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Proposed Maximum Residue Limit

PMRL2008-11

Spinetoram

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act \(PCPA\)](#), has granted conditional registration to technical grade spinetoram and end-use products Radiant SC Insecticide and Delegate WG Insecticide for use in Canada to control various pests on root vegetables (Crop Subgroup 1A), leafy vegetables (Crop Group 4), cole crops (Crop Group 5), fruiting vegetables (Crop Group 8), pome fruits (Crop Group 11), stone fruits (Crop Group 12), caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B), asparagus, barley, beet greens, grapes, oats, okra, rye, soybeans, strawberries, turnip greens and wheat. See Appendix I for a list of crop group/subgroup commodities. The specific uses that were approved in Canada are detailed on the Radiant SC Insecticide and Delegate WG Insecticide labels (PCPA Registration Number 28777 and 28778, respectively).

The evaluation of these spinetoram applications indicated that the end-use products have merit and value and that the human health and environmental risks associated with the new uses are acceptable. Details on these registrations can be found in Evaluation Report [ERC2008-01, Spinetoram](#).

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not pose an unacceptable health risk. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

In addition, the PMRA is proposing to establish import MRLs for spinetoram on tuberous and corm vegetables (Crop Subgroup 1C), leaves of root and tuber vegetables (Crop Group 2), legume vegetables (Crop Group 6), cucurbit vegetables (Crop Group 9), citrus fruits (Crop Group 10), corn (field, sweet, pop) and cranberries to permit the import and sale of food containing these residues. The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when spinetoram is used according to the label directions in the exporting country. The Agency has also determined that such residues will not pose an unacceptable dietary health risk.

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the *Canada Gazette*. Amendments to the *Food and Drugs Act* (FDA) via [Bill C-28](#), anticipated to come into force in 2008, will allow pesticide MRLs to be legally established under the PCPA without having to be adopted by regulation under the FDA. This will result in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed MRLs for spinetoram is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

The proposed MRLs for spinetoram in Canada in or on food are as follows.

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Chemical Name	Chemical Name of Substance	MRLs (ppm)	Food Commodities
Spinetoram	XDE-175-J: 1 <i>H</i> -as-indaceno[3,2- <i>d</i>]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3- <i>O</i> -ethyl-2,4-di- <i>O</i> -methyl- α -L-mannopyranosyl)oxy]-13-[[<i>(2R,5S,6R)</i> -5-(dimethylamino)tetrahydro-6-methyl-2 <i>H</i> -pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl- <i>(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)</i>	7.0	Leafy <i>Brassica</i> greens (Crop Subgroup 5B), leafy vegetables (Crop Group 4), leaves of root and tuber vegetables (Crop Group 2)
		3.0	Citrus oil
		2.0	Head and stem <i>Brassica</i> vegetables (Crop Subgroup 5A)
		1.0	Grape juice
	XDE-175-L: 1 <i>H</i> -as-indaceno[3,2- <i>d</i>]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3- <i>O</i> -ethyl-2,4-di- <i>O</i> -methyl- α -L-mannopyranosyl)oxy]-13-[[<i>(2R,5S,6R)</i> -5-(dimethylamino)tetrahydro-6-methyl-2 <i>H</i> -pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl- <i>(2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)</i>	0.7	Low growing berries (Crop Subgroup 13-07G; except lowbush blueberries, cranberries), raisins
		0.5	Caneberries (Crop Subgroup 13-07A), bushberries (Crop Subgroup 13-07B; except highbush cranberries, lingonberries)
	Includes the following metabolites:	0.4	Small fruit vine climbing, except fuzzy kiwifruit (Crop Subgroup 13-07F; except gooseberries)
	N-demethyl-175 J: <i>(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)</i> -9-ethyl-14-methyl-13-[[<i>(2S,5S,6R)</i> -6-methyl-5-(methylamino)tetrahydro-2 <i>H</i> -pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1 <i>H</i> -as-indaceno[3,2- <i>d</i>]oxacyclododecin-2-yl 6-deoxy-3- <i>O</i> -ethyl-2,4-di- <i>O</i> -methyl- α -L-mannopyranoside	0.3	Cucurbit vegetables (Crop Group 9), citrus fruits (Crop Group 10), edible-podded legume vegetables (Crop Subgroup 6A)
	N-formyl-175-J: <i>(2R,3S,6S)</i> -6-({ <i>(2R,3aR,5aR,5bS,9S,13S,14R,16aS,16bR)</i> -2-[(6-deoxy-3- <i>O</i> -ethyl-2,4-di- <i>O</i> -methyl- α -L-mannopyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1 <i>H</i> -as-indaceno[3,2- <i>d</i>]oxacyclododecin-13-yl)oxy)-2-methyltetrahydro-2 <i>H</i> -pyran-3-yl(methyl)formamide	0.2	Fruiting vegetables (Crop Group 8), stone fruits (Crop Group 12), okra
		0.1	Pome fruits (Crop Group 11), root vegetables (Crop Subgroup 1A), barley, oats, rye, wheat
	0.04	Tuberous and corm vegetables (Crop Subgroup 1C), succulent shelled pea and bean (Crop Subgroup 6B), dried shelled pea and bean (Crop Subgroup 6C), asparagus, corn (field, sweet, pop), cranberries, dry soybeans	

Common Chemical Name	Chemical Name of Substance	MRLs (ppm)	Food Commodities
		7.5 5.5 0.85 0.6 0.3 0.2 0.04	Milk, fat Fat of cattle, goats, horses and sheep Liver of cattle, goats, horses and sheep Meat byproducts (except liver) of cattle, goats, horses and sheep Milk Meat of cattle, goats, horses and sheep Eggs, fat, meat and meat byproducts of hogs and poultry

A complete list of all MRLs established in Canada can be found in [Table II, Division 15](#) of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's [MRL webpage](#), which will be updated to include the MRLs listed in this document.

International Situation and Trade Implications

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 livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

A number of the proposed MRLs in Canada differ from the corresponding tolerances established in the United States (listed in [40 CFR Part 180](#) by pesticide). Currently, there is no Codex¹ MRL established for spinetoram on any commodity ([Codex MRLs](#) searchable by pesticide or commodity). Table 2 identifies differences between MRLs in Canada and tolerances in the United States.

¹ Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs and American Tolerances (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Leaves of root and tuber vegetables (Crop Group 2)	7.0	10
Leafy vegetables, except <i>Brassica</i> (Crop Group 4)	7.0	8.0
Leafy <i>Brassica</i> greens (Crop Subgroup 5B)	7.0	10
Grape juice	1.0	0.5*
Low growing berries subgroup (Crop Subgroup 13-07G; except lowbush blueberries, cranberries)	0.7	1.0 (tolerance established for “Strawberry” only)
Caneberries (Crop Subgroup 13-07A)	0.5	0.7
Bushberries (Crop Subgroup 13-07B; except highbush cranberries, lingonberries)	0.5	0.25
Small fruit vine climbing subgroup except fuzzy kiwifruit (Crop Subgroup 13-07F; except gooseberries)	0.4	0.5 (tolerance established for “Grape” only)
Fruiting vegetables (Crop Group 8)	0.2	0.4
Okra	0.2	0.4
Pome fruits (Crop Group 11)	0.1	0.2
Beet, sugar, molasses	0.1**	0.75
Barley, oats, rye, wheat	0.1	0.04***
Tuberous and corm vegetables (Crop Subgroup 1C)	0.04	0.1
Hog, fat	0.04	0.4
Poultry, fat	0.04	0.1

- * No separate tolerance is established for the processed grape juice commodity and it is therefore covered by the tolerance for the raw agricultural commodity (RAC) “Grape.”
- ** No separate MRL is proposed for the processed sugar beet molasses commodity and it is therefore covered by the MRL proposed for the RAC sugar beet roots captured under “Root vegetables (Crop Subgroup 1A).”
- *** Covered by the tolerance established for “Grain, cereal, group 15, except rice, sorghum, pearl millet, and proso millet.”

Next Steps

The PMRA invites the public to submit written comments on the proposed domestic and import MRLs for spinetoram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs for spinetoram and posting an Established Maximum Residue Limit (EMRL) document on the PMRA’s website once the amendments to the FDA are in force.

Appendix I

Crop Groups: Numbers and Definitions

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
1A	Root and tuber vegetables/ Root vegetables	Black salsify roots Carrot roots Celeriac roots Chicory roots Edible burdock roots Garden beet roots Ginseng roots Horseradish roots Oriental radish roots Parsnip roots Radish roots Rutabaga roots Salsify roots Skirret roots Spanish salsify roots Sugar beet roots Turnip roots Turnip-rooted chervil roots Turnip-rooted parsley roots
1C	Root and tuber vegetables/ Tuberous and corm vegetables	Arracacha Arrowroot Cassava roots Chayote roots Chinese artichokes Chufa Edible canna Ginger roots Jerusalem artichokes Lerens Potatoes Sweet potato roots Tanier corm Taro corm True yam tubers Turmeric roots Yam bean roots

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
2	Leaves of root and tuber vegetables	Black salsify tops Cassava leaves Celeriac tops Chicory tops Edible burdock tops Garden beet tops Oriental radish tops Radish tops Rutabaga tops Tanier leaves Taro leaves Turnip tops Turnip-rooted chervil tops
4	Leafy vegetables except <i>Brassica</i>	Amaranth Arugula Cardoon Celery Celtuce Chinese celery Corn salad Dandelion leaves Dock Edible leaved chrysanthemum Endives Fresh chervil leaves Fresh Florence fennel leaves and stalk Fresh parsley leaves Garden cress Garden purslane Garland chrysanthemum Head lettuce Leaf lettuce New Zealand spinach Orach leaves Radicchio Rhubarb Spinach Swiss chard Upland cress Vine spinach Winter purslane
5A	<i>Brassica</i> (cole) leafy vegetables/ Head and stem <i>Brassica</i>	Broccoli Brussels sprouts Cabbages Cauliflower Chinese broccoli Chinese mustard cabbages Kohlrabi Napa Chinese cabbages

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
5B	<i>Brassica</i> (cole) leafy vegetables/ Leafy <i>Brassica</i> greens	Bok choy Chinese cabbages Broccoli raab Collards Kale Mustard greens Mustard spinach Rape greens
6A	Legume vegetables/ Edible-podded legume vegetables	Edible-podded dwarf peas Edible-podded jackbeans Edible-podded moth beans Edible-podded peas Edible-podded pigeon peas Edible-podded runner beans Edible-podded snap beans Edible-podded snow peas Edible-podded soybeans Edible-podded sugar snap peas Edible-podded swordbeans Edible-podded wax beans Edible-podded yardlong beans
6B	Legume vegetables/ Succulent shelled peas and beans	Succulent shelled blackeyed peas Succulent shelled broad beans Succulent shelled English peas Succulent shelled garden peas Succulent shelled green peas Succulent shelled lima beans Succulent shelled peas Succulent shelled pigeon peas Succulent shelled southern peas

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
6C	Legume vegetables/ Dried shelled peas and beans (except soybean)	Dry adzuki beans Dry beans Dry blackeyed peas Dry broad beans Dry catjang seed Dry chickpeas Dry field peas Dry guar seed Dry kidney beans Dry lablab beans Dry lentils Dry lima beans Dry moth beans Dry mung beans Dry navy beans Dry pigeon peas Dry pink beans Dry pinto beans Dry rice beans Dry southern peas Dry tepary beans Dry urd beans Grain lupin
8	Fruiting vegetables	Bell peppers Eggplants Groundcherries Non-bell peppers Pepinos Pepper hybrids Tomatillos Tomatoes
9	Cucurbit vegetables	Balsam apples Balsam pears Cantaloupes Chayote fruit Chinese cucumbers Chinese waxgourds Citron melons Cucumbers Edible gourds (other than those listed in this item) Muskmelons (other than those listed in this item) Pumpkins Summer squash Watermelons West Indian gherkins Winter squash

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
10	Citrus fruits	Calamondins Citrus citron Citrus hybrids Grapefruits Kumquats Lemons Limes Oranges Pummelos Satsuma mandarins Tangerines
11	Pome fruits	Apples Crabapples Loquats Mayhaws Oriental pears Pears Quinces
12	Stone fruits	Apricots Nectarines Peaches Plumcots Plums Prune plums Sweet cherries Tart cherries
13-07A	Berries and small fruits/ Caneberries	Blackberries Loganberries Raspberries (red and black) Wild raspberries Cultivars, varieties and hybrids of above commodities

Crop Group/ Subgroup Number	Name of the Crop Group/Subgroup	Food Commodities Included in the Crop Group/Subgroup
13-07B	Berries and small fruits/ Bushberries (Highbush cranberries and lingonberries are excluded from the proposed Subgroup MRL)	Aronia berries Buffalo currants Chilean guavas Currants (red and black) Elderberries European barberry Gooseberries Highbush blueberries Highbush cranberries Honeysuckle Huckleberries Jostaberries Lingonberries Lowbush blueberries Native currants Salal berries Saskatoon berries (juneberries) Sea buckthorn Cultivars, varieties and hybrids of above commodities
13-07F	Berries and small fruits/ Small fruits vine climbing, except fuzzy kiwifruit (Gooseberries are excluded from the proposed Subgroup MRL)	Amur river grapes Gooseberries Grapes Hardy kiwifruit Maypop Schizandra berries Cultivars, varieties and hybrids of above commodities
13-07G	Berries and small fruits/ Low growing berries (Lowbush blueberries and cranberries are excluded from the proposed Subgroup MRL)	Bearberries Bilberries Cloudberrries Cranberries Lingonberries Lowbush blueberries Muntries Partridgeberries Strawberries Cultivars, varieties and hybrids of above commodities