Proposed Registration Decision PRD2011-26

Penthiopyrad

(publié aussi en français)

23 December 2011

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

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/H113-9/2011-26E (print version)
H113-9/H113-9/2011-26E-PDF (PDF version)

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Overview

Registration Decision for Penthiopyrad

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Penthiopyrad Technical Fungicide, Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide, containing the technical grade active ingredient penthiopyrad, to control or suppress various fungal diseases on a broad range of agricultural crops and turfgrass.

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

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Penthiopyrad Technical Fungicide, Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on penthiopyrad, 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 penthiopyrad, 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 Penthiopyrad?

Penthiopyrad is a systemic fungicide that can be applied to plant foliage or in-furrow to control or suppress various fungal diseases on a broad range of agricultural crops and turfgrass. This fungicide is a new active ingredient found in four end-use products; one of which, is in combination with chlorothalonil (Treoris Fungicide).

Health Considerations

Can Approved Uses of Penthiopyrad Fungicide Affect Human Health?

Products containing penthiopyrad are unlikely to affect your health when used according to label directions.

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

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

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

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 pesticide products are used according to label directions.

In laboratory animals, the acute toxicity of the active ingredient penthiopyrad was low via the oral, dermal and inhalation routes of exposure. Penthiopyrad was minimally irritating to the eyes, non-irritating to the skin and did not cause an allergic skin reaction.

The acute toxicity of the end-use product Vertisan Fungicide was low via the oral, dermal and inhalation routes of exposure. It was mildly irritating to the skin and severely irritating to the eyes; consequently, the hazard signal words “DANGER – EYE IRRITANT” and “SKIN IRRITANT” are required on the label. Vertisan Fungicide has the potential to cause allergic skin reactions; consequently, the hazard signal words “POTENTIAL SKIN SENSITIZER” are required on the label.

The acute toxicity of the end-use product Fontelis Fungicide was low via the oral, dermal and inhalation routes of exposure. It was non-irritating to the skin and minimally irritating to the eyes. Fontelis Fungicide is considered to have the potential to cause an allergic skin reaction; consequently, the hazard signal words “POTENTIAL SKIN SENSITIZER” are required on the label.

The acute toxicity of the end-use product Treoris Fungicide was low via the oral and dermal routes of exposure. It was slightly toxic via the inhalation route following acute exposure; consequently, the hazard signal words “CAUTION - POISON” are required on the label. Treoris Fungicide was mildly irritating to the skin, minimally irritating to the eyes and has the potential to cause allergic skin reactions; consequently, the hazard signal words “SKIN IRRITANT” and “POTENTIAL SKIN SENSITIZER” are required on the label.

The acute toxicity of the end-use product DPX-LEM17 50WG Fungicide was low via the oral, dermal and inhalation routes of exposure. It was slightly irritating to the skin, mildly irritating to the eyes and did not cause an allergic skin reaction; consequently, the hazard signal words “CAUTION - EYE IRRITANT” are required on the label.

Health effects in animals given repeated doses of penthiopyrad included changes in the liver, thyroid, adrenals and kidneys. Penthiopyrad did not cause birth defects in animals and there were no effects on the ability to reproduce. When penthiopyrad was given to pregnant or nursing animals, effects on the developing fetus and juvenile animal (reduced survival, pup and litter weights, body size, thymus weight, altered thymus development and/or delayed sexual development) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to penthiopyrad than the adult animal. Penthiopyrad caused temporary functional effects, possibly related to the nervous system, however, there was no indication that penthiopyrad caused damage to the nervous system. There was no evidence to suggest that penthiopyrad damaged genetic material. Penthiopyrad did, however, cause thyroid tumours in rats. There was also evidence of an effect on the immune system at high doses.

The risk assessment protects against the effects of penthiopyrad by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

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 which would ingest the most penthiopyrad relative to body weight, are expected to be exposed to less than 19% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from penthiopyrad is not of concern for all population sub-groups. There were no cancer risks of concern.

An aggregate (food and water) dietary intake estimate for the highest exposed population (infants) was 6% of the acute reference dose, which is not a health concern.

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

Residue trials conducted throughout Canada and the United States using penthiopyrad on carrot, radish, sugar beet, potato, turnip, dry bulb onion, green onion, lettuce, spinach, celery, broccoli, cauliflower, cabbage, mustard green, pea, bean, soybean, tomato, pepper, cucumber, squash, cantaloupe, apple, pear, peach, plum, cherry, strawberry, almond, pecan, wheat, barley, sorghum, corn, canola, sunflower, cotton, peanut and alfalfa were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this consultation document.

Occupational Risks From Handling Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide

Occupational risks are not of concern when products containing penthiopyrad are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide, as well as field workers entering freshly treated fields and greenhouses, can come in direct contact with penthiopyrad residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying products containing penthiopyrad must wear a long-sleeved shirt, long pants, shoes, socks and chemical resistant gloves while mixing/loading, applying and during clean-up and repair. In addition, when handling Vertisan Fungicide, goggles or a face shield are required during mixing/loading and during clean-up and repair. The label also requires that workers do not enter corn fields for three days after application for detasseling and for 12 hours after application for all other agricultural activities, or until sprays have dried for turf. Taking into consideration these label statements, the number of applications and the expectation of the exposure period, risk to handlers and workers is not a concern. There were no cancer risks of concern.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern when Fontelis Fungicide and DPX-LEM17 50WG Fungicide are used according to label directions.

Adults and youth may be exposed to penthiopyrad while golfing on treated courses. Based on the expected short- to intermediate-term duration of this activity, risk to golfers is not a concern. Adults, youths and toddlers may be exposed to penthiopyrad when entering treated lawns or during pick-your-own harvesting activities. In addition, toddlers may have incidental oral exposure during hand-to-mouth activities or from ingesting treated grass or soil. Based on the expected short- to intermediate-term duration of these activities, risk to the general population is not of concern. There were no cancer risks of concern.

Environmental Considerations

What Happens When Penthiopyrad Is Introduced Into the Environment?

When applied as a foliar spray to control diseases on a variety of crops, penthiopyrad does not leach appreciably and is degraded rapidly on the soil surface. When applied in furrow, or if it leaches below the soil surface, penthiopyrad does not readily degrade. Penthiopyrad is not volatile and is not expected to bioaccumulate.

Penthiopyrad will be persistent in aquatic environments and can potentially affect aquatic life. Aquatic life stages of amphibians would potentially be at the highest risk through exposure from off-target spray drift and surface runoff entering aquatic systems. There is also a risk to freshwater invertebrates and fish and algae. The effects of penthiopyrad on aquatic ecosystems can be mitigated with the observance of precautionary measures, including spray drift buffer zones.

Value Considerations

What Is the Value of Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide?

Fontelis Fungicide is a suspension concentrate product for foliar and in-furrow uses on a broad range of crops, including cereals, fruit crops, vegetable crops and nuts.

Vertisan Fungicide is an emulsifiable concentrate for foliar and in-furrow application to field crops, including cereals, oilseeds, sugarbeets, legumes, and root and corm vegetables.

Treoris Fungicide is a pre-mix with chlorothalonil to control diseases on potatoes and cucurbits.

DPX-LEM17 50WG Fungicide is a water dispersible granule formulation to control turf diseases.

Penthiopyrad is a new mode of action fungicide for many crops that can be integrated into a spray program as a rotational product or tank mix partner. These products address primary diseases of major field crops as well as minor crops grown in Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As users may come into direct contact with penthiopyrad on the skin or through inhalation of spray mists, anyone mixing, loading and applying Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide must wear a long-sleeved shirt, long pants, shoes, socks and chemical resistant gloves, and users mixing/loading Vertisan Fungicide must also wear goggles or a face shield. For products that may be applied by aerial application equipment, pilots are not allowed to mix chemicals to be loaded onto the aircraft and the field crew and the mixer/loaders must wear chemical-resistant gloves, coveralls and goggles or face shield during mixing/loading. In addition, standard label statements to protect against drift during application were added to the label, and entry into treated areas is restricted for three days before performing detasseling activities on corn, for 12 hours after application for all other agricultural postapplication activities, and until sprays have dried for entering treated turf.

Environment

Label statements and no-spray buffer zones to mitigate the risk of spray drift to aquatic ecosystems are required. As well, label statements to identify sensitive components and mitigation measures to help reduce contamination of aquatic habitats are required.

Next Steps

Before making a final registration decision on penthiopyrad, 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

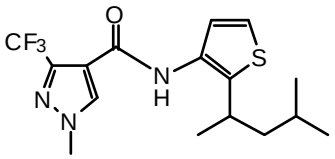
When the PMRA makes its registration decision, it will publish a Registration Decision on penthiopyrad (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the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

Science Evaluation

Penthiopyrad

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Penthiopyrad
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(*RS*)-*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide
2. Chemical Abstracts Service (CAS)	*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1*H*-pyrazole-4-carboxamide
CAS number	183675-82-3
Molecular formula	$C_{16}H_{20}F_3N_3OS$
Molecular weight	359.4 g/mol
Structural formula	
Purity of the active ingredient	99.5%

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

Technical Product—Penthiopyrad Technical Fungicide

Property	Result
Colour and physical state	White solid
Odour	Odourless
Melting range	108.7°C ± 0.2°C
Boiling point or range	Not applicable
Relative density at 20°C	1.256

Property	Result
Vapour pressure at 25°C	6.43×10^{-6} Pa
Ultraviolet (UV)-visible spectrum	$\lambda_{max} \approx 226$ nm under neutral, acidic and basic conditions
Solubility in water at 20°C	pH: Solubility (mg/L) 4: 2.535 7: 1.375 10: 1.657
Solubility in organic solvents at 20°C	Solvent: Solubility (g/L) Acetone: 557 Dichloromethane: 531 Methanol: 402 Ethyl acetate: 349 Ethanol: 234.5 Toluene: 67.0 Xylene: 42.7 Hexane: 0.75 Heptane: 0.74
n-Octanol-water partition coefficient (K_{OW})	pH: log K_{ow} 4: 4.36 7: 4.62 10: 4.54
Dissociation constant (pK_a)	$pK_a = 10.0 \pm 0.16$
Stability (temperature, metal)	Thermally stable in air under the test conditions (25 to 150°C at 10°C/minute).

End-Use Product—Vertisan Fungicide

Property	Result
Colour	Pale yellow
Odour	Noticeable pineapple odour
Physical state	Liquid
Formulation type	Emulsifiable concentrate
Guarantee	200 g/L nominal
Container material and description	1-1500 L glass or plastic jugs or totes
Relative density at 20°C	0.9681
pH of 1% dispersion in water	5.80
Oxidizing or reducing action	Product does not have oxidizing properties

Property	Result
Storage stability	Stable for 24 months at ambient temperature in polyethylene/ethyl vinyl alcohol and for 12 months under warehouse conditions in HDPE
Corrosion characteristics	Product was not corrosive to the packaging material
Explodability	Product is not explosive

End-Use Product—Fontelis Fungicide

Property	Result
Colour	Off-white
Odour	Faint ester-like odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	200 g/L nominal
Container material and description	1-1500 L glass or plastic jugs or totes
Relative density at 20°C	0.9789
pH of 1% dispersion in water	6.66
Oxidizing or reducing action	Product does not have oxidizing properties
Storage stability	Stable under warehouse conditions for two years in HDPE
Corrosion characteristics	Product was not corrosive to the packaging material
Explodability	Product is not explosive

End-Use Product—Treoris Fungicide

Property	Result
Colour	Off-white
Odour	Mild ester-like polymeric odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	Penthiopyrad 100 g/L nominal Chlorothalonil 250 g/L nominal
Container material and description	1-1500 L plastic jugs or totes
Density at 20°C	1.1245 g/mL
pH of 1% dispersion in water	6.33
Oxidizing or reducing action	Product does not contain any oxidizing or reducing agents

Property	Result
Storage stability	Stable for one year in HDPE at temperatures between 18 and 26°C and a relative humidity range of 40 to 60%. Stable for two years in HDPE under warehouse conditions.
Corrosion characteristics	Product was not corrosive to the packaging material
Explodability	Product is not explosive

End-Use Product—DPX-LEM17 50WG Fungicide

Property	Result
Colour	Off-white
Odour	Moderate sharp sour odour
Physical state	Solid
Formulation type	Wettable granules
Guarantee	50% nominal
Container material and description	500 g to 1000 kg plastic jugs, drums, bags or super sacks
Density (tapped)	0.52 g/mL
pH of 1% dispersion in water	8.4
Oxidizing or reducing action	Product does not contain any oxidizing or reducing agents
Storage stability	Stable for one year in HDPE at temperatures between 18 and 26°C and a relative humidity range of 40 to 60%.
Corrosion characteristics	Product was not corrosive to the packaging material
Explodability	Product is not explosive

1.3 Directions for Use

Fontelis Fungicide and Vertisan Fungicide may be applied to foliage at rates ranging between 1.0 – 2.25 L/ha (200 – 450 g a.i./ha). Vertisan may also be applied as an in-furrow application at 15.5 – 31.0 mL/100 m row (3.1 – 6.2 g a.i./100 m row).

Treoris Fungicide may be applied to potatoes and cucurbits at rates ranging between 1.5 - 2.5 L/ha (450 – 875 g a.i./ha). These rates will deliver between 150 – 250 g penthiopyrad/ha and 300 – 652 g chlorothalonil/ha.

DPX-LEM17 50WG may be applied to turf at rates ranging between 9 – 15 g/100 m^2 (4.5 - 7.5 g a.i./100 m^2). These rates may also be expressed as 0.9 – 1.5 kg/ha (450 - 750 g a.i./ha).

Please consult the respective product labels for details regarding use directions.

1.4 Mode of Action

Penthiopyrad stops growth of plant pathogenic fungi by blocking respiration and controls plant diseases caused by many Ascomycete and Basidiomycete fungi by blocking both spore germination and mycelial growth. By binding to the protein succinate:ubiquinone reductase in complex II of the electron transport chain, penthiopyrad inhibits two critical respiratory pathways, the citric acid cycle and mitochondrial electron transport. Foliar application exhibits translaminar movement across leaf surfaces and in-furrow application demonstrates systemic movement from root to foliar parts of plants.

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 Penthiopyrad Technical Fungicide, with the exception of one impurity method, have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

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

2.3 Methods for Residue Analysis

In plant and animal commodities, liquid chromatography methods with tandem mass spectrometry (LC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70-120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in several plant and animal matrices by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled cabbage leaf and wheat straw samples analyzed with the enforcement method.

In environmental media, high-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70-120%) were obtained in environmental media, with the exception of the method for the metabolite 753-T-DO in drinking water (recovery not possible due to instability of the analyte).

Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Penthiopyrad is a mitochondrial succinate dehydrogenase inhibitor, belonging to the pyrazole carboxamide class of chemicals.

A detailed review of the toxicological database for penthiopyrad was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The database also includes neurotoxicity, immunotoxicity, and special cancer mode of action (MOA) studies. In addition, the genotoxic potential of five metabolites/degradates (PAM, PCA, DM-PCA, 753-AOH and 753-T-DO) was characterized. The acute oral toxicity of these metabolites, except 753-T-DO, and the short-term oral toxicity of PCA and DM-PCA were also investigated. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to penthiopyrad.

The single-dose toxicokinetic behaviour, as well as the absorption, distribution, metabolism and excretion characteristics of single and multiple doses, were evaluated in rats. Orally administered penthiopyrad was rapidly and extensively absorbed at 10 and 100 mg/kg bw, the doses investigated. Maximal tissue concentrations were achieved within one hour of dosing. The systemic exposure was linearly dependent on the dose and slightly higher in females compared to males. With repeated dosing, the plasma radioactivity reached a plateau of approximately three times that of the single dose result. The absorption characteristics were not otherwise affected by repeated dosing, or by the dose level and sex of the animal. Absorbed penthiopyrad was widely distributed, with the concentration in the plasma being exceeded by the maximal levels in each of the following organs and tissues: the liver, fat, lymph nodes, adrenals, kidneys, ovaries and pancreas. With repeated dosing, there were small increases in the residues in these organs and tissues, as well as in the blood, lung and thyroid gland, compared to single dose administration. There were no major sex- or dose-related differences in tissue distribution. Excretion of penthiopyrad was rapid and dose-independent. Penthiopyrad was eliminated predominantly via the bile, with appreciable amounts also excreted in the urine. After cessation of dosing, organ and tissue concentrations of radioactivity decreased rapidly. There was no evidence that penthiopyrad accumulated in the tissues. Fecal elimination was essentially complete within 48 hours, and at 96 hours, mean residues were very low in the GI tract and in the carcass. Elimination of penthiopyrad via respired volatiles and CO_2 was negligible. There were no apparent or major sex- or dose-related differences in the tissue residues or in the extent or route of elimination.

Penthiopyrad was extensively metabolized via N-demethylation of the pyrazole ring, alkyl side-chain hydroxylation with subsequent dehydration or oxidation to carboxylic acids, thienyl ring oxidation with subsequent cleavage of the two ring structure, amide hydrolysis of the pyrazole moiety, or thienyl ring opening with subsequent breakdown via intermediary metabolism. Hydroxylated derivatives were also subject to either glucuronidation or glutathione conjugation with subsequent amino acid conjugation. The most abundant metabolite in both urine and feces was formed via N-demethylation and subsequent oxidation of the terminal methyl moiety of the alkyl side chain to a carboxylic acid. The intermediate demethylated and hydroxylated metabolites formed glucuronic acid conjugates that were mainly recovered in the bile. The most abundant metabolites in the bile were formed as a result of thienyl ring oxidation to 753-F-DO followed by conjugation with glutathione and subsequent catabolism of the glutathione. Four metabolites detected in the urine and feces, PAM, DM-PAM, PCA and DM-PCA, retained the pyrazole moiety following cleavage from the thienyl ring. The two acids, PCA and DM-PCA, are likely formed by amide hydrolysis from PAM and DM-PAM, respectively. The thienyl ring appears to be completely degraded and the radiocarbon incorporated into other molecules via normal metabolic processes. There was no evidence that these underlying metabolic reactions and the resulting metabolites differed with repeated dosing.

The acute toxicity of technical penthiopyrad was low via the oral, dermal and inhalation routes in rats. It was also minimally irritating to the eyes and non-irritating to the skin of rabbits and was not a skin sensitizer in guinea pigs. Except for Treoris Fungicide, which is considered slightly toxic via the inhalation route, the acute systemic toxicity of the end-use products discussed in this document was low via the oral, dermal and inhalation routes in rats. Treoris Fungicide was also minimally irritating to the eyes and mildly irritating to the skin of rabbits and was a skin sensitizer in guinea pigs. Similarly, Vertisan Fungicide was mildly irritating to the skin of rabbits and was a skin sensitizer in guinea pigs. However, it was severely irritating to the eyes of rabbits. Fontelis Fungicide was non-irritating to the skin and minimally irritating to the eyes of rabbits and was a skin sensitizer in guinea pigs. DPX-LEM17 50WG Fungicide was mildly irritating to the eyes and slightly irritating to the skin of rabbits and was not a skin sensitizer in guinea pigs.

The liver was the main target organ in mice, rats and dogs. Hepatotoxicity was manifest as increased liver weight, liver enlargement and centrilobular hepatocellular hypertrophy, as well as alterations in clinical chemistry (elevated plasma/serum levels of liver enzymes, cholesterol and/or phospholipids, triglycerides and protein). The rat was the most sensitive species following short-term oral dosing. In the rat, increased liver weight was associated with micro/macrovesicular fatty change, suggesting an effect on hepatic fat metabolism. At high doses, Kupffer cell proliferation and hepatocellular degeneration were also evident in the rat, but not in the mouse or the dog. In several studies, effects on the liver at lower doses were mild and considered to be non-adverse, reflecting an adaptive response of the liver rather than overt hepatotoxicity. The spectrum of liver effects and the doses eliciting hepatotoxicity did not change significantly with the duration of dosing. At doses higher than those causing liver effects, mild hematological changes (decreases in red blood cells, hemoglobin and hematocrit) were observed in the mouse, rat and dog. The thyroid was also a target in short-term studies in the mouse and dog but not in the rat, with effects observed only at the highest doses tested. In the

mouse, increased thyroid weight and thyroid follicular cell hypertrophy were observed in both sexes. In dogs, increased thyroid weights were observed only in the females of the 90-day study. Adrenal cortical hypertrophy occurred at the highest dose tested in dogs after 90 days and one year. Adrenal effects were not observed in the mouse, and were found in the rat only with longer term dosing (i.e. the reproductive toxicity study and long term rat study beginning at six months). Also evident in dogs in the 90-day and 1-year studies were gall bladder mucosal effects (foamy macrophage infiltration, loss of mucosal folds, epithelial hyperplasia).

Dermal dosing of rats for 28 days resulted in no adverse dermal or systemic toxicity at 1000 mg/kg bw/day, the highest dose tested. A repeat-dose inhalation toxicity study was not available in the toxicity database.

The liver and thyroid remained the primary target organs in the mouse and rat with chronic dosing. With long-term dosing in mice, thyroid effects that occurred over shorter dosing periods became evident at lower doses and also included altered colloid and increased brown pigment in the follicular cells. In rats, the kidney was also a target organ. In rats dosed orally for six or twelve months, plasma potassium levels were increased in both sexes and kidney weight was increased in males, implicating kidney function as a probable target of penthiopyrad. These apparent functional effects occurred at doses that were equal to or higher than those leading to hepatotoxicity in the shorter-term rat studies. After 24 months, the kidneys of male rats exhibited increased incidences of interstitial fibrosis and renal glomerulosclerosis at doses lower than those leading to hepatotoxicity. Although there was a response plateau for these kidney effects at the top two doses tested, there were no pharmacokinetic data for the highest dose tested in this study; consequently, it could not be ruled out that this dose-response pattern reflects uncharacterized pharmacokinetic effects, such as a saturation of dose absorption. At the highest two doses tested in the 12- and 24-month rat studies, there were additional findings in the kidneys (pyelitus, lipofuscin, tubular basophilia), adrenals (cortical lipid vacuolation, discolouration, focal fatty change) and ovaries (interstitial cell hypertrophy, senile atrophy) in males and/or females.

Penthiopyrad was tested for *in vitro* and *in vivo* genotoxicity in a range of assays. Based on the negative results obtained in a battery of genotoxicity studies, penthiopyrad is considered unlikely to be genotoxic.

Tumours were observed in the mouse and the rat in the oncogenicity studies. The dosing was considered adequate in these studies. In the mouse, there was equivocal evidence of oncogenicity in the liver. Compared to the concurrent control, there were slight increases in the incidences of hepatocellular adenomas and carcinomas in the males at the highest dose tested. Nevertheless, the tumour incidences were within, or very close to, the historical control range. Further, the adenoma incidences in the concurrent control were atypically low for the mouse strain used, falling below the lower limit of the historical control range. Thus, for liver tumours in male mice, a clear association to treatment with penthiopyrad could not be made. Similarly, there was weak evidence of oncogenicity in male rats. The incidence of thyroid follicular cell adenomas at the highest dose tested was increased slightly compared with the concurrent control group, and also slightly exceeded the historical control range. However, there was no increase in follicular cell

carcinomas and no evidence of comparable changes in females. The proposed mode of action for the thyroid adenomas was chronic perturbation of thyroid hormone homeostasis. Cancer MOA studies were conducted to examine liver and thyroid effects in the mouse and rat. These studies showed that penthiopyrad increased microsomal protein and cytochrome P450 activity in the liver of both mice and rats, and specifically increased UDPGT-T4 in the rat at doses lower than that which resulted in tumours. Increased thyroid stimulating hormone (TSH) and thyroid follicular cell proliferation were also observed in rats; however, these changes were either transiently or inconsistently evident. Further, increased follicular cell hypertrophy and an associated decrease in colloid were evident, but only at doses that were greater than the tumourigenic dose. Finally, there was no evidence of thyroid follicular cell hyperplasia, which is a fundamental outcome of chronically increased TSH and a key event in the proposed cancer MOA. Overall, when the results from all of the MOA studies in rats are considered, there was insufficient evidence that the oncogenic effect in the thyroid was a specific consequence of chronically perturbed thyroid hormone homeostasis. A linear low dose extrapolation (q_1*) approach is frequently recommended for the cancer risk assessment in the absence of a sufficient weight of evidence to support a proposed threshold-based MOA. However, for penthiopyrad, this approach is considered overly conservative for the following reasons: i) adenomas occurred at a single high dose only, with no evident dose response at lower doses and no concordant evidence of genotoxicity, indicating that the tumour outcome is likely threshold-dependent, ii) the adenomas became evident near the end of the oncogenicity study, indicating that exposure to penthiopyrad over a majority of the lifespan of the animal is required for tumour formation, iii) there was no evidence of an increased incidence of carcinomas, or any effect on the lifespan of the animal, indicating that even with high doses over a majority of the lifespan of the animal the potential risk is limited to benign neoplasia, iv) treatment-related oncogenic effects occurred in only one sex and one rodent species, which reduces the concern for human relevance, and v) the acceptable daily intake (ADI) provides a margin of 2,780 to the thyroid tumours in male rats; consequently it is considered protective of this endpoint. For these reasons, a threshold approach for thyroid tumours was applied for the cancer risk assessment.

No effects on reproduction were noted in a multigeneration reproduction study in the rat. There was a decrease in offspring body weight during early lactation in both generations at the highest dose tested. Also at this dose, there were delays in preputial separation and vaginal opening. Furthermore, at this dose, there were decreases in thymus and spleen weights, with no histopathological correlates. Effects were observed in parental animals at the mid and high doses and included; decreased body weight and body weight gain, increased liver weight with centrilobular hepatocellular hypertrophy, and increased adrenal weight with adrenal cortical hypertrophy. At the high dose only, effects on the thyroid were also observed and comprised of increased thyroid weight and follicular cell hypertrophy. The no observed adverse effect level (NOAEL) for offspring toxicity was greater than that of the NOAEL for parental toxicity. There was no evidence of sensitivity of the young.

Developmental toxicity, in the form of increased early resorptions and post-implantation loss, decreased live young per litter and litter weight, and an increase in partially undescended thymus, was observed when pregnant rats were dosed at the highest dose tested over the period of major organogenesis. Reductions in body weight gain and food consumption were observed in maternal animals at this dose. In rabbits, gravid uterine weight, as well as litter and fetal weight, were reduced at the high dose in the definitive study. Also, one abortion occurred late in gestation at the high dose of 225 mg/kg bw/day following a period of marked reduction in food consumption and body weight in the doe. The occurrence of abortions in the preliminary rabbit developmental toxicity study revealed strong dose dependence for this endpoint, with none occurring at 250 mg/kg bw/day and high incidences at 500 to 1000 mg/kg bw/day. The outcomes for both of the rabbit developmental toxicity studies were taken into consideration before establishing the NOAEL for the definitive study in rabbits. Overall, penthiopyrad is not considered teratogenic and induced developmental toxicity only in the presence of maternal toxicity.

In the acute neurotoxicity study in rats, transient functional alterations were observed (decreased motor activity and body temperature, unsteady gait, hunched posture). There was no histological evidence of damage to the central or peripheral nervous system. These transient effects are considered broad systemic effects, potentially reflective of the mitochondrial inhibitor properties of penthiopyrad rather than evidence of neurotoxicity *per se*. There was no evidence of neurotoxicity in the 90-day neurotoxicity study in rats. A developmental neurotoxicity study in rats revealed no maternal effects up to the highest dose tested. In contrast, offspring exhibited decreased body weight at the mid to high dose levels. Increased motor activity and decreased peak amplitude of the auditory startle response were also observed in offspring at the highest dose tested. The apparent offspring sensitivity in this study is considered an outcome of the limited suite of maternal toxicity endpoints that were assessed within the study, and also a consequence of the shorter duration of maternal exposure, compared to that of the offspring. Offspring sensitivity is not evident when parental toxicity in rats in the broader database is considered. For instance, adverse liver effects occur after 28 days in rats at doses that are comparable to that which resulted in offspring effects in the developmental neurotoxicity study.

A 28-day oral immunotoxicity study in mice indicated immunosuppression at the highest dose tested. The resulting NOAEL for immunotoxicity was based on decreased plaque-forming cells in the spleen. In a comparable 28-day study in rats, there was no evidence of immunotoxicity.

The toxicity of five metabolites was also assessed. Each is a minor metabolite in the rat and is also found in livestock, plants and soil. The acute oral toxicity of the metabolites PCA, DM-PCA and 753-AOH was low in rats, and was not greater than that of the parent chemical. In contrast, the acute oral toxicity of the metabolite PAM was slight to high in rats, which is greater than that of penthiopyrad. Similarly, the metabolites PCA, DM-PCA, 753-AOH and 753-T-DO were negative, or equivocal, in a battery of *in vitro* genotoxicity assays, but the metabolite PAM was mutagenic without S9 in a mouse lymphoma assay and resulted in chromosome aberrations *in vitro* in the absence of S9. In contrast, PAM was negative in an Ames assay and in an *in vivo* micronucleus assay. In rats exposed to either PCA for 28 days by oral gavage or DM-PCA for 14 days via the diet, there were no observed effects up to the highest dose tested. Decreased

body weight and food consumption were observed in rats at the highest dose of DM-PCA tested in a 90-day feeding study. Although the toxicity of PAM appears to be greater than that of the parent chemical, the toxicological effects of short-term exposure to this metabolite were not investigated in repeated dose toxicity studies. Since PAM is a major phototransformation product in soil and a major metabolite in livestock (goats, poultry) and plants (grapes, cabbage), the absence of this toxicological information was considered to be of concern. As a result, a 28-day repeat-dose toxicity study in rats using the metabolite PAM is requested.

Results of the toxicology studies conducted on laboratory animals with penthiopyrad, five related metabolites/degradates, and its associated end-use products, are summarized in Appendix I, Tables 2 and 3. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 4.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada and the United States were searched for penthiopyrad. As of September 21, 2011, there were no reports of adverse health effects in the PMRA Incident Reporting database.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food, or from products used in or around homes or schools, the *Pest Control Products Act* (PCPA) requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for penthiopyrad. The database contains the full complement of required studies, including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats. A developmental neurotoxicity study in rats was also conducted.

With respect to potential prenatal and postnatal toxicity, there was no indication of increased susceptibility of fetuses or offspring compared to parental animals in the reproductive toxicity, prenatal developmental toxicity and developmental neurotoxicity studies. As discussed previously, the apparent offspring sensitivity in the developmental neurotoxicity study is negated when the evidence of parental toxicity in rats in the broader toxicity database is considered. In the 2-generation rat reproductive toxicity study, sexual maturation was delayed in both sexes, there were adverse effects on body size and weight, and the thymus and spleen weights were decreased in the offspring at the highest dose tested; however, these effects occurred in the presence of maternal toxicity (liver, adrenal, thyroid and bodyweight effects). Penthiopyrad is not considered teratogenic. In rats, developmental toxicity was manifest via effects on offspring body weight, motor activity, auditory startle response, viability (for example, increased early

resorptions and post-implantation loss) and thymus development; however, these effects either occurred, or are considered to have occurred, in the presence of maternal toxicity. The level of concern for neurotoxicity effects was low. There was no histopathological evidence of a toxicological impact on nervous system tissues.

In the definitive rabbit developmental toxicity study, one abortion occurred late in gestation at the high dose of 225 mg/kg bw/day following a period of marked reduction in food consumption and body weight in the doe. Although abortions are considered a serious developmental endpoint, concern in this instance was tempered by the presence of maternal toxicity, the equivocal relationship to treatment at this dose, and the absence of abortions in the relevant rat toxicity studies. Given these considerations, the NOAEL of 75 mg/kg bw/day from the rabbit developmental study is viewed as conservative; this conservatism is considered sufficient to account for the prenatal concerns (i.e., the serious nature of the endpoint) that would, under different circumstances, result in the retention of a 3-fold PCPA factor. Therefore, the PCPA factor was reduced to 1-fold when using the rabbit developmental toxicity study to establish the point of departure for assessing risk to women of child-bearing age and their fetuses. For exposure scenarios for children, the risk was considered well-characterized and the PCPA factor was reduced to 1-fold when using endpoints from either the multi-generation reproductive toxicity study or the acute neurotoxicity study in rats.

3.2 Determination of Acute Reference Dose

General Population
To estimate acute dietary risk (one day), the acute neurotoxicity study with a NOAEL of 125 mg/kg bw was selected for risk assessment. At the lowest observed adverse effect level (LOAEL) of 500 mg/kg bw, transient functional alterations (for example, decreased reactivity to handling, increased hunched posture and abnormal gait), decreased body temperature and decreased motor activity were observed. These effects were the result of a single exposure and are therefore relevant to an acute risk assessment. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold.

The composite assessment factor (CAF) is 100-fold.

The acute reference dose (ARfD) is calculated according to the following formula:

$$\text{ARfD (gen. pop)} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{125 \text{ mg/kg bw}}{100} = 1.25 \text{ mg/kg bw of penthiopyrad}$$

The ARfD provides a margin of 400 to the dose at which there was an unequivocal increase in abortions in rabbits in the range-finding study and 800 to the dose where there were adverse effects on offspring viability and thymus development in rats; consequently the ARfD is considered protective of pregnant women and their fetuses.

3.3 Determination of Acceptable Daily Intake

To estimate dietary risk of repeat exposure, the 24-month oncogenicity study in rats with a NOAEL of 9 mg/kg bw/day was selected for risk assessment. At the LOAEL of 27 mg/kg bw/day, increased kidney interstitial fibrosis and renal glomerulosclerosis were observed in males. This study provides the lowest NOAEL in the database. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold. The CAF is 100-fold.

The acceptable daily intake (ADI) is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{9 \text{ mg/kg bw/day}}{100} = 0.09 \text{ mg/kg bw/day of penthiopyrad}$$

The ADI provides a margin of 2,780 to the thyroid tumours in male rats; consequently it is considered protective of this endpoint and all other endpoints in the toxicity database.

Cancer Assessment
Penthiopyrad had weak evidence of oncogenicity. Given this, and for the reasons outlined in the toxicology summary, the use of a linear low dose extrapolation approach for cancer risk assessment was considered overly conservative. A threshold approach was used to assess the risk for the thyroid tumours in male rats. The dietary reference dose (i.e. the ADI), as well as the selected NOAELs and the target margins of exposure (MOE) for occupational and bystander exposure, provide a sufficient margin to this tumour.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational and residential exposure to penthiopyrad is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes. For residential scenarios, short- to intermediate-term exposure may occur in children via the same routes. In addition, short-term exposure in children may occur incidentally via the oral route.

Occupational exposure to penthiopyrad is characterized as short- to intermediate-term in duration with a possibility of long-term exposure for postapplication greenhouse use and is predominantly by the dermal and inhalation route. For residential scenarios, adult, youth and toddler exposure is characterized as short- to intermediate-term and to occur predominantly via the dermal route. For toddlers, incidental oral exposure was also assessed and is characterized as short-term in duration.

Short- and Intermediate-term Dermal Exposure (Adults)
For short- and intermediate-term dermal risk assessment for adults, the developmental toxicity study in rabbits was selected. The 28-day dermal toxicity study did not address the endpoint of concern, thus necessitating the use of an oral study for risk assessment. At doses of 225 mg/kg bw/day, litter and fetal weights were reduced in the presence of maternal toxicity, which consisted of an abortion and decreased gravid uterine weight. A NOAEL of 75 mg/kg bw/day was established.

For residential and occupational scenarios, the target MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. As outlined in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold. This MOE is considered to be protective of all adults, including pregnant and lactating women and their unborn children, as well as nursing infants and children of exposed female workers.

Short- and Intermediate-term Dermal Exposure (Children)
For short- and intermediate-term residential dermal risk assessment for children, the multi-generation reproductive toxicity study in rats was selected. The 28-day dermal toxicity study did not address the endpoint of concern, thus necessitating the use of an oral study for risk assessment. Offspring toxicity in the reproductive toxicity study occurred in the presence of maternal toxicity and was observed in the form of decreased bodyweight, increased small body size, delayed sexual maturation in both sexes and decreased thymus and spleen weights at 311 mg/kg bw/day. A NOAEL of 76 mg/kg bw/day was established.

For residential scenarios, the target MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. As outlined in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold. This MOE is considered to be protective of children.

Short- and Intermediate-term Inhalation Exposure (Adults and Children)
For short- and intermediate-term residential (adults and children) and occupational (adults) exposure via the inhalation route, the 90-day toxicity study in rats was selected for risk assessment. A NOAEL of 40 mg/kg bw/day was established based on increased liver weight, hepatocellular hypertrophy, histopathological alterations and perturbations in clinical chemistry and haematology at 99.9 mg/kg bw/day. This study provides the lowest short- to intermediate-term toxicity NOAEL in the database. A short-term inhalation study was not available.

The target MOE for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability.

For residential exposure, the study NOAEL and target MOE provide a margin of greater than 550 to offspring effects in the multi-generation reproductive toxicity study and the developmental toxicity studies in rats and rabbits. Consequently, and for reasons outlined in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold. In addition, this study and target MOE are considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Long-term Dermal and Inhalation Exposure (Adults)

For long-term dermal and inhalation risk assessment for adults, the 12-month chronic toxicity study in rats with a NOAEL of 25 mg/kg bw/day was selected for risk assessment. At the LOAEL of 100 mg/kg bw/day, increased liver weight, adrenal weight, adrenal diffuse hypertrophy of zona glomerulosa, adrenal cortical lipid vacuolation, thyroid diffuse follicular cell hypertrophy were observed, as well as increased kidney weight in males and increased hemoglobin distribution width, potassium, cholesterol and phospholipid levels in females. Repeat-dose inhalation toxicity studies were not conducted and the duration of the 28-day dermal toxicity study was not appropriate for long-term exposure scenarios, thus necessitating the use of an oral study for risk assessment. Although the NOAEL of 9 mg/kg bw/day in the two year oncogenicity study in rats was the lowest NOAEL in the toxicology database for penthiopyrad, the key effects at the LOAEL of 27 mg/kg bw/day (kidney interstitial fibrosis and glomerulosclerosis) were not observed in male rats until terminal sacrifice. The similarity of this effect level to the NOAEL in the chronic toxicity study in rats suggests that the above renal histopathological effects occurred after two years of penthiopyrad treatment. The 2-generation reproductive toxicity study also had a lower NOAEL (12 mg/kg bw/day) and LOAEL (60/76 mg/kg bw/day males/females) than the 12-month chronic toxicity study study in rats. This study was not considered to be as relevant for this scenario, since the key treatment-related effects in males were decreased body weight and body weight gains from weeks 2-10 only, and the adrenal and liver effects in females were also seen after a longer duration of dosing in the 12 month rat chronic toxicity study. Also, the NOAEL of 25 mg/kg bw/day is the highest NOAEL between the 12-month rat chronic toxicity study and the rat 2-generation reproductive toxicity study. Based on the intermittent nature of the proposed long-term exposure scenarios, the 12 month chronic toxicity in rats was considered to be most appropriate for long-term exposure risk assessment.

The target MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. This target MOE is considered to be protective of all adults including nursing infants and the unborn children of exposed female workers.

Non-Dietary Oral Ingestion (Children, Short-term)

For short-term residential exposure in children via non-dietary oral ingestion, the acute neurotoxicity study with a NOAEL of 125 mg/kg bw was selected for risk assessment. At the LOAEL of 500 mg/kg bw, transient functional alterations (for example, decreased reactivity to handling, increased hunched posture and abnormal gait), decreased body temperature and decreased motor activity were observed. These effects were the result of a single exposure and are, therefore, the most relevant endpoints for the assessment of risk related to short-term incidental oral ingestion.

The target MOE for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. For reasons outlined in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold.

3.4.1.1 Dermal Absorption

A rat *in vivo* dermal penetration study and three *in vitro* rat/human comparison studies (one for the Fontelis Fungicide formulation, one for the Vertisan Fungicide formulation and one for the Treoris Fungicide formulation) were submitted. Given the uncertainties identified in the *in vivo* study and the fact that only a high concentrated dose diluted in CMC and Tween 80 was assessed, it was not appropriate to derive a dermal absorption factor for penthiopyrad based on the results of this study. As the rat *in vivo* study was not a suitable estimator for dermal absorption, the rat/human *in vitro* studies cannot be used as a direct comparative tool for extrapolation of human absorption.

However, the physical and chemical properties of penthiopyrad are such that refinement of the dermal absorption value was possible. Based on the molecular mass (359.4 g/mol), water solubility (1.375 mg/L at pH 7 and 20 °C) and the octanol water partition coefficient (log K_{ow} of 4.62 at pH 7 and 20 °C), the dermal absorption of penthiopyrad is expected to be low to moderate. These properties in combination with the observations made during the *in vitro* dermal absorption studies, a dermal absorption value of 50% was used during the assessment of dermal exposure for penthiopyrad.

3.4.2 Occupational Exposure and Risk

Mixer/loader/applicator Exposure and Risk Assessment
Individuals have potential for exposure to penthiopyrad during mixing, loading and application of Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide. The use of Treoris Fungicide on potatoes and cucurbits fits within the registered use pattern for chlorothalonil, therefore chlorothalonil will not be further discussed in the occupational exposure and risk section. Exposure is expected to be short- to intermediate-term in duration and to occur through both the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying penthiopyrad to alfalfa, low growing berries, bulb vegetables, brassica vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, legume vegetables and foliage, pome fruits, root vegetables and leaves, stone fruit, tree nuts, peanuts, canola, dry legumes, cereal grains, corn, sorghum, millet, soybeans, sunflower, tuberous and corm vegetables, sugar beets, potatoes and turf grass using groundboom, aerial, airblast, backpack, low-pressure handwand or low-pressure nozzle sprayer equipment. The exposure estimates are based on mixers/loaders/applicators wearing a long-sleeved shirt, long pants, shoes, socks and chemical resistant gloves.

As chemical specific data for assessing human exposure were not submitted, dermal and inhalation exposure estimates for workers were estimated using the Pesticide Handlers Exposure Database, version 1.1. Risk assessments were performed for workers wearing a single layer and gloves during mixing/loading and application.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight. Exposure estimates were compared to the toxicological end points (NOAEL) to obtain the MOE; the target MOE is 100. The MOEs for mixers/loaders and applicators were above the target of 100 for dermal exposure and for inhalation exposure and, thus, occupational risk associated with mixing/loading and applying Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide is not of concern with the protective equipment specified on the label. The exposure and risk estimates are presented in Appendix I, Table 5.

3.4.2.1 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers entering areas treated with penthiopyrad while performing activities such as scouting, hand harvesting, thinning or maintenance tasks. The duration of exposure is considered to be short-term (up to 30 days per year) to intermediate-term (up to six months per year) for all uses except for greenhouse, where long-term exposure potential exists (year-round). The primary route of exposure for workers re-entering treated areas would be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route, since penthiopyrad is relatively non-volatile (6.43×10^{-9} kPa at 25°C) and meets the NAFTA criteria for a low volatility inhalation assessment waiver based on a vapour pressure less than 1.0×10^{-4} kPa for outdoor use and 1.0×10^{-5} kPa for indoor use.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values or transferable turf residue values with activity-specific transfer coefficients. Activity transfer coefficients are based on Agricultural Re-entry Task Force data. Chemical-specific dislodgeable foliar residue (DFR) data were submitted for airblast application on apple trees and for ground spray application on squash. For greenhouse DFR, a default value of 20% of the application rate was used in the exposure assessment, and for transferable turf residues, a default value of 5% of the application rate was used.

Exposure estimates were compared to the toxicological end-point to obtain the MOE; the target MOE is 100. The MOEs for entering treated areas were above the target of 100, except for detasseling corn, which required a 3-day restricted entry interval (REI). Thus, with the inclusion of the 3-day REI for corn detasseling, there were no postapplication risks of concern. The exposure and risk estimates are presented in Appendix I, Table 6.

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

There are no domestic class products, therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

There is potential for postapplication exposure to the general population entering areas treated with penthiopyrad. An assessment was required for adults and children who harvest crops from pick-your-own (PYO) farms and are exposed to treated lawns around their home, school, parks or public areas. The duration of exposure is considered to be short-term for PYO and short- to intermediate-term for residential and municipal lawns and golf courses. The primary route of exposure for these individuals would be through the dermal route. Penthiopyrad is considered non-volatile and is not an inhalation concern for postapplication exposure.

Risk calculations for dermal exposure were performed using the predicted DFR on the pre-harvest interval from the apple DFR study, the cucurbit DFR study or default Day 0 transferable turf residue, along with the average bodyweights for age group and the time spent on the activity each per day. Applicable transfer coefficients were scaled to represent the average surface area of individuals within various subpopulations.

Exposure estimates were compared to the toxicological end-point to obtain the MOE; the target MOE is 100. The MOEs for the general public entering treated areas were above the target of 100 and, thus, risk associated with residential postapplication exposure is not of concern. The exposure and risk estimates are presented in Appendix I, Table 7.

In addition to dermal exposure to residential lawns, default hand-to-mouth, turf ingestion and soil ingestion equations from the EPA *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment* including the revisions documented in the EPA HED Policy #12 were used to estimate incidental oral exposure for toddlers. The exposure and risk estimates are presented in Table 8, Appendix I and were not of concern.

3.4.3.3 Bystander Exposure and Risk

Risk to bystanders is considered negligible as exposure to spray drift is not expected to exceed the exposure for mixers/loaders and applicators.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

The residue definition for enforcement in plant products is penthiopyrad. The residue definition for risk assessment in plant products is penthiopyrad, and the metabolites PAM and PCA. The residue definition for risk assessment and enforcement in animal commodities is penthiopyrad and the metabolite PAM. The data gathering/enforcement analytical method is valid for the quantitation of penthiopyrad, PAM and PCA residues in crops and livestock matrices. The residues of penthiopyrad and the metabolites are stable in plant matrices when stored in a freezer at -20°C for 18 months. Raw agricultural commodities of sugar beet, potato, soybean, plum, field corn, canola, peanut, apple, wheat and tomato were processed. The processing data showed that residues of penthiopyrad concentrate in the following commodities: corn oil (4.0x), dried prune

(1.4x), canola oil (1.6x), peanut oil (1.5x), tomato paste (2.5x) and tomato puree (1.9x). The processing factor in wheat processed commodities cannot be determined due to the lack of quantifiable residues in wheat grain and wheat processed commodities. Supervised residue trials conducted throughout the United States and Canada using end-use products containing penthiopyrad at the label rates in, or on, all proposed crops are sufficient to support the proposed maximum residue limits (MRLs). Several proposed crops are animal feed items. Based on animal feeding studies and the estimated dietary burdens, MRLs in animal commodities are recommended to cover the secondary residues in livestock matrices.

3.5.2 Dietary Risk Assessment

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.16), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following assumptions were made in a refined chronic analysis: median residues of crop field trial data, experimental processing factors, and anticipated residues in animal commodities. The refined chronic dietary exposure from all supported penthiopyrad food uses (alone) for the total population, including infants and children, and all representative population subgroups are 5.4% of the ADI. Aggregate exposure from food and water was not of concern. The PMRA estimates that chronic dietary exposure to penthiopyrad from food and water is 7.1% (0.006393 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year) at 18.3% (0.016426 mg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were made in a refined acute analysis: the highest average field trial (HAFT) residues values from crop field trial data, experimental processing factors, and anticipated residues in animal commodities. The refined acute dietary exposure (food alone) for all supported penthiopyrad registered commodities is estimated to be 2.1% (0.026093 mg/kg/day) of the ARfD (95^{th} percentile, deterministic) for the total population. Aggregate exposure from food and water was not of concern: 3.1% (0.038877 mg/kg/day) of the ARfD for total population. The highest exposure and risk estimate is for infants <1 year old at 6.0% (0.075542 mg/kg bw/day) of the ARfD.

3.5.3 Aggregate Exposure and Risk

The aggregate risk for penthiopyrad consists of exposure from food and drinking water sources only. Aggregate risks were calculated based on acute and chronic endpoints.

3.5.4 Maximum Residue Limits

Table 3.5.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Leaves of root and tuber vegetables (Crop Group 2), leafy Brassica greens subgroup (Subgroup 5B)	50
Leafy vegetables (Crop Group 4)	30
Head and stem Brassica subgroup (Subgroup 5A)	5
Edible-podded legume vegetables subgroup (Subgroup 6A), stone fruits (Crop Group 12-09)	4
Tomato paste	3.5
Root vegetables (except sugar beet) subgroup (Subgroup 1B), bulb vegetables (Crop Group 3-07), fruiting vegetables (Crop Group 8-09), low growing berry subgroup (Subgroup 13-07G)	3
Oil seeds (Crop Group 20)	1.5
Barley bran	0.9
Sorghum, millet	0.8
Cucurbit vegetables (Crop Group 9)	0.6
Sugar beet, pome fruits (Crop Group 11-09)	0.5
Succulent shelled pea and bean subgroup (Subgroup 6B), dried shelled pea and bean (except soybean) subgroup (Subgroup 6C), soybean	0.4
Wheat bran & germ	0.3
Cereal grains (Crop Group 15, except corn, sorghum and millet)	0.15
Tuberous and corm vegetables subgroup (Subgroup 1C), tree nuts (Crop Group 14-11), peanut oil	0.06
Corn oil	0.05
Peanuts	0.04
Field corn, pop corn, sweet corn kernels plus cob with husks removed	0.01
Meat byproducts of cattle, goats, horses and sheep	0.09
Meat and fat of cattle, goats, horses and sheep.	0.03
Eggs; fat, meat & meat byproducts of hogs and poultry; milk	0.02

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

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, analytical methodology, field trial data, and the acute and chronic dietary risk estimates are summarized in Appendix I, Tables 1, 9 and 10.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The physical/chemical properties, fate and behaviour of penthiopyrad and its transformation products in the terrestrial environment are summarized in Appendix I, Tables 11 and 12. The fate and behaviour of penthiopyrad in the aquatic environment is summarized in Appendix I, Table 13.

Penthiopyrad has a water solubility of 2.54 (pH 4), 1.38 (pH 7) and 1.66 mg/L (pH 10) indicating it has low aqueous solubility. Penthiopyrad is expected to bioaccumulate based on its log K_{ow} of 4.36-4.62. The vapour pressure of penthiopyrad is 2.96×10^{-6} Pa (20°C) indicating it is relatively non-volatile under field conditions. Similarly, the calculated Henry's Law Constant of 1/H = 3.15×10^{6}, indicates penthiopyrad is not expected to volatilize from moist soil or water surfaces. The dissociation constant (pK_a) of 10.0 indicates penthiopyrad will not dissociate at environmentally relevant pH.

Hydrolysis was not a route of transformation as penthiopyrad was stable in water at pH 4, pH 7 and pH 9 after 15 days at 50°C. On soil, phototransformation was a route of transformation of penthiopyrad as the first-order half-life was 3.4 days for continous irradiation with artificial light and 6.8 days under conditions of 12 hours artificial light:12 hours dark. The major phototransformation products were PAM at a maximum of 26.7% of applied and PCA at a maximum of 22.7% of applied. In aerobic soil, penthiopyrad was moderately persistent to persistent (DT_{50} = 60-406 days). DM-PCA was the major transformation product in aerobic soil reaching maximums of 17-28% of applied. DM-PCA exhibited DT_{50}s of 32.6-155 days, indicating it was slightly persistent to moderately persistent in aerobic soil. In anaerobic soil, penthiopyrad was persistent as biotransformation was not evident.

Penthiopyrad is expected to have low mobility in soil as its laboratory-determined K_{oc} values were 616-996 mL/g. By contrast, its major aerobic soil transformation products, DM-PCA and PCA, have potential for very high mobility in soil as the K_{oc}s were 4-11 and 0.0002-3.5 mL/g, respectively. Similarly, the major phototransformation product, PAM, has potential to be very highly mobile in soil as its K_{oc} was 5-11 mL/g.

Under terrestrial field conditions, penthiopyrad was non-persistent to slightly persistent in soil with reported DT_{50} values ranging from 6.1-29.5 days. Penthiopyrad was transformed in the upper 5-30 cm soil depth and did not leach to lower soil depths. The major transformation product, DM-PCA, leached to lower soil depths (up to 70 cm depth). The other major transformation product, PCA, was not detected beyond the upper 15 cm of soil.

Hydrolysis was not a route of transformation as penthiopyrad was stable in water at pH 4, pH 7 and pH 9 after 15 days at 50°C. Phototransformation in water was not a route of transformation as penthiopyrad was photolytically stable under continous irradiation with artificial light. In aerobic water/sediment biotransformation studies, penthiopyrad is persistent with reported DT_{50} values of 223-384 days. Penthiopyrad steadily partitioned from the water phase to the sediment. In sediment, penthiopyrad increased from 5-6% of applied at day 0 to maximum levels of 63.3-68.1% applied radioactivity (AR) by day 56. Once in sediment, the dissipation of penthiopyrad was slow, declining slightly to 46.8-58.0% by day 185. PCA was the major transformation product in aerobic aquatic systems accounting for a maximum of 10.5% of applied by day 185 in the total system. In anaerobic water/sediment biotransformation studies, penthiopyrad was persistent as almost all of the applied radioactivity was present as unchanged parent after 100 days. Penthiopyrad partitioned from the anaerobic water phase to the sediment via adsorption (20:80 split in water: sediment after 100 days). The biotransformation of penthiopyrad in the total system was too slow for a meaningful determination of DT_{50}.

The bioconcentration of penthiopyrad in fish was low. For exposure to a low dose of penthiopyrad (0.98 µg a.i./L), the mean bioconcentration factor (BCF) values in rainbow trout were 79 for edible tissues, 226 for non-edible tissues, and 158 for whole fish tissues for total residues. At the high dose (10.22 µg a.i./L), the mean BCFs were 86 for edible tissues, 236 for non-edible tissues, and 155 for whole fish tissues for total residues. Depuration half-lives for whole fish were 0.86 days at the low dose and 0.65 days at the high dose.

4.2 Environmental Risk Characterization

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

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling for spray drift and surface runoff, field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

For characterizing acute risk, acute toxicity values (for example, LC_{50}, LD_{50}, and EC_{50}) are multiplied by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (for example, community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (for example, 0.1 for fish, 0.5 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e. feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied. Table 14 (Appendix I) outlines the toxicity endpoints considered in the risk assessment.

As toxicity studies were conducted with the Vertisan Fungicide and Fontelis Fungicide formulations (containing penthiopyrad) and with the co-formulated Treoris Fungicide (containing penthiopyrad + chlorothalonil), the risk assessment was conducted on the basis of the most sensitive endpoint for each of these end-use products (Appendix I, Table 14).

4.2.1 Risks to Terrestrial Organisms

Table 15 (Appendix I) summarizes the screening level risk to terrestrial organisms other than birds and mammals. In the risk assessment of earthworms and terrestrial plants, the EEC is based on the cumulative in-field application of penthiopyrad. For bees, the EEC is based on the single maximum application rate. For beneficial arthropods, the risk assessment is based on both the potential in-field and off-field exposure to penthiopyrad. In-field exposure assumes 100% of the cumulative application rate of penthiopyrad deposited onto foliage. Off-field exposure assumes exposure via spray drift deposition (based on the proposed ASAE fine droplet spray quality) of 11% (field sprayer application), 74% (airblast application) or 26% (aerial application) of the cumulative rate of penthiopyrad deposited onto foliage.

In earthworms and bees, penthiopyrad and the end-use formulations (Vertisan Fungicide, Fontelis Fungicide and Treoris Fungicide) pose a negligible risk (RQ <1) on an acute and chronic basis.

In terrestrial plants, the Fontelis Fungicide formulation poses a risk to plant emergence (RQ = 2.0) for uses in turf resulting from a direct in-field exposure. For exposure resulting from off-field spray drift, however, the risk to non-target plants is negligible (RQ <1) for treatment of turf. For use in field crops and orchards, the risk to terrestrial plants was negligible (RQ <1) for both seedling emergence and vegetative vigour.

Both the Vertisan Fungicide and Fontelis Fungicide formulations pose a potential acute in-field risk to beneficial arthropods in field crops (RQ < 6) and orchards (RQ < 5). The acute off-field risk for gound field applications of the Vertisan Fungicide and Fontelis Fungicide formulations are negligible, whereas the RQ's for orchards and aerial applications are less than four. The acute in-field risks for the Treoris Fungicide formulation are considered to be negligible in field crops (RQ < 1.2) based on the endpoint reported of >470 g a.i./ha.

On the basis of reproductive effects, the Fontelis Fungicide formulation poses an in-field risk in field crops (RQ = 78) and orchards (RQ = 67). The Fontelis Fungicide formulation also poses an off-field risk in field crops (RQ = 8.6) for ground application and RQ = 20.4 for aerial appliction) and orchards (RQ = 20.4). Treoris Fungicide poses an in-field reproductive risk in field crops (RQ = 65). Treoris Fungicide also poses an off-field reproductive risk in field crops (RQ = 7.1 for ground application and RQ = 16.9 for aerial application).

In the higher-tier field studies with the Fontelis Fungicide formulation, however, the population of predatory mites was reduced by only 19.4% and 11.8% from applications of 448 and 720 g a.i./ha, respectively. These results indicate there is a minimal concern for effects on the arthropod population as a 50% effect is considered to be acceptable, since between-season recovery is usually not impeded at this effect level, and is applicable to both in- and off-field habitats. As results of the laboratory studies indicate that the Treoris Fungicide and Fontelis Fungicide formulations exhibit similar effects on arthropod reproduction (ER_{50}s = 8.7 and 7.2 g a.i./ha, respectively), under field conditions, a similar effect with Treoris Fungicide is expected. Thus, as with the Fontelis Fungicide formulation, there is a minimal concern with the effects of the Treoris Fungicide on arthropod reproduction. In addition, the effects of chlorothalonil (the other fungicide active in Treoris Fungicide) on beneficial arthropods was not identified as a concern in the most recent re-evaluation of this fungicide (PRVD2011-14 - *Chlorothalonil*).

Tables 16, 17 and 18 (Appendix I) summarizes the screening level risk to birds and mammals resulting from the application of penthiopyrad to field crops, orchards and turf, respectively. The screening level risk assessment shows that penthiopyrad poses a negligible risk (RQ <1) to all feeding guilds and body sizes in birds and mammals on an acute and reproductive basis.

4.2.2 Risks to Aquatic Organisms

Table 19 (Appendix I) summarizes the screening level risk to aquatic organisms. In the determination of the RQs for invertebrates, fish, algae and aquatic vascular plants, the EECs in water are based on the cumulative application of penthiopyrad to a 80-cm deep pond. For determination of the RQs for exposure of aquatic life-stages of amphibians, the EECs in water are based on the cumulative applications of penthiopyrad to a 15-cm deep pond.

For freshwater invertebrates, penthiopyrad poses a negligible acute and chronic risk (RQ <1). Similarly, the Vertisan Fungicide formulation poses a negligible acute risk (RQ <1). The Fontelis Fungicide formulation, however, poses a risk on an acute and chronic basis with RQs of 3.7-13.4 and 10.4-37.7, respectively. The Treoris Fungicide formulation also poses a risk on an acute basis with an RQ of 13.9.

For freshwater fish, the Treoris Fungicide formulation is the most toxic test substance by posing the highest acute risk (RQ = 92.1). The less toxic penthiopyrad, Fontelis Fungicide and Vertisan Fungicide formulations, pose similar acute risks with RQs of 3.8-13.8, 3.1-11.2 and 3.6-12.9, respectively.

For aquatic life-stages of amphibians, the acute toxicity endpoints for fish were considered as surrogate data given the lack of data for amphibian species. For assessing risks to amphibians, a shallower receiving water body is used to determine EEC values. Here, the Treoris Fungicide formulation poses the highest acute risk to amphibians with an RQ of 490. The less toxic penthiopyrad, Fontelis Fungicide and Vertisan Fungicide formulations, pose similar acute risks with RQs of 20.3-73.5, 16.5-59.9 and 19.0-69.0, respectively.

For freshwater plants (algae and duckweed), penthiopyrad, Fontelis Fungicide and Vertisan Fungicide formulations pose a negligible acute risk (RQ <1). By contrast, the Treoris Fungicide formulation poses an acute risk to freshwater plants with an RQ of 5.1.

For marine fish, penthiopyrad and the Fontelis Fungicide formulation pose an acute risk for uses on turf with RQs of 2.9 and 1.5, respectively. For uses in field crops and orchards, the acute risk was negligible (RQ <1).

For marine algae, penthiopyrad poses a negligible acute risk (RQ <1).

Table 20 (Appendix I) summarizes the refined aquatic risk assessment for those species where the LOC was exceeded in the screening level risk assessment.

The refined assessment considered the off-target spray drift if penthiopyrad is applied by field sprayers, airblast sprayers or by aerial application. Here, the refined EECs are based on the spray drift from applications using the proposed fine spray quality. This off-field exposure assumes spray drift (based on the proposed ASAE fine droplet spray quality) of 11% (field sprayer application), 74% (airblast application) or 26% (aerial application) of the cumulative rate of penthiopyrad.

Refined assessments also considered exposure resulting from surface runoff of penthiopyrad to aquatic habitats. For aquatic invertebrates, fish, algae and amphibians, the peak EECs resulting from surface runoff are used to assess the acute risk, whereas for the chronic risk, 21-day EECs are considered.

In freshwater invertebrates, acute and chronic risks are identified for surface runoff and spray drift (RQ >1; LOC exceeded) for exposure to the Fontelis Fungicide and Treoris Fungicide formulations. The two exceptions are acute exposure to the Fontelis Fungicide formulation through spray drift in field crops and surface runoff in orchards (RQ <1; negligible risk). For runoff and spray drift resulting from the application of the Fontelis Fungicide formulation, the RQs are <1.0-9.0 and <1.0-7.6, respectively, indicating a negligible risk (RQ<1) or an exceedance of the LOC (RQ>1) depending on the exposure scenario. For runoff and spray drift resulting from the application of the Treoris Fungicide formulation, the RQs are 10.9 and 1.5-3.7, respectively, indicating the LOC is exceeded in all exposure scenarios.

For freshwater fish, various levels of risk are attributed to exposure via runoff and spray drift with the highest risk being associated with the application of the Treoris Fungicide formulation. Thus, for runoff and spray drift resulting from the application of Treoris Fungicide, the RQs are 72.1 and 10.0-24.3, respectively, indicating the LOC is exceeded in all exposure scenarios. For runoff and spray drift resulting from the application of penthiopyrad, the RQs are <1.0-3.5 and <1.0-2.8, respectively, indicating a negligible risk (RQ<1) or an exceedance of the LOC (RQ>1) depending on the exposure scenario. Similarly, for runoff and spray drift resulting from the application of the Fontelis Fungicide formulation, the RQs are <1.0-2.8 and <1.0-2.3, respectively, and for the application of the Vertisan Fungicide formulation, the RQs are <1.0-3.3 and <1.0-2.6, respectively.

For aquatic life-stages of amphibians, various levels of risk are attributed to runoff and spray drift with the highest risk being associated with the application of the Treoris Fungicide formulation. Thus, for runoff and spray drift resulting from the application of the Treoris Fungicide formulation, the RQs are 197.9 and 54.3-127.1, respectively, indicating the LOC is exceeded in all exposure scenarios. For runoff and spray drift resulting from the application of penthiopyrad, the RQs are 2.3-9.6 and 2.6-15.0, respectively, again indicating the LOC is exceeded in all exposure scenarios. Similarly, for runoff and spray drift resulting from the application of the Fontelis Fungicide formulation, the RQs are 1.8-7.8 and 2.1-12.2, respectively, and for the application of the Vertisan Fungicide formulation, the RQs are 2.1-9.0 and 2.5-14.1, respectively.

In freshwater algae, exposed to runoff and spray drift resulting from the application of the Treoris Fungicide formulation, the RQs are 4.0 and <1-1.3, respectively, indicating a negligible risk (RQ<1) or an exceedance of the LOC (RQ>1) depending on the exposure scenario.

In marine fish, there is negligible risk (RQ <1) attributed to runoff and spray drift resulting from the application of penthiopyrad or the Fontelis Fungicide formulation.

An additional spray drift risk assessment was conducted for the co-formulated Treoris Fungicide, which contains both penthiopyrad and chlorothalonil as active ingredients. As a medium spray quality is designated on the labels of chlorothalonil products, exposure resulting from this coarser spray quality is considered in refining the spray drift assessment for Treoris Fungicide. This off-field exposure assessment assumes spray drift (based on the ASAE Medium droplet spray quality) of 6% (field sprayer application) and 23% (aerial application) of the cumulative application rate of Treoris Fungicide. This spray drift risk assessment was also based on the same toxicity endpoints for Treoris Fungicide used in the preceding assessment.

Table 21 (Appendix I) summarizes the refined spray drift assessment for Treoris Fungicide. For freshwater invertebrates, there is a negligible acute risk (RQ <1) from ground application spray drift, however, the LOC is exceeded (RQ = 3.2) with spray drift resulting from aerial application of Treoris Fungicide. For freshwater fish, the LOC is exceeded for both ground and aerial application spray drift (RQs = 5.5 and 21.2, respectively). Similarly, for amphibians, the LOC is exceeded for both ground and aerial application spray drift (RQs = 29.4 and 112.7, respectively). For freshwater algae, there is a negligible acute risk (RQ <1) from ground application spray drift, however, the LOC is exceeded (RQ = 1.2) with spray drift resulting from aerial application.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

Efficacy evaluations were conducted on submitted data and scientific rationales. Where possible, extrapolations were accepted between crops and pests. For example, *Botrytis cinerea* is a pathogen that affects multiple crops in a similar way with respect to plant parts affected, symptoms expressed and disease cycle. Therefore, control of this pest was supported on all proposed crops based on the trial results and rationales. For diseases caused by host-specific pathogens (powdery mildew, rust), conclusions were based on trial data only for most crops. Extrapolations were supported if crops were affected by the same pathogen and the disease was manifested in the same way. Extrapolation of in-furrow use to suppress diseases caused by *Rhizoctonia solani* (excluding seed and seedling diseases) was supported on all proposed crops, but were amended to potatoes and sugar beets based on the health risk assessment. Claims were amended to suppression when the data demonstrated this level of control. Rates were adjusted based on tested rates that demonstrated efficacy. Crops were amended based on which crops are affected by the tested pathogen. Additional data is being requested for situations where the level of efficacy was not consistent or was unclear. Supported and unsupported uses are summarized by product in Appendix I, Tables 27 to 30.

Fontelis Fungicide
Uses on the following crops or crop groups were proposed: alfalfa, low growing berries, bulb vegetables, brassica leafy vegetables, cucurbits, fruiting vegetables, leafy vegetables, legumes, pome fruit, root vegetables, stone fruit, tree nuts and peanuts.

The following diseases or pathogens were included on the proposed label: powdery mildew, white mould/sclerotinia stem rot, grey mould/botrytis rots, alternaria diseases, soil-borne diseases caused by *Rhizoctonia solani*, rust diseases, brown rot/blossom blight, brown leaf spot, mummyberry, gummy stem blight, ascochyta blight, cercospora leaf spot, asian soybean rust, angular leaf spot, scab, cherry leaf spot, early leaf spot, late leaf spot, southern stem rot and web blotch.

A total of 120 trials were submitted to support the claims. Seven trials were not reviewed as they did not test the proposed use pattern (rate, number of applications, etc.) or the product was applied in a tank mix with another fungicide, such that the efficacy of penthiopyrad could not be determined. Forty-six trials were reviewed as supplementary data because the number of applications exceeded the proposed use pattern, disease pressure was low in the trial, or the trial was conducted in a greenhouse, which is not representative of field conditions. Rationales were provided to extrapolate some claims to other crops or crop groups. No data were submitted to demonstrate efficacy using aerial application.

Claims for control were supported based on the commercially acceptable level of disease reduction and comparable performance to a commercial standard. For example, trials submitted for apple scab assessed disease incidence and severity on leaves and disease incidence on fruit. Fontelis Fungicide applied at 1.0 L/ha (proposed rates 1.0 – 1.5 L/ha) provided an average of 77% control of disease incidence and an average of 87% control of disease severity on leaves under moderate to high disease pressure. An average of 87% control of disease incidence was also observed on fruit. The results were statistically comparable to the registered commercial standards. The claim of control of apple scab was supported as proposed based on the data. Trials on pear scab could not be reviewed as the product was not applied according to the proposed use pattern. Although pear is not affected by the same species of pathogen as apple, the disease is manifested in the same manner as apple scab. The results from the apple scab data were extrapolated to pear; the claim of control of pear scab was supported as proposed.

The level of control was deemed to be suppression if the average level of control of disease severity fell between 60 – 80%, or if the product was not consistently controlling the disease (>80% control). For example, assessments for early blight on tomato were made under moderate to high disease pressure; however, the number of applications made to tomato plants exceeded the proposed maximum. Application of Fontelis Fungicide at 1.2 L/ha (proposed rates 1.25 - 1.75 L/ha) provided levels of control of disease severity ranging from 45 – 95% (average level of control 79%). Application at 1.5 L/ha resulted in 56 – 94% control (average 73% control). At both rates, the level of control fluctuated between partial suppression and control and the average level of control fell below 80%. Due to inconsistent levels of efficacy and because the number of applications made exceeded the proposed maximum, the claim for early blight on tomato was supported as suppression.

A total of 35 claims were supported; some claims were amended to express a different level of control (suppression), to identify specific crops affected by the disease, to change the common name of the disease, or to alter the use pattern (rates). Eight claims were supported on the condition that additional data are submitted to confirm the level of efficacy. Eleven claims were not supported due to a lack of supporting evidence. Aerial application to alfalfa, lowbush blueberries and cucurbits is supported based on a rationale extrapolating data from Vertisan Fungicide to Fontelis Fungicide. Additional information for aerial application is required.

Please refer to Appendix I, Table 27, for a summary of supported uses.

Vertisan Fungicide

Uses on the following crops or crop groups were proposed: canola, dry legumes, cereals, corn, sorghum, soybeans, sunflower, tuberous and corm vegetables, and sugar beets.

The following diseases were included on the proposed label: white mould/sclerotinia head or stem rot, ascochyta blight, grey mould/botrytis rots, rusts, powdery mildew, soil-borne diseases caused by *Rhizoctonia solani*, asian soybean rust, net blotch, septoria leaf blotch, grey leaf spot, brown spot, frogeye leafspot, and early blight.

A total of 104 trials were submitted to support the claims. Fourteen trials were not reviewed as disease pressure was too low to determine efficacy with confidence. Fourteen trials were reviewed as supplementary data because the tested rates were lower than proposed, a different formulation was used in the trials or the trial was conducted in another country. Rationales were provided to extrapolate some claims to other crops or crop groups.

Assessment of disease data was conducted in the same manner as for Fontelis Fungicide. For example, assessments for leaf rust on wheat were conducted under moderate to high disease pressure. When applied at rates within the proposed rate range (1.2 – 1.75 L/ha), Vertisan Fungicide provided an average of 81 – 85% control of disease severity, which was statistically comparable to the registered commercial standard. The claim of control of leaf rust on wheat was supported as proposed. Assessments for early blight on potato were conducted under moderate disease pressure. When applied at rates within the proposed range (1.0 – 1.75 L/ha), Vertisan Fungicide provided average levels of control of disease severity that ranged between 64.4 – 96.7%, depending on the rate applied. Results for the commercial standard were statistically comparable, but the level of control expressed in the trials was more consistently at a control level. Since the product did not consistently control early blight symptoms on potatoes, the claim was supported as suppression.

A total of 19 claims were supported, including aerial application. Claims may have been amended for the reasons stated for Fontelis Fungicide. Two claims were supported on the condition that additional data are submitted to confirm the level of efficacy. Six claims were not supported due to a lack of supporting evidence.

Please refer to Appendix I, Table 28, for a summary of supported uses.

Treoris Fungicide
A total of nine trials were submitted to support claims on potato and cucurbit vegetables for the control of early blight and powdery mildew respectively. One trial was reviewed as supplementary data as the number of applications made exceeded the use pattern. The claims were supported as proposed. Aerial application to potatoes is supported based on a rationale extrapolating efficacy data from Vertisan Fungicide to Treoris Fungicide. Aerial application of chlorothalonil to potatoes is currently registered in Canada. Additional information is required; penthiopyrad must be tested alone (Fontelis Fungicide) and in combination with chlorothalonil. Efficacy of the application using nozzles that deliver fine and medium droplet sizes should be compared.

Please refer to Appendix I, Table 29, for a summary of supported uses.

DPX-LEM17 50WG Fungicide
A total of six trials were submitted to support the claims of control of dollar spot and brown patch on turf. Rationales were also submitted to extrapolate data to support the claims of control of large patch and powdery mildew. Trials submitted to assess dollar spot and brown patch demonstrated good control of both diseases (92 – 100% control) when golf course turf was treated as proposed with penthiopyrad. The claims were supported as proposed. The claim of control of powdery mildew on turf could not be extrapolated and was not supported. Large patch does not occur on cool-season turfgrasses, which are grown in Canada, so this claim was also not supported.

Please refer to Appendix I, Table 30, for a summary of supported uses.

5.2 Economics

For many crops, the economic benefit of controlling diseases is known to be significant. Plant diseases can decrease yield and quality. Damaged fruits and vegetables are unmarketable or significantly downgraded in value. For some minor crops, like tree nuts and peanuts, there are diseases that can severely affect the crop in the right environmental conditions and there are limited fungicides registered in Canada. Therefore, the economic benefit of controlling these diseases would be significant.

5.3 Sustainability

5.3.1 Survey of Alternatives

A number of fungicides are registered on the labelled crops to control or suppress plant diseases. Refer to Appendix I, Tables 23 – 26, for further information on alternative products.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Products containing penthiopyrad provide options for a number of crops where fungicide applications are part of a disease management plan. The use of integrated pest management (IPM) plans for the labelled crops would typically include disease monitoring, crop staging, and weather forecasting with the objective of maximizing marketable yield, minimizing the use of fungicide applications and minimizing the risk of disease resistance. Penthiopyrad is compatible with current IPM strategies and it provides an alternative to currently registered fungicides. The associated end-use products were also shown to be compatible with other fungicides in tank mixes or as a pre-mix product. It is expected that growers will be able to integrate the use of penthiopyrad into existing fungicide application plans.

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

Penthiopyrad has the same general target site as other carboxamide fungicides like boscalid, carboxin and flutolanil. The Fungicide Resistance Action Committee has assigned penthiopyrad to resistance group 7 with a medium to high risk of resistance development. Product labels and directions for use will include appropriate disease resistance management statements and guidelines for rotation and alternation of different mode of action chemicals for disease control.

5.3.4 Contribution to Risk Reduction and Sustainability

As a new mode of action fungicide, integration of products containing penthiopyrad in an IPM program will help delay the development of pest resistance to these products, ensuring sustainable use of penthiopyrad and other registered fungicides.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

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

- Penthiopyrad does not meet all the Track 1 criteria.

- Penthiopyrad does meet the Track 1 criterion for persistence because the half-life values in soil (272 days) and water (384 days) do exceed the Track 1 criterion for soil and water.

- Penthiopyrad does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 4.4-4.6) is just below the Track 1 criterion. In addition, the bioconcentration factor (BCF) in fish of 79-236 does not meet the Track 1 BCF criterion.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Aromatic petroleum distillates are present as impurities in the technical grade active ingredient and end-use products (<0.1%). Since the levels are quite low, no environmental risk is expected and no hazard statements are required on the label;

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

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

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

8 DIR2006-02, PMRA Formulants Policy.

- All end-use products being proposed for registration contain the preservative 1,2-benzisothiazoline-3-one which contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP.

The Agency's strategy to manage Track 1 contaminants in pest control products is outlined in DIR99-03.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for penthiopyrad is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of increased susceptibility of the young in reproduction or developmental toxicity studies. Penthiopyrad is not neurotoxic but there was evidence of immunotoxicity in adults. In short-term and chronic studies on laboratory animals, the primary target was the liver. Effects also occurred in the thyroid and adrenal glands, as well as in the gall bladder of the dog. In the chronic rat study, the most sensitive target was the kidney. Although penthiopyrad is not evidently genotoxic, there was weak evidence of oncogenicity in rats after chronic dosing. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Penthiopyrad exposure to mixers, loaders and applicators handling Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide, and to workers entering treated areas, is not of concern when these products are used according to label directions. Additionally, no risks of concern were identified for the general public entering golf courses, treated lawns or pick-your-own farms.

The nature of the residue in plants and animals is adequately understood. The residue definition for enforcement of MRLs in plants is penthiopyrad. The residue definition for enforcement of MRLs in animals is penthiopyrad + PAM. The use of penthiopyrad on the proposed crops does not constitute an unacceptable chronic, cancer, or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend MRLs to protect human health. The PMRA recommends that the following MRLs be specified for residues of penthiopyrad.

Commodity	Recommended MRL (ppm)
Leaves of root and tuber vegetables (Crop Group 2), leafy Brassica greens subgroup (Subgroup 5B)	50
Leafy vegetables (Crop Group 4)	30
Head and stem Brassica subgroup (Subgroup 5A)	5
Edible-podded legume vegetables subgroup (Subgroup 6A), stone fruits (Crop Group 12-09)	4
Tomato paste	3.5
Root vegetables (except sugar beet) subgroup (Subgroup 1B), bulb vegetables (Crop Group 3-07), fruiting vegetables (Crop Group 8-09), low growing berry subgroup (Subgroup 13-07G)	3
Oil seeds (Crop Group 20)	1.5
Barley bran	0.9
Sorghum, millet	0.8
Cucurbit vegetables (Crop Group 9)	0.6
Sugar beet, pome fruits (Crop Group 11-09)	0.5
Succulent shelled pea and bean subgroup (Subgroup 6B), dried shelled pea and bean (except soybean) subgroup (Subgroup 6C), soybean	0.4
Wheat bran & germ	0.3
Cereal grains (Crop Group 15, except corn, sorghum and millet)	0.15
Tuberous and corm vegetables subgroup (Subgroup 1C), tree nuts (Crop Group 14-11), peanut oil	0.06
Corn oil	0.05
Peanuts	0.04
Field corn, pop corn, sweet corn kernels plus cob with husks removed	0.01
Meat byproducts of cattle, goats, horses and sheep	0.09
Meat and fat of cattle, goats, horses and sheep.	0.03
Eggs; fat, meat & meat byproducts of hogs and poultry; milk	0.02

7.2 Environmental Risk

Penthiopyrad is moderately persistent to persistent in aerobic soil (DT_{50} = 60-406 days) and persistent in aerobic aquatic systems (DT_{50} = 223-384 days). Under field conditions, however, penthiopyrad is expected to be non-persistent to slightly persistent in soil (DT_{50} = 6.1-29.5 days). Hydrolysis is not a route of transformation for penthiopyrad at environmentally relevant pH. On soil, phototransformation is a route of transformation of penthiopyrad (half-life = 6.8 days). Phototransformation in water is not a route of transformation as penthiopyrad was photolytically stable under continous irradiation. In aquatic systems, penthiopyrad will steadily dissipate from the water phase to the sediment and decline slowly thereafter. The log K_{ow} of 4.4-4.6 indicates that penthiopyrad has the potential to bioaccumulate. In rainbow trout, however, the BCF values are 79-226 and the depuration half-lives are 0.65-0.86 days, indicating low bioconcentration of penthiopyrad in fish. On the basis of the TSMP assessment, penthiopyrad does not meet all the criteria for a Track I substance.

Penthiopyrad is non-volatile (HLC = 7.64 x 10^{-9} atm m^3/mole; 1/H = 3.15 x 10^6), has low mobility in soil (K_{oc} = 616-996 mL/g) under laboratory conditions and does not leach to lower soil depths under field conditions. Its major transformation products, DM-PCA and PCA have very high mobility in soil (K_{oc}s = 4-11 and 0.0002-3.5 mL/g, respectively). DM-PCA is expected to be mobile as it can leach to a soil depth of 70 cm. The other major transformation product, PCA, was not detected beyond the upper 15 cm soil depth.

For terrestrial organisms, penthiopyrad poses a negligible risk. In earthworms and bees, the RQs are <1 on an acute and chronic basis. For beneficial arthropods, the low risk demonstated in field studies (<50% mortality) was not a concern as predatory mite populations were reduced by only 19.4% and 11.8% from penthiopyrad applications of 448 and 720 g a.i./ha, respectively. In terrestrial plants, the risk resulting from off-target spray drift to non-target plants was negligible for both seedling emergence and vegetative vigour.

Of the aquatic organisms, the amphibians are the most susceptible species. By contrast, vascular aquatic plants, marine invertebrates, marine fish and marine algae were the least susceptible species with RQs <1 which indicate a negligible risk.

For freshwater invertebrates, fish, amphibians and freshwater algae, the highest risk is associated with the application of the Treoris Fungicide formulation. Thus, for exposure to runoff and spray drift resulting from the application of Treoris Fungicide, the respective RQs for freshwater invertebrates, freshwater fish, amphibians and freshwater algae are: 10.9 (runoff) and <1.0-3.2 (spray drift); 72.1 (runoff) and 5.5-21.2 (spray drift); 197.9 (runoff) and 29.4-112.7 (spray drift); and 4.0 (runoff) and <1.0-1.2 (spray drift).

The two other formulated products, Fontelis Fungicide and Vertisan Fungicide, exhibited similar risks to freshwater fish and amphibians. There is, however, a negligible risk to freshwater algae associated with the Fontelis Fungicide formulation, and for the Vertisan Fungicide formulation, there is a negligible risk to both aquatic invertebrates and freshwater algae.

For runoff and spray drift resulting from the application of the Fontelis Fungicide formulation, the respective RQs for aquatic invertebrates, freshwater fish and amphibians are: <1.0-9.0 (runoff) and <1.0-7.6 (spray drift); <1.0-2.8 (runoff) and <1.0-2.3 (spray drift); and 1.8-7.8 (runoff) and 2.1-12.2 (spray drift), thereby indicating a negligible risk (RQ<1) or an exceedance of the LOC (RQ>1) depending on the exposure scenario. Similarly, for runoff and spray drift resulting from the application of the Vertisan Fungicide formulation, the respective RQs for freshwater fish and amphibians are: <1.0-3.3 (runoff) and <1.0-2.6 (spray drift); and 2.1-9.0 (runoff) and 2.5-14.1 (spray drift), indicating a negligible risk (RQ<1) or an exceedance of the LOC (RQ>1) depending on the exposure scenario.

Overall, the highest risk to aquatic organisms is attributed to the Treoris Fungicide formulation (penthiopyrad + chlorothalonil) with amphibians being the most susceptible. The Fontelis Fungicide and Vertisan Fungicide formulations exhibited substantially lower risks compared to Treoris Fungicide, particularly in amphibians and fish. In terrestrial organisms, penthiopyrad or its end-use products poses either a negligible risk or a low risk that is not a cause for concern.

7.3 Value

The data submitted to register Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide are adequate to demonstrate efficacy for use on the labelled crops and diseases. The lowest effective rate for pests has been established and is supported by efficacy data. Confirmatory data are required to confirm the level of efficacy of penthiopyrad on several crops and aerial application for two products. Please refer to Appendix I, Tables 27 to 30, for a summary of supported and conditionally supported use claims.

The Canadian Grower Priority Database compiles and prioritizes grower-identified priorities for minor crop pest protection. Penthiopyrad was identified as a desired product to control, or suppress, five diseases on minor crops, including pome fruit, brassica vegetables, cucurbit vegetables and root vegetables. All identified priorities were fully supported or conditionally supported for registration. In addition to addressing grower-identified needs, the registration of penthiopyrad provides a new mode of action fungicide that can be integrated into IPM programs for the management of pest resistance in all labelled crops.

7.4 Unsupported Uses

Fontelis Fungicide
The following claims were not supported:

- control of gummy stem blight on cucurbits
- control of powdery mildew on fruiting vegetables
- control of powdery mildew on berries
- control of brown leaf spot on blueberries
- control of rust on peanuts
- control of powdery mildew on leafy vegetables
- control of powdery mildew on bulb vegetables
- control of powdery mildew on tree nuts

- control of powdery mildew on brassica leafy vegetables
- control of powdery mildew on legume vegetables
- control of cercospora leafspot on legume vegetables
- control of powdery mildew on alfalfa

Vertisan Fungicide
The following claims were not supported:
- control of net blotch on cereals
- control of powdery mildew on cereals
- control of stripe rust/yellow wheat rust on cereals
- control of powdery mildew on dry legume vegetables
- control of powdery mildew on tuberous and corm vegetables
- control of powdery mildew on sunflower

DPX-LEM17 50WG Fungicide
The following claims were not supported:
- control of large patch on turfgrass
- control of powdery mildew on turfgrass

8.0 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 Penthiopyrad Technical Fungicide, Fontelis Fungicide, Vertisan Fungicide, Treoris Fungicide and DPX-LEM17 50WG Fungicide, containing the technical grade active ingredient penthiopyrad, to control or suppress various fungal diseases on a broad range of agricultural crops and turfgrass.

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

List of Abbreviations

λ	wavelength
♀	female
♂	male
%	percent
°C	degree(s) Celsius
µg	micrograms
1/H	Henry's Law Constant
a.i.	active ingredient
AD	administered dose
ADI	acceptable daily intake
A/G ratio	albumin to globulin ratio
AP	alkaline phosphatase
appl	application
APTT	activated partial thromboplastin time
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
bwg	body weight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetre(s)
cm^2	centimetre(s) squared
CO_2	carbon dioxide
CYP	cytochrome P_{450} enzyme (alphanumeric suffixes denote families and subfamilies)
DFOP	double first-order in parallel
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC	emulsifiable concentrate
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ECOD	ethoxyresorufin O-dealkylase
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
ELS	early life stage
EPA	Environmental Protection Agency
ER_{50}	effective rate for 50% of the population

F_1	first filial generation
F_2	second filial generation
fc	food consumption
FDA	*Food and Drug Act*
g	gram
GGT	gamma-glutamyl transferase
GI	gastrointestinal
ha	hectare(s)
HAFT	highest average field trial
Hb	hemoglobin
Hct	hematocrit
HDPE	high density polyethylene
HDW	hemoblobin distribution width
HED	Health Effects Division
HLC	Henry's Law Constant
HPLC	high performance liquid chromatography
hr	hour(s)
IORE	indeterminate order rate equation
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
kPa	kilo Pascal(s)
L	litre(s)
LC	high performance liquid chromatography
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	level of detection
LOQ	limit of quantitation
LP	low pressure
LPHW	low pressure handwand
LR_{50}	lethal rate 50%
m	metre(s)
m^2	metre(s) squared
m^3	metre(s) cubed
MAS	maximum average score
max	maximum
MCHC	mean corpuscular haemoglobin concentration
mg	milligram
min.	minimum
MIS	maximum irritation score (subscript in hours indicates time after dosing)
mL	millilitre(s)
M/L/A	mixer/loader/applicator

MOA	mode of action
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
MS	mass spectrometry
m/z	mass-to-charge ratio
n	number of samples
na	not analysed
n.a.	not available
NA	not applicable
NAFTA	North American Free Trade Agreement
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NY	New York
Pa	Pascal
PBI	plantback interval
PCDD	Polychlorinated dibenzodioxins
PCDF	Polychlorinated dibenzofurans
PCPA	*Pest Control Products Act*
PES	post extraction solid
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PROD	pentoxyresorufin O-dealkylase
PYO	pick-your-own
q_1*	cancer potency factor
RBC	red blood cell
RD	residue definition
REI	restricted entry interval
RQ	risk quotient
SC	soluble concentrate
SFO	single first-order
Std. Dev.	standard deviation
STMdR	supervised trial median residues
STMR	supervised trial mean residues
$t_{1/2}$	half-life
T_4	thyroxine hormone
TC	transfer coefficient
TRR	total radioactive residue
Trt	treatment
TSH	thyroid stimulating hormone
TSMP	Toxic Substances Management Policy
TTR	turf transferable residues
UDPGT	uridine diphosphate glucuronosyl transferase enzyme

UDS	unscheduled DNA synthesis
UK	United Kingdom
US	United States
UV	ultraviolet
v/v	volume per volume dilutiont
wt	weight

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Plant	CEMR-3727 (CEM-3399/001)	penthiopyrad, 753-A-OH, 753-F-DO, PCA, DM-PCA, PAM	LC-MS/MS	0.01 ppm/analyte in prunes, cucumber, melon (pulp, rind), almond (nutmeat, hull), pecan, apples (fruit, pomace, juice), peach, plum, cherry, pea (vine, seed), bean seed, lettuce, radish roots, canola, peanut (nutmeat, meal, oil), grapes	1839250, 1839249, 1840767, 1840769
				0.05 ppm/analyte in pea hay, canola press cake, peanut hay	
Animal	LDA0082	penthiopyrad, PCA, PAM, 753-A-OH	LC-MS/MS	0.01 ppm/analyte in poultry tissues and eggs	1839259
	LDA0083			0.01 ppm/analyte in bovine tissues and milk	1839257
	CEMR-3574			0.01 ppm/analyte in bovine tissues	1839244
	CERM-3657			0.01 ppm/analyte in milk	1839245
Soil	ABC 63209	Penthiopyrad	HPLC-MS/MS	5.0 µg/kg	1840773, 1839260
			360.1 → 276.0 m/z		
		753-A-OH	376.1 → 152.1 m/z		
		753-F-DO	376.1 → 182.1 m/z		
		753-T-DO	392.1 → 177.0 m/z		
		PAM	194.1 → 174.0 m/z		
		PCA	193.1 → 109.0 m/z		
		DM-PCA	178.9 → 159.0 m/z		
Sediment	Extended from soil.				
Water (surface, ground and drinking)	CEMR-3236	Penthiopyrad	HPLC-MS/MS	0.05 µg/L	1839262, 1839261
			358.10 → 149.00 m/z		
		753-T-DO[1]	390.19 → 356.06 m/z		
		753-A-OH	374.10 → 149.04 m/z		
		PAM	194.10 → 174.10 m/z		
		PCA	193.10 → 109.00 m/z		
		DM-PCA	179.00 → 159.20 m/z		

[1] Method for 753-T-DO in drinking water not validated due to instability of the analyte.

Table 2 Toxicity Profiles of Vertisan Fungicide, Fontelis Fungicide, Treoris Fungicide and DPX-LEM17 50WG

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Vertisan Fungicide	
Acute oral toxicity Sprague-Dawley rats PMRA# 1838866	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA# 1838867	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA# 1838868	LC_{50} > 4. 89 mg/L_{air} Low Toxicity
Dermal irritation New Zealand White rabbits PMRA# 1838869	MAS = 1.67/8 Mildly Irritating
Eye irritation New Zealand White rabbits PMRA# 1838870	MAS = 42.7/110, MIS_{1h} = 51/110 Cornea and iris effects, irritation resolved by seven days Severely irritating
Dermal sensitization (Local lymph node assay) CBA/JHsd mice PMRA# 1838871	Potential skin sensitizer
Fontelis Fungicide	
Acute oral toxicity Wistar rats PMRA# 1838740	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute dermal toxicity Wistar rats PMRA# 1838741	LD_{50} > 5000 mg/kg bw Low Toxicity

Study Type/Animal/PMRA #	Study Results
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA# 1838742	LC_{50} > 3.5 mg/L_{air} Low Toxicity
Dermal irritation New Zealand White rabbits PMRA# 1838743	MAS = 0/8 Non-irritating
Eye irritation New Zealand White rabbits PMRA# 1838744	MAS = 0.45/110, MIS_{1h} = 6/110 Minimally Irritating
Dermal sensitization (Local lymph node assay) CBA/JHsd mice PMRA# 1838745	Potential skin sensitizer
Dermal sensitization (Maximization method) Hartley guinea pigs PMRA# 1838746	Potential skin sensitizer
Treoris Fungicide	
Acute oral toxicity Sprague-Dawley rats PMRA# 1838894	LD_{50} = 5000 mg/kg bw Low Toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA# 1838895	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA# 1838896	LC_{50} = 1.18 mg/L (combined) Slightly Toxic

Study Type/Animal/PMRA #	Study Results
Dermal irritation New Zealand White rabbits PMRA# 1838897	MAS = 1.9/8 Mildly Irritating
Eye irritation New Zealand White rabbits PMRA# 1838898	MAS = 3.1/110 Minimally Irritating
Dermal sensitization (Maximization method) Hartley guinea pigs PMRA# 1838899	Potential Skin Sensitizer
DPX-LEM17 50WG Fungicide	
Acute oral toxicity Sprague-Dawley rats PMRA# 1838940	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA# 1838941	LD_{50} > 5000 mg/kg bw Low Toxicity
Acute inhalation toxicity (nose-only) Sprague-Dawley rats PMRA# 1838942	LC_{50} > 4.7 mg/L Low Toxicity
Dermal irritation New Zealand White rabbits PMRA# 1838943	MAS = 1.11/8 Slightly Irritating
Eye irritation New Zealand White rabbits PMRA# 1838944	MAS = 3.33/110, MIS_{1h} = 15/110 Mildly irritating
Dermal sensitization (Local lymph node assay) CBA/JHsd mice PMRA# 1838946	Non-sensitizer

Study Type/Animal/PMRA #	Study Results
Dermal sensitization (Magnusson-Kligman maximization method) Hartley guinea pigs PMRA# 1838945	Non-sensitizer

Table 3 Toxicity Profile of Technical Penthiopyrad

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to body weights unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Wistar rats PMRA # 1839313	LD_{50} > 2000 mg/kg bw Low Toxicity
Acute dermal toxicity Wistar rats PMRA # 1839314	LD_{50} > 2000 mg/kg bw Low Toxicity
Acute inhalation toxicity (nose-only) Wistar rats PMRA # 1839315	LC_{50} > 5.59 mg/L_{air} Low Toxicity
Eye irritation New Zealand White rabbits PMRA # 1839318	MAS = 0.9/110 Minimally irritating
Dermal irritation New Zealand White rabbits PMRA # 1839316	MAS = 0/8 Non-irritating
Skin sensitization (Maximization method) Hartley guinea pigs PMRA # 1839319	Non-sensitizer

Study Type/Animal/PMRA #	Study Results
Metabolism/toxicokinetics (single and repeated dose, oral, gavage) Wistar rats PMRA# 1839266 PMRA# 1839263 PMRA# 1839265 PMRA# 1839300	**Absorption:** Absorption was rapid, extensive and linearly related to the dose. The internal dose was higher with repeated dosing and slightly higher in females compared to males, regardless of the dose. Clearance from the blood was rapid and followed first order kinetics. **Distribution:** Concentrations in the liver, fat, lymph nodes, adrenals, ovaries, pancreas and kidneys were greater than in the plasma. With repeated dosing, small increases in concentration occurred at these sites and in the blood, lungs, and thyroid. The overall tissue distribution was similar in both sexes following either single or repeated doses. **Metabolism:** Metabolism was extensive, particularly in the liver and in RBCs. The major transformations include: i) N-demethylation of the pyrazole ring, ii) hydroxylation of the alkyl side-chain, with subsequent dehydration or oxidation to carboxylic acids, iii) oxidation of the thienyl ring moiety to form the metabolites 753-F-DO and 753-T-DO with subsequent cleavage of the two-ring structure into PAM, containing the pyrazole moiety, and a thienyl ring, iv) hydrolysis of the amide group of the metabolite PAM, and v) opening and subsequent breakdown of the thienyl ring via intermediary metabolism. Hydroxylated derivatives were subject to glucuronidation or glutathione conjugation. Glutathione conjugates of 753-F-DO and 753-T-DO formed various amino acid conjugates prior N-acetylation and/or dehydration. Following two-ring cleavage, the pyrazole ring moiety was retained in the metabolites PAM, DM-PAM, PCA and DM-PCA. Although metabolite profiles were comparable following single and multiple doses, there were some quantitative differences in the levels of metabolites in males compared to females and according to the dose. At least 67 metabolites, but only trace amounts of parent chemical were detected in the bile. At least 22 metabolites and unchanged parent were identified in the feces. PAM, DM-PAM, PCA and DM-PCA occurred in urine, but no urine metabolites were present at > 5% AD. **Excretion:** Excretion was rapid. More than 75% AD was eliminated within 24 hours and tissue concentrations were generally very low at 72 hours after dosing. Elimination half-lives in tissues were as short as three hours and generally no greater than one to two days. Excretion occurred primarily via the feces (~70 – 80% AD) and to a lesser extent via the urine (~10 – 20% AD). Very little was eliminated via expired air. Females were slightly more reliant on the urinary elimination route compared to males. Apart from this minor difference, excretion characteristics were not generally dependent on the sex, dose level or repeated dosing.
28-Day oral (diet) toxicity CD-1 mice PMRA# 1839322	NOAEL (♂/♀) = 100/330 mg/kg bw/day LOAEL (♂) = 304 mg/kg bw/day; based on ↑ triglyceride, ↓ albumin and A/G ratio and ↑ liver weight LOAEL (♀) = 1088 mg/kg bw/day; based on ↓ RBC and Hb, ↓ albumin and A/G ratio and ↑ liver weight
90-Day oral (diet) toxicity CD-1 mice PMRA # 1839331	NOAEL (♂/♀) = 100/306 mg/kg bw/day LOAEL (♂) = 299 mg/kg bw/day; based on ↓ bw LOAEL (♀) = 1027 mg/kg bw/day; based on ↓ RBC and Hb, ↑ liver wt and diffuse hepatocellular hypertrophy and ↑ thyroid wt and thyroid follicular cell hypertrophy

Study Type/Animal/PMRA #	Study Results
28-Day oral (diet) toxicity Wistar rats PMRA # 1839327	NOAEL (♂/♀) = 148/142 mg/kg bw/day LOAEL (♂/♀) = 380/369 mg/kg bw/day; based on ↑ cholesterol, ↑ phospholipid, ↑ GGT, ↑ liver weight; ↓ bw, ↑ APTT (♂)
90-Day oral (diet) toxicity Wistar rats PMRA# 1839336 PMRA# 1839335	NOAEL (♂/♀) = 39.8/39.7 mg/kg bw/day LOAEL = 99.9/99.8 mg/kg bw/day; based on ↑ GGT, ↑ liver weight, ↑ hepatocelluar hypertrophhy; ↑ APTT, ↑ hepatocellular degeneration, ↑ Kupffer cell proliferation (♂); ↑ peripherolobular macrovesicular fatty change (♀)
28-Day oral (diet, range-finding) toxicity Beagle dogs PMRA # 1839320	Supplementary ≥ 316 mg/kg bw/day (♀): ↑ cholesterol, ↑ liver weight, ↑ diffuse hepatocellular hypertrophy 920 mg/kg bw/day (♂): ↓ bwg, ↓ hematological parameters (Hct, Hb & RBC), ↑ cholesterol and AP, ↑ liver wt and diffuse hepatocellular hypertrophy, ↑ vacuolation in proximal tubules and ↑ gall bladder hypoplasia
90-Day oral (diet) toxicity Beagle dogs PMRA# 1839340	NOAEL (♂/♀) = 76.7/80.9 mg/kg bw/day LOAEL = 811/864 mg/kg bw/day; based on ↓ bw, ↑ AP, ↑ GGT, ↓ albumin, ↓ A/G, ↑ cholesterol, ↑ triglyceride, ↑ liver weight and diffuse hepatocellular hypertrophy, ↑ gall bladder foamy macrophage infiltration and/or loss of mucosal folds; ↑ adrenal gland cortical cell hypertrophy (♂); ↑ thyroid weight (♀)
Chronic oral (diet) toxicity Beagle dogs PMRA# 1839343	NOAEL (♂/♀) = 54.4/56.6 mg/kg bw/day LOAEL = 461/445 mg/kg bw/day; based on ↑ bw loss, ↓ bw, ↓ fc, ↓ APTT, ↑ platelets, ↑ AP, ↑ GGT, ↓ albumin, ↑ globulin, ↓ A/G ratio, ↑ triglyceride,↑ cholesterol, ↑ liver weight, ↑ adrenal weight, ↑ diffuse hepatocellular hypertrophy, ↑ gall bladder mucosal epithelial hyperplasia (some instances accompanied by cholecystitis), ↑ adrenal cortical cell hypertrophy; ↓ RBC, ↓ Hb, ↓ MCHC, ↑ basophils, ↑ ascites (♂)
28-Day dermal toxicity Sprague Dawley rats PMRA# 1839346	Dermal NOAEL = 1000 mg/kg bw/day Systemic NOAEL = 1000 mg/kg bw/day LOAELs were not established
18-Month oncogenicity, oral (diet) CD-1 mice PMRA# 1839317	*Non-neoplastic lesions:* NOAEL (♂/♀) = 59.8/60.3 mg/kg bw/day LOAEL = 200/201 mg/kg bw/day; based on ↑ thyroid weight and thyroid follicular cell hypertrophy; ↑ liver weight, ↑ altered colloid (♂) *Neoplastic lesions:* 604 mg/kg bw/day: liver hepatocellular adenomas and carcinomas occurred but incidences were comparable to historical control values (♂) Equivocal evidence of oncogenicity

Study Type/Animal/PMRA #	Study Results
12-Month chronic, oral (diet) Wistar rats PMRA# 1839299	NOAEL = 25 mg/kg bw/day LOAEL = 100 mg/kg bw/day; based on ↑ liver weight, ↑ adrenal weight, ↑ adrenal diffuse hypertrophy of zona glomerulosa, ↑ adrenal cortical lipid vacuolation, ↑ thyroid diffuse follicular cell hypertrophy; ↑ kidney weight (♂); ↑ HDW, ↑ potassium, ↑ cholesterol, ↑ phospholipids (♀)
24-Month oncogenicity, oral (diet) Wistar rats PMRA# 1839302	*Non-neoplastic lesions:* NOAEL (♂/♀)= 9/27 mg/kg bw/day LOAEL (♂/♀) = 27/83 mg/kg bw/day; based on ↑ kidney interstitial fibrosis, ↑ renal glomerulosclerosis (♂); ↓ bw, ↑ discoloration of adrenals, ↑ adrenal diffuse hypertrophy, ↑ adrenal focal fatty change, ↑ lung focus/foci (♀) *Neoplastic lesions:* 250 mg/kg bw/day: ↑ thyroid follicular cell adenomas incidences exceed concurrent and historical control values (♂) Weak evidence of oncogenicity
Two-generation reproductive, oral (diet), preliminary study Wistar rats PMRA # 1839337	Supplementary *Parental Toxicity:* ≥ 187/358 mg/kg bw/day: ↑ liver weight; ↑ thyroid weight (♂); ↓ fc (♀) 477/829 mg/kg bw/day: ↓ bwg; ↓ bw, ↓ fc; ↑ enlarged thyroid (♂); ↑ dark liver, ↓ spleen weight (♀) *Reproductive Toxicity:* No signs of reproductive toxicity *Offspring toxicity:* 477/829 mg/kg bw/day: ↓ bw, ↓ thymus weight, ↓ spleen wt
Two-generation reproductive oral (diet) Wistar rats PMRA # 1839332	*Parental Toxicity* NOAEL = 12.3/15.3 mg/kg bw/day LOAEL = 60.5/75.9 mg/kg bw/day; based on ↓ bw & bwg (♂); ↑ liver weight and centrilobular hepatocyte hypertrophy, ↑ adrenal weight and adrenal cortical hypertrophy (♀) *Reproductive Toxicity* NOAEL > 311/372 mg/kg bw/day, the highest dose tested LOAEL not established *Offspring Toxicity* NOAEL = 60.5/75.9 mg/kg bw/day LOAEL = 311/372 mg/kg bw/day; based on ↑ small body size, ↓ bw during lactation (F_1 & F_2), ↓ spleen weight (F_1), ↓ thymus weight (F_2); ↓ thymus weight (F_1), ↓ spleen weight (F_2), ↑ age at preputial separation (F_1, 1.9 day delay) (♂); ↑ age at vaginal patency (F_1, 1.3 day delay) (♀) No evidence of sensitivity of the young
Prenatal development, oral (gavage); preliminary study Supplemental Wistar rats PMRA # 1839341	Supplementary No adverse maternal or developmental effects

Study Type/Animal/PMRA #	Study Results
Prenatal development, oral (gavage); definitive study Wistar rats PMRA # 1839339	*Maternal Toxicity:* NOAEL = 250 mg/kg bw/day LOAEL = 1000 mg/kg bw/day; based on ↓ bwg, ↓ fc, ↓ gravid uterine weight, ↑ early resorptions per animal, ↑ post-implantation loss, ↓ total live young per litter, ↓ litter weight *Developmental Toxicity:* NOAEL = 250 mg/kg bw/day LOAEL = 1000 mg/kg bw/day; based on ↑ early resorptions per animal, ↑ post-implantation loss, ↓ total live young per litter, ↓ litter weight ↑ partially undescended thymus No evidence of sensitivity of the young
Prenatal development (gavage); preliminary study Supplemental New Zealand White rabbits PMRA # 1839344	Supplementary ≥ 250 mg/kg bw/day: ↓ bwg and fc, ↑ bw loss, ↓ litter weight, ↓ gravid uterine weight ≥ 500 mg/kg bw/day: ↑ premature deaths with associated late abortions (associated with maternal clinical deterioration and clinical effects) 1000 mg/kg bw/day: ↓ fetal weight
Prenatal development (gavage); definitive study New Zealand White rabbits PMRA # 1839342	*Maternal Toxicity:* NOAEL = 75 mg/kg bw/day LOAEL = 225 mg/kg bw/day; based on ↓ gravid uterine weight and one abortion *Developmental Toxicity:* NOAEL = 75 mg/kg bw/day LOAEL = 225 mg/kg bw/day; based on ↓ fetal bw, ↓ litter weight and one abortion No evidence of sensitivity of the young
Gene mutations in bacteria (Ames test) PMRA# 1839351	Negative
DNA repair assay (rec-assay) PMRA# 1839349	Negative
Chromosome aberrations test *in vitro* PMRA# 1839353	Chromosomal aberrations at cytotoxic doses only Negative
Gene mutation in lymphoma cell *in vitro* PMRA# 1839354	Negative

Study Type/Animal/PMRA #	Study Results
Micronucleus assay *in vivo*(intraperitoneal injection) BDF_1 mice PMRA# 1839357	Cytotoxic to the bone marrow 2000 mg/kg bw Negative
Unscheduled DNA synthesis (UDS) *in vivo/in vitro* Sprague-Dawley rats PMRA# 1839359	Negative
Acute neurotoxicity, oral (gavage) Sprague-Dawley rats PMRA# 1839347 PMRA# 1839345	NOAEL = 125 mg/kg bw LOAEL = 500 mg/kg bw; based on ↑ hunched posture, ↓ body temperature, ↑ landing footsplay, ↓ rearing motor and ambulatory motor activity; ↓ reactivity to handling, ↓ body tone, ↑ abnormal gait, ↑ slight occasional whole-body tremor (♀) No evidence of neurotoxicity
90-Day neurotoxicity, oral (diet) Sprague-Dawley rats PMRA# 1839350	NOAEL (♂/♀) = 177/170 mg/kg bw/day LOAEL = 712/686 mg/kg bw/day; based on ↓ bwg; ↓ bw (♂)
Developmental neurotoxicity, oral (gavage) Sprague-Dawley rats PMRA# 1839363 PMRA# 1839358	*Maternal Toxicity* NOAEL = 500 mg/kg bw/day LOAEL not established *Offspring Toxicity* NOAEL = 100 mg/kg bw/day LOAEL = 250 mg/kg bw/day; based on ↓ bw and bwg during lactation No evidence of neurotoxicity No evidence of sensitivity of the young, when the broader effects occurring in adult rats in the toxicity database are considered
14-Day oral (diet) investigative study of liver function (cancer MOA) CD-1 mice PMRA# 1839321	Supplementary ≥ 25.1 mg/kg bw/day: ↑ PROD, ↑ CYP1A, ↑ CYP2B ≥ 61.6 mg/kg bw/day: ↑ liver weight, ↑ microsomal protein, ↑ microsomal P_{450}, ↑ ECOD, ↑ CYP3A ≥ 197 mg/kg bw/day: ↑ centrilobular hepatocyte hypertrophy 561 mg/kg bw/day: ↑ dark colored liver, ↑ hepatocyte proliferation
28-Day oral (diet) Immunotoxicity CD-1 mice PMRA # 1839309	NOAEL = 301 mg/kg bw/day LOAEL = 1136 mg/kg bw/day; based on ↓ plaque-forming cells Evidence of immunotoxicity at limit dose only A Jerne plaque forming cell assay was conducted A natural killer (NK) cell analysis, for non-specific effects, was not conducted

Study Type/Animal/PMRA #	Study Results
14-Day oral (diet) investigative study of liver function (cancer MOA) Wistar rats PMRA# 1839328	Supplementary ≥ 66.7 mg/kg bw/day: ↑ enlarged liver, ↑ UDPGT-T_4, ↑ CYP2B1, CYP3A2, CYP4A1 632 mg/kg bw/day: ↑ liver weight, ↑ dark liver, ↑ centrilobular hepatocyte hypertrophy ↑ microsomal protein,↑ PROD, ↑ hepatocyte proliferation
14-Day oral (diet) investigative study of thyroid function (cancer MOA) Wistar rats PMRA# 1839324	Supplementary ≥ 37.8 mg/kg bw/day: ↑ liver microsomal protein (transient), ↑ UDPGTs (reversible); ↑ TSH (variable, reversibility not evident); ↑ Prop-1 gene expression in pituitary (minimal, reversible); ↑ thyroid follicular cell proliferation (transient) ≥ 371 mg/kg bw/day: ↑ liver weight (reversible), ↑ cytochrome P_{450} (reversible); ↑ follicular cell hypertrophy with associated instances of ↓ colloid 1453 mg/kg bw/day: ↓ bw, ↓ fc, ↑ diffuse hepatocyte hypertrophy, ↓ T_4 (reversible)
28-Day oral (diet) Immunotoxicity Sprague-Dawley rats PMRA # 1839310	Immunotoxicity NOAEL = 710 mg/kg bw/day LOAEL not established No evidence of immunotoxicity A Jerne plaque forming cell assay was conducted A natural killer (NK) cell analysis, for non-specific effects, was not conducted Systemic changes 710 mg/kg bw/day: ↑ bw loss, ↓ bw, ↓ bwg, ↓ fc, ↑ water consumption, ↑ liver enlargement, ↑ liver weight, ↓ spleen weight
Metabolite Studies – DM-PCA	
Acute oral Sprague-Dawley rats PMRA # 1839400	LD_{50} > 2000 mg/kg bw Low Toxicity
14-Day oral (diet), preliminary study Wistar rats Supplementary PMRA # 1839399	Supplementary ≥ 718/742 mg/kg bw/day: ↓ bwg (♀)
90-Day oral (diet) Wistar rats PMRA # 1839396	NOAEL (♂/♀) = 258/1200 mg/kg bw/day LOAEL (♂) = 1038 mg/kg bw/day; based on ↓ bw, ↓ bwg, ↓ food intake LOAEL (♀) was not established

Study Type/Animal/PMRA #	Study Results
Gene mutations in bacteria (Ames test) PMRA # 1839394	Negative
Chromosome aberrations *in vitro* PMRA # 1839393	Negative
Gene mutation in lymphoma cell *in vitro* PMRA# 1839392	Negative
Metabolite Studies – PCA	
Acute oral (gavage) Sprague-Dawley rats PMRA# 1839391	$LD_{50} \geq 2000$ mg/kg bw Low Toxicity
28-Day oral (gavage) Wistar rats PMRA# 1839388	NOAEL = 1000 mg/kg bw/day LOAEL was not established
Gene mutations in bacteria (Ames test) *in vitro* PMRA# 1839387	Negative
Chromosome aberrations test *in vitro* PMRA# 1839386	Negative
Gene mutation in lymphoma cell *in vitro* PMRA# 1839385	Increased mutation frequencies occurred, but the dose-response was not clear. Equivocal
Micronucleus assay *in vivo* (intraperitoneal injection) BDF_1 mice PMRA# 1839384	Negative
Metabolite Studies – PAM	
Acute oral Sprague-Dawley rats PMRA # 1839383	300 mg/kg bw $< LD_{50} <$ 2000 mg/kg bw Slight to High Toxicity

Study Type/Animal/PMRA #	Study Results
Acute oral Sprague-Dawley rats PMRA # 1839381	300 mg/kg bw < LD_{50} < 2000 mg/kg bw Slight to High Toxicity
Gene mutations in bacteria (Ames test) PMRA # 1839380	Negative
Chromosome aberrations *in vitro* PMRA # 1839379	Continuous non-activated exposure for 24 hours induced chromosome aberrations Positive
Gene mutation in lymphoma cell *in vitro* PMRA# 1839377	Continuous non-activated exposure for 24 hours induced concentration-dependent gene mutations at ≥ 483 µg/mL Positive
Micronucleus assay *in vivo* B6D2F mice PMRA # 1839376	Negative
Metabolite Studies – 753-T-DO	
Gene mutations in bacteria (Ames test) PMRA # 1839369	Negative
Chromosome aberrations *in vitro* PMRA # 1839368	Negative
Gene mutation in lymphoma cell *in vitro* PMRA# 1839367	Evidence of extreme cytotoxicity in dose range finding study. Negative
Metabolite Studies – 753-A-OH	
Acute oral toxicity Sprague-Dawley rats PMRA# 1839375	Female LD_{50} ≥ 2000 mg/kg bw Low Toxicity
Gene mutations in bacteria (Ames test) PMRA# 1839374	Negative
Chromosome aberrations test *in vitro* PMRA# 1839371	Negative

Study Type/Animal/PMRA #	Study Results
Gene mutation in lymphoma cell *in vitro* PMRA# 1839370	Negative

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Penthiopyrad

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary general population	Acute neurotoxicity study in rats	NOAEL = 125 mg/kg bw, based on transient functional alterations, decreased body temperature and decreased motor activity on the day of administration at the LOAEL of 500 mg/kg bw	100
	ARfD = 1.25 mg/kg bw		
Repeated dietary	Oncogenicity study in rats	NOAEL = 9 mg/kg bw/day, based increased kidney interstitial fibrosis and glomerulosclerosis in males at the LOAEL of 27 mg/kg bw/day	100
	ADI = 0.09 mg/kg bw/day		
Adults: short- to intermediate-term exposure			
dermal[2]	Prenatal developmental toxicity study in rabbits	NOAEL = 75 mg/kg bw/day, based on an abortion and decreased gravid uterine weight at the LOAEL of 225 mg/kg bw/day	100
inhalation[3]	90-day toxicity study in rats	NOAEL = 40 mg/kg bw/day, based on increased liver weight and hepatocellular hypertrophy with concordant histopathological alterations and perturbations in clinical chemistry and haematology at the LOAEL of 99.9 mg/kg bw/day	100
Adults: long-term exposure			
dermal[2] and inhalation[3]	12 month toxicity study in rats	NOAEL = 25 mg/kg bw/day, based on increased liver weight, adrenal weight, adrenal diffuse hypertrophy of zona glomerulosa, adrenal cortical lipid vacuolation and thyroid diffuse follicular cell hypertrophy as well as increased kidney weight in males, and increased haemoglobin distribution width, potassium, cholesterol and phospholipid levels in females at the LOAEL of 100 mg/kg bw/day	100
Children: short- to intermediate-term exposure			
dermal[2]	Multi-generation reproduction toxicity study in rats	NOAEL = 76 mg/kg bw/day, based on offspring effects, which included an increased incidence of small body size, decreased body weight, delayed sexual development, decreased thymus gland weight and spleen weight at the LOAEL of 372 mg/kg bw/day	100

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
inhalation[3]	90-day toxicity study in rats	NOAEL = 40 mg/kg bw/day, based on increased liver weight and hepatocellular hypertrophy with concordant histopathological alterations and perturbations in clinical chemistry and haematology at the LOAEL of 100 mg/kg bw/day	100
Non-dietary oral ingestion (short-term)	Acute neurotoxicity study in rats	NOAEL = 125 mg/kg bw, based on transient functional alterations, decreased body temperature and decreased motor activity on the day of administration at the LOAEL of 500 mg/kg bw	100
Cancer	Oncogenicity study in rats	A threshold based approach was used for thyroid tumours (adenomas) in male rats.	N/A

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational and residential assessments. [2]Since an oral NOAEL was selected, a dermal absorption factor of 50% was used in a route-to-route extrapolation. [3]Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 5 Mixer/Loader/Applicator Dermal Exposure Estimates and Margin of Exposure (MOE)

Crop Scenario	Area treated per day (max)	Max use rate (g a.i./ha)	Unit exposure (µg/kg a.i.)		Daily Dose [a] (µg/kg bw/day)		MOE [b]	
			Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Alfalfa, cereal grains, corn, sunflower, tuberous and corm vegetables, potato								
Groundboom	360 ha	350	84.12	2.56	75.7	4.61	991	8 620
Aerial M/L	400 ha	350	51.14	1.60	51.1	3.20	1 470	12 500
Aerial applicator	400 ha	350	9.66	0.07	9.66	0.140	7 760	284 000
Canola, dry legumes, sugar beet								
Groundboom	360 ha	300	84.12	2.56	64.9	3.95	1 160	10 100
Aerial M/L	400 ha	300	51.14	1.60	43.8	2.74	1 710	14 500
Aerial applicator	400 ha	300	9.66	0.07	8.28	0.120	9 060	331 000
Legume vegetables, soybeans								
Groundboom	360 ha	450	84.12	2.56	97.3	5.92	771	6 700
Aerial M/L	400 ha	450	51.14	1.60	65.8	4.11	1 140	9 650
Aerial applicator	400 ha	450	9.66	0.07	12.4	0.180	6 040	221 000
Berries, low growing								
Groundboom	26 ha	350	84.12	2.56	5.47	0.333	13 700	119 000
Aerial M/L	26 ha	350	51.14	1.60	3.32	0.208	22 600	191 000
Aerial applicator	26 ha	350	9.66	0.07	0.628	0.00910	119 000	4 360 000
Backpack	2 ha	350	5445.85	62.1	27.2	0.621	2 750	63 900
LPHW	2 ha	350	943.37	45.2	4.72	0.452	15 900	87 800

Crop Scenario	Area treated per day (max)	Max use rate (g a.i./ha)	Unit exposure (µg/kg a.i.)		Daily Dose [a] (µg/kg bw/day)		MOE [b]	
			Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Bulb vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, peanuts								
Groundboom	26 ha	350	84.12	2.56	5.47	0.333	13 700	119 000
Backpack	2 ha	350	5445.85	62.1	27.2	0.621	2 750	63 900
LPHW	2 ha	350	943.37	45.2	4.72	0.452	15 900	87 800
Brassica vegetables, root vegetables								
Groundboom	26 ha	450	84.12	2.56	7.03	0.428	10 700	92 800
Backpack	2 ha	450	5445.85	62.1	35.0	0.798	2 140	49 700
LPHW	2 ha	450	943.37	45.2	6.06	0.581	12 400	68 300
Pome fruits, tree nuts								
Airblast	20 ha	300	612.86	7.40	26.3	0.634	2 860	62 600
Stone fruits								
Airblast	20 ha	350	612.86	7.40	30.6	0.740	2 450	53 600
Turf								
Groundboom	30 ha	750	196.75	1.98	31.6	0.339	2 370	117 000
Backpack	2 ha	750	5609.62	63.12	60.1	1.35	1 250	29 600
LPHW	2 ha	750	1107.14	46.22	11.9	0.990	6 320	40 400
LP nozzle gun	2.8 ha	750	1290	47.8	19.6	1.43	3 880	27 900

[a] Daily dose = (Area treated per day x use rate x unit exposure x absorption) / 70 kg. Dermal absorption = 50%. Inhalation absorption = 100%.

[b] Based on a NOAEL of 75 mg/kg bw/day for dermal exposure and a NOAEL of 40 mg/kg bw/day for inhalation exposure with a target MOE of 100 for both routes.

M/L = mixing/loading, LPHW= low pressure handwand, LP = low pressure

Table 6 Postapplication Margin of Exposures

Crop Scenario	Task	Transfer Coefficient (cm^2/hr)	Application Rate (g a.i./ha)	REI (days)	DFR [a] (µg/cm^2)	Dermal Exposure [b] (µg/kg bw/day)	MOE [c]
Alfalfa, Peanut, cereals	Scouting	1500	350	0	1.29	111	678
Sugar beet, Canola		1500	300	0	1.1	94.3	795
Soybean		1500	450	0	1.65	141	530
Sunflower		1000	350	0	1.29	73.7	1 020
Corn	Detasseling	17000	350	0	1.29	1250	60
Corn		17000	350	3	0.759	737	102
Bulbs, Cucurbits, Leafy veg, Tuberous and corm	Hand harvesting	2500	350	0	1.29	184	407
Brassica		5000	450	0	1.65	471	159
Dry legume		2500	300	0	1.1	157	477
Legume veg,		2500	450	0	1.65	236	318

Crop Scenario	Task	Transfer Coefficient (cm^2/hr)	Application Rate (g a.i./ha)	REI (days)	DFR [a] ($\mu g/cm^2$)	Dermal Exposure [b] (µg/kg bw/day)	MOE [c]
root veg							
Fruiting veg		1000	350	0	1.29	73.7	1 020
Low berry		1500	350	0	1.29	111	678
Pome fruit	Thinning	3000	300	0	0.988	169	443
Stone fruit		3000	350	0	1.15	197	380
Greenhouse	Hand harvesting	1800	350	0	1.4	144	174
Turf	Mowing, irrigation	3500	750	0	0.461	92.2	813
	Transplanting	6800	750			179	419

[a] Outdoor ground spray crops DFR = peak predicted value from cucurbit study adjusted form maximum rate. Outdoor airblast crops DFR = peak predicted value from apple study adjusted form maximum rate. Greenhouse DFR value = 20% of application rate with 0% dissipation per day. TTR value = 5% of application rate with 10% dissipation per day.

[b] Adjusted for dermal absorption value of 50%.

[c] NOAEL = 75 mg/kg bw/day with exception of greenhouse use where NOAEL = 25 mg/kg bw/day; target MOE of 100.

Table 7 Residential Dermal Exposure and Margins of Exposure (MOEs)

Scenario	Group		DFR/TTR ($\mu g/cm^2$)	TC [a] (cm^2/hr)	Dermal exposure [b] (µg/kg bw/day)	MOE [c]
Turf - Golf courses	Adult		0.461	500	6.59	11 400
	Youth (10 - 18)		0.461	344	8.13	9 350
Residential Lawn	Adult		0.461	14 500	95.5	785
	Toddler (0-9)		0.461	5 200	160	476
Pick-your-own - apples	Adults		0.214	3000	9.17	8 180
	Children	10-18	0.214	2070	11.4	6 690
		0-9	0.214	961	13.7	5 540
Pick-your-own - peaches	Adults		1.15	3000	49.3	1 520
	Children	10-18	1.15	2070	61.0	1 250
		0-9	1.15	961	73.7	1 030
Pick-your-own - strawberries	Adults		1.29	1500	27.6	2 710
	Children	10-18	1.29	1030	34.1	2 230
		0-9	1.29	481	41.4	1 840

[a] Transfer coefficients are scaled to represent the surface area of the age group. Adult (70 kg) surface area = 18440 cm^2; youth (39 kg) surface area = 12700 cm^2; child/toddler (15 kg) surface area = 5910 cm^2.

[b] Four hours per day were assumed for golfers and two hours per day were assumed for lawn and pick-your-own activities.

[c] Based on a NOAEL of 75 mg/kg bw/day for dermal exposure to adults; a NOAEL of 76 mg/kg bw/day for dermal exposure to children; and a target MOE of 100.

Table 8 Incidental Oral Exposure and Margins of Exposure (MOEs) for Toddlers

Group	Incidental Oral Exposure (mg/kg bw/day)			Combined exposure [a] (µg/kg bw/day)	MOE [b]
	Hand to mouth	Turf mouthing	Ingestion of soil		
Toddlers 0-9	0.0123	0.000384	0.0000335	0.0127	9 830

[a] Combined exposure is the sum of hand to mouth, turf mouthing and ingestion of soil.
[b] Based on a NOAEL of 125 mg/kg bw/day for incidental oral exposure and a target MOE of 100.

Table 9 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN *Grape*			PMRA # 1839422
Radiolabel Position	**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**		
Test Site	Test vines were grown outdoors at a field site located in Poplar, California		
Treatment	Single foliar treatment		
Rate	400 g a.i./ha		
End-use product	15 SC formulation		
Preharvest interval	30 days, 60 days		
Matrix	**PHI (days)**	**[^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad TRRs (ppm)**	
Grape berries	30	0.204 (Group I), 0.241 (Group II: 0.133 in juice + 0.108 in pomace)	
	60	0.083 (Group I), 0.210 (Group II: 0.119 in juice + 0.091 in pomace)	
Grape leaves	30	5.107	
	60	3.349	
Metabolites Identified	**Major Metabolites (> 10% TRR)**		**Minor Metabolites (< 10% TRR)**
Radiolabel Position	**[^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad**		
Grapes (30 days, Group I)	penthiopyrad, PAM		PCA, 753-A-OH, 753-F-DO, DM-753
Grapes (60 days, Group I)	PAM		penthiopyrad, PCA, 753-A-OH, 753-F-DO
Leaves (30 days)	PAM		penthiopyrad, PCA, 753-A-OH, 753-F-DO, DM-753, 753-T-DO
Leaves (60 days)	PAM, PCA		penthiopyrad, 753-A-OH, 753-F-DO, 753-T-DO
In 30-day grapes, 23.5% of the TRRs was rinsed with methanol/water (7/3,v/v) and 65.7% of the TRRs was extracted from rinsed grapes with methanol. Post extraction solid (PES) contained 6.4% of the TRRs. In 60-day grapes, 12.0% of the TRRs was rinsed with methanol/water (7/3,v/v) and 77.1% of the TRRs was extracted from rinsed grapes with methanol. The PES contained 10.8% of the TRRs. The methanol/water rinsing removed approximately 80% of the TRRs in leaves.			

NATURE OF THE RESIDUE IN *Tomato*		**PMRA # 1839421**
Radiolabel Position	**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**	
Test Site	The test crop was grown outdoors at a field site located in Madera, California.	
Treatment	Single foliar treatment	
Rate	300 g a.i./ha (1x), 1500 g a.i./ha (5x)	
End-use product	SC formulation	
Preharvest interval	14 days (mature fruit), 21 days (mature fruit, roots, stems and leaves)	
Matrix	**PHI (days)**	**[^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad TRRs (ppm)**
Tomato fruit (1x rate)	14	0.014 (Group I; 0.005 in rinse + 0.009 in rinsed tomato) 0.024 (Group II; 0.009 in rinse + 0.008 in juice + 0.007 in pomace)
	21	0.022 (Group I; 0.011 in rinse + 0.011 in rinsed tomato) 0.017 (Group II; 0.004 in rinse + 0.006 in juice + 0.007 in pomace)
Tomato fruit (5x rate)	14	0.456 (Group I; 0.346 in rinse + 0.110 in rinsed tomato) 0.294 (Group II; 0.096 in rinse + 0.049 in juice + 0.149 in pomace)
	21	0.281 (Group I; 0.190 in rinse + 0.091 in rinsed tomato) 0.098 (Group II; 0.030 in rinse + 0.027 in juice + 0.041 in pomace)
Leaves (1x rate)	21	0.648
Leaves (5x rate)	21	4.837
Metabolites Identified	**Major Metabolites (> 10% TRR)**	**Minor Metabolites (< 10% TRR)**
Radiolabel Position	**[^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad**	
Tomato fruits (5x rate, 14 day, Group I)	penthiopyrad	PAM, PCA, 753-F-DO
Tomato fruits (5x rate, 21day, Group I)	penthiopyrad	PAM, PCA, 753-A-OH, 753-F-DO
Tomato leaves (5x, 21-day)	penthiopyrad	PAM, PCA, 753-A-OH, 753-F-DO, 753-T-DO
In 14-day tomato fruits, 35.7-75.9% of the TRRs was rinsed with methanol/water (7/3,v/v), and 22.1% of the TRRs was extracted from rinsed tomato with methanol. Approximately 2.0-6.1% of the TRRs remained in PES. In 21-day tomato fruits, 50-67.6% of the TRRs was rinsed with methanol/water (7/3,v/v) , and 27.8- 36.3% of the TRRs was extracted from rinsed tomato with methanol. Approximately 4.1-9.1% of the TRRs remained in PES. In 21-day leaves, 59.1-77.3% of the TRRs was rinsed with methanol/water (7/3,v/v), and 28.1-14.9% of the TRRs was extracted from the rinsed leaves with methanol/water.		

NATURE OF THE RESIDUE IN *cabbage*			**PMRA # 1839419**
Radiolabel Position	**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**		
Test Site	The test crop was grown outdoors at a field site located in Madera, California.		
Treatment	Single foliar treatment		
Rate	200 g a.i./ha (1x), 1000 g a.i./ha (5x)		
End-use product	SC formulation		
Preharvest interval	21 days		
Matrix	**PHI (days)**	**^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad**	
		TRRs (ppm)	
Outer leaves	21	1.406 (1x) , 7.928 (5x)	
Heads	21	0.045 (1x), 0.155 (5x)	
Roots	21	0.019 (1x), 0.120 (5x)	
Metabolites Identified	**Major Metabolites (> 10% TRR)**		**Minor Metabolites (< 10% TRR)**
whole cabbage (1x)	penthiopyrad, PCA, PAM		DM-753, 753-F-DO, 753-A-OH, DM-PAM
whole cabbage (5x)	penthiopyrad, PAM		DM-753, 753-F-DO, 753-A-OH, PCA, DM-PAM
Most of the radioactivity was located in the outer leaves. The pattern of metabolites in the 1X and 5X cabbage was broadly similar.			

NATURE OF THE RESIDUE IN *wheat*			**PMRA # 1839417**
Radiolabel Position	**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**		
Test Site	The test crop was grown outdoors at a field site located in Madera, California.		
Treatment	foliar treatment		
Rate	Two applications at 250 g a.i./ha/application (1x) for a total of 500g a.i./ha or 750 g a.i./ha/application (3x) for a total of 1500 g a.i./ha.		
End-use product	SC formulation		
Preharvest interval	7 days after application (forage), 8 days after application 2 (hay), 32 days after application 2 (grain, straw)		
Matrix	**PHI (days)**	**^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad**	
		TRRs (ppm)	
forage (one application)	7	6.517 (1x), 22.131 (3x)	
hay	8	4.290 (1x), 17.827 (3x)	
straw	32	9.232 (1x), 43.686 (3x)	
grain	32	0.296 (1x), 0.753 (3x)	

Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)
forage (1x)	penthiopyrad	PAM, PCA, 753-A-OH, 753-F-DO
hay (1x)	penthiopyrad	PAM, PCA, 753-A-OH, 753-F-DO, 735-T-DO
straw (1x)	penthiopyrad , PCA	PAM, 753-A-OH, 753-F-DO, 735-T-DO
grain (1x)	none	penthiopyrad, PAM, PCA, 753-A-OH
In wheat forage, hay and straw, penthiopyrad constitutes the major individual component of the residue. No major free metabolites were identified in wheat grain.		

NATURE OF THE RESIDUE IN *canola*		**PMRA # 1839412**
Radiolabel Position	**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**	
Test Site	The test crop was grown outdoors at a field site located in Madera, California.	
Treatment	foliar treatment	
Rate	Two applications at 400 g a.i./ha/application for a total of 800 g a.i./ha	
End-use product	SC formulation	
Preharvest interval	14 days after 1st application (forage); 34 days after 2nd application (seed)	

Matrix	**PHI (days)**	**^{14}C-pyrazole]-penthiopyrad and [^{14}C-thienyl]-penthiopyrad TRRs (ppm)**
forage (one application)	14	12.184
seeds	34	0.139

Metabolites Identified	Major Metabolites (> 10% TRR)	Minor Metabolites (< 10% TRR)
seed	none	penthiopyrad, PAM, PCA, 753-A-OH, DM-PAM
forage	753-A-OH malonyl glucoside	penthiopyrad, PAM, PCA, DM-A-OH malonyl glucoside
Total radioactive residues in canola seed were very low (0.14 ppm) and a proportion (40 %) was not available for extraction with neutral solvents as observed for wheat grain.		

Overview of plant metabolism:
The metabolism of penthiopyrad in five diverse crops (grape, tomato, cabbage, wheat and canola) is similar. The metabolism of penthiopyrad in plants is characterised by the following metabolic processes:
Hydroxylation of the alkyl side chain leads to 753-A-OH and its isomers hydroxylated on different positions of the six-carbon alkyl chain. Conjugates of these metabolites were observed in all crops at higher amounts than the free metabolites. Conjugation was mainly with glucose and malonyl glucose. Canola forage and cabbage had the highest proportions of these conjugated metabolites. In canola forage over 50 % of the TRRs was recovered as conjugated metabolites.

Oxidation of the thienyl ring to 753-T-DO, which is further oxidised leading to replacement of the sulphur atom with oxygen to give the lactone 753-F-DO. Neither 753-T-DO nor 753-F-DO persists in plant matrices. Oxidative degradation of 753-F-DO leading to the cleavage of the two-ring structure and the formation of PAM which contains the pyrazole label which is then hydrolysed to form PCA.

N-demethylation on the pyrazole moiety of penthiopyrad can also occur but this pathway is thought to be less important than the other oxidative pathways: N-demethylated forms of the conjugates were identified in canola forage.

CONFINED ACCUMULATION IN ROTATIONAL CROPS – spinach/lettuce, radish, wheat			**PMRA # 2027547**
Radiolabel Position		**1:1 mixture of [^{14}C-pyrazole]-penthiopyrad (P-label) and [^{14}C-thienyl]-penthiopyrad (T-label)**	
Test site		The crops were grown outdoors in containers under natural climatic conditions.	
Formulation used for trial		SC formulation	
Application rate and timing		Soil was treated at 800 g a.i./ha, and aged for 30, 120 and 360 days.	
Metabolites Identified		**Major Metabolites (> 10% TRR)**	**Minor Metabolites (< 10% TRR)**
Matrix	**PBI (days)**		
Spinach/Lettuce	30	PCA, DM-PAM	penthiopyrad, DM-PCA, 753-A-OH
Radish tops	30	none	penthiopyrad, DM-PCA, PCA, 753-A-OH
Radish roots	30	DM-PCA	penthiopyrad, 753-A-OH, DM-PAM
Wheat forage	30	none	penthiopyrad, DM-PCA, PCA, 753-A-OH, DM-PAM
Wheat straw	30	none	penthiopyrad, DM-PCA, PCA, 753-A-OH, DM-PAM
Wheat chaff	30	none	penthiopyrad, DM-PCA, PCA, 753-A-OH, DM-PAM
Wheat grain	30	DM-PCA	penthiopyrad, PCA, 753-A-OH
Spinach	120	none	penthiopyrad, DM-PCA, 753-A-OH, DM-PAM
Wheat forage	120	none	DM-PCA, DM-PAM
Wheat straw	120	none	penthiopyrad, DM-PCA, 753-A-OH, DM-PAM
Wheat chaff	120	none	penthiopyrad, DM-PCA, 753-A-OH, DM-PAM
Wheat grain	120	none	none
Spinach	360	DM-PAM	penthiopyrad, DM-PCA, 753-A-OH,
Wheat forage	360	none	penthiopyrad, DM-PAM
Wheat straw	360	none	none
Wheat chaff	360	none	none
Wheat grain	360	none	none
Numerous metabolites (at least twelve) were detected in the plant extracts. Four fractions were identified as penthiopyrad, DM-PCA, PCA and 753-A-OH. DM-PAM was also tentatively identified. None of the unidentified fractions exceeded 0.01 ppm in human food or 0.02 ppm in animal feed. Analysis of the soil extract showed the same major components as detected in the plant extracts.			

NATURE OF THE RESIDUE IN LAYING HEN			PMRA # 1839423, 1839424	
Two metabolism studies in hens were conducted. The first study was performed with [pyrazole-14C]-penthiopyrad (P-label) and [thienyl-14C]-penthiopyrad (T-label), which were given orally as capsules to two separate groups of hens twice per day for 14 consecutive days at a target dose level of 10 mg/kg diet per day. Eggs and excreta were collected throughout the study and hens were sacrificed 6 - 8 hr after the last dose. A second study was undertaken to further elucidate the metabolic pathway and the nature of the residues in eggs and liver. This study was also performed with [pyrazole-14C]-penthiopyrad (P-label) and [thienyl-14C]-penthiopyrad (T-label), which were given orally as capsules to two separate groups of hens once per day for 7 consecutive days at a target dose level of 10 mg/kg diet per day. Eggs and excreta were collected throughout the study and hens were sacrificed 21-23 hr after the last dose.				
Matrices	% of Administered Dose			
	P-label		T-label	
Excreta	87.3		84.3	
Muscle	0.16 (0.052 ppm)		0.11 (0.038 ppm)	
Fat	0.02 (0.021 ppm)		0.04 (0.049 ppm)	
Skin	0.01 (0.053 ppm)		0.01(0.059 ppm)	
Liver	0.12 (0.632 ppm)		0.14 (0.682 ppm)	
Eggs	0.25 (0.095-0.124 ppm)		0.29 (0.105-0.132 ppm)	
Metabolites identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
Radiolabel Position	P-label	T-label	P-label	T-label
Muscle	PAM, DM-PAM	na	PCA	na
Fat	na	penthiopyrad	na	none
Skin	penthiopyrad, PAM	penthiopyrad	none	none
Liver	PAM, cys-T-DO isomer	dihydroxy-cys-T-DO	DM-PAM, dihydroxy-cys-F-DO isomers, hydroxyl-cys-F-DO, cys-F-DO isomers, dihydroxy-cys-T-DO, hydroxyl-MTF-753	dihydroxy-cys-F-DO isomers, hydroxyl-cys-F-DO, cys-F-DO isomers, dehydro-cys-F-DO, cys-T-DO isomers, hydroxyl-MTF-753
Eggs	PAM	none	DM-PAM, cys-F-DO isomers, cys-T-DO isomer, dihydroxy-MTF-753	penthiopyrad, 753-F-DO, dihydroxy-MTF-753, hydroxy-MTF-753

NATURE OF THE RESIDUE IN LACTATING GOAT			PMRA # 1839426, 1839428	
Two metabolism studies in goat were conducted. The first study was performed with [pyrazole-14C]-penthiopyrad (P-label) and [thienyl-14C]-penthiopyrad (T-label), which were given orally as capsules to two separate goats twice per day for 7 consecutive days at a target dose level of 20 mg/kg diet per day. Milk and excreta were collected throughout the study and goats were sacrificed 6 hr after the last dose. A second study was undertaken to further elucidate the metabolic pathway and the nature of the residues in liver and kidney. This study was also performed with [pyrazole-14C]-penthiopyrad (P-label) and [thienyl-14C]-penthiopyrad (T-label), which were given orally as capsules to two goats once per day for 5 consecutive days at a target dose level of 10 mg/kg diet per day. Goats were sacrificed 24 hours after the last dose.				
Matrices	% of Administered Dose			
	P-label		T-label	
Urine and feces	80.01		84.63	
Muscle	0.21 (0.038 ppm)		0.13 (0.011 ppm)	
Fat	0.05 (0.028 ppm)		0.05 (0.015 ppm)	
Kidney	0.01 (0.330 ppm)		0.01 (0.113 ppm)	
Liver	0.36 (1.878 ppm)		0.33 (0.988 ppm)	
Milk	0.08 (0.010-0.078 ppm)		0.11 (0.008-0.043 ppm)	
Metabolites identified	Major Metabolites (> 10% TRR)		Minor Metabolites (< 10% TRR)	
Radiolabel Position	P-label	T-label	P-label	T-label
Muscle	PAM, DM-PAM	none	none	none
Fat	penthiopyrad, PAM	none	DM-PAM	none
Kidney	PAM, dihydroxy-cys-F-DO isomer	none	penthiopyrad, DM-PAM, ydroxy-cys-F-DO, cys-F-DO isomer, dihydroxyl-cys-T-DO, cys-T-DO isomer, dihydroxy-MTF-753, hydroxy-MTF-753, dehydro-cys-F-DO/753-A-OH	Penthiopyrad, dihydroxy-cys-F-DO isomer, dihydroxy-cys-F-DO isomer, hydroxyl-cys-F-DO, cys-F-DO isomers, dihydroxy-cys-T-DO, cys-T-DO isomers, dihydroxy-MTF-753, hydroxyl-MTF-753
Liver	PAM, PCA	hydroxyl-MTF-753	Penthiopyrad, DM-PAM, dihydroxy-cys-F-DO isomers, dehydro-cys-F-DO, hydroxy-cys-F-DO, cys-F-DO isomers, cys-T-DO isomers, dihydroxy & hydroxyl-MTF-753, 753-A-OH	Penthiopyrad, dihydroxy-cys-F-DO isomers, hydroxy-cys-F-DO, cys-F-DO isomers, dehydroxy-cys-F-DO, dihydroxy-cys-T-DO, cys-T-DO isomers, 753-A-OH

Milk	PAM, cys-T-DO isomer	none	DM-PAM, dihydroxy-cys-F-DO isomers, dehydro-cys-F-DO, hydroxy-cys-F-DO, cys-F-DO isomer, dihydroxy-cys-T-DO, cys-T-DO isomer, dihydroxy & hydroxyl-MTF-753.	dihydroxy-cys-F-DO isomer, dehydro-cys-F-DO, hydroxy-cys-F-DO, cys-F-DO isomers, dihydroxy-cys-T-DO, cys-T-DO isomers, dihydroxy & hydroxyl-MTF-753, 753-A-OH

Proposed Metabolic Scheme in Livestock
Several metabolites were observed in poultry and goat indicating extensive degradation via several metabolic pathways.

Metabolism of penthiopyrad proceeds mainly by sequential oxidation of the thienyl ring to 753-T-DO and 753-F-DO followed by conjugation of both metabolites with glutathione and subsequent catabolism of the glutathione conjugates to yield cysteine conjugates (cys-T-DO and cys-F-DO). Hydroxylation of one or more positions on the alkyl side chain to form 753-A-OH analogues and dihydroxy metabolites may occur before or after oxidation of the thienyl ring and conjugation. Metabolism of 753-F-DO is thought to proceed via ring opening and subsequent cleavage of the two ring structure to give mainly PAM from the pyrazole moiety.

STORAGE STABILITY **PMRA # 1840774**

Samples of high water crops (lettuce), high oil (oilseed rape, rapeseed oil), high protein (dried beans), high starch (potatoes, wheat grain), high acid (apples, grapes, grape juice, grape dried pomace, and raisins) and dry crops (wheat straw & forage) were spiked with 0.2 ppm each of penthiopyrad, PAM, 753-A-OH, 753-F-DO, PCA, and DM-PCA. Spiked samples were stored frozen at approximately -20ºC. Samples were analyzed at 0, 1, 3, 6, 12, and 18 months. The results showed penthiopyrad, PAM, 753-A-OH, 753-F-DO, PCA, and DM-PCA were stable in the tested samples for 18 months.

CROP FIELD TRIALS - carrot, radish, sugar beet, turnip **PMRA # 1928240**

Ten trials were conducted on carrot in NAFTA Growing Regions 1, 3, 5, 6, 10 and 11 at a total rate of 860-937 g a.i./ha/season.
Six trials were conducted on radish in NAFTA Growing Regions 1, 3, 5, and 10 at a total rate of 877-945 g a.i./ ha /season.
Twelve trials were conducted on sugar beet in NAFTA Growing Regions 5, 7, 7A, 8, 10, and 11 at a total rate of 895-938 g a.i./ha/season. Each trial site had 2 treatment plots; Trt1: two foliar broadcast applications; Trt2: one in-furrow application + one foliar broadcast application.
Six trials were conducted on turnip in NAFTA Growing Regions 2, 4, 5, 6, and 10 at a total rate of 899-946 g a.i./ha/season.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Carrot roots	860-937	0	18	0.02	0.43	0.395	0.07	0.11	0.11
Radish roots	877-945	0-1	12	<0.01	1.20	1.15	0.28	0.46	0.44
Sugar beet, leaves	(Trt 1) 895-938	7	24	0.10	4.40	4.20	0.85	1.55	1.47
	(Trt 2) 896-937	7	24	0.09	3.70	3.15	0.69	1.05	1.01
Sugar beet, roots	(Trt 1) 895-938	7	24	0.013	0.350	0.270	0.090	0.105	0.089
	(Trt 2) 896-937	7	24	<0.01	0.180	0.175	0.047	0.066	0.055
Turnip leaves	899-946	0	12	3.50	27.00	23.00	10.15	11.73	7.94

CROP FIELD TRIALS - potato | **PMRA # 1840814**

Twenty two trials were conducted on potato in NAFTA Growing Regions 1, 2, 3, 5, 7A, 10, 11, 12 and 14 at a total rate of 1031-1110 g a.i./ha/season. All the trial sites had 2 treatment plots (Trt 1 & 2), and in 5 trials sites Trt 3 was also conducted.
Treatment 1 (Trt 1): three late-season foliar broadcast spray applications of penthiopyrad
Treatment 2 (Trt 2): one in-furrow application + two late-season foliar broadcast spray applications of penthiopyrad.
Treatment 3 (Trt 3): two early-season foliar broadcast spray applications + one late-season foliar broadcast spray application of penthiopyrad
The decline residue trials showed that residues of penthiopyrad in treatment 1 were all below LOQ (<0.01 ppm) at all PHIs. In treatment 2, residue levels for penthiopyrad decreased with increasing PHIs in one trial and were close to or below LOQ in the second trial.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Potato tuber	1038-1110 (Trt 1)	6-8	44	<0.01	0.037	0.033	0.010	0.011	0.005
	1031-1110 (Trt 2)	6-8	42	<0.01	0.058	0.052	0.010	0.016	0.010
	1044-1088 (Trt 3)	6-7	10	<0.01	0.028	0.025	0.010	0.013	0.006

CROP FIELD TRIALS - dry bulb onion, green onion | **PMRA # 1840808**

Eleven trials were conducted on dry bulb onion in NAFTA Growing Regions 1, 5, 6, 8, 10 and 11 at a total rate of 1044-1128 g a.i./ha/season.
Six trials were conducted on green onion in NAFTA Growing Regions 5, 6, and 10 at a total rate of 1044-1128 g a.i./ ha /season.
The decline residue trial on green onions showed that residues of penthiopyrad generally decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dry bulb onion	1044-1128	2-3	20	<0.01	0.450	0.445	0.064	0.132	0.145
Green onion	1044-1128	3	12	0.210	1.800	1.750	0.545	0.752	0.553

CROP FIELD TRIALS - celery, lettuce, spinach | **PMRA # 1840800**

Eleven trials were conducted on celery in NAFTA Growing Regions 3, 5, and 10 at a total rate of 054-1099 g a.i./ha/season.
Twelve trials were conducted on lettuce (head & leaf) in NAFTA Growing Regions 1, 3, 5, 10, and 12 at a total rate of 1028-1098 g a.i./ ha /season.
Ten trials were conducted on spinach in NAFTA Growing Regions 1, 2, 5, 6, 10 and 12 at a total rate of 1044-1085 g a.i./ha/season.
The decline residue trial showed that residues of penthiopyrad in/on head lettuce generally decreased with increasing PHIs. Residues of penthiopyrad in/on leaf lettuce generally increased between PHIs of 0 and 3 days, then decreased between PHIs of 3 to 10 days.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Celery	1054-1099	2-3	22	1.60	9.10	8.65	2.80	3.82	2.13
Head lettuce	1039-1084	3	24	0.01	3.90	3.40	0.58	1.22	1.16
Leaf lettuce	1028-1098	3	24	1.10	11.00	11.00	2.15	3.71	3.00

Spinach	1044-1185	3	20	0.76	17.00	15.00	2.70	4.79	4.90

CROP FIELD TRIALS - broccoli, cauliflower, cabbage, mustard greens	**PMRA # 1928238, 1928239**

Ten trials were conducted on broccoli/cauliflower in NAFTA Growing Regions 1, 5, 10 and 12 at a total rate of 1047-1082 g a.i./ha/season.
Ten trials were conducted on cabbage in NAFTA Growing Regions 1, 2,3, 5, 6 and 10 at a total rate of 1069-1085 g a.i./ ha /season.
Nine trials were conducted on mustard greens in NAFTA Growing Regions 1, 2, 3, 4, 5, 6, 10 and 12 at a total rate of 1017-1083 g a.i./ha/season.
The decline residue trial in broccoli and mustard greens showed that residues of penthiopyrad decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Broccoli	1047-1082	0	14	0.55	2.50	2.35	1.55	1.48	0.61
Cauliflower	1069-1082	0	6	0.099	0.590	0.505	0.425	0.370	0.213
Cabbage	1044-1085	0	20	0.022	2.300	2.250	0.335	0.723	0.721
Mustard greens	1017-1083	0	18	5.70	32.00	29.50	10.45	14.31	7.64

CROP FIELD TRIALS - Edible-podded and succulent shelled beans & peas	**PMRA # 1928240**

Eight trials were conducted on edible-podded bean in NAFTA Growing Regions 1, 2, 3, 5 and 11 at a total rate of 1053-1095 g a.i./ha/season.
Four trials were conducted on edible-podded pea in NAFTA Growing Regions 5 and 11 at a total rate of 1051-1077 g a.i./ ha /season.
Seven trials were conducted on succulent shelled bean in NAFTA Growing Regions 2, 5, 10 and 11 at a total rate of 1050-1093 g a.i./ha/season.
Seven trials were conducted on succulent shelled pea in NAFTA Growing Regions 1, 5, 11 and 12 at a total rate of 1021-1081g a.i./ha/season.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Podded bean	1053-1095	0	16	0.12	1.70	1.50	0.66	0.66	0.47
Podded pea	1051-1077	0	8	0.85	1.50	1.50	1.20	1.16	0.27
Shelled bean	1050-1093	0	14	0.01	0.29	0.25	0.04	0.08	0.08
Shelled pea	1021-1081	0	14	0.04	0.15	0.14	0.07	0.07	0.03

CROP FIELD TRIALS - dried bean & pea | **PMRA # 1840804**

Eleven trials were conducted on dried pea in NAFTA Growing Regions 5, 11 and 14 at a total rate of 594-621g a.i./ha/season.
Eleven trials were conducted on dried bean in NAFTA Growing Regions 5, 7, 7A, 8, 9, 10 and 11 at a total rate of 594-622 g a.i./ ha /season.
The decline residue trial showed that residues of penthiopyrad in/on pea hay increased over PHIs of 0 to 21 days, then are stable over PHIs of 21 to 28 days. Residues of penthiopyrad in/on pea vines increased over PHIs of 0 to 7 days, then decreased over PHIs of 7 to 28 days.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Dried pea	594-621	20-24	22	<0.01	0.12	0.09	0.01	0.02	0.025
Dried bean	594-622	21	22	<0.01	0.21	0.20	0.01	0.03	0.054

CROP FIELD TRIALS - soybean | **PMRA # 1928241, 1928242**

Twenty one trials were conducted on soybean in NAFTA Growing Regions 2, 4 and 5 at a total rate of 871-935 g a.i./ha/season.
The decline residue trials indicated that residues of penthiopyrad in/on soybean forage and hay decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Soybeans	871-935	13-15	38	<0.01	0.25	0.21	0.01	0.03	0.05

CROP FIELD TRIALS - tomato, bell pepper, non-bell pepper | **PMRA # 1840783**

Twenty trials were conducted on tomato in NAFTA Growing Regions 1, 2, 3, 5 and 10 at a total rate of 1039-1099 g a.i./ha/season.
Twenty trials were conducted on pepper (bell & non-bell) in NAFTA Growing Regions 2, 3, 5, 6, 8 and 10 at a total rate of 1051-1103 g a.i./ ha /season.

The decline residue trials indicated that residues of penthiopyrad in/on tomato fruits increased slightly or were stable over PHIs of 0 to 3 days and then decreased over PHIs of 3 to 10 days. Penthiopyrad residue levels in/on bell pepper fruit increased from PHIs of 0 to 1 day then decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Tomato	1039-1099	0	40	0.06	1.50	1.30	0.27	0.37	0.31
Bell pepper	1051-1103	0	22	0.07	0.91	0.77	0.20	0.27	0.23
Non-bell pepper	1051-1098	0	18	0.16	1.70	1.55	0.44	0.57	0.43

CROP FIELD TRIALS - greenhouse pepper, greenhouse tomato	**PMRA # 1941994, 1840781**

A residue study with penthiopyrad on greenhouse peppers was conducted in Europe. Nine trials were conducted in France (3 trials), Italy (2 trials), Greece (2 trials) and Spain (2 trials) At each test location, greenhouse pepper was treated with penthiopyrad for a total seasonal rate of 786-823 g a.i./ha.
A residue study with penthiopyrad on greenhouse tomato was conducted in Europe. Eleven trials were conducted in France (2 trials), Italy (2 trials), Greece (2 trials), Spain (3 trials) and Belgium (2 trials). At each test location, greenhouse tomato was treated with penthiopyrad for a total seasonal rate of 783-821 g a.i./ha.
The decline residue trials indicated that residues of penthiopyrad in/on greenhouse pepper fruits generally increased slightly over PHIs of 0 to 3 days, then decreased or stayed stable over PHIs of 3 to 14 days.
In five out of seven decline tests on tomato, the 0-day time-point specimen had the highest residue for the respective decline.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Greenhouse pepper	786-823	1	9	0.16	0.65	---	0.530	0.472	0.186
Greenhouse tomato	783-821	1	11	0.086	0.84	---	0.17	0.32	0.26

CROP FIELD TRIALS - cantaloupe, cucumber, squash	**PMRA # 1840787**

Eight trials were conducted on cantaloupe in NAFTA Growing Regions 2, 5, 6 and 10 at a total rate of 988-1022 g a.i./ha/season.
Ten trials were conducted on cucumber in NAFTA Growing Regions 2, 3, 5, 6 and 12 at a total rate of 972-1020 g a.i./ ha /season.
Nine trials were conducted on summer squash in NAFTA Growing Regions1, 2, 3, 5, 10 and 12 at a total rate of 972-1039 g a.i./ ha /season.
The decline residue trial showed that residues of penthiopyrad in/on cucumbers decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Cantaloupe	988-1022	1	16	0.086	0.350	0.265	0.180	0.200	0.076
Cucumber	972-1020	1	20	<0.01	0.130	0.125	0.054	0.063	0.042
Summer squash	972-1039	0-1	18	<0.01	0.250	0.205	0.130	0.131	0.069

CROP FIELD TRIALS - greenhouse cucumber	**PMRA # 1840791**

A total of nine residue trials were conducted on greenhouse cucumber in Europe: France (1 trial), Italy (2 trials), Greece (2 trials), Spain (3 trials), and Belgium (1 trial). At each test location, greenhouse cucumber was treated with penthiopyrad for a total seasonal rate of 777-803 g a.i./ha.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Greenhouse cucumber	777-803	1	9	0.096	0.320	--	0.150	0.174	0.085

CROP FIELD TRIALS - apple, pear **PMRA # 1840793**

Fourteen trials were conducted on apple in NAFTA Growing Regions 1, 2, 5, 9, 10 and 11 at a total rate of 906-964 g a.i./ha/season .
Ten trials were conducted on pear in NAFTA Growing Regions 1, 5, 10 and 11 at a total rate of 904-929 g a.i/ha /season.
The decline residue trial showed that residues of penthiopyrad in/on apple fruits decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Apple	906-964	27-29	28	<0.01	0.26	0.23	0.14	0.14	0.06
Pear	904-929	27-29	20	<0.01	0.26	0.25	0.14	0.13	0.08

CROP FIELD TRIALS - peach, plum, cherry **PMRA # 1840811**

Thirteen trials were conducted on peach in NAFTA Growing Regions 1, 2, 5, 6, 10 and 11 at a total rate of 858-937 g a.i./ha/season.
Ten trials were conducted on plum in NAFTA Growing Regions 1, 5, 10, 11 and 12 at a total rate of 865-936 g a.i./ ha /season.
Nine trials were conducted on cherry (4 sweet & 5 tart) in NAFTA Growing Regions 1, 5, 9, 10, 11 and 12 at a total rate of 865-930 g a.i./ ha /season.
The decline residue trial showed that residues of penthiopyrad in/on peaches decreased with increasing PHIs.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Peach	858-937	0	26	0.130	1.500	1.400	0.565	0.541	0.317
Plum	865-936	0	20	0.043	0.800	0.770	0.092	0.178	0.214
Cherry	865-930	0	20	0.36	1.80	1.70	0.995	1.041	0.449

CROP FIELD TRIALS - strawberry **PMRA # 1840817**

Nine trials were conducted on strawberry in NAFTA Growing Regions 1, 3, 5, 10 and 12 at a total rate of 1028-1150 g a.i./ha/season .
The decline residue trial showed that residues of penthiopyrad in/on strawberries decreased with increasing PHIs

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Strawberry	1028-1150	0	18	0.340	2.200	2.000	0.765	0.922	0.514

CROP FIELD TRIALS - almond, pecan **PMRA # 1840824**

Six trials were conducted on almond in NAFTA Growing Region 10 at a total rate of 904-929 g a.i./ha/season.
Six trials were conducted on pecan in NAFTA Growing Regions 2, 4, 6 and 8 at a total rate of 909-930 g a.i./ha/ season.

Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Almond	904-929	14	12	<0.01	0.045	0.037	0.010	0.014	0.011
Pecan	909-930	13-14	12	<0.01	<0.01	<0.01	0.010	0.010	0.00

CROP FIELD TRIALS - Wheat, barley, sorghum									**PMRA # 1928233, 1928234, 1928236, 1943561**
Twenty six trials were conducted on wheat in NAFTA Growing Regions 2, 4, 5, 6, 7, 7A, 8, 11 and 14 at a total rate of 677-725 g a.i./ha/season. Thirteen trials were conducted on barley in NAFTA Growing Regions 5, 7, and 14 at a total rate of 677-729 g a.i. /ha/season. Nine trials were conducted on sorghum in NAFTA Growing Regions 4, 5, 6, 7, and 8 at a total rate of 676-731 g a.i./ha/ season. The decline residue trial showed that residues of penthiopyrad in/on wheat forage decreased with increasing PHIs.									
Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Wheat	677-725	35-69	52	<0.01	0.03	0.03	0.01	0.01	0.00
Barley	677-729	47-69	26	<0.01	0.12	0.11	0.01	0.02	0.03
Sorghum	676-731	28-33	18	0.06	0.43	0.43	0.18	0.22	0.13
CROP FIELD TRIALS - field corn, sweet corn									**PMRA # 1928244, 1928243**
Fifteen trials were conducted on field corn in NAFTA Growing Regions 1, 2, 5 and 6 at a total rate of 686-736 g a.i./ha/season. Eleven trials were conducted on sweet corn in NAFTA Growing Regions 1, 2, 3, 5, 7A, 10, 11 and 12 at a total rate of 699-735 g a.i./ha/season. The decline residue trial showed that residues of penthiopyrad in/on corn forage decreased with increasing PHIs.									
Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Field corn	688-727	7	28	<0.01	<0.01	<0.01	0.010	0.010	0.0
Sweet corn	699-735	7	22	<0.01	<0.01	<0.01	0.010	0.010	0.0
CROP FIELD TRIALS - canola, sunflower, cotton seed									**PMRA # 1840795, 1928237, 1928246**
Eighteen trials were conducted on canola in NAFTA Growing Regions 2, 5, 7, 11 and 14 at a total rate of 587-620 g a.i./ha/season. Nine trials were conducted on sunflower in NAFTA Growing Regions 5, 7, 8 and 14 at a total rate of 904-937 g a.i./ha/season. Thirteen trials were conducted on cotton in NAFTA growing Regions 2, 4, 6, 8, 10 at a total rate of 1038-1110 g a.i./ha/season. The decline residue trial showed that residues of penthiopyrad in/on canola decreased with increasing PHIs.									
Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Canola	587-620	20-22	36	<0.01	0.470	0.415	0.037	0.065	0.094
Sunflower	904-937	13-15	18	<0.01	0.920	0.805	0.106	0.245	0.252
Cotton seed	1038-1110	19-22	26	<0.01	0.28	0.25	0.10	0.10	0.08

CROP FIELD TRIALS - peanut									**PMRA # 1840827**
Thirteen trials were conducted on peanut in NAFTA Growing Regions 2, 3, 6 and 8 at a total rate of 1054-1084g a.i./ha/season.									
Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Peanut nutmeat	1054-1184	13-15	26	<0.01	0.047	0.034	0.010	0.012	0.007
Peanut hay	1054-1184	13-15	26	1.20	17.00	16.50	5.4	5.71	4.15
CROP FIELD TRIALS - alfalfa									**PMRA # 1928248**
Fifteen trials were conducted on alfalfa in NAFTA Growing Regions 1, 2, 5, 7, 9, 10, 11 and 14 at a total rate of 685-737g a.i./ha/season. The decline residue trial indicated that residues of penthiopyrad in/on alfalfa forage and hay decreased with increasing PHIs.									
Commodity	Total Applic. Rate (g a.i./ha)	PHI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Alfalfa forage	685-737	13-15	30	0.03	4.00	3.95	0.48	0.86	0.99
Alfalfa hay	685-737	13-15	30	0.08	14.00	13.50	1.70	2.73	3.27

Summary of Residue Data in Rotational Crops Following Primary Treatment with Penthiopyrad									
Commodity	Total Applic. Rate (g a.i./ha)	PBI (days)	Penthiopyrad Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Lettuce, 50% maturity	970-981	5-30	4	<0.01	<0.01	<0.01	0.01	0.01	0
Lettuce, 100%maturity			4	<0.01	<0.01	<0.01	0.01	0.01	0
Radish, tops	970-1057	5-30	10	<0.01	<0.01	<0.01	0.01	0.01	0
Radish roots			10	<0.01	0.024	0.019	0.01	0.01	0
Wheat forage	994-1015	30-31	4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat hay			4	<0.05	<0.05	<0.05	0.05	0.05	0
Wheat grain			4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat straw			4	<0.05	<0.05	<0.05	0.05	0.05	0
Lettuce, 50% maturity	970-981	60-67	4	<0.01	<0.01	<0.01	0.01	0.01	0
Lettuce, 100%maturity			4	<0.01	<0.01	<0.01	0.01	0.01	0
Radish, tops	970-1057	60-67	6	<0.01	<0.01	<0.01	0.01	0.01	0
Radish roots			6	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat forage	994-1015	60-62	4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat hay			4	<0.05	<0.05	<0.05	0.05	0.05	0
Wheat grain			4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat straw			4	<0.05	<0.05	<0.05	0.05	0.05	0

Lettuce, 50% maturity	970-981	300-336	4	<0.01	<0.01	<0.01	0.01	0.01	0
Lettuce, 100%maturity			4	<0.01	<0.01	<0.01	0.01	0.01	0
Radish, tops	970-1057	300-336	4	<0.01	<0.01	<0.01	0.01	0.01	0
Radish roots			4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat forage	994-1015	380-381	4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat hay			4	<0.05	<0.05	<0.05	0.05	0.05	0
Wheat grain			4	<0.01	<0.01	<0.01	0.01	0.01	0
Wheat straw			4	<0.05	<0.05	<0.05	0.05	0.05	0

PROCESSED FOOD AND FEED - sugar beet	**PMRA # 1928275**
Test Site	Two trials in the US
Treatment	One in-furrow application & one foliar broadcast spray
Rate	2250 g a.i./ha/application for a total rate of 4500 g a.i./ha/season
End-use product	EC formulation
Preharvest interval	6-7 days
Processed Commodity	Processing Factor
Refined sugar	0.16x
Molasses	0.17x
Dried pulp	5.65x

PROCESSED FOOD AND FEED - potato	**PMRA # 1840839**
Test Site	Two trials in the US
Treatment	Foliar broadcast spray
Rate	Three applications at 1750 g a.i./ha/application for a total of 5250 g a.i./ha/season
End-use product	EC formulation
Preharvest interval	7 (±1) days
Processed Commodity	Processing Factor
Potato flakes	0.27x
Potato chips	0.27x
French fries (unpeeled)	0.59x
French fries (peeled)	0.27x
Washed tubers	0.93x
Cull tubers	0.87x

PROCESSED FOOD AND FEED - soybean	**PMRA # 1928268**
Test Site	Two trials in the US
Treatment	Foliar broadcast spray
Rate	Two applications at 2250 g a.i./ha/application for a total of 4500 g a.i./ha/season
End-use product	EC formulation
Preharvest interval	14 days
Processed Commodity	Processing Factor
Soybean meal	0.50x
Refined oil	0.99x
PROCESSED FOOD AND FEED - plum	**PMRA # 1840841**
Test Site	Two trials in the US
Treatment	Foliar broadcast spray
Rate	Three applications at 300 g a.i./ha/application for a total of 900 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	0 day
Processed Commodity	Processing Factor
Pitted dry prune	1.41x
PROCESSED FOOD AND FEED - field corn	**PMRA # 1928271**
Test Site	Two trials in the US
Treatment	Foliar broadcast spray
Rate	Three applications at 1750 g a.i./ha/application for a total of 3500 g a.i./ha/season
End-use product	EC formulation
Preharvest interval	7-8 days
Processed Commodity	Processing Factor
Corn starch	0.79x
Corn flour	1.32x
Corn meal	1.03x
Refined oil	4.01x

PROCESSED FOOD AND FEED - canola	**PMRA # 1840834**
Test Site	Two trials in the US and one trial in Canada
Treatment	Foliar broadcast spray
Rate	Two applications at 1500 g a.i./ha/application for a total of 3000 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	21 days
Processed Commodity	Processing Factor
Presscake	1.03x
Refined oil	1.56x
Meal	0.75x
PROCESSED FOOD AND FEED - peanut	**PMRA # 1840827**
Test Site	Two trials in the US
Treatment	Foliar broadcast spray
Rate	Three applications at 1750 g a.i./ha/application for a total of 5250 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	14 days
Processed Commodity	Processing Factor
Peanut meal	0.43x
Refined oil	1.54x
PROCESSED FOOD AND FEED - apple	**PMRA # 1840830**
Test Site	Three trials in the US
Treatment	Foliar broadcast spray
Rate	Three applications at 300 g a.i./ha/application for a total of 900 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	28 days
Processed Commodity	Processing Factor
Apple wet pomace	5.4x
Apple juice	<0.06x
Apple sauce	<0.06x

PROCESSED FOOD AND FEED - tomato	PMRA # 1840836
Test Site	Three trials in Europe
Treatment	Foliar broadcast spray
Rate	Two applications at 200 g a.i./ha and 600 g a.i./ha for a total of 800 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	1 day
Processed Commodity	Processing Factor
Tomato juice	0.31x
Tomato puree	1.93x
Tomato catsup	1.32x
Tomato paste	2.49x

PROCESSED FOOD AND FEED - wheat	PMRA # 1840838
Test Site	Three trials in Europe
Treatment	Foliar broadcast spray
Rate	Two applications at 400 g a.i./ha/application for a total of 800 g a.i./ha/season
End-use product	SC formulation
Preharvest interval	44-63 days
Processed Commodity	Processing Factor
Wheat flour	Residues in the grain samples before processing were <LOQ and residues in wheat processed commodities after processing were non-detectable, processing factors could not be calculated.
Wheat bran	
Wheat germ	

LIVESTOCK FEEDING – Dairy cattle — **PMRA # 1839432**

Eleven lactating cows were dosed with penthiopyrad for 28/29 days. The treated animal were divided into groups and were dosed twice daily at 8.4 ppm, 24.1 ppm and 74.6 ppm feeding levels.
Combined residues of penthiopyrad + PAM are reported as parent equivalent (penthiopyrad + PAMx1.86). For calculation, 0.01 ppm (LOQ) was used for value <LOQ.

Matrix	Feeding Level	n	LOD	Min.	Max.	Median	Mean	Standard Deviation
Liver	8.4 ppm	3	0.005	<0.02	<0.02	0.02	0.02	--
Kidney		3	0.005	<0.02	<0.02	0.02	0.02	--
Muscle		3	0.005	<0.02	<0.02	0.02	0.02	--
Fat		3	0.005	<0.02	<0.02	0.02	0.02	--
Milk		30	0.005	<0.02	<0.02	0.02	0.02	--
Liver	24.1 ppm	3	0.005	<0.0286	<0.0482	0.0472	0.041	0.011
Kidney		3	0.005	<0.02	<0.0286	0.02	0.023	0.005
Muscle		3	0.005	<0.02	<0.02	0.02	0.02	--
Fat		3	0.005	<0.0286	<0.0286	0.0286	0.0286	--
Milk		30	0.005	<0.02	<0.02	0.02	0.02	--

Liver	74.6 ppm	3	0.005	0.0858	0.1316	0.0944	0.1039	0.024
Kidney		3	0.005	<0.0472	<0.0658	0.0658	0.0596	0.011
Muscle		3	0.005	<0.0286	<0.0472	0.0286	0.0348	0.011
Fat		3	0.005	<0.02	<0.0472	0.02	0.0291	0.015
Milk		50	0.005	<0.02	0.0472	0.02	0.024	0.005

LIVESTOCK FEEDING – Laying hens	**PMRA # 1839431**

Sixty laying hens were used in the feeding study. The treated animal were divided into groups and were dosed twice daily at 5.9 ppm, 17.5 ppm, and 58.5 ppm feeding levels.
Combined residues of penthiopyrad + PAM are reported as parent equivalent (penthiopyrad + PAMx1.86). For calculation, 0.01 ppm (LOQ) was used for value <LOQ.

Matrix	Feeding Level	n	LOD	Min.	Max.	Median	Mean	Standard Deviation
Muscle	5.8 ppm & 17.5 ppm	6	0.005	<0.02	<0.02	0.02	0.02	--
Liver		6	0.005	<0.02	<0.02	0.02	0.02	--
Skin & fat		6	0.005	<0.02	<0.02	0.02	0.02	--
Fat		6	0.005	<0.02	<0.02	0.02	0.02	--
Eggs		72	0.005	<0.02	<0.02	0.02	0.02	--
Muscle	58.5 ppm	3	0.005	0.02	0.029	0.02	0.023	0.005
Liver		3	0.005	0.045	0.053	0.050	0.049	0.004
Skin & fat		3	0.005	0.02	0.028	0.026	0.025	0.004
Fat		3	0.005	0.026	0.046	0.033	0.035	0.010
Eggs		36	0.005	0.02	0.047	0.038	0.037	0.006

Table 10 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES	
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (corn)** **Rotational crops**	Penthiopyrad
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	Penthiopyrad, PAM and PCA
METABOLIC PROFILE IN DIVERSE CROPS	Similar
ANIMAL STUDIES	
ANIMALS	**Ruminant & Poultry**
RESIDUE DEFINITION FOR ENFORCEMENT	Penthiopyrad and PAM
RESIDUE DEFINITION FOR RISK ASSESSMENT	Penthiopyrad and PAM
METABOLIC PROFILE IN ANIMALS **(goat, hen, rat)**	Similar
FAT SOLUBLE RESIDUE	No

DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone	**Food and Water**
Refined chronic non-cancer dietary risk **ADI = 0.09 mg/kg bw/day** **Estimated chronic drinking water concentration = 199 μg/L**	**All infants < 1 year**	3.0	18.3
	Children 1–2 years	5.4	12.3
	Children 3 to 5 years	4.6	11.1
	Children 6–12 years	2.9	7.4
	Youth 13–19 years	2.0	5.4
	Adults 20–49 years	2.0	6.4
	Adults 50+ years	2.4	7.0
	Total population	2.4	7.1
Refined acute dietary exposure analysis, 95th percentile **Estimated acute drinking water concentration = 323 μg/L**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Alone	**Food and Water**
ARfD = 1.25 mg/kg bw	**All infants < 1 year**	2.37	6.04
	Children 1–2 years	3.76	5.25
	Children 3 to 5 years	3.29	4.54
	Children 6–12 years	2.37	3.29
	Youth 13–19 years	1.64	2.38
	Adults 20–49 years	1.65	2.54
	Adults 50+ years	1.92	2.66
	Total population	2.09	3.11

Table 11 Physical/Chemical Properties, Fate and Behaviour of Penthiopyrad in the Terrestrial Environment

Study	Results	Comments	Reference
Physical / Chemical Properties			
Vapour pressure (20°C)	2.96×10^{-6} Pa	Non-volatile	1839216
Henry's law constant (20°C)	7.74×10^{-4} Pa m^3/mol* 7.64×10^{-9} atm m^3/mol* $1/H = 3.15 \times 10^{6}$*	Not expected to be volatile from moist soil and water.	NA

Study	Results	Comments	Reference
Ultraviolet (UV) / visible spectrum	At 20°C: acidic solution (pH 0.8): λ_{max} =226 nm, ε= 14460 $L.mol^{-1}.cm^{-1}$ neutral solution (pH 7.4): λ_{max} =226 nm, ε= 14492 $L.mol^{-1}.cm^{-1}$ basic solution (pH 13.1): apparent λ_{max} =227 nm but artefact caused by the absorption of solvent, ε: n.a.	Not expected to phototransform under environmental conditions.	1839225
Solubility in water (20°C)	pH 4: 2.54 mg/L pH 7: 1.38 mg/L pH 10: 1.66 mg/L	Low solubility in water; solubility not pH dependent.	1839228
n-Octanol/water partition coefficient (log K_{ow})	pH 4: log K_{ow} = 4.36 pH 7: log K_{ow} = 4.62 pH 10: log K_{ow} = 4.54	Potential for bioaccumulation under acid, neutral and alkaline pH conditions.	1839234
Dissociation constant (pK_a) (20°C)	10.0	Does not dissociate at environmentally relevant pH.	1839239
Abiotic Transformation			
Hydrolysis	Stable at pH 4, pH 7, pH 9 at 50°C	Hydrolysis is not a route of transformation.	1839236; 1839235
Phototransformation on soil	Half-life = 6.8 days* **Major transformation products:** PAM at maximum of 26.7% (day 10); PCA at maximum of 22.7% (day 7).	Phototransformation on soil is a route of transformation.	1839456
Soil Biotransformation			
Aerobic soil (20°C) *sandy clay loam – NY, USA (Oakville)*	DT_{50} = 164 days; DT_{90} = 546 days (SFO)*	Moderately persistent	1839449; 1839450
Aerobic soil (20°C) *silt loam – France (Senozan)*	DT_{50} = 80.6 days; DT_{90} = 268 days (SFO)* **Major transformation product:** DM-PCA at maximum of 17% (day 120)	Moderately persistent	
Aerobic soil (20°C) *loam – Switzerland (Gartenacker)*	DT_{50} = 60.4 days; DT_{90} = 201 days (SFO)* **Major transformation product:** DM-PCA at maximum of 28% (day 161).	Moderately persistent	
Aerobic soil (20°C) *sandy clay loam – UK (Bruisyard)*	DT_{50} = 406 days; DT_{90} = 1350 days (SFO)*	Persistent	

Study	Results	Comments	Reference
Aerobic soil (20°C) *sandy loam – Georgia, US (Waddesdon 2)*	DT_{50} = 239 days; DT_{90} = 795 days (IORE)* (IORE DT_{90} x 0.301)	Moderately persistent	1839448
Anaerobic soil (20°C) *sandy loam – Georgia, US (Waddesdon 2)*	DT_{50} = 8660 days (SFO)*	Persistent	1839454
Field Dissipation			
Terrestrial Field Dissipation *Ontario – bareground, loam soil*	DT_{50} = 6.5 days; DT_{90} = 24.3 days (DFOP)*	Non-persistent in soil under field conditions. Penthiopyrad was readily transformed in the upper 15 cm of soil. The major transformation product, DM-PCA, has the potential to leach to lower soil depths.	1840864
Terrestrial Field Dissipation *Saskatchewan – bareground, clay loam/silty clay loam/silty clay soil*	DT_{50} = 12.2 days; DT_{90} = 233 days (DFOP)*	Slightly persistent in soil under field conditions. Penthiopyrad was readily transformed in the upper 15 cm of soil. DM-PCA, a major transformation product, has the potential to leach to lower soil depths.	1840865
Terrestrial Field Dissipation *Washington, US – bareground, sandy loam/loamy sand/sand soil*	DT_{50} = 6.1 days; DT_{90} = 91.5 days (DFOP)*	Non-persistent in soil under field conditions. Penthiopyrad was readily transformed in the upper 5 cm of soil and was not detected at lower soil depths. The major transformation product, DM-PCA, was not detected at lower soil depths.	1840860
Terrestrial Field Dissipation *New York, US – turf, loamy sand / sandy loam soil*	DT_{50} = 29.5 days; DT_{90} = 173 days (DFOP)*	Slightly persistent in soil under field conditions. Penthiopyrad transformed in the thatch and soil layers and was not detected at lower soil depths. The major transformation product, DM-PCA, has the potential to leach to lower soil depths.	1840868

Study	Results			Comments	Reference
Soil Mobility					
Adsorption/Desorption	Soil texture	K_d*	K_{oc}* (mL/g)		1839460
	sandy clay loam *(NY, US - Oakville)*	11.71	908	Low mobility	
	silt loam *(France - Senozan)*	10.16	996	Low mobility	
	loam *(Switzerland - Gartenacker)*	16.30	965	Low mobility	
	sandy clay loam *(UK - Bruisyard)*	16.15	841	Low mobility	
	silty clay *(France - Hesingue)*	16.83	616	Low mobility	

*PMRA-calculated values.

Table 12 Fate and Behaviour of the Transformation Products of Penthiopyrad in the Terrestrial Environment

Study / Property	Result			Comment	Reference
Soil Biotransformation					
	DM-PCA				
Aerobic soil (20°C) *silt loam – France*	DT_{50} = 102 days; DT_{90} = 338 days (SFO)*			Moderately persistent	1839458
Aerobic soil (20°C) *sand – Germany*	DT_{50} = 91.2 days; DT_{90} = 303 days (SFO)*			Moderately persistent	
Aerobic soil (20°C) *silt loam – France*	DT_{50} = 32.6 days; DT_{90} = 108 days (SFO)*			Slightly persistent	
Aerobic soil (20°C) *Sandy loam – Switzerland*	DT_{50} = 155 days; DT_{90} = 515 days (SFO)*			Moderately persistent	
Soil Mobility					
DM-PCA					
Adsorption/Desorption	Soil texture	K_d*	K_{oc}* (mL/g)		
	silt loam (*France - Attenschwiller*)	0.046	4	Very high mobility	1839458
	Sand (*Germany - Stolpe*)	0.066	11	Very high mobility	
	silt loam (*France - Fislis*)	0.139	5	Very high mobility	

Study / Property	Result			Comment	Reference
	sandy loam (*Switzerland - Gartenacker*)	0.058	4	Very high mobility	
PCA					
Estimation using HPLC	K_{oc} (mL/g) = 0.0002 (pH 6.8); 3.5 (pH 2.0)			Very high mobility	1839468
PAM					
Adsorption/Desorption	Soil texture	K_d*	K_{oc}* (mL/g)		1839463
	sandy clay loam	0.33	6.0	Very high mobility	
	sandy clay	0.39	8.0	Very high mobility	
	sandy loam	0.05	5.0	Very high mobility	
	clay loam	0.33	11.0	Very high mobility	

*PMRA-calculated values

Table 13 Fate and Behaviour of Penthiopyrad in the Aquatic Environment

Study	Results				Comments	Reference
Abiotic Transformation						
Hydrolysis	Stable at pH 4, pH 7, pH 9 at 50°C				Hydrolysis is not a route of transformation	1839236; 1839235
Phototransformation in water	Stable				Phototransformation in water is not a route of transformation	1839237
Aquatic Biotransformation						
Aerobic water/sediment	System (total)	Fit	DT_{50} (day)	DT_{90} (day)	Persistent Penthiopyrad partitions into sediment and once in sediment, its dissipation is slow. PCA is a major transformation product in aerobic aquatic systems.	1839470
	River (20°C)	SFO	223*	742*		
	Pond (20°C)	DFOP	384*	1230*		
Anaerobic water/sediment	After 100 days, almost all of the applied radioactivity was present as unchanged parent. DT_{50} = 35 days for dissipation of ^{14}C-penthiopyrad from water to sediment.				Persistent Penthiopyrad partitions into sediment and remains largely unchanged in the total system.	1839471
Bioconcentration	BCFs = 79-86 (edible tissues); 226-236 (non-edible tissues); and 155- 158 (whole fish tissues)				Low bioconcentration	1839578

Table 14 Endpoints Considered in the Risk Assessment

Organism	Test substance	Exposure	Endpoint	Value	Uncertainty factor applied
Earthworm *(Eisenia fetida)*	Penthiopyrad	Acute	14-day LC_{50}	>1000 mg a.i./kg soil	0.5
	Penthiopyrad	Reproduction	NOEC	48 mg a.i./kg soil	1.0
	Fontelis	Acute	14-day LC_{50}	>200 mg a.i./kg soil	0.5
	Fontelis	Chronic	56-day NOEC	50 mg a.i./kg soil	1.0
	Treoris	Acute	14-day LC_{50}	>91.7 mg a.i./kg soil	0.5
	Treoris	Chronic	28-day NOEC	18.3 mg a.i./kg soil	1.0
Bee (*Apis mellifera)*	Penthiopyrad	Acute oral	48-hr LC_{50}	>500 µg a.i./bee (560 kg a.i./ha)	1.0
	Penthiopyrad	Acute contact	48-hr LD_{50}	>500 µg a.i./bee (560 kg a.i./ha)	1.0
	Fontelis	Acute oral	48-hr LC_{50}	>107.2 µg a.i./bee (>120.1 kg a.i./ha)	1.0
	Fontelis	Acute contact	48-hr LD_{50}	>100.0 µg a.i./bee (>112 kg a.i./ha)	1.0
	Vertisan	Acute oral	48-hr LC_{50}	50.7 µg a.i./bee (56.8 kg a.i./ha)	1.0
	Vertisan	Acute contact	48-hr LD_{50}	23.5 µg a.i./bee (26.7 kg a.i./ha)	1.0
	Treoris	Acute oral	48-hr LC_{50}	>10.9 µg a.i./bee (>12.2 kg a.i./ha)	1.0
	Treoris	Acute contact	48-hr LD_{50}	>8.9 µg a.i./bee (>9.9 kg a.i./ha)	1.0
Predatory mite *(Typhlodromus pyri)*	Vertisan	Extended (bean leaves)	14-day LR_{50}	102.6 g a.i./ha	1.0
	Fontelis	Glass plates	7-day LR_{50}	124 g a.i./ha	1.0
	Fontelis	Glass plates	14-day ER_{50} (reprod)	7.2 g a.i./ha	1.0
	Treoris	Extended (bean leaves)	7-day LR_{50}	>470 g a.i./ha	1.0
			14-day ER_{50}	8.7 g a.i./ha	1.0
Predatory mite *(Typhlodromus pyri)*	Fontelis	Field study	mortality	19.4%	1.0
Predatory mite *(Kampimodromus aberrans)*	Fontelis	Field study	mortality	11.8%	1.0
Bobwhite quail	Penthiopyrad	Acute	LD_{50}	>2250 mg a.i./kg bw	0.10
	Penthiopyrad	Subacute	LD_{50}	>1913 mg a.i./kg bw/day	0.10
	Fontelis	Acute	LD_{50}	>2066 mg a.i./kg bw	0.10
Mallard duck	Penthiopyrad	Reproduction	20-week NOEL	718.7 mg a.i./kg bw/day	1.0
Mammals (rat)	Penthiopyrad	Acute	LD_{50}	>2000 mg a.i./kg bw	0.10
	Penthiopyrad	Reproduction	NOEL	250 mg a.i./kg bw/day	1.0

Organism	Test substance	Exposure	Endpoint	Value	Uncertainty factor applied
Terrestrial vascular plants (all 10 crop species)	Fontelis	Seedling emergence	21-day EC_{25}	>1.56 kg a.i./ha	1.0
		Vegetative vigour	21-day EC_{25}	>1.56 kg a.i./ha	1.0
Freshwater invertebrates (*Daphnia magna*)	Penthiopyrad	Acute	48-hr EC_{50}	2531 µg a.i./L	0.5
	Penthiopyrad	Chronic	21-day NOEC	471 µg a.i./L	1.0
	Fontelis	Acute	48-hr EC_{50}	59.6 µg a.i./L	0.5
	Fontelis	Chronic	21-day NOEC	10.6 µg a.i./L	1
	Vertisan	Acute	48-hr EC_{50}	1215 µg a.i./L	0.5
	Treoris	Acute	48-hr EC_{50}	18.5 µg a.i./L	0.5
Freshwater fish	Penthiopyrad	Acute	96-hr LC_{50}	290 µg a.i./L	0.10
	Penthiopyrad	ELS	33-day NOEC	100 µg a.i./L	1.0
	Fontelis	Acute	96-hr LC_{50}	356 µg a.i./L	0.10
	Vertisan	Acute	96-hr LC_{50}	309 µg a.i./L	0.10
	Treoris	Acute	96-hr LC_{50}	14.0 µg a.i./L	0.10
Amphibians (surrogate fish acute)	Penthiopyrad	Acute	96-hr LC_{50}	290 µg a.i./L	0.10
	Fontelis	Acute	96-hr LC_{50}	356 µg a.i./L	0.10
	Vertisan	Acute	96-hr LC_{50}	309 µg a.i./L	0.10
	Treoris	Acute	96-hr LC_{50}	14.0 µg a.i./L	0.10
Aquatic vascular plants	Penthiopyrad	Acute	7-day EC_{50}	>1205 µg a.i./L	0.5
Algae	Penthiopyrad	Acute	96-hr EC_{50}	1533 µg a.i./L	0.5
	Fontelis	Acute	72-hr EC_{50}	1400 µg a.i./L	0.5
	Treoris	Acute	72-hr EC_{50}	51 µg a.i./L	0.5
Marine invertebrates	Penthiopyrad	Acute	96-hr EC_{50}	1200 µg a.i./L	0.5
Marine fish	Penthiopyrad	Acute	96-hr LC_{50}	1381 µg a.i./L	0.10
	Fontelis	Acute	96-hr LC_{50}	2634 µg a.i./L	0.10
Marine algae	Penthiopyrad	Acute	96-hr EC_{50}	1200 µg a.i./L	0.5

Table 15 Risk to Terrestrial Organisms Other Than Birds and Mammals

Organism	Test substance	Exposure	Endpoint value	EEC	RQ	Risk
Earthworm	Penthiopyrad	Acute	>500 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible
	Penthiopyrad	Reproduction	48 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible
	Fontelis	Acute	>100 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible
	Fontelis	Chronic	50 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible
	Treoris	Acute	46 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible
	Treoris	Chronic	18.3 mg a.i./kg soil	1.4 mg a.i./kg soil	<1	Negligible

Organism	Test substance	Exposure	Endpoint value	EEC	RQ	Risk
Bee	Penthiopyrad	Acute oral	>560 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Penthiopyrad	Acute contact	>560 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Fontelis	Acute oral	>120.1 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Fontelis	Acute contact	>112 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Vertisan	Acute oral	56.8 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Vertisan	Acute contact	26.7 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Treoris	Acute oral	>12.2 kg a.i./ha	450 g a.i./ha	<1	Negligible
	Treoris	Acute contact	>9.9 kg a.i./ha	450 g a.i./ha	<1	Negligible
Predatory arthropod	Vertisan	Acute	102.6 g a.i./ha (mortality)	In field: 565 g a.i./ha (field crops) 485 g a.i./ha (orchards)	 5.5 4.7	 LOC exceeded LOC exceeded
				Off-field (ground appl): 62 g a.i./ha (field crops) 359 g a.i./ha (orchards) Off-field (aerial appl): 147 g a.i./ha (field crops)	<1 3.5 1.4	Negligible LOC exceeded LOC exceeded
	Fontelis	Acute	124 g a.i./ha (mortality)	In field: 565 g a.i./ha (field crops) 485 g a.i./ha (orchards)	 4.6 3.9	 LOC exceeded LOC exceeded
				Off-field (ground appl): 62 g a.i./ha (field crops) 359 g a.i./ha (orchards) Off-field (aerial appl): 147 g a.i./ha (field crops)	<1 2.9 1.2	Negligible LOC exceeded LOC exceeded

Organism	Test substance	Exposure	Endpoint value	EEC	RQ	Risk
	Fontelis	Chronic	7.2 g a.i./ha (reprod)	In field: 565 g a.i./ha (field crops) 485 g a.i./ha (orchards) Off-field (ground appl): 62 g a.i./ha (field crops) 359 g a.i./ha (orchards) Off-field (aerial appl): 147 g a.i./ha (field crops)	 78 67 8.6 50.0 20.4	 LOC exceeded LOC exceeded LOC exceeded LOC exceeded LOC exceeded
	Fontelis	Field study	19.4% reduction in population	448 g a.i./ha (3 applications at 225 g a.i./ha with 7 day application interval)		Risk not a concern as <50% effect at 448 g a.i./ha
	Fontelis	Field study	11.8% reduction in population	720 g a.i./ha		Risk not a concern as <50% effect at 720 g a.i./ha
	Treoris	Contact	>470 g a.i./ha (mortality)	In field: 565 g a.i./ha (field crops)	 <1.2	 LOC exceeded
				Off-field (ground appl): 62 g a.i./ha (field crops) Off-field (aerial appl): 147 g a.i./ha (field crops)	 <1 <1	 Negligible Negligible
			8.7 g a.i./ha (reprod)	In field: 565 g a.i./ha (field crops)	 65	 LOC exceeded

Organism	Test substance	Exposure	Endpoint value	EEC	RQ	Risk
				Off-field (ground appl): 62 g a.i./ha (field crops) Off-field (aerial appl): 147 g a.i./ha (field crops)	7.1 16.9	LOC exceeded LOC exceeded
Vascular plants	Fontelis	Seedling emergence	>1.56 kg a.i./ha	In field: 3.1 kg a.i./ha (turf) 1.0 kg a.i./ha (field crops) 0.87 kg a.i./ha (orchards)	2.0 <1 <1	LOC exceeded Negligible Negligible
				Off-field: 344 g a.i./ha (turf)	<1	Negligible
		Vegetative vigour	>1.56 kg a.i./ha	1.1 kg a.i./ha (turf) 0.57 kg a.i./ha (field crops) 0.49 kg a.i./ha (orchards)	<1 <1 <1	Negligible Negligible Negligible

Table 16 Screening Level Risk to Birds and Mammals: Field Crops

	Toxicity (mg a.i./kg bw/day)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	206.60	Insectivore (small insects)	28.47	0.14
Reproduction	718.70	Insectivore (small insects)	28.47	0.04
Medium Sized Bird (0.1 kg)				
Acute	206.60	Insectivore (small insects)	22.22	0.11
Reproduction	718.70	Insectivore (small insects)	22.22	0.03

	Toxicity (mg a.i./kg bw/day)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Large Sized Bird (1 kg)				
Acute	206.60	Herbivore (short grass)	23.18	0.11
Reproduction	718.70	Herbivore (short grass)	23.18	0.03
Small Mammal (0.015 kg)				
Acute	200.00	Insectivore (small insects)	16.37	0.08
Reproduction	250.00	Insectivore (small insects)w	16.37	0.07
Medium Sized Mammal (0.035 kg)				
Acute	200.00	Herbivore (short grass)	51.30	0.26
	200.00	Herbivore (leafy foliage)	96.69	0.48
Reproduction	250.00	Herbivore (short grass)	51.30	0.21
	250.00	Herbivore (leafy foliage)	96.69	0.39
Large Sized Mammal (1 kg)				
Acute	200.00	Herbivore (short grass)	27.41	0.14
	200.00	Herbivore (leafy foliage)	51.66	0.26
Reproduction	250.00	Herbivore (short grass)	27.41	0.11
	250.00	Herbivore (leafy foliage)	51.66	0.21

Table 17 Screening Level Risk to Birds and Mammals: Orchards.

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	206.60	Insectivore (small insects)	24.44	0.12
Reproduction	718.70	Insectivore (small insects)	24.44	0.03
Medium Sized Bird (0.1 kg)				
Acute	206.60	Insectivore (small insects)	19.07	0.09
Reproduction	718.70	Insectivore (small insects)	19.07	0.03
Large Sized Bird (1 kg)				
Acute	206.60	Herbivore (short grass)	19.90	0.10
Reproduction	718.70	Herbivore (short grass)	19.90	0.03
Small Mammal (0.015 kg)				
Acute	200.00	Insectivore (small insects)	14.06	0.07
Reproduction	250.00	Insectivore (small insects)	14.06	0.06

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Medium Sized Mammal (0.035 kg)				
Acute	200.00	Herbivore (short grass)	44.04	0.22
	200.00	Herbivore (leafy foliage)	83.00	0.41
Reproduction	250.00	Herbivore (short grass)	44.04	0.18
	250.00	Herbivore (leafy foliage)	83.00	0.33
Large Sized Mammal (1 kg)				
Acute	200.00	Herbivore (short grass)	23.53	0.12
	200.00	Herbivore (leafy foliage)	44.35	0.22
Reproduction	250.00	Herbivore (short grass)	23.53	0.09
	250.00	Herbivore (leafy foliage)	44.35	0.18

Table 18 Screening Level Risk to Birds and Mammals: Turf

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	206.60	Insectivore (small insects)	57.54	0.28
Reproduction	718.70	Insectivore (small insects)	57.54	0.08
Medium Sized Bird (0.1 kg)				
Acute	206.60	Insectivore (small insects)	44.91	0.22
Reproduction	718.70	Insectivore (small insects)	44.91	0.06
Large Sized Bird (1 kg)				
Acute	206.60	Herbivore (short grass)	46.86	0.23
Reproduction	718.70	Herbivore (short grass)	46.86	0.07
Small Mammal (0.015 kg)				
Acute	200.00	Insectivore (small insects)	33.10	0.17
Reproduction	250.00	Insectivore (small insects)	33.10	0.13
Medium Sized Mammal (0.035 kg)				
Acute	200.00	Herbivore (short grass)	103.69	0.52
	200.00	Herbivore (leafy foliage)	195.43	0.98
Reproduction	250.00	Herbivore (short grass)	103.69	0.41
	250.00	Herbivore (leafy foliage)	195.43	0.78
Large Sized Mammal (1 kg)				
Acute	200.00	Herbivore (short grass)	55.41	0.28
	200.00	Herbivore (leafy foliage)	104.42	0.52
Reproduction	250.00	Herbivore (short grass)	55.41	0.22
	250.00	Herbivore (leafy foliage)	104.42	0.42

Table 19 Screening Level Risk to Aquatic Organisms

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)	RQ	Risk
Freshwater species						
Invertebrates	Penthiopyrad	Acute	1265.5	400 (turf)	<1	Negligible
				129 (field crops)	<1	Negligible
				110 (orchards)	<1	Negligible
	Penthiopyrad	Chronic	471	400 (turf)	<1	Negligible
				129 (field crops)	<1	Negligible
				110 (orchards)	<1	Negligible
	Fontelis	Acute	29.8	400 (turf)	13.4	LOC exceeded
				129 (field crops)	4.3	LOC exceeded
				110 (orchards)	3.7	LOC exceeded
	Fontelis	Chronic	10.6	400 (turf)	37.7	LOC exceeded
				129 (field crops)	12.2	LOC exceeded
				110 (orchards)	10.4	LOC exceeded
	Vertisan	Acute	607.5	400 (turf)	<1	Negligible
				129 (field crops)	<1	Negligible
				110 (orchards)	<1	Negligible
	Treoris	Acute	9.3	129 (field crops)	13.9	LOC exceeded
Fish	Penthiopyrad	Acute	29.0	400 (turf)	13.8	LOC exceeded
				129 (field crops)	4.4	LOC exceeded
				110 (orchards)	3.8	LOC exceeded
	Penthiopyrad	ELS	100	400 (turf)	4.0	LOC exceeded
				129 (field crops)	1.3	LOC exceeded
				110 (orchards)	1.1	LOC exceeded
	Fontelis	Acute	35.6	400 (turf)	11.2	LOC exceeded
				129 (field crops)	3.6	LOC exceeded
				110 (orchards)	3.1	LOC exceeded
	Vertisan	Acute	30.9	400 (turf)	12.9	LOC exceeded
				129 (field crops)	4.2	LOC exceeded
				110 (orchards)	3.6	LOC exceeded

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)	RQ	Risk
	Treoris	Acute	1.4	129 (field crops)	92.1	LOC exceeded
Amphibians	Penthiopyrad	Acute	29.0	2131 (turf)	73.5	LOC exceeded
				686 (field crops)	23.7	LOC exceeded
				588 (orchards)	20.3	LOC exceeded
	Fontelis	Acute	35.6	2131 (turf)	59.9	LOC exceeded
				686 (field crops)	19.3	LOC exceeded
				588 (orchards)	16.5	LOC exceeded
	Vertisan	Acute	30.9	2131 (turf)	69.0	LOC exceeded
				686 (field crops)	22.2	LOC exceeded
				588 (orchards)	19.0	LOC exceeded
	Treoris	Acute	1.4	686 (field crops)	490.0	LOC exceeded
Freshwater alga	Penthiopyrad	Acute	766.5	400 (turf)	<1	Negligible risk
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk
	Fontelis	Acute	700	400 (turf)	<1	Negligible risk
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk
	Treoris	Acute	25.5	129 (field crops)	5.1	LOC exceeded
Vascular plants	Penthiopyrad	Acute	603	400 (turf)	<1	Negligible risk
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk
Marine species						
Invertebrates	Penthiopyrad	Acute	600	400 (turf)	<1	Negligible risk
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)	RQ	Risk
Fish	Penthiopyrad	Acute	138.1	400 (turf)	2.9	LOC exceeded
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk
	Fontelis	Acute	263.4	400 (turf)	1.5	LOC exceeded
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk
Marine alga	Penthiopyrad	Acute	600	400 (turf)	<1	Negligible risk
				129 (field crops)	<1	Negligible risk
				110 (orchards)	<1	Negligible risk

Table 20 Refined Risk to Aquatic Organisms

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)		RQ		Risk
				Runoff	Drift	Runoff	Drift	
Freshwater species								
Invertebrates	Fontelis	Acute	29.8	45 (turf)	44 (turf)	1.5	1.5	Runoff - LOC exceeded Drift – LOC exceeded
				101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	3.4	<1 1.1	Runoff - LOC exceeded Drift – Negligible Drift – LOC exceeded
				21 (orchards)	81 (orchards)	<1	2.7	Runoff - Negligible Drift – LOC exceeded
	Fontelis	Chronic	10.6	41 (turf)	44 (turf)	3.9	4.2	Runoff - LOC exceeded Drift – LOC exceeded
				95 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	9.0	1.3 3.2	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
				20 (orchards)	81 (orchards)	1.9	7.6	Runoff - LOC exceeded Drift –

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)		RQ		Risk
				Runoff	Drift	Runoff	Drift	
								LOC exceeded
	Treoris	Acute	9.3	101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	10.9	1.5 3.7	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
Fish	Penthiopyrad	Acute	29.0	45 (turf)	44 (turf)	1.6	1.5	Runoff - LOC exceeded Drift – LOC exceeded
				101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	3.5	<1 1.2	Runoff - LOC exceeded Drift – Negligible Drift – LOC exceeded
				21 (orchards)	81 (orchards)	<1	2.8	Runoff - Negligible Drift – LOC exceeded
	Penthiopyrad	ELS	100	41 (turf)	44 (turf)	<1	<1	Runoff - Negligible Drift – Negligible
				95 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	<1	<1 <1	Runoff - Negligible Drift – Negligible Drift – Negligible
				20 (orchards)	81 (orchards)	<1	<1	Runoff - Negligible Drift – Negligible
	Fontelis	Acute	35.6	45 (turf)	44 (turf)	1.3	1.2	Runoff - LOC exceeded Drift – LOC exceeded
				101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	2.8	<1 <1	Runoff – LOC exceeded Drift – Negligible Drift – Negligible
				21 (orchards)	81 (orchards)	<1	2.3	Runoff – Negligible Drift – LOC exceeded
	Vertisan	Acute	30.9	45 (turf)	44 (turf)	1.5	1.4	Runoff - LOC exceeded Drift – LOC exceeded

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)		RQ		Risk
				Runoff	Drift	Runoff	Drift	
				101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	3.3	<1 1.1	Runoff - LOC exceeded Drift – Negligible Drift – LOC exceeded
				21 (orchards)	81 (orchards)	<1	2.6	Runoff - Negligible Drift – LOC exceeded
	Treoris	Acute	1.4	101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	72.1	10.0 24.3	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
Amphibians	Penthiopyrad	Acute	29.0	134 (turf)	234 (turf)	4.6	8.1	Runoff - LOC exceeded Drift – LOC exceeded
				277 (field crops)	76 (field crops - ground) 178 (field crops –aerial)	9.6	2.6 6.1	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
				66 (orchards)	435 (orchards)	2.3	15.0	Runoff - LOC exceeded Drift – LOC exceeded
	Fontelis	Acute	35.6	134 (turf)	234 (turf)	3.8	6.6	Drift – LOC exceeded Runoff - LOC exceeded
				277 (field crops)	76 (field crops - ground) 178 (field crops –aerial)	7.8	2.1 5.0	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
				66 (orchards)	435 (orchards)	1.8	12.2	Runoff - LOC exceeded Drift – LOC exceeded

Organism	Test substance	Exposure	Endpoint value (µg a.i./L)	EEC in water (µg a.i./L)		RQ		Risk
				Runoff	Drift	Runoff	Drift	
	Vertisan	Acute	30.9	134 (turf)	234 (turf)	4.3	7.6	Runoff - LOC exceeded Drift – LOC exceeded
				277 (field crops)	76 (field crops - ground) 178 (field crops –aerial)	9.0	2.5 5.8	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
				66 (orchards)	435 (orchards)	2.1	14.1	Runoff - LOC exceeded Drift – LOC exceeded
	Treoris	Acute	1.4	277 (field crops)	76 (field crops - ground) 178 (field crops –aerial)	197.9	54.3 127.1	Runoff - LOC exceeded Drift – LOC exceeded Drift – LOC exceeded
Freshwater algae	Treoris	Acute	25.5	101 (field crops)	14 (field crops - ground) 34 (field crops –aerial)	4.0	<1 1.3	Drift – Negligible Runoff - LOC exceeded Drift – LOC exceeded
Marine fish	Penthiopyrad	Acute	138.1	45 (turf)	44 (turf)	<1	<1	Runoff - Negligible Drift – Negligible
	Fontelis	Acute	263.4	45 (turf)	44 (turf)	<1	<1	Runoff - Negligible Drift – Negligible

Table 21 Refined Spray Drift Assessment for Treoris Fungicide

Organism	Exposure	Endpoint value (µg a.i./L)	EEC_{Drift} in water (µg a.i./L)	RQ	Risk
Freshwater invertebrates	Acute	9.3	7.7 (field crops – ground) 29.7 (field crops – aerial)	<1 3.2	Negligible LOC exceeded
Freshwater fish	Acute	1.4	7.7 (field crops – ground) 29.7 (field crops – aerial)	5.5 21.2	LOC exceeded LOC exceeded

Organism	Exposure	Endpoint value (µg a.i./L)	EEC_{Drift} in water (µg a.i./L)	RQ	Risk
Amphibians	Acute	1.4	41.2 (field crops – ground)	29.4	LOC exceeded
			157.8 (field crops – aerial)	112.7	LOC exceeded
Freshwater algae	Acute	25.5	7.7 (field crops – ground)	<1	Negligible
			29.7 (field crops – aerial)	1.2	LOC exceeded

Table 22 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes	
Predominantly anthropogenic[2]	Yes		Yes	
Persistence[3]:	Soil	Half-life ≥ 182 days	Half-life = 272 days (80^{th} percentile)	
	Water	Half-life ≥ 182 days	Half-life = 384 days	
	Sediment	Half-life ≥ 365 days	Not available	
	Air	Half-life ≥ 2 days or evidence of long range transport	Not required	
Bioaccumulation[4]	Log K_{ow} ≥ 5		4.4-4.6	
	BCF ≥ 5000		79-236	
	BAF ≥ 5000		Not available	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	

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

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

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

[4] Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

Table 23 Registered Alternative Products for the Crops and Pests Proposed for Registration on the Fontelis Fungicide Label

Crop (group)	Pest(s)	Alternative Products	Alternative Chemical Classes
Pome Fruit	Powdery mildew, scab	Dikar, Dithane, Flint, Manzate Prostick, Nova 40W, Nustar, Polyram DF, Scala SC, Sovran	Dithiocarbamate (Group M3), strobilurin (Group 11), triazole/DMI (Group 3), anilinopyrimidine (Group 9)
Stone Fruit	Blossom blight, brown rot, powdery mildew	Bravo 500, Elevate 50 WDG, Indar 75 WSP, Lance WDG, Nova 40W, Pristine WG, Supra Captan 80 WDG	Chloronitrile (Group M5), hydroxyanilide (Group 17), triazole (Group 3), anilide (carboxamide) (Group 7), QoI (Group 11), phthalimide (Group M4)
Leafy vegetables	Botrytis grey mould, Sclerotinia white mould	Ferbam 76 WDG, Lance WDG, Botran 75W, Serenade Max,	Dithiocarbamate (Group M3), carboxamide (Group 7), chlorophenyl (Group 14), biological (Group 44)
Bulb vegetables	Botrytis grey mould, purple blotch	Bravo 500, Cabrio EG, Dithane, Lance WDG, Pristine WG, Rovral, Switch 62.5 WG, Zineb 80 W	Chloronitrile (Group M5), QoI (Group 11), dithiocarbamate (Group M3), carboxamide (Group 7), phenyl pyrroles (Group 12)
Cucurbit vegetables	Anthracnose, alternaria, gummy stem blight, powdery mildew, scab	Bravo 500, Cabrio EG, Dithane, Lance WDG, Supra Captan 80 WDG	Chloronitrile (Group M5), QoI (Group 11), dithiocarbamate (Group M3), carboxamide (Group 7), phthalimide (Group M4)
Small fruit & berries	Botrytis grey mould, anthracnose, septoria leaf spot, rusts	Elevate 50 WDG, Lance WDG, Pristine WG, Scala SC, Switch 62.5 WG	Hydroxyanilide (Group 17), anilide carboxamide (Group 7), QoI (Group 11), anilinopryimidine (Group 9), phenyl pyrroles (Group 12)
Fruiting vegetables	Early blight, Septoria leaf spot, anthracnose, botrytis grey mould	Bravo 500, Cabrio EG, Dithane, Manzate Prostick, Polyram DF, Lance WDG, Tanos 50 DF, Quadris	Chloronitrile (Group M5), QoI (Group 11), carboxamide (Group 7), anilide carboxamide (Group 7)
Tree nuts	Powdery Mildew, *Monilinia* spp., *Botrytis*, *Alternaria* spp.	No products registered for these diseases on tree nuts.	n/a
Peanuts	Late leaf spot, rust, stem rot, web blotch	Serenade Max (leaf spot only)	Bacteria (Group 44)

*Some alternatives may not be registered on all pests and all members of the crop group.

Table 24 Registered Alternative Products for the Crops and Pests Proposed for Registration on the Vertisan Fungicide Label

Crop (group)	Pest(s)	Alternative active ingredients
Canola	Sclerotinia stem rot	Boscalid (Group 7), Prothioconazole (Group 3), Azoxystrobin (Group 11), Vinclozin , Iprodione
Dry legumes crop group*	Ascochyta Blight	Prothioconazole, Pyraclostrobin, Chlorothalonil, Mancozeb, Boscalid, Azoxystrobin
	Botrytis	Vinclozolin (Group 2), Iprodione (Group 3)
	Powdery mildew	Pyraclostrobin (Group 11), Sulphur (Group M2)
	Rhizoctonia solani in-furrow	None
Tuberous and corm vegetables crop group*	*Alternaria*	Chlorothalonil (Group M5), Copper (Group M1), Copper hydroxide (Group M1),Mancozeb, Maneb (Group M3), Mancozeb+Zoxamide (Group M3+22), Pyraclostrobin (Group 11), Boscalid (Group 7), Boscalid+ pyraclostrobin (Group 7+11), Metiram (Group M3), Azoxystrobin (Group 11), Chlorothalonil + metalaxyl (Group M5+4), Metalaxyl+ Mancozeb (Group 4+M3)
	Botrytis	Chlorothalonil (Group M5), Metalaxyl+mancozeb (Group 4+M3)
	Rhizoctonia solani in-furrow	Azoxystrobin (Group 11)
	Powdery mildew	none

*Some alternatives may not be registered on all pests and all members of the crop group.

Table 25 Registered Alternative Products for the Crops and Pests Proposed for Registration on the Treoris Fungicide Label

Crop (group)	Pest(s)	Alternative Products	Active Ingredients
Potatoes	Early blight	Bravo 500, Copper spray, Kocide 2000, Dithane, Gavel 75 DF, Headline EC, Rainshield NT, Lance WDG, Pristine WG, Rovral, Tanos 50DF, Manzate Pro Stick, Quadris, Ridomil Gold, Polyram DF, Parasol	Chlorothalonil (Group M5), Copper (Group M1), Copper hydroxide (Group M1), Mancozeb (Group M3), Maneb (Group M3), Mancozeb + Zoxamide (Group M3+22), Pyraclostrobin (Group 11), Boscalid (Group 7), Boscalid+ pyraclostrobin (Group 11+7), Metiram (Group M3), Azoxystrobin (Group 11), Chlorothalonil + metalaxyl (Group M5+4), Metalaxyl+ Mancozeb (Group 4+M3),
Cucurbit vegetables	Powdery mildew	Bravo 500, Cabrio EG, Dithane, Lance WDG, Supra Captan 80 WDG	Chlorothalonil (Group M5), Mancozeb (Group M3), Boscalid (Group 7), Captan (Group M4)

Table 26 Registered Alternative Products for the Crops and Pests Proposed for Registration on the DPX-LEM17 50WG Fungicide Label

Crop (group)	Pest(s)	Alternative Products	Alternative Chemical Classes
Turf	Brown Patch, (*Rhizoctonia solani*)	Senator 70WP, Daconil Ultrex, Heritage MAXX, Banner Maxx, Compass 50WG, Proturf Granular fungicide, Premis 200F	Triazole (Group 3), Aromatic hydrocarbon (Group 14), strobilurin (Group 11), benzimidazole (Group 1)
Turf	Dollar Spot, (*Sclerotinia homeocarpa*)	Senator 70WP, Daconil Ultrex, Banner MAXX, Cadence 70 WDG, Proturf Granular Fungicide	Triazole (Group 3), Aromatic hydrocarbon (Group 14), Benzimidizole (Group 1), Dicarboximide (Group 2)

Table 27 Use (label) Claims Proposed by Applicant for Fontelis Fungicide and Whether Acceptable or Unsupported

Proposed use claim	Supported / Unsupported
Control of apple scab (*Venturia inaequalis*) on pome fruit at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as proposed.
Control of pear scab (*Venturia pirina*) on pome fruit at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as proposed.
Control of powdery mildew (*Podosphaera leucotricha*) on pome fruit at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as proposed.
Control of cedar apple rusts (*Gymnosporangium* spp.) on pome fruit at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	The claim of control is conditionally supported for cedar-apple rust (*Gymnosporangium juniperi-virginianae*) on pome fruit.
Control of brown rot, blossom blight and fruit rot (*Monilinia* spp.) on stone fruit at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Supported as proposed.
Control of botrytis rots (*Botrytis cinerea*) on stone fruit at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as proposed.
Control of scab (*Cladosporium carpophilum, Venturia carpophila*) on stone fruit at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Supported as control of scab at **1.0 – 1.5 L/ha (200 – 300 g a.i./ha)**.
Control of powdery mildew (*Podosphaera clandestina, Sphaerotheca pannosa*) on stone fruit at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	The claim of control of powdery mildew (*Podosphaera clandestina*) is conditionally supported on stone fruit.
Suppression of cherry leafspot (*Blumeriella jaapii*) on stone fruit at a rate of 1.5 – 1.75 L/ha (300 – 350 g a.i./ha).	The claim of suppression of cherry leafspot is conditionally supported on cherry at **1.5 L/ha**.

Proposed use claim	Supported / Unsupported
Control of grey mould (*Botrytis cinerea*) on cucurbits, including greenhouse cucumbers, at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as proposed.
Control of control of powdery mildew (*Sphaerotheca fuliginea, Erysiphe cichoracearum*) on cucurbits, including greenhouse cucumbers, at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as control of powdery mildew (both pathogens) on cucurbits, including greenhouse cucumbers, at **1.25 L/ha (250 g a.i./ha)**.
Control of gummy stem blight (*Didymella bryoniae*) on cucurbits at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of early blight (*Alternaria solani*) on fruiting vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as **suppression** at the proposed rates.
Control of grey mould (*Botrytis cinerea*) on fruiting vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as proposed.
Control of powdery mildew (*Leveillula taurica*) on fruiting vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of lettuce drop (*Sclerotinia minor*) on leafy vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as **suppression** at the proposed rates.
Control of grey mould (*Botrytis cinerea*) on leafy vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as proposed.
Control of soil-borne diseases caused by *Rhizoctonia solani* on leafy vegetables at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of powdery mildew (*Erysiphe cichoracearum*) on leafy vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of grey mould (*Botrytis cinerea*) on low growing berries at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Supported as proposed.
Suppression of mummyberry (*Monilinia vacciniicorymbosi*) on lowbush blueberries at a rate of 1.5 – 1.75 L/ha (300 – 350 g a.i./ha).	Supported as suppression at **1.75 L/ha (350 g a.i./ha)**.
Control of powdery mildew (*Sphaerotheca* spp.) on low growing berries at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Not supported.
Control of brown leaf spot (*Septoria* sp.) on lowbush blueberry at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of botrytis blight, neck rot (*Botrytis*) on bulb vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as **suppression** of neck rot and **botrytis fleck** at the proposed rates.
Control of purple blotch (*Alternaria porri*) on bulb vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	The claim of **suppression** of purple blotch is conditionally supported as proposed on bulb vegetables.

Proposed use claim	Supported / Unsupported
Control of powdery mildew (*Leveillula taurica, Oidiopsis* spp.) on bulb vegetables at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of botrytis rots, blights (*Botrytis cinerea*) tree nuts at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as control of botrytis blight at proposed rates.
Control of alternaria leafspot, blight (*Alternaria* spp.) on tree nuts at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as **suppression** of alternaria leafspot, blight **(*Alternaria alternata*)** at the proposed rates.
Control of brown rot, blossom blight and fruit rot (*Monilinia* spp.) on tree nuts at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	The claim of control of brown rot, blossom blight, and fruit rot is conditionally supported as proposed on tree nuts.
Control of powdery mildew (*Podosphaera tridactyla* var. *tridactyla, Sphaerotheca pannosa, Phyllactinia angulata, Phyllactinia guttata* f. sp. *coryli, Microsphaera* spp., *Oidium* spp.) on tree nuts at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Not supported.
Control of web blotch (*Mycosphaerella arachidis*) on peanuts at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as **suppression** at the proposed rates.
Control of late leaf spot (*Cercosporidium personatum*) on peanuts at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as proposed.
Control of early leaf spot (*Cercospora arachidicola*) on peanuts at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as proposed.
Control of soil-borne diseases caused by *Rhizoctonia solani* on peanuts at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of sclerotinia blight (*Sclerotinia* spp.) on peanuts at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Supported as **suppression of sclerotinia blight (*Sclerotinia sclerotiorum*)** at the proposed rates**.**
Control of southern stem rot (*Sclerotium rolfsii*) on peanuts at a rate of 1250 – 1.75 L/ha (250 – 350 g a.i./ha).	The claim of control of southern stem rot was conditionally supported as proposed on peanuts.
Control of rust (*Puccinia arachidis*) on peanuts at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Control of sclerotinia stem rot (*Sclerotinia* spp.) on brassica leafy vegetables at a rate of 1.25 – 2.25 L/ha (250 – 450 g a.i./ha).	Supported as **suppression** of sclerotinia stem rot **(*Sclerotinia sclerotiorum*) at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).**
Control of grey mould (*Botrytis cinerea*) on brassica leafy vegetables at a rate of 1.25 – 2.25 L/ha (250 – 450 g a.i./ha).	Supported as proposed.
Control of soil-borne diseases caused by *Rhizoctonia solani* on brassica leafy vegetables at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of powdery mildew (*Erysiphe polygoni, E. cruciferarum*) on brassica leafy vegetables at a rate of 1.25 – 2.25 L/ha (250 – 450 g a.i./ha).	Not supported.
Control of alternaria blight, leafspot (*Alternaria* spp.) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Supported as control of alternaria blight, leafspot **(*Alternaria alternata*)** on the legume crop group at proposed rates.

Proposed use claim	Supported / Unsupported
Control of angular leafspot (*Phaseoisariopsis griseola*) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Supported as proposed on beans only (*Phaseolis, Vigna*).
Control of anthracnose (*Colletotrichum lindemuthianum*) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Supported as **suppression** at the proposed rates on beans (*Phaseolis, Vigna*) and soybean.
Control of grey mould (*Botrytis cinerea*) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Supported as proposed on the legume crop group.
Control of soil-borne diseases caused by *Rhizoctonia solani* on legume vegetables at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of Asian soybean rust (*Phakopsora pachyrhizi*) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Supported as **suppression** at **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)**.
Control of rust (*Uromyces* spp.) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	The claim of control of rust (*Uromyces appendiculatus*) is conditionally supported as proposed on beans only (*Phaseolis, Vigna*).
Control of ascochyta blight, leafspot (*Ascochyta* spp.) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	The claim of control of ascochyta blight (*Ascochyta* spp.) is conditionally supported on the legume crop group at **1.0 – 1.5 L/ha**.
Control of powdery mildew (*Erysiphe* spp.) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Not supported.
Control of cercospora leafspot (*Cercospora* spp.) on legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	Not supported.
Control of alternaria leaf spot, blight, brown spot, early blight (*Alternaria dauci*) on root vegetables at a rate of 1.25 – 2.25 L/ha (250 - 450 g a.i./ha).	Supported control of **alternaria leafspot (*Alternaria dauci*) on carrot only** at proposed rates.
Control of grey mould (*Botrytis cinerea*) on root vegetables at a rate of 1.25 – 2.25 L/ha (250 – 450 g a.i./ha).	Supported as control at **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)**.
Control of powdery mildew (*Erysiphe* spp.) on root vegetables at a rate of 1.25 – 2.25 L/ha (250 - 450 g a.i./ha).	Conditionally supported as **suppression or powdery mildew (*Erysiphe heraclei*) on carrot** at the proposed rates.
Control of rust (*Uromyces* spp.) on root vegetables at a rate of 1.25 – 2.25 L/ha (250 - 450 g a.i./ha).	The claim was withdrawn by the applicant.
Control of sclerotinia stem rot (S*clerotinia sclerotiorum*) on alfalfa at a rate of 1.25 – 1.5 L/ha (250 – 300 g a.i./ha).	Supported as proposed.
Control of powdery mildew (*Erysiphe pisi, Leveillula taurica*) on alfalfa at a rate of 1.25 – 1.75 L/ha (250 – 350 g a.i./ha).	Not supported.
Fontelis Fungicide may be applied by air to alfalfa, lowbush blueberries and cucurbits. The minimum aerial application volume is 40 L/ha.	Conditionally supported as proposed.

Table 28 Use (label) Claims Proposed by Applicant for Vertisan Fungicide and Whether Acceptable or Unsupported

Proposed use claim	Supported / Unsupported
Control of ascochyta blight (*Ascochyta* spp.) on dry legume vegetables at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported on **chickpea and lentil** as proposed. **Extrapolation to the crop group is conditionally supported.**
Control of grey mould (*Botrytis cinerea*) on dry legume vegetables at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Supported as proposed.
Control of Asian soybean rust (*Phakopsora pachyrhizi*) on dry legume vegetables at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	**Suppression** of ASR on legume vegetables at a rate of **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)** is supported.
Control of soil-borne diseases caused by *Rhizoctonia solani* on dry legume vegetables at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of powdery mildew (*Erysiphe* spp.) on dry legume vegetables at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Not supported.
Control of rust (*Uromyces* spp.) on dry legume vegetables at a rate of 1.25 – 1.5 L/ha (250 – 300 g a.i./ha).	The claim was withdrawn by the applicant.
Control of early blight (*Alternaria solani*) on tuberous and corm vegetables at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	**Suppression** of early blight on potatoes, sweet potatoes and yams only, with the proposed use pattern is supported.
Control of grey mould (*Botrytis cinerea*) on tuberous and corm vegetables at a rate of 1.25 – 1.5 L/ha (250 – 300 g a.i./ha).	Supported as proposed.
Control of soil-borne diseases caused by *Rhizoctonia solani* on tuberous and corm vegetables at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	**Suppression** of stem canker on potato and sweet potato, and transplant rot on sweet potato, caused by *Rhizoctonia solani* with the proposed use pattern is supported.
Control of powdery mildew (*Erysiphe* spp.) on tuberous and corm vegetables at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Not supported.
Control of stem rot/white mould (*Sclerotinia sclerotiorum*) on canola at a rate of 1.25 – 1.5 L/ha (250 – 300 g a.i./ha).	**Suppression** of stem rot/white mould on canola as proposed.
Control of septoria leaf spot (*Septoria* spp.) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha).	**Suppression** of septoria leaf spot (*Septoria tritici*) on wheat, barley and triticale with the proposed use pattern is supported.
Control of brown leaf rust/orange leaf rust (*Puccinia recondita* f. sp. *tritici*) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha).	Supported as proposed on wheat, rye and triticale.
Control of black stem rust (*Puccinia graminis* f. sp. *tritici*) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha.	Supported as proposed on wheat, barley, oats and triticale.
Control of net blotch (*Pyrenophora teres*) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha).	Not supported.

Proposed use claim	Supported / Unsupported
Control of powdery mildew (*Erysiphe graminis f. sp. tritici*) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha).	Not supported.
Control of stripe rust/yellow wheat rust (*Puccinia striiformis*) on cereals at a rate of 1.2 – 1.75 L/ha (240 – 350 g a.i./ha).	Not supported.
Control of grey leaf spot (*Cercospora zeae-maydis*) on corn (field, sweet, seed, popcorn), sorghum (milo, sudangrass and hybrids), millet (pearl, proso) at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	**Suppression** of grey leaf spot on corn (field, sweet, seed, popcorn), sorghum (milo, sudangrass and hybrids) with the proposed use pattern is supported.
Control of common rust (*Puccinia sorghi*) on corn at a rate of 1.0 – 1.75 L/ha (200 – 350 g a.i./ha).	Conditionally supported as proposed on corn (field, sweet, seed, popcorn).
Control of sclerotinia stem rot (*Sclerotinia* spp.) on sunflower at 1.75 L/ha (350 g a.i./ha).	**Suppression** of **sclerotinia head rot (*Sclerotinia sclerotiorum*)** on sunflower with the proposed use pattern is supported.
Control of rust (*Puccinia helianthi*) on sunflower at 1.75 L/ha (350 g a.i./ha).	**Suppression** of rust on sunflower with the proposed use pattern is supported.
Control of soil-borne diseases on sunflower caused by *Rhizoctonia solani* at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Control of powdery mildew (*Erysiphe cichoracearum*) on sunflower at a rate of 1.75 L/ha (350 g a.i./ha).	Not supported.
Control of soil-borne diseases on sugarbeet caused by *Rhizoctonia solani* at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	Control of crown and root rot caused by *Rhizoctonia solani* with the proposed use pattern is supported.
Control of powdery mildew (*Erysiphe betae*) on sugarbeet at a rate of 1.0 – 1.5 L/ha (200 – 300 g a.i./ha).	Conditionally supported as **suppression**.
Control of brown spot (*Septoria glycines*) on soybean at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	**Suppression** of brown spot on soybeans at **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)** is supported.
Control of frogeye leafspot (*Cercospora sojina*) on soybean at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	**Suppression** of frogeye leafspot on soybeans at **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)** is supported.
Control of Asian soybean rust (*Phakopsora pachyrhizi*) on soybean at a rate of 1.0 – 2.25 L/ha (200 – 450 g a.i./ha).	**Suppression** of ASR on soybeans at **1.0 – 1.75 L/ha (200 – 350 g a.i./ha)** is supported.
Control of soil-borne diseases on soybean caused by *Rhizoctonia solani* at a rate of 15.5 – 31 ml per 100 m row. Apply in-furrow at planting.	This use was not supported by food residue data.
Vertisan Fungicide may be applied by air to canola, dry legumes, cereals, corn, soybeans, sunflower, sugarbeet and tuberous and corm vegetables. The minimum aerial application volume is 40 L/ha.	Supported as proposed.

Table 29 Use (label) Claims Proposed by Applicant for Treoris Fungicide and Whether Acceptable or Unsupported

Proposed label claim	Supported / Unsupported
To control early blight (*Alternaria solani*) on potatoes, apply Treoris at a rate of 1.5 – 2.5 L/ha. Begin applications prior to disease development and continue on a 7- to 14-day interval. Use higher rate and shorter interval when disease pressure is high.	Supported as proposed.
To control powdery mildew (*Erysiphe cichoracearum*) on cucurbits, apply Treoris at a rate of 1.5 – 2.5 L/ha. Begin applications prior to disease development and continue on a 7- to 14-day interval. Use higher rate and shorter interval when disease pressure is high.	Supported as proposed.
Treoris Fungicide may be applied by air to potatoes.	Conditionally supported as proposed.

Table 30 Use (label) Claims Proposed by Applicant for DPX-LEM17 50WG Fungicide and Whether Acceptable or Unsupported

Proposed label claim	Supported / Unsupported
To control dollar spot (*Sclerotinia homeocarpa*) on turfgrass, apply DPX-LEM17 50 WDG at a rate of 9 – 15 g/100m^2 (0.9 – 1.5 kg/ha).	Supported as proposed.
To control brown patch (*Rhizoctonia solani*) on turfgrass, apply DPX-LEM17 50 WDG at a rate of 9 – 15 g/100m^2 (0.9 – 1.5 kg/ha).	Supported as proposed.
To control large patch (*Rhizoctonia solani*) on turfgrass, apply DPX-LEM17 50 WDG at a rate of 9 – 15 g/100m^2 (0.9 – 1.5 kg/ha).	Not supported.
To control powdery mildew (Erysiphe graminis), apply DPX-LEM17 50 WDG at a rate of 9 – 15 g/100m2 (0.9 – 1.5 kg/ha).	Not supported.

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

Penthiopyrad is a new active ingredient which is concurrently being registered in the US. The US EPA is in agreement with the specified Canadian maximum residue limits (MRLs) and will be promulgating the same tolerances (40 CFR Part 180) except no US tolerances are recommended for poultry and hog commodities.

Currently, there are no Codex MRLs established for penthiopyrad.

Table 1 Differences Between Canadian MRLs and in Other Jurisdictions

Commodity	Canada (ppm)	U.S. (ppm)	Codex* (ppm)
Eggs; fat, meat & meat byproducts of hogs and poultry	0.02	None	Not reviewed by Codex

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

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

Under the North American Free Trade Agreement (NAFTA), Canada, the US 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.

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A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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