

Trade Advice Notice

on

Flubendiamide

in the product

Belt 480 SC Insecticide
[APVMA product number 61223]

Date: 19 June 2009

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Australian Pesticides and Veterinary Medicines Authority
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Australia

1. PREFACE

1.1 About this Document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this notice.

The APVMA will only consider comment on submissions that relate to the **trade implications** of the extended use of the product. Comments received outside these grounds will not be considered by the APVMA. Comments made on appropriate grounds will be considered with details posted on the APVMA website noting what action has/will be taken in regard to concerns.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found at:

http://www.apvma.gov.au/registration/data_requirements_subpage.shtml

1.2 Prior to Submission

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent (you) unless a request for anonymity accompanies your submission. If no request for anonymity is made, you will be taken to have consented to the disclosure of your identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988*.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and you have provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

1.3 About this consultation

The APVMA invites comment on this Trade Advice Notice until the 17th July, 2009
Submissions should be addressed to:

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CONTENTS

1. PREFACE	
1.1 About this Document	
1.2 Prior to Submission	
1.3 About this consultation	
2. INTRODUCTION	5
3. TRADE CONSIDERATIONS	
2.1 Commodities Exported	7
2.2 Destination and Value of Exports of Animal Products	7
2.3 Results from residues trials presented to the APVMA	9
2.4 Overseas registration and approved label instructions	11
2.5 Codex Alimentarius commission and overseas MRLs	12
2.6 Current and proposed Australian MRLs	13
2.7 Potential Risk to Trade	14
4. CONCLUSION	15

1. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Limited to vary the registration of Belt 480 SC Insecticide to include control of *Heliothis* in capsicums, lettuce and tomatoes.

The proposed Australian use pattern for Belt 480 SC Insecticide is given below:

Belt 480 SC Insecticide (480 g/L flubendiamide)

Crop	Pest	Rate per ha	Critical Comments
Capsicum	<i>Heliothis</i> (<i>Helicoverpa</i> spp.)	48 or 72 g ai/ha (100 or 150 mL/ha) or 4.8 or 7.2g a.i./100L (10 or 15 mL/100 L)	<p>Monitor crops and commence insecticide applications once local economic spray thresholds are reached. Apply soon after egg hatch to target young larvae.</p> <p>Apply up to 3 sequential applications of Belt 480 SC at intervals of up to 14 days. The lower rate should be used where the spray interval is 7 days. Use the higher rate where the spray interval exceeds 7 days or where sequential applications are not made. Application intervals of greater than 14 days are not recommended for control of <i>heliothis</i>.</p> <p>If required, further treatments should be made with alternate mode of action insecticides.</p> <p>Belt 480 SC is compatible with integrated pest management (IPM) production systems.</p>
Lettuce		36 or 48 g ai/ha (75 or 100 mL/ha)	<p>Monitor crops and commence insecticide applications once local economic spray thresholds are reached. Apply soon after egg hatch to target young larvae. Repeat applications may be required when fresh egg lays occur.</p> <p>Apply a maximum of 3 applications of Belt 480 SC per crop. Use the higher rate when not applying sequential applications or where repeat applications are made at intervals exceeding 14 days.</p> <p>If required, further treatments should be made with alternate mode of action insecticides, in accordance with CropLife Australia resistance management strategies.</p> <p>Belt 480 C is compatible with integrated pest management (IPM) production systems.</p>

Tomato	<p>Heliothis (<i>Helicoverpa</i> spp.)</p> <p>Tomato leaf miner (<i>Phthorimaea</i> <i>operculella</i>)</p>	<p>48 or 72 g ai/ha (100 or 150 mL/ha) or 4.8 or 7.2g a.i./100L (10 or 15 mL/100L)</p>	<p>Monitor crops and commence insecticide applications once local economic spray thresholds are reached.</p> <p>Heliothis: Apply up to 3 sequential applications of Belt 480 SC at intervals of up to 14 days. The lower rate should be used where the spray interval is 7 days. Use the higher rate where the spray interval exceeds 7 days or where sequential applications are not made. Application intervals of greater than 14 days are not recommended for control of heliothis.</p> <p>Tomato leaf miner: Apply up to 3 sequential applications of Belt 480 SC. The lower rate should be used where the spray interval is 14 days or less. Use the higher rate where sequential applications are not made or where the spray interval exceeds 14 days.</p> <p>Apply a maximum of 3 applications of Belt 480 SC per crop.</p> <p>If required, further treatments should be made with alternate mode of action insecticides, in accordance with CropLife Australia resistance management strategies.</p> <p>Belt 480 SC is compatible with integrated pest management (IPM) production systems.</p>
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Withholding periods:

Harvest: DO NOT harvest for 1 day after application.

Export of treated produce

Growers should note that MRLs or import tolerances may not exist in all markets for edible produce treated with Belt 480SC. If you are growing edible produce for export, please check with Bayer CropScience Pty Ltd for the latest information on MRLs and import tolerances before using Belt 480SC.

2. TRADE CONSIDERATIONS

2.1 Commodities Exported

Lettuce, capsicums and tomatoes are exported, however they are not considered major export commodities in Appendix 1 of Part 5B of Ag MoRaG. Animal commodities derived from livestock that have been fed tomato pomace from treated tomato crops may be exported and are considered here.

2.2 Destination and Value of Exports of Animal Products

The value and destinations of Australian exports of beef, live cattle, mutton, lamb, live sheep and dairy products are summarised in the following tables.¹

Table 1: Value of Australian beef exports from 1998 – 2005.

Value of beef exports	1998	1999	2000	2001	2002	2003	2004	2005
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
Beef and veal								
Americas								
Canada	104.6	128.0	148.1	204.4	320.2	110.9	38.1	32.6
United States	735.2	805.1	1 172.8	1 699.7	1 593.6	1 332.3	1 374.4	1 186.4
Asia								
Chinese Taipei	108.2	123.2	116.7	132.6	152.3	126.7	124.2	148.3
Hong Kong, China	23.6	16.6	18.2	17.8	17.1	15.0	27.3	18.7
Indonesia	6.1	33.3	40.8	37.2	46.1	38.4	26.7	33.6
Japan	1 312.4	1 369.7	1 537.3	1 728.2	1 237.7	1 384.4	2 189.8	2 244.8
Korea, Rep. of	87.6	201.9	221.7	228.9	320.4	250.7	434.4	494.8
Malaysia–Singapore	66.7	68.7	70.6	78.7	91.4	86.8	74.4	48.9
Philippines	40.4	38.5	34.3	55.8	36.1	23.0	4.3	5.9
Europe								
European Union	58.6	61.3	37.4	48.4	53.5	49.2	62.8	56.8
CIS	58.2	18.1	3.8	14.4	2.9	0.7	2.0	4.6
Eastern Europe	43.6	6.9	6.3	1.2	9.1	4.5	1.3	0.4
Middle East								
Kuwait	3.6	1.6	0.3	4.6	1.8	9.8	3.4	1.0
Saudi Arabia	7.4	3.3	2.1	23.0	11.6	7.8	3.1	1.7
United Arab Emirates	5.4	2.5	4.4	11.6	10.9	7.8	12.0	13.7
Oceania								
New Zealand	4.5	5.0	11.1	6.3	25.6	15.9	9.8	8.8
Pacific Isles	6.2	4.1	5.2	7.2	7.4	5.4	4.5	4.0
Papua New Guinea	12.3	14.1	14.1	11.5	9.8	4.9	5.2	4.3
Total beef and veal	2 768.3	2 963.3	3 464.1	4 357.3	4 002.6	3 475.3	4 390.2	4 346.7
Live cattle								
Asia								
Indonesia	18.0	68.5	143.1	171.8	254.0	203.4	207.3	209.1
Japan	11.6	7.8	9.8	12.7	11.2	16.6	14.6	20.5
Malaysia	15.3	29.9	25.7	38.5	45.1	38.9	25.2	20.1
Philippines	87.7	126.7	117.8	58.4	65.8	39.1	30.1	11.6
Middle East								
Egypt	61.6	131.2	129.7	153.8	94.9	5.0	0.0	3.8
Israel	5.7	3.8	9.0	15.4	23.9	22.8	11.9	20.6
Jordan	7.7	15.7	18.1	6.7	2.4	12.9	15.3	10.2
Libya	64.9	13.5	0.0	0.0	0.0	0.0	0.0	0.0
Saudi Arabia	0.0	0.0	0.0	14.9	32.5	9.4	0.0	11.0
Total live cattle	280.3	409.2	471.7	514.4	580.8	376.5	327.7	337.1

¹ Australian Commodity Statistics, 2006, ABARE.

Table 2: Value of Australian sheep exports from 1998 – 2005.

Value of sheep exports	1998	1999	2000	2001	2002	2003	2004	2005
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
Mutton								
Canada	3.2	3.1	4.6	6.8	5.2	3.6	5.8	5.4
Chinese Taipei	29.1	27.6	26.3	36.9	48.9	32.2	41.9	34.8
CIS	9.2	0.9	3.1	3.7	5.4	1.3	5.8	13.5
European Union	44.8	28.2	34.1	42.0	41.4	28.1	43.2	48.3
Japan	37.9	32.6	34.0	42.7	51.1	29.9	47.1	38.1
Korea, Rep. of	2.3	2.1	1.7	2.3	3.3	2.2	3.1	3.1
Malaysia	11.6	13.7	16.5	21.7	22.9	15.9	22.6	18.5
Papua New Guinea	8.0	7.5	6.2	7.4	6.6	6.1	5.1	5.2
Saudi Arabia	37.4	36.8	43.9	90.1	77.5	65.0	53.0	63.9
Singapore	16.4	16.5	18.4	23.4	23.2	20.4	22.0	18.6
South Africa	34.6	35.3	46.3	30.9	17.6	11.1	14.1	18.7
United States	40.3	37.1	43.9	56.4	64.7	67.9	48.6	44.4
Other	77.9	84.2	97.1	146.3	152.0	91.7	113.4	119.7
Total	352.5	325.8	376.3	510.6	519.7	375.3	425.9	432.0
Lamb								
European Union b	48.2	52.3	74.3	105.7	89.3	96.9	93.4	83.9
Japan	22.9	25.1	30.7	37.0	40.7	42.3	53.5	79.1
Papua New Guinea	12.0	13.0	16.0	18.0	15.7	14.4	17.3	19.4
South Africa	9.7	10.0	15.3	5.5	1.2	2.1	3.5	5.3
United Arab Emirates	18.1	18.2	24.2	27.4	31.6	29.9	27.0	32.8
United States	97.6	103.2	150.2	219.9	218.2	257.5	259.9	324.2
Other	87.2	96.3	137.0	165.7	169.5	159.7	184.7	233.1
Total	295.6	318.0	447.7	579.1	566.2	602.8	639.3	777.8
Live sheep c								
Middle East	187	177	204	349	395	330	223	275
Bahrain	13	15	13	20	25	29	33	35
Egypt	1	6	12	14	9	1	0	0
Jordan	32	35	24	28	39	35	58	53
Kuwait	53	47	61	79	101	105	84	60
Oman	18	17	20	26	24	19	20	25
Qatar	17	13	15	16	21	13	10	12
Saudi Arabia	0	0	27	120	127	104	0	74
United Arab Emirates	49	35	29	34	30	16	13	15
Other	2	3	2	5	7	8	3	4
Total	189	180	206	355	402	338	225	279

Table 3: Value of Australian dairy exports from 1999 – 2006.

Value of dairy exports	Unit	1999-00	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06
Cheese								
Japan	\$m	306.6	338.8	429.2	272.0	299.6	378.9	298.5
Philippines	\$m	16.4	18.6	20.0	15.7	11.1	18.2	13.7
Saudi Arabia	\$m	94.1	123.6	148.2	98.9	69.0	81.5	103.5
United Kingdom	\$m	23.9	38.7	21.5	15.2	18.3	20.5	20.1
United States	\$m	28.8	39.1	48.3	36.1	33.9	45.4	54.8
Other	\$m	336.8	391.0	366.3	361.9	306.6	330.9	345.5
Total	\$m	806.6	949.9	1 033.4	799.8	738.4	875.4	836.1
Butter and butterfat								
Egypt	\$m	33.7	34.6	23.5	18.9	6.4	10.5	12.5
Malaysia	\$m	15.8	14.7	14.4	12.7	13.5	11.6	15.8
Philippines	\$m	11.9	8.6	5.1	3.7	1.9	2.8	5.1
Singapore	\$m	19.4	16.7	20.4	15.5	18.2	16.8	21.1
Thailand	\$m	27.3	19.8	23.0	13.2	12.7	13.5	12.0
Other	\$m	182.6	196.6	211.0	160.0	129.4	133.0	157.6
Total	\$m	290.5	291.0	297.4	224.0	182.1	188.3	224.1
Skim milk powder								
Japan	\$m	56.2	48.9	53.7	29.6	13.3	10.6	12.5
Malaysia	\$m	78.3	87.4	88.4	51.4	52.7	64.2	77.1
Philippines	\$m	102.0	181.4	143.5	69.0	59.8	49.4	72.0
Singapore	\$m	26.7	51.8	52.8	38.4	41.3	57.7	56.1
Thailand	\$m	55.1	67.2	69.1	33.2	20.0	21.7	76.8
Other	\$m	159.8	257.5	290.5	184.1	198.8	216.3	234.3
Total	\$m	478.1	694.2	697.9	405.6	386.0	419.9	528.9
Casein								
Japan	\$m	15.3	19.9	26.7	20.6	23.3	23.1	30.4
United States	\$m	62.6	56.7	80.5	81.4	68.8	56.6	27.3
Other	\$m	15.3	23.4	15.5	26.4	30.4	36.4	31.3
Total	\$m	93.2	100.1	122.6	128.4	122.5	116.1	88.9
Whole milk powder								
Malaysia	\$m	27.0	26.9	39.2	22.3	28.9	33.1	23.8
Singapore	\$m	15.7	31.7	29.7	25.2	21.4	30.9	44.6
Taiwan	\$m	49.2	54.9	54.1	44.9	40.0	31.5	22.8
Thailand	\$m	28.8	24.9	22.6	14.0	12.0	8.6	10.5
Other	\$m	282.8	441.8	425.5	273.4	218.9	220.3	231.9
Total	\$m	403.4	580.2	571.1	379.8	321.1	324.4	333.6
Other products								
Fresh milk	\$m	81.4	82.0	98.1	98.1	104.0	108.7	107.3
Other fresh products	\$m	20.2	12.7	7.9	5.5	9.6	9.1	6.3
Condensed milk	\$m	87.6	111.5	123.7	133.3	121.0	139.8	147.5
Other powders	\$m	182.2	223.2	276.6	272.1	253.9	244.9	241.2
Total	\$m	371.5	429.4	506.2	509.1	488.6	502.6	502.3

2.3 Results from supervised residues trials presented to the APVMA

Capsicum: Capsicum data were generated from trials at 6 Australian sites where flubendiamide had been applied at 48 g ai/ha, 72 g ai/ha, 4.8 g ai/100 L or 9.6 g ai/100 L. Highest flubendiamide residues from 1-day until 14-days after treatment were 0.03 (n=3), 0.04, 0.05, 0.06 (n=2), 0.07, 0.08, 0.09 (n=3), 0.14, 0.16, 0.17, 0.21, 0.22 and 0.37 mg/kg. These values confirm that the current temporary MRL of 1 mg/kg is appropriate, for flubendiamide in capsicum in conjunction with a 1-day WHP. The residues data support approval for field grown capsicums only as no protected cropping data were submitted.

Lettuce: Australian residue data for lettuce were generated from 12 sites, and included trials on both leafy and head lettuce varieties. In leafy lettuce, flubendiamide residues in samples taken at 1-day after application at the proposed rate (48 g ai/ha) were 1.11, 1.43, 1.77, 2.15, 3.15 and 4.09 mg/kg. Unlike the data for tomatoes and capsicum, flubendiamide residues declined over the period that the trials were conducted. Therefore, a new MRL of 7 mg/kg is recommended for flubendiamide in leafy lettuce in conjunction with a 1-day WHP. The data for head lettuce showed that at 1-day after application at 48 g ai/ha flubendiamide residues were 0.12, 0.33, 0.98, 1.15, 1.28 and 2.32 mg/kg. As these values are below the current temporary MRL of 5 mg/kg and the data in general shows declining flubendiamide residues over the 10-day experimental period, a permanent MRL of 5 mg/kg in conjunction with a 1-day WHP is recommended for head lettuce. As none of the trials were conducted on lettuce grown in greenhouse situations, the residues data support approval for field grown lettuce only.

Tomato: Data were generated from 7 Australian sites in which flubendiamide was applied to tomatoes at 48 g ai/ha, 72 g ai/ha, 4.8 g ai/100 L, 7.2 g ai/100L or 9.6 g ai/100 L. The highest flubendiamide residues from 1-day until 14-days after treatment, were 0.03 (n=2), 0.04, 0.05, 0.07, 0.08, 0.10, 0.11, 0.15 (n=2), 0.16 (n=2), 0.17 (n=2), 0.24, 0.28, 0.35 (n=2) and 0.63 mg/kg. These values confirm that the current temporary MRL of 2 mg/kg is appropriate for flubendiamide in tomatoes in conjunction with a 1-day WHP. The STMR for tomato is 0.15 mg/kg. The residues data support approval for field grown tomatoes only as no protected cropping data were submitted.

In a European study where tomatoes were processed into pomace, paste, raw puree and puree, flubendiamide residues were shown to concentrate by a factor of 4.5 in wet tomato pomace. Using the highest flubendiamide residue of 0.63 mg/kg in tomatoes and the processing factor of 4.5, a highest residue of 2.83 mg/kg is estimated in wet tomato pomace, which is equivalent to 14.2 mg/kg on a dry weight basis. An MRL of 20 mg/kg is recommended for flubendiamide in dry tomato pomace.

Animal Commodities: Cattle may be fed tomato pomace. The livestock burden is estimated as:

Cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake	Residue, mg/kg	% DM	Livestock dietary exposure		
					mg/animal	ppm	mg/kg bw
Tomato pomace	10	2	0.68 (STMR-P) ^a	20	6.8	0.34	0.0136

^a STMR for flubendiamide in tomato is 0.15 mg/kg. Processing value of 4.5x was used.

An animal transfer study was provided with the original Category 1 application for flubendiamide. Lactating cattle were dosed with flubendiamide at the equivalent of 2.9, 8.5, 38 or 60 ppm in the feed for 29 days. On day 29, the animals were sacrificed and liver, kidney, composite muscle, subcutaneous fat, omental fat and perirenal fat were collected for analysis.

Two additional lactating cattle from the 69 ppm group were sacrificed on study days 38 and 52 respectively to examine residue depuration. Samples of liver, kidney, composite muscle, subcutaneous fat, omental fat and perirenal fat were collected for analysis.

Highest observed residues in tissues and milk at a feeding level of 2.9 ppm, estimated residues at a maximum livestock burden of 0.34 ppm are summarised below.

	Total flubendiamide residue (mg/kg) after dosing at 2.9 ppm	Predicted flubendiamide residue (mg/kg) after feeding at 0.34 ppm
Liver	0.06	0.007
Kidney	0.06	0.007
Muscle	0.01	0.001
Fat (perirenal)	0.11	0.013
Milk	0.02	0.0023
Milk fats	Based on calculated processing factor of 14	0.033*

* Milk from the 60 ppm dose group in the animal transfer study were taken during the plateau phase and separated into skim milk and milk fats. Residues present in whole milk were observed to concentrate by a factor of 14x into milk fats. Therefore expected residues in milk fats after feeding at 0.34 ppm are 0.0023 x 14 = 0.033 (2 sig. figs.).

On the basis of these results, the following animal commodity residues are recommended:

MO 0105	Edible offal [mammalian]	0.03 mg/kg
MM 0095	Meat [mammalian] (in the fat)	0.05 mg/kg
ML 0106	Milks	*0.01 mg/kg
	Milk fats	0.05 mg/kg

2.4 Overseas registration and approved label instructions

The Applicant advised that flubendiamide is currently registered in a number of overseas countries.

2.5 Codex Alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods.

Flubendiamide is included on the 2010 schedule of the JMPR and therefore Codex MRLs have not yet been established. No animal commodity MRLs have been established in Japan, Taiwan or Korea.

The following relevant residue tolerances for animal commodities have been established.

Commodity ^a	Tolerance for residues arising from the use of flubendiamide (mg/kg)	
	USA	EU
Animal Commodities		
Residue Definition	Parent	Parent
Edible offal (mammalian)		
Cattle kidney	0.3	*0.01
Sheep kidney	0.3	*0.01
Cattle liver	0.3	*0.01
Sheep liver	0.3	*0.01
Cattle mbyp† except kidney		
Sheep mbyp† except kidney		
Edible offal, sheep		*0.01
Chicken liver	0.01 (Poultry liver)	*0.01 (Poultry liver)
Other terrestrial mammals, liver		
Other terrestrial mammals, offal		
Other terrestrial mammals, kidney		
Cattle, edible offal		*0.01
Other poultry liver		*0.01 (Poultry liver)
Chicken kidney		*0.01 (Poultry kidney)
Other poultry kidney		*0.01 (Poultry kidney)
Chicken edible offal		*0.01 (Poultry edible offal)
Other poultry edible offal		*0.01 (Poultry edible offal)
Meat (mammalian) [in the fat]		
Cattle fat	0.3	*0.01
Sheep fat	0.3	*0.01
Other terrestrial mammals fat		
Chicken fat	0.02 (Poultry fat)	*0.01 (Poultry fat)
Other poultry fat		*0.01 (Poultry fat)
Cattle, muscle	0.05	
Cattle, meat		*0.01
Sheep meat		*0.01
Other terrestrial mammals muscle	0.05 (Sheep muscle)	
Chicken muscle	0.01 (Poultry muscle)	*0.01 (Poultry meat)
Other poultry muscle		*0.01 (Poultry meat)
Milks	0.04 (Milk fat 0.30)	*0.01 (Milk and cream for cattle and sheep)
Eggs	0.01	*0.01 (Chicken, duck, goose and quail)

^a Commodity covered by tolerance. For instance, tolerance may be for bovine liver which covers cattle liver.

† meat by-products

2.6 Current and proposed Australian MRLs for flubendiamide

The Australian residue definition for flubendiamide is:

Commodities of plant origin: Flubendiamide

Commodities of animal origin: sum of flubendiamide and 3- iodo-*N*-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl)phthalimide, expressed as flubendiamide.

Table 1 - Current

Compound	Food	MRLs mg/kg	
Flubendiamide	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	T3
	VP 0526	Common bean (pods and/or immature seeds)	T2
	VL 0482	Lettuce, Head	T5
	VL 0483	Lettuce, Leaf	T5
	VO 0445	Peppers, Sweet [capsicums]	T1
	VO 0448	Tomato	T2
	VL 0447	Sweet corn (corn-on-the-cob)	T*0.05

Table 1 - Proposed

Compound	Food	MRL (mg/kg)	
DELETE:			
Flubendiamide	VL 0482	Lettuce, Head	T5
	VL 0483	Lettuce, Leaf	T5
	VO 0445	Peppers, Sweet [capsicums]	T1
	VO 0448	Tomato	T2
ADD:			
Flubendiamide	MO 0105	Edible offal [mammalian]	0.03
	VL 0482	Lettuce, Head	5
	VL 0483	Lettuce, Leaf	7
	MM 0095	Meat [mammalian] (in the fat)	0.05
	ML 0106	Milks	*0.01
		Milk fats	0.05
	VO 0445	Peppers, Sweet [capsicums]	1
	VO 0448	Tomato	2

Table 4 - Proposed

Compound	Animal feed commodity	MRL (mg/kg)
ADD: Flubendiamide	Tomato pomace	20

Proposed Withholding Period

Harvest (Capsicum, lettuce and tomato): DO NOT harvest for 1 day after application;

Note: For full details of Australian flubendiamide MRLs, please refer to the APVMA website <http://www.apvma.gov.au> and follow the Chemical Residues link.

2.7 Potential Risk to Trade

Export of treated produce containing finite (measurable) residues of flubendiamide may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Lettuce, capsicums and tomatoes

These crops are not considered major export commodities and the overall risk to Australian export trade is therefore considered to be small. However, the use of flubendiamide is expected to result in detectable residues in tomatoes, capsicums and lettuce. Growers/ producers/ stakeholders should be made aware of any potential risks to the industry.

The applicant has proposed that the following statement will be included on the product label.

“Export of treated produce

Growers should note that MRLs or import tolerances may not exist in all markets for edible produce treated with Belt 480SC. If you are growing edible produce for export, please check with Bayer CropScience Pty Ltd for the latest information on MRLs and import tolerances before using Belt 480SC.”

Stakeholders are requested to provide comment on the potential risks to trade in these horticultural commodities and the inclusion of the above statement on the product label.

Animal commodities derived from livestock that have been fed treated tomato pomace

Relevant overseas residue MRLs/ tolerances for flubendiamide in animal commodities have been established in some countries (see Section 2.5 above). Some key Australian export markets for animal commodities such as Japan, Korea and Taiwan have not established relevant standards. As detectable residues may occur if the product is used as directed, there is a potential risk to trade in these commodities.

It is necessary for residues in animal tissues to be below 0.01 mg/kg (<LOQ) to comply with tolerances of markets where no standard has been set or default MRLs apply. The LOQ when based on the Australian residue definition is 0.023 mg/kg (flubendiamide + metabolite as flubendiamide equivalents). Following feeding of tomato pomace from treated crops the maximum residue expected to occur in animal tissues is 0.013 mg/kg in fat. The estimated half-life in fat is 10 days and it would take about 4 days on clean feed for residues to fall below detectable limits. Residues above a reasonable limit of quantitation (0.01 mg/kg) are not expected in other tissues.

The National Vendor Declaration for cattle requires vendors to declare the feeding of by-products within 60 days of consignment. Any flubendiamide residues in meat, fat, liver and kidney occurring as a result of feeding tomato pomace are expected to decline to levels below 0.01 mg/kg within 4 days of withdrawal from the treated pomace. If animals are marketed within the 60 day period it is expected that the use of by-product stock feeds would be declared and appropriate risk mitigation be undertaken by the purchaser of the cattle.

Residues in whole milk are expected to be below the LOQ, however low levels of residues may occur in milk fats. The highest flubendiamide residue estimated in milk fats (based on the highest daily residue in milk) following consumption of tomato pomace from crops treated with flubendiamide is 0.033 mg/kg. As milk can generally be considered a bulked commodity the risk to trade in milk and milk products associated with the proposed use of flubendiamide on tomatoes is low.

Comment is sought on the risk to trade in animal commodities from the proposed use of Belt 480 SC Insecticide on tomatoes.

3. CONCLUSION

Use of flubendiamide (as Belt 480 SC Insecticide) is expected to result in detectable residues in tomatoes, capsicums and lettuce. None of these three crops are considered major export commodities and the overall risk to export trade is therefore considered to be small.

The applicant has proposed that the following statement will be included on the product label.

“Export of treated produce

Growers should note that MRLs or import tolerances may not exist in all markets for edible produce treated with Belt 480SC. If you are growing edible produce for export, please check with Bayer CropScience Pty Ltd for the latest information on MRLs and import tolerances before using Belt 480SC.”

Several key Australian export markets for animal commodities have not established tolerances for flubendiamide in animal commodities. As detectable residues are expected to occur if the product is used as directed this creates a potential risk to trade. The National Vendor Declaration for cattle requires vendors to declare the feeding of by-products within 60 days of consignment. Any flubendiamide residues in meat, fat, liver and kidney occurring as a result of feeding tomato pomace are expected to decline to levels below 0.01 mg/kg within 4 days of withdrawal from the

treated pomace. If animals are marketed within the 60 day period it is expected that the use of by-product stock feeds would be declared and appropriate risk mitigation be undertaken by the purchaser of the cattle.

Although residues in whole milk are expected to be below the LOQ, low levels of residues may occur in milk fats. It is considered that the risk to trade in milk products associated with the proposed use of flubendiamide on tomatoes is low.

Comments are sought on the potential for Belt 480 SC Insecticide to unduly prejudice Australian export trade when it is used on tomatoes, capsicums and lettuce to control *Heliothis spp.*

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA on (02) 6210 4748, or alternatively, the reports can be viewed at the APVMA Library which is located at:

18 Wormald Street
Symonston ACT, 2609
Office hours: 9.00 - 5.00 (EST) Monday to Friday