

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Overview

Proposed Registration Decision for Trifloxystrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing amended full registration for the sale and use of Trifloxystrobin Technical Fungicide (Registration Number 27526) and full registration for the sale and use of Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide containing the technical grade active ingredient trifloxystrobin. The PMRA is also proposing conditional registration for the end-use products Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, which also contain the technical grade active ingredient trifloxystrobin. The proposed conditional registration of these two products is a result of the current conditional registration status of clothianidin, one of the active ingredients in these products. The end-use products are seed treatments to control fungal diseases on canola, rapeseed, mustard, bean, chickpea, pea, lentil and soybean seeds and seedlings. The insecticide component of the Prosper T 200 and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatments controls flea beetle on rapeseed and canola seeds and seedlings.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Trifloxystrobin Technical Fungicide, Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide, Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed treatment.

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, as well as on 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 trifloxystrobin, 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 trifloxystrobin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

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

What is Trifloxystrobin?

Trifloxystrobin is a fungicide that is currently registered as a foliar use on grapes, pome fruits, wheat, spring barley, oats, turf and ornamentals.

Trifloxystrobin is the active ingredient in the end-use product Trilex FL Seed Treatment Fungicide. This product is used for the control of seed and seedling diseases on canola, rapeseed, mustard, bean, chickpea, pea, lentil, soybean and corn.

Trilex AL Seed Treatment Fungicide is a ready-to-use seed treatment product for use on bean, chickpea, pea, lentil and soybean, for control of various seed and seedling diseases. It is a mixture of the fungicides trifloxystrobin and metalaxyl.

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment is composed of three fungicides, trifloxystrobin, metalaxyl and carbathiin, and the insecticide clothianidin. Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment contains the same fungicide active ingredients; however, it has double the amount of the insecticide clothianidin. These are ready-to-use seed treatment products for use on canola and rapeseed, for the control of various seed and seedling diseases as well as flea beetles.

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Trifloxystrobin Affect Human Health?

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

Potential exposure to trifloxystrobin may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which 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 trifloxystrobin products are used according to label directions.

Trifloxystrobin was of low toxicity by the oral, dermal and inhalation routes in rats. It was mildly irritating to the skin and eyes of rabbits. Trifloxystrobin was negative for dermal sensitization according to the Buehler method, but positive according to the Maximization test.

Trifloxystrobin did not cause cancer in animals and was not genotoxic. There was also no indication that trifloxystrobin caused damage to the nervous system, and there were no effects on reproduction. Repeated dermal administration to rats over 28 days was tolerated by females without any local or systemic reactions at high doses; increased liver and kidney weights were observed in males of the high-dose group. The first signs of toxicity in animals given daily oral doses of trifloxystrobin over longer periods of time were decreased body-weight gain and food consumption as well as effects in the liver. Additional effects in the liver were also observed after longer term exposure to trifloxystrobin. 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 trifloxystrobin 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 trifloxystrobin than the adult animal. Because of this observation, extra protective measures were not retained during the risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation who would ingest the most trifloxystrobin relative to body weight, are expected to be exposed to less than 69% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from trifloxystrobin is not of concern for all population subgroups.

Animal studies revealed no acute health effects. Consequently, a single dose of trifloxystrobin is not likely to cause acute health effects in the general population (including infants and children).

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

Radiotracer studies conducted in canola, corn and soybean indicated it is unlikely there would be any quantifiable residues of trifloxystrobin in crops harvested from seed treated according to the approved label rates. As per DIR2003-02, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United Sates*, MRLs will be proposed for the parent compound trifloxystrobin at the limit of quantitation (LOQ) of the established enforcement method AG-659A. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Occupational Risks From Handling Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment, Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide are not of concern when the label directions are followed.

Farmers and custom applicators have potential for exposure to trifloxystrobin during mixing, loading and application, during seed treatment as well as during bagging, loading and planting treated seed. The occupational exposure for these use scenarios are not of concern when the products are used according to the label directions.

In addition to the standard personal protective equipment for seed treatment the following statement is found on the bags of treated seed to protect workers from the dust that may come from bags of treated seed.

> This seed has been treated with [product name] fungicide containing [List of active ingredients]. Use chemical-resistant gloves when handling treated seed.

Environmental Considerations

What Happens When Trifloxystrobin Is Introduced Into the Environment?

The expected release of trifloxystrobin to the environment through the use of treated seeds will be less than the currently registered foliar use and poses negligible risk to animals, birds and aquatic organisms. For details on the fate and toxicity of trifloxystrobin to the environment, please refer to Regulatory Note REG2004-03 and Proposed Registration Decision PRD2008-01 for details.

Value Considerations

What Is the Value of Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment, Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide?

The value of registering Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment is that they contain a systemic fungicide with reduced risk status (trifloxystrobin) that will replace an older contact fungicide, thiram. Trilex AL Seed Treatment and Trilex FL Seed Treatment also contain trifloxystrobin as a replacement for thiram and can be used simultaneously with liquid seed inoculants.

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 Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment, Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In addition to the standard personal protective equipment for seed treatment the following statement is found on the bags of treated seed to protect workers from the dust that may come from bags of treated seed.

> This seed has been treated with [product name] fungicide containing [list of active ingredients]. Use chemical-resistant gloves when handling treated seed.

Environment

Standard seed treatment label statements will apply.

Next Steps

Before making a final registration decision on trifloxystrobin, 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

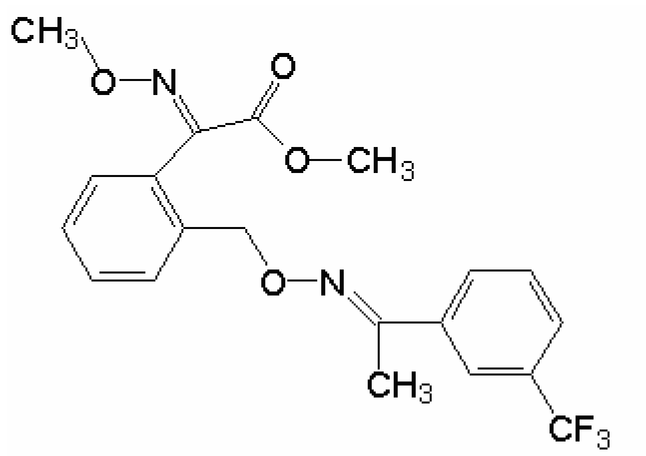
When the PMRA makes its registration decision, it will publish a Registration Decision on trifloxystrobin (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in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

Science Evaluation

Trifloxystrobin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Trifloxystrobin
Function	Fungicide
Chemical name:	
International Union of Pure and Applied Chemistry (IUPAC)	methyl (*E*)-methyoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate
Chemical Abstracts Service (CAS)	methyl (*E*,*E*)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetate
CAS number	141517-21-7
Molecular formula	$C_{20}H_{19}F_3N_2O_4$
Molecular weight	408.38
Structural formula	
Nominal purity of active	98.0% (Limits 96.0%, 100%)
Identity of relevant impurities of toxicological, environmental or other significance	The technical grade trifloxystrobin does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances

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

Technical Product—Trifloxystrobin Technical

Property	Result
Colour and physical state	White to off-white solid powder
Odour	Odourless to slightly sweet
Melting range	72.9°C
Boiling point or range	Approximately 312°C. Thermal decomposition begins about 285°C
Density	1.36 g/mL
Vapour pressure at 20°C	3.4×10^{-6} Pa by extrapolation
Henry's law constant at 20°C	$K = 2.25 \times 10^{-8}$ atm m^3/mol
Ultraviolet (UV)–visible spectrum	λmax **ε** Methanol: 250 17500 90% MeOH : +10% HCl 250 17300 252 15800 No absorption between 340 and 750 nm.
Solubility in water at 25°C	0.61 mg/L
Solubility in organic solvents at 25°C	**Solvent** **g/L** methanol 76 acetone >500 ethyl acetate >500 *n*-hexane 11 dichloromethane >500 toluene 500 *n*-octanol 18
n-Octanol–water partition coefficient (K_{ow})	Log K_{ow} = 4.5 at 25°C
Dissociation constant (pK_a)	No dissociation constant in the pH range 2–12.
Stability (temperature, metal)	No thermal effect observed between room temperature and the melting point. The product is compatible with stainless steel, galvanized sheet metal, tin plate and polyethylene. Iron steel shows a slight corrosion but no weight loss.

End-Use Products—Prosper T 200 and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, Trilex AL and Trilex FL Seed Treatment Fungicide

Property	Prosper 200	Prosper 400
Colour	Blue	Blue
Odour	Slight sweet odour	Slight sweet odour
Physical state	Liquid	Liquid
Formulation type	Aqueous suspension concentrate fungicide	Aqueous suspension concentrate fungicide
Guarantee	Clothianidin:142.8 g/L (138–147 g/L) Carbathiin: 50 g/L (47.5–52.5g/L) Trifloxystrobin: 7.14 g/L (6.5–7.9 /L) Metalaxyl: 5.36 g/L (4.8–5.9 g/L)	Clothianidin: 285.7 g/L (277–295 g/L) Carbathiin: 50 g/L (47.5–52.5 g/L) Trifloxystrobin: 7.14 g/L (6.5–7.9 g/L) Metalaxyl: 5.36 g/L (4.8–5.9 g/L)
Container material and description	High density polyethylene (HDPE) bottle	High density polyethylene (HDPE) bottle
Density	1.295 g/mL	1.315 g/mL
pH of 1% dispersion in water	8.26	8.26
Oxidizing or reducing action	The product contains no oxidizing or reducing agents	The product contains no oxidizing or reducing agents
Storage stability	No change after 12 months storage at ambient temperature	No change after 12 months storage at ambient temperature
Corrosion characteristics	Not corrosive	Not corrosive
Explodability	Not explosive	Not explosive

Property	Trilex AL	Trilex FL
Colour	Red	White
Odour	Faint odour, sort of plastic smell	Light odour reminiscent of propylene glycol
Physical state	Liquid	Liquid
Formulation type	Aqueous suspension concentrate	Aqueous suspension concentrate
Guarantee	Trifloxystrobin: 13.5 g/L (12.8–14.2 g/L) Metalaxyl: 10.8 g/L (10.3–11.3 g/L)	Trifloxystrobin: 240 g/L (233–247 g/L)
Container material and description	High density polyethylene (HDPE) bottle	High density polyethylene (HDPE) bottle
Density	1.06 g/mL	1.09 g/mL

Property	Trilex AL	Trilex FL
pH of 1% dispersion in water	5.02	7.38
Oxidizing or reducing action	Does not contain any oxidizing or reducing substances.	Does not contain any oxidizing or reducing substances.
Storage stability	No change after 12 months storage at ambient temperature	No change after 12 months storage at ambient temperature
Corrosion Characteristics	Not corrosive	Not corrosive
Explodability	Not explosive	Not explosive

1.3 Details of Uses and Further Information

Prosper T 200 and T 400 Flowable Insecticide and Fungicide Seed Treatment are systemic insecticide and fungicide seed treatments for use on canola and rapeseed to control flea beetles, seed rot and postemergent damping-off caused by *Pythium* spp., *Rhizoctonia solani, Fusarium* spp. and seed borne *Alternaria* spp.; seedling blight caused by *Pythium* spp., *Rhizoctonia solani, Fusarium* spp; early season root rot caused by *Pythium* spp. and seed borne blackleg. These products are for the protection of seeds and emerging seedlings only.

Trilex AL Seed Treatment Fungicide is a ready-to use seed treatment product for use on bean, chickpea, pea, lentil and soybean, for control of seed rot and damping-off caused by *Rhizoctonia solani, Fusarium* spp., and *Pythium* spp. and seed-borne *Botrytis cinerea* on lentil and seed-borne *Phomopsis longicolla* on soybean. It is a mixture of the fungicides trifloxystrobin and metalaxyl.

Trilex FL Seed Treatment Fungicide contains the fungicide trifloxystrobin and is for the control of seed rot and damping-off caused by *Rhizoctonia solani* and *Fusarium* spp. on canola, rapeseed, mustard, bean, chickpea, pea, lentil, and soybean; seed rot and pre-emergence damping-off caused by *Fusarium* spp. on corn as well as seed rot and damping-off caused by *Phomopsis longicolla* on soybean.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.3 Methods for Residue Analysis

The established enforcement method in plant and animal matrices is AG-659A (GC-NPD). Bayer Method Number 200177 (LC-MS/MS), a modified version of AG-659A, was developed for the determination of trifloxystrobin and CGA-321113 in tomato and pepper fruit. Bayer Method FL030919 (LC-MS/MS), a modified version of Bayer Method 200177, was developed for the determination of trifloxystrobin in soybean matrices. Bayer Methods 200177 and FL030919 fulfilled the requirements with regards to specificity, accuracy and precision at the limit of quantitation. Acceptable recoveries were obtained in plant matrices.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Regulatory Note REG2004 03, *Trifloxystrobin*, for a detailed assessment of the toxicological database for trifloxystrobin.

Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment
Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment (Basic) is of low acute toxicity via the oral (LD_{50} > 5000 mg/kg bw), dermal (LD_{50} > 5000 mg/kg bw) and inhalation routes (LC_{50} > 2.52 mg/L). It is minimally irritating to the eyes and the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment
Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment was similar to Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment and, therefore, the toxicity profile for Prosper T 400 was used as a surrogate for Prosper T 200. This was considered sufficient information for the registration of Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and no further toxicological data were required.

Trilex FL Seed Treatment Fungicide
Trilex FL Seed Treatment Fungicide (Basic) is of low acute toxicity via the oral (LD_{50} > 5000 mg/kg bw), dermal (LD_{50} > 5000 mg/kg bw) and inhalation routes (LC_{50} > 2.52 mg/L) in rats. It is minimally irritating to the eyes and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Trilex AL Seed Treatment Fungicide
Trilex AL Seed Treatment Fungicide has a low acute toxicity by the oral, dermal, and inhalation routes in rats. It was slightly irritating to the skin and minimally irritating to the eyes of rabbits. Trilex AL Seed Treatment Fungicide was not a dermal sensitizer in guinea pigs according to the Buehler Method.

3.2 Occupational and Residential Risk Assessment

3.2.1 Toxicological Endpoints

Workers that mix, load and treat seed commercially could be exposed for up to two months of the year (intermediate-term duration) and those that treat on-farm could be exposed for only a few days (short-term duration). For workers that plant treated seed, exposure is expected to be short-term in duration; because, planting can only happen during a period of less than a month.

Based on the anticipated exposure, the following endpoints were used for trifloxystrobin:

- Short-term oral endpoint (oral and inhalation)–based on a no observed adverse effect level (NOAEL) of 16.5 mg/kg bw/day from the 28-day oral study in rats with a target margin of exposure (MOE) of 100.
- Short-term dermal endpoint (dermal)–based on a NOAEL of 100 mg/kg bw/day from the 28-day dermal study in rats with a target MOE of 100.
- Intermediate endpoint (oral, dermal and inhalation)–based on a NOAEL of 3.8 mg/kg bw/day from the two-generation reproduction study with a target MOE of 100.

3.2.1.1 Dermal Absorption

In an in vivo dermal absorption study (PMRA# 1069477), groups of four male Sprague Dawley rats were administered nominal doses of 25 or 1120 μg/cm^2 trifloxystrobin in 100 μL of formulation to a 10 cm^2 area of the back, and were monitored for up to 48 hours postdosing. The skin wash was conducted at 8 hours and animals were sacrificed at 8, 24 or 48 hours.

The high dose used in the study exceeds the maximum recommended guideline dose, it is not considered to be useful to determine dermal absorption, saturation of the treated site may have occurred. At the low dose (25 μg/cm^2), the mean dermal absorption was 37.76% of the administered dose after 48 hours of exposure. Estimates of dermal absorption were based on the sum of residues retained at the skin site, in urine (including cage wash), in feces, in the carcass and in the blood. Skin bound residues were included in the calculation of dermal absorption as the exposure duration was not long enough to characterize skin bound residues. Based on these results, a dermal absorption value of 38% is considered appropriate for use in a risk assessment. This value is considered conservative as approximately 21% of the administered dose was retained at the skin site and it is unlikely that all of the skin bound residues will become systemically available.

3.2.2 Occupational Exposure and Risk

Workers that mix, load and apply a seed treatment commercially could be exposed for up to two months of the year and those that treat on-farm could be exposed for only a few days. For workers that plant treated seed, exposure is expected to be short-term in duration because planting can only happen over a period of less than a month.

3.2.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

A dust off study (PMRA# 1335562) designed to measure the potential dusting off of various seeds treated with different end-use products showed wheat has a higher dust potential than either the legumes or canola and formulation differences do not appear to impact dust potential within a crop grouping for the formulations tested. Therefore, extrapolating seed treatment exposure data from wheat seed treatment studies to either canola or legumes should not underestimate exposure.

In a study to assess the exposure of agricultural workers during the treatment and planting of wheat grain seeds, twelve trials were conducted with on-farm treater/planters and four were conducted with commercial applicators. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under a single layer of clean clothing. Workers wore normal work clothing and gloves, and most wore a hat and glasses. Inhalation exposure for each worker was measured by means of a personal air sampling pump with an OSHA Versatile Sampler tube containing a fibre filter and XAD-2 adsorbent.

The analytical method was validated for all matrices and recoveries were acceptable, ranging from 77% to 105%. Incurred residue values were adjusted based on the recovery of residues from the appropriate field fortification samples. Dermal and inhalation exposures were normalized for each worker based on the amount of active ingredient handled to give unit exposures. For farmers that mix/load/apply and plant treated seed, the mean unit exposure was 145.22 µg/kg a.i. handled for dermal and 7.61 µg/kg a.i. handled for inhalation. For commercial seed treatment workers that mix/load and apply, the mean unit exposure was 159.09 µg/kg a.i. handled for dermal and 1.20 µg/kg a.i. handled for inhalation. The majority of the exposure was through the dermal route with the greatest exposure usually being via contact with the worker’s hands. Inhalation exposure only accounted for 0.5–2% of the total exposure.

Worker activities and numbers of people involved vary at different seed treatment facilities depending on the size of the operation and degree of automation. Usually one worker prepares the treatment slurry (mixer/loader), which involves open transfer of the product into the premix tank for smaller containers and closed transfer for bulk containers. Another worker (often the mixer/loader) oversees the seed treatment area (treater/coater). One or more workers are involved in bagging the seeds as well as sewing, tagging and stacking seed bags. Most seed treatment plant workers have eight-hour shifts and workers may rotate duties to other areas.

Exposure and risk estimates are required for a farmer performing all tasks, including mixing, loading, calibrating, treating, and planting, for a short term duration of exposure (i.e. up to 30 days). Unit exposures (arithmetic mean) from the on-farm treater/planter study were used to estimate exposure while treating and planting (PMRA# 1335563).

Individuals in medium to large commercial facilities may rotate through and perform all tasks for an intermediate duration of exposure (i.e., up to 6 months). The worker exposure study monitored only single individuals performing mixer, loader and treater tasks in a small facility, but no bagging, sewing, or stacking activities were monitored. However, monitoring a single individual doing all the tasks should not underestimate exposure since larger facilities will rotate worker positions throughout the day and tend to use closed mixing and loading equipment.

Systemic exposure (mg/kg bw/day) =

$$\frac{\text{systemic unit exposure} \times \text{fraction absorbed} \times \text{application rate} \times \text{kg seeds treated/d} \times \text{conversion factor}}{\text{bw}}$$

A dermal absorption value of 38% was used for estimating systemic exposure and absorption from inhalation was considered to be 100%.

Depending on the size of the facility, type of seed treating equipment and type of seed being treated, seed treatment capacity varies from 10 000 kg to over 200 000 kg seed per day.

The following assumptions were used to calculate exposure estimates.

- Typical amount canola/mustard/rapeseed treated/day = 40 000 kg
- Typical amount corn seed treated/day = 60 000 kg
- Typical amount legume seed treated/day = 216 000 kg
- Amount seed treated/day (small facility) = 20 000 kg
- Typical amount legume seed treated/day (on farm) = 10 000 kg (PMRA# 1069475)
- Body weight = 70 kg

Margins of exposure (MOEs) for short and intermediate durations of exposure for treatment of seeds ranged from 400 to 1400 and are considered to be acceptable.

3.2.2.2 Exposure and Risk Assessment for Workers Planting Treated Seed

In a study to measure exposure of workers planting treated canola seeds, a dermal unit exposure of 424.17 µg/kg a.i. handled and an inhalation unit exposure of 1.11 µg/kg a.i. handled were considered appropriate for estimating exposure to farmers planting canola, corn, and soybean seeds treated with trifloxystrobin (PMRA# 1672418).

At a typical seeding rate of 6 kg/ha, a farmer could plant about 100 ha of canola in a day, handling 600 kg of seed. At the maximum application rate of 10 g a.i./100 kg seed, a farmer planting canola seed could handle 60 g a.i. per day. At a typical seed rate of 22 kg/ha, a farmer could plant 60 ha of corn per day, handling 1320 kg seed. At the maximum application rate of

5 g a.i./100 kg seed, a farmer planting corn seed could handle 66 g a.i. per day. At a typical seed rate of 90 kg/ha, a farmer could plant approximately 100 ha of legumes per day, handling 9,000 kg seed (PMRA# 1069475). At the maximum application rate of 5 g a.i./100 kg seed, a farmer planting legume seed could handle 450 g a.i. per day. A dermal absorption value of 38% was used for estimating systemic exposure and absorption from inhalation was considered to be 100%.

Systemic exposure (mg/kg bw/d) =

$$\frac{\text{unit exposure} \times \text{amount handled a.i. per day} \times \text{fraction absorbed}}{\text{bw}}$$

Where:

Dermal unit exposure = 424.17 µg/kg a.i. handled (body + hands)
Inhalation unit exposure = 1.11 µg/kg a.i. handled
Amount active ingredient handled/day planting canola/mustard/rapeseed = 0.060 kg
Amount handled/day planting corn = 0.066 kg
Amount handled/day planting legumes = 0.45 kg
Body weight = 70 kg

On-farm exposure is expected to be short-term. Target margins of exposure (MOEs) were achieved for workers planting treated canola, corn, and legume seed, while wearing a long-sleeved shirt, long pants and chemical-resistant gloves. Dermal MOEs ranged from 36 000 to 275 000 and inhalation MOEs ranged from 2 300 000 to 17 340 000; these values are considered to be acceptable.

3.2.3 Residential Exposure and Risk Assessment

3.2.3.1 Bystander Exposure and Risk

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

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant and Animal Foodstuffs

The established residue definition for enforcement in crops (primary and rotational) based on foliar application and in animals is trifloxystrobin and CGA-321113. For risk assessment, the established residue definition is trifloxystrobin and CGA-321113 in crops (primary and rotational) and in poultry. In ruminants the residue definition for risk assessment is trifloxystrobin and CGA-321113 in milk and all tissues except liver, and in liver is trifloxystrobin, CGA-321113 and the taurine conjugate of CGA-321113-metabolite $L7_A$.

The total radioactive residues were less than the LOQ (<0.005 ppm) in matrices of canola and corn plants and ranged from <0.005 ppm to 0.007 ppm in matrices of soybean plants grown from seed treated with radiolabeled trifloxystrobin at up to three times the approved label rates. Further characterization of the residues was not conducted and was not required as per DIR2003-02 (*Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States*). Maximum residue limits (MRLs) for trifloxystrobin as a seed treatment on the approved crops will therefore be proposed for residues of the parent compound trifloxystrobin at the LOQ of the established enforcement method AG659A. The data gathering method Bayer Method FL030919 is valid for the quantitation of trifloxystrobin residues in soybean and canola matrices. Supervised residue trials conducted in the United States with trifloxystrobin applied as a seed treatment on soybean at exaggerated rates indicated that residues of trifloxystrobin were below the limit of quantitation in forage, hay and progeny seed.

3.3.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model–Functional Configuration Identification (DEEM–FCID™, Version 2.3), which uses food consumption data from the United States Department of Agriculture’s Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.3.2.1 Chronic Dietary Exposure Results and Characterization

The following assumptions were made in a refined chronic analysis: default and experimental processing factors, median values for certain commodities and American tolerances for all other commodities. The refined chronic dietary exposure from all supported trifloxystrobin food uses (alone) for the total population and all representative population subgroups is <27.9% of the acceptable daily intake (ADI). The PMRA estimates that chronic dietary exposure to trifloxystrobin from food and water is 26.6% of the ADI (0.010 mg/kg bw/day) for the total population. The highest exposure and risk estimate is for all infants (<1 year) at 69.0% of the ADI (0.026 mg/kg bw/day). Aggregate exposure from food and water is considered acceptable.

3.3.2.2 Acute Dietary Exposure Results and Characterization

No endpoint of concern attributable to a single exposure for the general population (including children and infants) was identified in the oral toxicity studies.

3.3.3 Maximum Residue Limits

Table 3.3.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Legume vegetables (Crop Group 6), field corn, mustard seeds (condiment type), mustard seeds (oilseed type), popcorn grain, rapeseed (canola), sweet corn kernels plus cob with husks removed	0.02

For additional information on MRLs in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices (based on foliar application), analytical methodology and storage stability are summarized in Regulatory Note REG2004-03. The established residue definitions for trifloxystrobin in plants (foliar application) and animals are summarized in Appendix I, Table 4; the nature of the residue in plants (seed treatment), analytical methods, soybean field trial data (seed treatment) and chronic dietary risk estimates are summarized in Appendix I, Tables 1, 3 and 4.

4.0 Impact on the Environment

The properties, environmental fate and toxicity characterization of trifloxystrobin have been previously reviewed and reported in REG2004-03 and PRD2008-01.

4.1 Fate and Behaviour in the Environment

The properties, environmental fate and toxicity characterization of trifloxystrobin have been previously reviewed and reported in REG2004-03 and PRD2008-01. The proposed seed-treatment use will result in the release of less trifloxystrobin to the environment than the currently registered spray uses.

4.2 Effects on Non-Target Species

The effects on non-target species have been previously reviewed and reported in REG2004-03.

4.2.1 Effects on Terrestrial Organisms

The properties, environmental fate and toxicity characterization of trifloxystrobin have been previously reviewed and reported in REG2004-03. 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 risk quotient (RQ) was not exceeded; therefore, there is negligible risk to birds or mammals exposed to treated seed.

4.2.2 Effects on Aquatic Organisms

The effects on aquatic organisms have been previously reviewed and reported in REG2004-03 and PRD2008-01.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Intended Use

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment

These products are for use on canola and rapeseed at the rate of 1400 mL product/100 kg seed. They are intended for control of seed rot, postemergent damping-off, seedling blight, and early season root rot caused by *Pythium, Rhizoctonia*, *Fusarium*, and seed-borne *Alternaria* spp. They also control seed-borne blackleg and are for the protection of seeds and emerging seedlings only.

The insecticide component, clothianidin, is for control of flea beetles on seed and seedlings of canola (including *Brassica napus* and *Brassica rapa*) and rapeseed. Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment, applied at 1400 mL (200 g clothianidin) per 100 kg seed, is for use under low to moderate flea beetle pressure and will provide protection from flea beetle feedings up to the 2-leaf stage of canola and rapeseed. Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment, applied at 1400 mL (400 g clothianidin) per 100 kg seed, is for use under moderate to high flea beetle pressure and when longer season control of flea beetles is required, providing protection from flea beetle feeding up to the 4-leaf stage of canola and rapeseed.

Trilex AL Seed Treatment Fungicide
When applied at 370 mL/100 kg seed on bean, chickpea, pea, lentil and soybean, Trilex AL Seed Treatment Fungicide is intended to control seed rot and damping-off caused by *Rhizoctonia solani*, *Fusarium* spp. and *Pythium* spp., seed-borne *Botrytis cinerea*, seed-borne *Phomopsis* spp., and root rot caused by *Phomopsis* spp.

Trilex FL Seed Treatment Fungicide
When applied at 42 mL/100 kg seed, Trilex FL Seed Treatment Fungicide is intended to control seed rot and damping-off caused by *Rhizoctonia solani* on canola, rapeseed and mustard. When applied at 21 mL/100 kg seed, Trilex FL also controls the following:

- Seed rot and damping-off caused by *Rhizoctonia solani* and *Fusarium* spp. on pea, beans, chickpea, lentil and soybeans;
- Seed rot and pre-emergence damping-off caused by *Fusarium* spp. on corn;

- Seed-borne *Botrytis cinerea* on lentil; and
- Seed-borne *Phomopsis longicolla* on soybean.

5.1.2 Mode of Action

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and T 400 Flowable Insecticide and Fungicide Seed Treatment products contain the fungicides carbathiin, trifloxystrobin and metalaxyl. The Trilex formulations contain either trifloxystrobin alone or trifloxystrobin and metalaxyl. Trifloxystrobin is a systemic Group 11 fungicide and works by interfering with cellular respiration which ultimately prevents energy production in the fungal cell. Metalaxyl is a Group 4 fungicide, with systemic properties; it inhibits ribosomal Ribonucleic acid synthesis in target fungi. Carbathiin is a Group 7 Fungicide with systemic characteristics. It interferes with the mitochondrial transport chain, and ultimately with cellular respiration.

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment formulations also contain the insecticide clothianidin. Clothianidin is a broad-spectrum insecticide that belongs to the chemical compound class of neonicotinoids. Neonicotinoids are believed to interfere with the nicotinic acetylcholine receptors of the insect's nervous system, although different compounds may have specific binding site(s) or receptor(s). Clothianidin has a different mode of action than organophosphate, carbamate and pyrethroid insecticides. Clothianidin is reported to display systemic activity and act through contact and ingestion.

5.1.3 Crops

Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment products are both intended for use on canola and rapeseed.

Trilex AL Seed Treatment Fungicide is intended for use on bean, chickpea, pea, lentil and soybean, while Trilex FL Flowable Seed Treatment Fungicide is for use on canola, rapeseed, mustard, bean, chickpea, pea, lentil, soybean and corn.

5.1.4 Effectiveness Against Pests: Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatments

5.1.4.1 Control of Seed Rot (Pre-emergent Damping-Off)

Pythium

Five lab trials were conducted, four on *P. irregulare* (tested on four rapeseed varieties) and one on *P. ultimum* (on five different canola varieties). Percent germination was assessed seven days after planting. Results show Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment provided excellent control of seed rot on rapeseed caused by *P. irregulare* and *P. ultimum* (an average of 92% germination). For both pathogens, Prosper T 200 Flowable Insecticide and

Fungicide Seed Treatment resulted in emergence values similar to or better than the commercial standards.

Alternaria alternata

Four rapeseed trials tested for control of *A. alternata* by assessing the seeds either six or seven days after planting. Results show that seeds treated with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and inoculated with *A. alternata* resulted in an average of 93.5% germination, compared to the untreated seeds, which averaged 26% germination. Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment resulted in emergence values similar to or better than the commercial standards.

Rhizoctonia solani

Eight rapeseed or summer canola trials tested for control of *R. solani*, assessing the seeds either 13, 14, 18 or 20 days after planting. Results show that seeds treated with Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment and inoculated with *R. solani* resulted in an average of 69.1% germination, compared to the inoculated and uninoculated control seeds, which averaged 30.9% and 93.6% germination, respectively. When compared to the commercial standard, Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment treated seeds had statistically the same or better emergence.

Fusarium

Four rapeseed or summer canola trials tested for control of *F. avenaceum*, two tested for control of *F. solani*, and two trials were identified as testing for *Fusarium* spp. Seeds were assessed for emergence or stand count 13, 14 and 18, days after planting. Results showed that seeds treated with Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment had statistically greater emergence than the untreated seeds and had similar or better control compared to the commercial standard.

5.1.4.2 Control of Postemergent Damping-Off

Pythium

One trial assessed Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment on five canola varieties for control of *P. ultimum*. Assessments were made 3, 4, 7, 10, 14 and 20 days after planting. Results indicate that seeds treated with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment provided acceptable control of postemergent damping-off due to *P. ultimum*.

Alternaria

Three canola trials were reviewed for control of *A. alternata* and *A. brassicae* 12 to 13 days after planting. Results show that Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment provided only moderate suppression (not control) of postemergent damping-off caused by *A. alternata* and *A. brassicae*.

Rhizoctonia

Eleven trials were reviewed, nine on rapeseed and two on mustard. Data that assessed the seedlings prior to 18 days after planting (DAP) were not submitted for review. The bulk of the trials assessed crops between 23 DAP and 137 DAP (harvest). Trials with a single emergence/stand count were not assessed because there was no way to determine if seedling loss has occurred over time.

***Rhizoctonia* on Rapeseed**

Data trends showed that seed counts in almost all trials decreased from 31 to 50 DAP, suggesting seedling death did occur as a result of postemergent damping-off or flea beetle damage (in some trials). Treating seeds with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment resulted in consistently higher seed counts compared to untreated, inoculated seeds, although trends indicate that seedling loss still occurred. Stand counts were consistently similar to or better than the commercial standard.

***Rhizoctonia* on Mustard**

Two mustard trials tested Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment applied at the proposed and half the proposed rate. Results showed that the half rate resulted in lower stand counts. However, the difference between the two rates was not statistically significant.

***Fusarium*:**

Of the five trials submitted, only two were used to assess the claim of control of postemergent damping-off, as the others assessed only a single stand. The data showed that Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment provided control of postemergent damping-off, as demonstrated by little or no loss in stand count during the assessment periods. In comparison to the commercial standard, Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment provided control of postemergent damping-off caused by *Fusarium* spp.

5.1.4.3 Control of Seedling Blight

Pythium

There were insufficient data provided to assess the claim of control of seedling blight, since there was no information provided on the health of the stand and no data on the plants at 20 DAP. However, it has been clearly established in previous submissions and in published literature that metalaxyl has good activity against *Pythium*. The metalaxyl rate proposed for Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment is the same as that on the Prosper FL Flowable Insecticide and Fungicide Seed Treatment (Registration Number 27564) label and the data provided clearly demonstrated similar efficacy for the two products. Therefore, the claim that Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment will control seedling blight caused by *Pythium* is supported.

Alternaria

There were insufficient data provided to assess the claim of control of seedling blight, as there was no information provided on the health of the stand and there were no data on the plants past 13 DAP. Therefore, this claim cannot be supported.

Rhizoctonia

No data that assessed the health of the plants were submitted, which is necessary to evaluate this claim. However, season-long stand counts (at least three assessments within a season) were conducted in four trials. Results showed that under low inoculation, stand counts from the treatment with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment were not statistically different from either the uninoculated check, the inoculated check, or the commercial standard. However, under high inoculation levels, stand counts from the treatment with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment were significantly higher than the inoculated check, and similar to or better then the commercial standards.

Fusarium

No data were submitted which assessed the health of the plants, which is necessary to evaluate this claim. Season long stand counts (at least three assessments within a season) were collected in one trial only. Results showed no significant differences between any of the check treatments and the rest of the fungicides tested for the first two assessments. However, for the final assessment, treatment with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment demonstrated a significantly higher stand count compared to the check treatments, but not significantly different from the commercial standard.

5.1.4.4 Control of Early Season Root Rot

Pythium

No data were submitted that assessed the claim of control of early season root rot (data that actually assessed the roots for the presence of disease). However, it has been clearly established in previous submissions and in published literature that metalaxyl has good activity against *Pythium*. The metalaxyl rate proposed for Prosper T 200 is the same as that on the Prosper FL Flowable Insecticide and Fungicide Seed Treatment (Registration Number 27564) label, and the data provided clearly demonstrated similar efficacy for the two products. Therefore, the proposed claim that Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment will control root rot caused by *Pythium* spp. will be supported.

Alternaria*, *Rhizoctonia* and *Fusarium

No data were submitted that assessed the claim of control of early season root rot (data that actually assessed the roots for the presence of disease) for these three pathogens. Bayer Crop Science acknowledged that they did not generate data to assess this deficiency. Therefore, these claims cannot be assessed.

5.1.4.5 Control of Seed-Borne Blackleg

One study was reviewed that assessed four varieties of canola for evidence of seed-borne *Phoma lingam* (asexual stage of the blackleg pathogen) after 7 or 14 days of germination. Results were consistent across all trials, with seeds from the untreated check having between 11% and 27% disease incidence levels, while seeds from all other fungicide treatments (with the exception of one) had no visible disease incidence.

5.1.4.6 Long-Term (18-Month) Storage Trials (Germination Studies)

In the 3 long-term, 18-month storage and germination studies, results showed that seeds treated with Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and stored prior to germination resulted in 88.5%, 92.5% and 96% germination by 7 DAP. This is acceptable to support this claim.

5.1.4.7 Control of Flea Beetles (Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment)

Five field trials were conducted in Saskatchewan to test the efficacy of Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment for the control of flea beetles in canola. In all studies, at all assessment times (cotyledon, 1- to 2-leaf stage, 3- to 4-leaf stage, from DAP 21 up to 42), the proposed product performed at least as well as the commercial standard treatment (Prosper FL + Poncho 600 FS). As well, flea beetle damage was significantly lower for Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment compared to both the treated and untreated controls up to the 2-leaf stage of development.

5.1.4.8 Control of Flea Beetles (Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment)

Twelve studies were conducted to test the efficacy of Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment for the control of flea beetles in canola. These studies included three from Alberta and nine from Saskatchewan. In all studies, at all assessment times (cotyledon, 1- to 2-leaf stage, 3- to 4-leaf stage, from DAP 9 up to 42), there were no significant differences between the commercial standard treatment (Prosper FL + Poncho 600 FS) and the Prosper T 400 treatment. As well, flea beetle damage was significantly lower for the Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment compared to both the treated and untreated controls up to the 4-leaf stage of development.

5.1.5 Effectiveness Against Pest: Trilex AL

5.1.5.1 Control of Seed Rot/Pre-Emergence Damping-Off and Postemergence Damping-Off

***Pythium* spp.**

Twelve laboratory trials and ten greenhouse pot trials on pea, soybean, lentil, chickpea and bean were submitted to support the claims. All trials had adequate disease pressure. The results show that Trilex AL Seed Treatment Fungicide provided control of seed rot/pre-emergence damping-off caused by *Pythium* spp. on pea, lentil, chickpea, soybean and bean. The claim for control of postemergence damping-off caused by *Pythium* spp on these legume crops can be supported based on metalaxyl's systemic movement within plants as well as the well-established activity of metalaxyl on oomycete pathogens, including *Pythium* spp.

***Fusarium* spp.**

Twenty field trials conducted in Canada on pea (five), chickpea (two), bean (three), lentil (eight) and soybean (two) were submitted to support the claims. Generally, the results showed that the percent emergence or plant stand counts were significantly increased by the application of trifloxystrobin. The data support the claims for control of (a) seed rot/pre-emergence damping-off in pea, lentil and bean, and (b) postemergence damping-off in chickpea and pea. The following claims can be supported based on data from pea, lentil, chickpea and bean because *Fusarium* species attack these crops and the disease development follows the same pattern: (a) control of seed rot/pre-emergence damping-off in chickpea and soybean, and (b) control of postemergent damping-off in lentil, bean, and soybean.

Rhizoctonia solani

Twenty-six field trials on peas, chickpea, bean, lentil and soybean were submitted to support the claims. The results show that control of seed rot/pre-emergence damping-off was obtained. Control of postemergence damping-off was demonstrated in the lentil trials. The data support the claims for control of (a) seed rot/pre-emergence damping-off in pea, lentil, chickpea, soybean and bean, and (b) postemergence damping-off in lentil. Control of postemergent damping-off in pea, chickpea, pea, bean, and soybean can be supported based on data from lentil because *R. solani* attacks these crops and the disease development follows the same pattern.

5.1.5.2 Control of Seed Rot, Damping-Off and Seedling Blight Caused By Seed-Borne *Botrytis Cinerea* on Lentil

Eleven field trials were submitted to support the claims. The results show that Trilex AL Seed Treatment Fungicide provided control of seed rot and pre-emergence and postemergence damping-off. The trials also demonstrated that the number of healthy plants in plots treated with trifloxystrobin plus metalaxyl was comparable to those treated with the commercial standard. The data support the claim for control of seed rot/pre-emergence damping-off and postemergence damping-off and seedling blight caused by seed-borne *Botrytis cinerea* on lentil.

5.1.5.3 Control of Seed Rot, Damping-Off and Seedling Blight Caused By Seed Borne *Phomopsis Longicolla* on Soybean

Three laboratory trials and thirteen field trials were submitted to support the claims. The proposed rate was tested in the field trials. In the laboratory trials, both 2.5 g and 5.0 g trifloxystrobin/100 kg seed were tested. The data support the claim for the control of seed rot/pre-emergence damping-off caused by *Phomopsis* spp. on soybean. The claim for control of postemergence damping-off caused by *Phomopsis* spp. on soybean is not supported and was withdrawn by the applicant.

5.1.5.4 Long-Term Storage and Compatibility with Rhizobium-Based Inoculants

In laboratory germination trials using pea (2), chickpea (3), dry bean (1) and soybean (3), seeds stored from 6 to 408 days showed that treatment with trifloxystrobin and metalaxyl did not affect seedling counts and percentage of emergence. Four field trials (two lentil, one field pea and one chickpea) using seed stored for 313 days prior to the germination test demonstrated that no negative effects on the percentage of emergence resulted from fungicide treatment. The overall finding was that Trilex AL Seed Treatment Fungicide at the 1× and 2× rates did not produce any adverse effect on the germination of treated seed stored for various time periods. Trilex AL performed as well as the commercial standards.

A total of thirteen trials on chickpea (four), dry bean (two), field pea (three), and lentil (four) showed that treatment of seeds with trifloxystrobin and metalaxyl did not affect nodulation or nitrogen fixation. Trilex AL Seed Treatment Fungicide was compatible with Rhizobia used to inoculate seeds of these legume crops.

5.1.6 Effectiveness Against Pests: Trilex FL

5.1.6.1 Control of Seed Rot/Pre-Emergence Damping-Off and Postemergence Damping-Off

***Fusarium* spp.**

Six trials were submitted to support the claims on legume crops: chickpeas (three), lentils (two), soybeans (one). No trials were provided for beans and peas. The data showed that trifloxystrobin provided similar control to the commercial standards. The data support the claims for control of (a) seed rot/pre-emergence damping-off caused by *Fusarium* spp. on lentil and (b) postemergence damping-off caused by *Fusarium* spp. on chickpea and soybean. The following claims can be supported based on extrapolation from soybean, chickpea and/or lentil data, because *Fusarium* spp. attack these crops and the disease development follows the same pattern: (a) control of seed rot/pre-emergence damping-off and postemergence damping-off in pea and bean; (b) control of postemergent damping-off in lentil; and (c) control of seed rot/pre-emergence damping-off in chickpea and soybean.

Four laboratory trials and four field trials were submitted to support the claims on corn. All the field trials had high disease pressure and tested the 1× and 2× rates. The data showed that emergence was consistently increased by the seed treatment with trifloxystrobin. The data support the claim for control of seed rot/pre-emergence damping-off caused by *Fusarium* spp. on corn. The supported claim can be extrapolated to popcorn from field studies on sweet corn and field corn.

Rhizoctonia solani

Five trials on canola were submitted. Multiple emergence/plant stand measurements were reported. Trilex FL Seed Treatment Fungicide provided adequate seed rot/pre-emergence and postemergence damping-off control. Three of the five trials compared the proposed rate (10 g a.i./100 kg seed) with half the proposed rate (5 g a.i./100 kg seed). The data showed that the proposed rate (42 mL/100 kg seed) consistently provided higher emergence than the half rate (21 mL/100 kg seed).

No data were submitted for rapeseed. However, claims supported for canola can be extended to rapeseed since they are very closely related. In addition, *R. solani* has been reported as a pathogen of rapeseed and the seed and seedling diseases it causes will develop in the same way as in canola.

One trial on *B. juncea* was submitted. Plant stands at 6 and 13 DAP were recorded. The data showed that emergence/plant stands were significantly increased by the application of Trilex FL Seed Treatment Fungicide. The data also showed that Trilex FL provided adequate control of postemergence damping-off. Although only one trial was provided for mustard, the trials provided for canola and rapeseed can be considered to support the claim on mustard because these plant species are closely related and infection by *R. solani* follows the same pattern in these crops.

A total of seven trials were submitted for legume crops: lentil (three), pea (three) and soybean (one). No data were submitted for beans and chickpeas. Disease pressure in the trials ranged from low to high. The trials compared the proposed rate (5 g a.i./100 kg seed) with half the proposed rate (2.5 g a.i./100 kg seed). The data showed that the proposed rate consistently provided higher emergence than the half rate. The results demonstrated that emergence counts were significantly different from controls and were comparable to commercial standards. The data support the claims for control of (a) seed rot/pre-emergence damping-off and postemergence damping-off caused by *R. solani* on pea and lentil and (b) seed rot/pre-emergence damping-off caused by *R. solani* on soybean. The following claims on bean, chickpea, and soybean can be supported based on extrapolation from pea and lentil data because *R. solani* attacks these crops and the disease development follows the same pattern: (a) control of seed rot/pre-emergence damping-off and postemergence damping-off caused by *R. solani* on chickpea and bean and (b) control of postemergent damping-off in soybean.

5.1.6.2 Control of Seed Rot/Pre-Emergence Damping-Off and Postemergence Damping-Off Caused By *Phomopsis Longicolla* on Soybean

Two lab trials and one field trial with moderate disease pressure were submitted to support the claims. Both the 1× and 0.5× rates were tested. The data showed that percentage germination was significantly increased in one trial, but no increase was observed in the other study showing an inconsistency in results. Evidence presented in six additional trials indicated that trifloxystrobin controlled seed rot/pre-emergence damping-off as well as or better than the commercial standards. The claim for postemergent damping-off on soybean was withdrawn at the request of the registrant. No additional data were provided using immature soybean seed.

5.2 Phytotoxicity to Target Plants or to Target Plant Products

No phytotoxicity to host plants was reported in any of the fungicide or insecticide trials.

5.3 Impact on Succeeding Crops, Adjacent Crops and Treated Plants or Plant Products Used for Propagation

Not assessed.

5.4 Economics

Not assessed.

5.5 Sustainability

5.5.1 Survey of Alternatives

A list of alternatives can be found in Appendix I, Tables 7 to 10.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Use of a seed treatment product is consistent with standard preventative integrated pest management practices for canola and rapeseed. The proposed seed treatment, Trilex AL Seed Treatment Fungicide, is also compatible with current management practices in pulse production under both conventional and integrated pest management programs, particularly because it has little or no activity against most of the beneficial insect and mite predators that do not feed directly on the host plant's tissues.

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

One approach for managing the development of fungicide resistance in plant pathogens is the use of mixtures of fungicides with different modes of action. The Prosper T 200 and T 400 Flowable Insecticide and Fungicide Seed Treatment products contain three fungicides with different modes of action (Group 4, 7 and 11 Fungicides). In Trilex AL Seed Treatment Fungicide, trifloxystrobin (Group 11) is combined with metalaxyl (Group 4). Furthermore, selection pressure is expected to be low for seed treatments since they are applied only once per season. Therefore, a minimal risk of fungicide resistance is associated with this use pattern.

As clothianidin has a similar mode of action to other chloro-nicotinic compounds (Group 4 Insecticides), appropriate resistance-management strategies should be followed, including rotating the use of these products with different groups that control the same pest.

5.5.4 Contribution to Risk Reduction and Sustainability

Replacement of thiram (currently part of the existing Prosper formulation registered in Canada) with trifloxystrobin, which is a reduced risk fungicide, contributes to the risk reduction. In addition, these seed treatment products contribute to risk reduction through the use of low rates, precise soil placement resulting in exposure being limited to target crops and reduced exposure to workers handling the product or the treated seed because less product is handled.

5.6 Summary of Supported and Unsupported Disease Claims

Tables 11 to 19 in Appendix I summarize the supported and unsupported claims.

6.0 Pest Control Product Policy Considerations

The TSMP characterization of trifloxystrobin, transformation products and formulants has been previously reviewed and reported in the Regulatory Note REG2004-03, *Trifloxystrobin*.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for trifloxystrobin is adequate to define the majority of toxic effects that may result from human exposure to trifloxystrobin. In subchronic and chronic studies on laboratory animals, the primary target was the liver in rats, mice and dogs, with the exception of the long-term study in rats where pituitary gland developmental cysts occurred in males and females and angiomatous hyperplasia of the mesenteric lymph nodes occurred only in males at lower doses than the liver effects. There was no evidence of carcinogenicity in rats or mice after longer-term dosing. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Trifloxystrobin is not considered to be a neurotoxicant.

Mixers, loaders and applicators handling trifloxystrobin and workers planting treated seed are not expected to be exposed to levels of trifloxystrobin that will result in an unacceptable risk when the Trilex AL, Trilex FL Prosper T 200 and Prosper T 400 are used according to label directions. The personal protective equipment on the product labels is adequate to protect workers.

Radiotracer studies conducted in canola, corn and soybean indicated that it is unlikely there would be any quantifiable residues of trifloxystrobin in crops harvested from seed treated according to the approved label rates. The proposed use of trifloxystrobin as a seed treatment on commodities in Crop Group 6, Legume Vegetables (Succulent or Dried), mustard seed (oilseed and condiment types), rapeseed (canola), field corn, popcorn and sweet corn does not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. The PMRA recommends that the following maximum residue limits be specified under the authority of the *Pest Control Products Act* for residues of trifloxystrobin in and on:

- field corn (0.02 ppm);
- legume vegetables (Crop Group 6) (0.02 ppm);
- mustard seeds (condiment type) (0.02 ppm);
- mustard seeds (oilseed type) (0.02 ppm);
- popcorn grain (0.02 ppm);
- rapeseed (canola) (0.02 ppm); and
- sweet corn kernels plus cob with husks removed (0.02 ppm).

7.2 Environmental Risk

The proposed use of trifloxystrobin as a seed treatment will not present any unacceptable risk to the environment.

7.3 Value

The value of Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment is that the products are effective in controlling the listed seed and seedling diseases and insect pest. In addition, the reduced-risk fungicide trifloxystrobin is a replacement for thiram.

Trilex AL Seed Treatment and Trilex FL Seed Treatment also contain the reduced-risk fungicide trifloxystrobin as a replacement for thiram. These products can be used simultaneously with liquid seed inoculants.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Trifloxystrobin Technical Fungicide, Trilex AL Seed Treatment Fungicide and Trilex FL Seed Treatment Fungicide, containing the technical grade active ingredient trifloxystrobin.

The PMRA is proposing conditional registration for the sale and use of Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment and Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment containing the active ingredient trifloxystrobin due to the conditional registration status of clothianidin, one of the other active ingredients in these end-use products.

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

List of Abbreviations

µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DAP	days after planting
DF	dry flowable
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in the test population)
DT_{75}	dissipation time 75% (the dose required to observe a 75% decline in the test population)
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
ER_{25}	effective rate for 25% of the population
GC-NPD	gas chromatography with a nitrogen phophorus detector
g	gram
ha	hectare(s)
HAFT	highest average field trial
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol – water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre(s)
mg	milligram
mL	millilitre

MAS	maximum average score
MIS	maximum irritation score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
Nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon
OM	organic matter
Pa	pascal
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
RSD	relative standard deviation
RQ	risk quotient
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Plant	AG-659A	Trifloxystrobin and CGA-321113	Data Gathering and Enforcement (GC-NPD)	0.02 ppm per analyte	All plant matrices except peanut hay	REG2004-03
				0.05 ppm per analyte	Peanut hay	
	Bayer Method No. 200177	Trifloxystrobin and CGA-321113	Data Gathering (LC-MS/MS)	0.01 per analyte	Pepper fruit; Tomato fruit	1554046
	Bayer Method No. FL030919	Trifloxystrobin	Data Gathering (LC-MS/MS)	0.01	Soybean—forage, hay and seed; canola seed	1554047; 1069482; 1069486
Animal	AG-659A	Trifloxystrobin and CGA-321113	Data Gathering and Enforcement (GC-NPD)	0.02 per analyte	All animal matrices except milk	REG2004-03
				0.01 per analyte	Milk	

Table 2 Summary of Acute Toxicity Studies with Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment (Basic) and Label Recommendations

Parameter	Species	Result
Acute Oral LD$_{50}$ (425)	3 Sprague-Dawley rats/sex/dose at 5000 mg/kg	LD$_{50}$ ♀ >5000 mg/kg
Acute Dermal LD$_{50}$	5 Sprague-Dawley rats/sex/dose at 5000 mg/kg	LD$_{50}$ ♂♀ >5000 mg/kg
Acute Inhalation LC$_{50}$	5 Sprague-Dawley rats/sex/dose at 2.52 mg/L	LC$_{50}$ ♂♀ >2.52 mg/L
Primary Eye Irritation	3 New Zealand Albino rabbits (2 males, 1 female) at 0.1 mL for 24 hours	MIS[a] = 12/110 MAS[b] = 2.22/110
Primary Skin Irritation	3 female New Zealand Albino rabbits/dose at 0.5 mL for 4 hours	MIS[a] =3/8 MAS[c] = 0.33/8
Skin Sensitisation	20 female Hartley albino guinea pigs/dose	Negative
Buehler	10 females for naive control	
	Topical application of 0.4 mL 100% solution for 3 weeks as induction	
	Topical application fo 0.4 mL 50% solution on 4th week as challenge	

[a] MIS = Maximum irritation score (at 1 hour)
[b] MAS = Maximum average score (for 24, 48 and 72 hours)
[c] MAS = Maximum average score (for 1, 24 and 72 hours)

Table 3 Summary of Acute Toxicity Studies with Trilex FL Seed Treatment Fungicide (Basic) and Label Recommendations

Parameter	Species	Result
Acute Oral LD_{50} (401)	5 Sprague-Dawley rats/sex at 5000 mg/kg	LD_{50} ♂♀ >5000 mg/kg
Acute Dermal LD_{50}	5 Sprague-Dawley rats/sex at 5000 mg/kg	LD_{50} ♂♀ >5000 mg/kg
Acute Inhalation LC_{50}	5 Sprague-Dawley rats/sex at 2.52 mg/L	LC_{50} ♂♀ >2.52 mg/L
Primary Eye Irritation	3 New Zealand Albino rabbits/sex at 0.1 mL for 24 hours	MISa = 5/110 MAS[b] = 0.44/110
Primary Skin Irritation	6 male New Zealand Albino rabbits at 0.5 mL for 4 hours	MIS[a] = 1/4 MAS[b] = 0.17
Skin Sensitisation	20 male Hartley albino guinea pigs	Negative
Buehler	10 males for naive control	
	Topical application of 0.4 mL 100% solution for 3 weeks as induction	
	Topical application of 0.4 mL 100% solution on 4th week as challenge	

[a] MIS = Maximum irritation score (at 1 hour)
[b] MAS = Maximum average score (for 24, 48 and 72 hours)

Table 4 Summary of Acute Toxicity Studies with Trilex AL Seed Treatment Fungicide (Basic) and Label Recommendations

Study Type	Species	Result	Comment	Reference
Oral	Rat	LC_{50} (females) > 5000 mg/kg bw	Low toxicity	1069198
Dermal	Rat	LC_{50} > 5000 mg/kg bw	Low toxicity	1069199
Inhalation	Rat	LC_{50} > 2.55 mg/L	Low toxicity	1069200
Skin Irritation	Rabbit	MAS = 0/8 MIS = 1/8	Slightly irritating	1069202
Eye Irritation	Rabbit	MAS = 0/110 MIS = 2/110	Minimally irritating	1069201
Skin Sensitization	Guinea pig	Negative	Not a dermal sensitizer	1069203

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN CANOLA		PMRA# 1069485
Radiolabel Position	[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin	
Test Site	Canola seeds, planted into separate metal tubs filled with sandy loam soil, were grown outdoors.	
Treatment	Seed treatment	
Rate	5.52 g a.i./100 kg seed (55.2 ppm) or 11.0 g a.i./100 kg seed (110 ppm)	
End-use product	Not reported	
Preharvest interval	Samples of whole canola plants were harvested 119 days after planting (DAP). The harvested canola plants were spread to dry on separate tables in the greenhouse for four days.	
Matrix	**DAP**	[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin
		Mean TRR (ppm)
		5.52 g a.i./100 kg seed (55.2 ppm)

Canola Seed	52	<0.005	
		11.0 g a.i./100 kg seed (110 ppm)	
Canola Seed	52	<0.005	
NATURE OF THE RESIDUE IN CORN			**PMRA# 1069483**
Radiolabel Position	[benzeneacetic acid-phenyl-UL-^{14}C]-trifloxystrobin		[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin
Test Site	Corn seeds, planted into separate metal tubs filled with sandy loam soil, were grown outdoors.		
Treatment	Seed treatment		
Rate	5.51 g a.i./100 kg seed (55.1 ppm) or 11.02 g a.i./100 kg seed (110.2 ppm) or 16.54 g a.i./100 kg seed (165.4 ppm)		5.3 g a.i./100 kg seed (53 ppm) or 10.59 g a.i./100 kg seed (105.9 ppm) or 15.89 g a.i./100 kg seed (158.9 ppm)
End-use product	Not reported		
Preharvest interval	Corn forage and sweet corn (kernels plus cob with husk removed) were harvested 73 days after planting (DAP); corn stover and corn grain were harvested 132 DAP.		
Matrix	**DAP**	[benzeneacetic acid-phenyl-UL-^{14}C]-trifloxystrobin	[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin
		Mean TRR (ppm)	**Mean TRR (ppm)**
		5.51 g a.i./100 kg seed (55.1 ppm)	5.3 g a.i./100 kg seed (53 ppm)
Corn Forage	73	<0.005	<0.005
Sweet Corn	73	<0.005	<0.005
Corn Grain	132	<0.005	<0.005
Corn Stover	132	<0.005	<0.005
		11.02 g a.i./100 kg seed (110.2 ppm)	10.59 g a.i./100 kg seed (105.9 ppm)
Corn Forage	73	<0.005	<0.005
Sweet Corn	73	<0.005	<0.005
Corn Grain	132	<0.005	<0.005
Corn Stover	132	<0.005	<0.005
		16.54 g a.i./100 kg seed (165.4 ppm)	15.89 g a.i./100 kg seed (158.9 ppm)
Corn Forage	73	<0.005	<0.005
Sweet Corn	73	<0.005	<0.005
Corn Grain	132	<0.005	<0.005
Corn Stover	132	<0.005	<0.005
NATURE OF THE RESIDUE IN SOYBEAN			**PMRA# 1069480 and 1069481**
Radiolabel Position	[benzeneacetic acid-phenyl-UL-^{14}C]-trifloxystrobin		[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin
Test Site	Soybean seeds, planted into separate metal tubs filled with sandy loam soil, were grown outdoors.		
Treatment	Seed treatment		
Rate	5.53 g a.i./100 kg seed (55.3 ppm) or 11.1 g a.i./100 kg seed (111 ppm)		5.52 g a.i./100 kg seed (55.2 ppm) or 11.0 g a.i./100 kg seed (110 ppm)
End-use product	Not reported		

Preharvest interval	• 52 DAP (soybean forage); 70 DAP (soybean hay); 126 DAP (soybean seed). • The harvested soybean hay samples were spread to dry on separate tables in the greenhouse for four days.		
Matrix	**DAP**	[benzeneacetic acid-phenyl-UL-^{14}C]-trifloxystrobin	[trifluoromethyl-phenyl-UL-^{14}C]-trifloxystrobin
		Mean TRR (ppm)	**Mean TRR (ppm)**
		5.53 g a.i./100 kg seed (55.3 ppm)	5.52 g a.i./100 kg seed (55.2 ppm)
Soybean Forage	52	<0.005	<0.005
Soybean Hay	70	<0.005	<0.005
Soybean Seed	126	<0.005	<0.005
		11.1 g a.i./100 kg seed (111 ppm)	11.0 g a.i./100 kg seed (110 ppm)
Soybean Forage	52	0.006	<0.005
Soybean Hay	70	0.007	0.007
Soybean Seed	126	<0.005	<0.005

Summary of the Metabolism in Plants Following Seed Treatment

The plant metabolism studies were conducted at 0.6–1.1× (canola), 1.1–3.3× (corn) and 1.1–2.2× (soybean) the respective approved label rates. The total radioactive residues (TRR) (trifloxystrobin equivalents) were less than the LOQ (<0.005 ppm) in canola seed, corn forage, sweet corn, stover and grain and in soybean seed. Residues were only slightly above the LOQ in soybean forage (0.006 ppm; benzeneacetic acid-phenyl label only) and in soybean hay (0.007 ppm; both labels) at treatment rates of 11.0–11.1 g a.i./100 kg seed (2.2× the approved label rate). As the TRR ranged from <0.005 ppm (<LOQ) to 0.007 ppm in all plant matrices analyzed, further characterization of the TRR was not conducted and was not required. According to DIR2003-02 *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States*, when the radiolabeled data for a crop grown from treated seed show no uptake of residues to the aerial portion and root portion of the crop (both human and livestock consumption), i.e. the TRR in all plant tissues is less than 5 ppb, no further studies are required. However, the analytical methodology is always required. A MRL would be established at the LOQ of the method provided.

STORAGE STABILITY	**REG2004-03**

The data indicated that residues of trifloxystrobin and its acid metabolite, CGA-321113, were relatively stable at 18^{o}C for 24 months in grapes, cucumbers, potatoes and wheat (plant, straw and grain) and for 18 months in apples (fruit and wet pomace), peanuts (nutmeats, hay and oil), potato granules and grape juice.

CROP FIELD TRIALS ON SOYBEAN PROCESSED FOOD AND FEED- SOYBEAN	**PMRA# 1069486, 1555987, 1560357 and 1069489**

Three crop field trials were conducted in the United States in zone 4 (Mississippi) and zone 5 (Kansas and Indiana) during the 2002 growing season to evaluate the magnitude of the residue of trifloxystrobin in/on soybean. For the domestic registration on soybean, DIR98-02 recommends a total of 12 trials with 11 trials in zone 5 and 1 trial in zone 5B. At each test location, soybean seeds were treated with trifloxystrobin (Flint 50 WG; 50% trifloxystrobin) at either 25.2 g a.i./100 kg seed (252 ppm) or 50.1 g a.i./100 kg seed (501 ppm). The target treatment rates were 250 ppm (25 g a.i./100 kg seed) and 500 ppm (50 g a.i./100 kg seed). An adjuvant was not used. Soybean matrices were harvested 49–62 (green forage), 62–78 (hay) and 113–183 (mature seed) days after planting (DAP). Harvested hay samples were dried in the field or under shelter for 2–7 days. Only the soybean samples harvested from seeds treated at the 501 ppm treatment rate were analyzed. The LOQ was reported as 0.01 ppm in soybean forage, hay and seed.

<table>
<tr><th rowspan="2">Commodity</th><th rowspan="2">Seed Treatment Rate (g a.i./100 kg seed)</th><th rowspan="2">DAP</th><th colspan="7">Trifloxystrobin Residue Levels (ppm)</th></tr>
<tr><th>n</th><th>Min.</th><th>Max.</th><th>HAFT</th><th>Median (STMdR)</th><th>Mean (STMR)</th><th>Std. Dev.</th></tr>
<tr><td>Soybean Forage</td><td rowspan="3">50.1</td><td>49–62</td><td>6</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td>0</td></tr>
<tr><td>Soybean Hay</td><td>62–78</td><td>6</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td>0</td></tr>
<tr><td>Soybean Seed</td><td>131–183</td><td>5</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td><0.01</td><td>0</td></tr>
<tr><td colspan="10">A rationale was submitted by the applicant to waive the requirements for the location and number of residue trials for soybeans, for a soybean processing study and for additional data for the other members of Crop Group 6– legume vegetables. The basis of the rationale is i) residue levels detected in harvested soybeans following application at a 10× rate were below the LOQ for forage, hay and seed, ii) data generated from a radiolabeled tracer study indicated that residues will not exceed the LOQ in the harvested portion of the plant and iii) the similarity in harvest and planting for all members of Crop Group 6– legume vegetables. The basis of this rationale was deemed acceptable.</td></tr>
<tr><td colspan="7">CROP FIELD TRIALS ON CANOLA, RAPESEED AND MUSTARD
PROCESSED FOOD AND FEED–CANOLA, RAPESEED AND MUSTARD</td><td colspan="3">PMRA# 1069487 and 1068808</td></tr>
<tr><td colspan="10">The applicant submitted a rationale to waive the field trial data requirements and processing studies for canola, rapeseed and mustard-condiment and oilseed types. The basis of the rationale is that i) data generated from the radiolabeled tracer study on canola indicated that residues will not exceed the LOQ in the harvested portion of the plant, ii) based on the maximum 3× concentration factor for canola seed, residues in canola oil are unlikely to approach the LOQ and iii) the similarity between canola, rapeseed and mustard make additional data unnecessary. The basis of this rationale was deemed acceptable.</td></tr>
<tr><td colspan="7">CROP FIELD TRIALS ON CORN–SWEET, POPCORN AND FIELD
PROCESSED FOOD AND FEED–CORN</td><td colspan="3">PMRA# 1069488</td></tr>
<tr><td colspan="10">The applicant submitted a rationale to waive the field trial data requirements for corn (field, pop and sweet) and for corn processing studies. The basis of the rationale is that the radiolabeled tracer study on corn indicated that residues will not exceed the LOQ in the harvested portion of the plant. The basis of this rationale was deemed acceptable.</td></tr>
</table>

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES–FOLIAR APPLICATION (REG2004-03)	
ESTABLISHED RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops** **Rotational crops**	Trifloxystrobin and CGA-321113 Trifloxystrobin and CGA-321113
ESTABLISHED RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	Trifloxystrobin and CGA-321113 Trifloxystrobin and CGA-321113
METABOLIC PROFILE IN DIVERSE CROPS	Similar in apples, cucumbers and wheat

PLANT STUDIES–SEED TREATMENT	
CANOLA, CORN AND SOYBEAN	As the TRR ranged from <0.005 ppm to 0.007 ppm in matrices of canola, corn and soybean plants grown from seed treated with trifloxystrobin, further characterization of the TRR was not conducted and was not required as per DIR2003-02.

ANIMAL STUDIES (REG2004-03)		
ANIMALS	Poultry	Ruminant
ESTABLISHED RESIDUE DEFINITION FOR ENFORCEMENT	Trifloxystrobin and CGA-321113	
ESTABLISHED RESIDUE DEFINITION FOR RISK ASSESSMENT	Trifloxystrobin and CGA-321113	Trifloxystrobin and CGA-321113 (for milk and all tissues, except liver); Trifloxystrobin, CGA-321113 and the taurine conjugate of CGA-321113-metabolite L_{7a} (liver only)
METABOLIC PROFILE IN ANIMALS	Similar in both animals	
FAT SOLUBLE RESIDUE	Yes	

REFINED DIETARY RISK FROM FOOD AND WATER
(includes both the registered uses and proposed seed treatments)

	POPULATION	ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)	
		Food Only	**Food and Water**
Refined chronic non-cancer dietary risk **ADI = 0.038 mg/kg bw/day** **Estimated chronic drinking water concentration = 300 μg/L**	**All infants < 1 year**	14.4	69.0
	Children 1–2 years	27.9	52.7
	Children 3–5 years	22.7	45.8
	Children 6–12 years	14.5	30.4
	Youth 13–19 years	9.3	21.4
	Adults 20–49 years	8.0	23.5
	Adults 50+ years	7.0	23.4
	Total population	7.6	23.1

Table 7 List of Active Ingredients Currently Registered on Pea, Bean, Chickpea, Lentil and Soybean for Control or Suppression of the Listed Diseases

Disease	Fungicide Active Ingredients
Seed rot caused by *Rhizoctonia* spp.	• fludioxonil + metalaxyl-M (soybean and dry edible bean only)
	• fludioxonil
	• carbathiin + thiram
	• azoxystrobin (dry beans only)
Seed rot caused by *Fusarium* spp.	• fludioxonil + metalaxyl-M
	• carbathiin + thiabendazole (lentil only)
	• fludioxonil
	• carbathiin + thiram
Seed rot caused by *Pythium* spp.	• metalaxyl
	• fludioxonil + metalaxyl-M
	• fludioxonil + metalaxyl-M and S-isomer
	• carbathiin + thiram
	• carbathiin + thiram + metalaxyl
Damping-Off caused by *Rhizoctonia* spp.	• fludioxonil + metalaxyl-M
	• fludioxonil
	• carbathiin + thiram
	• azoxystrobin (dry beans only)
Damping-Off caused by *Fusarium* spp.	• fludioxonil + metalaxyl-M
	• carbathiin + thiabendazole (lentil only)
	• fludioxonil
	• carbathiin + thiram
Damping-Off caused by *Pythium* spp.	• metalaxyl
	• fludioxonil + metalaxyl-M and S-isomer
	• fludioxonil + metalaxyl-M
Seed rot caused by *Phomopsis longicolla*	• fludioxonil + metalaxyl-M
Damping-Off caused by *Phomopsis longicolla*	• fludioxonil + metalaxyl-M
Seed rot caused by *Botrytis cinerea*	• carbathiin + thiram
	• carbathiin + thiabendazole (lentil only)
Damping-Off caused by *Botrytis cinerea*	• carbathiin + thiram
	• carbathiin + thiabendazole (lentil only)
Seedling blight caused by *Botrytis cinerea*	• carbathiin + thiram
	• carbathiin + thiabendazole (lentil only)

Table 8 List of Active Ingredients Currently Registered on Corn for Control or Suppression of the Listed Diseases

Disease	Fungicide Active Ingredients
Seed rot caused by *Fusarium* spp.	• azoxystrobin
	• captan
	• carbathiin + thiram
	• fludioxonil
	• fludioxonil + metalaxyl-M
	• difenoconazole + metalaxyl
Damping-Off caused by *Fusarium* spp.	• azoxystrobin

Table 9 List of Active Ingredients Currently Registered on Canola or Rapeseed as Seed Treatments for Control or Suppression of the Listed Diseases

Disease	Fungicide Active Ingredients
Seed rot caused by *Pythium* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seed rot caused by *Rhizoctonia* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seed rot caused by *Fusarium* spp.	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seed rot caused by *Alternaria* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Damping-Off caused by *Pythium* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Damping-Off caused by *Rhizoctonia* spp.	• carbathiin + thiram
	• iprodione + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Damping-Off caused by *Fusarium* spp.	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Damping-Off caused by *Alternaria* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seedling blight caused by *Pythium* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seedling blight caused by *Rhizoctonia* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram

Seedling blight caused by *Fusarium* spp.	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Seedling blight caused by *Alternaria* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Root rot caused by *Pythium* spp.	• carbathiin + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Root rot caused by *Rhizoctonia* spp.	• carbathiin + thiram
	• iprodione + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Root rot caused by *Fusarium* spp.	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram
Root rot caused by *Alternaria* spp.	• carbathiin + thiram
	• carbathiin + metalaxyl + thiram
Blackleg (*Phoma*)	• carbathiin + thiram
	• iprodione + thiram
	• difenconazole + metalaxyl-M + fludioxonil
	• carbathiin + metalaxyl + thiram

Table 10 List of Active Ingredients Currently Registered on Canola or Rapeseed as Seed Treatments for Control or Suppression of the Listed Insect Pests

Insect Pest	Insecticide Active Ingredients
Flea beetles	• malathion
	• cypermethrin
	• carbaryl
	• deltamethrin
	• imidacloprid
	• thiamethoxam
	• clothianidin
	• acetamiprid

Table 11 Summary of Supported Disease Label Claims for Prosper T 200 and T 400 Flowable Insecticide and Fungicide Seed Treatment

Proposed Claims	Claims Supported
Applied once as a seed treatment at the rate of 1400 mL per 100 kg seed on canola and rapeseed	Supported as proposed
Control of seed rot caused by *Pythium* spp.	Supported as proposed
Control of seed rot caused by *Rhizoctonia solani*	Supported as proposed
Control of seed rot caused by *Fusarium* spp.	Supported as proposed
Control of seed rot caused by *Alternaria* spp.	Supported as proposed
Control of damping-off caused by *Pythium* spp.	Supported as proposed
Control of damping-off caused by *Rhizoctonia solani*	Supported as proposed
Control of damping-off caused by *Fusarium* spp.	Supported as proposed
Control of damping-off caused by *Alternaria* spp.	Supported as proposed
Control of seedling blight caused by *Pythium* spp.	Supported as proposed
Control of seedling blight caused by *Rhizoctonia solani*	Supported as proposed
Control of seedling blight caused by *Fusarium* spp.	Supported as proposed
Control of root rot caused by *Pythium* spp.	Supported as proposed
Control of Blackleg (*Phoma*)	Supported as proposed

Table 12 Summary of Supported Insect Label Claims for Prosper T 200 Flowable Insecticide and Fungicide Seed Treatment

Proposed Claims	Claims Supported
Applied once as a seed treatment at the rate of 1400 mL product (200 g clothianidin) per 100 kg seed on canola and rapeseed	Supported as proposed
Protection from flea beetle under low to moderate flea beetle pressure, up to the 2-leaf stage of canola and rapeseed	Supported as proposed

Table 13 Summary of Supported Insect Label Claims for Prosper T 400 Flowable Insecticide and Fungicide Seed Treatment

Proposed Claims	Claims Supported
Applied once as a seed treatment at the rate of 1400 mL product (200 g clothianidin) per 100 kg seed on canola and rapeseed	Supported as proposed
Protection from flea beetle feeding under moderate to high flea beetle pressure and when longer season control of flea beetles is required, up to the 4-leaf stage of canola and rapeseed	Supported as proposed

Table 14 Summary of Prosper T 200 and T 400 Flowable Insecticide and Fungicide Seed Treatment Disease Claims Not Supported

Proposed Diseases	**Reason for not supporting**
Control of seedling blight caused by *Alternaria* spp.	No acceptable data submitted
Control of root rot caused by *Rhizoctonia solani*	No data submitted
Control of root rot caused by *Fusarium* spp.	No data submitted
Control of root rot caused by *Alternaria* spp.	No data submitted

Table 15 Summary of Supported Disease Label Claims for Trilex AL Seed Treatment Fungicide

Proposed Claims	**Claims Supported**
Applied once as a seed treatment at the rate of 370 mL per 100 kg seed on pea, lentil, chickpea, bean and soybean	Supported as proposed
Control of seed rot caused by *Pythium* spp.	Supported as proposed
Control of seed rot caused by *Rhizoctonia solani*	Supported as proposed
Control of seed rot caused by *Fusarium* spp.	Supported as proposed
Control of damping-off caused by *Pythium* spp.	Supported as proposed
Control of damping-off caused by *Rhizoctonia solani*	Supported as proposed
Control of damping-off caused by *Fusarium* spp.	Supported as proposed
Control of seed rot caused by *Botrytis cinerea* (on lentil only)	Supported as proposed
Control of damping-off caused by *Botrytis cinerea* (on lentil only)	Supported as proposed
Control of seed rot caused by *Phomopsis longicolla* (on soybean only)	Supported as proposed
Control of damping-off caused by *Phomopsis longicolla* (on soybean only)	Supported as proposed

Table 16 Summary of Supported Label Claims for Trilex FL Seed Treatment Fungicide on Canola, Rapeseed and Mustard

Proposed Claims	**Claims Supported**
Applied once as a seed treatment at the rate of 370 mL per 100 kg seed on canola, rapeseed and mustard	Supported as proposed
Control of seed rot caused by *Rhizoctonia solani*	Supported as proposed
Control of damping-off caused by *Rhizoctonia solani*	Supported as proposed

Table 17 Summary of Supported Label Claims for Trilex FL Seed Treatment Fungicide on Pea, Lentil, Chickpea, Bean and Soybean

Proposed Claims	Claims Supported
Applied once as a seed treatment at the rate of 21 mL per 100 kg seed on pea, lentil, chickpea, bean, and soybean	Supported as proposed
Control of seed rot caused by *Rhizoctonia solani*	Supported as proposed
Control of damping-off caused by *Rhizoctonia solani*	Supported as proposed
Control of seed rot caused by *Fusarium* spp.	Supported as proposed
Control of damping-off caused by *Fusarium* spp.	Supported as proposed
Control of seed rot caused by *Phomopsis longicolla* (on soybean only)	Supported as proposed
Control of damping-off caused by *Phomopsis longicolla* (on soybean only)	Supported as proposed

Table 18 Summary of Supported Label Claims for Trilex FL Seed Treatment Fungicide on Corn

Proposed Claims	Claims Supported
Applied once as a seed treatment at the rate of 21 mL per 100 kg seed on corn	Supported as proposed
Control of seed rot caused by *Fusarium* spp.	Supported as proposed
Control of pre-emergence damping-off caused by *Fusarium* spp.	Supported as proposed

Table 19 Summary of Disease Claims not Supported for Trilex FL

Proposed Claims	Reason for not supporting the use
Control of postemergence damping-off caused by *Phomopsis longicolla* on soybean	Use withdrawn at the request of the registrant
Control of seed rot and damping-off caused by *Rhizoctonia solani*, *Fusarium* spp., and *Phomopsis longicolla* on soybean (immature seed)	No data submitted

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

None of the specified Canadian MRLs is the same as those in the United States. A tolerance is established for soybean seed only and not for legume vegetables (Crop Group 6). The MRLs for legume vegetables, including soybean seed, and corn (field, pop and sweet) differ from the tolerances established in the United States (40 CFR Part 180). The MRLs for corn (field, pop and sweet) are the same as the CODEX (Codex MRLs) MRL for maize.

Table 1 Difference between Canadian MRLs and those in Other Jurisdictions

Commodity	Canada (ppm)	United States (ppm)	Codex* (ppm)
Legume vegetables (succulent or dried)	0.02	0.08 ("Soybean, seed" only)	No MRL established
Field corn	0.02	0.05	0.02 (Maize)
Popcorn grain	0.02	0.05	0.02 (Maize)
Sweet corn kernels plus cob with husks removed	0.02	0.04	0.02 (Maize)
Mustard seeds (condiment type)	0.02	No tolerance established	No MRL established
Mustard seeds (oilseed type)	0.02	No tolerance established	No MRL established
Rapeseed (canola)	0.02	No tolerance established	No MRL established

* 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.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

Appendix III Crop Groups: Numbers and Definitions

Crop Group Number	Name of the Crop Group	Commodity
Crop Group 6	Legume vegetables (succulent or dried)	Dry adzuki beans Dry beans Dry blackeyed peas Dry broad beans Dry catjang seed Dry chickpeas Dry field peas Dry guar seed Dry kidney beans Dry lablab beans Dry lentils Dry lima beans Dry moth beans Dry mung beans Dry navy beans Dry pigeon peas Dry pink beans Dry pinto beans Dry rice beans Dry southern peas Dry soybeans Dry tepary beans Dry urd beans Edible-podded dwarf peas Edible-podded jackbeans Edible-podded moth beans Edible-podded peas Edible-podded pigeon peas Edible-podded runner beans Edible-podded snap beans Edible-podded snow peas Edible-podded soybeans Edible-podded sugar snap peas Edible-podded sword beans Edible-podded wax beans Edible-podded yardlong beans Grain lupin Succulent shelled blackeyed peas Succulent shelled broad beans Succulent shelled English peas Succulent shelled garden peas Succulent shelled green peas Succulent shelled lima beans Succulent shelled peas Succulent shelled pigeon peas Succulent shelled southern peas

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

1.1 The Active Ingredient, Its Properties and Uses

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1.2 Methods of Analysis

2.0 Human and Animal Health

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B. Additional Information Considered

i) Published Information

Trifloxystrobin Regulatory Note REG2004-03
Trifloxystrobin Proposed Regulatory Document PRD2008-01

1.0 Chemistry

2.0 Human and Animal Health

DIR98-02 Residue Chemistry guidelines
DIR2003-02 Haromization of Regulation of Pesticide Seed Treatment in Canada and the United States