UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 26-MAR-2013

Subject: **Spirotetramat.** Proposed Uses in/on Taro, Leaves; Watercress; Pomegranate; Banana; Vegetable, Bulb, Group 3-07; Low growing Berry Subgroup 13-07H, Except Strawberry and Lowbush Blueberry; Bushberry Subgroup 13-07B; Artichoke, Globe; Vegetable, Fruiting, Group 8-10; Fruit, Pome, Group 11-10; Fruit, Citrus, Group 10-10; Pineapple; and Coffee; and Tolerances without U.S. Registration in/on Corn, Sweet, Kernel Plus Cob with Husks Removed as Part of the U.S.-Canada Regulatory Cooperation Council (RCC) Pilot Project. **Summary of Analytical Chemistry and Residue Data**.

PC Code: 392201
Decision Nos.: 459092, 459087
Petition No.: 1E7958
Risk Assessment Type: NA
TXR No.: NA
MRID Nos.: 486976-01 thru -10, 48770501

DP Barcodes: D398856, D400037
Registration Nos.: 264-1050, 264-1065, 264-1051
Regulatory Action: Sec. 3 Registration
Case No.: 7452
CAS No.: 382608-10-8
40 CFR: §180.641

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To: Barbara Madden/Laura Nollen, RM 05
Registration Division (RD; 7505P)

Executive Summary

Spirotetramat is a tetramic acid derivative (ketoenole) developed by Bayer CropScience AG. This foliar insecticide is active against sucking insects in vegetables, citrus, pome fruit, stone fruit, grapes, cotton, and other plants. It is systemic (xylem and phloem mobile) and can control hidden pests and protect new shoots.

The Interregional Research Project Number 4 (IR-4) has submitted a Section 3 request to register a 2 lb ai/gal suspension-concentrate (SC) formulation (Movento®; EPA Reg. No. 264-1050), a 1.25 lb ai/gal SC formulation (Ultor®; EPA Reg. No. 264-1065), and a 1.25 lb ai/gal oil-dispersion (OD) formulation (BYI 8330 OD; EPA Reg. No. 264-1051) for use on taro, watercress, pomegranates, bananas, bulb vegetables, low-growing berries (except strawberries),

bushberries, globe artichokes, fruiting vegetables, pome fruit, citrus fruit, pineapples, and coffee. The end-use products are proposed for 2 to 5 foliar spray applications at 0.05-0.25 lb ai/A/application with minimum retreatment intervals (RTIs) of 7-30 days, for maximum seasonal rates of 0.16-1.25 lb ai/A. Applications may be made using ground or aerial equipment, and use of an adjuvant is required. Preharvest intervals (PHIs) of 1-14 days are proposed. The rotational crop plantback intervals (PBIs) are 30 days for all non-labeled crops.

Concurrently, IR-4 has submitted a petition for the establishment of permanent tolerances for the residues of the insecticide spirotetramat, including its metabolites and degradates, in or on the commodities summarized below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spirotetramat (*cis*-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate]) and its metabolites *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, *cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat, in or on the following commodities:

Taro, leaves	9 ppm
Watercress	1.5 ppm
Pomegranate	0.5 ppm
Banana	4 ppm
Vegetable, bulb, group 3-07	0.6 ppm
Low growing berry subgroup 13-07H, except strawberry	0.3 ppm
Bushberry subgroup 13-07B	3 ppm
Artichoke, globe	2 ppm
Vegetable, fruiting, crop group 8-10	2.5 ppm
Fruit, pome, crop group 11-10	0.7 ppm
Fruit, citrus, crop group 10-10	0.6 ppm
Pineapple	0.3 ppm
Pineapple, process residue	0.36 ppm
Coffee, green bean	0.2 ppm
Coffee, roasted bean	0.32 ppm

Permanent tolerances are currently established for the combined residues of the insecticide spirotetramat, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-enol-Glc, and BYI 08330-mono-hydroxy, calculated as the stoichiometric equivalent of spirotetramat, in/on bulb onions, citrus, cucurbit vegetables, fruiting vegetables, grapes, hops, leafy *Brassica* vegetables, leafy non-*Brassica* vegetables, pome fruit, tuberous and corm vegetables, stone fruit, tree nuts, cotton, legume vegetables including soybean (crop groups 6 and 7A), and tropical fruit (40 CFR §180.641(a)(1)). Tolerances are also established for residues of the insecticide spirotetramat, including its metabolites and degradates, in or on livestock commodities. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat and its metabolite BYI 08330-enol, calculated as the stoichiometric equivalent of spirotetramat (40 CFR §180.641(a)(2)).

No new data were submitted to support the proposed tolerances for residues in/on vegetable, fruiting, crop group 8-10, citrus, group 10-10; or fruit, pome, group 11-10. IR-4 has requested that existing tolerances be expanded to their respective crop groups or crop subgroups. Residue

data for green and bulb onion, globe artichoke, and sweet corn were reviewed by the Pest Management Regulatory Agency (PMRA) of Canada as part of a U.S.-Canada RCC pilot project. RD has also requested that HED make a recommendation on establishing a tolerance on sweet corn imported from Canada based on PMRA's evaluation of the Canadian residue data for this commodity.

The nature of the residue in plants, rotational crops, and livestock is adequately understood based on acceptable metabolism studies conducted on apple, lettuce, cotton, potato, rotational crops, lactating goats, and laying hens. The residues of concern for the tolerance expression and risk assessment for primary and rotational crops are spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-enol-Glc, and BYI 08330-mono-hydroxy; the residues of concern for the tolerance expression for livestock commodities are spirotetramat and its metabolite BYI 08330-enol and the residues of concern for the risk assessment for livestock commodities are spirotetramat and its metabolites BYI 08330-enol and BYI 08330-enol-GA (Memo, J. Tyler *et al.*, 16-APR-2008; D333437).

Samples were analyzed for residues of spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, and BYI 08330-enol-glucoside using a high-performance liquid chromatography method with tandem mass spectroscopy detection (HPLC-MS/MS), Method 00857, the current enforcement method for crop commodities. Residues of each metabolite were reported in parent equivalents. The method was adequate for data collection based on acceptable concurrent method recovery data.

The submitted magnitude of the residue data for the raw agricultural commodities (RACs) of watercress, pomegranates, bananas, bulb vegetables, low-growing berries (except strawberries), bushberries, globe artichokes, pineapples, and coffee will support the proposed use patterns. There are adequate storage stability data to validate the storage conditions and intervals of samples collected from the field trials. As no residue data were submitted for an OD or equivalent formulation, the use directions for the subject crops should be removed from the BYI 8330 OD label. In addition, as all of the banana field trials were performed in HI, the registration for use on this crop should be limited to the state of HI.

Acceptable coffee and pineapple processing studies are available. The processing studies show that following processing of RAC samples bearing quantifiable residues, total residues of spirotetramat and its metabolites concentrated in roasted coffee bean (<1.9X), instant coffee (<10X), and pineapple process residue (1.2X).

The only feedstuff associated with the proposed new uses is pineapple process residue, a minor feed item. The established tolerances for residues of spirotetramat and its metabolite in livestock commodities are adequate to support the proposed new uses.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of revised Sections B and F (see requirements under Directions for Use and Proposed Tolerances) and analytical reference standards (see requirements under Submittal of Analytical Reference Standards), there are no residue chemistry issues that would preclude granting an unconditional registration for the use of spirotetramat on the requested crops.

The proposed uses and the submitted data support the following permanent tolerances for

residues of the insecticide spirotetramat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spirotetramat (*cis*-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate]) and its metabolites *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, *cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat, in or on the following commodities:

Taro, leaves	9.0 ppm	Artichoke, globe	1.50 ppm
Watercress	2.0 ppm	Vegetable, fruiting, crop group 8-10	2.50 ppm
Bushberry subgroup 13-07B	3.0 ppm	Fruit, pome, crop group 11-10	0.70 ppm
Pomegranate	0.50 ppm	Fruit, citrus, crop group 10-10	0.60 ppm
Banana[1]	4.0 ppm	Pineapple	0.30 ppm
Vegetable, bulb, group 3-07	0.80 ppm	Coffee, green bean	0.15 ppm
Low growing berry subgroup 13-07H, except strawberry and lowbush blueberry	3.0 ppm	Coffee, instant	0.50 ppm
		Corn, sweet, kernel plus cob with husks removed[2]	1.5 ppm

[1] This tolerance should be established under 40 CFR §180.641(c) Tolerances with regional registrations.
[2] There are no U.S. registrations as of [date] for use on corn, sweet.

Note to RD: With the establishment of these tolerances, the following tolerances for the following commodities should be deleted: onion, bulb, subgroup 3A-07; vegetable, fruiting group 8; citrus, group 10; fruit, pome, group 11; and okra. HED also notes that the established tolerances for residues in/on feijoa, papaya, and Spanish lime in 40 CFR §180.641 are incorrect and the previously recommended tolerance for residues in/on persimmon is missing. The correct tolerances are: 2.5 ppm for feijoa, 0.35 ppm for papaya, 13 ppm for Spanish lime, and 2.5 ppm for persimmon (Memo, J. Van Alstine *et al.*, 22-DEC-2010; D368785). 40 CFR §180.641(a)(1) should be updated to reflect the recommended tolerances.

860.1200 Directions for Use

- A 260-day PBI for rotational crops is required to support the proposed use on watercress.
- As no residue data were submitted for an OD or equivalent formulation and higher residues result from this formulation type (Memo, G. Kramer, 17-APR-2008; D339694), the use directions for the subject crops should be removed from the BYI 8330 OD label.
- As all of the banana field trials were performed in HI, the registration for use on this crop should be limited to the state of HI.

860.1650 Submittal of Analytical Reference Standards

The analytical reference standard for BYI 08330-ketohydroxy has expired and the standards for the isotopically labeled internal standards of BYI 08330-enol and BYI 08330-ketohydroxy will soon expire (7/11/2013). The registrant should either recertify the lot in the repository and send an updated certificate of analysis (COA), or submit new standards (different lot #) if the previous lots will not be recertified. If new standards are being submitted, then they should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Thuy Nygen at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road

Fort George G. Meade, MD 20755-5350

860.1550 Proposed Tolerances

The petitioner is requested to submit a revised Section F specifying the following:

- Revised tolerance levels and commodity definitions presented in Table 27 (summarized above).

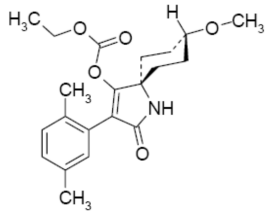
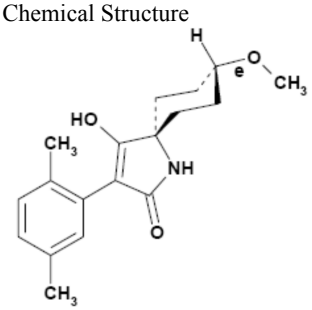
A human-health risk assessment is forthcoming.

Background

Spirotetramat is a tetramic acid derivative (ketoenole) developed by Bayer CropScience AG. This foliar insecticide is active against sucking insects in vegetables, citrus, pome fruit, stone fruit, grapes, cotton, and other plants. It is systemic (xylem and phloem mobile) and can control hidden pests and protect new shoots.

Details of the test compound nomenclature for spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, BYI 08330-enol-GA, and BYI 08330-enol-Glc are presented in Table 1. The physicochemical properties of technical grade spirotetramat are listed in Table 2.

Table 1. Test Compound Nomenclature.

Compound	Chemical Structure 
Common name	Spirotetramat
Company experimental name	BYI 08330
IUPAC name	*cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one
CAS name	*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate
CAS #	382608-10-8
End-use product/EP	Movento®, Ultor®, BYI 8330 OD
Compound: BYI 08330-enol	Chemical Structure 
Common name	BYI 08330-enol
Company experimental name	BYI 08330-enol
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one

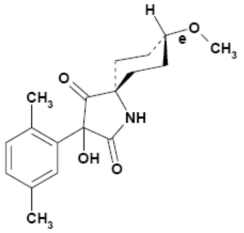
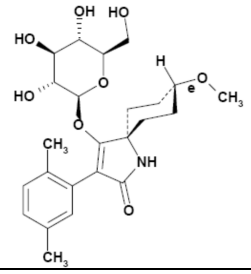
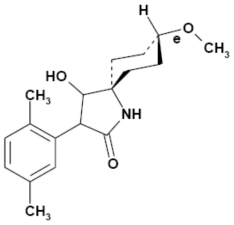
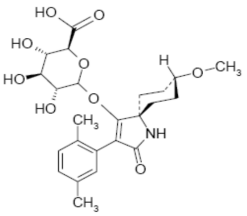
CAS #	None provided
Compound: BYI 08830-ketohydroxy	Chemical Structure 
Common name	BYI 08830-ketohydroxy
Company experimental name	BYI 08830-ketohydroxy
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione
CAS #	None provided
Compound: BYI 08330-enol-Glc	Chemical Structure 
Common name	BYI 08330-enol-Glc
Company experimental name	BYI 08330-enol-Glc
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside
CAS #	None provided
Compound: BYI 08330-mono-hydroxy	Chemical Structure 
Common name	BYI 08330-mono-hydroxy
Company experimental name	BYI 08330-mono-hydroxy
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one
CAS #	None provided
Compound: BYI 08330-enol-GA	Chemical Structure 
Common name	BYI 08330-enol-GA
Company experimental name	BYI 08330-enol-GA
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-(β-D-glucopyranosyloxy)-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one
CAS #	None provided

TABLE 2. Physicochemical Properties of the Spirotetramat.		
Parameter	Value	Reference
Melting point	142 °C	EPA Chemical Fact Sheet for Spirotetramat, June 2008
pH	6.3	
Density	D_4^{20} = 1.22	
Water solubility (20 ºC)	pH 4: 33.5 mg/L pH 7: 29.9 mg/L pH 9: 19.1 mg/L	
Solvent solubility (20 ºC)	Solvent — g/L n-hexane — 0.055 Dichloromethane — >600 Dimethyl Sulfoxide — 200-300 Toluene — 60 Acetone — 100-120 Ethyl acetate — 67 Ethanol — 44	
Vapor pressure	Extrapolated Values: 5.6 x 10^{-9} Pa (20 ºC) 1.5 x 10^{-8} Pa (25 ºC) 1.5 x 10^{-6} Pa (50 ºC)	
Dissociation constant, pK_a	10.7	Included in MRID 47648203
Octanol/water partition coefficient, Log(K_{OW})	pH 4: 2.51 pH 7: 2.51 pH 9: 2.50	EPA Chemical Fact Sheet for Spirotetramat, June 2008
UV/visible absorption spectrum	Peak Maxima (nm) — Molar Absorptivity (1000 cm^2/ mol) 211 — 22.0 x 10^3 276 — 0.8 x 10^3	

860.1200 Directions for Use

The petitioner has submitted draft labels for the 2 lb ai/gal SC formulation (Movento®; EPA Reg. No. 264-1050), for the 1.25 lb ai/gal SC formulation (Ultor®; EPA Reg. No. 264-1065), and the 1.25 lb ai/gal OD formulation (BYI 8330 OD; EPA Reg. No. 264-1051). Information pertaining to the proposed end-use product is listed in Table 3. A summary of the proposed use patterns on taro, watercress, pomegranates, bananas, bulb vegetables, low-growing berries (except strawberries), bushberries; globe artichokes, fruiting vegetables, pome fruit, citrus fruit, pineapples, and coffee is detailed in Table 4.

Table 3. Summary of Proposed End-Use Products.						
Trade Name	Reg. No.	ai (% of formulation)	Formulation Type	Target Crops	Target Pests	Label Date
Movento®	264-1050	22.4	SC	taro, watercress, pomegranates, bananas, bulb vegetables, low-growing berries (except strawberries), bushberries, globe artichokes, fruiting vegetables, pome fruit, citrus fruit, pineapples, and coffee.	sucking insects	Draft labels submitted 7/24/12
Ultor®	264-1065	14.5	SC			
BYI 8330 OD	264-1051	15.3	OD			

Table 4. Summary of Directions for Use of Spirotetramat.

Trade Names	Application Timing, Type, and Equipment	Application Rate (lb ai/A)	Maximum Number Applications per Season	Maximum Seasonal Application Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Banana and Plantain						
BYI 8330 OD Movento® Ultor®	Ground & aerial	0.16-0.25	7	1.25	1	Minimum RTI: 14 days Minimum spray volume: 50 gallons per acre (GPA) ground, 10 GPA aerial
Bushberry subgroups 13-07B and 13-07H						
BYI 8330 OD Movento® Ultor®	Ground & aerial	0.13-0.16	3	0.47	7	Minimum RTI: 7 days Minimum spray volume: 30 GPA ground, 10 GPA aerial
Coffee						
BYI 8330 OD Movento® Ultor®	Ground & aerial	0.13-0.16	3	0.47	14	Minimum RTI: 21 days Minimum spray volume: 30 GPA ground, 10 GPA aerial
Pineapple						
BYI 8330 OD Movento® Ultor®	Ground & aerial	0.16	2	0.32	1	Minimum RTI: 14 days Minimum spray volume: 30 GPA ground, 10 GPA aerial
Pomegranate						
BYI 8330 OD Movento® Ultor®	Ground & aerial	0.13-0.16	2	0.32	1	Minimum RTI: 14 days Minimum spray volume: 50 gallons per acre (GPA) ground, 10 GPA aerial
Bulb vegetables subgroups 3-07A and 3-07B						
BYI 8330 OD Movento® Ultor®	Ground, chemigation, & aerial	0.08	2	0.16	3 (3-07A) 7 (3-07B)	Minimum RTI: 7 days Minimum spray volume: 15 GPA ground, 5 GPA aerial
Globe artichoke						
BYI 8330 OD Movento® Ultor®	Ground, chemigation, & aerial	0.05-0.13	6	0.5	3	Minimum RTI: 7 days Minimum spray volume: 15 GPA ground, 5 GPA aerial
Watercress						
BYI 8330 OD Movento® Ultor®	Ground, chemigation, & aerial	0.06-0.2	6	0.4	3	Minimum RTI: 7 days Minimum spray volume: 15 GPA ground, 5 GPA aerial
Additional Restrictions for all Crops:						
Movento® and Ultor® must be tank-mixed with a spray adjuvant/additive. BYI 8330 OD may not be tank-mixed with a spray adjuvant/additive having sticking properties. Use in enclosed structures, such as greenhouses or planthouses, is not permitted. Rotational crop PBIs: 30 days for all non-labeled crops.						

Conclusions: The submitted use directions for Movento® and Ultor® are adequate to allow evaluation of the residue data relative to the proposed uses except that a 260-day PBI is required to support the proposed use on watercress. As all of the banana field trials were performed in HI, the registration for use on this crop should be limited to the state of HI. In addition, as no residue data were submitted for an OD or equivalent formulation and higher residues result from this formulation type (Memo, G. Kramer, 17-APR-2008; D339694), the use directions for the subject crops should be removed from the BYI 8330 OD label. **Revised labels are required.**

860.1300 Nature of the Residue - Plants

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

The nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on apple, lettuce, cotton, and potato. The major metabolic reaction involved the hydrolytic cleavage of the carbonate ester parent bond of the parent compound to form BYI 08330-enol. Further reduction of the double bond in the tetramic acid moiety of BYI 08330-enol occurred to form the BYI 08330-mono-hydroxy metabolite. Hydroxylation in the tetramic acid moiety resulted in BYI 08330-ketohydroxy. Demethylation of the methoxy group of the cyclohexyl ring resulted via a proposed intermediate (BYI 08330-desmethyl-enol) in BYI 08330-desmethyl-ketohydroxy (after the corresponding hydroxylation). Oxidation of the methoxy group resulted in BYI 08330-ketohydroxy-formiate. Partly, metabolites bearing a hydroxy group were conjugated with glucose. The residues of concern for the tolerance expression and risk assessment for plant commodities are spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-enol-Glc, and BYI 08330-mono-hydroxy (Memo, J. Tyler *et al.*, 16-APR-2008; D333437).

860.1300 Nature of the Residue - Livestock

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

The nature of the residue in livestock is adequately understood based on acceptable metabolism studies conducted on lactating goats and laying hens. In livestock, the biodegradation of spirotetramat in livestock can be characterized as cleavage of the carbonate ester group to the primary metabolite BYI 08330-enol followed by conjugation of the enol hydroxy group with glucuronic acid to BYI 08330-enol-GA. Oxidation of the azaspirodecenyl moiety to BYI 08330-ketohydroxy and demethylation of the methoxy group to BYI 08330-desmethyl-enol were minor metabolic reactions in ruminants as well as reduction of the azaspirodecenyl moiety to BYI 08330-monohydroxy. Based on the currently proposed uses, the residues of concern for the tolerance expression for livestock commodities are spirotetramat and its metabolite BYI 08330-enol and the residues of concern for the risk assessment for livestock commodities are spirotetramat and its metabolites BYI 08330-enol and BYI 08330-enol-GA (Memo, J. Tyler *et al.*, 16-APR-2008; D333437).

860.1340 Residue Analytical Methods

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

Samples were analyzed for residues of spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, and BYI 08330-enol-glucoside using a HPLC-MS/MS method, Method 00857, the current enforcement method for crop commodities. Residues of each metabolite were reported in parent equivalents. Analytical method 00857 was developed for the determination of residues of spirotetramat, the metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, and BYI 08330-enol-Glc in plant matrices by HPLC-MS/MS using isotopically labeled internal standards. Spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, and BYI 08330-enol-Glc were extracted from the plant commodity using a blender with acidic acetonitrile/water (4/1, v/v). After

subsequent clean-up of the extract through a Bond Elut clean polyethylene frit, the corresponding internal standards were added. The solution was made up to volume, diluted, and subjected to HPLC-MS/MS with multiple-reaction monitoring of two transitions for each matrix and analyte for quantitation and confirmation purposes. The limit of quantitation (LOQ) was 0.01 ppm for each analyte on all tested plant commodities with the exception of roasted coffee bean (BYI 08830-glucoside had an LOQ of 0.05 ppm) and freeze-dried coffee (the LOQ was 0.1 ppm for each analyte). The method was adequate for data collection based on acceptable concurrent method recovery data.

860.1360 Multiresidue Methods (MRMs)

DER Reference List: 46904496.der.doc

Spirotetramat and five metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, BYI 08330-enol-Glc, and BYI 08330-enol-GA were screened through multiresidue methods described in the U.S. Food and Drug Administration (FDA) Pesticide Analytical Manual, Vol. I (PAM I). Spirotetramat and the metabolites were tested for natural fluorescence using procedures outlined in Protocol A of PAM I. BYI 08330-mono-hydroxy was the only compound found to be naturally fluorescent; no further test with this protocol was performed.

Spirotetramat and its metabolites were subjected to Protocol C, modules DG1, DG5, DG13, DG17, and DG18. Due to the poor sensitivity of the test substances to detection by method described in Protocol C, no further analyses were performed for Protocols D, E, or F. Since the test substances are not acidic, phenols or substituted ureas, analyses were not performed using Protocols B or G.

Conclusions: The MRMs are not suitable for the analysis of spirotetramat or its metabolites.

860.1380 Storage Stability

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

Freezer storage stability data are available for five diverse crops (i.e., a fruiting vegetable-tomato; a root crop-potato, a leafy vegetable-head lettuce; a nut-almond nutmeat; and a legume-bean with pod) which demonstrate stability of residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy for up to 718 days of frozen storage. These data support the storage conditions and intervals of samples collected from the various crop field trials. There are no unresolved storage stability issues, and no corrections need to be applied to the various residue crop studies.

860.1480 Meat, Milk, Poultry, and Eggs

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

The currently established livestock tolerances are based on the following reasonably balanced dietary burdens (RBDBs) for spirotetramat and its metabolites: 2.7 ppm for beef cattle, 10.2 ppm for dairy cattle, 1.2 ppm for poultry, and 0.75 ppm for swine. The only feedstuff associated

with the proposed new uses is pineapple process residue, a minor feed item. As the calculated maximum residue calculated for pineapple process residue (0.14 ppm, see 860.1520 Processed Food and Feed) is very low relative to the RBDBs, addition of this feed item to the livestock diets would not have a significant effect on the estimated residue levels in livestock commodities. The currently established tolerances for residues of spirotetramat and its metabolite in livestock commodities are thus adequate to support the proposed new uses.

860.1500 Crop Field Trials

Bushberry subgroup 13-07B

DER Reference List: 48697601.der.doc

Eleven blueberry field trials were conducted in the U.S. or Canada encompassing North Atlantic Free Trade Agreement (NAFTA) Growing Zones 1 (NB and ME; 2 trials on lowbush blueberries), 1A (NS; 2 trials on lowbush blueberries), 2 (NC and NJ; 3 trials on highbush blueberries), 5 (ON; 1 trial on highbush blueberries), 5A (MI; 2 trials on highbush blueberries), and 12 (OR; 1 trial on highbush blueberries) during the 2009 growing season.

Two trials on highbush blueberries in Zone 5A were conducted by the same Principal Field Investigator (PFI) and at the same location in Michigan. Based on examination of the field trial records, it is concluded that MI trials AAFC09-030R-136 and AAFC09-030R-137 constitute a single trial with replicate samples for purposes of 860.1500 data requirements. Other than having independently prepared tank-mixes, there were no differences between the trials judging by the HED Science Advisory Council for Chemistry (ChemSAC) criteria for differentiation of field trials. With the classification of these trials as replicates, the number of separate trials for the purposes of 860.1500 data requirements is adjusted to 10 for lowbush and highbush blueberries combined, with there being six trials, instead of seven, for highbush blueberries, distributed among Zones 2 (3 trials), 5 (1 trial), 5A (1 trial), and 12 (1 trial).

At each trial location, a 2 lb ai/gal SC formulation of spirotetramat was applied to blueberries in three foliar applications during various fruiting (berry-formation) stages, at rates of 0.152-0.167 lb ai/A/application, for total seasonal rates of 0.466-0.497 lb ai/A (1X). Applications were made using ground equipment in volumes of 12.3-61.3 GPA. RTIs were 5-8 days. A non-ionic surfactant (NIS) was added to the spray mixture as an adjuvant for all applications. Each field trial site consisted of one untreated plot and one treated plot. Blueberries were harvested at PHIs of 6-8 days. In one lowbush blueberry trial, samples were harvested at PHIs of 1, 3, 7, and 10 days after treatment to assess residue decline.

Following three foliar broadcast applications of the 2 lb ai/gal SC formulation of spirotetramat totaling 0.466-0.497 lb ai/A per season, combined residues (and per-trial averages) of spirotetramat and its metabolites in/on blueberries harvested at a 6- to 8-day PHI were 0.369-1.235 (0.378-1.209) ppm for lowbush blueberries and 0.400-1.560 (0.448-1.548) ppm for highbush blueberries (Table 5). Residue-decline data show that residues of spirotetramat and its metabolites decrease in blueberries with increasing PHIs.

Table 5. Summary of Residue Data from Crop Field Trials with Spirotetramat.										
			Combined Residue Levels (ppm)[1]							
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.47 lb ai/A total application rate; PHI of 7 days										
Lowbush Blueberries	0.466-0.469	7-8	4	0.369	1.235	0.378	1.209	0.548	0.671	0.378
Highbush Blueberries	0.466-0.497	6-7	6[3]	0.400[4]	1.560	0.448	1.548	0.589	0.789	0.435

[1] Except for sample min/max, values reflect per-trial means; n = number of field trials. Calculation assumed LOQ residues for residues <LOQ.
[2] LAFT = lowest-average field trial; HAFT = highest-average field trial.
[3] N is 6 instead of 7 because trial pair AAFC09-030R-136/AAFC09-030R-137 constitutes a single trial with replicate samples for purposes of 860.1500 data requirements.
[4] The sample minimum was from one of four samples collected in the replicate trial pair AAFC09-030R-136/AAFC09-030R-137.

Conclusions: The number and locations of the crop field trials are not in accordance with OPPTS Guideline 860.1500 (Table 6) as a highbush blueberry trial was not performed in Zone 1. HED will not require additional data as four lowbush blueberry trials were performed in this zone and residues in highbush lowbush blueberries are comparable. The submitted residue data are thus adequate to fulfill data requirements for highbush blueberries as a representative crop of the bushberry subgroup 13-07B. The available data will support the proposed use pattern.

Table 6. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Blueberry		
		Requested	
	Submitted	Canada	U.S.
1	2 (both lowbush)		1 (highbush)
1A	2 (both lowbush)		
2	3 (all highbush)		3 (all highbush)
5	1 (highbush)		3 (all highbush)
5A	1[1] (highbush)		
12	1 (highbush)		1 (highbush)
Total	10 (4 lowbush and 6 highbush)		8 (all highbush)

[1] Trial pair AAFC09-030R-136/AAFC09-030R-137 constitutes a single trial with replicate samples for purposes of 860.1500 data requirements.

The residue data for highbush blueberries were analyzed using the Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 3.0 ppm in/on the bushberry subgroup 13-07B.

Low-growing berry subgroup 13-07H, except strawberry

DER Reference List: 48697602.der.doc

Six cranberry field trials were conducted in the U.S. or Canada encompassing NAFTA Growing Zones 1 (MA; 1 trial), 2 (NJ; 1 trial), 5A (WI; 2 trials), and 12 (BC and OR; 1 trial in each) during the 2009 growing season. MRID 48697602 identifies the trial in Chatsworth, NJ, as being in NAFTA Growing Zone 1; however, according to OCSPP 860.1500, that trial would be in Zone 2 because it was located south of Rt. 1, which would place it about 25 miles outside of Zone 1.

Two trials on cranberries in Zone 5A were conducted by the same PFI and at the same location in Wisconsin. Based on examination of the field trial records, it is concluded that WI trials

AAFC09-050R-145 and AAFC09-050R-146 constitute a single trial with replicate samples for purposes of 860.1500 data requirements as only three of the four variables of the HED ChemSAC criteria for differentiation of field trials were met: (1) having independently prepared tank-mixes, (2) using different varieties, and (3) using spray volumes that were sufficiently and consistently different. With the classification of these trials as replicates, the number of separate trials for the purposes of 860.1500 data requirements is five, with one in Zone 1, one in Zone 2, one in Zone 5A, and two in Zone 12.

At each trial location, a 2 lb ai/gal SC formulation of spirotetramat was applied to cranberries in three foliar applications during various fruiting (berry-formation) or mature-fruit stages, at rates of 0.151-0.165 lb ai/A/application, for total seasonal rates of 0.462-0.489 lb ai/A (1X). Applications were made using ground equipment in volumes of 25.7-59.3 GPA. RTIs were 6-8 days. A NIS was added to the spray mixture for all applications. Each field trial site consisted on one untreated plot and one treated plot. Cranberries were harvested at PHIs of 7-8 days. Additional samples of cranberries were harvested from one trial at PHIs of 1, 4, and 11 days after treatment to assess residue decline.

Following three foliar broadcast applications of the 2 lb ai/gal SC formulation of spirotetramat totaling 0.462-0.489 lb ai/A per season, combined residues (and per-trial averages) of spirotetramat and its metabolites in/on cranberries harvested at a 7- to 8-day PHI were <0.05-0.153 (0.052-0.152) ppm (Table 7). Residue-decline data show that residues of spirotetramat and its metabolites decrease in cranberries with increasing PHIs.

Table 7. Summary of Residue Data from Crop Field Trials with Spirotetramat.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels (ppm)[1]							
			n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.47 lb ai/A total application rate; PHI of 7 days										
Cranberries	0.462-0.489	7-8	5[3]	<0.05	0.153	0.052	0.152	0.076	0.085	0.041

[1] Except for sample min/max, values reflect per-trial means; n = number of field trials. Calculation assumed LOQ residues for residues <LOQ.
[2] LAFT = lowest-average field trial; HAFT = highest-average field trial.
[3] N is 5 instead of 6 because trial pair AAFC09-050R-145/AAFC09-050R-146 constitutes a single trial with replicate samples for purposes of 860.1500 data requirements.

Conclusions: The submitted residue data are adequate to fulfill data requirements for cranberries as a representative crop of the low-growing berry subgroup 13-07H, except strawberry. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 8). The available data will support the proposed use pattern.

Table 8. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Cranberry		
	Submitted	Requested	
		Canada	U.S.
1	1		2
2	1[1]		
5			2
5A	1[2]		
12	2		1
Total	5		5

[1] MRID 48697602 identifies the trial in Chatsworth, NJ, as being in NAFTA Growing Zone 1; however, according to OCSPP 860.1500, that trial would be in Zone 2 because it was located south of Rt. 1, which would place it about 25 miles outside of Zone 1.
[2] Trial pair AAFC09-050R-145/AAFC09-050R-146 constitutes a single trial with replicate samples for purposes of 860.1500 data requirements.

The residue data for cranberries were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.30 ppm in/on the low-growing berry subgroup 13-07H, except strawberry and lowbush blueberry. The exclusion of lowbush blueberry is necessitated by the residue data that show that a tolerance level of 3.0 ppm is required for this crop (see Appendix II). Since lowbush blueberries are also a member of bushberry subgroup 13-07B, a separate tolerance for residues in/on "blueberry, lowbush" is not required.

Watercress

DER Reference List: 48697603.der.doc

Three field trials were conducted in the U.S. during the 2008 growing season in the NAFTA Growing Zones 1 (MD; 1 trial) and 3 (FL; 2 trials). The FL38 and FL39 trials were conducted in the same county and under similar soil (sand) and similar growing conditions (re-circulating the water using pumps and man-made drainage systems simulating natural water flow). These trials would not normally satisfy the HED ChemSAC criteria for differentiation of field trials; however, because the trials were conducted by different personnel in different ponds and the geographic area suitable for watercress cultivation is limited, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements.

Each trial consisted of one untreated plot and one or two treated plots. At each trial location, one treated plot received two foliar broadcast applications of Movento® (2 lb ai/gal SC) at 0.189-0.199 lb ai/A/application, for a total seasonal rate of 0.379-0.395 lb ai/A (~1X). Applications were made at 7- to 8-day RTIs using ground equipment in spray volumes of 29.94-38.16 GPA. At the FL38 trial site, a second plot received two chemigation applications using overhead mini-sprinklers at the same treatment rate in spray volumes of 601.76-608.98 GPA (RTI = 8 days). A non-ionic surfactant/organosilicone surfactant (NIS/OSS) was added to the spray mixture for each of the applications, with the exception of application 1 at the FL39 trial which did not use an adjuvant. Samples of watercress were harvested from all trials at a 3-day PHI.

Following two foliar broadcast applications of the 2 lb ai/gal SC formulation of spirotetramat at 0.379-0.395 lb ai/A (use pattern 1), combined residues (and per-trial averages) of spirotetramat and its metabolites in/on watercress leaves and stems harvested at a 3-day PHI were <0.29-<0.70 (<0.29-<0.67) ppm; corresponding residues (and per-trial averages) following two chemigation applications at 0.392 lb ai/A (use pattern 2) were <0.53-<0.59 (<0.56) ppm (Table 9).

Examination of the results indicates that the residues from the chemigation samples fell within the range of residues of samples from both treatment types. Thus, there were no significant differences in residues resulting from the conventional spray application and the chemigation application.

Table 9. Summary of Residue Data from Watercress Field Trials with Spirotetramat (Combined Broadcast and Chemigation Trials).

Commodity	Analyte	Total Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]							
				n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.4 lb ai/A total application rate; PHI of 3 days											
Watercress, leaves and stems	Spirotetramat	0.379-0.395	3	4	<0.01	0.054	<0.01	0.049	0.013	0.021	0.019
	Enol[3]				0.16	0.40	0.17	0.37	0.28	0.28	0.083
	Enol-glucoside[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Ketohydroxy[3]				0.090	0.28	0.094	0.27	0.25	0.21	0.081
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Combined[4]				<0.29	<0.70	<0.29	<0.67	0.58	0.53	0.17

[1] Except for sample min/max, values reflect per-trial averages; n = no. of field trials. N/A= not applicable
[2] LAFT = lowest-average field trial; HAFT = highest-average field trial.
[3] Data reflect conversion of quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc to parent equivalents.
[4] Combined residues include spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc, expressed as parent equivalents.

Conclusions: The submitted residue data for watercress are adequate to fulfill data requirements. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 10). The available data will support the proposed use pattern.

Table 10. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Watercress		
	Submitted	Requested[1]	
		Canada	U.S.
1	1	--	--
3	2	--	--
Total	3	--	2

[1] As per OPPTS 860.1500, Table 1 for watercress; Table 5 does not include watercress. Two field trials are required in major watercress producing regions.

The residue data for watercress were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 2.0 ppm.

Coffee

DER Reference List: 48697604.der1.doc

Five field trials were conducted in the U.S. during the 2009 growing season in the NAFTA Growing Zone 13 (HI). All trials were conducted by the same principal field investigator (PFI) but trials 09-HI09 & 09-HI11, 09-HI10, and 09-HI12 & 09-HI13 were conducted on different Hawaiian Islands; thus, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements. Trial pairs 09-HI09 & 09-HI11 and 09-HI12 & 09-HI13 would not normally satisfy the HED ChemSAC criteria for differentiation of field trials; however, because the geographic area suitable for coffee cultivation is limited, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements.

Each trial consisted of one untreated plot and one treated plot. At each trial location, the treated

plot received three foliar directed applications of Movento® (2 lb ai/gal SC) at 0.1584-0.1727 lb ai/A/application, for a total seasonal rate of 0.4778-0.5052 lb ai/A (1X). Applications were made at 20- to 22-day RTIs using ground equipment in spray volumes of 25.39-49.82 GPA; the interval between the second and third application was shortened to 13 and 7 days, respectively, in trials 09-HI11 and 09-HI12 because the beans were ripening earlier than expected. A NIS/OSS was added to the spray mixture for each of the applications. Samples of coffee bean "cherries" were harvested from four trials at a 13-14-day PHI; samples were collected at a 7-day PHI in trial 09-HI11. Additional samples were collected at PHIs of 1, 7, and 21 days from one trial (09-HI13) to assess residue decline. The coffee bean cherries were processed by field personnel into the green bean coffee RAC.

Following three foliar directed applications of the 2 lb ai/gal SC formulation of spirotetramat at 0.4778-0.5052 lb ai/A, residues (and per-trial averages) of BYI 08330-enol, BYI 08330-glucoside, and combined residues of parent and all metabolites, respectively, in/on green bean coffee harvested at a 14-day PHI were <0.01-0.033 (<0.01-0.028), <0.01-0.016 (<0.01-0.014), and <0.05-<0.079 (<0.05-<0.072) ppm; residues of spirotetramat, BYI 08330-ketohydroxy, and BYI 08330-monohydroxy were <LOQ (0.01 ppm) in/on all samples of green bean coffee (Table 11).

The residue-decline data indicate that residues of BYI 08330-enol and combined residues increased with increasing PHIs. Residues of spirotetramat, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were near to or <LOQ at each sampling interval; therefore, residue decline could not be assessed.

Table 11. Summary of Residue Data from Coffee Field Trials with Spirotetramat.

Commodity	Analyte	Total Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]							
				n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.47 lb ai/A total application rate; PHI of 14 days											
Coffee, Green bean	Spirotetramat	0.4778-0.5052	14	4	<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Enol[3]				<0.01	0.033	<0.01	0.028	0.018	0.019	0.007
	Ketohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Glucoside[3]				<0.01	0.016	<0.01	0.014	0.011	0.011	0.002
	Combined[4]				<0.05	<0.079	<0.05	<0.072	0.058	0.060	0.009

[1] Except for sample min/max, values reflect per-trial averages; n = no. of field trials. N/A= not applicable
[2] LAFT = lowest-average field trial; HAFT = highest-average field trial.
[3] Data reflect conversion of quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330- Glc to parent equivalents.
[4] Combined residues include spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc, expressed as parent equivalents.

Conclusions: The submitted residue data for coffee are adequate to fulfill data requirements. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 12). The available data will support the proposed use pattern.

Table 12. Trial Numbers and Geographical Locations.			
	Coffee		
		Requested[1]	
NAFTA Growing Regions	Submitted	Canada	U.S.
13	5	--	5
Total	5	--	5

[1] As per OPPTS 860.1500, Table 5 for coffee.

The residue data for coffee, green bean were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.20 ppm.

Banana

DER Reference List: 48697605.der.doc

Five field trials were conducted in the U. S. during the 2008-2009 growing seasons in the NAFTA Growing Zone 13 (HI). All trials were conducted by the same PFI, but trials 08-HI05 & 08-HI10 and 08-HI06 & 08-HI09 & 09-HI14 were conducted on different Hawaiian Islands and trial pair 08-HI05 & 08-HI10 were conducted in different growing seasons; thus, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements. Trials 08-HI06 & 08-HI09 & 09-HI14 were separated by >20 miles, had a >30 day-off set in application dates, and used a different variety of banana (trial 08-HI06 only). Trials 08-HI09 & 09-HI14 would not normally satisfy the HED ChemSAC criteria for differentiation of field trials; however, because the geographic area suitable for banana cultivation is limited, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements.

Each trial consisted of one untreated plot and one treated plot. At each trial location, the treated plot received five foliar directed applications of Movento® (2 lb ai/gal SC) at 0.245-0.267 lb ai/A/application, for a total seasonal rate of 1.25-1.30 lb ai/A (1X). The test substance was applied to bagged bunches at trial HI05; the bunches were not bagged at the remaining trial sites. Applications were made at 13- to 15-day RTIs using ground equipment in spray volumes of 40.99-80.16 GPA. A NIS/OSS was added to the spray mixture for each of the applications. Samples of bananas (fruit with peel) were harvested from all trials at a 1-day PHI; samples of peeled fruit were also collected from one trial (HI06). Additional samples were collected at PHIs of 3, 7, and 14 days from one trial (HI14) to assess residue decline.

Following five foliar-directed applications of Movento® (2 lb ai/gal SC) at 1.25-1.30 lb ai/A, residues (and per-trial averages) of combined residues of spirotetramat and its metabolites in/on unbagged banana fruit, bagged banana fruit, and combined bagged and unbagged fruit, respectively, harvested at a 1-day PHI were <0.51-<2.1 (<0.62-<1.8), <0.19-<0.20 (<0.20), and <0.19-<2.1 (<0.20-<1.8) ppm (Table 13). Residues of BYI 08330-monohydroxy were below the LOQ (<0.01 ppm) in/on all samples of banana; residues of BYI 08330-glucoside were only detected at the HI10 trial site (0.014-0.015 ppm). Combined residues of spirotetramat and its metabolites in/on peeled fruit were <0.19 ppm (0.31X the residue in the corresponding unpeeled sample). Residues were highest in fruit samples that were not bagged.

The residue-decline data indicate that average combined residues of spirotetramat and its metabolites were <1.5 ppm at the 1-day PHI, decreased to <0.49 ppm at the 7-day PHI, and

increased to <0.63 ppm at the 14-day PHI. Individual residues of spirotetramat reflected this same trend, whereas BYI 08330-enol decreased with increasing PHIs. Residues of BYI 08330-ketohydroxy increased with increasing PHIs. At a 1-day PHI average residues of BYI 08330-ketohydroxy were 0.048 ppm and increased to 0.086 ppm by the 14-day PHI. Residues of BYI 08330-monohydroxy and BYI 08330-glucoside were <LOQ at each sampling interval; therefore, residue decline could not be assessed.

Table 13. Summary of Residue Data from Unbagged Banana Field Trials with Spirotetramat.

Commodity	Analyte	Total Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1] n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 1.25 lb ai/A total application rate; PHI of 1 days											
Banana, Whole Fruit	Spirotetramat	1.25-1.29	1	4	0.20	1.5	0.29	1.2	0.77	0.76	0.46
	Enol[3]				0.21	0.61	0.26	0.60	0.38	0.40	0.17
	Ketohydroxy[3]				0.034	0.092	0.048	0.087	0.052	0.060	0.018
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Glucoside[3]				<0.01	0.015	<0.01	0.015	0.010	0.011	<0.001
	Combined[4]				<0.51	<2.1	<0.62	<1.8	1.4	1.3	0.50
Banana, Peeled Fruit	Spirotetramat	1.26	1	1	0.013	0.017	0.015	0.015	0.015	0.015	N/A
	Enol[3]				0.12	0.12	0.12	0.12	0.12	0.12	N/A
	Ketohydroxy[3]				0.033	0.033	0.033	0.033	0.033	0.033	N/A
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Glucoside[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Combined[4]				<0.19	<0.19	<0.19	<0.19	0.19	0.19	N/A

[1] Except for sample min/max, values reflect per-trial averages; n = no. of field trials. N/A= not applicable.
[2] LAFT = lowest average field trial; HAFT = highest average field trial.
[3] Data reflect conversion of quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330- Glc to parent equivalents.
[4] Combined residues include spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc, expressed as parent equivalents.

Conclusions: The number and locations of the crop field trials are not in accordance with OPPTS Guideline 860.1500 (Table 14) as a banana trial was not performed in Zone 3. Provided that the registration is limited to HI, the submitted residue data for bananas are adequate to fulfill data requirements for a regional registration. The available data will support the proposed use pattern.

Table 14. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Banana		
	Submitted	Requested[1]	
		Canada	U.S.
3	--	--	1
13	5	--	4
Total	5	--	5

[1] As per OCSPP 860.1500, Table 5 for banana.

The residue data for unbagged bananas were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.50 ppm.

Pomegranate

DER Reference List: 48697606.der.doc

Four field trials were conducted in the U.S. during the 2009 growing season in NAFTA Growing Zone 10 (CA). Trial pairs 09-CA71 & 09-CA72 and 09-CA69 & 09-CA70 were each conducted at the same location and used the same variety of pomegranate. Examination of the field trial records indicates that the only differences between trials 09-CA69 & 09-CA70, in addition to different tank mixes, were: a >30-day off-set in application dates and the spray volume varied by >25%; there were no differences (other than separate tank mixes) for the 09-CA71 & 09-CA72 trials. These trials would not normally satisfy the HED ChemSAC criteria for differentiation of field trials; however, because areas suitable for pomegranate production are limited, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements.

Each trial consisted of one untreated plot and one treated plot. At each trial location, the treated plot received two foliar directed applications of Movento® (2 lb ai/gal SC) at 0.154-0.162 lb ai/A/application, for a total seasonal rate of 0.311-0.318 lb ai/A (1X). Applications were made at a 14-day RTI using ground equipment in spray volumes of 58.71-113.69 GPA. A NIS was added to the spray mixture for each of the applications at the Reedley, CA trial sites and a crop-oil concentrate (COC) was added to the spray mixture at the Gridley, CA trial sites. Samples of pomegranate were harvested from all trials at a 1-day PHI. Additional samples were collected at PHIs of 3, 7, and 14 days from one trial (CA69) to assess residue decline.

Following two foliar directed applications of the 2 lb ai/gal SC formulation of spirotetramat at 0.311-0.318 lb ai/A, residues (and per-trial averages) of spirotetramat, BYI 08330-enol, BYI 08330-glucoside, and combined residues, respectively, in/on pomegranates harvested at a 1-day PHI were 0.025-0.13 (0.029-0.11), 0.015-0.085 (0.017-0.073), <0.01-0.024 (<0.01-0.022), and <0.070-<0.199 (<0.076-<0.174) ppm; residues of BYI 08330-ketohydroxy and BYI 08330-monohydroxy were <LOQ (0.01 ppm) in/on all samples of pomegranate (Table 15).

The residue-decline data indicate that residues of spirotetramat, BYI 08330-enol, and combined residues decreased with increasing PHIs. Residues of BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were near to or <LOQ at each sampling interval; therefore, residue decline could not be assessed.

Table 15. Summary of Residue Data from Pomegranate Field Trials with Spirotetramat.

Commodity	Analyte	Total Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]							
				n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.32 lb ai/A total application rate; PHI of 1 day											
Pomegranate, Fruit	Spirotetramat	0.311-0.318	1	4	0.025	0.13	0.029	0.11	0.054	0.062	0.035
	Enol[3]				0.015	0.085	0.017	0.073	0.052	0.048	0.028
	Ketohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Glucoside[3]				<0.01	0.024	<0.01	0.022	0.015	0.016	0.006
	Combined[4]				<0.070	<0.199	<0.076	<0.174	0.165	0.145	0.047

[1] Except for sample min/max, values reflect per-trial averages; n = no. of field trials. N/A= not applicable.
[2] LAFT = lowest average field trial; HAFT = highest average field trial.
[3] Data reflect conversion of quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330- Glc to parent equivalents by the petitioner.

[4] Combined residues include spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc, expressed as parent equivalents.

Conclusions: The submitted residue data for pomegranate are adequate to fulfill data requirements. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 16). The available data will support the proposed use pattern.

Table 16. Trial Numbers and Geographical Locations.

	Pomegranate		
		Requested[1]	
NAFTA Growing Regions	Submitted	Canada	U.S.
10	4	--	--
Total	4	--	3 or 2[2]

[1] As per OCSPP 860.1500, Table 1 for pomegranate; Table 5 does not include pomegranate. The field trials are required in major pomegranate producing regions. According to OCSPP 860.1500, Table 6, 99% of pomegranate production is in Zone 10.
[2] As per OCSPP 860.1500, Table 1, the petitioner has the option of doing three trials with two treated samples (1X rate) per-trial or two trials with four treated samples (two at 1X rate, two at 2X rate) per-trial.

The residue data for pomegranate were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.50 ppm.

Artichoke, globe

DER Reference List: 48697607.der.doc (prepared by PMRA)

Agriculture and Agri-Food has submitted field trial data for spirotetramat on globe artichoke. A total of five globe artichoke field trials were conducted in Canada and the U.S. during the 2009-2010 growing seasons encompassing NAFTA Growing Zones 5B (1 trial in QC), 10 (3 trials in CA), and 12 (1 trial in BC). At each trial site, Movento® (2 lb ai/gal SC) was applied to globe artichoke plants as four foliar applications at rates of 0.12-0.13 lb ai/A, with RTIs of 5-9 days, for a total application rate of 0.49-0.50 lb ai/A/season (1X). A NIS was included in each of the spray mixtures at a rate of 0.25-0.26%, v/v. Globe artichoke flower heads (buds) were harvested 2-3 DALA. At Trial ID# 125 in L'Acadie, Quebec, additional samples were harvested at 1, 3, and 10 DALA to assess residue decline behavior.

Total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on globe artichokes treated with a suspension concentrate formulation, as four foliar applications at total rates of 0.49-0.50 lb ai/A/season and harvested at PHIs of 2-3 days ranged from <0.22-<0.75 ppm (Table 17). The residue decline data indicate that total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on globe artichoke decreased with increasing PHIs.

Table 17. Summary of Residue Data from Globe Artichoke Crop Field Trials with Spirotetramat.										
	Total Applic. Rate	PHI	Residue Levels (ppm)							
Analyte	(lb ai/A)	(days)	n	Min.	Max.	LAFT*	HAFT*	Median	Mean	Std. Dev.
Proposed use = 0.5 lb ai/A total application rate; PHI of 3 days										
Spirotetramat	0.49-0.50	2-3	5	0.012	0.38	0.016	0.32	0.06	0.14	0.14
BYI 08330-enol[1]			5	0.11	0.23	0.11	0.21	0.16	0.17	0.042
BYI 08330-enol-Glc[1]			5	0.02	0.051	0.026	0.036	0.033	0.031	0.004
BYI 08330-ketohydroxy[1]			5	0.066	0.19	0.07	0.17	0.095	0.10	0.037
BYI 08330-mono-hydroxy[1]			5	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Total[2]			5	<0.22	<0.75	<0.23	<0.70	0.41	0.46	0.19

* LAFT = lowest average field trial; HAFT = highest average field trial.
[1] Residues of the metabolites BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-Keto-OH, and BYI 08330-Mono-OH were reported in the study as parent equivalents.
[2] Total Residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy, all expressed as parent equivalents

Conclusions: The submitted residue data for globe artichoke are adequate to fulfill data requirements. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 18). The available data will support the proposed use pattern.

TABLE 18. Trial Numbers and Geographical Locations.			
	Globe Artichoke		
		Requested[1]	
NAFTA Growing Regions	Submitted	Canada	U.S.
5B	1		
10	3		
12	1		
Total	5	2	3

[1] As per OCSPP 860.1500, Table 5 does not include globe artichoke. The field trials are required in major globe artichoke producing regions. According to OCSPP 860.1500, Table 6, 100% of globe artichoke production is in Zone 5.

The residue data for globe artichoke were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 1.5 ppm.

Vegetable, bulb, group 3-07

DER Reference List: Green Onion, 48697609.der.doc (prepared by PMRA)
Bulb Onion, 48697608.der.doc (prepared by PMRA)

Agriculture and Agri-Food Canada has submitted field trial data for spirotetramat on **green onions**. A total of two green onion field trials were conducted in Canada during the 2009 growing season encompassing NAFTA Growing Zones 5 (1 trial in ON) and 5B (1 trial in QC). At each trial site, Movento® (2 lb ai/gal SC) was applied to green onion as two foliar applications at rates of 0.081-0.082 lb ai/A, with RTIs of 6-7 days, for a total application rate of 0.16 lb ai/A/season (1X). A NIS was included in each of the spray mixtures at a rate of 0.25%, v/v. Green onion plants were harvested 6-7 DALA. At the Ontario trial, additional samples were harvested at 1, 4, and 11 DALA to assess residue-decline behavior.

Total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on green onions treated with Movento®, as two foliar applications at total rates of 0.16 lb ai/A/season and harvested at PHIs of 6-7 days ranged from <0.15-<0.34 ppm (Table 19). The residue decline data indicate

that total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on green onions decreased with increasing PHIs.

At a meeting held on 9/14/2011, the HED ChemSAC concluded that these data could be used to support a conditional registration and a tolerance for the bulb vegetable crop group. The registration should be made conditional pending submission of data from one additional green onion residue trial (conducted in NAFTA Growing Zone 10, four samples at proposed PHI). A preliminary report of the residue data from this trial has been received by HED (Personal Communication from Barbara Madden, 1/31/2013). These data are included in Table 19 and in the OECD tolerance-calculation procedures (see Appendix II).

Table 19. Summary of Residue Data from Green Onion Crop Field Trials with Spirotetramat.

Analyte	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)							
			n	Min.	Max.	LAFT*	HAFT*	Median	Mean	Std. Dev.
Proposed use = 0.16 lb ai/A total application rate; PHI of 7 days										
Spirotetramat	0.16	6-7	3	<0.01	0.10	<0.01	0.10	0.040	0.049	0.045
BYI 08330-enol[1]			3	<0.01	0.16	<0.01	0.14	0.054	0.068	0.066
BYI 08330-enol-Glc[1]			3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
BYI 08330-ketohydroxy[1]			3	<0.01	0.075	<0.01	0.065	0.050	0.042	0.028
BYI 08330-mono-hydroxy[1]			3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Total[2]			3	<0.051	<0.34	<0.050	<0.32	0.17	0.18	0.135

* LAFT = lowest-average field trial; HAFT = highest-average field trial.
[1] Residues of the metabolites BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-Keto-OH, and BYI 08330-Mono-OH were reported in the study as parent equivalents.
[2] Total Residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy, all expressed as parent equivalents.

Agriculture and Agri-Food Canada has submitted field trial data for spirotetramat on **dry bulb onions**. A total of 12 dry bulb onion field trials were conducted in Canada and the U.S. during the 2008-2009 growing seasons encompassing NAFTA Growing Zones 1 (1 trial in NY), 5 (2 trials in ON), 5A (1 trial in WI), 5B (2 trials in QC), 6 (1 trial in TX), 8 (1 trial in CO), 10 (2 trials in CA), 11 (1 trial in ID), and 12 (1 trial in OR). At each trial site, Movento® (2 lb ai/gal SC) was applied to dry bulb onions as two broadcast foliar applications at rates of 0.074-0.083 lb ai/A, with RTIs of 6-8 days, for a total application rate of 0.15-0.17 lb ai/A/season (1X). A NIS was included in each of the spray mixtures at a rate of 0.25%, v/v. Dry bulb onions were harvested at PHIs of 2-4 days. At two of the trial sites, additional samples were harvested at 1, 6 or 7, and 9 or 10 DALA to assess residue-decline behavior.

Total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on dry bulb onion samples treated with Movento®, as two broadcast foliar applications at total rates of 0.15-0.17 lb ai/A/season and harvested at PHIs of 2-4 days ranged from <0.054-<0.34 ppm (Table 20). The residue-decline data indicate that total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on dry bulb onion remained fairly stable between PHIs of 1-10 days.

Table 20. Summary of Residue Data from Dry Bulb Onion Crop Field Trials with Spirotetramat.										
			Residue Levels (ppm)							
Analyte	Total Applic. Rate (lb ai/A)	PHI (days)	n	Min.	Max.	LAFT*	HAFT*	Median	Mean	Std. Dev.
Proposed use = 0.16 lb ai/A total application rate; PHI of 7 days										
Spirotetramat	0.15-0.17	2-4	12	<0.01	0.012	<0.01	<0.011	0.010	0.010	0.00
BYI 08330-enol[1]			12	<0.012	0.297	<0.012	0.266	0.042	0.071	0.083
BYI 08330-enol-Glc[1]			12	<0.008	<0.008	<0.008	<0.008	<0.008	<0.008	0.00
BYI 08330-ketohydroxy[1]			12	<0.012	0.016	<0.012	0.015	0.012	0.012	0.001
BYI 08330-mono-hydroxy[1]			12	<0.012	<0.012	<0.012	<0.012	<0.012	<0.012	0.00
Total[2]			12	<0.054	<0.34	<0.054	<0.31	0.085	0.11	0.084

* LAFT = lowest-average field trial; HAFT = highest-average field trial.
[1] Residues of the metabolites BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-Keto-OH, and BYI 08330-Mono-OH were converted to parent equivalents.
[2] Total Residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy, all expressed as parent equivalents

Conclusions: The number and locations of the onion crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 21) for green and bulb onions as a representative crop of the bulb vegetable group 3-07, except for an additional green onion trial (see footnote 2). The available data will support the proposed use pattern.

Table 21. Trial Numbers and Geographical Locations.						
	Dry Bulb Onion			Green Onion		
		Requested			Requested	
NAFTA Growing Zones	Submitted	Canada	U.S.[1]	Submitted	Canada	U.S.[1]
1	1	1	1			
5	2	2		1	1	
5A	1	1				
5B	2	2		1	1	
6	1	1	1			
8	1	1	1			
10	2	2	2	1		
11	1	1	1			
12	1	1				
Total	12	12	6	3	2	3[2]

[1] The requested number of trials required for the crop as a representative commodity used to obtain a crop group tolerance.
[2] Specific zones are not recommended for crops requiring ≤3 trials; however, 54% and 18% of green onions are grown in Zones 10 and 6, respectively.

The residue data for green onions were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.80 ppm in/on the vegetable, bulb, group 3-07.

Pineapple

DER Reference List: 48697610.der1.doc

Five field trials were conducted in the U.S. during the 2011 growing season in NAFTA Growing Zone 13 (HI). All trials were conducted by the same PFI, but trials HI01, HI02, & HI05 and HI03 & HI04 were conducted on different Hawaiian Islands; thus, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements. Careful

examination of the field trial records indicates that the only differences between trial groups HI01, HI02, & HI05 and HI03 & HI04, in addition to different tank mixes, were: a >30-day off-set in application dates and the spray volume varied by >25% (HI01, HI02, & HI05 trials only). These trials would not normally satisfy the HED ChemSAC criteria for differentiation of field trials; however, because areas suitable for pineapple production are limited, HED concludes that these trials may be counted as separate trials for purposes of 860.1500 data requirements.

Each trial consisted of one untreated plot and one treated plot. At each trial location, the treated plot received two foliar broadcast applications of Movento® (2 lb ai/gal SC) at 0.154-0.161 lb ai/A/application, for a total seasonal rate of 0.313-0.320 lb ai/A (1X). Applications were made at 13- to 14-day RTIs using ground equipment in spray volumes of 89-204 GPA. A NIS was added to the spray mixture for each of the applications. Samples of pineapple were harvested from all trials at a 1-day PHI. Additional samples were collected at PHIs of 0, 3, 7, and 14 days from one trial to assess residue decline.

Following two foliar broadcast applications of the 2 lb ai/gal SC formulation of spirotetramat at 0.313-0.320 lb ai/A, residues (and per-trial averages) of spirotetramat, BYI 08330-enol, and combined residues of spirotetramat and all metabolites, respectively, in/on pineapple harvested at a 1-day PHI were 0.013-0.065 (0.014-0.060), <0.01-0.016 (<0.01-0.016), and <0.053-<0.111 (<0.054-<0.106) ppm; residues of BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were <LOQ (0.01 ppm) in/on all samples of pineapple (Table 22).

The residue-decline data indicate that residues of spirotetramat and combined residues decreased with increasing PHIs. Residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were <LOQ at each sampling interval; therefore, residue decline could not be assessed.

Table 22. Summary of Residue Data from Pineapple Field Trials with Spirotetramat.

Commodity	Analyte	Total Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]							
				n	Sample Min.	Sample Max.	LAFT[2]	HAFT[2]	Median	Mean	Std. Dev.
Proposed use = 0.32 lb ai/A total application rate; PHI of 1 days											
Pineapple, Fruit	Spirotetramat	0.313-0.320	1	5	0.013	0.065	0.014	0.060	0.030	0.033	0.018
	Enol[3]				<0.01	0.016	<0.01	0.016	0.010	0.011	0.003
	Ketohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Monohydroxy[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Glucoside[3]				<0.01	<0.01	<0.01	<0.01	0.01	0.01	N/A
	Combined[4]				<0.053	<0.111	<0.054	<0.106	0.070	0.074	0.020

[1] Except for sample min/max, values reflect per-trial averages; n = no. of field trials. N/A= not applicable.
[2] LAFT = lowest average field trial; HAFT = highest average field trial.
[3] Data reflect conversion of quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330- glucoside to parent equivalents by the petitioner.
[4] Combined residues include spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside, expressed as parent equivalents.

Conclusions: The submitted residue data for pineapple are adequate to fulfill data requirements. The number and locations of the crop field trials are in accordance with OPPTS Guideline 860.1500 (Table 23). The available data will support the proposed use pattern.

Table 23. Trial Numbers and Geographical Locations.

	Pineapple		
		Requested[1]	
NAFTA Growing Regions	Submitted	Canada	U.S.
13	5	--	8/6
Total	5	--	8/6[2]

[1] As per OCSPP 860.1500, Table 5 for pineapple. The second number reflects a 25% reduction in the number of trials allowed for the crop as a representative commodity in support of a crop group/subgroup tolerance or when application results in no quantifiable residues.

[2] At a meeting held on 11/3/2010, the HED ChemSAC agreed that five trials are sufficient for new residue studies in support of a pesticide tolerance on pineapple. This number is in the draft revisions for crop field trials, but the revisions have not yet been published.

The residue data for pineapple were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 0.30 ppm.

Corn, Sweet

DER Reference List: 48770501.DER.DOC (prepared by PMRA)

Agriculture and Agri-Food has submitted field trial data for spirotetramat on sweet corn. A total of eight sweet corn field trials were conducted in Canada during the 2009 growing season encompassing NAFTA Growing Zones 5 (4 trials in ON), 5B (2 trials in QC), 7A (1 trial in AB), and 12 (1 trial in BC). At each trial site, Movento® (2 lb ai/gal SC) was applied to sweet corn as three foliar applications at rates of 0.069-0.085 lb ai/A, with RTIs of 3-8 days, for a total application rate of 0.22-0.25 lb ai/A/season. A NIS (Agral 90 or AgSurf) was included in each of the spray mixtures at a rate of 0.25%, v/v. Sweet corn kernels plus cob with husks removed (K+CWHR) and forage samples were harvested 6-8 DALA. Stover samples were harvested at PHIs of 33-85 days. At Trial ID# 116 in Delhi, Ontario additional K+CWHR and forage samples were harvested at 1, 3, and 9 DALA and additional stover samples were harvested at PHIs of 50, 64, and 69 days to assess residue-decline behavior.

Total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on sweet corn samples treated with Movento®, as three foliar applications at total rates of 0.22-0.25 lb ai/A/season and harvested at PHIs of 6-8 days (K+CWHR and forage) and 33-85 days (stover), ranged from <0.061-<0.75 ppm in K+CWHR, <0.05-<2.1 ppm in forage, and <0.05-<1.23 ppm in stover (Table 24). The residue decline data indicate that total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on K+CWHR increased slightly from a PHI of 1-7 days and then decreased by a PHI of 9 days. Total residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy (all expressed as parent equivalents) in/on forage decreased with increasing PHIs, while in/on stover they remained relatively constant at PHIs ranging from 50-69 days.

Table 24. Summary of Residue Data from Sweet Corn Crop Field Trials with Spirotetramat.										
	Total Applic. Rate	PHI	Residue Levels (ppm)							
Analyte	(lb ai/A)	(days)	n	Min.	Max.	LAFT*	HAFT*	Median	Mean	Std. Dev.
Sweet Corn K+CWHR										
Spirotetramat	0.22-0.25	6-8	8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
BYI 08330-enol[1]			8	0.021	0.61	0.028	0.54	0.16	0.23	0.21
BYI 08330-enol-Glc[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
BYI 08330-ketohydroxy[1]			8	<0.01	0.16	<0.01	0.14	0.058	0.068	0.049
BYI 08330-mono-hydroxy[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Total[2]			8	<0.061	<0.75	<0.068	<0.70	0.24	0.33	0.26
Sweet Corn Forage										
Spirotetramat	0.22-0.25	6-8	8	<0.01	1.7	<0.01	1.5	0.032	0.23	0.52
BYI 08330-enol[1]			8	0.011	0.29	0.012	0.29	0.093	0.11	0.089
BYI 08330-enol-Glc[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
BYI 08330-ketohydroxy[1]			8	0.011	0.15	0.012	0.14	0.098	0.086	0.049
BYI 08330-mono-hydroxy[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Total[2]			8	<0.05	<2.1	<0.05	<1.9	0.30	0.44	0.60
Sweet Corn Stover (Corrected for % Dry Matter)										
Spirotetramat	0.22-0.25	33-85	8	<0.01	0.78	<0.01	0.71	0.022	0.12	0.24
BYI 08330-enol[1]			8	<0.01	0.12	<0.01	0.11	0.029	0.034	0.031
BYI 08330-enol-Glc[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
BYI 08330-ketohydroxy[1]			8	<0.01	0.31	<0.01	0.29	0.099	0.11	0.088
BYI 08330-mono-hydroxy[1]			8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Total[2]			8	<0.05	<1.23	<0.05	<1.12	0.18	0.28	0.35

* LAFT = lowest-average field trial; HAFT = highest-average field trial.
[1] Residues of the metabolites BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-Keto-OH, and BYI 08330-Mono-OH were reported in the study as parent equivalents.
[2] Total Residues of spirotetramat, BYI 08330-enol, BYI 08330-enol-Glc, BYI 08330-ketohydroxy, and BYI 08330-mono-hydroxy, all expressed as parent equivalents.

Conclusions: The submitted residue data for sweet corn are adequate to establish a tolerance for residues in/on imported corn, sweet, kernel plus cob with husks removed. The residue data for corn, sweet, kernel plus cob with husks removed were analyzed using the OECD tolerance-calculation procedures (see Appendix II). The recommended tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc, expressed as parent equivalents, is 1.5 ppm.

Vegetable, fruiting, group 8-10

No fruiting vegetable field trial data were submitted. A tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc in/on the vegetable, fruiting, group 8 has been established at 2.5 ppm [40 CFR §180.641]. IR-4 has proposed to convert this tolerance to a vegetable, fruiting, group 8-10 tolerance at the same level.

As the proposed use on vegetable, fruiting, group 8-10 is identical to the existing use on vegetable, fruiting, group 8 on the product labels for Movento® (EPA Reg. No. 264-1050), Ultor® (EPA Reg. No. 264-1065), and BYI 8330 OD (EPA Reg. No. 264-1051), the existing vegetable, fruiting, group 8 tolerance can be translated to vegetable, fruiting, group 8-10.

Fruit, citrus, group 10-10

No citrus fruit field trial data were submitted. A tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI

08330-enol-Glc in/on the fruit, citrus, group 10 has been established at 0.60 ppm [40 CFR §180.641]. IR-4 has proposed to convert this tolerance to a fruit, citrus, group 10-10 tolerance at the same level.

As the proposed use on fruit, citrus, group 10-10 is identical to the existing use on fruit, citrus, group 10 on the product labels for Movento® (EPA Reg. No. 264-1050), Ultor® (EPA Reg. No. 264-1065), and BYI 8330 OD (EPA Reg. No. 264-1051), the existing fruit, citrus, group 10 tolerance can be translated to fruit, citrus, group 10-10.

Fruit, pome, group 11-10

No pome fruit field trial data were submitted. A tolerance for the combined residues of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc in/on the fruit, pome, group 11 has been established at 0.70 ppm [40 CFR §180.641]. IR-4 has proposed to convert this tolerance to a fruit, pome, group 11-10 tolerance at the same level.

As the proposed use on fruit, pome, group 11-10 is identical to the existing use on fruit, pome, group 11 on the product labels for Movento® (EPA Reg. No. 264-1050), Ultor® (EPA Reg. No. 264-1065), and BYI 8330 OD (EPA Reg. No. 264-1051), the existing pome, group 11 tolerance can be translated to pome, group 11-10.

Taro, leaves

From Minutes of the 05/12/2010 ChemSAC Meeting

"Data translation proposal for taro leaves (G. Kramer for K. Dorschner, IR-4): IR-4 has received a request for the registration of spirotetramat (Movento® insecticide from Bayer CropScience, EPA Reg. No. 264-1050) on taro leaves. Spirotetramat is already registered on taro corms but not on taro leaves. As an alternative to conducting an MOR study for this ultra-minor crop, IR-4 proposes that the registrant's leafy vegetable data be used to establish a taro leaf tolerance and registration. The spirotetramat tolerance for leafy vegetables, except *Brassica*, crop group 4 is 9.0 ppm (40 CFR Part 180.641). Use directions will be identical to leafy vegetables on the Movento® label. Although taro leaves (leaves of root and tuber vegetables), the IR-4/USDA International Crop Grouping Symposium recommended that this crop group be redefined to include animal feed items only. Bernie Schneider confirmed that human food items like taro leaves will be moved to Crop Group 4 (leafy vegetables). Thus, ChemSAC recommends for approval of this proposal."

Note: Subsequent to this decision, ChemSAC recommended that human food items that are currently members of Crop Group 2 not be moved to Crop Group 4. However, this data translation for taro leaves is still appropriate because leafy vegetables like leaf lettuce have a leaf-surface shape and texture that would be a worst case for residue levels in/on taro leaves, which are smooth and waxy (Personal Communication, Bernie Schneider, 11/16/2012). In addition, taro leaf consumption is very low compared to leafy vegetables.

860.1520 Processed Food and Feed

Coffee

DER Reference List: 48697604.der2.doc

In one crop field trial conducted in HI, coffee received three foliar directed applications of Movento® (2 lb ai/gal SC) at a rate of 0.1584-0.1604 lb ai/A/application for a total seasonal rate of 0.4778 lb ai/A (1X). Applications were made at a 21-day RTI between applications 1 and 2 and at a 7-day RTI between applications 2 and 3 using ground equipment in spray volumes of 25.39-25.70 GPA. A NIS/OSS was added to the spray mixture for each of the applications. Coffee cherries were harvested from the plots at a 14-day PHI, processed into green bean coffee at the field site, and then further processed into roasted coffee bean and freeze-dried coffee using simulated commercial procedures. Processing was conducted by University of Hawaii at Manoa (Honolulu, HI). Adequate descriptions were provided of the processing procedures, including material balance summaries.

Following application of spirotetramat at 0.4778 lb ai/A, residues of spirotetramat, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were each below the LOQ (<0.01, <0.05, or <0.1 ppm) in/on all samples of green bean seed (RAC), roasted coffee bean, and freeze-dried coffee; therefore, the apparent processing factors may be a result of the higher LOQs in the processed commodities. Average residues of BYI 08330-enol and combined residues of spirotetramat and metabolites, respectively, were <0.011 and <0.051 ppm in/on green bean coffee, 0.018 and <0.058 ppm in roasted coffee bean, and below the LOQ (<0.1 ppm) and combined LOQs (<0.5 ppm) in freeze-dried coffee. The processing data indicate that residues of BYI 08330-enol and combined residues of spirotetramat and metabolites may concentrate in roasted coffee bean (processing factors of <1.6X and <1.9X, respectively) and in freeze-dried coffee (processing factor of <10X).

The processing factors calculated in this study were greater than the maximum theoretical concentration factor for coffee of 1.2X for roasted bean and of 4.4X for instant coffee (based on separation into components; OPPTS 860.1520, Table 3).

Table 25. Residue Data from Coffee Processing Study with Spirotetramat.

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Combined Residues[1] [Average]	Processing Factor[2]
Coffee	Green Bean Coffee (RAC)	0.4778	14	<0.052, <0.05 [<0.051]	--
	Roasted Coffee Bean			<0.098	<1.9X
	Freeze-Dried Coffee			<0.5	<10X

[1] All values are the average of replicate analyses. The LOQ was 0.01 ppm for all analytes in green bean coffee RAC and roasted coffee bean, with the exception of BYI 08330-Glc which had an LOQ of 0.05 ppm in roasted coffee bean. The LOQ was 0.1 ppm for all analytes in freeze-dried coffee. Per-trial averages were calculated using the LOQ for all residues reported as <LOQ. Quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-enol-Glc, were converted to parent equivalents.

[2] Processing Factor = [Measured residue for analyte in the processed fraction] / [Measured residue for analyte in the green bean RAC].

Conclusions: The submitted coffee processing data are adequate to fulfill data requirements. The total spirotetramat residues were found to concentrate in roasted bean (<1.9X). A tolerance value of 0.14 ppm (i.e., 0.072 ppm (HAFT) x 1.9 = 0.14 ppm) is calculated for roasted beans.

However, as this value is the less than as the recommended tolerance for coffee, green bean, a separate tolerance for coffee, roasted bean will not be required.

The processing residue data for freeze-dried coffee are classified as scientifically unacceptable as the LOQ of the enforcement method was 10X higher in freeze-dried coffee than in the RAC. Thus, an actual processing factor for freeze-dried coffee could not be determined. Based on the maximum theoretical concentration factor, the maximum residue for freeze-dried coffee is 0.32 ppm (i.e., 0.072 ppm (HAFT) x 4.4 = 0.32 ppm). As this value is less than the LOQ of the analytical enforcement method, a more sensitive method would be required to determine the actual processing factor for freeze-dried coffee. As freeze-dried coffee is a very minor commodity, HED will not request that the coffee processing study be repeated with a more sensitive method. Instead, a LOQ-level tolerance of 0.50 ppm is recommended for coffee, instant.

Pineapple

DER Reference List: 48697610.der2.doc

In one crop field trial conducted in HI, pineapple received two foliar broadcast applications of Movento® (2 lb ai/gal SC) at a field rate of 0.154-0.161 lb ai/A/application for a total seasonal rate of 0.315 lb ai/A (1X). Applications were made at a 14-day RTI using ground equipment in spray volumes of 89-93 GPA. A NIS was added to the spray mixture for each of the applications. Pineapple was harvested from the plots at a 1-day PHI, and processed into juice and process residue using simulated commercial procedures at the University of Hawaii at Manoa (Honolulu, HI). Adequate descriptions were provided of the processing procedures, including material balance summaries.

Following two foliar broadcast applications at 0.154-0.161 lb ai/A/application (RTI = 14 days), residues of BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside were each below the LOQ (<0.01 ppm) in/on all samples of pineapple (RAC), juice, and process residue; therefore, processing factors were not calculated. Average residues of spirotetramat, BYI 08330-enol, and combined residues of spirotetramat and metabolites, respectively, were 0.042, <0.01, and <0.082 ppm in/on pineapple, 0.019, <0.01, and <0.059 ppm in juice, and 0.050, 0.015, and <0.095 ppm in process residue. The processing data indicate that residues of spirotetramat, BYI 08330-enol, and combined residues of spirotetramat and metabolites may concentrate in process residue (processing factors of 1.2X, >1.5X, and 1.2X, respectively), but do not concentrate in juice (processing factors of 0.46X, not calculated, and 0.72X, respectively).

The processing factors calculated in this study were less than the maximum theoretical concentration factor for pineapple of 3.8X for process residue (based on separation into components; OCSPP 860.1520, Table 3).

Table 26. Residue Data from Pineapple Processing Study with Spirotetramat.

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Combined Residues[1, 4] [Average]	Processing Factor[2, 3]
Pineapple	Fruit (RAC)	0.315	1	<0.078, <0.085 [<0.082]	--
	Juice			<0.059	0.72X
	Process Residue			<0.095	1.2X

[1] All values are the average of replicate analyses.
[2] Processing Factor = [Measured residue for analyte in the processed fraction] / [Measured residue for analyte in the pineapple

RAC].
[3] NC = not calculated; residues were below the LOQ in both RAC and processed fraction.
[4] Quantifiable residues of BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-monohydroxy, and BYI 08330-glucoside, respectively, were converted to parent equivalents. Residues of the metabolites reported below the LOQ were not converted to parent equivalents.

Conclusions. The submitted pineapple processing data are adequate to fulfill data requirements. Total spirotetramat residues were found to concentrate in pineapple process residue (1.2X). No concentration (<1X) of the total spirotetramat residue was found juice. A tolerance value of 0.13 ppm (i.e., 0.106 ppm (HAFT) x 1.2 = 0.13 ppm) is calculated for process residue. However, as this value is the less than as the recommended tolerance for pineapple, a separate tolerance for pineapple process residue will not be required.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy, and BYI 08330-enol-Glc, including their corresponding isotopically labeled internal standards, are currently available in the National Pesticide Standards Repository [Source: personal communication with Theresa Cole of ACL/BEAD, 02-JAN-2013]:

Chemical Name	Expiration Date
Spirotetramat	5/24/2016
Spirotetramat-^{13}C3 (K1767) (internal standard)	5/12/2018
Enol	4/3/2018
Enol-^{13}C3 (1778) (internal standard)	7/11/2013
Ketohydroxy	**1/31/2013**
Ketohydroxy-^{13}C3 (K1777) (internal standard)	7/11/2013
Monohydroxy	6/3/2020
Monohydroxy-^{13}C3 (K1768) (internal standard)	5/12/2018
Glucoside	6/20/2022
Glucoside-^{13}C3 (K1766) (internal standard)	4/28/2018

The analytical reference standard for BYI 08330-ketohydroxy has expired and the standards for the isotopically labeled internal standards of BYI 08330-enol and BYI 08330-ketohydroxy will soon expire (7/11/2013). The registrant should either recertify the lot in the repository and send an updated COA, or submit new standards (different lot #) if the previous lots will not be recertified. If new standards are being submitted, then they should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Thuy Nygen at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

860.1850/860.1900 Confined/Field Accumulation in Rotational Crops

Reference List: Memo, G. Kramer, 17-APR-2008; D339694

The metabolism of spirotetramat in rotational crops appears to be consistent with the pathway observed in the plant metabolism studies. The residues of concern for rotational crops are spirotetramat and BYI 08330-ketohydroxy and free and conjugated BYI 08330-desmethyl-ketohydroxy, BYI 08330-desmethyl-di-hydroxy, and BYI 08330-ketohydroxy-alcohol (Memo, J. Tyler *et al.*, 16-APR-2008; D333437). The available field accumulation data indicate that residues of the parent and its metabolites (BYI 08330-ketohydroxy, BYI 08330-desmethyl-ketohydroxy, BYI 08330-desmethyl-di-hydroxy and BYI 08330-ketohydroxy-alcohol) were each <0.020 ppm in/on all rotational crop matrices at a 30-day PBI. Unless the petitioner requests PBIs shorter than 30 days or use rates in excess of 0.16 lb ai/A for annual crops, no additional data are required, and tolerances for inadvertent residues in/on rotational crops need not be established in conjunction with the currently proposed uses. However, the proposed use rate for watercress is 0.4 lb ai/A. Based on the results of the confined rotational crop study (conducted at an application rate of 0.36 lbs. ai/A), a 260-day PBI is required to support the proposed use on watercress.

860.1550 Proposed Tolerances

Permanent tolerances are currently established for the combined residues of the insecticide spirotetramat, including its metabolites and degradates. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat, BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-enol-Glc, and BYI 08330-mono-hydroxy, calculated as the stoichiometric equivalent of spirotetramat, in/on bulb onions, citrus, cucurbit vegetables, fruiting vegetables, grapes, hops, leafy *Brassica* vegetables, leafy non-*Brassica* vegetables, pome fruit, tuberous and corm vegetables, stone fruit, tree nuts, cotton, legume vegetables including soybean (crop groups 6 and 7a), and tropical fruit (40 CFR §180.641(a)(1)). Tolerances are also established for residues of the insecticide spirotetramat, including its metabolites and degradates, in or on livestock commodities. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat and its metabolite BYI 08330-enol, calculated as the stoichiometric equivalent of spirotetramat (40 CFR §180.641(a)(2)).

The Codex tolerances/maximum residue limits (MRLs) for residues of spirotetramat in/on bulb onions, fruiting vegetables, and citrus and pome fruits cannot be harmonized as the U.S./Canadian residue definition includes metabolites not included in the Codex residue definition (Appendix I). The U.S. and Canadian tolerance/MRL levels for the subject crops are being harmonized as part of this RCC pilot project.

A summary of the recommended tolerances for the current petition are listed in Table 27. The petitioner should submit a revised section F reflecting the recommended tolerances and commodity definitions presented in Table 27.

The OECD tolerance-calculation procedures were utilized for determining appropriate tolerance levels; see Appendix II for tolerance calculations.

Table 27. Tolerance Summary for Spirotetramat.

Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Taro, leaves	9	9.0	
Watercress	1.5	2.0	
Pomegranate	0.5	0.50	
Banana[1]	4	4.0	
Vegetable, bulb, group 3-07	0.6	0.80	
Low growing berry subgroup 13-07H, except strawberry	0.3	0.30	Low growing berry subgroup 13-07H, except strawberry and lowbush blueberry
Bushberry subgroup 13-07B	3	3.0	
Artichoke, globe	2	1.5	
Vegetable, fruiting, crop group 8-10	2.5	2.5	Vegetable, fruiting, group 8-10
Fruit, pome, crop group 11-10	0.7	0.70	Fruit, pome, group 11-10
Fruit, citrus, crop group 10-10	0.6	0.60	Fruit, citrus, group 10-10
Pineapple	0.3	0.30	
Pineapple, process residue	0.36	-	
Coffee, green bean	0.2	0.20	
Coffee, instant	-	0.50	
Coffee, roasted bean	0.32	-	
Corn, sweet, kernel plus cob with husks removed[2]	-	1.5	

[1] This tolerance should be established under 40 CFR §180.641(c) Tolerances with regional registrations.
[2] There are no U.S. registrations as of [date] for use on corn, sweet.

Attachments:
Appendix I - International Residue Limits
Appendix II - Tolerance-Assessment Calculations

cc: G. Kramer (RAB1)
RDI: RAB1 Chemists (11/7/12)
G.F. Kramer:S10957:PY-S:(703)305-5079:7509P:RAB1

Appendix I - International Residue Limits

Spirotetramat (392201; Date of Request: 10/15/2012)

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	Canada		Mexico[2]	Codex[3]
40 CFR §180.641 (a)(1): sum of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate) and its metabolites cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat	Plants: BYI 08330: *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate, including the metabolites:enol: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy: *cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, enol-Glc: *cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β-D-glucopyranoside, and monohydroxy: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one calculated as parent equivalent Livestock:*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate, including the metabolite enol: *cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one calculated as parent equivalent		Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat. Animal Commodities: Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat. The residue is not fat-soluble.
Commodity[1]	*Tolerance (ppm)/Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex[3]
Taro, leaves	9.0			
Watercress	2.0			
Pomegranate	0.50			
Banana	4.0			
Vegetable, bulb, group 3-07	0.80	0.3 dry bulb onions		0.4 onion, bulb (proposed)
Low growing berry subgroup 13-07H, except strawberry and lowbush blueberry	0.30			
Bushberry subgroup 13-07B	3.0			
Artichoke, globe	1.5			
Vegetable, fruiting, crop group 8-10	2.5	2.5 bell peppers, eggplants, ground cherries, non-bell peppers, pepinos, pepper hybrids, tomatillos, tomatoes		1 Fruiting vegetables, other than cucurbits (except chili pepper) 2 peppers chili 15 peppers chili, dried

Fruit, pome, crop group 11-10	0.70	0.7 apples, crabapples, loquats, mayhaws, pears, quinces		0.7 pome fruits
Fruit, citrus, crop group 10-10	0.60	0.6 calamondin, citrus citron, citrus hybrids, grapefruits, kumquats, lemons, limes, oranges, pummelos, Satsuma mandarins, tangerines 6.0 citrus oil		0.5 citrus fruits
Pineapple	0.30			
Coffee, green bean	0.20			
Coffee, instant	0.50			
Corn, sweet, kernel plus cob with husks removed	1.5			
Completed: M. Negussie; 10/17/2012				

[1] Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.
[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

[3] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

Appendix I. Tolerance-Assessment Calculations.

Spirotetramat & Metabolites (expressed as parent equivalents)
Sweet Corn (K+CWHR)
Canada
0.22-0.25 lb ai/A; PHI = 6-8 days

Total number of data (n)	8
Percentage of censored data	0%
Number of non-censored data	8
Lowest residue	0.068
Highest residue	0.700
Median residue	0.245
Mean	0.329
Standard deviation (SD)	0.258
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.700
- Mean + 4 SD	1.361
- CF x 3 Mean	0.986
Unrounded MRL	1.361
Rounded MRL	**1.5**

Residues (mg/kg)	n
0.068	1
0.071	1
0.13	1
0.18	1
0.31	1
0.57	1
0.6	1
0.7	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Globe Artichoke
Canada/USA
0.49-0.50 lb ai/A; PHI = 2-3 days

Total number of data (n)	5
Percentage of censored data	0%
Number of non-censored data	5
Lowest residue	0.230
Highest residue	0.700
Median residue	0.410
Mean	0.458

Standard deviation (SD)	0.194
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.700
- Mean + 4 SD	1.232
- CF x 3 Mean	1.374
Unrounded MRL	1.374
Rounded MRL	**1.5**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.23	1
0.34	1
0.41	1
0.61	1
0.7	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Coffee, Green bean
USA
0.48-0.51 lb a.i./A; PHI = 14 days

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4
Lowest residue	0.051
Highest residue	0.072
Median residue	0.058
Mean	0.060
Standard deviation (SD)	0.009
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.072
- Mean + 4 SD	0.096
- CF x 3 Mean	0.179
Unrounded MRL	0.179
Rounded MRL	**0.2**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.051	1
0.055	1
0.061	1
0.072	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Watercress
USA
0.379-0.395 lb ai/A; PHI = 3 days

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4
Lowest residue	0.290
Highest residue	0.670
Median residue	0.575
Mean	0.528
Standard deviation (SD)	0.165
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.670
- Mean + 4 SD	1.188
- CF x 3 Mean	1.583
Unrounded MRL	1.583
Rounded MRL	**2**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.29	1
0.56	1
0.59	1
0.67	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Banana, Whole Fruit
USA
1.25-1.29 lb ai/A; PHI = 1 day; Unbagged

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4

Lowest residue	0.620
Highest residue	1.800
Median residue	1.350
Mean	1.280
Standard deviation (SD)	0.504
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	1.800
- Mean + 4 SD	3.294
- CF x 3 Mean	3.840
Unrounded MRL	3.840

Rounded MRL **4**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.62	1
1.2	1
1.5	1
1.8	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Pomegranate
USA
0.311-0.318 lb ai/A; PHI = 1 day; Unbagged

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4
Lowest residue	0.076
Highest residue	0.174
Median residue	0.165
Mean	0.145
Standard deviation (SD)	0.047
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.174
- Mean + 4 SD	0.331
- CF x 3 Mean	0.434
Unrounded MRL	0.434

Rounded MRL **0.5**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.076	1
0.156	1
0.173	1
0.174	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Pineapple
USA
0.313-0.320 lb ai/A; PHI = 1 day; Unbagged

Total number of data (n)	5
Percentage of censored data	0%
Number of non-censored data	5
Lowest residue	0.054
Highest residue	0.106
Median residue	0.070
Mean	0.074
Standard deviation (SD)	0.021
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.106
- Mean + 4 SD	0.157
- CF x 3 Mean	0.223
Unrounded MRL	0.223
Rounded MRL	**0.3**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.054	1
0.06	1
0.07	1
0.082	1
0.106	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Cranberries
USA
0.462-0.489 lb ai/A; PHI = 7-8 day

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4
Lowest residue	0.052
Highest residue	0.152
Median residue	0.082
Mean	0.092
Standard deviation (SD)	0.043
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.152
- Mean + 4 SD	0.263
- CF x 3 Mean	0.276
Unrounded MRL	0.276
Rounded MRL	**0.3**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.052	1
0.076	1
0.088	1
0.152	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Green Onion
Canada/USA
0.16 lb a.i./A; PHI = 6-7 day

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue	0.051
Highest residue	0.320
Median residue	0.170
Mean	0.180
Standard deviation (SD)	0.135
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.320
- Mean + 4 SD	0.720
- CF x 3 Mean	0.541

Unrounded MRL	0.720
Rounded MRL	**0.8**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.051	1
0.17	1
0.32	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Bulb Onion
Canada
0.15-0.17 lb ai/A; PHI = 2-4 day

Total number of data (n)	12
Percentage of censored data	0%
Number of non-censored data	12
Lowest residue	0.054
Highest residue	0.310
Median residue	0.085
Mean	0.114
Standard deviation (SD)	0.084
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	0.310
- Mean + 4 SD	0.450
- CF x 3 Mean	0.342
Unrounded MRL	0.450
Rounded MRL	**0.5**

Residues (mg/kg)	n
0.054	3
0.059	1
0.078	1
0.084	1
0.085	1
0.09	1
0.11	1
0.13	1
0.26	1
0.31	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Lowbush Blueberries
USA
0.466-0.469 lb ai/A; PHI = 7-8 day

Total number of data (n)	4
Percentage of censored data	0%
Number of non-censored data	4
Lowest residue	0.378
Highest residue	1.209
Median residue	0.549
Mean	0.671
Standard deviation (SD)	0.378
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	1.209
- Mean + 4 SD	2.183
- CF x 3 Mean	2.013
Unrounded MRL	2.183
Rounded MRL	**3**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.378	1
0.441	1
0.656	1
1.209	1

Spirotetramat & Metabolites (expressed as parent equivalents)
Highbush Blueberries
USA
0.466-0.497 lb ai/A; PHI = 6-7 day

Total number of data (n)	7
Percentage of censored data	0%
Number of non-censored data	7
Lowest residue	0.448
Highest residue	1.548
Median residue	0.602
Mean	0.758
Standard deviation (SD)	0.410
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	1.548
- Mean + 4 SD	2.398
- CF x 3 Mean	2.275
Unrounded MRL	2.398
Rounded MRL	**3**

High uncertainty of MRL estimate.
[Small dataset]

Residues (mg/kg)	n
0.448	1
0.466	1
0.486	1
0.602	1
0.686	1
1.073	1
1.548	1