



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



## TRADE ADVICE NOTICE

on bixafen and prothioconazole in the product Aviator Xpro Foliar Fungicide  
for use on canola and chickpeas

APVMA Product Number 69361

FEBRUARY 2017

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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 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 Aviator Xpro Foliar 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 28 March 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)<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

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](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 [www.apvma.gov.au](http://www.apvma.gov.au)

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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 Bayer CropScience to vary the registration of Aviator Xpro Foliar Fungicide to include uses for the control of *sclerotinia* in canola and *ascochyta* in chickpeas.

This is the first time the registration of the use of bixafen without the Grazing restraint 'DO NOT graze livestock producing milk for human consumption on treated crops' has been considered.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Canola and chickpeas 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 treated bixafen and prothioconazole. Residues in these commodities resulting from the use of Aviator Xpro Foliar Fungicide may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

#### Canola

Australian exports of canola grain, oil and meal totalled 1,945 kt (value \$1,097 m), 154 kt and 23 kt respectively in 2015–16 (ABARES). The major export markets for canola grain in 2014–15 included China, Belgium, Japan, the Netherlands, France, Germany and Pakistan. Destinations for canola oil included China, New Zealand, Malaysia and the Republic of Korea. The major market for Canola meal was New Zealand.

#### Chickpeas

Chickpeas exports were 1140 kt, valued at \$1013 million, in 2015–16 (ABARES). Major export markets for Australian pulses including chickpeas are Asia, the Middle East, Europe and Egypt.

#### Meat and Offal

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).

## Dairy products

The value of Australian dairy exports in 2015–16 was \$3 billion<sup>2</sup>. The major export markets for Australian dairy products including butter and butterfat, cheese, milk, milk powder and other dairy products in 2015–16 are presented in the following table:

| COUNTRY             | GREATER CHINA*   | JAPAN            | SINGAPORE       | INDONESIA      | MALAYSIA       | PHILIPPINES    | NEW ZEALAND    | THAILAND       |
|---------------------|------------------|------------------|-----------------|----------------|----------------|----------------|----------------|----------------|
| Volume (tonnes)     | 178,101<br>(22%) | 103,140<br>(13%) | 82,794<br>(10%) | 61,025<br>(7%) | 58,147<br>(7%) | 40,257<br>(5%) | 37,052<br>(5%) | 27,048<br>(3%) |
| Value (A\$ million) | 795<br>(27%)     | 464<br>(16%)     | 188<br>(6%)     | 202<br>(7%)    | 181<br>(6%)    | 107<br>(4%)    | 168<br>(6%)    | 91<br>(3%)     |

\*Includes China, Hong Kong, and Macau

## 2.3 Proposed Australian use-pattern

Table 1: Aviator Xpro Foliar Fungicide (75 g/L bixafen and 150 g/L prothioconazole)

| CROP   | PEST  | RATE             | CRITICAL COMMENTS  |
|--------|---|------------------|--|
| Canola | Sclerotinia stem rot<br><i>(Sclerotinia sclerotiorum)</i> | 550 to 800 mL/ha | <p>Apply between 20% and 50% (full bloom) flowering. For best results apply as a preventative application at 20–30% flowering prior to significant disease expression (refer to general instructions—disease control in canola).</p> <p>Good coverage throughout the entire canopy is essential, particularly ensuring spray coverage down to the base of the canopy is important. Using a water rate at the higher end of the range (see application instructions) will improve spray coverage.</p> <p>Apply the higher rate (up to 800 mL/ha) under high disease pressure. A second application may be required if seasonal conditions are conducive for continued disease development or when the risk of disease is high.</p> <p>A maximum of two applications may be made per crop, with a minimum re-treatment interval of 21 days.</p> <p>DO NOT apply after 50% (full bloom) flowering growth stage.</p> |

<sup>2</sup> Australian Dairy Industry in Focus 2016, [www.dairyaustralia.com.au/Industry-information/About-Dairy-Australia/Publications-2/Australian-Dairy-industry-in-Focus.aspx](http://www.dairyaustralia.com.au/Industry-information/About-Dairy-Australia/Publications-2/Australian-Dairy-industry-in-Focus.aspx)

| CROP      | PEST  | RATE             | CRITICAL COMMENTS  |
|-----------|---|------------------|--|
| Chickpeas | Ascochyta blight<br>( <i>Phoma rabiei</i> ) | 400 to 600 mL/ha | <p>Aviator Xpro is most effective when applied before an infection event occurs (e.g. before rain). Monitor crops from emergence, and apply at the first sign of disease infection. A second application may be required if seasonal conditions are conducive for continued disease development or when the risk of disease is high.</p> <p>Under extended conditions of high disease risk and for susceptible varieties, more than 2 fungicide sprays may be required. In these situations, Aviator Xpro should be applied as part of a preventative spray program that incorporates other fungicides. Refer to industry guidelines for information on disease risk and recommended fungicide spray programs in specific situations.</p> <p>Use the higher rate (up to 600 mL/ha) when conditions favour severe disease development.</p> <p>A maximum of two applications may be made per crop, with a minimum re-treatment interval of 28 days.</p> <p>DO NOT apply after early flowering (BBCH 60/61)</p> |

## RESTRAINTS

A maximum of two applications may be made per crop.

### DO NOT apply by aircraft

**Canola:** DO NOT apply after 50% (full bloom) flowering growth stage.

**Chickpeas:** DO NOT apply after early flowering (BBCH 60/61).

## WITHHOLDING PERIODS

**Harvest:** Canola, chickpeas - NOT REQUIRED WHEN USED AS DIRECTED

**Grazing:** Canola- DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

Chickpeas- DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 5 WEEKS AFTER APPLICATION

## EXPORT SLAUGHTER INTERVAL (ESI)—7 DAYS

Livestock that have been grazing on treated crops should be placed on clean feed for 7 days prior to export slaughter.

## Export of treated produce

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Aviator Xpro. If you are growing produce for export, please check with Bayer CropScience for the latest information on MRLs and import tolerances before using Aviator Xpro.

## 2.4 Results from residues trials presented to the APVMA

### Canola

For bixafen in canola grain, an MRL for Rape seed [canola] at \*0.01 mg/kg is supported by the available data as the five relevant trials involving 2 applications up to the 50% (full bloom) flowering stage at  $\approx$  60 g ai/ha (1 $\times$  the proposed rate), found parent bixafen residues to be <0.01 mg/kg at harvest. This MRL is the same as that currently established. For bixafen in canola stubble (at harvest) and forage (4 weeks after treatment), the high residues were 0.11 and 2.6 mg/kg on a dry weight basis. Bixafen MRLs for 'Canola forage' at 5 mg/kg and 'Canola straw and fodder (dry)' at 0.3 mg/kg are considered to be appropriate for the proposed use with a four week grazing withholding period.

For prothioconazole in canola grain, an MRL for Pulses at \*0.02 mg/kg is supported by the available data as the five relevant trials involving 2 applications of bixafen canola up to the 50% (full bloom) flowering stage at  $\approx$  120 g ai/ha (1 $\times$  the proposed rate), found prothioconazole residues to be <0.02 mg/kg at harvest. This MRL is the same as that currently established. For prothioconazole in canola stubble (at harvest) and forage (4 weeks after treatment), the high residues were 0.13 and 5.3 mg/kg on a dry weight basis. A prothioconazole MRL for the Rape seed [canola] forage, fodder and straw' at 10 mg/kg is considered to be appropriate for the proposed use with a four week grazing withholding period.

### Chickpeas

For bixafen in chickpea grain, an MRL of \*0.01 mg/kg is supported by the available data as the twelve relevant trials involving 2 applications of bixafen to chickpeas (4), lentils (4) and field peas (4) at BBCH 15-35 & BBCH 60-63 at  $\approx$  45 g ai/ha (1 $\times$  the proposed rate), found parent bixafen residues to be <0.01 mg/kg at harvest. For bixafen in pulse stubble (at harvest) and forage (5 weeks after treatment), the high residues were 1.4 and 2.4 mg/kg on a dry weight basis. For chickpea forage and fodder, a bixafen MRL at 5 mg/kg is considered to be appropriate for the proposed use with a five week grazing withholding period.

For prothioconazole in chickpea grain, an MRL of \*0.02 mg/kg is supported by the available data as the twelve relevant trials involving 2 applications of prothioconazole to chickpeas (4), lentils (4) and field peas (4) at BBCH 15-35 & BBCH 60-63 at  $\approx$  90 g ai/ha (1 $\times$  the proposed rate), found prothioconazole residues to be <0.02 mg/kg at harvest. For prothioconazole in pulse stubble (at harvest) and forage (5 weeks after treatment), the high residues were 3.1 and 3.5 mg/kg on a dry weight basis. For chickpea forage and fodder, a prothioconazole MRL at 7 mg/kg is considered to be appropriate for the proposed use with a five week grazing withholding period.

### Rotational crops

The proposed uses of Aviator Xpro Foliar Fungicide in canola and chickpeas will result in a similar rotational cropping situation as is approved for prothioconazole. Bixafen is however registered for use in canola only and the proposed use may result in an increased potential for residues in rotational crops.

The currently proposed uses of bixafen involve two seasonal applications to chickpeas at 45 g ai/ha and canola at 60 g ai/ha. The maximum seasonal exposure is therefore associated with the proposed use on canola (120 g ai/ha). High residues for parent bixafen (the residue definition for enforcement) expected as a

result of the maximum Australian use pattern are estimated to be 0.01 mg/kg in food crops and 0.03 mg/kg in animal feeds following a simulated failed crop scenario. Bixafen residues above the LOQ (0.01 mg/kg) were not observed in cereal grains.

Based on the available information, bixafen MRLs for 'All other foods' at 0.03 mg/kg and 'Primary feed commodities' at 0.05 mg/kg are considered to be appropriate to account for residues that may occur in rotational crops (including pastures) following treatments of cereals, pulses and canola with the use of bixafen considered here.

For grain commodities that are major export commodities (cereals, oilseeds and pulses), rotational crop data exists for wheat and barley and bixafen residues were not detected in grain following any rotation. Rotational crop data is not available for any oilseed or pulse crops but residues data for pulses and canola treated as a primary crop with two applications at 90 – 95 g ai/ha at various timings did not detect finite parent bixafen residues in grain. Based on the available rotational crop data for cereals and primary crop data for pulses and canola, bixafen residues are not expected in grains from rotational sources for the uses on canola and chickpeas currently under consideration. Group bixafen MRLs are recommended for cereals, pulses and oilseeds at \*0.01 mg/kg.

## Animal commodities

The highest anticipated maximum feeding level for beef and dairy cattle associated with the proposed use of bixafen on canola and chickpeas is 2.6 ppm in the feed (canola forage). The maximum residues that may result in meat, fat, kidney and liver were estimated to be 0.04, 0.14, 0.10 and 0.45 mg/kg. Bixafen MRLs for MM 0095 Meat [mammalian] [in the fat] at 0.2 mg/kg and MO 0105 Edible offal (Mammalian) at 0.7 mg/kg are considered to be appropriate. The feeding level associated with bixafen that may result in animal feed commodities from rotational sources (0.03 ppm in the feed) should not result in finite residues in animal commodities including milk.

This is the first time the use of bixafen without the Grazing restraint 'DO NOT graze livestock producing milk for human consumption on treated crops' has been considered. For milk, total bixafen residues expected as a result of the feeding of treated crops was 0.025 mg/kg. Bixafen residues were found to concentrate into cream (9.9X) and milk fat (15X), and therefore calculated total bixafen residues are 0.25 mg/kg in cream and 0.38mg/kg in milk fat. Bixafen MRLs for Milks at 0.05 mg/kg and Milk fats at 0.5 mg/kg are supported by the available information.

The lactating cattle feeding study included a depuration phase in which cattle were fed on clean feed for 7, 14 and 21 days following 28 days of dietary exposure to bixafen at 40 ppm in the feed. Following a 7 day depuration period, the highest total bixafen residue level expected in cattle tissues as a result of the proposed use on cereals, pulses and canola was 0.008 mg/kg in liver. It is therefore concluded that a 7 day depuration period should prevent total bixafen residue levels above the LOQ of 0.02 mg/kg in mammalian animal commodities.

For poultry, no changes to the established bixafen MRLs at \*0.02 mg/kg for PE 0112 Eggs, PO 0111 Poultry, edible offal of and PM 0110 Poultry, meat [in the fat] are required for the proposed use on canola and chickpeas.

For prothioconazole, the available forage, fodder and grain data for canola and chickpeas suggests that prothioconazole MRLs at the same or lower levels as currently established are required for the proposed uses. The potential as livestock dietary exposure to animals a result of the proposed use is therefore not greater than that previously considered. It is concluded that the current animal commodity MRLs for prothioconazole remain appropriate for the proposed use and no further consideration is required at this time.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that bixafen is approved for use in canola in the EU. Bixafen is not currently approved for use in chickpeas overseas.

## 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.

### Bixafen

The 2013 JMPR evaluation of bixafen recommended the establishment of a residue definition, which has been adopted by Codex. The 2016 JMPR evaluation of bixafen recommended the establishment of various MRLs including MRLs for animal commodities and rape seed (canola)<sup>3</sup>. The following relevant international MRLs have been established for bixafen:

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<sup>3</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/>

Table 2: Current and proposed Australian and overseas MRLs/tolerances for bixafen

| COMMODITY                  | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF BIXAFEN (mg/kg)   |  |  |   |   |   |
|----------------------------|--|--|--|---|---|---|
|                            | AUSTRALIA  | CODEX <sup>4</sup><br>(PROPOSED)   | EU <sup>5</sup>  | NEW ZEALAND <sup>6</sup>  | JAPAN <sup>7</sup>  | USA <sup>8</sup> ,<br>KOREA <sup>9</sup><br>AND<br>TAIWAN <sup>10</sup> |
| Residue Definition         | Plants:<br>Bixafen (enforcement)<br>Animals:<br>Sum of bixafen and bixafen-desmethyl, expressed as bixafen | Plants:<br>Bixafen (enforcement)<br>Animals:<br>Sum of bixafen and bixafen-desmethyl, expressed as bixafen | Plants:<br>Bixafen (enforcement)<br>Animals:<br>Sum of bixafen and bixafen-desmethyl, expressed as bixafen | Plants:<br>Bixafen<br>Animals:<br>Sum of bixafen and bixafen-desmethyl (expressed as bixafen) | Plants:<br>Bixafen<br>Animals:<br>Sum of bixafen and bixafen-desmethyl (expressed as bixafen) | Not established   |
| Oilseeds including Canola  | *0.01 (ESTABLISHED FOR CANOLA, PROPOSED FOR GROUP)   | 0.04   | 0.07   | -   | -   | -   |
| Pulses including Chickpeas | *0.01 (PROPOSED)   | -  | *0.01  | -   | -   | -   |
| Cereals                    | *0.01 (PROPOSED)   | 0.45 (barley & oats)<br>0.05 (wheat & rye)   | 0.5 (barley)<br>0.05 (wheat)   | *0.01   | 0.5 (barley)<br>0.05 (wheat)  | -   |
| Meat (mammalian)           | 0.2 (meat in the fat) (PROPOSED)   | 2 (fat)  | 0.15 <sup>a</sup>  | 0.15  | 0.2   | -   |
| Fat (mammalian)            |  | 2  | 0.4 <sup>a</sup>   | 0.4   | 0.4   | -   |
| Kidney (mammalian)         | 0.7 (offal) (PROPOSED)   | 4  | 0.3 <sup>a</sup>   | 0.3   | 0.3   | -   |
| Liver (mammalian)          |  |  | 1.5 <sup>a</sup>   | 1.5   | 2   | -   |

<sup>4</sup> <http://www.codexalimentarius.net>, <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/>

<sup>5</sup> <http://ec.europa.eu>

<sup>6</sup> <http://www.foodsafety.govt.nz>

<sup>7</sup> <http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

<sup>8</sup> <http://www.ecfr.gov>

<sup>9</sup> <http://eng.kfda.go.kr/policy/pesticides.php>

<sup>10</sup> <http://www.fda.gov.tw/EN/law.aspx?cid=16&cchk=d49032f6-b48e-4ab3-8fb9-223dad1b0407>

| COMMODITY | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF BIXAFEN (mg/kg) |                                  |                   |                          |                    |   |
|-----------|--|----------------------------------|-------------------|--------------------------|--------------------|---|
|           | AUSTRALIA  | CODEX <sup>4</sup><br>(PROPOSED) | EU <sup>5</sup>   | NEW ZEALAND <sup>6</sup> | JAPAN <sup>7</sup> | USA <sup>8</sup> ,<br>KOREA <sup>9</sup><br>AND<br>TAIWAN <sup>10</sup> |
| Milk      | *0.02<br>(ESTABLISHED)<br><br>0.05 (PROPOSED)                  | 0.2                              | 0.04 <sup>a</sup> | 0.04                     | 0.04               | -   |
| Milk fats | 0.5 (PROPOSED)   | 5                                | -                 | -                        | -                  | -   |

Note a: MRLs for cattle (bovine), sheep and goats only.

## Prothioconazole

The following relevant Codex and international MRLs have been established for prothioconazole:

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

| COMMODITY          | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF PROTHIOCONAZOLE (mg/kg)   |                         |  |  |  |
|--------------------|--|-------------------------|--|--|--|
|                    | AUSTRALIA  | CODEX                   | EU                                       | JAPAN  | USA  |
| Residue Definition | Plants:<br>Prothioconazole and the desthio metabolite<br><br>Animals:<br>Prothioconazole and the desthio, 3-hydroxy-desthio and 4-hydroxy-desthio metabolites<br>(ESTABLISHED) | Prothioconazole-desthio | Prothioconazole-desthio (sum of isomers) | Plants:<br>Prothioconazole and the desthio metabolite (M17)<br><br>Animals:<br>metabolites M17 [2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1 <i>H</i> -1,2,4-triazole-1-yl)-2 propanol] calculated as prothioconazole and glucronic acid conjugates of prothioconazole and metabolite M17 | Plants:<br>Prothioconazole and the desthio metabolite<br><br>Animals:<br>prothioconazole and its metabolites prothioconazole-desthio, or $\alpha$ -(1-chlorocyclopropyl)- $\alpha$ -[(2-chlorophenyl)methyl]-1 <i>H</i> -1,2,4-triazole-1-ethanol, and conjugates that can be converted to these two compounds by acid hydrolysis. |
| Rape seed (canola) | *0.02<br>(ESTABLISHED)   | 0.1                     | 0.15                                     | 0.2  | 0.15   |
| Chickpeas          | T0.7<br>(ESTABLISHED - PULSES)<br><br>*0.02<br>(PROPOSED)  | 1                       | 1  | 1  |  |
| Offal              | 0.2<br>(ESTABLISHED)   | 0.5                     | 0.5                                      | 0.5 (liver and kidney)   | 0.2 (meat by-products)   |

| COMMODITY | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF PROTHIOCONAZOLE (mg/kg) |        |       |                            |                           |
|-----------|--|--------|-------|----------------------------|---------------------------|
|           | AUSTRALIA  | CODEX  | EU    | JAPAN                      | USA                       |
| Meat      | 0.02<br>(ESTABLISHED)  | 0.01   | 0.05  | 0.01 (meat),<br>0.05 (fat) | 0.02 (meat),<br>0.1 (fat) |
| Milk      | *0.004<br>(ESTABLISHED)  | *0.004 | *0.01 | 0.004                      | 0.02                      |

## 2.7 Current and proposed Australian MRLs for bixafen and prothioconazole

Table 4: Current MRL Standard—Table1

| COMPOUND        | FOOD                          | MRL (mg/kg) |
|-----------------|-------------------------------|-------------|
| Bixafen         |                               |             |
| PE 0112         | Eggs                          | *0.02       |
| MO 0105         | Edible offal (Mammalian)      | T1          |
| MM 0095         | Meat [mammalian] [in the fat] | T0.3        |
| ML 0106         | Milks                         | *0.02       |
| PO 0111         | Poultry, Edible offal of      | *0.02       |
| PM 0110         | Poultry meat [in the fat]     | *0.02       |
| VD 0070         | Pulses                        | T0.1        |
| SO 0495         | Rape seed                     | *0.01       |
| Prothioconazole |                               |             |
| MO 0105         | Edible offal (Mammalian)      | 0.2         |
| PE 0112         | Eggs                          | *0.01       |
| MM 0095         | Meat (mammalian) [in the fat] | 0.02        |
| ML 0106         | Milks                         | *0.004      |
| PO 0111         | Poultry, Edible offal of      | *0.05       |
| PM 0110         | Poultry meat [in the fat]     | *0.05       |
| VD 0070         | Pulses                        | T0.7        |
| SO 0495         | Rape seed [canola]            | *0.02       |

Table 5: Proposed MRL Standard – Table1

The following amendments to the APVMA MRL Standard are required for the current application:

| COMPOUND        | FOOD                          | MRL (mg/kg) |
|-----------------|-------------------------------|-------------|
| Bixafen         |                               |             |
| ADD:            |                               |             |
|                 | All other foods               | 0.03        |
| GC 0080         | Cereal grains                 | *0.01       |
| MO 0105         | Edible offal (Mammalian)      | 0.7         |
| MM 0095         | Meat [mammalian] [in the fat] | 0.2         |
| ML 0106         | Milks                         | 0.05        |
| FM 0183         | Milk fats                     | 0.5         |
| SO 0088         | Oilseed                       | *0.01       |
| VD 0070         | Pulses                        | *0.01       |
| Prothioconazole |                               |             |
| ADD:            |                               |             |
| VD 0070         | Pulses                        | *0.02       |

## 2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of bixafen and prothioconazole 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.

The following label advice relating to export is supported:

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

Livestock that have been grazing on treated crops should be placed on clean feed for 7 days prior to export slaughter.

### Export of treated produce

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Aviator Xpro. If you are growing produce for export, please check with Bayer CropScience for the latest information on MRLs and import tolerances before using Aviator Xpro.

For bixafen and prothioconazole in canola and chickpeas grain, residues are not expected above the limit of quantitation (LOQ). The proposed uses on those crops is therefore not expected to result in an undue risk to international trade.

Bixafen residues are not expected in cereal, pulse or oilseed grains from rotational sources and LOQ MRLs for those crop groups are recommended. The livestock feeding level associated with the high residue of 0.03 mg/kg in cereal straw that was observed in the rotational crop studies should not result in finite bixafen residues in animal tissues including milk. The trade risk associated with rotational crops is considered to be low.

Bixafen MRLs for meat [mammalian] [in the fat] and edible offal (Mammalian) at 0.2 and 0.7 mg/kg respectively are required for the proposed use on canola and chickpeas. The proposed Export Slaughter Interval of 7 days should adequately mitigate the risk of residues above the LOQ of 0.02 mg/kg in animal commodities destined for export.

For milk, total bixafen residues estimated as a result of the feeding of treated canola meal was 0.03 mg/kg. Bixafen residues were found to concentrate into cream (9.9X) and milk fat (15X), and therefore estimated total bixafen residues are 0.25 mg/kg in cream and 0.38 mg/kg in milk fat. A bixafen MRL for Milks at 0.05 and Milk fats at 0.5 mg/kg is supported by the available information. The estimated high residue in milk is lower than the MRLs established in the EU, NZ and Japan and the proposed Codex MRL. The trade risk is considered to be low.

### 3 CONCLUSIONS

Bayer CropScience has applied for a variation of the registration of Aviator Xpro Foliar Fungicide to include uses for the control of *sclerotinia* in canola and *ascochyta* in chickpeas. Comment is sought on the potential risk to trade in canola, chickpeas and animal commodities from the proposed use and the ability of the industry to manage any potential risk.