



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



## TRADE ADVICE NOTICE

on fluxapyroxad and pyraclostrobin in the Product Merivon Fungicide for use on  
cherries

APVMA Product Number 85698

**MARCH 2019**

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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 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 Merivon 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 **Wednesday 10 April 2019** 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)**<sup>1</sup> 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  
Risk Assessment Capability  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

Phone: +61 2 6210 4701

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 public release summaries can be found on the [APVMA website](#).

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<sup>1</sup> 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 BASF Australia Ltd. to register a new product Merivon Fungicide containing 250 g/L fluxapyroxad and 250 g/L pyraclostrobin for use in cherries.

The use of pyraclostrobin on cherries (in combination with boscalid) was previously allowed under PER12709 (4 June 2013 to 30 June 2017) with a use pattern involving three applications at 5.12 g pyraclostrobin/100L and a 10 day withholding period. The use of fluxapyroxad on cherries has not been previously considered.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Cherries are considered to be a major export commodity<sup>2</sup>.

### 2.2 Destination and value of exports

Australia exported 1915 tonnes of cherries, a total value of approximately \$ 34.5 million in the first quarter of 2017<sup>3</sup>. For the year ending June 2016, Australian cherry exports were \$76 million<sup>4</sup>.

Asian market destinations, such as China, Hong Kong, Singapore and Taiwan receive the majority of Australian exports. Emerging and potential export markets include the United States and the Middle East.

Table 1: Major export destinations for Australian cherries—Q1 2017

CROP	MAJOR DESTINATIONS
Cherries	Hong Kong, China, Taiwan, Singapore, USA, UAE, Indonesia, South Korea, Malaysia, Thailand

### 2.3 Proposed Australian use-pattern

Table 2: Proposed use pattern

#### MERIVON FUNGICIDE (250 G/L FLUXAPYROXAD AND 250 G/L PYRACLOSTROBIN)

CROP	PEST	RATE/CONCENTRATION	CRITICAL COMMENTS
Cherries	Blossom blight and brown rot	25 ml/100L 6.25 g ai/100 L fluxapyroxad + 6.25 g ai/100 L pyraclostrobin	For best blossom blight/brown rot control commence the application at early flowering follow by an application at full bloom.  Apply a maximum of three application of MERIVON a year, and no more than two consecutive applications.  Ensure that fungicides from an alternative chemical group are included in the spray program each season.

Withholding periods:

Harvest: DO NOT harvest for two days after application

<sup>2</sup> [https://apvma.gov.au/node/1017#Major\\_export\\_food\\_commodity\\_groups](https://apvma.gov.au/node/1017#Major_export_food_commodity_groups)

<sup>3</sup> [https://www.cherrygrowers.org.au/assets/Q1\\_2017\\_Cherry-trade-intelligence-report.pdf](https://www.cherrygrowers.org.au/assets/Q1_2017_Cherry-trade-intelligence-report.pdf)

<sup>4</sup> <https://www.cherrygrowers.org.au/market-statistics/>

Restrains: DO NOT apply with aircraft

Apply in a maximum spray volume of 2000 L/ha

Trade advice:

*EXPORT OF TREATED PRODUCE: Growers should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cherries treated with MERIVON. If you are growing cherries for export, please check with BASF Australia Ltd for the latest information on MRLs and import tolerances before using MERIVON.*

## 2.4 Results from residues trials presented to the APVMA

The proposed use of Merivon Fungicide on cherries involves up to three applications per year at 6.25 g ai/100 L fluxapyroxad and 6.25 g ai/100L pyraclostrobin with a harvest withholding period of two days.

### Fluxapyroxad in cherries

In 2016–17 Australian trials, residues in cherries following three fluxapyroxad applications at 6.32 g ai/100 L ( $\approx 1x$  the proposed concentration) at one day PHI were: 0.04 and 0.17 mg/kg.

In 2011–12 New Zealand trials, fluxapyroxad residues in cherries following three applications at the nominal concentration of 6 g ai/100L ( $\approx 1x$  the proposed concentration) at 0 day PHI were: 0.15 and 0.18 mg/kg.

In 2008–11 US trials, fluxapyroxad residues in cherries following three applications of fluxapyroxad at 125 g ai/ha ( $1x$  the proposed concentration assuming a spray volume of 2000 L/ha) at one day PHI (or later if higher residues were observed), in rank order, were: 0.20, 0.29, 0.41, 0.49, 0.58, 0.59, 1.10 and 1.44 mg/kg ( $n=8$ ).

The combined dataset suitable for the MRL estimation, in rank order is: 0.04, 0.15, 0.17, 0.18, 0.20, 0.29, 0.41, 0.49, 0.58, 0.59, 1.10 and 1.44 mg/kg ( $n=12$ ). The OECD MRL calculator estimates a MRL of 3 mg/kg. The STMR was 0.35 mg/kg.

Based on the available information, a Fluxapyroxad MRL of 3 mg/kg for Cherries [FS 0013] will cover fluxapyroxad residues arising in cherries as a result of the proposed use in conjunction with a harvest withholding period of two days.

### Pyraclostrobin in cherries

In 2013–17 Australian trials, residues in cherries following three applications at 5.12–6.32 g ai/100 L ( $\approx 0.8$ – $1x$  the proposed rate) at one day PHI were: 0.03 (2) and 0.16 mg/kg.

In 2011–12 New Zealand trials, pyraclostrobin residues in cherries following three applications at the nominal concentration of 6.4 g ai/100L ( $\approx 1x$  the proposed concentration) at 0 day PHI were: 0.09 and 0.23 mg/kg.

In 2003–05 EU trials, pyraclostrobin residues in cherries following three treatments at 5 g ai/100 L ( $\approx$  0.8x the proposed concentration) at 0 day PHI (or later if higher residues were observed) were: 0.05, 0.06, 0.08 (2), 0.12, 0.13, 0.15 (2), 0.16, 0.18, 0.20 (2), 0.21, 0.29, 0.40 and 0.41 mg/kg (n=16).

The combined dataset suitable for MRL estimation, in rank order, is: 0.03 (2), 0.05, 0.06, 0.08 (2), 0.09, 0.12, 0.13, 0.15 (2), 0.16 (2), 0.18, 0.20 (2), 0.21, 0.23, 0.29, 0.40, 0.41 mg/kg (n=21). The OECD MRL calculator estimated an MRL of 0.6 mg/kg. The STMR was 0.15 mg/kg.

Based on the available information, a MRL of 0.7 mg/kg for Cherries [FS 0013] will cover pyraclostrobin residues arising in cherries as a result of the proposed use in conjunction with a harvest withholding period of two days.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that fluxapyroxad and pyraclostrobin products are registered in several formulations around the world on a range of crop commodities including cherries.

## 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. Fluxapyroxad and pyraclostrobin have been considered by Codex. The following relevant Codex CXLs have been established for fluxapyroxad and pyraclostrobin.

Table 3: Current and proposed Australian and overseas MRLs/tolerances for fluxapyroxad

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUXAPYROXAD (MG/KG)					
	AUSTRALIA	CODEX <sup>5</sup>	USA <sup>6</sup>	JAPAN <sup>7</sup>	TAIWAN <sup>8</sup>	KOREA <sup>9</sup>
Residue definition	Commodities of plant origin: Fluxapyroxad	Plant and animal commodities (for compliance with MRL): Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad
Cherries	3 (proposed)	3	3 (Fruit, stone group 12–12)	3	2	3

EU<sup>10</sup> definition is fluxapyroxad, cherry MRL established at 3 mg/kg

Chinese<sup>11</sup> definition is fluxapyroxad, currently no MRL has been established for cherries or stone fruit.

<sup>5</sup><http://www.codexalimentarius.net>

<sup>6</sup><http://www.ecfr.gov>

<sup>7</sup><http://db.ffcr.or.jp/front/>

<sup>8</sup><https://www.fda.gov.tw/EN/law.aspx?cid=16&key=residue%20limits%20>

<sup>9</sup><http://www.foodsafetykorea.go.kr/residue/main.do>

<sup>10</sup><http://ec.europa.eu>

<sup>11</sup>[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Notifies%20Draft%20Maximum%20Residue%20Limits%20for%20Pesticides%20in%20Food%20\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_3-20-2018.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Notifies%20Draft%20Maximum%20Residue%20Limits%20for%20Pesticides%20in%20Food%20_Beijing_China%20-%20Peoples%20Republic%20of_3-20-2018.pdf)

Table 4: Current and proposed Australian and overseas MRLs/tolerances for pyraclostrobin

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF PYRACLOSTROBIN (MG/KG)					
	AUSTRALIA	CODEX <sup>12</sup>	USA <sup>13</sup>	JAPAN <sup>14</sup>	TAIWAN <sup>15</sup>	KOREA <sup>16</sup>
Residue definition	Commodities of plant origin: Pyraclostrobin	Pyraclostrobin	The sum of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate), calculated as the stoichiometric equivalent of pyraclostrobin.	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin
Cherries	T1 (0.7 proposed)	3	2.5 (Fruit, stone group 12-12)	3	1	2

EU<sup>17</sup> definition is pyraclostrobin, cherry MRL is established at 3 mg/kg

Chinese<sup>18</sup> definition is pyraclostrobin, currently no MRL has been established for cherries or stone fruit.

<sup>12</sup><http://www.codexalimentarius.net>

<sup>13</sup><http://www.ecfr.gov>

<sup>14</sup><http://db.ffcr.or.jp/front/>

<sup>15</sup><https://www.fda.gov.tw/EN/law.aspx?cid=16&key=residue%20limits%20>

<sup>16</sup><http://www.foodsafetykorea.go.kr/residue/main.do>

<sup>17</sup><http://ec.europa.eu>

<sup>18</sup>[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Releases%20New%20Maximum%20Residue%20Limit%20for%20Pesticides%20in%20Food\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_4-28-2017.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/China%20Releases%20New%20Maximum%20Residue%20Limit%20for%20Pesticides%20in%20Food_Beijing_China%20-%20Peoples%20Republic%20of_4-28-2017.pdf)

## 2.7 Current and proposed Australian MRLs for fluxapyroxad and pyraclostrobin

Table 5: Current MRL Standard—Table 1

COMPOUND	FOOD	MRL (MG/KG)
FLUXAPYROXAD		
	All other foods	0.1
PYRACLOSTROBIN		
FS 0013	Cherries	T1

Table 6: Proposed MRL Standard—Table 1

COMPOUND	FOOD	MRL (MG/KG)
FLUXAPYROXAD		
ADD:		
FS 0013	Cherries	3
PYRACLOSTROBIN		
DELETE:		
FS 0013	Cherries	T1
ADD:		
FS 0013	Cherries	0.7

## 2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluxapyroxad and pyraclostrobin 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.

A fluxapyroxad MRL for cherries is proposed at 3 mg/kg which is equivalent to that established by the EU, Japan, Codex, Korea and US. An MRL has not been established by China. The Taiwanese MRL of 2 mg/kg is lower than the proposed MRL of 3 mg/kg but is higher than the HR of 1.44 mg/kg.

A pyraclostrobin MRL for cherries is proposed at 0.7 mg/kg which is lower than the current pyraclostrobin MRLs for cherries established by the EU, Japan, Codex, Korea, Taiwan and US. An MRL has not been established by China.

The applicant has proposed the following risk mitigation statement:

Trade advice:

*EXPORT OF TREATED PRODUCE: Growers should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for cherries treated with MERIVON. If you are growing cherries for export, please check with BASF Australia Ltd for the latest information on MRLs and import tolerances before using MERIVON.*

### 3 CONCLUSIONS

BASF Australia Ltd has applied for registration of a new product Merivon Fungicide containing 250 g/L Fluxapyroxad and 250 g/L pyraclostrobin for use on cherries which will require the establishment of permanent MRLs for fluxapyroxad and pyraclostrobin in cherries.

Comment is sought on the potential for Merivon Fungicide to prejudice Australian trade when used on cherries according to the proposed label directions.