Proposed Registration Decision PRD2016-13

Cyantraniliprole

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Overview

Proposed Registration Decision for Cyantraniliprole

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 DuPont Cyazypyr Technical Insecticide (registration number 30890) and DuPont Okina Insect Control, containing the technical grade active ingredient cyantraniliprole, to control cabbage looper and whiteflies and to suppress thrips on greenhouse cucumber, eggplant, pepper and tomato.

Cyantraniliprole is currently registered in several insecticide end-use products for use on fruits and vegetables, oilseeds, greenhouse ornamentals and outdoor ornamentals. For the detailed review see the Proposed Registration Decision PRD2013-09, *Cyantraniliprole* and Regulatory Decision RD2013-25, *Cyantraniliprole.*

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 DuPont Cyazypyr Technical Insecticide and DuPont Okina Insect Control.

What Does Health Canada Consider When Making a Registration Decision?

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

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and

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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."

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 cyantraniliprole, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on cyantraniliprole, which will include the decision, the reasons for it, a summary of comments received on the proposed 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 Cyantraniliprole?

Cyantraniliprole is a member of the diamide group of insecticides, which interfere with insect muscle and nerve action causing paralysis and death to the insect. It is active by ingestion and contact. Cyantraniliprole is the active ingredient in DuPont Okina Insect Control, which is applied to the foliage of greenhouse cucumber, eggplant, pepper and tomato to control cabbage looper and whiteflies and suppress thrips. Other products that contain cyantraniliprole are applied as seed treatments, foliar sprays or soil treatments against a range of insect pests of field, fruit and tree nut crops, and greenhouse and outdoor ornamentals.

Health Considerations

Can Approved Uses of Cyantraniliprole Affect Human Health?

DuPont Okina Insect Control, containing cyantraniliprole, is unlikely to affect your health when used according to label directions.

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

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels

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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*.

to which humans are normally exposed when using pesticide products according to label directions.

In laboratory animals, cyantraniliprole was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was non-irritating to the skin and minimally irritating to the eyes, and did not cause an allergic skin reaction. DuPont Okina Insect Control was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. Moderate irritation to the skin was identified and, consequently, the signal word and hazard statement "WARNING-SKIN IRRITANT' are required on the label. DuPont Okina Insect Control was minimally irritating to the eyes. The potential for an allergic skin reaction was identified and, therefore, the hazard statement "POTENTIAL SKIN SENSITIZER" is required on the label.

Short-term and long-term (lifetime) animal toxicity tests were assessed for the potential of cyantraniliprole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, genetic damage, and various other effects. The most sensitive endpoints for risk assessment included effects on the liver, thyroid and adrenal glands. When cyantraniliprole was given to the pregnant animal, reduced fetal and offspring weights were observed. However, the results indicated that the young animal did not appear to be more sensitive than the adult animal. The risk assessment protects against these effects of cyantraniliprole and other potential effects 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 drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children one to two years of age, the subpopulation which would ingest the most cyantraniliprole relative to body weight, are expected to be exposed to less than 92.5% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from cyantraniliprole is not of health concern for all population subgroups.

Cyantraniliprole is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

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

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

Residue trials conducted throughout the United States using cyantraniliprole on greenhouse tomatoes, peppers, and cucumbers are acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of this document.

Occupational Risks From Handling DuPont Okina Insect Control

Workers who mix, load, and apply DuPont Okina Insect Control as a foliar spray, as well as greenhouse workers re-entering freshly treated crops, can come in direct contact. Therefore, the label specifies that anyone mixing, loading, and applying DuPont Okina Insect Control, and during cleanup and repair, must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, faceshield, socks and chemical-resistant footwear. The label also requires that workers do not enter treated greenhouses for 12 hours after application. Taking into consideration these label statements, the use pattern, and the duration of exposure for workers, risks to these individuals are not a concern.

For bystanders, exposure is expected to be negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Cyantraniliprole Is Introduced Into the Environment?

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

DuPont Okina Insect Control will not be released directly into the environment when used on greenhouse tomatoes, peppers, eggplants and cucumbers. Should cyantraniliprole enter the environment, it is expected to transform quickly in both soil and water. There are a total of eight major transformation products formed in soil and/or water. The degradation of the major transformation products ranges from not persistent to persistent. Cyantraniliprole and its transformation products have the potential to leach through the soil profile to enter ground water, if it enters the environment. Cyantraniliprole is systemic and, therefore, can also reach pollen and nectar through movement inside the plant.

When cyantraniliprole is used as a foliar spray for control of pests on greenhouse tomatoes, peppers, eggplants and cucumbers, beneficial arthropods and bees, which may be used for greenhouse pest management and pollination, could be exposed to spray droplets or residues through contact or oral exposure. As such, cyantraniliprole may affect bees and beneficial arthropods from foliar applications; therefore, label statements are required to reduce exposure to bees and beneficial insects that may be used in greenhouse production.

Cyantraniliprole also is toxic to some species of aquatic invertebrates; therefore, label statements prohibiting release of greenhouse effluent into aquatic systems are required.

Environmental risk is considered to be acceptable when cyantraniliprole is used in accordance with the label and the required risk reduction measures are applied.

Value Considerations

What Is the Value of DuPont Okina Insect Control?

DuPont Okina Insect Control is a new tool for the management of cabbage looper, thrips and whiteflies on greenhouse cucumber, eggplant, pepper and tomato, and represents a new mode of action for resistance management of whiteflies and thrips on these crops.

Cabbage looper, thrips and whiteflies are important pests of greenhouse vegetable crops. DuPont Okina Insect Control represents a new mode of action for the management of whiteflies and thrips on greenhouse cucumber, eggplant, pepper and tomato; therefore, cyantraniliprole will contribute to resistance management of these crop-pest combinations.

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 DuPont Okina Insect Control to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because workers can come into direct contact with DuPont Okina Insect Control on the skin or through inhalation of spray mists, anyone mixing, loading and applying DuPont Okina Insect Control, and during clean-up and repair, must wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, faceshield, socks and chemical-resistant footwear. The label also requires that workers not re-enter treated greenhouses for 12 hours after application.

Environment

Risk-based label statements are required on the label that informs users that cyantraniliprole may affect bees and some species of beneficial arthropods. Hazard-based label statements are also required to protect aquatic organisms and to prevent contamination of irrigation, drinking water supplies and aquatic habitats.

Next Steps

Before making a final registration decision on cyantraniliprole, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please 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

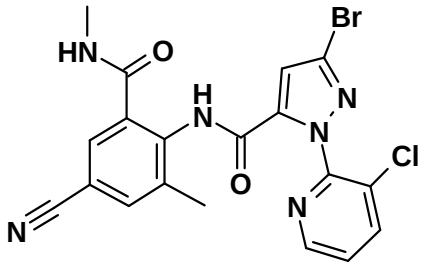
When the PMRA makes its registration decision, it will publish a Registration Decision on cyantraniliprole (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in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

Science Evaluation

Cyantraniliprole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Cyantraniliprole
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide
2. Chemical Abstracts Service (CAS)	3-bromo-1-(3-chloro-2-pyridinyl)-*N*-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide
CAS number	736994-63-1
Molecular formula	$C_{19}H_{14}BrClN_6O_2$
Molecular weight	473.7 g/mol
Structural formula	
Purity of the active ingredient	96.7 % nominal

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

Technical Product—Cyantraniliprole Technical (DuPont Cyazypyr Technical Insecticide)

Property	Result
Colour and physical state	Off-white fine powder
Odour	No characteristic odour
Melting range	217–219 °C
Boiling point or range	Decomposes at 350 °C prior to boiling
Density	1.38 g/cm^3

Property	Result
Vapour pressure at 20°C	5×10^{-12} mPa (estimated)
Ultraviolet (UV)-visible spectrum	Neutral methanol λmax = 205 nm , 267 nm ε = 7801 L/(mol cm) at 290 nm Acidic methanol λmax = 204 nm , 264 nm ε = 7267 L/(mol cm) at 290 nm Basic methanol λmax = 222 nm , 272 nm, 312 nm ε = 12249 L/(mol cm) at 290 nm
Solubility in water at 20°C	pH solubility Purified water 14.2 mg/L pH 4 buffer 17.4 mg/L pH 7 buffer 12.3 mg/L pH 9 buffer 5.9 mg/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent Solubility Acetone 0.654 Dichloromethane 0.505 Methanol 0.473 Acetonitrile 0.245 Ethyl Acetate 0.196 n-Octanol 0.079 o-Xylene 0.029 n-Hexane 6.7×10^{-6}
n-Octanol-water partition coefficient (K_{ow})	pH $\log K_{ow}$ distilled water 1.97 pH 4 buffer 1.97 pH 7 buffer 2.02 pH 9 buffer 1.74
Dissociation constant (pK_a)	$pK_a = 8.80$
Stability (temperature, metal)	Stable at elevated temperatures, and at elevated temperatures in contact with iron and aluminum metal and their acetate salts.

End-Use Product—DuPont Okina Insect Control

Property	Result
Colour	Off-white
Odour	Mild phenyl compound odour
Physical state	Liquid
Formulation type	Suspension
Guarantee	100 g/L
Container material and description	HDPE plastic bottles, jugs, drums, totes, tanks
Density	0.982 g/mL
pH of 1% dispersion in water	5.6
Oxidizing or reducing action	Not an oxidizing substance
Storage stability	Stable on storage at 54 °C for fourteen days and at ambient temperatures for two years.
Corrosion characteristics	Non-corrosive to HDPE

Property	Result
Explodability	Not explosive

1.3 Directions for Use

DuPont Okina Insect Control is applied as a foliar spray to greenhouse cucumber, eggplant, pepper and tomato at 250 mL/ha to control cabbage looper, at 750-1000 mL/ha to control whiteflies and at 500-1000 mL/ha to suppress thrips, with a re-application interval of seven days. There is a maximum of four applications per crop cycle. The higher rate for thrips and whiteflies is recommended on large plants or crops with dense foliage. The use of adjuvants, Hasten NT Spray Adjuvant at 0.25% v/v or MSO Concentrate with Leci-Tech at 0.5% v/v, is recommended to improve efficacy against thrips and whiteflies.

1.4 Mode of Action

The active ingredient, cyantraniliprole, is a diamide insecticide in Group 28 of the Insecticide Resistance Action Committee Mode of Action Classification scheme. Diamides affect the action of nerves and muscles. Insects which ingest or contact cyantraniliprole become paralysed, stop feeding and die. It has translaminar activity when applied as a foliar treatment.

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 cyantraniliprole have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

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

2.3 Methods for Residue Analysis

Please refer to PRD2013-09, *Cyantraniliprole* for the detailed review of the methods for residue analysis.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for cyantraniliprole was conducted previously and is summarized in the Proposed Registration Decision PRD2013-09, *Cyantraniliprole*. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. 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 cyantraniliprole.

Results of the toxicology studies conducted on laboratory animals with cyantraniliprole, as well as toxicology endpoints for use in human health risk assessment, can be found in PRD2013-09, *Cyantraniliprole*.

The acute toxicity studies to support the registration of DuPont Okina Insect Control were previously reviewed and the results of the studies can be found in PRD2013-09, *Cyantraniliprole*, for DuPont Exirel Insecticide (registration number 30895), which has a comparable formulation. DuPont Okina Insect Control was of low acute toxicity via the oral, dermal, and inhalation routes of exposure in rats. It was moderately irritating to the skin and minimally irritating to the eyes of rabbits. It was considered to be a potential skin sensitizer when tested on guinea pigs (maximization method).

Incident Reports

Since 26 April 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. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 4 November 2015, no human, domestic animal or environment incident reports involving cyantraniliprole had been submitted to the PMRA.

3.2 Occupational Exposure and Risk

Occupational exposures to DuPont Okina Insect Control are characterized as short- to intermediate-term in duration for mixers, loaders, and applicators and are predominantly by the dermal and inhalation routes. Post-application exposures from entry into treated commercial greenhouses are considered long-term in duration and predominantly by the dermal route.

3.2.1 Dermal Absorption

Please refer to Proposed Registration Decision PRD2013-09, *Cyantraniliprole* for the detailed review of dermal absorption.

A dermal absorption value was not required for route-to-route extrapolation for short- to intermediate-term durations of exposure. For long-term, post-application dermal exposures of workers to treated greenhouse crops, the dermal absorption value of 2% is applied in the risk assessment of DuPont Okina Insect Control.

3.2.2 Occupational Exposure and Risk

3.2.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Individuals have potential for exposure to DuPont Okina Insect Control during mixing, loading and application to vegetables in commercial greenhouses. Inhalation exposure estimates for workers were generated using the Pesticide Handlers Exposure Database (PHED).

Exposures to workers mixing, loading and applying DuPont Okina Insect Control are expected to be short- to intermediate-term duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were determined for mixers, loaders, and applicators applying foliar treatments of DuPont Okina Insect Control to greenhouse cucumbers, peppers, tomatoes and eggplants using manually pressurized handheld equipment, backpack, and mechanically pressurized handheld equipment (addresses automatic and manually pulled sprayer carts).

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted.

Dermal exposures were not estimated as no toxicological endpoint was chosen for this route.

Inhalation exposures were estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposures were normalized to mg/kg bw/day by using the adult body weight of 80 kg.

Exposure estimates were compared to the inhalation toxicological endpoint to obtain the Margin of Exposure (MOE).The target MOE is 100 for the inhalation route.

Table 3.2.2.1 Exposure and risk estimates of mixer, loader, and applicator when handling DuPont Okina Insect Control

Exposure scenario*	PHED inhalation unit exposure (µg/kg a.i. handled)**	Equipment Volume per day (volume/ha)† / spray volumeΦ	Rate (kg a.i./ha)	Daily exposure (mg/kg bw/day)‡	MOE¶ (rounded)
Manually pressurized handheld equipment	45.21	150L / 1400L/ha	0.100	6.05E-06	4.31E06
Backpack	62.10	150L / 1400L/ha		8.32E-06	3.14E06
Mechanically pressurized handheld equipment (covers mixer/loader for robotic or automatic equipment, and manually pulled rail carts)	151	3800L / 1400L/ha		5.12E-04	5.1E04
		Area treated per day (max) = 6haΨ		1.13E-03	2.3E4

* Worker wearing a long-sleeved shirt, long pants, and gloves when mixing/loading/applying and during clean-up and repair;

** Light inhalation rate for manual and mechanically pressurized equipment; moderate inhalation rate for backpack;

No toxicological endpoint for short- to intermediate-term dermal exposure
† Default Area Treated Per Day tables (2010)
Φ Minimum spray volume per hectare (L/ha)
Ψ Based on applicant-supplied information
‡ Daily exposure = (PHED unit exposure × equipment volume/day / spray volume/ha × Rate) / (80 kg bw × 1000 µg/mg)
¶ Based on NOAEL = 26.1 mg/kg bw/day, target MOE = 100

3.2.2.2 Exposure and Risk Assessment for Workers Re-entering Greenhouses

There are potential exposures for workers re-entering greenhouses where vegetable crops have been treated with DuPont Okina Insect Control. Given the nature of activities performed, the primary route of exposure for workers entering treated greenhouse vegetable crops is through the dermal route. The duration of exposure is considered to be long-term, since several crop cycles can be completed year-round.

Dermal exposures to workers entering treated greenhouse vegetables (Table 3.2.2.2) are estimated by coupling dislodgeable foliar residue values for foliar treatments with activity-specific transfer coefficients. Chemical-specific dislodgeable foliar residue data were not submitted. Therefore, a default dislodgeable foliar residue value of 25% of the application rate for each treatment was used in the exposure assessment. No greenhouse dissipation of product residue was assumed. A dermal absorption value of 2% was required for route-to-route extrapolation from an oral toxicological endpoint. Exposures were normalized to mg/kg bw/day by using 80 kg adult body weight.

The dermal exposure estimate was compared to the oral study endpoint to obtain the MOE. The target MOE is 100.

Table 3.2.2.2. Postapplication exposure and risk estimate for workers re-entering treated greenhouse vegetable crops treated with DuPont Okina Insect Control

Re-entry activity	Dislodgeable Foliar Residue (DFR) (µg/cm^2)*	Transfer Coefficient (TC) (cm^2/hour)†	Dermal exposure (mg/kg bw/day)‡	Margin of Exposure (MOE)¶	Restricted Entry Interval (REI)◊
Greenhouse, all tasks	1.00	1400	0.00280	357	0

* Calculated using the default 25% dislodgeable residue on the day of application after each treatment; 0% daily dissipation; 4 treatments applied at the minimum re-treatment interval of 7 days was assumed
† ARTF Agricultural Transfer Coefficients (August 2012)
‡ Exposure = (DFR [µg/cm^2] × TC [cm^2/hour] × ET (hours) × DA (%)) / (bw (kg) × 1000 (µg/mg))
Where, ET = 8 hour workday; DA = 2% dermal absorption; bw = 80kg body weight
¶ Based on a NOAEL of 1 mg/kg bw/day, from a 1 year dog oral study; target MOE = 100
◊ Minimum REI for commercial products is 12 hours, to allow residues to dry

Risks to workers entering treated greenhouse vegetables are not of concern. The default restricted entry interval (REI) of 12 hours is adequate to protect workers.

3.2.3 Residential Exposure and Risk Assessment

3.2.3.1 Handler Exposure and Risk

No homeowner applicator scenario is proposed.

3.2.3.2 Post-application Exposure and Risk

No residential post-application scenario is proposed.

3.2.3.3 Bystander Exposure and Risk

Bystander exposure should be negligible since bystanders are not expected to be inside greenhouses being treated and potential for drift is expected to be minimal when bystanders are outside greenhouses.

3.3 Food Residues Exposure Assessment

3.3.1 Residues in Plant and Animal Foodstuffs

Please refer to PRD2013-09, *Cyantraniliprole* for the complete review of residues of cyantraniliprole in plants and animal foodstuffs.

In the context of the current submission, crop field trials were conducted in greenhouses throughout the United States using end-use products containing cyantraniliprole at approved rates in or on greenhouse tomatoes, peppers, and cucumbers are sufficient to support the proposed maximum residue limits.

3.3.2 Dietary Risk Assessment

Chronic [non-cancer] dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 3.16), which uses updated food consumption data based on the National Health and Nutrition Examination Survey two-day food consumption data for 2003-2008.

3.3.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic non-cancer analysis for cyantraniliprole: 100% crop treated, default and experimental processing factors (where available), residues of crops based on supervised trial median residue (STMdR) values and anticipated residues for all animal commodities. The refined chronic dietary exposure from all supported cyantraniliprole food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 89.2% (0.008920 mg/kg bw/day) of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to cyantraniliprole from food and drinking water is 23% (0.002304 mg/kg bw/day) of the ADI for the total

population. The highest exposure and risk estimate is for children one to two years of age at 92.5% (0.009253 mg/kg bw/day) of the ADI.

3.3.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.3.3 Aggregate Exposure and Risk

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

3.3.4 Maximum Residue Limits

Residues of cyantraniliprole from the use of DuPont Okina Insect Control on greenhouse tomatoes, and peppers will be covered by existing MRLs on CG8-09.

Table 3.3.4.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Cucurbit vegetables (Crop Group 9)	0.7[1]

[1]The recommended MRL is to replace the currently established MRL of 0.4 ppm on CG9.

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 methodologies, field trial data, and acute and chronic dietary risk estimates are summarized in Appendix I.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

DuPont Okina Insect Control will be used in closed greenhouses as a foliar applied insecticide for the control of thrips, whiteflies and loopers in greenhouse tomatoes, cucumbers, peppers and eggplants. As such, cyantraniliprole will not be released directly into the environment.

The fate and environmental behaviour of cyantraniliprole have been previously assessed for foliar use on agricultural crops (for further details see Proposed Regulatory Decision PRD2013-09, *Cyantraniliprole* and Regulatory Decision RD2013-25, *Cyantraniliprole*).

4.2 Environmental Risk Characterization

The environmental risk characterisation of cyantraniliprole had been previously assessed for foliar use on agricultural crops (for further details see Proposed Regulatory Decision PRD2013-09, *Cyantraniliprole* and Regulatory Decision RD2013-25, *Cyantraniliprole*).

As the proposed use for DuPont Okina Insect Control falls within the existing use pattern (application type and rate) for cyantraniliprole, the previous assessment for organisms that may be exposed during greenhouse uses is considered relevant.

Based on the potential risk identified for beneficial arthropods and bees, statements are required on the label to reduce exposure to beneficial arthropods and bees that may be used in greenhouse production. Based on the hazard identified for some species of aquatic invertebrates, mitigation is required to reduce effluent discharge of cyantraniliprole.

4.3 Incident reports / additional considerations

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

As of 17 September 2015, no environmental incident reports involving cyantraniliprole had been submitted to the PMRA.

5.0 Value

5.1 Consideration of Benefits

DuPont Okina Insect Control controls cabbage looper and whiteflies, and suppresses thrips on greenhouse cucumber, eggplant, pepper and tomato. These insects are important pests of these crops. Numerous alternative active ingredients are registered for all crop-pest combinations, including conventional and non-conventional active ingredients. However, cases of resistance to various alternatives have been reported. Cyantraniliprole represents a new mode of action for whiteflies and thrips on greenhouse cucumber, eggplant, pepper and tomato. Therefore, this product will contribute to resistance management of these pest-crop combinations.

This product is an additional pest control tool that growers can use to manage these important pests of major greenhouse vegetable crops.

5.2 Effectiveness Against Pests

The results from three field trials against cabbage looper, six greenhouse trials against thrips and four field trials against whiteflies demonstrated that DuPont Okina Insect Control controls cabbage looper and whiteflies, and suppresses thrips on the labelled crops. The results from the trials, as well as scientific rationales, supported the use of surfactants with the product to improve efficacy.

5.3 Non-Safety Adverse Effects

No phytotoxicity to host plants was reported in the efficacy trials which were conducted on a wide variety of field and greenhouse vegetable crops.

5.4 Supported Uses

Foliar application of DuPont Okina Insect Control is supported at 250 mL/ha to control cabbage looper, at 750-1000 mL/ha to control whiteflies and at 500-1000 mL/ha to suppress thrips on greenhouse cucumber, eggplant, pepper and tomato, with a re-application interval of seven days. There is a maximum of four applications per crop cycle. The use of adjuvants, Hasten NT Spray Adjuvant at 0.25% v/v or MSO Concentrate with Leci-Tech at 0.5% v/v, is supported to improve efficacy against thrips and whiteflies.

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, cyantraniliprole 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:

- Cyantraniliprole does not meet Track 1 criteria, and is not considered a Track 1 substance. Please refer to PRD2013-09, *Cyantraniliprole* for details.

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

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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.*

is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

> Technical-grade cyantraniliprole and the associated end-use product do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.
>
> The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for cyantraniliprole was adequate to define the majority of toxic effects that may result from exposure. The most sensitive endpoints used for risk assessment included effects on the liver, thyroid, and adrenal glands. The effects on the thyroid were secondary to liver enzyme activation by cyantraniliprole. There was no evidence of increased susceptibility of the young to cyantraniliprole. 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. The end-use product, DuPont Okina Insect Control, was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was moderately irritating to the skin and was minimally irritating to the eyes. The potential for an allergic skin reaction was identified.

Mixers, loaders, and applicators handling DuPont Okina Insect Control, and workers re-entering treated commercial greenhouses, are not expected to be exposed to residues of cyantraniliprole that will result in an unacceptable risk when this product is used according to label directions.

Residential and bystander exposures are not of concern.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is cyantraniliprole in plant products and in animal matrices. The proposed use of cyantraniliprole on greenhouse tomatoes, cucumbers, and peppers does not constitute a risk of concern for chronic exposure (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. The PMRA recommends that the following MRL be specified for residues of cyantraniliprole.

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

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

Residues of cyantraniliprole from the use of DuPont Okina Insect Control on greenhouse tomatoes, and peppers will be covered by existing MRLs on CG8-09.

Commodity	Recommended MRL (ppm)
Cucurbit vegetables (Crop Group 9)	0.7[1]

[1]The recommended MRL is to replace the currently established MRL of 0.4 ppm on CG9.

7.2 Environmental Risk

When used according to label directions, cyantraniliprole does not pose an unacceptable risk to the environment. Mitigative label statements are required to reduce exposure aquatic organisms, beneficial arthropods and bees.

7.3 Value

DuPont Okina Insect Control controls cabbage looper and whiteflies, and suppresses thrips on greenhouse cucumber, eggplant, pepper and tomato. These insects are important pests of these crops. The product contributes to resistance management because the mode of action of cyantraniliprole is new for use against thrips and whiteflies on these crops. Another diamide, chlorantraniliprole, is registered for use against cabbage looper on the crops listed on the DuPont Okina Insect Control label. This product is an additional pest control tool that growers can use to manage these important pests of major greenhouse vegetable crops.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of DuPont Cyazypyr Technical Insecticide (registration number 30890) and DuPont Okina Insect Control, containing the technical grade active ingredient cyantraniliprole, to control cabbage looper and whiteflies and to suppress thrips on greenhouse cucumber, eggplant, pepper and tomato.

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

List of Abbreviations

°C	degrees centigrade
λ	wavelength
ε	molar attenuation coefficient (molar absorptivity)
µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ARTF	Agricultural Transfer Coefficients
bw	body weight
CAS	Chemical Abstracts Service
CG	crop group
cm	centimetres
DA	dermal absorption
DEEM-FCID	Dietary Exposure Evaluation Model
DFR	dislodgeable foliar residue
EIIS	US EPA Ecological Incident Information System
ET	exposure time
g	gram
FDA	Food and Drug Act
ha	hectare(s)
HAFT	highest average field trial
HDPE	High Density Polyethylene
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*-Octanol-water partition coefficient
L	litre
LAFT	lowest average field trial
LOQ	limit of quantitation
mg	milligram
mL	millilitre
mPa	milliPascals
MOE	margin of exposure
MRL	maximum residue limit
n	number of trials
nm	nanometres
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRD	Proposed Regulatory Decision
RD	Registration Decision
REI	restricted entry interval

SD	standard deviation
STMdR	supervised trial median residue
TC	Transfer Coefficient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Integrated Food Residue Chemistry Summary

CROP FIELD TRIALS ON GREENHOUSE CUCUMBERS | **PMRA # 2439513**

Five field trials were conducted in/on greenhouse cucumbers in 2010 in representative North American Free Trade Agreement (NAFTA) Growing Regions [2(2), 1(3), 1 (5), and 1(10)] using cyantraniliprole. In all trials, greenhouse cucumbers were treated with three foliar applications at intervals of 4 to 6 days. The application rates were in the range of 0.147-0.157 kg a.i./ha for a total of 0.445-0.462 kg a.i./ha/season. All applications were made using appropriate spray equipment, and the spray volume of 281 to 1210 L/ha was sufficient to provide adequate dispersal of the test substance. A tank-mix adjuvant was added at all test sites. At all field trials, treated samples of cucumbers were harvested at 0-day after the last application.

Commodity	Total Application Rate (g a.i./ha)	PHI (days)	Residue Levels of Cyantraniliprole (ppm)							
			n	Min. [#]	Max. [#]	LAFT [*]	HAFT [*]	Median [*]	Mean [*]	SD [*]
Cucumber	445-462	0	5	0.027	0.330	0.032	0.325	0.180	0.155	0.121

CROP FIELD TRIALS ON GREENHOUSE TOMATOES | **PMRA # 2439511**

Five field trials were conducted in/on greenhouse tomatoes in 2009 in representative North American Free Trade Agreement (NAFTA) Growing Regions [2(2), 5 (1), 10 (1), and 12 (1)] using cyantraniliprole. In all trials, greenhouse tomatoes were treated with three foliar applications at intervals of 4 to 6 days. The application rates were in the range of 0.144-0.158 kg a.i./ha for a total of 0.437-0.461 kg a.i./ha/season. All applications were made using appropriate spray equipment, and the spray volume of 187 to 1000 L/ha was sufficient to provide adequate dispersal of the test substance. A tank-mix adjuvant was added at all test sites. At all field trials, treated samples of tomatoes were harvested one day after the last application. Additional samples were harvested at 3, 6, 11, and 15 days after the last application to monitor residue decline.

Crop Matrix	Total Application Rate (g a.i./ha)	PHI (days)	n	Residue Levels of Cyantraniliprole (ppm)						
				Min.[1]	Max.[1]	LAFT[2]	HAFT[2]	Median[2]	Mean[2]	SD[2]
Tomatoes	437-461	1	5	0.053	0.367	0.054	0.355	0.111	0.144	0.120

CROP FIELD TRIALS ON GREENHOUSE PEPPERS | **PMRA # 2439512**

Five field trials were conducted in/on greenhouse peppers in 2009 in representative North American Free Trade Agreement (NAFTA) Growing Regions [2(2), 1(5), 1(10), and 1(11)] using cyantraniliprole. In all trials, greenhouse peppers were treated with three foliar applications at intervals of 5 to 6 days. The application rates were in the range of 0.149-0.158 kg a.i./ha for a total of 0.449 kg a.i./ha for non-bell peppers. The application rates were in the range of 0.144-0.153 kg a.i./ha for a total of 0.447-0.484 kg a.i./ha/season for bell peppers. All applications were made using appropriate spray equipment, and the spray volume of 178-421 L/ha for non-bell peppers and 365-1000 L/ha for bell peppers, was sufficient to provide adequate dispersal of the test substance. A tank-mix adjuvant was added at all test sites. At all field trials, treated samples were harvested one day after the last application. Additional bell pepper samples were harvested at 3, 7, 10, and 14 days after the last application to monitor residue decline.

Crop Matrix	Total Application Rate [g a.i./ha]	PHI (days)	n	Residue Levels of Cyantraniliprole (ppm)						
				Min.[1]	Max.[1]	LAFT[1]	HAFT[2]	Median[2]	Mean[2]	SD[2]
Bell pepper	447-484	1	3	0.101	0.146	0.110	0.141	0.130	0.127	0.016
Non-bell pepper	449	1	2	0.206	0.349	0.213	0.319	0.266	0.266	0.066

[#] Values based on total number of samples.
[*] Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.
n = number of field trials.

Table 2 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

DIETARY RISK FROM FOOD AND WATER (NHANES 2003-2008 2-day)			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Refined chronic non-cancer dietary risk **ADI = 0.01 mg/kg bw** **Estimated chronic drinking water concentration = 0.011 ppm**	General Population	20.7	23.0
	All Infants	38.4	44.3
	Children 1-2 years old	89.2	92.5
	Children 3-5 years old	54.4	57.2
	Children 6-12 years old	28.9	30.9
	Youth 13-19 years old	14.1	15.8
	Adults 20-49 years old	14.7	17.0
	Adults 50-99 years old	16.9	19.2

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

Table 1 Differences Between MRLs in Canada and in Other Jurisdictions

Table 1 compares the MRLs proposed for cyantraniliprole in Canada with corresponding American tolerances and Codex MRLs[9]. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 1 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Cucurbit vegetables (Croup Group 9)	0.7	0.7	0.3

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

[9] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number	Reference
2070884	2009, Cyantraniliprole (DPX-HGW86) 100 g/L SE: In vivo dermal absorption of cyantraniliprole in the rat, DACO: 5.8, Document K, IIIA 7.6.1
2070885	2009, Cyantraniliprole (DPX-HGW86) 100 g/L SE: In vitro kinetics of cyantraniliprole in rat and human skin, DACO: 5.8, Document K, IIIA 7.6.2
2439510	2014, Use Description/Scenario for use of Cyantraniliprole in Greenhouse Tomatoes, Peppers, Eggplants and Cucumbers, DACO: 5.2
2439511	2012, Cyantraniliprole: Magnitude Of The Residue On Tomato (Greenhouse), USA, DACO: 7.4, 7.4.1
2439512	2012, Cyantraniliprole: Magnitude Of The Residue On Pepper (Greenhouse), USA, DACO: 7.4, 7.4.1
2439513	2012, Cyantraniliprole: Magnitude Of The Residue On Cucumber (Greenhouse), USA, DACO: 7.4, 7.4.1

2.0 Value

PMRA Document Number	Reference
2070893	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070894	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070895	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070897	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070898	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070899	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070900	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070901	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070902	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
2070903	2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.2, 12.7, Document M
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2070927 2011, Biological Assessment Dossier For Cyantraniliprole 100 g/L SE Canada, 2011, DACO: 10.2.3.1, 12.7, Document M
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