



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



**Trade Advice Notice**

on flupyradifurone in the product Sivanto Prime 200 SL Insecticide for use in animal feeds (bean forage and fodder) and rotational cropping situations

APVMA product number 84727

July 2021

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## Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

## About this document

This Trade Advice Notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered 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 document.

## Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of Sivanto Prime 200 SL Insecticide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on Monday 2 August 2021 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)

- email or postal address (if available)
- the date you made the submission.

**Please note:** submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

## Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: [apvma.gov.au](http://apvma.gov.au).

## Introduction

The APVMA has before it an application from Bayer CropScience Pty Ltd to vary the registration of Sivanto Prime 200 SL Insecticide (containing flupyradifurone) to add uses on selected tropical fruit (avocado, mango and papaya) and vegetables (cucurbits, fruiting vegetables other than cucurbits, green beans, potatoes and sweet potatoes). The proposed primary crops are not significant export commodities according to the APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B).

However, a use is proposed on green beans, the forage and fodder of which may be fed to livestock. The proposed use of flupyradifurone on vegetables is also the first use in Australia in rotational cropping situations and has the potential to cause detectable residues in rotational or following crops that are major export commodities and are significant feeds for livestock, such as cereals, oilseeds and pulses.

The potential for the proposed use to result in residues in animal commodities and rotational crops which are major export commodities (such as cereals, oilseeds and pulses) will be discussed in this Trade Advice Notice.

## Trade considerations

### Commodities exported

Cereals, selected pulses (lupins, field peas, chickpeas, faba beans, navy beans and mung beans) and selected oilseeds (canola and cotton seed) are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock-fed feeds produced from green bean forage/fodder and following crops. Residues in these commodities resulting from the use of Sivanto Prime 200 SL Insecticide may have the potential to unduly prejudice trade.

### Destination and value of exports

Exports of Australian cereals, pulses, canola and cotton are detailed below (Agricultural Commodity Statistics, Australian Bureau of Agriculture and Resource Economics and Sciences, Commonwealth of Australia).

Total exports of barley were estimated at 3,784 kilotonnes in 2019/20, valued at \$1.49 billion. Total exports of wheat (including flour) were 9,805 kilotonnes in 2018/19, valued at \$3.67 billion. Total exports of oats in 2019/20 were estimated at 145 kilotonnes, valued at \$136 million. Exports of sorghum in 2019/20 were estimated at 72 kilotonnes, valued at \$34.8 million. Maize exports in 2019/20 were estimated at 41.4 kilotonnes, valued at \$21.9 million.

Total oilseed exports in 2019/20 (including canola, cottonseed, linseed, peanuts, safflower, soya bean and sunflower) were 1,727 kilotonnes, worth \$1.19 billion. Total vegetable oil exports (including canola, cottonseed, linseed, palm, peanut, safflower, soya bean, sunflower and olive) were 224 kilotonnes, at a value of \$380 million, in 2019/20. Total oilseed meal exports in 2019/20 were 8.3 kilotonnes at a value of \$7.2 million.

Total pulse exports were valued at \$1.246 billion, in 2019/20, with the most significant export commodities being chickpeas (370 kt, \$306 million), lupins (230 kt, \$95 million) and field peas (59.9 kt, \$38.6 million)

**Table 1: Major destinations for Australian cereal, oilseed and pulse exports**

Commodity	Major destinations
Barley	China, Thailand, Japan, Vietnam, Korea, United Arab Emirates, the Philippines, Taiwan
Wheat	The Philippines, Indonesia, Korea, Japan, Vietnam, Malaysia, Iraq, New Zealand, Kuwait, Yemen, Thailand
Sorghum	China, Taiwan, Japan
Cottonseed (including seed, oil, and meal)	Japan, Korea
Canola (including seed, oil and meal)	China, Germany, the Netherlands, Belgium, Japan

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B).

## Proposed Australian use pattern

Table 2: Proposed use pattern – Sivanto Prime 200 SL Insecticide (200 g/L flupyradifurone)

Crop	Pest	Rate	WHP	Critical comments
Avocados, mangoes, papayas	Banana spotting bug ( <i>Amblypelta lutescens</i> ), fruit spotting bug ( <i>Amblypelta nitida</i> ), mango planthopper, green planthopper	75 or 100 mL/100 L (up to 20 g ai/100 L)	Avocado 1 day (H)	<p>Monitor crops and apply once local thresholds are reached. Where applicable, use the higher rate during periods of high pest pressure or when longer residual control is desired. Do not re-apply within 14 days of previous Sivanto Spray.</p> <p>Apply a maximum of 2 applications of Sivanto Prime to a block in a 12-month period. DO NOT exceed 1 L of Sivanto Prime per hectare per application. DO NOT apply more than one application during flowering.</p> <p>Calibrate spray equipment to ensure thorough coverage of foliage, flowers and fruit using dilute spraying equipment to the point of run-off. In papaya a minimum water volume of 360 L/ha is recommended.</p> <p>Concentrate spraying is not appropriate for this use. Refer to 'Application' section in GENERAL INSTRUCTIONS for more information.</p>
			Mango, papaya 3 days (H)	
Cucurbits, eggplant, peppers (capsicum and chili), tomatoes (includes protected cropping production systems)	Silverleaf whitefly ( <i>Bemisia tabaci</i> Biotype B)	750 mL/ha	1 day (H)	<p>Monitor crops and commence applications once local thresholds are reached. Continue to monitor crops and make subsequent applications as necessary. Do not reapply within 7 days of a previous Sivanto Prime spray.</p> <p>Do not apply more than 2 applications of Sivanto Prime per hectare per year to the same cropping ground, including areas which have been double cropped.</p>
		OR		
	Greenhouse whitefly ( <i>Trialeurodes vaporariorum</i> )	Dilute spraying		<p>Ensure thorough spray coverage of the target crop. Dilute spraying is recommended for most trellised crops, particularly those grown in protected cropping systems. For dilute spraying apply to the point of run-off, using application volumes of up to 1000 L/ha – refer 'Application' section in GENERAL INSTRUCTIONS.</p>
	75 mL/100 L (150 g ai/ha or 15 g ai/100 L)	75 mL/100 L		
Green peach aphid ( <i>Myzus persicae</i> )	Cotton aphid ( <i>Aphis gossypii</i> )	750 mL/ha	<p>Note: This use is subject to a CropLife resistance management strategy. Refer to <a href="http://croplife.org.au">croplife.org.au</a> for more information.</p>	
		OR		
		Dilute spraying		
		75 mL/100 L		

Crop	Pest	Rate	WHP	Critical comments
Green beans, potatoes, sweet potatoes	Silverleaf whitefly ( <i>Bemisia tabaci</i> Biotype B)	750 mL/ha (150 g ai/ha)	7 days (H) Beans 7 days (G)	<p>Monitor crops and commence applications once local thresholds are reached. Continue to monitor crops and make subsequent applications as necessary. Do not reapply within 7 days of a previous Sivanto Prime spray.</p> <p>Do not apply more than 2 applications of Sivanto Prime per hectare per year to the same cropping ground, including areas which have been double cropped.</p> <p>Ensure thorough coverage of the target crop – refer 'Application' section in GENERAL INSTRUCTIONS.</p> <p>Note: This use is subject to a CropLife resistance management strategy. Refer to <a href="http://croplife.org.au">croplife.org.au</a> for more information.</p>

Withholding periods:

Harvest:

Avocados, cucurbits, eggplant, peppers (capsicum and chili), tomatoes: DO NOT harvest for one day after application; mangoes, papayas: DO NOT harvest for 3 days after application; green beans, potatoes, sweet potatoes: DO NOT harvest for 7 days after application.

Grazing:

Tree crops: DO NOT graze treated orchards; green beans: DO NOT graze or cut for stock food for 7 days after application.

Restrictions:

DO NOT apply by aircraft to tree crops.

DO NOT apply if heavy rain or storms are forecast within 3 days.

DO NOT irrigate to the point of run-off for at least 3 days after application.

#### LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the Export Slaughter Interval is observed before stock are sold or slaughtered.

#### EXPORT SLAUGHTER INTERVAL (ESI) – 7 DAYS

LIVESTOCK THAT HAS BEEN GRAZED ON OR FED TREATED CROPS SHOULD BE PLACED ON CLEAN FEED FOR 7 DAYS PRIOR TO SLAUGHTER.

Trade advice:

Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Sivanto Prime 200 SL. If you are growing produce for export, please check with Bayer CropScience Pty Ltd or your industry body for the latest information on any potential trade issues and their management before using Sivanto Prime.

## Results from residues trials presented to the APVMA

### Green beans

The applicant provided full details of GLP Australian residue trials on green beans. Residues in the bean pods (with seeds) and the animal feeds of forage and fodder are summarised below:

**Table 3: Parent residues in green bean pods and succulent seeds**

Crop	Location	Treatment	Portion analysed	Parent residues after 7 day WHP (mg/kg)
Green beans	Australia	150 g ai/ha × 2	Pods	<0.01, 0.02, 0.02, 0.07, 0.16, 0.17, 0.38 and 0.44
Snap beans and snow peas	North America	205 g ai/ha × 2	Pods	0.01, 0.06, 0.13, 0.16, 0.18, 0.21, 0.24, 0.57, 0.58, 0.81, 0.95, 0.98, 1.18 and 1.21
Lima beans	North America	205 g ai/ha × 2	Succulent seeds	<0.01, <0.01, 0.01, 0.01, 0.02, 0.03, 0.07, 0.10 and 0.11

**Table 4: Parent + DFA residues in green bean pods and succulent seeds**

Crop	Location	Treatment	Portion analysed	Highest total parent + DFA residues after 7 day WHP (mg/kg)
Green beans	Australia	150 g ai/ha × 2	Pods	0.50 (2), 0.52 (2), 0.60, 0.64, 0.85 and 1.27
Snap beans and snow peas	North America	205 g ai/ha × 2	Pods	0.50, 0.66, 0.77, 0.90, 0.98, 1.0 (2), 1.4, 1.5 (2), 1.6, 2.0, 2.1 and 2.6
Lima beans	North America	205 g ai/ha × 2	Succulent seeds	<0.06 (2), 0.06, 0.08, 0.13 (2), 0.30, 0.32 and 0.74

Based on the available data for beans (pods and succulent seeds) the OECD MRL calculator recommends an MRL of 2 mg/kg (STMR = 0.13 mg/kg, n = 31). An MRL of 2 mg/kg is recommended for flupyradifurone on VP 0526 common bean (pods and/or immature seeds) based on a highest residue in pods of 1.21 mg/kg from the overseas trials and 0.44 mg/kg from the Australian trials.

6-Chloronicotinic acid (6-CNA) is a metabolite which is not included in the residue definition flupyradifurone as it is also a metabolite of imidacloprid. It is the target analyte for imidacloprid common moiety analytical methods and therefore consideration of appropriate imidacloprid MRLs for coverage of expected 6-CNA

residues is required. Residues of 6-CNA in the Australian green bean trials were 0.07, 0.08, 0.13, 0.16, 0.33, 0.43, 0.44 and 0.55 mg/kg. A highest 6-CNA residue of 0.55 mg/kg in bean pods after application of flupyradifurone would be equivalent to 0.89 mg imidacloprid equivalents/kg ( $0.55 \times 255.7 \div 157.6$ ). The current MRL of T1 mg/kg for imidacloprid on VP 0526 common bean (pods and/or immature seeds) should be replaced with a permanent MRL of 2 mg/kg to cover residues resulting from the proposed use of flupyradifurone.

**Table 5: Parent residues in green bean forage and fodder**

Crop	Location	Treatment	Parent residues after 7 day WHP (mg/kg, dry weight)
Green bean forage	Australia	150 g ai/ha × 2	0.14, 2.13, 4.29 and 8.08
Green bean fodder	Australia	150 g ai/ha × 2	0.35, 0.42, 1.15, 5.19, 6.74, 9.27, 11.50 and 12.87

**Table 6: Parent + DFA residues in green bean forage and fodder**

Crop	Location	Treatment	Highest total parent + DFA residues after 7 day WHP (mg/kg, dry weight)
Green bean forage	Australia	150 g ai/ha × 2	3.14, 5.13, 6.24 and 10.08
Green bean fodder	Australia	150 g ai/ha × 2	2.70, 3.85, 4.95, 8.79, 9.33, 12.41, 13.50 and 16.47

*DFA = difluoroacetic acid (metabolite included in the residue definition for dietary risk assessment).*

Based on the combined data set for parent residue in forage and fodder the OECD MRL calculator recommends an MRL of 30 mg/kg (unrounded MRL 23.3 mg/kg, STMR 4.74 mg/kg, n = 12). MRLs of 20 mg/kg are recommended for flupyradifurone on both AL 0061 bean fodder and AL 1030 bean forage (green) based on highest dry weight residues of 12.87 and 8.08 mg/kg of parent in fodder and forage respectively.

Residues of 6-CNA in green bean fodder from the Australian trials were 0.25, 0.30, 0.32, 0.95, 1.16, 1.17, 1.19 and 1.60 mg/kg on a dry weight basis. Residues of 6-CNA in green bean forage from the Australian trials were 0.29, 0.56, 0.88 and 1.00 mg/kg on a dry weight basis. Residues of 6-CNA in bean forage and fodder resulting from use of flupyradifurone would be covered by the current MRL for imidacloprid in legume animal feeds at 15 mg/kg.

## Rotational crops

The applicant has provided full details of a number of overseas GLP field rotational crop studies. Residues of 6-CNA were not significant in rotational crops. Highest residues of parent and of parent + DFA metabolite are summarised in the following tables.

Table 7: Highest residues of parent in field rotational crop studies

Rotational crop	No. of trials	Rate (g ai/ha)	High flupyradifurone residue, mg/kg after application to bare soil or primary crop			
			13 – 14 day PBI	21 – 41 day PBI	61 – 204 day PBI	266 – 363 day PBI
Cereal forage	4	200		0.02 (bare soil)	0.01 (primary crop)	0.03 (primary crop)
Cereal grain	4	200		<0.01 (bare soil)	<0.01 (primary crop)	<0.01 (primary crop)
Cereal straw	4	200		0.04 (bare soil)	0.02 (primary crop)	<0.01 (primary crop)
Root and tuber veg. (roots) (carrot and turnip)	4	200		<0.01 (bare soil)	<0.01 (primary crop)	<0.01 (primary crop)
Leafy veg	4	200		0.08 (bare soil)	0.03 (primary crop)	0.02 (primary crop)
Sugar cane	4	400	<0.01 (bare soil)			
Sugar cane (processing)	1	2100	<0.01 – in cane (bare soil)			
Potato	4	2 × 125		<0.01 (bare soil)		
Cucumber	4	2 × 125		<0.01 (bare soil)		
Leek	4	2 × 125		<0.01 (bare soil)		
French bean	4	2 × 125		<0.01 (bare soil)		
Onion	4	2 × 125		<0.01 (bare soil)		
Pea, field (dry)	4	2 × 125		<0.01 (bare soil)		
Winter rape (seed)	4	2 × 125		<0.01 (bare soil)		
Strawberry	4	300		<0.01 (bare soil)	<0.01 (bare soil)	<0.01 (bare soil)
Potato	4	300			<0.01 (bare soil)	<0.01 (bare soil)

Rotational crop	No. of trials	Rate (g ai/ha)	High flupyradifurone residue, mg/kg after application to bare soil or primary crop			
			13 – 14 day PBI	21 – 41 day PBI	61 – 204 day PBI	266 – 363 day PBI
Cauliflower/broccoli	4	300		<0.01 (bare soil)	<0.01 (bare soil)	<0.01 (bare soil)
Rape seed (seed)	4	175 – 214			<0.01 (bare soil)	<0.01 (bare soil)
Rape seed (green material)	5	175 – 214			<0.01 (bare soil)	<0.01 (bare soil)
Barley green material	4	175			0.013 (bare soil)	<0.01 (bare soil)
Barley grain	4	175			<0.01 (bare soil)	<0.01 (bare soil)
Barley straw	4	175			0.032 (bare soil)	0.019 (bare soil)
Corn green material	4	175 – 186			0.030 (bare soil)	0.012 (bare soil)
Corn kernel	4	175 – 186			<0.01 (bare soil)	<0.01 (bare soil)
Corn, rest of plant	4	175 – 186			0.020 (bare soil)	0.010 (bare soil)

**Table 8: Highest residues of parent + DFA metabolite in field rotational crop studies**

Rotational crop	No. of trials	Rate (g ai/ha)	High flupyradifurone + DFA residue, mg equiv/kg after application to bare soil or primary crop			
			13 – 14 day PBI	21 – 41 day PBI	61 – 204 day PBI	266 – 363 day PBI
Cereal forage	4	200		0.39 (bare soil)	0.11 (primary crop)	0.18 (primary crop)
Cereal grain	4	200		0.64 (bare soil)	0.27 (primary crop)	0.38 (primary crop)
Cereal straw	4	200		0.38 (bare soil)	0.12 (primary crop)	0.18 (primary crop)
Root and tuber veg. (roots) (carrot and turnip)	4	200		0.13 (bare soil)	0.06 (primary crop)	0.05 (primary crop)
Leafy veg	4	200		0.20 (bare soil)	0.11 (primary crop)	0.10 (primary crop)

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Rotational crop	No. of trials	Rate (g ai/ha)	High flupyradifurone + DFA residue, mg equiv/kg after application to bare soil or primary crop			
			13 – 14 day PBI	21 – 41 day PBI	61 – 204 day PBI	266 – 363 day PBI
Sugar cane	4	400	<0.06 (bare soil)			
Sugar cane (processing)	1	2100	<0.06 – in cane (bare soil)			
Potato	4	2 × 125		0.26 (bare soil)		
Cucumber	4	2 × 125		0.42 (bare soil)		
Leek	4	2 × 125		0.24 (bare soil)		
French bean	4	2 × 125		1.1 (bare soil)		
Onion	4	2 × 125		0.17 (bare soil)		
Pea, field (dry)	4	2 × 125		2.3 (bare soil)		
Winter rape (seed)	4	2 × 125		0.16 (bare soil)		
Strawberry	4	300		0.37 (bare soil)	0.38 (bare soil)	0.24 (bare soil)
Potato	4	300			0.27 (bare soil)	0.067 (bare soil)
Cauliflower/broccoli	4	300		0.21 (bare soil)	0.19 (bare soil)	0.13 (bare soil)
Rape seed (seed)	4	175 – 214			0.077 (bare soil)	0.05 (bare soil)
Rape seed (green material)	5	175 – 214			0.26 (bare soil)	0.15 (bare soil)
Barley green material	4	175			0.143 (bare soil)	0.091 (bare soil)
Barley grain	4	175			0.38 (bare soil)	0.27 (bare soil)
Barley straw	4	175			0.142 (bare soil)	0.119 (bare soil)
Corn green material	4	175 – 186			0.091 (bare soil)	0.038 (bare soil)
Corn kernel	4	175 – 186			0.12 (bare soil)	0.099 (bare soil)

Rotational crop	No. of trials	Rate (g ai/ha)	High flupyradifurone + DFA residue, mg equiv/kg after application to bare soil or primary crop			
			13 – 14 day PBI	21 – 41 day PBI	61 – 204 day PBI	266 – 363 day PBI
Corn, rest of plant	4	175 – 186			0.086 (bare soil)	0.035 (bare soil)

The highest parent residue in a rotational crop for human consumption was 0.08 mg/kg in lettuce after a 28 day plant back interval in European trials. Scaled for the total seasonal application rate of 300 g ai/ha, the estimated HR is 0.12 mg/kg ( $0.08 \times 300 \div 200$ ). An MRL of 0.2 mg/kg is recommended for flupyradifurone on 'all other foods'. It is noted that residues of parent in cereal grains, dry peas and rape seed were all <0.01 mg/kg, however application rates were less than the total proposed seasonal rate (175 – 250 g ai/ha, 0.58 – 0.83× total rate). The highest total residue of parent plus the DFA metabolite for dietary exposure assessment was 2.76 mg/kg in field peas (dry) ( $2.3 \times 300 \div 250$ ).

Based on a highest estimated scaled parent dry weight residue of 0.18 mg/kg ( $0.03 \div 0.25 \times 300 \div 200$ ) in cereal green material an MRL of 0.3 mg/kg is recommended for flupyradifurone on primary feed commodities, except bean fodder and bean forage (green). The highest estimated scaled total parent + DFA residue in an animal feed for risk assessment was 2.34 mg/kg in cereal forage on a dry weight basis ( $0.39 \div 0.25 \times 300 \div 200$ ).

### Animal commodities

The expected maximum livestock dietary burden for cattle will be as a result of the consumption of green bean fodder at 60% of the diet for beef cattle and 70% for dairy (OECD feed calculator) with a parent HR of 12.87 ppm. The maximum livestock dietary exposure to parent for compliance with MRLs is therefore 7.72 ppm for beef cattle and 9.01 ppm for dairy cattle from feeding on green bean fodder. Estimated residues of parent in tissues and milk based on extrapolation from residues observed in the transfer study after dosing at 23.1 ppm are calculated below:

**Table 9: Estimated residues in cattle milk and tissues**

Feeding level (ppm)	Flupyradifurone residue (mg/kg)				
	Milk	Muscle	Liver	Kidney	Fat
23.1	0.125	0.260	0.821	0.894	0.120
7.72 – estimated burden (beef)	–	0.087	0.274	0.299	0.040
9.01 – estimated burden (dairy)	0.049	–	–	–	–
Established MRLs	–	–	–	–	–
Recommended MRLs	0.07 (milks)	0.1 (meat)		0.5 (offal)	–

The following mammalian commodity MRLs are recommended for flupyradifurone:

MO 0105 Edible offal (mammalian)	0.5 mg/kg
MM 0095 Meat [mammalian]	0.1 mg/kg
ML 0106 Milks	0.07 mg/kg

None of the primary crops in this submission are considered to be feeds for poultry. Residues of parent were also below the LOQ in cereal grains from the rotational crop studies, although at slightly lower rates than proposed (0.58 – 0.83× total seasonal rate), noting also parent residues in tissues and eggs were <LOD after feeding with flupyradifurone at 1.5 ppm in a poultry transfer study. The following poultry commodity MRLs are recommended for flupyradifurone at the LOQ:

PE 0112 Eggs	*0.01 mg/kg
PO 0111 Poultry, edible offal of	*0.01 mg/kg
PM 0110 Poultry meat	*0.01 mg/kg

## Overseas registration and approved label instructions

The applicant indicated that Sivanto Prime 200 SL Insecticide is approved in numerous countries. A Good Agricultural Practice (GAP) of 2 applications applied at 1.05 L/ha each as foliar applications is approved for use in the proposed crops in the USA and/or Europe.

## Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in GAP employed by various countries. Some countries may accept Codex CXLs when importing foods. Flupyradifurone has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for flupyradifurone.

Table 10: International MRLs for flupyradifurone

Commodity	Tolerance for residues arising from the use of flupyradifurone (mg/kg)						
	Australia	EU	Japan	Codex	Korea	Taiwan	USA
Residue definition	Flupyradifurone (for enforcement)	Flupyradifurone (Note the metabolite DFA has separate MRLs)	Flupyradifurone	Plant commodities for compliance with MRLs: Flupyradifurone  Animal commodities: Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents	–	–	Flupyradifurone
Edible offal (mammalian)	0.5 (proposed)	*0.01 (flupyradifurone) 0.1 (DFA) [bovine liver] *0.01 (flupyradifurone) 0.15 (DFA) [bovine kidney]	1 (cattle liver, kidney) 0.04 (pig, liver, kidney)	4	–	–	1.0 (cattle/sheep meat byproducts) 0.04 (hog meat byproducts)
Mammalian fats (except milk fats)	–	*0.01 (flupyradifurone) 0.1 (DFA) [Bovine fat]	0.2 (cattle fat) 0.01 (pig fat)	1	–	–	0.2 (cattle/sheep fat) 0.01 (hog fat)
Meat (from mammals other)	0.1 (proposed)	*0.01 (flupyradifurone)	0.3 (cattle muscle) 0.01 (pig muscle)	1.5	–	–	0.30 (cattle/sheep meat)

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Commodity	Tolerance for residues arising from the use of flupyradifurone (mg/kg)						
	Australia	EU	Japan	Codex	Korea	Taiwan	USA
than marine mammals)		0.1 (DFA) bovine muscle]					0.01 (Hog meat)
Milks	0.07 (proposed)	*0.01 (flupyradifurone) 0.03 (DFA)	0.2	0.7	–	–	0.15
Cereal grains	0.2 (all other foods, proposed)	*0.01 (flupyradifurone) 0.3 (DFA)	3 (wheat, barley, rye, other cereal grains) 0.05 (corn) 0.05 (rice)	3	3 (cereal grains without rice) 1 (wheat) 0.05 (corn)	3 (barley) 0.05 (corn) 1.5 (corghum, wheat)	0.05 (corn, field) 3 (grain, cereal except rice and corn)
Pulses	0.2 (all other foods, proposed)	*0.01 (flupyradifurone) 0.8 (DFA)	3 (beans, dried, peas, other legumes/pulses) 2 (soybeans, dried)	0.4 (beans, dry) 3 (peas, dry)	1.5 (beans) 3.0 (pea)	2 (pea, dry) 0.5 (soybean)	3 (pea and bean, dried, except soybean) 1.5 (soybean seed)
Oilseeds	0.2 (all other foods, proposed)	*0.01 (flupyradifurone) 0.05 (DFA) [canola and cotton seed]	0.8 (cotton seeds)	0.8 (cotton seed)	0.05 (rape seed)	0.8 (cotton seed)	0.8 (cotton seed) 0.03 (rape seed)

## Current and proposed Australian MRLs for flupyradifurone

Table 11: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Flupyradifurone		
TN 0669	Macadamia nuts	*0.01

Table 12: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Flupyradifurone		
ADD:		
	All other foods	0.2
FI 0326	Avocado	0.7
VP 0526	Common bean (pods and/or immature seeds)	2
MO 0105	Edible offal (mammalian)	0.5
PE 0112	Eggs	*0.01
VC 0045	Fruiting vegetables, cucurbits	0.5
VO 0050	Fruiting vegetables, other than cucurbits	1
FI 0345	Mango	0.7
MM 0095	Meat (mammalian)	0.1
ML 0106	Milks	0.07
FI 0350	Papaya [pawpaw]	0.5
VR 0589	Potato	0.07
PM 0110	Poultry meat	*0.01
PO 0111	Poultry, edible offal of	*0.01
VR 0508	Sweet potato	0.07
Imidacloprid		
DELETE:		
VP 0526	Common bean (pods and/or immature seeds)	T1

Compound	Food	MRL (mg/kg)
ADD:		
FI 0326	Avocado	0.2
VP 0526	Common bean (pods and/or immature seeds)	2
FI 0345	Mango	0.2
FI 0350	Papaya [pawpaw]	0.2

Table 13: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
ADD:		
Flupyradifurone		
AL 0061	Bean fodder	20
AL 1030	Bean forage (green)	20
	Primary feed commodities, except bean fodder and bean forage (green)	0.3
	Tomato pomace, dry	5

## Potential risk to trade

Export of treated produce containing finite (measurable) residues of flupyradifurone 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.

## Tropical fruit and vegetable crops

The risk to international trade of tropical fruit and vegetable crops is not considered to be undue as these crops are not major export commodities.

## Milk – exposure from primary crops

Finite residues of parent flupyradifurone and its DFA metabolite are expected in milk following feeding of green bean (primary crop) forage and fodder. The recommended MRL at 0.07 mg/kg is higher than that in the EU (\*0.01 mg/kg for flupyradifurone and 0.03 mg/kg for DFA) but lower than those established by Codex, Japan and the USA.

## Meat and offal – exposure from primary crops

Finite residues of parent flupyradifurone and its DFA metabolite are expected in meat and offal following feeding of green bean (primary crop) forage and fodder. The recommended MRLs for meat (mammalian) at 0.1 mg/kg and edible offal (mammalian) at 0.5 mg/kg are lower than those established in Japan, the USA and Codex and the trade risk to markets that recognise those MRLs is considered low.

Consideration of an Export Slaughter Interval (ESI) is however required to manage the risks to trade associated with both flupyradifurone and DFA residues in meat and offal to the European Union (separate MRLs for flupyradifurone and DFA) and to Korea and Taiwan (no MRLs established). Given a residue definition and MRLs are not established in some major markets at this time, the LOQ of 0.01 mg/kg for both flupyradifurone and DFA has been considered as the ESI endpoint.

In the flupyradifurone dairy cattle transfer study after dosing at 135 ppm, residues of parent + DFA (and 2 other metabolites) in all tissues were below the LOQ after 7 days on clean feed. For kidney, the tissue with the highest residue, an average parent residue of 4.72 mg/kg declined to 0.045 mg/kg after 3 days depuration to give an estimated half-life of 0.45 days. Based on this half-life it would take 2.21 days for the estimated parent residue of 0.299 mg/kg in kidney to decline to 0.01 mg/kg (the LOQ and established MRL for mammalian tissues in the EU).

Extrapolation from the flupyradifurone and DFA dairy cattle transfer studies, gives an estimated maximum DFA residue in kidney of 0.323 mg/kg in parent equivalents or 0.107 mg/kg as DFA. In the DFA transfer study an average residue of 1.1 mg/kg in kidney declined to 0.33 mg/kg over 3 days, to give an estimated half-life of 1.73 days. It would take approximately 6 days for the estimated DFA residue of 0.107 mg/kg to decline to 0.01 mg/kg. The estimated DFA residue in fat is 0.327 mg/kg in parent equivalents, or 0.109 mg/kg as DFA. The estimated time to 0.01 mg/kg is approximately 7 days based on a half-life of 2.14 days in subcutaneous fat.

It is considered that a 7 day ESI should manage the risk to trade for the primary crops.

## Meat, offal and milk – exposure from rotational crops

An ESI cannot readily be used to manage the risk for livestock that have been fed on rotational crops. In the rotational crop studies, residues of parent in cereal forage of up to 0.18 mg/kg dry weight were observed. Estimated parent residues in tissues and milk by extrapolation from residues observed from feeding at 4.81 ppm are summarised below:

**Table 14: Estimated residues of parent from feeding at 0.18 ppm**

Matrix	Parent residue from feeding at 4.81 ppm (mg/kg)	Estimated parent residue from feeding at 0.18 ppm (mg/kg)
Milk	0.026	0.0010
Fat	0.028	0.0010
Kidney	0.222	0.0083

Matrix	Parent residue from feeding at 4.81 ppm (mg/kg)	Estimated parent residue from feeding at 0.18 ppm (mg/kg)
Liver	0.172	0.0064
Muscle	0.048	0.0018

Estimated residues of parent flupyradifurone are below the method LOQs for meat, milk and offal.

It is noted that the Codex residue definition for animal commodities is the sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents. The estimated feeding level of flupyradifurone + DFA due to residues in rotational crops is 2.34 ppm in flupyradifurone equivalents. Of this residue 2.22 mg/kg was DFA (in parent equivalents), or 0.74 mg/kg as DFA.

Estimated DFA residues in tissues and milk by extrapolation from residues observed from feeding at 0.89 ppm are summarised below:

**Table 15: Estimated residues of DFA from feeding at 0.74 ppm**

Matrix	DFA (mg/kg) after feeding with DFA at 0.89 ppm (2.7 ppm in flupyradifurone equivalents)	Estimated DFA residue (mg/kg) after feeding at 0.74 ppm (2.22 ppm in flupyradifurone equivalents)
Milk	0.0197 (0.059 pe)	0.0164 (0.049 pe)
Fat	0.131 (0.39 pe)	0.109 (0.32 pe)
Kidney	0.119 (0.36 pe)	0.0989 (0.30 pe)
Liver	0.0648 (0.19 pe)	0.0539 (0.16 pe)
Muscle	0.0896 (0.27 pe)	0.0745 (0.22 pe)

*pe = parent equivalents*

Therefore, estimated residues of DFA (in parent equivalents) in tissues and milk would be below the Codex flupyradifurone MRLs. Estimated DFA residues in tissues and milk would also be below the MRLs established for DFA in the EU, with the exception of fat which would be approximately equivalent to the EU MRL at 0.1 mg/kg. It is noted that flupyradifurone MRLs for animal commodities are not established in Korea or Taiwan.

### Rotational cereal, oilseed and pulse crops

Residues in cereal grains, oilseeds and pulses will be covered by the proposed 'All other foods' MRL at 0.2 mg/kg. It is noted that in the rotational crop trials residues of parent in cereal grains, dry peas and rape seed were all <0.01 mg/kg, however application rates were less than the proposed total seasonal rate (175 – 250 g ai/ha, 0.58 – 0.83× the maximum proposed seasonal rate).

The highest scaled residue of DFA in cereal grains (in parent equivalents) was 0.95 mg/kg ( $0.63 \times 300 \div 200$ ) or 0.32 mg/kg as DFA. This is approximately equivalent to the current EU MRL of 0.3 mg/kg for DFA on cereal grains.

The highest scaled residue of DFA in rape seed (in parent equivalents) was 0.18 mg/kg ( $0.15 \times 300 \div 250$ ) or 0.06 mg/kg as DFA. This is just above the current EU MRLs of 0.05 mg/kg for DFA on canola and cotton seed.

The highest scaled residue of DFA in pulses (in parent equivalents) was 2.76 mg/kg in field peas (dry) ( $2.3 \times 300 \div 250$ ) or 0.92 mg/kg as DFA. This is just above the current EU MRL of 0.8 mg/kg for DFA on pulses.

## Conclusion

Bayer CropScience Pty Ltd has applied to vary the registration of Sivanto Prime 200 SL Insecticide (containing flupyradifurone) to add uses on selected tropical fruit and vegetables. Use on green beans will require the establishment of finite animal commodity MRLs. The vegetable uses will also be the first uses in rotational cropping situations which may lead to residues in following crops that are major export commodities or significant feeds for livestock should those crops be grown in rotation with treated vegetables.

Comment is sought on the potential risk to Australian trade if Sivanto Prime 200 SL Insecticide is used on selected tropical fruit and vegetables as proposed.