

October 28, 2021

**DIETARY EVALUATION - INTEGRATED ASSESSMENT****CATEGORY B.5.0**

<b>TGAI:</b>	Abamectin	S2020-5848
<b>Action Requested:</b>	Import MRLs on various commodities	
<b>Level D Deadline:</b>	2021-12-31	

The purpose of the current submission is to establish new import MRLs in/on tropical and subtropical fruits, small fruits, inedible peel (CSG 24A), carrot, chives (dried leaves), guava, pineapple, sweet corn when imported into Canada from the United States, and tea from Japan. In addition, the applicant has requested the revision or extension of currently established Canadian MRLs in/on green onions (CSG 3-07B), fruiting vegetables (CG8-09), citrus fruits (CG 10-R), pome fruits (CG 11-09), stone fruits (CG 12-09), small fruits vine climbing, except fuzzy kiwifruit (CSG 13-07F), low-growing berries (CSG 13-07G), tree nuts (CG 14-11), and papaya to align with US EPA tolerances.

There were no deficiencies identified under DACO Parts 6 and 7.

Label Amendments:

- None

**Dietary Exposure (Food Residue) Level D Status is PASSED.**

Completed by Louise Gabrielle Croteau on October 28, 2021.  
Sent for electronic approval to:  
Monique Thomas, Section Head, EXP-1, Health Evaluation Directorate

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**PART A. LIST OF SUBMITTED STUDIES FOR DACO PARTS 6 AND 7**

<b>PMRA Document Number</b>	<b>References</b>	<b>Review Status</b>
657891	Norton, J., 1991, Summary of Field Phases of Tree Nut Trials Supporting Residue Tolerances for Abamectin and Its Delta 8,9-Isomer In/On the Raw Agricultural Commodity, Tree Nuts, DACO: 7.4.1	Previously reviewed
1238942	Bull, D.L. et al, 1984, FATE OF AVERMECTIN B1A IN SOIL AND PLANTS, JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY, D.L. BULL ET AL, 1984 (32:94-102), Journal of Agricultural and Food Chemistry, Vol. 32, No.1, 1984, DACO: 6.3	Previously reviewed
1238978	1986, THE METABOLISM OF AVERMECTIN B1A IN GOATS, DACO: 6.2	Previously reviewed
1238979	Maynard, S.M. et al, 1989, FATE OF AVERMECTIN B1A IN LACTATING GOATS, Fate of Avermectin B1A In Lactating Goats, J. Agric. Food Chem., Vol. 37, No. 6, 1989, 0021-8561/89/1437-1491S01.S0/0, DACO: 6.4	Not relevant to current submission
1238980	1988, COMPARATIVE DEGRADATION OF AVERMECTIN B1A IN COTTON LEAF, CITRUS FRUIT, CELERY AND IN VITRO, DACO: 6.3	Previously reviewed
1238985	Iwata, Y., et al, 1985, RESIDUES OF AVERMECTIN B1A ON AND IN CITRUS FRUITS AND FOLIAGE, Residues of Avermectin B1a on and in Citrus Fruits and Foliage, J. of Agricultural and Food Chemistry, 1985., DACO: 6.3	Previously reviewed
1238986	1984, METABOLISM OF AVERMECTIN B1A IN CITRUS FRUITS, DACO: 6.3	Previously reviewed
1238987	1988, AVERMECTIN B1A METABOLISM IN CELERY. FINAL REPORT, DACO: 6.3	Previously reviewed
1238988	1986, FATE OF AVERMECTIN B1A ON COTTON PLANTS, DACO: 6.3	Previously reviewed
1289402	1996, Minor Use - Determination of the Magnitude of Residues of Avermectin B1 and 8,9-Z Avermectin B1 in/on the Raw Agricultural Commodity, Grapes, and in Grape Processing Fractions, from Abamectin 0.15 EC Applied with Non-Ionic Surfactant by Ground Equipment, DACO: 7.4.2	Previously reviewed
1995222	1998, M-073.1: HPLC-Fluorescence method for the quantification of avermectin B1 and 8,9-Z avermectin B1 in/on Fruits and Vegetables. Commodity - Stonefruit, DACO: 7.4.1	Previously reviewed
2334955	1999, Abamectin - Magnitudes of the Residue In or On Representative Commodities of Crop Group 12: Stone Fruits, DACO: 7.4.1	Previously reviewed
2352134	2008, Abamectin - Magnitude of the Residues in or on Apples and Pears as Representative Commodities of Fruit, Pome, Group 11, DACO: 7.4.1	Previously reviewed
2352135	2008, Abamectin - Magnitude of the Residues in or on Oranges, Grapefruit and Lemon as Representative Commodities of Citrus, Group 10, DACO: 7.4.1	Previously reviewed
2352169	2010, Abamectin - Magnitude of the Residues in or on Strawberries (A15368D), DACO: 7.4.2	Previously reviewed
2429153	2007, Abamectin - Storage Stability in Crops Stored Deep Frozen for up to Two Years - Final Report, DACO: 7.3	Previously reviewed
2429154	2013, Stability of Abamectin Residues in Representative Crop Raw Agricultural and Processed Commodities Under Freezer Storage Conditions, DACO: 7.3	Previously reviewed
2461282	1996, M-073: HPLC-Fluorescence Method for the Quantification of Avermectin B1 and 8,9-z Avermectin B1 in/on Fruits and Vegetables, DACO: 7.4.1	Previously reviewed

PMRA Document Number	References	Review Status
2461283	2014, Abamectin: Magnitude of the Residue on Tomato (Greenhouse), DACO: 7.4.1	Previously reviewed
2554149	2008, Determination of Abamectin Residues in Fruits and Vegetables (Raw Agricultural Commodity) by LC-MS/MS, DACO: 7.2.1	Previously reviewed
3180612	2020, EPA Approval of E-Submission of Amended Labeling for Avicta 400 FS Per Petition Proposing Tolerances for Abamectin in or on Edible-podded Legume Vegetables Subgroup 6A, Succulent Shelled Pea and Bean Subgroup 6B, and Dried Shelled Pea and Bean (Except Soybean) Subgroup 6C, D-537646, D-538792, D-D-538794, D-537648, D-538797, D-538798, D-537647, D-D-538800, D-538801, D-537649, D-555938, D-555932, D-537650, DACO: 1.4	US EPA labels
3180613	2017, EPA Approval of Avicta 500 FS Label Amendment to Revise Personal Protective Equipment, Seed Bag Tag and Other Revisions, D-509994, DACO: 1.4	US EPA labels
3180614	2016, EPA Approval of Revised Labeling for Epi-Mek 0.15 EC Miticide/Insecticide to Include Additional New Uses on Bean, Green Onion, Pome Fruit, Small Vine Climbing Fruit, Low Growing Berry, Fruiting Vegetable, Citrus, Stone Fruit, Nut, Tree, Various Tropical Fruits, D-478518, D-495161, D-495162, DACO: 1.4	US EPA labels
3180615	2020, EPA Approval of Email Submission of an Agri-Mek SC Miticide/Insecticide Supplemental Label that Failed to Progress Through the Last Stages of the Review and E-Submission of Notification for Agri-Mek SC Miticide/Insecticide to Address to Minor Revisions and Revised Final Printed Labeling Per EPA Approval Letter Dated January 16, 2020, D-559200, D-562589, DACO: 1.4	US EPA labels
3180616	2020, Agrimec A8612AI Japan Label Translation, DACO: 1.4	Tea label
3180617	2016, HED Review of Abamectin Petition for the Establishment of Permanent Tolerances and Registration for Use on Sweet corn and Soybeans; Summary of Analytical Chemistry and Residue Data, DP D414022, D-480190, PP3F8184; MRIDs 49071008, 49071010, 49071012, 49071016, DACO: 12.5.7	US EPA DERs (Sweet corn, storage stability)
3180618	2016, HED Review of Abamectin Petition for the Establishment of Tolerances and New uses on Bean, Various Tropical Fruits, Onion, Green, Subgroup 3-07B; Fruit, Pome, Group 11-10; Fruit, Small Vine Climbing, except Fuzzy Kiwifruit, Subgroup 13-07F; Berry, Low Growing, Subgroup 13-07G; and Conversion of Existing Crop Groups to Vegetable, Fruiting, Group 9-10 (and Addition of Greenhouse-grown Tomato); Fruit, Citrus, Group 10-10; Fruit, Stone, Group 12-12; and Nut, Tree, Group 14-12, Summary of Analytical Chemistry and Residue Data, DP D424008, D-495169, MRIDs 49455901, 49455902, 49455903, 49455904, 49455905, 49455906, 49455907, 49455908, DACO: 12.5.7	US EPA DER (greenhouse tomatoes, green onions, guava, lychee, papaya, and pineapple)
3180619	2019, HED Review of Abamectin Petition for Establishment of Tolerances and New Uses on Edible-podded Legume Vegetables Subgroup 6A, Succulent Shelled Pea and Bean Subgroup 6B, Dried Shelled Pea and Bean (except soybean) Subgroup 6C, and Carrots; Crop Group Expansions/Conversions of Tolerances to Tropical and Subtropical Small Fruit Inedible Peel Subgroup 24A, Leafy Greens Subgroup 4-16A, Leaf Petiole Vegetables Subgroup 22B; and Establish Individual Tolerances on Arugula, Garden Cress, Upland Cress, Celtuce, and Fennel Florence; Summary of Analytical Chemistry and Residue Data; DP D450916, D449498; D-537650, D-538802; PP7F8642, PP8E8664; MRIDs 50424401, 50426301, DACO: 12.5.7	US EPA DERs (carrots, CSG24A)

PMRA Document Number	References	Review Status
3180634	2017, 110917 Abamectin Tolerance Petition for abamectin on tea 2017, DACO: 7.1	Reviewed
3180635	2020, Abamectin - Available Data to Support Maximum Residue Limits in Imported Crops, DACO: 7.1	Applicant Summary Report.
3180636	2017, 110917 Abamectin_Japanese Report and MRL Report_Imp Tol Tea - Confidential Attachment, DACO: 7.4.1	Reviewed
3180637	2013, Abamectin 500 FS (A14006B) and Abamectin SC (A15368D) - Magnitude of the Residues in or on Sweet Corn Resulting from Seed Treatment Followed by Foliar Applications - USA, 2011, DACO: 7.4.1	Reviewed
3180638	2020, Crop Residue Analysis Report, Tea, DACO: 7.4.1	Reviewed
3180639	2018, Abamectin - Magnitude of the Residue on Carrot (Seed Treatment), DACO: 7.4.1	Reviewed
3180640	2014, Abamectin - Magnitude of the Residue on Guava, DACO: 7.4.1	Reviewed
3180641	2014, Abamectin - Magnitude of the Residue on Lychee, DACO: 7.4.1	Reviewed
3180642	2012, Abamectin - Magnitude of the Residue on Onion (Green), DACO: 7.4.1	Reviewed
3180643	2013, Abamectin - Magnitude of the Residue on Papaya, DACO: 7.4.1	Reviewed
3180644	2009, Abamectin - Magnitude of Residue on Chives, DACO: 7.4.1	Reviewed
3180645	2014, Abamectin - Magnitude of the Residue on Pineapple, DACO: 7.4.1	Reviewed
3196528	2016, EPA, Residues Resulting from Supervised Trials, DACO: 12.5.7	US EPA DER
3196535	2016, EPA, Residues Resulting from Supervised Trials, DACO: 12.5.7	US EPA DER
3196912	2016, EPA, EPA memorandum: Abamectin. Petition for the Establishment of Permanent Tolerances and Registration for Use on Sweet Corn and Soybeans. Summary of Analytical Chemistry and Residue Data, DACO: 12.5.7	US EPA DER
3196915	2016, EPA, EPA memorandum: Abamectin. Petition for the Establishment of Permanent Tolerances and Registration for New Uses on Bean, Various Tropical Fruits, Onion, Green. Subgroup 3-07B: Fruit, Pome. Group 11-10; Fruit, Small Vine Climbing, except Fuzzy Kiwifruit, Subgroup 13-07F; Berry, Low Growing, Subgroup 13-07G; and Conversion of Existing Crop Groups to Vegetable. Fruiting, Group 8-10 (and Addition of Greenhouse-grown Tomato); Fruit, Citrus, Group 10-10; Fruit, Stone, Group 12-12; and Nut, Tree, Group 14-12. Summary of Analytical Chemistry and Residue Data, DACO: 12.5.7	US EPA DER
3196921	2019, EPA memorandum: Abamectin. Petition for the Establishment of Permanent Tolerances and Registration for New Uses on Edible-podded Legume Vegetables Subgroup 6A, Succulent Shelled Pea and Bean Subgroup 6B, Dried Shelled Pea and Bean (except soybean) Subgroup 6C, and Carrots; Crop Group Expansions/Conversions of Tolerances to Tropical and Subtropical Small Fruit Inedible Peel Subgroup 24A, Leafy Greens Subgroup 4-16A, Leaf Petiole Vegetables Subgroup 22B; and Establish Individual Tolerances on Arugula, Garden Cress, Upland Cress, Celtnce, and Fennel Florence. Summary of Analytical Chemistry and Residue Data, DACO: 12.5.7	US EPA DER
3198172	2011, Residues Resulting from Supervised Trials, DACO: 12.5.7	US EPA DER

**PART B. BACKGROUND INFORMATION AND CHEMICAL IDENTITY**

Abamectin is an insecticide/miticide used to control mites, leaf miners, and other insects in commercially important crops. Avermectins are macrocyclic lactones produced as natural fermentation products of the soil bacterium *Streptomyces avermitilis*. Abamectin is a mixture of avermectin B1 [a mixture of avermectins containing greater than or equal to 80% avermectin B1a (5-*O*-demethyl avermectin A1) and less than or equal to 20% avermectin B1b (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A1)] and its delta-8,9-isomer. Abamectin has limited plant systemic activity, but does exhibit some translaminar movement. Abamectin acts as an insecticide by interfering with the nervous system of the insect, causing the insect to become paralyzed. Available mechanistic data indicate a neurotoxic mechanism of action, related to interference with GABA-mediated neurotransmission.

Abamectin is currently registered in Canada for use site categories (USCs): 5 (Greenhouse food crops), 6 (Greenhouse non-food crops), 13 (Terrestrial feed crops), 14 (Terrestrial food crops), and 20 (Structural).

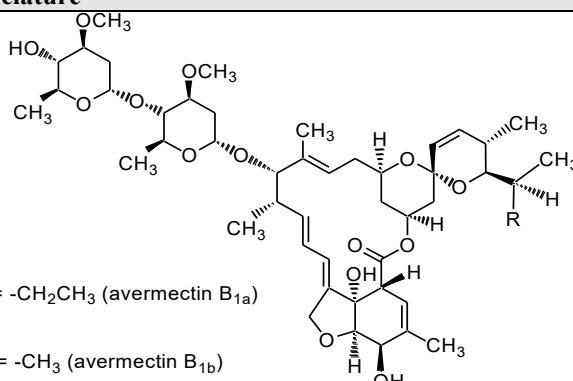
The applicant has proposed the following import MRLs (PMRA # 3180610).

Crop/CSG/CG	Proposed Harmonized MRL (ppm)	Rationale
Green Onions (CSG3-07B)	0.08	Harmonize Canadian MRL with established US crop subgroup tolerance based on US data only
Fruiting vegetables (CG8-09)	0.07	Harmonize Canadian MRL with established US crop group tolerance CG8-10
Citrus fruits (CG10-R)	0.02	Extrapolate established Canadian MRL to entire CG10-Revised
Pome fruits (CG11-09)	0.02	Extrapolate established Canadian MRL to entire crop group CG11-09
Stone fruits (CG12-09)	0.09	Extrapolate established Canadian MRL to entire crop group CG12-09
Small fruits vine climbing (CSG13-07F)	0.02	Extrapolate grape MRL to entire crop group 13-07F
Low growing berries (CSG13-07G)	0.05	Extrapolate strawberry MRL to entire crop group 13-07G
Tree nuts (CG14-11)	0.01	Extrapolate established Canadian MRL to entire crop group CG14-11
Tropical and subtropical fruits, small fruits inedible peel (CSG 24A)	0.01	New Canadian MRL requested based on lychee data
Carrots	0.03	New Canadian MRL requested
Chive, dried leaves	0.02	New Canadian MRL requested
Guava	0.015	New Canadian MRL requested
Papayas	0.4	Harmonize Canadian MRL with established US Tolerance; Current MRL is based on Brazil GAP
Pineapple	0.015	New Canadian MRL requested
Sweet corn	0.01	New Canadian MRL requested
Tea	1.0	New Canadian MRL requested

The nature of the residue of abamectin in plant commodities is adequately understood based on metabolism studies in/on citrus, celery, and cotton (S1991-1531, -1532, 1533; PMRA # 2160929). Adequate enforcement methods are available for plant commodities. The acceptability of the data gathering methods will be discussed as part of DACO 7.4.1 for each of the petitioned crops. Adequate storage stability data are available for residues of abamectin in five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries). The intervals of demonstrated storage stability cover the actual intervals of frozen storage of samples from the crop field trials.

Abamectin is currently under re-evaluation (S2015-1559). For a summary of the previously reviewed residue data on file refer to the Level D NTF for S2013-4347 (PMRA# 2532261) and to the preliminary review of the current submission (PMRA# 3191130). Only DACO Part 7.4.1 relevant to the current submission will be reported herein.

**The PMRA has utilized US EPA DERs for abamectin to facilitate the review process and establishment of MRLs on imported commodities. The studies reviewed by the US EPA were submitted to the PMRA.**

<b>TABLE B.1. Pesticide Nomenclature</b>	
Structure	 <p>(i) R = -CH<sub>2</sub>CH<sub>3</sub> (avermectin B<sub>1a</sub>)</p> <p>(ii) R = -CH<sub>3</sub> (avermectin B<sub>1b</sub>)</p>
Common name	Abamectin
IUPAC name	<p>Avermectin B<sub>1</sub>*            (i) abamectin B<sub>1a</sub>: (10E,14E,16E,22Z)-            (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'[(S)-sec-butyl]-21,24-dihydroxy-            5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo-[15.6.1.1<sup>4,8</sup>.0<sup>20,24</sup>]pentacosa-            10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-            (2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-            hexopyranoside</p> <p>ii) Abamectin B<sub>1b</sub>: (10E,14E,16E,22Z)-            (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-            5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1<sup>4,8</sup>.0<sup>20,24</sup>]pentacosa-            10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-            (2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-            hexopyranoside</p> <p>* including avermectin B<sub>1a</sub>, avermectin B<sub>1b</sub> (4:1) and the 8,9-Z isomers</p>
CAS name	5-O-demethylavermectin A <sub>1a</sub> + 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)avermectin A <sub>1a</sub> (4:1)
CAS #	71751-41-2

Parameter	Value	
Melting point/range	161.8-169.4 °C ( <u>decomp.</u> )	
Density (22 °C)	1.18	
Water solubility (25°C)	1.21 mg/L	
Solvent solubility (25°C)	Solvent	Solubility (g/L)
	Toluene	23
	Acetone	72
	Methanol	13
	Octanol	83
	Ethyl acetate	160
	Dichloromethane	470
Hexane	0.11	
Vapour pressure at 25°C	<3.7 x 10 <sup>-3</sup> mPa	
Octanol/water partition coefficient (log K <sub>ow</sub> ) @ pH 7.2, room temperature	4.4±0.3	

## PART C. REGULATORY STATUS

### CANADA

Country	Matrices	Dietary Exposure <sup>2</sup>	Enforcement <sup>1</sup>
Canada	Animal	Ruminant, poultry	Abamectin (including avermectin B <sub>1a</sub> , avermectin B <sub>1b</sub> (4:1) and the 8,9-Z isomers)
	Plant	Celery, citrus, cotton	
	Drinking Water		Abamectin and its transformation products NOA44811 and NOA44812
United States	All matrices	Avermectin B1 a mixture of avermectins containing greater than or equal to 80% avermectin B1 a (5- <i>O</i> -demethyl avermectin A1) and less than or equal to 20% avermectin B1b (5- <i>O</i> -demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A1) and its delta-8,9-isomer	

<sup>1</sup> RDs established in Health Canada's RD Table

<sup>2</sup> RD as per Sub. No. 2013-4347/ PMRA# 2532260.

Crop/CSG/CG	CDN MRL (ppm)	US Tolerance (ppm)	Codex MRL (ppm)
Green Onions	0.01(CSG3-07B)	0.08 (CSG3-07B)	0.01
Fruiting vegetables	0.02 (CG8-09, except tomatoes)	0.07 (CG8-10)	0.09 (peppers, sweet including pimento or pimienta)
	0.07 (GH tomatoes)		0.05 (tomatoes)
Citrus fruits	0.02 (CG10)	0.02 (CG10-10)	0.02
Apples, pears	0.02	0.02 (CG11-10)	0.01 (pome fruits)
Stone fruits	0.09 (CG12)	0.09 (CG12-12)	0.07 (cherries); 0.03 (peaches including apricots and nectarine subgroup);



<b>TABLE C.2. Abamectin: Currently Established Canadian MRLs, US Tolerances, and Codex MRLs.</b>			
<b>Crop/CSG/CG</b>	<b>CDN MRL (ppm)</b>	<b>US Tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
			0.005 (plums including fresh prunes)
Grapes	0.02	0.02 (CSG 13-07F)	0.03
Strawberries	0.05	0.05 (CSG 13-07G)	0.15
Tree nuts and pistachios	0.01(CG14)	0.01 (CG 14-12)	0.005
Tropical and subtropical fruits, small fruits inedible peel (CSG 24A)	-	0.01	-
Carrots	-	0.03	-
Sweet corn	-	0.01	0.002
Pineapple	-	0.015	0.002
Guava	-	0.015	-
Chive, dried leaves <sup>1</sup>	-	0.02	0.08
Tea	-	1.0	-
Papayas	0.03	0.4	0.01

1. An MRL of 0.01 ppm is currently established for fresh chive leaves.

## **PART D. DIRECTIONS FOR USE**

### ***DACO 1 - Directions for Use***

<b>PMRA #</b>	<b>References</b>
3180612	Avicta 400 FS -US EPA label: EPA Reg. No. 100-1211
3180613	Avicta 500 FS - US EPA label: EPA Reg. No. 100-1204
3180614	Epi-Mek 0.15 EC Miticide/Insecticide - US EPA label: EPA Reg. No. 100-1154
3180615	Agri-Mek SC Miticide/Insecticide - US EPA label: EPA Reg. No. 100-1351
3180616	AgriMec (Japan Reg. No. 23235); Label Translation

<b>Registered Use Directions for Avicta® 400 FS (EPA Reg. No. 100-1211)</b>			
<b>Seed treatment – Guarantee: 37% Abamectin (400 g a.i./L)</b>			
<b>Crop</b>	<b>Use Rate/Appl. (mg ai/seed)</b>	<b># Application / RTI</b>	<b>PHI and Crop Specific Restrictions</b>
Carrots	0.016	N/A	Treated seed of carrot must be planted at a depth of at least 0.125 inches.

<b>Registered Use Directions for Avicta® 500 FS (EPA Reg. No. 100-1204)</b>				
<b>Flowable concentrate – Guarantee: 46.3% Abamectin (500 g a.i./L)</b>				
<b>Crop</b>	<b>Use Rate/Appl. (mg a.i./seed)</b>	<b># Application / RTI</b>	<b>Max. Rate (g a.i./ha/year)<sup>1</sup></b>	<b>PHI and Crop Specific Restrictions</b>
Corn Seed	0.2-0.25	N/S	37	Do not use treated seed for feed food, or oil purposes. Treated seed must be planted into the soil at a depth greater than 1 inch.

<b>Registered Use Directions for Avicta® 500 FS (EPA Reg. No. 100-1204)</b>				
<b>Flowable concentrate – Guarantee: 46.3% Abamectin (500 g a.i./L)</b>				
<b>Crop</b>	<b>Use Rate/Apl. (mg a.i./seed)</b>	<b># Application / RTI</b>	<b>Max. Rate (g a.i./ha/year)<sup>1</sup></b>	<b>PHI and Crop Specific Restrictions</b>
<b>Tank mixes:</b>				
<ul style="list-style-type: none"> <li>To add early-season disease and insect protection, treat corn seed with a mixture of Avicta 500 FS plus Apron XL®, Cruiser® 5FS, Dynasty®, and/or Maxim XL®. Follow complete label directions on all products used to treat seeds.</li> </ul>				

<sup>1</sup> Do not use at a rate that will result in more than 0.033 lb (15 g ai) as a corn seed treatment application per acre per calendar year (Avicta label; PMRA# 3180613).  $g\ a.i./ha/year = (15\ g\ ai/A) \times (1\ A/0.404686\ ha) = 37\ g\ a.i./ha.$

Note: Only registered use directions relevant to the current submission were included in the above table.

<b>Registered Use Directions</b>					
<b>Epi-Mek® 0.15 EC Miticide/Insecticide (EPA Reg. No. 100-1154)– Guarantee: 2.0% Abamectin (18 g a.i./L)</b>					
<b>Agri-Mek® SC Miticide/Insecticide (EPA Reg. No. 100-1351)- Guarantee: 8.0% (84 g a.i./L)</b>					
<b>Application</b>	<b>Use Rate/Apl. (g a.i./ha)</b>	<b># Application<sup>1</sup> /RTI</b>	<b>Max. Rate (g a.i./ha)</b>	<b>Use of Adjuvant</b>	<b>PHI (days)</b>
<b>Crop Subgroup 3-07B [Green onion]</b>					
Postemergence; Broadcast foliar spray; Ground or aerial	10.5-21.3	2/ 7 days	85.1	Non-ionic activator type wetting, spreading, and/or penetrating adjuvant	7
<b>Crop Group 8-10 [Fruiting vegetables] (except Greenhouse-Grown Tomatoes)</b>					
Postemergence; Broadcast foliar spray; Ground or aerial	10.5-21.3	2/ 7 days	62.7	Must be applied in combination with a non-ionic surfactant to improve wetting of foliage and to smooth out spray deposits.	7
<b>Greenhouse-grown Tomatoes (Agri-Mek SC Only)</b>					
Postemergence; Broadcast foliar spray; Ground only	10.5-21.3	2/7 days	62.7	Must always be mixed with non-ionic activator type wetting, spreading and/or penetrating spray adjuvant or horticultural oil (not a dormant oil).	1
<b>Crop Group 10-10 [Citrus fruits]</b>					
Broadcast foliar spray; Ground or aerial	6.6-25.8	3 / 30 days	52.6	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	7
<b>Crop Group 11-10 [Pome Fruits]</b>					
Postemergence; Broadcast foliar spray; Ground only	13.4-25.8	2/ 21 days	52.6	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	28
<b>Crop Group 12-12 [Stone fruits]</b>					
Broadcast foliar spray; Ground only	13.4-25.8	2/ 21 days	52.6	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	21
<b>Crop Subgroup 13-07F [Small Fruit Vine Climbing Subgroup (Except Fuzzy Kiwifruit)]</b>					

<b>Registered Use Directions</b>					
<b>Epi-Mek® 0.15 EC Miticide/Insecticide (EPA Reg. No. 100-1154)– Guarantee: 2.0% Abamectin (18 g a.i./L)</b>					
<b>Agri-Mek® SC Miticide/Insecticide (EPA Reg. No. 100-1351)- Guarantee: 8.0% (84 g a.i./L)</b>					
Application	Use Rate/Apl. (g a.i./ha)	# Application <sup>1</sup> /RTI	Max. Rate (g a.i./ha)	Use of Adjuvant	PHI (days)
Postemergence; Broadcast foliar spray; Ground only	10.5-21.3	2/ 21 days	42.6	Must be applied in combination with a non-ionic surfactant to improve wetting of foliage and to smooth out spray deposits.	28
<b>Crop Subgroup 13-07G [Low Growing Berry]</b>					
Postemergence; Broadcast foliar spray; Ground only	21.3	minimum 3 / 7-21 days	85.1	Not specified.	3
<b>Crop Group 14-12 [Tree Nuts]</b>					
Broadcast foliar sprays; Ground only	13.4-25.8	2 / 21 days	52.6	Dilute or concentrate spray. Always use with a horticultural spray oil (not a dormant oil).	21
<b>Crop Subgroup 19A [Herbs]</b>					
Broadcast foliar spray; Ground only	10.6-21.3	2 / 7 days	62.7	Do not use a surfactant when applying this product to chives.	Chives: 7 Others: 14
<b>Guava</b>					
Broadcast foliar spray; Ground only	13.4-25.8	3/ 14 days	78.4	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	7
<b>Crop Subgroup 24A [Tropical and subtropical fruits, small fruits inedible peel]</b>					
Broadcast foliar spray; Ground only	13.4-25.8	2 / 30 days	51.5	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	14
<b>Papaya</b>					
Broadcast foliar spray; Ground only	13.4-25.8	3 / 14 days	78.4	Dilute or concentrate sprays. Apply with horticultural spray oil (not a dormant oil) in the spray mixture.	3 (EC) 7 (SC)
<b>Pineapple</b>					
Broadcast foliar spray; Ground only	13.4-25.8	2 / 7 days	51.5	Not specified.	16 weeks
<b>Sweet Corn – Agri-Mek SC ONLY</b>					
Broadcast foliar spray; Ground or aerial	10.8-21.3	2/ 7 days	42.6	Must always be mixed with non-ionic activator type wetting, spreading and/or penetrating spray adjuvant or horticultural oil (not a dormant oil).	7
<b>Specific Restrictions:</b>					
Apply in a minimum of 50 GPA with conventional ground equipment or 5 GPA with an electro-static sprayer.					

<sup>1</sup> NS = not specified

Note: Only registered use directions relevant to the current submission were included in the above table.

<b>Use Directions for Agrimec (Japan Reg. No. 23235) on Tea.</b>					
<b>Liquid Emulsion – Guarantee: 1.8% Abamectin; 1.44% Avermectin B1a; 0.36% Avermectin B1b</b>					
<b>Application</b>	<b>Dilution Rate (fold)</b>	<b>Use Rate/Appl. (L/10a) [g a.i./ha]<sup>1</sup></b>	<b># Application</b>	<b>Max. Rate (L/10a) [g a.i./ha]</b>	<b>PHI</b>
Spray; 7 days before plucking	1000	200-400 [36-72]	1 app	400 [72]	7 days

<sup>1</sup> Application rates in g a.i./ha were calculated by the evaluator as follows: (Note 10a=1000m<sup>2</sup>=0.1 ha)

(200 L/10a)\*(10a/0.1 ha) = 2000 L/ha.

(2000 L/ha)/ 1000 dilution = 2 L/ha.

(2 L/ha)\* (1.8 g/100 mL) \* (100 mL/0.1 L) = 36 g a.i./ha

Note: Only registered use directions relevant to the current submission were included in the above table.

### **Final Assessment:**

The registered labels from the U.S. and Japan are acceptable to allow evaluation of the submitted field trials relative to the requested import MRLs.

## **PART E. RESIDUE DATA IN COMMODITIES OF PLANT ORIGIN - PRIMARY CROPS**

### ***DACO 7.4 – Crop Residue Data (Food and/or Feed Commodities)*** ***[OECD B.7.6.1 Residues in Target Crops]***

## **PART 1. RE-ASSESSMENT OF FILE DATA- NO NEW DATA SUBMITTED**

Harmonize Canadian MRL with US Tolerances: CSG3-07B; CG8-09

Update Crop Groups to include all commodities: CG10-R, CG12-09, CG14-11

Extend Representative Crops to Crop Subgroup:

Apples and Pears	→	CG11-09
Grapes	→	CSG13-07F
Strawberries	→	CSG13-07G

Under S2013-4347, Syngenta had requested that import MRLs be established on CG8-09, CG10-Revised, CG11-09, CG12-09, CSG13-07F (based on grapes), CSG13-07G (based on strawberries), and CG14-11. At the time, there were no US tolerances established for uses on these revised/updated crop groups/subgroups. Therefore, MRLs were set on crop groups listed under DIR98-02 (CG8, CG10, CG11, CG12, CG14, grapes and strawberries). Under S2016-7442, the MRL for CG8 was extended to all crops within CG8-09. The United States has since established tolerances on the relevant revised crop groups/subgroups. Previously reviewed residue data from field trials conducted on the representative commodities from each of the crop groups/subgroups were reassessed under the current submission.

The registered use directions for the Agri-Mek SC Miticide/Insecticide are identical to those on the Epi-Mek EC Miticide/Insecticide in terms of timing, application rate, minimum PHI, and other use restrictions. The only difference is that the label for the SC requires the addition of a horticultural oil or surfactant to the spray mix for applications to all crops. It should be noted that

bridging data in/on leafy vegetables, fruiting vegetables, cucurbit vegetables, citrus fruits, and strawberries conducted with EC and SC formulated products indicated that the total abamectin residues were generally of the same order of magnitude. As per S2013-4347 (PMRA# 2532261) and S2013-5526 (PMRA# 2459314), EC data has been used to support the registration of the SC formulated product.

The data reported below reflects the highest residues, observed from either the EC or the SC formulation, used to establish the MRLs.

<b>TABLE E.1. Summary of Field Trial and Processing Data Used to Support Existing MRLs.</b>						
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues* (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT		
<b>CSG3-07B (Level D NTF PMRA# 2321578)- EC data</b>						
Green onions	Foliar/88.5 – 91.5	6-8	<0.004	<0.0046	0.01 (CSG3-07B)	None (See Final Assessment)
<b>Fruiting Vegetables: CG8-09 (Tomato GH: Level D NTF; PMRA# 2497904)- EC data (Nonbell peppers/Bell peppers: Level D NTF; PMRA# 2532261)- SC data</b>						
Tomatoes (standard size and cherry tomatoes)	Foliar/66-70	1	0.006	0.041	0.07 (GH tomatoes)	0.07 (CG 8-09)
Non-bell peppers	Foliar/62-64	7	<0.006	<0.010	0.02 (CG8-09, except tomatoes)	
Bell peppers	Foliar/ 63-66	7	<0.006	<0.012		
<b>Citrus Fruits: CG10 (Level D NTF PMRA# 2532261)- SC data</b>						
Oranges	Foliar/ 51.1 – 54.4	7	<0.004	<0.007	0.10 (citrus oil) 0.02 (CG10)	0.02 (CG10-R)
Grapefruit	Foliar/ 51.1 – 53.4	6 – 7	<0.004	<0.006		
Lemons	Foliar/ 51.5 – 53.1	7	<0.004	<0.008		
<b>Apples and Pears (S1991-1531, -1532, 1533; PMRA # 2160929)- EC data</b>						
Apples	Foliar/54-56	28	<0.004	0.0126	0.02 (apples)	0.02 (CG11-09)
Pears	Foliar/54	21	<0.004	0.0105	0.02 (pears)	
<b>Stone Fruits: CG12 (Level D NTF PMRA# 2532261)- EC data</b>						
Sweet cherries	Foliar/ 52.4	21	<0.006	<0.019	0.09 (CG12)	0.09 (CG 12-09)
Tart cherries	Foliar/ 52.4	21	<0.008	0.053		
Peaches	Foliar/ 52.4	21 – 22	<0.004	0.026		
Plums	Foliar/ 53.8	21	<0.004	<0.006		
<b>Grapes (Level D NTF PMRA# 1748779)- EC data</b>						
Grapes	Foliar/41.5-43.7	28	<0.004	<0.0079	0.02 (grapes)	0.02 (CSG13-07F)
<b>Strawberries (Level D NTF PMRA# 2459314)- SC data</b>						

<b>TABLE E.1. Summary of Field Trial and Processing Data Used to Support Existing MRLs.</b>						
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues* (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT		
Strawberries	Foliar/88	3	0.009	0.027	0.05	0.05 (CSG13-07G)
<b>Tree Nuts: CG14 (Level D NTF PMRA# 2532261)- EC data</b>						
Almonds	Foliar/ 81	21	<0.01	<0.01	0.01 (CG14)	0.01 (CG 14-11)
Pecans	Foliar/ 81	21	<0.01	<0.01		

LAFT = lowest average field trial; HAFT = highest average field trial

\* Total residues of avermectin B<sub>1</sub> (avermectin B<sub>1a</sub> and avermectin B<sub>1b</sub>) and the 8,9-Z isomer

### **Final Assessment:**

No new data have been submitted. Adequate data have previously been submitted and reviewed to support extrapolating the current MRLs to the revised crop groups/subgroups of CG10-R, CG11-09, CG12-09, CSG13-07F, CSG13-07G, and CG14-11 and aligning the Canadian MRL for CG8-09 with the US Tolerance. However, aligning the MRL for CSG3-07B with the US tolerance could not be supported. The following provides a detailed assessment of the file data.

- **CSG3-07B:** The applicant requested that the current MRL of 0.01 ppm for CSG 3-07B be aligned with the US tolerance of 0.08 ppm, which was established following the submission of an IR-4 petition (PMRA# 3180633). While the same green onion field trial data, summarized above and in the IR-4 report, were reviewed by the US EPA and the PMRA, no scientific justification is provided in this report for increasing the US tolerance from 0.01 ppm to 0.08 ppm. Based on e-mail exchanges with Syngenta (PMRA# 3278706), there are no new green onion field trial data available to support a higher MRL. In turn, there is insufficient scientific evidence to support increasing the MRL from 0.01 ppm to 0.08 ppm for CSG3-07B.
- **CG8-09:** Tomato (standard size and one cultivar of small tomato), bell pepper and one cultivar of nonbell pepper; once cultivar of small nonbell pepper or one cultivar of small eggplant are the representative crops for fruiting vegetables (CG8-09). Adequate field trial data are available reflecting the use of EC and SC formulations on tomato (field and greenhouse), bell pepper, and chili pepper from field uses. The same data was reviewed by the US EPA and the PMRA. Currently, an MRL of 0.02 ppm is established in/on CG8-09, except tomatoes, and an MRL of 0.07 ppm is established in/on tomatoes based on greenhouse data. The US EPA has revised the tolerance of CG8-09 to 0.07 ppm to cover the residue data on greenhouse-grown tomatoes. Aligning the MRL with the US tolerance of 0.07 ppm can be supported as it will cover any potential residues in all fruiting vegetables grown in the field. Although the PHI is 1 day for greenhouse tomatoes, it will represent the worse case scenario as residue decline data show that residues of abamectin decrease with increasing PHIs.
- **CG10-R:** Orange or tangerine, lemon or lime and grapefruit are the representative crops for citrus fruits (CG10-R). Adequate field trial data are available reflecting the use of EC

and SC formulations on oranges, lemons and grapefruits. Therefore, the established MRL of 0.02 ppm in/on CG10 can be extended to all commodities within CG10-Revised.

- CG11-09: Apples and pears are the representative crops for pome fruits (CG11-09). Adequate field trial data are available reflecting the use of EC and SC formulations on apple and pear. Therefore, the established MRL of 0.02 ppm in/on apples and pears can be extended to all commodities within CG11-09.
- CG12-09: Sweet cherry or tart cherry, peach, and plum or prune plum are the representative crops for stone fruits (CG12-09). Adequate field trial data are available reflecting the use of EC and SC formulations on cherries, peaches, and plums. Therefore, the established MRL of 0.09 ppm in/on CG12 can be extended to all commodities within CG12-09.
- CSG13-07F: Grapes are the representative crop for small fruits vine climbing, except fuzzy kiwifruit (CSG13-07F). Adequate field trial data are available reflecting the use of an EC formulation on grapes. The data can be used to support the SC formulation as the use directions for the SC formulation are identical, with the exception of the requirement for a non-ionic surfactant or a horticultural oil in the spray mix. Furthermore, bridging data in/on leafy vegetables, fruiting vegetables, cucurbit vegetables, citrus fruits, and strawberries conducted with EC and SC formulated products demonstrated that the total abamectin residues were generally of the same order of magnitude. Therefore, the established MRL of 0.02 ppm in/on grapes can be extended to all commodities within CSG13-07F.
- CSG13-07G: Strawberries are the representative crop for low growing berries (CSG13-07G). Adequate field trial data are available reflecting the use of EC and SC formulations on strawberries. Therefore, the established MRL of 0.05 ppm in/on strawberries can be extended to all commodities within CSG13-07G.
- CG14-11: Almonds and pecans are the representative crop for tree nuts (CG14-11). Adequate field trial data are available reflecting the use of EC and SC formulations on almonds and pecans. Therefore, the established MRL of 0.01 ppm in/on almond nuts, pecan nuts and pistachios can be extended to all commodities within CG14-11.

**PART 2. Newly Submitted Data for the Establishment of Import MRLs****[Carrots, dried chive leaves, guava, lychee (extended to CSG24A), papaya, pineapple, sweet corn, and tea].****CARROTS****Submitted Data:**

PMRA #	References	Comments
3180639	2018, Abamectin - Magnitude of the Residue on Carrot (Seed Treatment), DACO: 7.4.1	US EPA DER PMRA#:3196528

NUMBER AND LOCATION OF FIELD TRIALS							
Crop	No. Trials	NAFTA Growing Zone					Total
		3	5	6	10	11	
Carrot	Submitted	1	2	1	4	1	9
	Required <sup>1</sup>	1	1	1	4	1	8
<sup>1</sup> As per Table 5 of OPPTS Guideline 860.1500 for carrot.							
USE PATTERN							
US EPA registered use pattern (GAP) for Avicta® 400 FS [Reg. No. 100-1211]				Use pattern in the study			
Seed treatment using a 400 g ai/L flowable concentrate formulation at 0.016 mg a.i./seed. PHI not specified.				Seed treatment using a 400 g ai/L flowable concentrate formulation at 0.016-0.017 mg a.i./seed. Samples were harvested 71-128 days after planting.			
ANALYTICAL METHOD AND FREEZER STORAGE							
RAC	Method ID (Type)					Actual storage duration <sup>2</sup>	
Carrot root	LC-MS/MS method, Morse Analytical Method, Meth-192/Revision #2 (with modifications) LOQ = 0.002 ppm for each of avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub> Combined LOQ = 0.006 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>					456-731 days (15-24 months)	
<sup>2</sup> Interval from harvest to extraction. Samples were analyzed within 0-1 days of extraction.							

Residue Data from Carrot Field Trials with Abamectin.									
Location: City, State; Year (Trial ID 10893.13-)	Zone	Crop Variety	Matrix	Rate (mg ai/seed)	PHI (days)	Residues (ppm parent equivalents) [Average]			
						Avermectin B <sub>1a</sub>	8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined <sup>4</sup>
Holtville, CA; 2013-2014 (CA83)	10	Maverick	Root	0.0163	124	<0.002, <0.002	<0.002, <0.002	<0.002, <0.002	<0.006, <0.006
						[<0.002]	[<0.002]	[<0.002]	[<0.006]
Parlier, CA; 2013 (CA84)	10	Scarlet Nantes	Root	0.0165	99	<0.002, <0.002	<0.002, <0.002	<0.002, <0.002	<0.006, <0.006
						[<0.002]	[<0.002]	[<0.002]	[<0.006]
Riverside, CA; 2013 (CA85)	10	Sugar Snax 54	Root	0.0162	71	0.0025, 0.0022	<0.002, <0.002	<0.002, <0.002	<0.0065, <0.0062
						[0.0023]	[<0.002]	[<0.002]	[<0.0064]
Salinas, CA; 2013 (CA*86)	10	Mokum	Root	0.0158	79	<0.002, <0.002	<0.002, <0.002	<0.002, <0.002	<0.006, <0.006
						[<0.002]	[<0.002]	[<0.002]	[<0.006]



Residue Data from Carrot Field Trials with Abamectin.									
Location: City, State; Year (Trial ID 10893.13-)	Zone	Crop Variety	Matrix	Rate (mg ai/seed)	PHI (days)	Residues (ppm parent equivalents) [Average]			
						Avermectin B <sub>1a</sub>	8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined <sup>4</sup>
Citra, FL; 2013 (FL30)	3	Nelson	Root	0.0168	75	0.0032, 0.0038 [0.0035]	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.0072, <0.0078 [<0.0075]
Willard, OH; 2013 (OH*13)	5	Scarlet Nantes	Root	0.0161	117	0.0131, 0.0163 [0.0147]	<0.002, <0.002 [<0.002]	0.0003, <0.002 [<0.003]	<0.0171, 0.0203 [<0.0187]
Weslaco, TX; 2013-2014 (TX15)	6	Mokum F1	Root	0.0161	128	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.006, <0.006 [<0.006]
Moxee, WA; 2013 (WA*25)	11	Chantenay Red Core	Root	0.0167	120	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.006, <0.006 [<0.006]
Arlington, WI; 2013 (WI17)	5	Naval	Root	0.0161	105	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.006, <0.006 [<0.006]

Summary of Residues from Carrot Field Trials with Abamectin.									
Crop	Analytes	Total Rate (mg a.i./seed)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Carrot root	Avermectin B <sub>1a</sub>	0.016-0.017	71-128	9	<0.002	0.015	<0.002	0.004	0.004
	8,9-Z-avermectin B <sub>1a</sub>				<0.002	<0.002	<0.002	<0.002	-
	Avermectin B <sub>1b</sub>				<0.002	<0.002	<0.002	<0.002	-
	Total Abamectin <sup>4</sup>				<0.006	0.019	<0.006	0.008	0.004

<sup>1</sup>PHI = Preharvest interval.

<sup>2</sup> n = number of independent field trials.

<sup>3</sup>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 (0.002 ppm).

<sup>4</sup>Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### Final Assessment – CARROTS:

- Nine field trials were conducted in the **United States** during the 2013-2014 growing season in the North American Free Trade Agreement (NAFTA) Growing Zones 3 (FL; 1 trial), 5 (OH and WI; 2 trials), 6 (TX; 1 trial), 10 (CA; 4 trials), and 11 (WA; 1 trial). The US EPA determined that a sufficient number of trials were conducted in geographically appropriate regions to support the establishment of a tolerance. All trials were considered independent.
- The submitted carrot field trials were conducted at a rate equivalent to 1.06-fold the maximum registered GAP of Avicta 400 FS. Samples from all trials were harvested at PHIs of 71 to 128 days, corresponding to mature harvest. The label does not specify a PHI for seed treatment.
- Samples of carrot from the field trials study were analyzed for residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> using a high performance liquid chromatography method with tandem mass spectrometric detection (LC-MS/MS), Morse Analytical Method Meth-192/Revision #2. Briefly, abamectin residues were extracted with acetonitrile (ACN):0.1% phosphoric acid (25:75, v:v), and the residues were partitioned

into hexane. An aliquot of the hexane extract was purified using aminopropyl solid-phase extraction; residues were eluted with ethyl acetate:methanol (75:25, v:v). The eluate was evaporated to dryness and redissolved in ACN for additional cleanup with 3-aminopropyl-functionalized silica gel prior to analysis.

- The method was adequate for data collection based on acceptable concurrent recovery data, generally within 70-120%. The fortification levels for avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> were 0.002-0.02 ppm, and 0.0016 ppm for avermectin B<sub>1b</sub>. (0.002 ppm), (0.002-0.020 ppm) used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation (LLMV) was 0.002 ppm for each analyte in carrot matrices, for a combined LLMV of 0.006 ppm.
- Carrot field trial samples were stored frozen (<-18°C) at the analytical laboratory from collection to analysis for 24 months. Samples were analyzed within 1 day of extraction. Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.
- In addition, concurrent storage stability data were provided for carrot roots, which demonstrate that residues of avermectin B<sub>1a</sub>, avermectin B<sub>1b</sub>, and 8,9-Z avermectin B<sub>1a</sub> are stable under frozen storage conditions in/on carrot roots for 749 days (25 months). Therefore, the available storage stability data is acceptable to support the storage conditions and durations in carrot as a high starch content commodity.
- Per-trial average residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>, respectively, in carrots harvested at PHIs of 71-128 days were <0.002-0.015 ppm, <0.002 ppm, and <0.002 ppm. Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> were <0.006-0.019 ppm. Residue decline was not evaluated.

**Recommended MRL**

Abamectin Carrots US 982-1382 g a.i./100 kg seeds	
Total number of data (n)	9
Percentage of censored data	67%
Number of non-censored data	3
Lowest residue	0.006
Highest residue	0.019
Median residue	0.006
Mean	0.008
Standard deviation (SD)	0.004
Correction factor for censoring (CF)	0.556
<b><u>Proposed MRL estimate</u></b>	
- Highest residue	0.019
- Mean + 4 SD	0.024
- CF x 3 Mean	0.013
Unrounded MRL	<u>0.024</u>
Rounded MRL	<u><b>0.03</b></u>
High uncertainty of MRL estimate. [High level of censoring]	

Residues (mg/kg)	n
< 0.006	6
0.0064	1
0.0075	1
0.0187	1

MRLs in/on Carrot Roots for Abamectin				
OECD MRL Calculator Output (ppm)	Recommended Canadian MRL (ppm)	Current Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
0.03	0.03	Not established	0.03	Not established

Acceptable abamectin residue data were provided to calculate the recommended MRL on imported carrots from the United States.

**DRIED CHIVE LEAVES****Submitted Data:**

PMRA #	References	Comments
3180644	2009, Abamectin - Magnitude of Residue on Chives, DACO: 7.4.1	US EPA DER: PMRA# 3198172

NUMBER AND LOCATION OF FIELD TRIALS				
Crop	No. Trials	NAFTA Growing Zone		Total
		2	11	
Chives	Submitted	2	1	3
	Required <sup>1</sup>			3

<sup>1</sup> As per Table 1 of OPPTS Guideline 860.1500; three crop field trials are required for chive. Geographic distribution is not specified for crops requiring ≤ 3 trials. Chive is not included in Table 6 of OPPTS 860.1500, which reports regional distribution of crop production.

USE PATTERN	
Registered Use Pattern (GAP) for Epi-Mek 0.15 EC and Agri-Mek SC	Study Use Pattern
Two foliar broadcast applications, 10.6-21.3 g a.i./ha/application, maximum of 62.7 g a.i./ha. 7-day RTI; 7-day PHI. A non-ionic surfactant and/or horticultural oil is required for use with SC formulation.	Three applications of an EC formulation of abamectin (Agri-Mek 0.15 EC) were made to the treatment plots as foliar broadcast applications at 21.3-22.4 g a.i./ha/application, with RTI of 6-7 days for a total seasonal rate of 63.8-66.1 g a.i./ha. Fresh chives were harvested at a PHI of 7 days. An additional sample was harvested at 13 days to assess residue decline. An adjuvant was not used for any of the applications.

ANALYTICAL METHOD AND FREEZER STORAGE		
RAC	Method ID (Type)	Actual storage duration <sup>2</sup>
Chive leaves	Merck Method No. M-073 (HPLC with fluorescence detection) LLMV = 0.002 ppm for avermectin B <sub>1a</sub> , and 8,9-Z avermectin B <sub>1a</sub> LLMV = 0.002 ppm for avermectin B <sub>1b</sub> Combined LOQ = 0.004 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	Trial WA 27: Fresh Chives: 637 days (20.9 months) Dried Chives: 615 days (20.2 months)

<sup>2</sup> Interval from harvest to extraction. Samples were analyzed within 1 day of extraction.

Residue Data from Crop Field Trials with Abamectin.								
Trial ID (City, State/Year)	Zone	Crop/ Variety	Commodity	Total Rate (g a.i./ha)	PHI (days)	Avermectin B <sub>1a</sub> and 8,9-Z Avermectin B <sub>1a</sub> (ppm)	Avermectin B <sub>1b</sub> and 8,9-Z Avermectin B <sub>1b</sub> (ppm)	Combined Residues (ppm)
						[Average Residues]		
Bridgeton, NJ/2001 (07102.01- NJ36)	2	Chives/Chive	Fresh leaves	66.1	5	<0.0020	<0.0020	<0.0040
						<0.0020	<0.0020	<0.0040
Moxee, WA/2000 (07102.00- WA*27)	11	Chives/Staro	Fresh leaves	66.1	7	0.0022	<0.0020	0.0042
						<0.0020	<0.0020	0.0040
					13	<0.0020	<0.0020	<0.0040
						[<0.0020]	[<0.0020]	[<0.0040]

Salisbury, MD/1999 (07102.99- MD05)	2	Chives/Fancy	Fresh leaves	63.8	7	<0.0020 0.0025 [0.0022]	<0.0020 0.0020 [<0.0020]	<0.0040 0.0045 [0.0042]
Moxee, WA/2000 (07102.00- WA*27)	11	Chives/Staro	Dried leaves	66.1	7	0.0101	<0.0020	0.0121

#### Summary of Residue Data from Fresh Chive Leaves.

Commodity	Total Applic. Rate (g a.i./ha)	PHI <sup>1</sup> (days)	Residue Levels <sup>4</sup> (ppm)					
			n <sup>2</sup>	LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	Std. Dev. <sup>3</sup>
<b>Total Combined Residues (Avermectin B<sub>1a</sub>, 8,9-Z Avermectin B<sub>1a</sub> and Avermectin B<sub>1b</sub>)</b>								
Fresh chive leaves	63.8-66.1	5-7	3	<0.0040	0.0042	<0.0041	0.0041	0.0

<sup>1</sup>PHI = Preharvest interval.

<sup>2</sup>n = number of independent field trials.

<sup>3</sup>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 (0.002 ppm).

<sup>4</sup>Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

<b>Determination of Processing Factor for Dried Chive Leaves.</b>					
RAC	Processed Commodity	Total Rate (g a.i./ha)	PHI (days)	Residues <sup>1</sup> (ppm)	Processing Factor
<b>Total Combined Residues</b>					
Chives	Fresh chives (RAC)	66.1	7	0.0041	--
	Dried chives			0.0121	2.95

<sup>1</sup>Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

#### Anticipated Residues (AR) = HAFT (from residue trials) \* Processing Factor (Pf)

Processed Commodity	HAFT [fresh chives] (ppm)	PF	AR (ppm)
Dried chive leaves	0.0043	2.95	0.013

#### Final Assessment of the Chives (Dried Leaves) Residue Data:

- Residue data were provided for fresh chives and dried leaves. The chive trials were reviewed by the US EPA and found scientifically acceptable.
- Three field trials were conducted in the United States during the 1999-2001 growing season in the North American Free Trade Agreement (NAFTA) Growing Zones 2 (NJ; 1 trial, MD; 1 trial) and 11 (WA; 1 trial). At the WA trial site, an additional control and treated sample of fresh chive were collected 7 days after the final application and dried in a drying cabinet for 2 days.
- The submitted fresh and dried chive leaves field trial was conducted at 1.05-fold the maximum registered GAP for CSG19A [Herbs] on the Epi-Mek 0.15 EC or Agri-Mek SC labels, with samples harvested at 7 days, which is within the prescribed interval on both labels.

- Samples of fresh chives and dried leaves were analyzed for residues of avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> as a single analyte, and residues of avermectin B<sub>1b</sub> using a high performance liquid chromatography (HPLC) method with fluorescence detection adapted from Merck Method No. M-073. Briefly, residues in fresh and dry chive samples were extracted with acetonitrile, diluted with deionized water, and purified using solid phase extraction. The extract was then derivatized with 1-methylimidazole and trifluoroacetic anhydride. External standardization technique was used.
- Method validation fortifications of control fresh chives and dried leaves were at 0.002, 0.025, and 0.100 ppm for avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> and at 0.002 ppm for avermectin B<sub>1b</sub>. The method validation recoveries for fresh chives and dried chives were within the acceptable range of 70-120%. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation, LLMV was 0.002 ppm for avermectin B<sub>1a</sub>, and 8,9-Z avermectin B<sub>1a</sub>, and 0.002 ppm for avermectin B<sub>1b</sub>, for a combined LOQ of 0.004 ppm.
- Fresh chive leaves were stored at -20°C prior to extraction for analysis for up to 637 days (20.9 months), and dried chive leaves for 615 days (20.2 months). Analysis took place within 1 day of extraction. Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.
- The total combined average residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> in fresh chives harvested at a PHI of 5-7 days ranged from <0.0040-0.0042 ppm. Residues declined to less than LOQ in fresh chive leaves at a PHI of 13 days. Only one dried chive sample was collected and analyzed at the Washington trial site. The combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> were <0.0121 ppm in dried chive leaves.
- The chive residue data generated with the EC formulation can be used to support the SC formulation.
- A processing factor of 2.95 was derived for dried chive leaves. No theoretical concentration factors are available for dried herbs. Based on the HAFT (0.0043 ppm) from the three fresh chive residue trials, anticipated residues of the total abamectin residues would be 0.013 ppm. According to the OECD rounding classes, an MRL of 0.015 ppm would be recommended, however, to align with the US Tolerance and facilitate trade, an MRL of 0.02 ppm will be recommended.

**Recommended MRL**

<b>MRLs in/on Chives (Dried Leaves) for Abamectin.</b>			
<b>Recommended Canadian MRL (ppm)</b>	<b>Current Canadian MRL (ppm)</b>	<b>American Tolerance (ppm)</b>	<b>Codex MRL<sup>1</sup> (ppm)</b>
0.02	None established	0.02	0.08

<sup>1</sup>Note: A processing factor of 5 was estimated by JMPR as opposed to 2.95 (PMRA and EPA).

**Acceptable abamectin residue data were provided to calculate the recommended MRL on imported dried chives from the United States.**

**PAPAYA****Submitted Data:**

<b>PMRA #</b>	<b>References</b>	<b>Comments</b>
3180643	2013, Abamectin - Magnitude of the Residue on Papaya, DACO: 7.4.1	US EPA DER PMRA#: 3196915

<b>NUMBER AND LOCATION OF FIELD TRIALS</b>			
<b>Crop</b>	<b>No. Trials</b>	<b>NAFTA Growing Zone</b>	<b>Total</b>
		<b>3</b>	
Papaya	Submitted	3	3
	Required <sup>1</sup>		3 or 2
<sup>1</sup> As per Table 1 of 860.1500 for papaya; three trials with a minimum of 6 samples or two trials with a minimum of 8 samples are required. Geographic distribution is not specified for crops requiring ≤ 3 trials. Per Table 6 of OPPTS 860.1500, Zone 13 accounts for 96% of U.S. papaya production.			
<b>USE PATTERN</b>			
<b>Registered use pattern (GAP) for Epi-Mek 0.15 EC and Agri-Mek SC</b>		<b>Use pattern in the study</b>	
Three foliar broadcast applications, 13.4-25.8 g a.i./ha/application with a maximum of 78.4 g a.i./ha/season. 14-day RTI; PHI of 3-days for Epi-Mek 0.15 EC or 7-days for Agri-Mek SC. An adjuvant must be used with SC formulation.		Three foliar applications of 0.15 EC at 27.6-30.5 g a.i./ha/application for a total seasonal rate of 82.6-91.4 g a.i./ha/season. RTIs of 13-15 days. A horticultural oil spray adjuvant was used. Papayas were harvested at PHIs of 3-5 days.	
<b>ANALYTICAL METHOD AND FREEZER STORAGE</b>			
<b>RAC</b>	<b>Method ID (Type)</b>	<b>Actual storage duration<sup>2</sup></b>	
Papaya	Merck Method No. M-073 (HPLC with fluorescence detection) LOQ = 0.002 ppm for avermectin B <sub>1a</sub> , and 8,9-Z avermectin B <sub>1a</sub> LOQ = 0.002 ppm for avermectin B <sub>1b</sub> Combined LOQ = 0.004 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	98-337 days (3.2-11.1 months)	
<sup>2</sup> Interval from harvest to extraction. Samples were analyzed within 1-3 days of extraction.			

Residue Data from Papaya Field Trials with Abamectin.								
Location: City, State; Year (Trial ID)	Zone	Crop Variety	Matrix	Rate (g ai/ha)	PHI (days)	Residues (ppm parent equivalents) [Average]		
						Avermectin B <sub>1a</sub> + 8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined Residues
Goulds, FL; 1998 (FL15)	3	Known You#1	Fruit	82.6	3	0.0905, 0.149 [0.120]	0.00806, 0.0147 [0.0114]	0.0986, 0.164 [0.131]
Homestead, FL; 1998 (FL17)	3	Red Lady	Fruit	91.4	5	0.00266, 0.00352 [0.0031]	<0.002, <0.002 [<0.002]	<0.0047, <0.0055 [<0.0051]
Homestead, FL; 1998 (FL63)	3	Know You#1	Fruit	82.6	3	0.0937, 0.131 [0.112]	0.00857, 0.0122 [0.0104]	0.102, 0.143 [0.123]

Summary of Residues from Papaya Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Papaya	Avermectin B <sub>1a</sub>	82.6-91.4	3-5	3	0.0031	0.120	0.112	0.078	0.065
	8,9-Z-avermectin B <sub>1a</sub>								
	Avermectin B <sub>1b</sub>								
	Total Abamectin <sup>4</sup>								

<sup>1</sup> PHI = Preharvest interval

<sup>2</sup> n = number of independent field trials.

<sup>3</sup> 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 (0.002 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### **Final Assessment – PAPAYA:**

- Residue data were provided for papayas. The papaya trials were reviewed by the US EPA and found scientifically acceptable.
- Three field trials were conducted in the **United States** during the 1998 growing season in NAFTA Growing Region 3 (FL). At each trial location, papaya was treated with three foliar applications of Epi-Mek 0.15EC at 27.6-30.5 g a.i./ha/application at a retreatment interval of 13-15 days for a total rate of 82.6-91.4 g a.i./ha/season. A horticultural oil spray adjuvant was used. Papaya were harvested at a PHI of 3-5 days, which represents the most restrictive of the PHI on the labels (EC: 3 days, SC: 7 days). The field trials were conducted within 1.2-fold of the registered use pattern on the Epi-Mek 0.15 EC and Agri-Mek SC Miticide/Insecticide labels.
- Although the trials were conducted at the same location with the same varieties, the trials were considered independent by the US EPA based on the fact that there is limited geographic cultivation area for papaya in the United States.
- Samples of papaya were analyzed for residues of avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> as a single analyte, and residues of avermectin B<sub>1b</sub> using a high performance liquid chromatography (HPLC) method with fluorescence detection adapted from Merck Method No. M-073. Briefly, samples were extracted with acetonitrile (ACN):0.1% phosphoric acid (25:75;v:v) and then partitioned with hexane three times. The hexane phases were combined, dried with anhydrous sodium sulfate, and purified on an aminopropyl solid



phase extraction (SPE) column. Residues were eluted with ethyl acetate:methanol (75:25; v:v). The eluate was evaporated to dryness under nitrogen and redissolved in ACN, then subjected to derivatization with trifluoroacetic anhydride prior to analysis.

- Acceptable method validation and concurrent recoveries were reported for samples fortified with avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> at 0.002-0.3 ppm and with avermectin B<sub>1b</sub> at 0.002-0.008 ppm, thus validating the method. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation, LLMV, was 0.002 ppm for avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> and 0.002 ppm for avermectin B<sub>1b</sub>; the combined LOQ was 0.004 ppm.
- Samples of papaya were placed in frozen storage at the field sites within 90 minutes of harvest and were shipped frozen within 12-18 days of harvest to the analytical laboratory, where the samples were stored frozen (-21±7°C) prior to preparation and analysis. The maximum storage interval for samples between harvest and extraction was 337 days (11.1 months). Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.
- Per-trial average residues of abamectin (sum of avermectin B<sub>1a</sub>/8,9-Z avermectin B<sub>1a</sub> and avermectin B<sub>1b</sub>) were <0.0051-0.131 ppm in papaya samples harvested 3-5 days following the last of three foliar applications (0.15 EC) at a total rate of 91.4 g a.i./ha/season. Residue decline was not evaluated.

### **Recommended MRL**

<b>Abamectin</b>	
<b>Papaya</b>	
<b>US EPA</b>	
<b>Study GAP:91 g a.i./ha/season; PHI= 3-5 days</b>	
<b>Total number of data (n)</b>	3
<b>Percentage of censored data</b>	0%
<b>Number of non-censored data</b>	3
<b>Lowest residue</b>	0.005
<b>Highest residue</b>	0.131
<b>Median residue</b>	0.123
<b>Mean</b>	0.086
<b>Standard deviation (SD)</b>	0.070
<b>Correction factor for censoring (CF)</b>	1.000
<b><u>Proposed MRL estimate</u></b>	
- Highest residue	0.131
- Mean + 4 SD	0.368
- CF x 3 Mean	0.259

<b>Unrounded MRL</b>		0.368
<b>Rounded MRL</b>		0.4
<b>Residues (mg/kg)</b>	<b>n</b>	
0.131	1	
0.123	1	
0.0051	1	

<b>MRLs in/on Papaya for Abamectin.</b>				
<b>OECD MRL Calculator Output (ppm)</b>	<b>Recommended Canadian MRL (ppm)</b>	<b>Current Canadian MRL (ppm)</b>	<b>American Tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
0.4	0.4	0.03	0.4	0.01

- The current Canadian MRL is based on the GAP from Brazil.

**NOTE:** The US EPA, as per eCFR, extended the papaya tolerance to star apple, black sapote, sapodilla, canistel and mamey sapote (PMRA# 3180618). Syngenta did not request that the PMRA apply those extensions (PMRA# 3180610).

**Acceptable abamectin residue data were provided to calculate the recommended MRL on imported papaya from the United States.**

## SWEET CORN

### Submitted Data:

<b>PMRA #</b>	<b>References</b>	<b>Comments</b>
3180637	2013, Abamectin 500 FS (A14006B) and Abamectin SC (A15368D) - Magnitude of the Residues in or on Sweet Corn Resulting from Seed Treatment Followed by Foliar Applications - USA, 2011, DACO: 7.4.1	US EPA DER PMRA#: 3196912

<b>NUMBER AND LOCATION OF FIELD TRIALS</b>									
<b>Crop</b>	<b>No. Trials</b>	<b>NAFTA Growing Zone</b>							<b>Total</b>
		<b>1</b>	<b>2</b>	<b>3</b>	<b>5</b>	<b>10</b>	<b>11</b>	<b>12</b>	
<b>Sweet corn</b>	Submitted	2	1	1	5	1	1	1	12
	Required <sup>1</sup>	2	1	1	5	1	1	1	12

<sup>1</sup> As per Table 5 of 860.1500 for sweet corn.

<b>USE PATTERN</b>	
<b>US EPA registered use pattern (GAP)</b>	<b>Use pattern in the study</b>

<p><b>Avicta® 500 FS (Reg. No. 100-1204):</b> Seed treatment at 0.2-0.25 mg ai/seed corresponding to a maximum of 37 g a.i./ha.</p> <p><b>Agri-Mek® SC Miticide/Insecticide [Reg. No. 100-1351]:</b> Broadcast foliar application, 10.8-21.3 g a.i./ha/application, maximum of 42.6 g a.i./ha, 7-day RTI and 7-day PHI.</p>	<p>A seed treatment at 0.234-0.262 mg ai/seed followed by two foliar broadcast applications (SC formulation) at 20.6-22.1 g a.i./ha/application. The total foliar applications were 42.1-43.4 g a.i./ha. The first foliar application was made 51-103 days after planting, the second foliar application was made at an RTI of 6-8 days for a total of 42.1-43.4 g a.i./ha. Total application rates for the seed and foliar treatments were 56.4-89.0 g a.i./ha. An NIS or COC was added to the foliar spray mixture for each trial. Samples of sweet corn forage, K+CWHR and stover were harvested at PHIs of 6-7 days. Residue decline trials were conducted with samples collected at PHIs of 1, 3, 10, and 14 days.</p>	
<b>ANALYTICAL METHOD AND FREEZER STORAGE</b>		
<b>RAC</b>	<b>Method ID (Type)</b>	<b>Actual storage duration<sup>2</sup></b>
Sweet corn, forage	LC-MS/MS method, Morse Analytical Method, Meth-192/Revision #2 (with modifications)	242-357 days (8.0-11.7 months)
Sweet corn, K+CWHR	LOQ = 0.002 ppm for each of avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	232-342 days (7.6-11.2 months)
Sweet corn, stover	Combined LOQ = 0.006 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	278-38 days (9.1-12.5 months)
<sup>2</sup> Interval from harvest to extraction. Samples were analyzed within 0-14 days of extraction.		

Residue Data from Sweet Corn Field Trials with Abamectin.									
Location: City, State; Year (Trial ID)	Zone	Crop Variety	Matrix	Total Rate <sup>1</sup> (g ai/ha)	PHI (Days)	Residues (ppm parent equivalents) [Average]			
						Avermectin B <sub>1a</sub>	8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined
North Rose, NY, 2011 (TK01)	1	SS Garrison	Forage	58.6	7	0.00890, 0.123 [0.0106]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0129, <0.0163 [0.0146]
			K+CWH R		7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.0174, 0.0188 [0.0181]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0214, <0.0228 [<0.0221]
Germansville, PA, 2011, (TK02)	1	SS Jubilee Plus	Forage	60.3	6	0.0800, 0.111 [0.0955]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0840, <0.115 [<0.0995]
			K+CWH R		6	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		6	0.355, 0.288 [0.322]	0.00251, 0.00267 [0.00259]	0.00540, 0.00429 [0.00485]	0.363, 0.295 [0.329]
Seven Springs, NC, 2011, (TK03)	2	SS Garrison	Forage	66.6	7	0.0210, 0.0194 [0.0202]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0250, 0.0234 [<0.0242]
			K+CWH R		7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.0178, 0.0288 [0.0233]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0250, <0.0234 [<0.0242]
Oviedo, FL, 2011, (TK04)	3	SS Jubilee Plus	Forage	70.0	7	0.0468, 0.0565 [0.0516]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0508, <0.0605 [<0.0556]
			K+CWH R		7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.0674, 0.0660 [0.0667]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0714, <0.0700 [<0.0707]
Lenexa, KS, 2011, (TK05)	5	SS Garrison	Forage	65.3	6	0.100, 0.0950 [0.0975]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.104, <0.0990 [<0.102]
			K+CWH R		6	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		6	0.0913, 0.151 [0.121]	<0.002, <0.002 [0.002]	<0.002, 0.00256 [0.00228]	<0.0953, <0.156 [<0.125]
Delawan, WI, 2011, (TK06)	5	SS Jubilee Plus	Forage	63.2	1	0.350	0.00655	0.00515	0.362
					3	0.158	0.00382	0.00226	0.164
					7	0.0683, 0.0478 [0.0580]	0.00201, <0.002 [<0.002]	<0.002, <0.002 [<0.002]	<0.0723, <0.0518 [<0.0620]
					10	0.0590	<0.002	<0.002	<0.0630
					14	0.0255	<0.002	<0.002	<0.0295
			K+CWH R		1	<0.002	<0.002	<0.002	<0.006
					3	<0.002	<0.002	<0.002	<0.006
					7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
					10	<0.002	<0.002	<0.002	<0.006
					14	<0.002	<0.002	<0.002	<0.006

			Stover		1 3 7 10 14	0.153 0.106 0.0492, 0.0362 [0.0427] 0.0404 0.0251	0.00276 0.00222 <0.002, <0.002 [<0.002] <0.002 <0.002	0.00225 <0.002 <0.002, <0.002 [<0.002] <0.002 <0.002	0.158 <0.110 <0.0532, <0.0402 [0.0467] <0.0444 <0.0291
Campbell, MN, 2011, (TK07)	5	SS Garrison	Forage	60.0	1 3 7 10 14	0.244 0.0975 0.0742, 0.0524 [0.0633] 0.0352 0.0263	0.0030 <0.002 <0.002, <0.002 [<0.002] <0.002 <0.002	0.0342 <0.002 <0.002, <0.002 [<0.002] <0.002 <0.002	0.281 <0.102 <0.0782, <0.0564 [<0.0673] <0.0392 <0.0303
			K+CWH R		1 3 7 10 14	<0.002 <0.002 <0.002, <0.002 [0.002] <0.002 <0.002	<0.002 <0.002 <0.002, <0.002 [0.002] <0.002 <0.002	<0.002 <0.002 <0.002, <0.002 [0.002] <0.002 <0.002	<0.006 <0.006 <0.006, <0.006 [<0.006] <0.006 <0.006
			Stover		1 3 7 10 14	0.136 0.0564 0.0440, 0.0664 [0.0552] 0.0533 0.0310	0.00354 <0.002 <0.002, <0.002 [<0.002] <0.002 <0.002	0.00319 <0.002 <0.002, <0.002 [<0.002] <0.002 <0.002	0.143 <0.0604 <0.0480, <0.0704 [0.0592] <0.0573 <0.0350
			Forage		6	0.0645, 0.0575 [0.0610]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0685, <0.0615 [<0.0650]
Bagley, IA, 2011, (TK08)	5	SS Jubilee Plus	K+CWH R	56.4	6	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		6	0.174, 0.257 [0.216]	<0.002, 0.00293 [<0.00247]	0.0296, 0.00398 [0.0168]	<0.206, 0.264 [<0.253]
			Forage		7	0.0193, 0.0333 [0.0263]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0233, <0.0373 [<0.0303]
Rice, MN, 2011, (TK09)	5	SS Garrison	K+CWH R	70.2	7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.0606, 0.0422 [0.0514]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0646, <0.0462 [<0.0554]
			Forage		7	0.0780, 0.0543 [0.0662]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0820, <0.0583 [<0.0702]
Paso Robles, CA, 2011, (TK10)	10	SS Jubilee Plus	K+CWH R	89.0	7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.129, 0.138 [0.134]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.133, <0.142 [<0.138]
			Forage		7	0.0155, 0.0134 [0.0144]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0195, <0.0174 [<0.0184]
Parkdale, OR, 2011, (TK11)	11	SS Garrison	K+CWH R	60.0	7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Forage		7	0.0155, 0.0134 [0.0144]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0195, <0.0174 [<0.0184]

			Stover		7	0.0118, 0.0299 [0.0208]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0158, <0.0339 [<0.0248]
Hillsboro, OR, 2011, (TK12)	12	SS Jubilee Plus	Forage	61.7	7	0.0650, 0.0543 [0.0596]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.0690, <0.0583 [<0.0636]
			K+CWH R		7	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.006, <0.006 [<0.006]
			Stover		7	0.108, 0.0476 [0.0778]	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.112, <0.0516 [<0.0818]

Total rate = 1 seed treatment followed by 2 foliar applications

Summary of Residues from Sweet Corn Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Sweet corn (K+CWHR)	Avermectin B1a	56.4-89.0	6-7	12	<0.002	<0.002	<0.002	<0.002	-
	8,9-Z-avermectin B1a				<0.002	<0.002	<0.002	<0.002	-
	Avermectin B1b				<0.002	<0.002	<0.002	<0.002	-
	Total Abamectin <sup>4</sup>				<0.006	<0.006	<0.006	<0.006	-

<sup>1</sup> PHI = Preharvest interval.

<sup>2</sup> n = number of independent field trials.

<sup>3</sup> 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 (0.002 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### **Final Assessment – SWEET CORN:**

- The sweet corn field trials were reviewed and found scientifically acceptable.
- Twelve field trials were conducted in the United States during the 2011 growing season in the North American Free Trade Agreement (NAFTA) Growing Zones I (NY and PA; 2 trials), 2 (NC; 1 trial) 3 (FL; 1 trial), 5 (IA, KS, MN, WI; 5 trials), 10 (CA; 1 trial), 11 (OR; 1 trial), and 12 (OR; 1 trial). The US EPA determined that a sufficient number of trials were conducted in geographically appropriate regions to support the establishment of a tolerance. All trials were considered independent.
- The submitted sweet corn field trials were conducted at a rate equivalent to 1.05-fold the maximum registered Avicta 500 FS seed treatment rate (0.25 mg a.i./seed). The two foliar applications were conducted at a rate equivalent to 1.03-fold the maximum registered Agri-Mek SC (42.6 g a.i./ha). Samples from all trials were harvested at PHIs of 6 to 7 days as per label, with additional samples collected at 1, 3, 10 and 14 days to assess residue decline.
- The seed treatment was conducted using a flowable concentrate (FS) and the foliar applications with a suspension concentrate (SC). A non-ionic surfactant (NIS) or crop oil concentrate (COC) was added to the foliar spray mixture for each trial as prescribed on the registered labels.
- Samples of sweet corn forage, K+CWHR, and stover from the field trials study were analyzed for residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> using a high performance liquid chromatography method with tandem mass spectrometric

detection (LC-MS/MS), Morse Analytical Method Meth-192/Revision #2. Briefly, samples were extracted with acetonitrile:1% phosphoric acid (25:75; v:v). Samples of sweet corn (K+CWHR) were allowed to soak in the extraction solvent for 10-15 minutes prior to homogenization. Residues were then partitioned into hexane. An aliquot of the extract was purified on an aminopropyl solid phase extraction (SPE) column. The purified extract was evaporated to dryness and redissolved in acetonitrile for LC-MS/MS analysis.

- The method was adequate for data collection based on acceptable concurrent recovery data, generally within 70-120%. The fortification levels for avermectin B<sub>1a</sub> (0.002-0.0336 ppm), avermectin B<sub>1b</sub> (0.002 ppm), and 8,9-Z avermectin B<sub>1a</sub> (0.002-0.020 ppm) used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation (LLMV) was 0.002 ppm for each analyte in sweet corn matrices, for a combined LLMV of 0.006 ppm.
- Sweet corn field trial samples were stored frozen (-25 to -10°C) at the analytical laboratory from collection to analysis for 232-342 days (7.6-11.2 months) for K+CWHR. Samples were analyzed within 0-14 days of extraction. Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.
- Per-trial average residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>, respectively, in sweet corn harvested at PHIs of 6-7 days were <0.002 ppm for all analytes in/on K+CWHR. Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> were <0.006 ppm. Residues of all analytes were below the LOQ (<0.002 ppm) in/on all samples of K+CWHR; therefore, residue decline could not be evaluated.

### Recommended MRL

MRLs in/on Sweet Corn for Abamectin				
OECD MRL Calculator Output (ppm)	Recommended Canadian MRL (ppm)	Current Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Residues less than LOQ	0.01	Not established	0.01	0.002

- As total residues of abamectin are less than LOQ, the MRL can be rounded up to 0.01 ppm in order to align with the US EPA tolerance.

**Acceptable abamectin residue data were provided to recommend an MRL on imported sweet corn from the United States.**

**Crop Subgroup 24A: Tropical and subtropical fruits, small fruits inedible peel****Representative Commodity: LYCHEE****Submitted Data:**

PMRA #	References	Comments
3180641	2014, Abamectin - Magnitude of the Residue on Lychee, DACO: 7.4.1	US EPA DER PMRA #: 3196915

NUMBER AND LOCATION OF FIELD TRIALS			
		NAFTA Growing Zone	
<b>Crop</b>	<b>No. Trials</b>	<b>3</b>	<b>Total</b>
<b>Lychee</b>	Submitted	3	3
	Required <sup>1</sup>		1

<sup>1</sup> As per Table 1 of OPPTS 860.1500 for lychee; one crop field trial with a minimum of four samples is required.

**USE PATTERN**

Registered use pattern (GAP) for Epi-Mek 0.15 EC and Agri-Mek SC	Use pattern in the study
Two foliar broadcast applications, 13.4-25.8 g a.i./ha/application, maximum of 51.5 g a.i./ha/season. 30-day RTI; 14-day PHI.	Two foliar applications of Agimek 0.15 EC at 26.9-28.0 g a.i./ha/application for a total seasonal rate of 53.8-56.0 g a.i./season. RTIs of 14-15 days. A nonionic surfactant was added to the spray mixture for all applications. Lychee were harvested at PHIs of 8-13 days.

**ANALYTICAL METHOD AND FREEZER STORAGE**

RAC	Method ID (Type)	Actual storage duration <sup>2</sup>
Lychee	Method M-073.1 (HPLC with fluorescent detection) LOQ = 0.002 ppm for avermectin B <sub>1a</sub> , and 8,9-Z avermectin B <sub>1a</sub> Avermectin B <sub>1b</sub> not monitored in the study.	97-102 days (3.2-3.4 months)

<sup>2</sup> Interval from harvest to extraction. Samples were analyzed on the day of extraction.

**Residue Data from Lychee Field Trials with Abamectin.**

Location: City, State; Year (Trial ID)	Zone	Crop Variety	Matrix	Rate (g ai/ha)	PHI (days)	Residues (ppm parent equivalents) [Average]		
						Avermectin B <sub>1a</sub> + 8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined Residues
Homestead, FL; 2001 (FL19)	3	Mauritas	Fruit	53.8	9	0.0021, 0.0028 [0.0024]	Not monitored	0.0021, 0.0028 [0.0024]
Homestead, FL; 2001 (FL20)	3	Mauritas	Fruit	53.8	8	<0.002, 0.0034 [0.0027]	Not monitored	<0.002, 0.0034 [0.0027]
Homestead, FL; 2001 (FL21)	3	Red guava	Fruit	56.0	13	<0.002, <0.002 [0.002]	Not monitored	<0.002, <0.002 [<0.002]



Summary of Residues from Lychee Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Lychee	Avermectin B <sub>1a</sub>	53.8-56.0	8-13	3	<0.002	0.0027	0.0024	0.0024	0.0004
	8,9-Z-avermectin B <sub>1a</sub>								
	Avermectin B <sub>1b</sub>				Not monitored				
	Total Abamectin <sup>4</sup>				<0.002	0.0027	0.0024	0.0024	0.0004

<sup>1</sup> PHI = Preharvest interval.

<sup>2</sup> n = number of independent field trials.

<sup>3</sup> 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 (0.002 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub>.

### **Final Assessment – LYCHEE:**

- Residue data were provided for lychee, the representative crop of tropical and subtropical fruits, small fruits inedible peel (CSG 24A). The lychee trials were reviewed by the US EPA and found scientifically acceptable.
- Three field trials were conducted in the United States during the 2001 growing season in NAFTA Growing Region 3 (FL). At each trial location, lychee was treated with two foliar applications of Epi-Mek 0.15EC at 26.9-28.0 g a.i./ha/application at a retreatment interval of 14-15 days for a total rate of 53.8-56.0 g a.i./ha/season. A horticultural oil spray adjuvant was used. Lychee were harvested at a PHI of 8-13 days. The field trials were conducted within 1.1-fold of the registered use pattern on the Epi-Mek 0.15 EC and Agri-Mek SC Miticide/Insecticide labels.
- Although the trials were conducted at the same location with the same varieties, the trials were considered independent based on the fact that there is limited geographic cultivation area for lychee in the United States.
- Samples of lychee were analyzed for residues of avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> as a single analyte using a high performance liquid chromatography (HPLC) method with fluorescence detection adapted from Merck Method No. M-073. Briefly, samples were extracted with acetonitrile (ACN):0.1% phosphoric acid (25:75;v:v) and then partitioned with hexane three times. The hexane phases were combined, dried with anhydrous sodium sulfate, and purified on an aminopropyl solid phase extraction (SPE) column. Residues were eluted with ethyl acetate:methanol (75:25; v:v). The eluate was evaporated to dryness under nitrogen and redissolved in ACN, then subjected to derivatization with trifluoroacetic anhydride prior to analysis.
- Acceptable method validation and concurrent recoveries were reported for samples fortified with avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> at 0.002-0.1 ppm, thus validating the method. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The LOQ was 0.002 ppm for both analytes.
- Samples of lychee were placed in frozen storage at the field sites within 90 minutes of harvest and were shipped frozen within 12-18 days of harvest to the analytical laboratory,

where the samples were stored frozen ( $-21\pm 7^{\circ}\text{C}$ ) prior to preparation and analysis. The maximum storage interval for samples between harvest and extraction was 102 days (3.4 months). Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.

- Per-trial average residues of abamectin (sum of avermectin B<sub>1a</sub>/8,9-Z avermectin B<sub>1a</sub>) were <0.002-0.0027 ppm in lychee samples harvested 8-13 days following the last of two foliar applications of Epi-Mek 0.15EC at a total of 56 g a.i./ha/season. Residue decline was not evaluated.

### **Recommended MRL**

<b>Abamectin Lychee US EPA Study GAP: 56 g a.i./ha/season; PHI= 8-13d</b>									
<b>Total number of data (n)</b>	3								
<b>Percentage of censored data</b>	67%								
<b>Number of non-censored data</b>	1								
<b>Lowest residue</b>	0.002								
<b>Highest residue</b>	0.003								
<b>Median residue</b>	0.003								
<b>Mean</b>	0.002								
<b>Standard deviation (SD)</b>	0.000								
<b>Correction factor for censoring (CF)</b>	0.556								
<b><u>Proposed MRL estimate</u></b>									
- Highest residue	0.003								
- Mean + 4 SD	0.004								
- CF x 3 Mean	0.004								
<b>Unrounded MRL</b>	<u>0.004</u>								
<b>Rounded MRL</b>	<u><b>0.01</b></u>								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Residues (mg/kg)</th> <th style="text-align: center;">n</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">&lt; 0.002</td> <td style="text-align: center;">1</td> </tr> <tr> <td style="text-align: center;">0.0024</td> <td style="text-align: center;">1</td> </tr> <tr> <td style="text-align: center;">0.0027</td> <td style="text-align: center;">1</td> </tr> </tbody> </table>		Residues (mg/kg)	n	< 0.002	1	0.0024	1	0.0027	1
Residues (mg/kg)	n								
< 0.002	1								
0.0024	1								
0.0027	1								

MRLs in/on Lychee (CSG24A) for Abamectin.				
OECD MRL Calculator Output (ppm)	Recommended Canadian MRL (ppm)	Current Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
0.01	0.01	Not established	0.01	Not established

Acceptable abamectin residue data were provided to calculate the recommended MRL on imported lychee from the United States. The calculated MRL can be extended to all commodities within CSG24A.

## PINEAPPLE

### Submitted Data:

PMRA #	References	Comments
3180645	2014, Abamectin - Magnitude of the Residue on Pineapple, DACO: 7.4.1	US EPA DER PMRA#: 3196915

NUMBER AND LOCATION OF FIELD TRIALS			
Crop	No. Trials	NAFTA Growing Zone	Total
		13	
Pineapple	Submitted	8	8
	Required <sup>1</sup>	8	8

<sup>1</sup> As per Table 5 of 860.1500 for pineapple.

USE PATTERN	
Registered use pattern (GAP) for Epi-Mek 0.15 EC and Agri-Mek SC	Use pattern in the study
Two foliar broadcast applications, 13.4-25.8 g a.i./ha/application for a maximum of 51.5 g a.i./ha/season. 7-day RTI; PHI of 16 weeks (112 days).	Two foliar applications of 0.15 EC at 26.0-26.8 g a.i./ha/application for a total seasonal rate of 52.4-53.2 g a.i./ha/season. RTIs of 7 days. No adjuvants were used. Pineapples were harvested at PHIs of 78-112 days.

ANALYTICAL METHOD AND FREEZER STORAGE		
RAC	Method ID (Type)	Actual storage duration <sup>2</sup>
Pineapple	Merck Method No. M-073 (HPLC with fluorescence detection) LOQ = 0.002 ppm for avermectin B <sub>1a</sub> and 8,9-Z avermectin B <sub>1a</sub> LOQ = 0.002 ppm for avermectin B <sub>1b</sub> Combined LOQ = 0.004 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	7-142 days (0.2-4.7 months)

<sup>2</sup> Interval from harvest to extraction.

Note: At three of the trial sites (H109, H110 and H111), a second plot received two foliar broadcast applications for a total of 259-267 g a.i./ha with samples harvested at 98 to 108 days, corresponding to 5-fold registered GAP. The combined residues of abamectin were less than LOQ (<0.004 ppm).

Residue Data from Pineapple Field Trials with Abamectin.								
Location: City, State; Year (Trial ID)	Zone	Crop Variety	Matrix	Rate (g ai/ha)	PHI (days)	Residues (ppm parent equivalents) [Average]		
						Avermectin B <sub>1a</sub> + 8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined Residues
Whaiawa, HI, 2002 (H109)	13	Tropical Gold	Fruit	53.0	108	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Whaiawa, HI, 2002 (H109)	13	Tropical Gold	Fruit	53.0	105	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Makawao, HI, 2002 (H110)	13	Hawaiian Gold	Fruit	52.0	98	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Makawao, HI, 2002 (H111)	13	Cayenne	Fruit	53.0	91	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Makawao, HI, 2002 (H112)	13	Cayenne	Fruit	53.2	88	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Whaiawa, HI, 2002 (H114)	13	Cayenne	Fruit	53.0	112	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Whaiawa, HI, 2002 (H115)	13	Tropical Gold	Fruit	53.0	112	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]
Whaiawa, HI, 2002 (H116)	13	Hawaiian Gold	Fruit	52.4	78	<0.002, <0.002 [0.002]	<0.002, <0.002 [<0.002]	<0.004, <0.004 [<0.004]

Summary of Residues from Pineapple Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Pineapple	Avermectin B <sub>1a</sub> 8,9-Z-avermectin B <sub>1a</sub>	52.4-53.2	78-112	8	<0.002	<0.002	<0.002	<0.002	-
	Avermectin B <sub>1b</sub>				<0.002	<0.002	<0.002	<0.002	-
	Total Abamectin <sup>4</sup>				<0.004	<0.004	<0.004	<0.004	-

<sup>1</sup> PHI = Preharvest interval.

<sup>2</sup> n = number of independent field trials.

<sup>3</sup> 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 (0.002 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### **Final Assessment – PINEAPPLE:**

- Residue data were provided for pineapple. The pineapple trials were reviewed by the US EPA and found scientifically acceptable.
- Eight field trials were conducted in the **United States** during the 2002 growing season in NAFTA Growing Region 13 (HI). At each trial location, pineapple was treated with two foliar applications of Epi-Mek 0.15EC at 26.0-26.8 g a.i./ha/application at a retreatment interval of 7 days for a total rate of 52.4-53.2 g a.i./ha/season. No adjuvants were used. Pineapple trials were conducted at 1-fold the rate on the registered Epi-Mek 0.15 EC and Agri-Mek SC labels. Pineapples were harvested at a preharvest interval of 78-112 days, which is shorter than the prescribed PHI of 16 weeks on the registered labels. Residues were less than LOQ at all PHIs, therefore, it is not likely that residues will be higher after 16 weeks.

- Although the trials were conducted at the same location, the trials were considered independent based on the fact that there is limited geographic cultivation area for pineapple in the United States.
- Samples of pineapple were analyzed for residues of avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> as a single analyte, and residues of avermectin B<sub>1b</sub> using a high performance liquid chromatography (HPLC) method with fluorescence detection adapted from Merck Method No. M-073. Briefly, samples were extracted with acetonitrile (ACN):0.1% phosphoric acid (25:75;v:v) and then partitioned with hexane three times. The hexane phases were combined, dried with anhydrous sodium sulfate, and purified on an aminopropyl solid phase extraction (SPE) column. Residues were eluted with ethyl acetate:methanol (75:25; v:v). The eluate was evaporated to dryness under nitrogen and redissolved in ACN, then subjected to derivatization with trifluoroacetic anhydride prior to analysis.
- Acceptable method validation and concurrent recoveries were reported for samples fortified with avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> at 0.002-0.02 ppm and with avermectin B<sub>1b</sub> at 0.002 ppm, thus validating the method. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation, LLMV was 0.002 ppm for each analyte; the combined LOQ was 0.004 ppm.
- Samples of pineapple were placed in frozen storage at the field sites on the day of harvest and were shipped frozen to the analytical laboratory, where the samples were stored frozen (<0°C) prior to preparation and analysis. The maximum storage interval for samples between harvest and extraction was 142 days (4.7 months). Samples were analyzed within 1 day of extraction. Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). These data adequately support the sample storage conditions and durations from the submitted study.
- Per-trial average residues of abamectin (sum of avermectin B<sub>1a</sub>/8,9-Z avermectin B<sub>1a</sub> and avermectin B<sub>1b</sub>) were <0.004 ppm in pineapple samples harvested 78-112 days following the last of two foliar applications of Epi-Mek 0.15EC at a total of 52.4-53.2 g a.i./ha/season. Residue decline was not evaluated.

### **Recommended MRL**

<b>MRLs in/on Pineapple for Abamectin.</b>				
<b>OECD MRL Calculator Output (ppm)</b>	<b>Recommended Canadian MRL (ppm)</b>	<b>Current Canadian MRL (ppm)</b>	<b>American Tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
<b>Residues less than LOQ</b>	0.015	Not established	0.015	0.002

- While total residues of abamectin are less than LOQ, an MRL of 0.015 ppm is recommended to align with the US tolerance.

**Acceptable abamectin residue data were provided to recommend an MRL on imported pineapple from the United States.**

## GUAVA

### Submitted Data:

PMRA #	References	Comments
3180640	2014, Abamectin - Magnitude of the Residue on Guava, DACO: 7.4.1	US EPA DER PMRA#: 3196915

NUMBER AND LOCATION OF FIELD TRIALS			
Crop	No. Trials	NAFTA Growing Zone	
		3	
Guava	Submitted	3	
	Required <sup>1</sup>	2	
1 As per Table 1 of 860.1500 for guava; a minimum of two field trials with a minimum of eight samples is required. Geographic distribution is not specified for crops requiring ≤ 3 trials.			
USE PATTERN			
Registered use pattern (GAP) for Epi-Mek 0.15 EC and Agri-Mek SC		Use pattern in the study	
Three foliar broadcast applications, 13.4-25.8 g a.i./ha/application, and maximum of 78.4 g a.i./ha/season. 14-day RTI; PHI of 7-days.		Three foliar applications of Agri-Mek 0.15 EC at 26.9-28.0 g a.i./ha/application for a total seasonal rate of 81.8-82.9 g a.i./ha/season. RTIs of 13-14 days. A horticultural oil spray adjuvant was used. Guavas were harvested at PHIs of 8 days.	
ANALYTICAL METHOD AND FREEZER STORAGE			
RAC	Method ID (Type)		Actual storage duration <sup>2</sup>
Guava	Merck Method No. M-073 (HPLC with fluorescence detection) LOQ = 0.002 ppm for avermectin B <sub>1a</sub> and 8,9-Z avermectin B <sub>1a</sub> LOQ = 0.002 ppm for avermectin B <sub>1b</sub> Combined LOQ = 0.004 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>		1056-1068 days (34.7-35.1 months)
<sup>2</sup> Interval from harvest to extraction. Samples were analyzed within 0-2 days of extraction.			

Residue Data from Guava Field Trials with Abamectin.								
Location: City, State; Year (Trial ID)	Zone	Crop Variety	Matrix	Rate (g ai/ha)	PHI (days)	Residues (ppm parent equivalents) [Average]		
						Avermectin B <sub>1a</sub> + 8,9-Z Avermectin B <sub>1a</sub>	Avermectin B <sub>1b</sub>	Combined
Homestead, FL; 1999 (FL51)	3	Mauritas	Fruit	81.8	8	<0.002, <0.0039 [0.0030]	<0.002, <0.002 [0.002]	<0.004, 0.0059 [0.0050]
Homestead, FL; 1999 (FL52)	3	Mauritas	Fruit	82.9	8	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.004, <0.004 [<0.004]
Homestead, FL; 1999 (FL53)	3	Red guava	Fruit	82.9	8	<0.002, <0.002 [0.002]	<0.002, <0.002 [0.002]	<0.004, <0.004 [<0.004]

Summary of Residues from Guava Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Guava	Avermectin B <sub>1a</sub>	81.8-82.9	8	3	<0.002	0.003	<0.002	0.0023	0.0006
	8,9-Z-avermectin B <sub>1a</sub>								
	Avermectin B <sub>1b</sub>								
	Total Abamectin <sup>4</sup>								

<sup>1</sup> PHI = Preharvest interval.

<sup>2</sup> n = number of independent field trials.

<sup>3</sup> 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 (0.002 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### **Final Assessment – GUAVA:**

- Residue data were provided for guava. The guava trials were reviewed by the US EPA and found scientifically acceptable.
- Three field trials were conducted in the United States during the 1999 growing season in NAFTA Growing Region 3 (FL). At each trial location, guava was treated with three foliar applications of Epi-Mek 0.15EC at 26.9-28.0 g a.i./ha/application at a retreatment interval of 13-14 days for a total rate of 81.8-82.9 g a.i./ha/season. A horticultural oil spray adjuvant was used. Guavas were harvested at a PHI of 8 days. The field trials were conducted within 1-fold of the registered use pattern.
- Although the trials were separated by <30 km and FL51 and FL52 used the same variety of guavas (Mauritas), the trials were considered independent based on the fact that there is limited geographic area for guava cultivation in the U.S.
- Samples of guava were analyzed for residues of avermectin B<sub>1a</sub>/8,9-Z avermectin B<sub>1a</sub> as a single analyte, and residues of avermectin B<sub>1b</sub> using a high performance liquid chromatography (HPLC) method with fluorescence detection adapted from Merck Method No. M-073. Briefly, samples were extracted with acetonitrile (ACN):0.1% phosphoric acid (25:75;v:v) and then partitioned with hexane three times. The hexane phases were combined, dried with anhydrous sodium sulfate, and purified on an aminopropyl solid phase extraction (SPE) column. Residues were eluted with ethyl acetate:methanol (75:25; v:v). The eluate was evaporated to dryness under nitrogen and redissolved in ACN, then subjected to derivatization with trifluoroacetic anhydride prior to analysis.
- Acceptable method validation and concurrent recoveries were reported for samples fortified with avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> at 0.002-0.1 ppm and with avermectin B<sub>1b</sub> at 0.002-0.008 ppm, thus validating the method. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation, LLMV was 0.002 ppm for each analyte; the combined LLMV was 0.004 ppm.
- Samples of guava were placed in frozen storage at the field sites within 1 hour of harvest and were shipped frozen within 38-45 days of harvest to the analytical laboratory, where



the samples were stored frozen (<-20°C) prior to preparation and analysis. The maximum storage interval for samples between harvest and extraction was 1068 days (35.1 months). Freezer storage stability data were generated concurrently with the guava trials. After 1013 days of freezer storage, the storage stability samples were analyzed for avermectin B<sub>1a</sub>, avermectin B<sub>1b</sub>, and 8,9-Z avermectin B<sub>1a</sub>. The recoveries for the storage stability samples were in the range 81-101% for avermectin B<sub>1a</sub>, 91-98% for avermectin B<sub>1b</sub>, and 105-119% for 8,9-Z avermectin B<sub>1a</sub>. Concurrent recoveries indicate that residues of avermectin B<sub>1a</sub>, 8,9-Z-avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub> are stable for at least 1013 days. The samples were stored an additional 55 days following the concurrent storage stability testing. However, since residues were determined to be stable for 1013 days, it is not expected that significant dissipation of residues will have occurred within the additional storage duration of 55 days. Therefore acceptable storage stability data are available to support the storage conditions and durations of the field trial samples.

- Per-trial average residues of abamectin (sum of avermectin B<sub>1a</sub>/8,9-Z avermectin B<sub>1a</sub> and avermectin B<sub>1b</sub>) were <0.004-0.0050 ppm in guava samples harvested 8 days following the last of three foliar applications of Epi-Mek 0.15EC at a total of 81.8-82.9 g a.i./ha/season. Residue decline was not evaluated.

### Recommended MRL

Abamectin	
Guava	
US EPA	
Study GAP: 81.8-82.9 g a.i./ha/season; PHI= 8 days	
Total number of data (n)	3
Percentage of censored data	67%
Number of non-censored data	1
Lowest residue	0.004
Highest residue	0.005
Median residue	0.004
Mean	0.004
Standard deviation (SD)	0.001
Correction factor for censoring (CF)	0.556
<b>Proposed MRL estimate</b>	
- Highest residue	0.005
- Mean + 4 SD	0.007
- CF x 3 Mean	0.007
Unrounded MRL	<u>0.007</u>
Rounded MRL	<u>0.01</u>

Residues (mg/kg)	n
<0.004	2
0.005	1

MRLs in/on Guava for Abamectin.				
OECD MRL Calculator Output (ppm)	Recommended Canadian MRL (ppm)	Current Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
0.01	0.015	Not established	0.015	Not established



Although the OECD MRL calculator output was 0.01 ppm, the proposed MRL is 0.015 ppm to align with US Tolerance.

**NOTE:** The US EPA, as per eCFR, extended the guava tolerance to wax jambu, starfruit, passionfruit and acerola (PMRA# 3180618). Syngenta did not request that the PMRA apply those extensions (PMRA# 3180610).

**Acceptable abamectin residue data were provided to calculate the recommended MRL on imported guava from the United States.**

## TEA

### Submitted Data:

PMRA #	References	Comments
3180634	2017, 110917 Abamectin_Tolerance Petition for abamectin on tea 2017, DACO: 7.1	Same information reported under PMRA# 3180636
3180636	2017, 110917 Abamectin_Japanes Report and MRL Report_Imp Tol Tea - Confidential Attachment, DACO: 7.4.1	Japanese report.
3180638	2020, Crop Residue Analysis Report, DACO: 7.4.1	Residue data.

NUMBER AND LOCATION OF FIELD TRIALS		
Crop	No. Trials	Total
Tea	Submitted	2
	Required <sup>1</sup>	2

<sup>1</sup> Minimum number of trials required in Japan (Guidance Document on Overview of Residue Chemistry Studies; ENV/JM/MONO(2009)31)

USE PATTERN	
Registered use pattern (GAP) for Agrimec (Japan Reg. No. 23235)	Use pattern in the study
One foliar broadcast application of liquid emulsion, 36-72 g a.i./ha/application with a maximum of 72 g a.i./ha/season. PHI of 7 days.	One foliar broadcast application of 1.8% abamectin EC, at 108 g a.i./ha. PHI of 7 days. Residue decline: 3, 7, 14 days.

ANALYTICAL METHOD AND FREEZER STORAGE		
RAC	Method ID (Type)	Storage interval from harvest to analysis
Crude processed tea leaves (dry tea)	LC-MS/MS; LOQ = 0.003 ppm for each avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> and avermectin B <sub>1b</sub> Combined LOQ = 0.009 ppm for avermectin B <sub>1a</sub> , 8,9-Z avermectin B <sub>1a</sub> , and avermectin B <sub>1b</sub>	148-163 days (4.9-5.4 months)

Summary of Residues from Tea Field Trials with Abamectin.									
Crop	Analytes	Total Rate (g a.i./ha)	PHI (days) <sup>1</sup>	n <sup>2</sup>	Residues <sup>4</sup> (ppm parent equivalents)				
					LAFT <sup>3</sup>	HAFT <sup>3</sup>	Median <sup>3</sup>	Mean <sup>3</sup>	SD <sup>3</sup>
Tea leaves	Avermectin B <sub>1a</sub>	108	3	2	0.314	0.362	-	0.338	-
	8,9-Z-avermectin B <sub>1a</sub>				0.039	0.046	-	0.043	-
	Avermectin B <sub>1b</sub>				0.031	0.042	-	0.037	-
	<b>Total Abamectin<sup>4</sup></b>				<b>0.384</b>	<b>0.450</b>	-	<b>0.418</b>	-
	Avermectin B <sub>1a</sub>		7	2	0.050	0.333	-	0.192	-
	8,9-Z-avermectin B <sub>1a</sub>				0.016	0.102	-	0.059	-
	Avermectin B <sub>1b</sub>				0.006	0.042	-	0.024	-
	<b>Total Abamectin<sup>4</sup></b>				<b>0.072</b>	<b>0.477</b>	-	<b>0.275</b>	-

	Avermectin B <sub>1a</sub>		14	2	0.014	0.050	-	0.032	-
	8,9-Z-avermectin B <sub>1a</sub>				0.009	0.014	-	0.012	-
	Avermectin B <sub>1b</sub>				<0.003	0.008	-	0.006	-
	<b>Total Abamectin<sup>4</sup></b>				<b>0.026</b>	<b>0.072</b>	-	<b>0.049</b>	-

1 PHI = Preharvest interval.

2 n = number of independent field trials.

3 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 (0.003 ppm).

<sup>4</sup> Combined residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub>, and avermectin B<sub>1b</sub>.

### **Final Assessment – TEA:**

- Two field trials were conducted in Japan (Kanagawa ATC and Kagoshima IAD) during the 2006 growing season. At each trial location, tea was treated with one foliar application of Abamectin 1.8% emulsion at 108 g a.i./ha. Tea leaves were harvested at 3, 7 and 14 days. The field trials were conducted within 1.5-fold of the Japan registered use pattern.
- Samples of tea were analyzed for residues of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub> and residues of avermectin B<sub>1b</sub> using a high performance liquid chromatography (HPLC) method with mass spectrometry (no method number identified). Briefly, samples were extracted with acetonitrile and washed with hexane prior to analysis.
- Acceptable concurrent recoveries were reported for samples fortified with avermectin B<sub>1a</sub> and 8,9-Z avermectin B<sub>1a</sub> at 0.003 and 0.15 ppm; and with avermectin B<sub>1b</sub> at 0.003 ppm, 0.15 ppm, and 0.5 ppm, thus validating the method. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels. The lowest level of method validation, LLMV was 0.003 ppm for each analyte; the combined LOQ was 0.009 ppm.
- The maximum storage interval for samples between harvest and extraction was 163 days (5.4 months). Storage stability data are on file for one commodity from each of the five OECD commodity categories: high water content (tomatoes and celery), high oil content (sunflower seed), high protein content (runner beans), high starch content (potatoes) and high acid content (strawberries), demonstrating stability of residues of avermectin B<sub>1a</sub>, avermectin B<sub>1a</sub> 8,9-Z isomer, and avermectin B<sub>1b</sub> for up to 24 months (Level D NTF: PMRA # 2532261). Therefore, the available storage stability data is acceptable to support the storage conditions and durations in crude processed tea leaves.
- Per-trial average residues of abamectin (sum of avermectin B<sub>1a</sub>, 8,9-Z avermectin B<sub>1a</sub> and avermectin B<sub>1b</sub>) were 0.072-0.477 ppm in crude processed tea leaf samples harvested 7 days following one foliar application (EC formulation) at a total of 108 g a.i./ha/season. Residues of each analyte declined with increasing PHIs, with the exception of 8,9-Z avermectin B<sub>1a</sub>, which increased from a PHI of 3 days to 7 days, but declined by 14 days.
- The two trials conducted are in compliance with Japan's trial requirement.

**Recommended MRL**

<b>MRLs in/on Tea for Abamectin</b>				
<b>OECD MRL Calculator Output (ppm)</b>	<b>Recommended Canadian MRL (ppm)</b>	<b>Current Canadian MRL (ppm)</b>	<b>American Tolerance and Japanese MRL (ppm)</b>	<b>Codex MRL (ppm)</b>
N= 2	1.0	Not established	1.0	Not established

- The OECD calculator is unable to calculate maximum residue limits for sample sizes <3. As per RCC memo (Y:\HC\PMRA\HED\DIETARY\X\_REFERENCE\HEALTH RISK PROTECTION\PROCEDURES\RCC Memos\PMRA\_HED Memo\_MRL Methodology for n=2\_signed.pdf), when n=2, the MRL is calculated as the mean residue value  $\times 5$ . The mean residue value is  $0.275 \text{ ppm} \times 5 = 1.4 \text{ ppm}$ . Given that the HAFT is  $0.477 \text{ ppm}$ , the alignment of the MRL with that of the US tolerance and Japanese MRL of  $1 \text{ ppm}$  will cover potential residues of total abamectin in tea leaves.

**Acceptable abamectin residue data were provided to calculate the recommended MRL on imported tea from Japan.**

**PART F. DIETARY EXPOSURE ASSESSMENT (DEA)**

- There is a DEA on file for abamectin dated August 11<sup>th</sup> 2015 that was conducted under S2013-4347 (PMRA # 2532260).
- US/Canadian data for tomatoes, bell peppers, non-bell peppers, oranges, lemon, grapefruit, apples, pears, cherries, peaches, plums, grape, strawberries, almonds, pecans, walnuts and papaya were included in the DEA.
- The refined aggregate (food + water) acute dietary exposure, for all supported abamectin registered and/or imported commodities, was estimated to be 8% to 25% for all population subgroups, which is not of health concern.
- The refined aggregate (food + water) chronic non-cancer dietary exposure, for all supported abamectin registered and/or imported food uses, for the representative population subgroups ranged from 6% to 20% of the ADI, which is not of health concern.
- As the purpose of this submission is to specify MRLs for crops imported from the US, the EEC values on file for abamectin are adequate. A Level 1 EEC value is on file for abamectin (1.4 µg a.i./L, surface water; maximum application rate of 95 g a.i./ha/year) and are adequate to cover the proposed maximum use pattern.
- The DEA for abamectin will be updated as part of the re-evaluation (S2015-1559) as follows:
  - The addition of carrots, dried chive leaves, sweet corn, tropical and subtropical fruits, small fruits inedible peel (CSG 24A), papaya, pineapple, guava and tea.
  - Extending the residue data/MRLs from CGs 10, 12 and 14 to the revised crops in CGs 10-R, 12-09 and 14-11, respectively.
  - Extending the residue data/MRL for apples and pears to all crops in CG11-09; grapes to all crops in CSG 13-07F; strawberries to all crops in CSG 13-07G.

**Dietary Exposure (Food Residue) Level D Status is PASSED.**

*Abamectin*	
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