



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



TRADE ADVICE NOTICE

on Fluopyram and Trifloxystrobin in the Product Luna Sensation Fungicide

APVMA Product Number P65560

MAY 2015

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), and State Departments of Primary Industry.

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 is a Trade Advice Notice.

It 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 Luna Sensation Fungicide containing the existing active constituents fluopyram and trifloxystrobin 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. In relation to this document, these grounds relate to the trade implications of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 4 June 2015 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 group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701

Email: enquiries@apvma.gov.au

Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Limited to register the new product, *Luna Sensation Fungicide*, containing 250 g/L fluopyram and 250 g/L trifloxystrobin. The product is proposed for use on almonds, apples, pears and stone fruit. The proposed variation of use requires the establishment of MRLs for fluopyram on almonds, pome and stone fruit and for trifloxystrobin on almonds and stone fruit. It is also proposed to establish permanent MRLs for fluopyram in animal commodities.

The potential for fluopyram and trifloxystrobin residues to unduly prejudice trade in almonds, apples, pears and stone fruit, arising from the proposed use, is discussed below. The risk to trade in animal commodities from livestock fed on almond hulls and apple pomace from treated crops is also considered.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome and stone fruits are considered to be major export commodities thus the presence of detectable residues has the potential to prejudice trade. Almonds are not considered to be a major export commodity so further consideration is not required.

Animal commodities from livestock that have been fed feeds (almond hulls and apple pomace) containing residues arising from the proposed use are exported.

2.2 Destination and value of exports

Pome Fruit

Values of recent exports of Australian pome fruit are not readily available. Major markets for Australian apples by volume in 2010–2011 were Papua New Guinea, Indonesia, the United Kingdom, Sri Lanka and Thailand (Australian Bureau of Statistics). Leading markets for Australian pears in 2013 were New Zealand, Indonesia and Canada.²

Stone Fruit

Australia exported \$1.4 million worth of apricots, \$31.5 million worth of cherries, \$18.2 million worth of nectarines and peaches and \$7.1 million worth of plums in the 2012–2013 financial year. The major markets are summarised below:

² apal.org.au/supply-chain/trade/export-markets/

Table 1: Largest Export markets by value for stone fruit in 2012-2013 financial year

Stone Fruit	Destination
Apricots	United Arab Emirates
	Hong Kong
	Singapore
	Saudi Arabia
	Netherlands
	France
	Russia
	Kuwait
	Bahrain
Cherries	Hong Kong
	Taiwan
	Singapore
	Malaysia
	United Arab Emirates
	Vietnam
	Indonesia
	China
	United Kingdom
	Netherlands
Nectarines and Peaches	Hong Kong
	United Arab Emirates
	Singapore
	New Caledonia
	Taiwan
	Saudi Arabia

Stone Fruit	Destination
	Kuwait
	Qatar
	Malaysia
	Indonesia
Plums	Hong Kong
	Singapore
	Malaysia
	United Arab Emirates
	Vietnam
	Russia
	Kuwait
	Indonesia
	New Caledonia
	Papua New Guinea

Source of data: Australian Bureau of Statistics

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).

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Luna Sensation Fungicide* (250 g/L fluopyram, 250 g/L trifloxystrobin) on almonds, apples, pears and stone fruit is summarised below.

Table 2: Proposed use pattern of *Luna Sensation Fungicide* (250 g/L fluopyram, 250 g/L trifloxystrobin) on almonds, apples, pears and stone fruit

CROP	DISEASE	RATE	CRITICAL COMMENTS
Almonds	Blossom blight Stone fruit rust	<u>Dilute spraying</u> 30 mL/100 L <u>Concentrate spraying</u> Refer to the Application section	Apply in a fungicide spray program according to target disease, observing the restrictions on total number of applications detailed below. Blossom blight Apply as part of a blossom blight spray program. The critical application timings for blossom blight control are early (1–10%) blossom, full bloom and petal fall/shuck fall. Stone fruit rust
	Shot hole Hull rot	<u>Dilute spraying</u> 40 mL/100 L <u>Concentrate spraying</u> Refer to the Application section (not appropriate for hull rot control)	Apply at or prior to the first signs of disease. Repeat applications may be required later in the crop cycle if weather conditions favour disease development or new foliage growth occurs. Shot hole Apply as part of a protectant spray program at intervals of 10 to 14 days starting at early pink bud. Repeat applications may be required later in the crop cycle if weather conditions favour disease development. Use the short spray intervals when disease pressure is high or plants are growing rapidly or weather conditions favour disease development. Hull rot Apply at early hull split. Repeat as required when heavy disease pressure is present. Apply to the point of run-off to give thorough coverage of fruit. General Apply a maximum of 3 applications of Luna Sensation per season. Apply a maximum of 2 litres of Luna Sensation per hectare per season. Apply thoroughly to ensure complete coverage. Apply by dilute or concentrate spraying equipment (except for hull rot control where concentrate application is not appropriate). Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. For concentrate spraying, do not use at rates greater than two times the dilute spraying rate (i.e. at a concentration factor greater than 2X) – refer ' Application ' section in GENERAL INSTRUCTIONS. Tank mixes with foliar fertilizers may result in minor leaf tipping. Resistance Management This use is subject to a CropLife Australia fungicide resistance management strategy which limits the total number and consecutive number of applications of Luna Sensation and other Group 7 and 11 fungicides.

CROP	DISEASE	RATE	CRITICAL COMMENTS
Stone fruit	Blossom blight Shot hole	<u>Dilute spraying</u> 40 mL/100 L <u>Concentrate spraying</u> Refer to the Application section	Apply in a fungicide spray program according to target disease, observing the restrictions on total number of applications detailed below. Blossom blight Apply as part of a blossom blight spray program. The critical application timings for blossom blight control are early (1–10%) blossom, full bloom and petal fall/shuck fall. Shot hole Apply as part of a shot hole spray program at intervals of 10 to 14 days starting at early pink bud. Repeat applications may be required later in the crop cycle if weather conditions favour disease development.
	Brown rot	<u>Dilute spraying</u> 30 mL/100 L <u>Concentrate spraying</u> Refer to the Application section	Brown rot Apply as part of a brown rot spray program. The critical period for brown rot control begins at fruit ripening and extends through to harvest. A spray interval of 7–10 days should be utilised. General Apply a maximum of 2 applications of Luna Sensation per season. Apply a maximum of 2 litres of Luna Sensation per hectare per season. Apply thoroughly to ensure complete coverage. Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. For concentrate spraying, do not use at rates greater than three times the dilute spraying rate (i.e. at a concentration factor greater than 3X) – refer ' Application ' section in GENERAL INSTRUCTIONS. Resistance Management This use is subject to a CropLife Australia fungicide resistance management strategy which limits the total number and consecutive number of applications of Luna Sensation and other Group 7 and 11 fungicides.
Apples	Black spot (apple scab) Powdery mildew Alternaria leaf blotch (suppress ion only)	<u>Dilute spraying</u> 30 mL/100 L <u>Concentrate spraying</u> Refer to the Application section	Apply in a fungicide spray program according to target disease, observing the restrictions on total number of applications detailed below. Black spot Apply as part of a black spot (apple scab and pear scab) spray program at 7 to 10 day intervals, commencing applications at green tip or at spur burst following a recommended green tip fungicide spray. Powdery mildew Apply as part of a powdery mildew spray program at 14 day intervals commencing applications at early pink stage.

CROP	DISEASE	RATE	CRITICAL COMMENTS
Pears	Black spot (pear scab)		<p>Alternaria leaf blotch</p> <p>Apply as part of an Alternaria spray program at 14 day intervals commencing following blossom and extending through early fruit development.</p> <p>General</p> <p>Apply a maximum of 3 applications of Luna Sensation per season. Apply a maximum of 2 litres of Luna Sensation per hectare per season.</p> <p>Apply thoroughly to ensure complete coverage. Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. For concentrate spraying, do not use at rates greater than three times the dilute spraying rate (i.e. at a concentration factor greater than 3X) – refer 'Application' section in GENERAL INSTRUCTIONS.</p> <p>Resistance Management</p> <p>This use is subject to a CropLife Australia fungicide resistance management strategy which limits the total number and consecutive number of applications of Luna Sensation and other Group 7 and 11 fungicides.</p>

WITHHOLDING PERIODS

Almonds: DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION

Apples and pears: DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION

Stone fruit: DO NOT HARVEST FOR 1 DAY AFTER APPLICATION

Grazing: DO NOT GRAZE LIVESTOCK ON TREATED ORCHARDS

2.4 Results from residues trials presented to the APVMA

Pome fruit

Trials were conducted on pome fruit at 10 sites in Australia to measure residues of fluopyram and trifloxystrobin in apples (6 sites) and pears (4 sites). The local data is supported by data for pome fruit from the EU.

In the Australian trials, residues of fluopyram in apples and pears at 28 – 29 days after 3 applications at the proposed concentration of 7.5 g ai/100 L were 0.07, 0.11 (31 days), 0.12, 0.15 and 0.17 mg/kg.

In the European trials involving fluopyram application at 125 - 150 g ai/ha (~0.8x - 1x) residues in apples and pears at 28 days after the last application were 0.08 (3), 0.09, 0.10, 0.11 (2), 0.12, 0.13, 0.14, 0.15, 0.16 (2), 0.18 (2) and 0.34 mg/kg.

An MRL of 0.5 mg/kg is recommended for fluopyram on FP 0009 Pome fruit in conjunction with a 28 day withholding period, based on a highest residue of 0.17 mg/kg in the Australian trials and 0.34 mg/kg in the overseas trials.

Total residues of trifloxystrobin in apples and pears from the Australian trials at 28 – 29 days after 3 applications at the proposed concentration of 7.5 g ai/100 L were 0.05, 0.05, 0.06, 0.09 and 0.09 mg/kg.

No changes are required to the current MRL of 0.3 mg/kg for trifloxystrobin on FP 0009 Pome fruit.

Based on a highest fluopyram residue of 0.34 mg/kg in apples and pears and the highest dry pomace processing factor of 11.88x the highest estimated residue in dry pomace is 4.05 mg/kg. An MRL of 5 mg/kg is recommended for fluopyram on apple pomace, dry. The estimated STMR-P for pomace is 1 mg/kg, based on a median residue in apples and pears of 0.12 mg/kg and a mean processing factor of 8x).

Stone fruit

Sixteen Australian trials were conducted on stone fruit (peaches, nectarines, apricots and cherries), although the cherry trials did not match the proposed GAP. The local data is supported by data for stone fruit from the EU and USA.

In the Australian trials, highest residues of fluopyram in stone fruit (except cherries) at 1 or more days after the last of 2 applications at 10 g ai/100 L were 0.12, 0.17, 0.18 (7 days), 0.20, 0.22, 0.24 (10 days), 0.25 (3 days), 0.27 (7 days) 0.29, 0.30 (9 days), 0.36, 0.37, 0.48 (3 days) and 0.49 mg/kg.

Residues of fluopyram in peaches and plums at 0 - 1 day after the last of 2 applications at 208 - 250 g ai/ha (1.0x - 1.3x) in overseas trials were 0.02, 0.03 (3), 0.05 (2), 0.06, 0.07, 0.08 (3), 0.09, 0.12, 0.16, 0.17, 0.18, 0.19, 0.20, 0.23, 0.25, 0.27, 0.28, 0.29 (2), 0.30, 0.31 (5), 0.32 (2), 0.33, 0.35, 0.36, 0.38, 0.43, 0.45, 0.46, 0.46, 0.56, 0.59, 0.63 and 0.98 mg/kg.

Residues of fluopyram in cherries at 0 days after the last of 2 applications at 250 g ai/ha (1.3x) in overseas trials were 0.07, 0.16, 0.22, 0.23, 0.31, 0.34, 0.36, 0.37, 0.55, 0.58, 0.60 (2), 0.64 (2), 0.66, 0.70, 0.71, 0.75, 0.79, 0.82, 1.2, 1.3 and 1.8 mg/kg.

An MRL of 2 mg/kg is recommended for fluopyram on FS 0012 Stone fruits [except cherries] based on a highest residue of 0.49 mg/kg in apricots from Australian trials matching GAP and 0.98 mg/kg in peaches from overseas trials at ~1.3x the expected rate. Australian data for cherries matching the proposed GAP have not been provided. In the overseas trials at higher rates and shorter PHIs the HR was 1.8 mg/kg. An MRL of 3 mg/kg is recommended for fluopyram on FS 0013 Cherries.

In the Australian trials, highest total residues of trifloxystrobin in stone fruit (except cherries) at 1 or more days after the last of 2 applications at 10 g ai/100 L were 0.17, 0.19, 0.19 (10 days), 0.20 (7 days), 0.23, 0.23 (3 days), 0.25, 0.25 (7 days), 0.30 (3 days), 0.32, 0.33, 0.40, 0.42 and 0.51 mg/kg.

Total residues of trifloxystrobin in peaches and plums at 1 day after the last of 4 applications at 141 g ai/ha (0.71x) in overseas trials were 0.07, 0.08 (3), 0.11, 0.17, 0.21, 0.23 (3), 0.27, 0.34, 0.36, 0.41, 0.43, 0.55, 0.70, 0.86, 0.88, 0.94, 1.9 and 2.0 mg/kg.

Total residues of trifloxystrobin in cherries at 0 - 1 day after the last of 3 - 4 applications at 141 – 255 g ai/ha (0.71 – 1.3x) in overseas trials were 0.25, 0.28, 0.38 (2), 0.39, 0.41 (2), 0.42 (2), 0.47, 0.50, 0.55, 0.58, 0.59 (2), 0.60, 0.61, 0.62, 0.69, 0.73 and 0.90 mg/kg.

An MRL of 5 mg/kg is recommended for trifloxystrobin on FS 0012 Stone fruits based on a highest residue of 0.51 mg/kg in peaches in the Australian trials matching GAP and 2.0 mg/kg in peaches from the overseas at ~0.71x the expected rate. This MRL should also cover residues in cherries.

Almond hulls

Residues of fluopyram in almond hulls and shells at 14 days or more after the last application at 10 g ai/100 L (maximum proposed concentration) were 1.4, 2.1, 2.3, 2.9, 3.0, 3.3, 3.8, 3.9, 4.2, 4.8, 11 and 13 mg/kg on a dry weight basis. An MRL of 15 mg/kg is proposed for fluopyram on Almond hulls.

Residues of trifloxystrobin in almond hulls and shells at 14 or more days after the last application at 10 g ai/100 L (maximum proposed concentration) were 0.68, 1.2, 1.7, 1.8, 1.9 and 8.7 mg/kg on a dry weight basis. An MRL of 15 mg/kg is proposed for trifloxystrobin on almond hulls.

Animal commodities

Apple pomace can form up to 20% of the diet for beef cattle and 10% of the diet for dairy cattle in Australia. Almond hulls can form 10% of the diet for beef and dairy cattle in Australia.

No changes are required to the current trifloxystrobin animal commodity MRLs as the anticipated maximum livestock dietary exposure to trifloxystrobin is not expected to change as a result of this application. A dairy cattle transfer study showed that no finite trifloxystrobin residues occurred in animal tissues/milk from animals fed commodities containing trifloxystrobin residues at up to 6 mg/kg in the diet. Even if cattle were to consume apple pomace and grape pomace from crops treated under registered uses (at 20% of the diet), and treated almond hulls from this application (at 10% of the diet), the intake of trifloxystrobin would still be below 6 ppm (approx. 5.1 ppm based on MRLs), noting that other Table 4 entries for trifloxystrobin in animal feeds are all at the LOQ (*0.02 mg/kg).

The livestock dietary exposure to fluopyram as a result of the proposed uses for beef cattle is 0.6 ppm (0.4 ppm from almond hulls and 0.2 ppm from apple pomace) and for dairy cattle is 0.5 ppm (0.4 ppm from almond hulls and 0.1 ppm from apple pomace).

Residues of fluopyram (parent plus the benzamide metabolite) observed after dosing at 1.5 ppm in a dairy cattle transfer study are summarised below, along with the estimated residues after dosing at 0.6 ppm for beef cattle and 0.5 ppm for dairy cattle:

	RESIDUES OF FLUOPYRAM OBSERVED AT A 1.5 PPM FEEDING LEVEL(mg/kg)	ESTIMATED RESIDUES (FEEDING AT 0.6 PPM FOR TISSUES AND 0.5 PPM FOR MILK)(mg/kg)
Milk	0.03	0.010
Muscle	0.03	0.012
Fat, peri renal	<0.02	<0.02
Fat, mesenteric	<0.02	<0.02
Fat, subcutaneous	0.02	0.008
Liver	0.36	0.14
Kidney	0.04	0.016

The current temporary animal commodity MRLs for fluopyram should be replaced with the following permanent MRLs:

MO 0105 Edible offal (Mammalian)	0.2 mg/kg
MM 0095 Meat [mammalian]	*0.02 mg/kg
ML 0106 Milks	*0.02 mg/kg

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. Fluopyram and trifloxystrobin have both been considered by Codex. The following relevant international MRLs have been established for fluopyram and trifloxystrobin.

Table 3: Comparison of fluopyram and trifloxystrobin MRLs (mg/kg) for apples, pears and stone fruit

COMPOUND	COUNTRY	COMMODITY	MRL (mg/kg)
Fluopyram	Australia (proposed)	Pome fruit	0.5
		Stone fruit (except cherries)	2
		Cherries	3
	Codex	Cherries	0.7
		Peach	0.4
		Pome fruits	0.5
	EU	Apples	0.6
		Pears	0.5
		Apricots	0.7
		Cherries (Sweet)	1.5
		Peaches	0.7
		Plums	*0.01
	Japan	Apple	0.3
		Pear	3
		Peach	0.5
		Nectarine	5

COMPOUND	COUNTRY	COMMODITY	MRL (mg/kg)
		Japanese plum (including prune)	1
		Cherry	5
	USA	Apple	0.3
		Cherry	0.6
Trifloxystrobin	Australia (proposed)	Stone fruit	5
	Codex	Pome fruits	0.7
		Stone fruits	3
	EU	Pome fruit	0.5
		Apricots	1
		Cherries (Sweet)	1
		Peaches)	1
		Plums	0.2
	Japan	Apple	3
		Pear	5
		Peach	0.2
		Nectarine	3
		Apricot	5
		Japanese plum (including prune)	3
		Cherry	3
	Taiwan	Apples	0.7
		Pears	0.5
		Apricots	3
		Cherries	3
		Nectarines	3
		Peaches	3
		Plums	3
		Prune	3
USA	Fruit, pome	0.5	

COMPOUND	COUNTRY	COMMODITY	MRL (mg/kg)
		Fruit, stone, group 12	2

Table 4: Comparison of fluopyram and trifloxystrobin MRLs (mg/kg) for animal commodities

COMMODITY	AUSTRALIA (PROPOSED) (mg/kg)	CODEX (mg/kg)	US (mg/kg)	EU (mg/kg)	JAPAN (mg/kg)
Edible offal (mammalian)	0.2	3 (Liver of cattle, goats, pigs & sheep) 0.5 (Kidney of cattle, goats, pigs & sheep))	1.1 (cattle meat by products)	0.7 (bovine edible offal) 3 (bovine liver)	0.7 (cattle edible offal)
Meat (mammalian)	*0.02	0.5	0.15 (cattle meat)	0.5 (bovine meat)	0.1 (cattle muscle)
Milks	*0.02	0.3	0.07	0.3	0.07
Compliance residue definition	Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram	Sum of fluopyram and 2-(trifluoromethyl) benzamide expressed as fluopyram	Sum of fluopyram and its metabolite, 2-(trifluoromethyl) benzamide calculated as the stoichiometric equivalent of fluopyram	Sum fluopyram and fluopyram-benzamide (M25) expressed as fluopyram	Sum of fluopyram and 2-(trifluoromethyl)benzamide), calculated as fluopyram

Animal commodity MRLs for fluopyram have not been established by Korea, Russia or Taiwan.

2.6 Current and proposed Australian MRLs for fluopyram and trifloxystrobin

Current relevant MRLs and the residue definition for fluopyram and trifloxystrobin are presented below. A full listing of MRLs can be found at www.apvma.gov.au/residues/standard.php.

Table 5: Current relevant entries in the MRL Standard - Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
FLUOPYRAM		
TN 0660	Almonds	T0.05
FS 0013	Cherries	T5
MO 0105	Edible offal (Mammalian)	T0.7
MM 0095	Meat [mammalian]	T0.05
ML 0106	Milks	T0.2
FP 0009	Pome fruits	T0.5
FS 0012	Stone fruits [except cherries]	T2
TRIFLOXYSTROBIN		
TN 0660	Almonds	T0.05
MO 0105	Edible offal (Mammalian)	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.02
FP 0009	Pome fruit	0.3
FS 0012	Stone fruits	T5

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
FLUOPYRAM	<p>{T} Commodities of plant origin: Fluopyram</p> <p>{T} Commodities of animal origin for enforcement: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram.</p> <p>{T} Commodities of animal origin for dietary exposure assessment: sum of fluopyram, 2-(trifluoromethyl) benzamide and the combined residues of <i>N</i>-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-(trifluoromethyl) benzamide and <i>N</i>-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-(trifluoromethyl) benzamide, all expressed as fluopyram.</p>
TRIFLOXYSTROBIN	Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminooxymethyl]phenyl] acetic acid), expressed as trifloxystrobin equivalents

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
FLUOPYRAM	Almond hulls	T15
	Apple pomace, dry	T5
TRIFLOXYSTROBIN	Almond hulls	T15
	Pome fruit pomace, dry	15

The following changes are proposed to Australian fluopyram and trifloxystrobin MRLs:

Table 6: Proposed changes to the MRL Standard - Table 1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
FLUOPYRAM		
DELETE:		
TN 0660	Almonds	T0.05
FS 0013	Cherries	T5
MO 0105	Edible offal (Mammalian)	T0.7
MM 0095	Meat (mammalian)	T0.05
ML 0106	Milks	T0.2
FP 0009	Pome fruits	T0.5
FS 0012	Stone fruits [except cherries]	T2
ADD:		
TN 0660	Almonds	0.05
FS 0013	Cherries	3
MO 0105	Edible offal (Mammalian)	0.2
MM 0095	Meat [mammalian]	*0.02
ML 0106	Milks	*0.02
FP 0009	Pome fruits	0.5
FS 0012	Stone fruits [except cherries]	2
TRIFLOXYSTROBIN		
DELETE		

COMPOUND	FOOD	MRL (mg/kg)
TN 0660	Almonds	T0.05
FS 0012	Stone fruits	T5
ADD:		
TN 0660	Almonds	0.05
FS 0012	Stone fruits	5

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
FLUOPYRAM		
DELETE:		
	Almond hulls	T15
	Apple pomace, dry	T5
ADD:		
	Almond hulls	15
	Apple pomace, dry	5
TRIFLOXYSTROBIN		
DELETE:		
	Almond hulls	T15
ADD:		
	Almond hulls	15

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluopyram and trifloxystrobin 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.

Although MRLs for fluopyram and trifloxystrobin are established for various pome and stone fruit in several markets they are often lower than the proposed Australian MRLs. The applicant is proposing to address the risk to trade in pome and stone fruit by the following label statement:

Export of treated produce

Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Luna Sensation. If you are growing edible produce for export, please check with Bayer CropScience Pty Ltd for the latest information on MRLs and import tolerances and for advice on any potential trade issues and their management.

Risk to trade in animal commodities

Residues of trifloxystrobin are not expected to occur in animal commodities as a result of the proposed use. The overall risk to export trade in animal commodities due to trifloxystrobin is considered to be low.

Fluopyram animal commodity MRLs have been established by Codex, the EU, Japan and the USA at higher levels than those proposed for Australia. Bayer CropScience have indicated that an application for import tolerance establishment in Taiwan has been made and a decision is expected late 2015 at the earliest. Residues above the limit of quantification of 0.02 mg/kg are not expected in milk. Depuration data are available which indicate that residues in animal commodities resulting from the proposed uses would be below quantifiable limits after approximately 2 weeks on clean feed.

ESIs establishment is generally not appropriate for by-products such as almond hulls and apple pomace. However such by-products would not normally be fed to animals within 60 days of slaughter for export without declaration.

3 CONCLUSIONS

Bayer CropScience Pty Limited has made an application to register the new product, Luna Sensation Fungicide, containing 250 g/L fluopyram and 250 g/L trifloxystrobin. The product is proposed for use on almonds, apples, pears and stone fruit. It is proposed to establish permanent MRLs for fluopyram in almonds, pome and stone fruit and for trifloxystrobin in almonds and stone fruit. It is also proposed to establish permanent MRLs for fluopyram in animal commodities. Comment is sought on the potential for fluopyram and trifloxystrobin residues resulting from the proposed use of Luna Sensation Fungicide on almonds, apples, pears and stone fruit to unduly prejudice Australian trade, and the ability of industry systems to manage any identified risk.