



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



TRADE ADVICE NOTICE

on fluopyram and trifloxystrobin in the product Luna Sensation Fungicide for
use on apples and pears

APVMA Product Number 65560

APRIL 2017

© Australian Pesticides and Veterinary Medicines Authority 2017

ISBN 978-1-925390-70-4 (electronic)

Ownership of intellectual property rights in this publication

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Creative Commons licence

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.



A summary of the licence terms is available from www.creativecommons.org/licenses/by/3.0/au/deed.en. The full licence terms are available from www.creativecommons.org/licenses/by/3.0/au/legalcode.

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

Source: Licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 3.0 Australia Licence.

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as the author, publisher and copyright owner.

Use of the Coat of Arms

The terms under which the Coat of Arms can be used are set out on the Department of the Prime Minister and Cabinet website (see www.dpmc.gov.au/pmc/publication/commonwealth-coat-arms-information-and-guidelines).

Disclaimer

The material in or linking from this report may contain the views or recommendations of third parties. Third party material does not necessarily reflect the views of the APVMA, or indicate a commitment to a particular course of action.

There may be links in this document that will transfer you to external websites. The APVMA does not have responsibility for these websites, nor does linking to or from this document constitute any form of endorsement.

The APVMA is not responsible for any errors, omissions or matters of interpretation in any third-party information contained within this document.

Comments and enquiries regarding copyright:

Director Public Affairs and Communication
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

CONTENTS

PREFACE	IV
About this document	iv
Making a submission	iv
Further information	v
<hr/>	
1 INTRODUCTION	6
2 TRADE CONSIDERATIONS	6
2.1 Commodities exported	6
2.2 Destination and value of exports	6
2.3 Proposed Australian use-pattern	7
2.4 Results from residues trials presented to the APVMA	8
2.5 Overseas registration and approved label instructions	10
2.6 Codex alimentarius commission and overseas MRLs	10
2.7 Current and proposed Australian MRLs for fluopyram and trifloxystrobin	12
2.8 Potential risk to trade	14
<hr/>	
3 CONCLUSIONS	15

LIST OF TABLES

Table 1: Relevant overseas MRLs for fluopyram	11
Table 2: Relevant overseas MRLs for trifloxystrobin	12
Table 3: Current relevant entries in the MRL Standard—Table 1	12
Table 4: Proposed changes to MRL Standard—Table 1	13
Table 5: Proposed changes to MRL Standard—Table 4	13

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 Aging, Department of the Environment and Energy, 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 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 Tuesday 9 May 2017 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

Scientific Assessment and Chemical Review

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 can be obtained via the contact details provided above.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

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 Ltd, to vary the registration of Luna Sensation Fungicide (a suspension concentrate formulation containing 250 g/L fluopyram and 250 g/L trifloxystrobin), to allow a change of withholding period for apples and pears from 4 weeks to 14 days. Other than a reduction in harvest withholding period, the use is the same as currently approved (P65560).

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Apples and pears are considered to be major export commodities² as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds containing residues arising from the proposed use. Residues in these commodities resulting from the use of Luna Sensation Herbicide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

In 2015/16 Australia exported 4.7 kt of fresh apples at a value of \$12.4 million³.

In 2015/16 Australia exported 12.3 kt of fresh pears at a value of \$21.7 million³.

The Applicant noted that export of apples and pears is relatively minor, with <1% of apples and approximately 6.5% of pear production exported in 2013/14. Major markets for Australian apples in 2010/11 were Papua New Guinea, Indonesia, the United Kingdom, Sri Lanka and Thailand and for pears, New Zealand, Indonesia and Canada in 2013.

² APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

³ Australian Agricultural Statistics 2016, Department of Agriculture and Water Resources, December 2016, http://data.daff.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022016_Sn9Dg/ACS_2016_v1.0.0.pdf

2.3 Proposed Australian use-pattern

Luna Sensation Fungicide (250 g/L fluopyram and 250 g/L trifloxystrobin)

CROP	PEST	CONCENTRATION	CRITICAL COMMENTS
Apples	Black spot (apple scab) Powdery mildew Alternaria leaf blotch (suppression only)	Dilute spraying: 30 mL/100 L (7.5 + 7.5g ai/100 L) Concentrate spraying: 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. Alternaria leaf blotch Apply as part of an Alternaria spray program at 14 day intervals commencing following blossom and extending through early fruit development. 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. 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.
Pears	Black spot (pear scab)		

Withholding periods:

Apples and Pears: DO NOT harvest for 14 days after application.

Grazing: DO NOT graze livestock on treated orchards.

Restrains:

DO NOT apply with aircraft.

Export of treated produce

Growers should note that suitable MRLs or import tolerances may not exist in all markets for edible produce treated with Luna Sensation. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing 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.

2.4 Results from residues trials presented to the APVMA

The proposed GAP for apples and pears is for a maximum of three applications of fluopyram and trifloxystrobin at 7.5 g a.i./ 100L each, with a harvest WHP of 'DO NOT harvest for 14 days after application', and a grazing restraint 'DO NOT graze livestock on treated orchards'. The Applicant has submitted data from apple (6) and pear (4) trials conducted in Australia.

Apples and pears—fluopyram

Residues of fluopyram in apples and pears at 14 days (or longer if higher residues were observed) after 3 applications at the proposed concentration of 7.5 g ai/100 L, were 0.16, 0.18, 0.20, 0.23, 0.26, 0.26, 0.27, 0.30, 0.33 and 0.42 mg/kg (n=10, STMR = 0.26 mg/kg).

The available data indicate that an MRL at 1 mg/kg is appropriate to replace the current MRL of 0.5 mg/kg for fluopyram on FP 0009 Pome fruit in conjunction with a 14 day withholding period.

Apples and pears—trifloxystrobin

Total residues of trifloxystrobin in apples and pears at 14 days (or longer if higher residues were observed) after 3 applications at the proposed concentration of 7.5 g ai/100 L, were 0.07, 0.10, 0.11, 0.13, 0.14, 0.15, 0.19, 0.25, 0.35 and 0.39 mg/kg (n=10, STMR = 0.145 mg/kg).

The available data indicate that an MRL at 0.7 mg/kg is appropriate to replace the current MRL of 0.3 mg/kg for trifloxystrobin on FP 0009 Pome fruit in conjunction with a 14 day withholding period.

Apple pomace—fluopyram

Based on a highest fluopyram residue of 0.42 mg/kg in apples and pears, at a 14 day WHP (or longer if higher residues were observed) and the highest processing factor of 11.88x, from previously submitted data, the highest estimated residue in dry pomace is 4.99 mg/kg. The available data indicate that an MRL of 7 mg/kg is appropriate to replace the current MRL of 5 mg/kg for fluopyram on apple pomace, dry.

Apple pomace—trifloxystrobin

A highest residue of 0.39 mg/kg was determined in the local trials, at the proposed 14 day WHP. Considering the highest processing factor to dry pomace of 46.5x, this results in a highest estimated residue in dry pomace of 18.1 mg/kg.

The available data indicate that an MRL of 25 mg/kg is appropriate to replace the current MRL of 15 mg/kg for trifloxystrobin on pome fruit pomace, dry.

The proposed harvest and grazing WHPs of 'DO NOT harvest for 14 days after application', and 'DO NOT graze livestock on treated orchards' respectively, are considered to be acceptable.

Animal commodities—fluopyram

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

The anticipated maximum livestock dietary exposure to fluopyram, through consumption of almond hulls and apple pomace, is calculated to be 0.78 and 0.57 ppm for beef and dairy cattle respectively.

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 0.78 ppm for beef cattle and 0.57 ppm for dairy cattle.

MATRIX	RESIDUES OF FLUOPYRAM OBSERVED AT A 1.5 ppm FEEDING LEVEL (mg/kg)	ESTIMATED RESIDUES (FEEDING AT 0.78 ppm FOR TISSUES AND 0.57 ppm FOR MILK) (mg/kg)
Milk	0.03	0.011
Muscle	0.03	0.016
Fat, perirenal	<0.02	<0.02
Fat, mesenteric	<0.02	<0.02
Fat, subcutaneous	0.02	0.010
Liver	0.36	0.19
Kidney	0.04	0.021

Based on predicted residues, it is considered that the established MRLs for meat (mammalian) and milks should remain at *0.02 mg/kg. The MRL for edible offal (mammalian) should increase from 0.2 to 0.3 mg/kg, based on a highest calculated liver residue of 0.19 mg/kg.

Animal commodities—trifloxystrobin

The anticipated maximum livestock dietary exposure to trifloxystrobin, through consumption of almond hulls and apple pomace, is calculated to be 1.13 and 0.65 ppm for beef and dairy cattle respectively. A previously submitted dairy cattle transfer study showed that no finite trifloxystrobin residues occurred in animal tissues and milk from animals fed commodities containing trifloxystrobin residues at up to 6 ppm in the diet. No changes are therefore required to the animal commodity MRLs for trifloxystrobin established at the respective LOQs, which remain appropriate for the proposed use.

2.5 Overseas registration and approved label instructions

The Applicant has noted that products containing either fluopyram or trifloxystrobin (or mixtures of both) are registered for use in apples and pears in many countries including United States, Canada, South Africa, Chile, Japan and several countries in the European Union including Germany, France and Italy.

2.6 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 been considered by Codex.

The following relevant international MRLs have been established for fluopyram:

Table 1: Relevant overseas MRLs for fluopyram

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUOPYRAM (mg/kg)						
	AUSTRALIA	CANADA	EU	JAPAN	CODEX	USA	TAIWAN
PLANT COMMODITIES							
COMPLIANCE RESIDUE DEFINITION - PARENT							
Apple		0.8	0.6	1			
Pear		0.8	0.5	3			
Pome fruits	0.5 (current) 1 (proposed)				0.5	0.8	0.5
ANIMAL COMMODITIES							
COMPLIANCE RESIDUE DEFINITION - SUM OF FLUOPYRAM AND 2-(TRIFLUOROMETHYL) BENZAMIDE, EXPRESSED AS FLUOPYRAM							
Bovine kidney			0.7	0.5	0.8		
Edible offal (Mammalian)	0.2 (current) 0.3 (proposed)	10				7.5 (cattle meat by-products)	
Bovine liver			3	3	5		
Meat (mammalian)	*0.02	1.5 (meat of cattle)	0.5 (bovine muscle)	0.5 (cattle muscle)	0.8	0.80 (cattle meat)	
Milks	*0.02	2	0.3	0.3	0.6	0.40	

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

The following relevant international MRLs have been established for trifloxystrobin:

Table 2: Relevant overseas MRLs for trifloxystrobin

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF TRIFLOXYSTROBIN (mg/kg)							
	AUSTRALIA	CANADA	EU	JAPAN	CODEX	USA	KOREA	TAIWAN
PLANT COMMODITIES								
Compliance Residue Definition	Parent + acid metabolite	Parent+ acid metabolite	Parent	Parent	Parent	^		
Apple		0.5	0.7	3			0.7	0.7
Pear		0.5	0.7	5			0.7	0.5
Pome fruit	0.3 (current) 0.7 (proposed)				0.7	0.5		

^ The sum of trifloxystrobin, benzeneacetic acid, (E,E)- α -(methoxyimino)-2-[[[1-[3-(trifluoromethyl) phenyl]ethylidene] amino]oxy]methyl]-, methyl ester, and the free form of its acid metabolite CGA-321113, (E,E)-methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino]oxy]methyl]-phenyl]acetic acid, calculated as the stoichiometric equivalent of trifloxystrobin, in or on the commodity. No changes are proposed to the established trifloxystrobin animal commodity MRLs at the respective LOQs.

2.7 Current and proposed Australian MRLs for fluopyram and trifloxystrobin

Table 3: Current relevant entries in the MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
FLUOPYRAM		
MO 0105	Edible offal (Mammalian)	0.2
MM 0095	Meat [mammalian]	*0.02
ML 0106	Milks	*0.02
FP 0009	Pome fruits	0.5
Trifloxystrobin		
MO 0105	Edible offal (Mammalian)	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.02
FP 0009	Pome fruit	0.3

Table 4: Proposed changes to MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
FLUOPYRAM		
DELETE:		
MO 0105	Edible offal (Mammalian)	0.2
FP 0009	Pome fruits	0.5
ADD:		
MO 0105	Edible offal (Mammalian)	0.3
FP 0009	Pome fruits	1
TRIFLOXYSTROBIN		
DELETE:		
FP 0009	Pome fruits	0.3
ADD:		
FP 0009	Pome fruits	0.7

Table 5: Proposed changes to MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
FLUOPYRAM		
DELETE:		
	Apple pomace, dry	5
ADD:		
	Apple pomace, dry	7
TRIFLOXYSTROBIN		
DELETE:		
	Pome fruit pomace, dry	15
ADD:		
	Pome fruit pomace, dry	25

2.8 Potential risk to trade

Plant commodities

Fluopyram

The residue definition for plant commodities in Australia and overseas is fluopyram.

The proposed MRL for fluopyram in pome fruit is 1 mg/kg. It is noted that pome fruit MRLs set at lower levels are established by Codex and Taiwan (0.5 mg/kg) and the USA (0.8 mg/kg). Canada, the EU and Japan have MRLs of 0.8, 0.6 and 1 mg/kg for apples respectively and MRLs at 0.8, 0.5 and 3 mg/kg for pears respectively.

The highest residue observed in apples or pears in the ten submitted Australian trials carried out at the proposed GAP, was 0.42 mg/kg, which is lower than established overseas MRLs.

Trifloxystrobin

The residue definition for plant commodities in Australia and Canada is parent + the acid. Codex, the EU and Japan have a definition of parent only.

The proposed MRL for pome fruit is 0.7 mg/kg. An MRL at the same level is established by Codex while the USA has an MRL for pome fruit at 0.5 mg/kg. MRLs for apples are established at 0.5 mg/kg (Canada), 0.7 mg/kg (EU, Korea and Taiwan) and 3 mg/kg (Japan). MRLs for pears are established at 0.5 mg/kg (Canada and Taiwan), 0.7 mg/kg (EU and Korea) and 5 mg/kg (Japan).

The highest residue observed in apples or pears in the ten submitted Australian trials carried out at the proposed GAP, was 0.39 mg/kg, which is lower than established overseas MRLs.

The Applicant has proposed to manage the risk to trade in apples and pears through the following label statement:

Export of treated produce

Growers should note that suitable MRLs or import tolerances may not exist in all markets for edible produce treated with Luna Sensation. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing 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.

Animal commodities

Fluopyram

The residue definition for animal commodities in Australia and overseas is the sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram.

The edible offal MRL will be increased from 0.2 mg/kg to 0.3 mg/kg. A cattle meat by-products MRL is established in the USA at 7.5 mg/kg and a mammalian edible offal MRL in Canada at 10 mg/kg. Bovine kidney MRLs are established in the EU, Japan and by Codex at 0.7, 0.5 and 0.8 mg/kg respectively, while bovine liver MRLs are established in the EU, Japan and by Codex at 3, 3 and 5 mg/kg respectively. Animal commodity MRLs have not been established by Korea, Russia or Taiwan.

Calculations based on available depuration data indicate residues in animal commodities from the proposed uses would be below quantifiable limits after approximately three weeks on clean feed.

ESI establishment is generally not appropriate for by-products such as apple pomace, which may not be produced directly on the farm where it is consumed. However, such by-products would not normally be fed to animals within 60 days of slaughter for export without declaration.

Trifloxystrobin

No changes to the established trifloxystrobin animal commodity MRLs were necessary. Residues of trifloxystrobin are not expected to occur in animal commodities as a result of the proposed use. Therefore there is no change to the risk to trade through export of commodities of animal origin which is considered to be low.

3 CONCLUSIONS

Bayer CropScience Pty Ltd, has applied for a variation of the registration of *Luna Sensation Fungicide* to allow a change of withholding period for apples and pears from 4 weeks to 14 days. Comment is sought on the potential risk to trade in apples and pears and animal commodities from the proposed use and the ability of the industry to manage any potential risk.