

Trade Advice Notice

on

Boscalid and pyraclostrobin

in the product

Nufarm Pristine Fungicide
(product number 62974)

December 2009

© Australian Pesticides and Veterinary Medicines Authority [2009]

This work is copyright protected. Apart from any use permitted under the *Copyright Act 1968*, no part may be reproduced without permission from the Australian Pesticides and Veterinary Medicines Authority. Requests and enquiries concerning reproduction and rights can be made at communications@apvma.gov.au or addressed to:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Australia

CONTENTS

1. PREFACE	3
About this Document	3
Prior to Submission	3
About this Consultation	3
2. INTRODUCTION	5
3. TRADE CONSIDERATIONS	5
3.1 Commodities Exported	5
3.2 Destination and Value of Exports	5
3.3 Proposed Australian Use-Pattern	6
3.4 Results from residues trials presented to the APVMA	7
3.5 Codex Alimentarius Commission and overseas MRLs	8
3.6 Current and proposed Australian MRLs for boscalid and pyraclostrobin	12
3.7 Potential Risk to Trade	12
4. CONCLUSION	14

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 that 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/assessment/advice/index.php>

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 8/02/2010. Submissions should be addressed to:

Kim Garsia
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4753
Fax: (02) 6210 4776

2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Nufarm Australia Ltd to vary the use of *NUFARM PRISTINE FUNGICIDE*, containing the active ingredients boscalid and pyraclostrobin at 252 g/kg and 128 g/kg respectively, to reduce the withholding period in apples from 28 days to 14 days, and to add use of the product in pears. The product is a fungicide used for control of blackspot, powdery mildew, alternaria leaf blotch and alternaria fruit spot in apples, and blackspot in pears.

The potential for boscalid and pyraclostrobin residues in these commodities to unduly prejudice trade in apples and pears is discussed below.

3. TRADE CONSIDERATIONS

3.1 Commodities Exported

Apples and pears, together with meat and dairy products from animals that may have been feed apple pomace containing boscalid and pyraclostrobin residues, are exported in varying quantities. It is proposed to replace the apple MRLs for boscalid and pyraclostrobin with group MRLs for pome fruit, and to increase the pyraclostrobin MRL for edible offal (mammalian). Current and previously proposed MRLs for boscalid remain appropriate and therefore boscalid residues in animal commodities will not be considered further.

3.2 Destination and Value of Exports

The destinations and value of exports of apples and pears are summarised below:

Export markets for Australian apples are tabulated below for the year 2007/08 (Australian Bureau of Statistics figures). Total exports in that year were valued at \$7.13 million.

Australian Apple Exports (2007/2008)

Destination	Value, \$ million
United Kingdom	2.124
Indonesia	1.550
Papua New Guinea	0.926
Taiwan	0.754
Sri Lanka	0.487
Malaysia	0.318
India	0.228
Singapore	0.151
Hong Kong	0.111
New Caledonia	0.097

Export markets for Australian pears are tabulated below for the year 2007/08 (Australian Bureau of Statistics figures). Total exports in that year were valued at \$6.64 million.

Australian Pear Exports (2007/2008)

Destination	Value, \$ million
Canada	2.411
New Zealand	1.546
New Caledonia	0.560
Netherlands	0.330
Indonesia	0.284
Papua New Guinea	0.272
Fiji	0.253
Singapore	0.191
Hong Kong	0.122
Malaysia	0.103

3.3 Proposed Australian Use-Pattern

The proposed modified Australian use pattern for *NUFARM PRISTINE FUNGICIDE*, is detailed in the table below.

Crop	Pest	Rate	Critical Comments
Apple	<p>Blackspot (scab) <i>Venturia inaequalis</i></p> <p>Powdery mildew <i>Podosphaera leucotricha</i></p> <p>Alternaria leaf blotch and Alternaria fruit spot <i>Alternaria mali</i></p>	<p><u>Dilute spray:</u> 40 g/100 L (10 g ai/100 L boscalid + 5.1 g ai/100 L pyraclostrobin)</p> <p><u>Concentrate spray:</u> Refer to the Application section.</p>	<p><u>Apple</u> Application may commence at spurburst for blackspot (scab), and at early pink stage for powdery mildew control. Applications for control of Alternaria leafy blotch and Alternaria fruit spot should begin after blossom and during early fruit development.</p> <p><u>Pear</u> Application should commence during the blossom period, or earlier if conditions favour disease.</p>

Pear	Blackspot (scab) <i>Venturia inaequalis</i>		<p><u>Apple and pear</u> Apply at 7 to 10 day intervals prior to petal fall and during periods of rapid growth. Later applications should be at 10 to 14 day intervals, or according to prevailing weather conditions and disease incidence.</p> <p>Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the crop whether applying this product by dilute or concentrate spraying methods.</p> <p>DO NOT use in equipment that requires concentrations greater than 200 g of Pristine/100 L of water (5x concentration), as crop safety has not been assessed at these concentrations.</p> <p>Ensure thorough and even coverage of all plant parts.</p> <p>May be used with the recommended rate of a non-ionic wetting agent.</p> <p>The use of Pristine is subject to a CropLife Australia Resistance Management Strategy. DO NOT apply more than three applications of Pristine or other Group 7 or 11 fungicides per season. Refer to Resistance Management Strategy or General Instructions for further details.</p>
------	--	--	--

Restrains:

DO NOT apply by aerial application.

DO NOT apply Pristine Fungicide if waterbodies, watercourses or wetlands are within 30 m downwind of the application area.

Withholding periods:

Harvest: Do not harvest for 14 days after application.

Grazing: Do not treat orchards that will or may be grazed by livestock.

Export slaughter interval (ESI):

Do not feed treated produce to livestock for 7 days before slaughter.

Fruit and fruit products intended for export:

Consult your peak industry body or Nufarm for the recommended withholding period.

3.4 Results from residues trials presented to the APVMA

Pome fruit

The applicant provided four Australian trials in pears. Multiple plots were treated using different formulations at some of the sites, giving seven residues results that matched the proposed GAP. Reference was made to the Australian and European

residues trials for apples previously supplied with the application to register *Pristine Fungicide* (61377/40565), and to the apple processing study supplied with that application. The previously supplied Australian apple studies yielded nine results from trials that match the proposed GAP.

Combining the residues of boscalid in apples and pears found at 14 days after the last of three applications at 7-10 day intervals at 1.5x the proposed rate gives a pome fruit data set of 0.13, 0.14, 0.15, 0.26, 0.31, 0.44, 0.48, 0.58, 0.66, 0.67, 0.73 (2), 0.91, 0.94, 1.01, and 1.36 mg/kg. The combined data set for pyraclostrobin residues in apples and pears 14 days after the last application is <0.02 (3), 0.03, 0.05 (4), 0.06 (2), 0.12, 0.16, 0.30, 0.44, 0.53, and 0.64 mg/kg.

These data are sufficient to support replacing the apple MRLs of 2 and 1 mg/kg for boscalid and pyraclostrobin, respectively with group MRLs for pome fruit at 2 and 1 mg/kg for boscalid and pyraclostrobin respectively.

Consideration of the highest residue and STMR for boscalid in apples at the new 14-day withholding period together with the processing study evaluated previously shows that an increase in the stockfeed MRL (Table 4 entry) for boscalid in apple pomace, dry from 20 to 30 mg/kg is required. No change to the MRL for pyraclostrobin in apple pomace, dry is needed.

Livestock

To account for residues arising from feeding apple pomace containing pyraclostrobin residues, the existing MRLs for meat (mammalian) and milk are adequate, while the MRL for mammalian edible offal requires an increase from 0.05 to 0.1 mg/kg.

3.5 Codex Alimentarius Commission and overseas MRLs

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

OVERSEAS TOLERANCES FOR BOSCALID IN RELEVANT COMMODITIES

Country/status	Commodity	Tolerance, mg/kg (expiry date)	Reference
Codex	Apple	2	Codex Alimentarius, Pesticide Residues in Food, Maximum Residue Limits, last updated 30 March 2009
Canada	Meat byproducts (mammalian)	0.35	List of Maximum Residue Limits Regulated under the Pest Control Products Act, as updated on 26 November 2009
	Meat byproducts (poultry)	0.1	
	Meat (mammalian)	0.1	
	Fat (mammalian)	0.3	
	Poultry meat	0.05	
	Fat (poultry)	0.05	
	Milk	0.1	
Japan (full)	Eggs	0.02	Table in item 6(1), Section A, General Compositional Standards for Food, Part I Food (MRLs List), updated on 5 February 2007.
	Apple	3	
	Japanese pear	3	
	Pear	3	
	Quince	3	
	Loquat	3	
	Muscle of cattle, sheep, horse or goat	0.1	
	Pig muscle	0.05	
	Fat of cattle, sheep, horse or goat	0.3	
	Pig fat	0.1	
	Liver of cattle, sheep, horse or goat	0.35	
	Pig liver	0.1	
	Kidney of cattle, sheep, horse or goat	0.35	
	Pig kidney	0.1	
	Other edible offal of cattle, sheep, horse or goat	0.35	
	Other edible offal of pig	0.1	
	Milk	0.1	
	Poultry muscle	0.05	
	Poultry fat	0.05	
	Poultry liver	0.1	
	Poultry kidney	0.1	
Poultry, other edible offal	0.1		
Poultry eggs	0.02		
Japan (provisional)	Muscle of other terrestrial mammals	0.05	Table in item 7(1), Section A, General Compositional Standards for Food, Part I Food (Provisional MRLs List), updated on 5 February 2007.
	Fat of other terrestrial mammals	0.1	
	Liver of other terrestrial mammals	0.05	
	Kidney of other terrestrial mammals	0.05	
	Other edible offal of other terrestrial mammals	0.05	
USA	Apple, wet pomace	10	Electronic Code of Federal Regulations, Title 40 (Protection of Environment), Chapter I (EPA), Subchapter E (Pesticide Programs), Part 180 (Tolerances and Exemptions for Pesticide Chemical Residues in Food), subpart C, section 180.589 (boscalid)
	Pome fruit	3	
	Meat of cattle, goat, horse or sheep	0.1	
	Pig meat	0.05	
	Fat of cattle, goat, horse or sheep	0.3	
Pig fat	0.1		

Country/status	Commodity	Tolerance, mg/kg (expiry date)	Reference
	Meat byproducts of cattle, goat, horse or sheep	0.35	tolerances), last updated 1 December 2009.
	Pig meat byproducts	0.1	
	Milk	0.1	
	Poultry meat	0.05	
	Poultry fat	0.05	
	Poultry meat byproducts	0.1	
	Eggs	0.02	
New Zealand	Pome fruit	*0.05	New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2009, Gazette Notice 4895, effective 9 July 2009.
Taiwan	Apples	2	Standards for Pesticide Residue Limits in Foods, in accordance with paragraph 2 of Article 11 of the Act Governing Food Sanitation, Department of Health, Taiwan, amended 7 October 2009
	Pears	1	
Korea	Apple	0.5	MRLs for Pesticides, Korea Food and Drug Administration, updated September 2009
	Pear	1	
European Union	Apples	2	EU Pesticides Database (http://ec.europa.eu).
	Pears	2	
	Quinces	2	
	Medlar	2	
	Loquat	2	
	Other pome fruit	2	
	Meat (swine, bovine, sheep, goat, horses, asses, mules or hinnies, other farm animals)	*0.05	
	Fat (swine)	0.1	
	Fat (bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	0.3	
	Liver (bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	0.2	
	Liver (swine)	0.1	
	Kidney (bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	0.3	
	Kidney (swine)	0.1	
	Other edible offal (bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	0.3	
	Other edible offal (swine)	0.1	
	Other products (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Poultry meat	*0.05	
	Poultry fat	0.1	
	Poultry liver	0.1	
	Poultry kidney	0.05	
	Poultry, other edible offal of	0.1	
Other poultry products	*0.05		
Milk	*0.05		
Eggs	*0.05		

OVERSEAS TOLERANCES FOR PYRACLOSTROBIN IN RELEVANT COMMODITIES

Country/status	Commodity	Tolerance, mg/kg (expiry date)	Reference
Codex	Apple	0.5	Codex Alimentarius, Pesticide Residues in Food, Maximum Residue Limits, last updated 30 March 2009
	Edible offal (mammalian)	*0.05	
	Eggs	*0.05	
	Meat (mammalian)	0.5	
	Milk	0.03	
	Poultry, edible offal of	*0.05	
	Poultry meat	*0.05	
Canada	Apples	1.5	List of Maximum Residue Limits Regulated under the Pest Control Products Act, as updated on 26 November 2009
	Pears	1.5	
	Meat byproducts except liver (mammalian)	0.2	
	Liver (mammalian)	1.5	
	Meat byproducts (poultry)	0.1	
	Meat (mammalian)	0.1	
	Fat (mammalian)	0.1	
	Poultry meat	0.1	
	Milk	0.1	
	Eggs	0.1	
Japan (full)	Apple	1	Table in item 6(1), Section A, General Compositional Standards for Food, Part I Food (MRLs List), updated on 5 February 2007.
	Japanese pear	1.5	
	Pear	1.5	
	Quince	1.5	
	Loquat	1.5	
	Muscle of cattle, sheep, pig, horse or goat	0.1	
	Fat of cattle, sheep, pig, horse or goat	0.1	
	Fat of other terrestrial mammals	0.05	
	Liver of cattle, sheep, pig, or goat	1.5	
	Horse liver	0.1	
	Liver of other terrestrial mammals	0.05	
	Kidney of cattle, sheep, pig, horse or goat	0.2	
	Kidney of other terrestrial mammals	0.05	
	Other edible offal of cattle, sheep, pig, horse or goat	0.2	
	Other edible offal of other terrestrial mammals	0.05	
	Milk	0.1	
	Poultry muscle	0.05	
	Poultry fat	0.05	
	Poultry liver	0.05	
	Poultry kidney	0.05	
Poultry, other edible offal	0.05		
Poultry eggs	0.05		
USA	Apple, wet pomace	8	Electronic Code of Federal Regulations, Title 40 (Protection of Environment), Chapter I (EPA), Subchapter E (Pesticide Programs), Part 180 (Tolerances and Exemptions for Pesticide Chemical Residues in Food), subpart C, section 180.582 (pyraclostrobin tolerances), last updated 1
	Pome fruit	1.5	
	Meat of cattle, goat, horse, pig or sheep	0.1	
	Fat of cattle, goat, horse, pig or sheep	0.1	
	Meat byproducts (except liver) of cattle, goat, horse, pig or sheep	0.2	

Country/status	Commodity	Tolerance, mg/kg (expiry date)	Reference
	Liver of cattle, goat, pig or sheep	1.5	December 2009.
	Horse liver	0.1	
	Milk	0.1	
New Zealand	Apple	*0.02	New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2009, Gazette Notice 4895, effective 9 July 2009.
	Pears	*0.02	
	Mammalian fat	*0.02	
	Mammalian meat	*0.02	
	Mammalian liver	*0.02	
	Mammalian kidney	*0.02	
	Milk	*0.02	
Taiwan	Apples	0.5	Standards for Pesticide Residue Limits in Foods, in accordance with paragraph 2 of Article 11 of the Act Governing Food Sanitation, Department of Health, Taiwan, amended 7 October 2009
	Pears	1	
Korea	Apple	0.2	MRLs for Pesticides, Korea Food and Drug Administration, updated September 2009
	Pear	1	
Russia	Pome fruit	0.3	Consolidation of Russian Pesticide MRL Legislation, Freshfel Europe, 16 November 2009.
European Union	Apples	0.3	EU Pesticides Database (http://ec.europa.eu).
	Pears	0.3	
	Quinces	0.3	
	Medlar	0.3	
	Loquat	0.3	
	Other pome fruit	0.3	
	Meat (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Fat free of lean meat (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Liver (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Kidney (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Other edible offal (swine, bovine, sheep, goat, horses, asses, mules and hinnies, other farm animals)	*0.05	
	Poultry meat	*0.05	
	Poultry fat	*0.05	
	Poultry liver	*0.05	
	Poultry kidney	*0.05	
	Poultry, other edible offal of	*0.05	
Milk	*0.05		
Eggs	*0.05		

3.6 Current and proposed Australian MRLs for boscalid and pyraclostrobin

The following changes are proposed to Australian boscalid and pyraclostrobin MRLs:

Table 1

Compound	Food		MRL (mg/kg)
Boscalid			
DELETE:	FP 0226	Apple	2
ADD:	FP 0009	Pome fruit	2
Pyraclostrobin			
DELETE:	FP 0226	Apple	1
ADD:	MO 0105	Edible offal (mammalian)	*0.05
	MO 0105	Edible offal (mammalian)	0.1
	FP 0009	Pome fruit	1

*MRL set at the limit of quantitation.

Table 4

Compound	Food		MRL (mg/kg)
Boscalid			
DELETE:	AB 0226	Apple pomace, dry	20
ADD:	AB 0226	Apple pomace, dry	30

For full details of Australian boscalid and pyraclostrobin MRLs, please refer to the MRL page on the APVMA website at <http://www.apvma.gov.au/residues/standard.php>

3.7 Potential Risk to Trade

As a result of the new MRL in pome fruit and proposed use in pears, there is a possible risk to Australia's exports of pears to Canada (which has no MRL for boscalid), to the Netherlands, as the EU MRL for pyraclostrobin is lower than that proposed for Australia, and to New Caledonia, Indonesia, Papua New Guinea, Fiji, Hong Kong, Malaysia and Singapore, as there is no Codex MRL for pyraclostrobin in pears.

The existing label covering use only in apples, and the proposed label that will cover use in both apples and pears include a 7-day export slaughter interval for livestock consuming treated apple and pear pomace. Depuration data from feeding studies for both boscalid and pyraclostrobin show that this is a sufficient period to ensure that residues of these two compounds in animal commodities will drop below the LOQ. Based on the established ESI and existing industry systems for managing risks associated with feeding byproduct stockfeeds, there is unlikely to be any increased risk to Australian exports of meat or dairy products provided the label instructions are followed.

4 CONCLUSION

Comment is sought on the potential for boscalid and pyraclostrobin in *Nufarm Pristine Fungicide* to unduly prejudice Australian trade when it is used on apples and pears to control blackspot, powdery mildew, alternaria leaf blotch and alternaria fruit spot.

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. 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