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Registration Decision

RD2013-25

# Cyantraniliprole

*(publié aussi en français)*

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## Registration Decision for Cyantraniliprole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Dupont Cyazypyr Technical Insecticide and Cyantraniliprole Technical and the end-use products Dupont Verimark Insecticide, Dupont Benevia Insecticide, Dupont Lumiderm Insecticide Treatment, Dupont Exirel Insecticide, A17960A 600FS, and A17960B 600FS, containing the technical grade active ingredient cyantraniliprole. A16901B 40WG Insecticide and Mainspring Insecticide, containing both cyantraniliprole and thiamethoxam, are proposed for conditional registration based on the conditional registration of thiamethoxam. The end-use products are proposed to control a variety of insect pests on fruits and vegetables, oilseeds, greenhouse ornamentals and outdoor ornamentals.

Subsequent to the completion of the risk assessment for cyantraniliprole the following product name changes were made: the brand name for A16901B 40WG Insecticide is now Minecto Duo 40WG; the brand name for A17960A 600FS is now Fortenza; and the name for A17960B 600FS is Fortenza Colourless.

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.

These products were first proposed for registration in the consultation document<sup>1</sup> Proposed Registration Decision PRD2013-09, *Cyantraniliprole*. This Registration Decision<sup>2</sup> describes this stage of the PMRA's regulatory process for cyantraniliprole and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2013-09.

For more details on the information presented in this Registration Decision, please refer to PRD2013-09, which contains a detailed evaluation of the information submitted in support of this registration.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

## 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<sup>3</sup> 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 conditions of registration. The Act also requires that products have value<sup>4</sup> when used according to 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 (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](http://healthcanada.gc.ca/pmra).

## What Is Cyantraniliprole?

Cyantraniliprole is a diamide insecticide, Mode of Action (MoA) Group 28. Diamides affect ryanodine receptors in insect muscle, causing paralysis. Formulated as DuPont Verimark Insecticide, DuPont Benevia Insecticide, DuPont Lumiderm Insecticide Seed Treatment, DuPont Exirel Insecticide, A17960A 600FS, A17960B 600FS, A16901B 40WG Insecticide and Mainspring Insecticide and applied as a seed treatment, as a foliar spray or as a soil drench, it controls, suppresses or reduces damage caused by listed insect pests of field, tree fruit, tree nut and bushberry crops, and greenhouse and outdoor ornamentals. A16901B 40WG and Mainspring Insecticides are formulated with the neonicotinoid insecticide thiamethoxam.

## Health Considerations

### Can Approved Uses of Cyantraniliprole Affect Human Health?

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

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<sup>3</sup> "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

<sup>4</sup> "Value" as defined by subsection 2(1) of *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".

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

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

In laboratory animals, the technical grade active ingredient cyantraniliprole was of low acute toxicity via the oral, dermal and inhalation routes. It was non-irritating to the skin, non- to minimally irritating to the eye and did not cause an allergic skin reaction.

Results of testing in laboratory animals with the various end-use products containing cyantraniliprole revealed the following:

DuPont Verimark Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to the skin and eyes and did not cause an allergic skin reaction.

DuPont Benevia Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was slightly irritating to skin and minimally irritating to eyes. It demonstrated the potential to cause an allergic skin reaction and, consequently, the hazard statement “POTENTIAL SKIN SENSITIZER” is required on the label.

DuPont Lumiderm Insecticide Seed Treatment was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin and minimally irritating to eyes and did not cause an allergic skin reaction.

DuPont Exirel Insecticide was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. Moderate irritation to the skin was identified and, consequently, the hazard statement “WARNING-SKIN IRRITANT” is required on the label. It 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.

A17960A 600FS was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin and minimally irritating to eyes. It did not cause an allergic skin reaction.

A17960B 600FS was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not irritating to skin. Mild irritation to eyes was identified and, consequently, the hazard statement “CAUTION-EYE IRRITANT” is required on the label. It did not cause an allergic skin reaction.

A16901B 40WG Insecticide and Mainspring Insecticide were of low acute toxicity via the oral, dermal, and inhalation routes of exposure. They were not irritating to the skin and were minimally irritating to the eyes. They did not cause an allergic skin reaction.

Cyantraniliprole did not cause cancer in animals and did not damage genetic material. There was no indication that cyantraniliprole caused damage to the nervous system or immune system. Cyantraniliprole did not cause birth defects in animals and there were no effects on the ability to reproduce. Health effects in animals given repeated doses of cyantraniliprole included effects on the liver, thyroid and adrenal glands. The evidence indicated that the thyroid effects were caused by alteration of liver enzymes and that cyantraniliprole is not directly toxic to the thyroid gland. Effects were noted in the adrenal glands but were not considered to be adverse in nature.

When cyantraniliprole was given to pregnant animals, reduced fetal body weight was observed at doses that were clearly toxic to the mother as demonstrated by reduced body weight, mortality, increased incidence of early deliveries and abortion. In reproductive toxicity testing in animals, reductions in offspring body weight were observed at doses that were toxic to the mother as reflected by effects in the thyroid gland. These results indicate that the young do not appear to be more sensitive to cyantraniliprole than the adult animal.

The risk assessment protects against the effects of cyantraniliprole 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 children, the subpopulation which would ingest the most cyantraniliprole relative to body weight, are expected to be exposed to less than 43% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from cyantraniliprole is not of concern for all population subgroups.

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 cyantraniliprole on a range of representative commodities were deemed acceptable. Residue trials conducted throughout the United States using cyantraniliprole in/on citrus fruits, cotton, and in the European Union on grapes and olives were also acceptable for these imported commodities.

The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

## **Risks in Residential and Other Non-Occupational Environments**

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Applications are limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity, such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

## **Occupational Risks From Handling Cyantraniliprole Products**

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

Farmers and custom applicators who mix, load or apply cyantraniliprole as well as field workers re-entering freshly treated fields, nurseries and greenhouses, and workers in commercial and on-farm seed treatment facilities can come in direct contact with cyantraniliprole residues on the skin or through inhalation. Therefore, the labels recommend a variety of personal protective equipment depending on the use scenario/end-use product, as well as various mitigation measures such as closed seed treatment systems and closed cab planting.

The labels also require that workers do not enter treated areas for 12 hours after application. Taking into consideration these label statements, the precautionary measures, the number of applications and the expectation of the exposure period for handlers and workers, it was determined that the risk to these individuals is not a concern for most uses/end-use products.

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

## **Environmental Considerations**

### **What Happens When Cyantraniliprole Is Introduced Into the Environment?**

**Cyantraniliprole may pose a risk to beneficial arthropods, bees and aquatic organisms.**

Cyantraniliprole can enter the environment when it is used as an insecticide for control of a large number of pests in a variety of crops. Cyantraniliprole can be applied as a seed treatment, by foliar spray application, and also soil application. Cyantraniliprole is systemic and, therefore, can also reach pollen and nectar through the movement of cyantraniliprole inside the plant. In both soil and water cyantraniliprole transforms quickly. 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.

The two end-use products A16901B 40WG Insecticide and Mainspring Insecticide contain both cyantraniliprole and thiamethoxam. The fate and ecotoxicity information pertaining to thiamethoxam can be found under Evaluation Report ERC2007-01, *Thiamethoxam*.



Overall, cyantraniliprole and its major transformation products present a negligible risk to soil dwelling organisms, aquatic plants, algae, (freshwater and marine), fish (freshwater and marine), some species of aquatic invertebrates, and amphibians. However, cyantraniliprole may affect some species of aquatic invertebrates from soil and foliar applications. Cyantraniliprole may also affect beneficial arthropods, and bees from foliar applications.

In order to mitigate the potential effects of cyantraniliprole to aquatic organisms, buffer zones and reduction of run-off are required on the label. In order to mitigate the potential effects of cyantraniliprole to terrestrial organisms (beneficial arthropods and bees), foliar applications are limited while bees are actively foraging, and reduction of drift are required on the label.

## **Value Considerations**

### **What Is the Value of DuPont Verimark Insecticide?**

**DuPont Verimark Insecticide controls or reduces early season damage by certain insect pests of potato and brassica vegetables.**

Applied to seed pieces or in furrow at planting of potatoes, DuPont Verimark Insecticide provides control of Colorado potato beetle and spring adults of potato flea beetle. Applied in furrow, in transplant water or as a banded surface application at transplanting, DuPont Verimark Insecticide provides control of imported cabbageworm, diamondback moth and cabbage looper and reduces early season damage by flea beetles and swede midge on brassica vegetables.

Seed piece treatment and soil application are new methods of application for active ingredients from MoA Group 28.

### **What Is the Value of DuPont Benevia Insecticide?**

**DuPont Benevia Insecticide provides control or suppression of a variety of insect pests of potato and oilseed crops.**

Applied to foliage of potatoes by ground or aerial application, DuPont Benevia Insecticide provides control or suppression of Colorado potato beetle, European corn borer, variegated cutworm and aphids. Applied to foliage of oilseed crops by ground application, DuPont Benevia Insecticide provides control or suppression of diamondback moth, bertha armyworm, cabbage looper, cabbage seedpod weevil, cutworms, imported cabbageworm, sunflower head moth and swede midge. Cyantraniliprole is a new MoA for use against the pests on oilseeds. There are no alternative active ingredients registered against sunflower head moth and swede midge on oilseed crops.

This product can contribute to resistance management because use on oilseed crops is new for active ingredients from MoA Group 28.

## **What Is the Value of DuPont Lumiderm Insecticide Seed Treatment?**

**DuPont Lumiderm Insecticide Seed Treatment provides protection from early season damage by certain insect pests of canola, rapeseed and oilseed mustard.**

Applied to seed of canola, rapeseed and oilseed mustard, DuPont Lumiderm Insecticide Seed Treatment provides protection from early season feeding damage by flea beetles and cutworms. Cyantraniliprole is a new MoA for use against the pests on these crops.

This product can contribute to resistance management because use on oilseed crops is new for active ingredients in MoA Group 28. Seed treatment is a new application method for this group.

## **What Is the Value of DuPont Exirel Insecticide?**

**DuPont Exirel Insecticides provides control or suppression of a wide variety of insect pests of field vegetables, berries, tree fruits and nuts.**

Applied to the foliage of tuberous and corm, leafy, brassica, fruiting and cucurbit vegetables by ground or aerial application, DuPont Exirel Insecticide provides control or suppression of Colorado potato beetle, cabbage looper, imported cabbageworm, diamondback moth, corn earworm/tomato fruitworm, cutworms, armyworms, hornworms, swede midge, dipteran leafminers and aphids. Applied to the foliage of bulb vegetables by ground or aerial application, it provides suppression of thrips. Applied to the foliage of bushberries by ground or aerial application, DuPont Exirel Insecticide provides control or suppression of blueberry aphid, blueberry gall midge, blueberry maggot, cranberry fruitworm, plum curculio, Japanese beetle and leafrollers. Applied to the foliage of pome fruit, stone fruit, and nut trees by ground application, it provides control of leafrollers, codling moth, European fruit moth, apple maggot, peach twig borer, plum curculio, European apple sawfly, Japanese beetle, tentiform leafminers, leafhoppers and aphids. There are no alternative active ingredients registered against eyespotted budmoth and peach twig borer on tree nuts.

Cyantraniliprole is a new MoA for use against aphids on tuberous and corm vegetables, thrips on bulb vegetables, aphids and dipteran leafminers on leafy and fruiting vegetables, aphids and dipteran leafminers on brassica vegetables, aphids, corn earworm and dipteran leafminers on cucurbit vegetables, apple maggot, European apple sawfly, eyespotted budmoth, tufted apple budmoth, green peach aphid, rosy apple aphid, Japanese beetle, plum curculio and white apple leafhopper on pome fruit, cherry fruit flies, eyespotted budmoth, green peach aphid, plum aphid, Japanese beetle and plum curculio on stone fruit, blueberry aphid, blueberry gall midge (cranberry tipworm), blueberry maggot, eyespotted budmoth, Japanese beetle, leafrollers and plum curculio on bushberries, and eyespotted budmoth, oriental fruit moth and peach twig borer on tree nuts.

This product can contribute to resistance management because use on bulb vegetables is new for active ingredients from MoA Group 28.

This product is a replacement for uses of older chemistries, such as azinphos-methyl and endosulfan which are being phased out, in pome fruits, stone fruits, blueberry and bulb vegetables.

## **What Is the Value of A17960A 600FS and A17960B 600FS?**

**A17901A 600FS and A17901B 600FS provide early season control of Colorado potato beetle.**

Applied to potato seed pieces, A17890A 600FS and A17960B 600FS provide early season control of Colorado potato beetle, a key pest of potato.

Seed piece treatment is a new method of application for active ingredients from MoA Group 28.

## **What Is the Value of A16901B 40WG Insecticide?**

**A16901B 40WG Insecticide provides control or suppression of a variety of insect pests of field vegetable crops.**

Applied to the soil at planting or transplanting, A16901B 40WG Insecticide provides control or suppression of Colorado potato beetle, flea beetles, dipteran leafminers, armyworms, cabbage loopers, corn earworm, diamondback moth, imported cabbageworm, cucumber beetles, aphids and leafhoppers on potato and leafy, brassica, fruiting and cucurbit vegetables.

Cyantraniliprole is a new MoA for use against potato leafhopper on potatoes, aphids, dipteran leafminers, flea beetles and leafhoppers on leafy vegetables, aphids, dipteran leafminers, flea beetles and thrips on brassica vegetables, aphids, dipteran leafminers, flea beetles, leafhoppers, potato psyllids, thrips and tomato fruitworm on fruiting vegetables, and aphids, cucumber beetles dipteran leafminer, flea beetles and thrips on cucurbit vegetables.

A16901B 40WG Insecticide contains the new active ingredient cyantraniliprole combined with the active ingredient thiamethoxam. Thiamethoxam alone is registered for soil application to all the supported crops. For soil application, more pests are supported for the premix than for either active ingredient alone.

## **What Is the Value of Mainspring Insecticide?**

**Mainspring Insecticide provides control or suppression of a variety of insect pests of greenhouse and outdoor ornamentals.**

Applied to the foliage of greenhouse and outdoor ornamentals, Mainspring Insecticide provides control or suppression of aphids, lace bugs, leafhoppers, mealy bugs, psyllids, soft scales, black vine weevil, dipteran leafminers and thrips. Applied as a soil drench to greenhouse ornamentals, Mainspring Insecticide provides control or suppression of aphids, mealybugs, whiteflies, dipteran leafminers, thrips and fungus gnats. Cyantraniliprole is a new MoA for use against the pests on ornamentals.

Mainspring Insecticide contains two active ingredients, cyantraniliprole and thiamethoxam. Cyantraniliprole alone is not proposed for registration for use on ornamentals, and thiamethoxam alone is not registered for use on greenhouse ornamentals. More pests and crops are supported for the premix than for either active ingredient alone.

## Measures to Minimize Risk

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

The key risk-reduction measures being proposed on the labels of the proposed end-use products to address the potential risks identified in this assessment are as follows.

### Key Risk-Reduction Measures

#### Human Health

Because there is a concern with workers coming into direct contact with cyantraniliprole on the skin or through inhalation, additional personal protective equipment and mitigation measures are recommended (for example, closed seed treatment systems and closed cab planting).

#### Environment

*Terrestrial:* DuPont Exirel Insecticide and DuPont Benevia Insecticide cannot be sprayed within a maximum of 15 metres of susceptible non-target terrestrial plant species. Mainspring Insecticide cannot be sprayed within 1 metre of susceptible non-target terrestrial plant species.

*Aquatic:* DuPont Exirel Insecticide and DuPont Benevia Insecticide cannot be sprayed within a maximum of 5 metres from freshwater aquatic habitats. Mainspring Insecticide cannot be sprayed within a maximum of 1 metre from freshwater aquatic habitats.

Hazard and risk based label statements for toxicity will be required for predators and parasites, bees and aquatic organisms on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide, DuPont Verimark Insecticide, and A16901B 40WG labels, and for plants on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide labels.

Run-off reduction statements will be required on the DuPont Exirel Insecticide, DuPont Benevia Insecticide, Mainspring Insecticide, DuPont Verimark Insecticide, and A16901B 40WG labels.

Drift reduction statements will be required on the DuPont Exirel Insecticide, DuPont Benevia Insecticide and Mainspring Insecticide labels.

## Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-09) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail ([pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)).

Any person may file a notice of objection<sup>5</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)) or contact the PMRA's Pest Management Information Service.

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<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Appendix I Comments and Responses

**1. With regard to table 29: Summary of laboratory and higher Tier studies for pollinators, we would like to comment that in PMRA #2070723 - the reductions in colony strength as indicated are not appropriate as similar reductions were also observed in the controls. Similarly, the same observation applies to colony strength. The wording of the impact to colonies column is ambiguous as reductions occurred across all groups including the control. Also, it is not clear what lack of appropriate controls means, as controls were applied in the same manner as in the treatments during the test.**

The phrase "lack of appropriate controls" is referring to the fact that the second of the test item treatment applications was applied during flowering, after bee flight, whereas the reference and control treatments were applied during flowering, during bee flight, and the treatment item was applied using drip irrigation, whereas the reference and control treatments were applied as spray applications. The PMRA will change the current wording (same conclusion but clarified) to the following in order to be more clear with respect to effects:

There was a reduction of colony strength in all hives (including controls) during the entire study duration.	Timing of spray in the control groups were in some cases different than timing of spray in the treatment groups. A decrease in brood was observed during exposure in treatment, control and reference groups, which could be the result of the quality of the test system.
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**2. Regarding the reference study DuPont-30544, the pollen value for IN-MLA84 should be 15.5.**

Regarding DuPont-30544, the pollen value in IN-MLA84 can be changed from 15.7 to 15.5 µg/kg. The PMRA will change this value.

**3. Regarding Table 32: Effects on aquatic organisms (screening level assessment), PMRA has listed the no observed effect concentration (NOEC) for the chronic daphnid test as 0.0065 mg/L. However, the draft version of the regulation (EC) No. 1107/2009 of the European Council and Parliament for Cyantraniliprole (May 2013) lists the chronic endpoint (NOEC) for daphnid studies as 0.00969 mg/L. Dupont has also commented on this to United States Environmental Protection Agency requesting harmonization with the European Union decision for the daphnid chronic tox endpoint. In the event that the other Global Joint Review (GJR) partners settle on the 0.00969 mg/L, Dupont requests that PMRA consider harmonizing the chronic daphnid endpoint with other GJR partners for regulatory consistency across global regions.**

If all of the global partners agree on an endpoint of 0.00969 mg/L, then the PMRA agrees to include that as a relevant endpoint (to be reported in Table 32). It should be noted that the PMRA already presented the EC<sub>50</sub> for adult survival in Table 32; and the PMRA used an SSD<sub>5</sub> value for buffer zone calculations, which considered the data for all aquatic invertebrates (0.0123 mg/L), and not just the most "sensitive" endpoint. A change in the endpoint will not impact the risk assessment for the PMRA.

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**4. A comment was received related to the ability of chemicals to migrate through the plant, leading to consumers eating a constant low dose in the food they eat.**

Health Canada's priority is to protect the health and safety of Canadians, their environment and their food supply. This priority is applied when approving pesticides for use in Canada, which includes the importation of foods containing pesticide residues.

Prior to the registration of a pesticide or importation of food containing pesticide residues, Health Canada must determine whether the consumption of residues that are likely to remain on food at the farm gate, is acceptable (i.e., unlikely to cause human health concerns to any segment of the population such as infants and toddlers, pregnant and nursing mothers, and the elderly). The maximum amount of expected residue is legally established under *the Pest Control Products Act* as a Maximum Residue Limit (MRL).

Canadian MRLs (domestic and import) are set, according to Health Canada's stringent pesticide residue standards, at levels far below the amount of pesticide residue that could pose health concerns. In addition, pesticide residues may remain in or on food at the point of purchase; however, the pesticide breaks down over time, potentially resulting in even lower residues at the point of consumption (i.e., dinner plate).

**5. A comment was received expressing concern over the reports of bee deaths and colony losses by beekeepers related to neonicotinoids.**

The PMRA would like to clarify that cyantraniliprole is not a neonicotinoid chemical. For cyantraniliprole, the PMRA has reviewed approximately 53 different pollinator studies (including but not limited to laboratory, semi-field and field toxicity studies as well as numerous pollen and nectar residue studies) in order to assess the potential risk associated with cyantraniliprole, its end-use products, and be required to minimize its transformation products. In cases where potential risk was identified, mitigation measures will the risk to pollinators.