



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



Trade Advice Notice

on fludioxonil and pydiflumetofen in the product Miravis Star Adepidyn
Technology Fungicide for use on canola and pulses

APVMA product number 89771

April 2021

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the 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 Trade Advice Notice 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 register Miravis Star Adepidyn Technology 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 13 May 2021 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 organisation name (if relevant)
- email or postal address (if available)

- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au.

Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Australia Pty Limited for registration of Miravis Star Adepidyn Technology Fungicide, containing fludioxonil and pydiflumetofen, for use on canola and pulses including lentils, chickpeas and faba beans.

Pydiflumetofen is registered for use on canola. The registered use on canola involves a single foliar application at 120 g ai/ha applied at the 4 to 6 leaf growth stage with a harvest withholding period of 'Not required when used as directed', and a 6 week grazing withholding period. There are no registered foliar uses for fludioxonil on canola and there are no registered uses for fludioxonil or pydiflumetofen on pulses.

The current proposal represents an increase to the maximum dietary burden for fludioxonil and pydiflumetofen for livestock which will be discussed in this Trade Advice Notice. The establishment of permanent fludioxonil poultry commodity MRLs at the LOQ are also proposed but do not pose a potential risk to trade.

Trade considerations

Commodities exported

Canola (including derived oils and meals) and specified pulses (lupins, field peas, chickpeas, faba beans, navy beans, mung beans) are major export commodities¹, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated canola and pulses. Residues in these commodities resulting from the use of Miravis Star Adepidyn Technology Fungicide may have the potential to unduly prejudice trade.

Destination and value of exports

Australian exports of canola seed, oil and meal totalled 1.7 kt, 165 kt and 0.2 kt respectively in 2019–20². The total value of oilseed exports was \$1.2 billion for seed, \$380 million for oil and \$7.2 million for meal. The main export markets for Australian canola include China, Germany, the Netherlands, Belgium, Japan and Pakistan.

Australian exports of pulses totalled 1,731 kt valued at \$1.2 billion in 2019–20. The export volume and value of chickpeas, field peas and lupins was 370 kt (\$306 million), 60 kt (\$39 million) and 230 kt (\$95 million) respectively³. The main export markets for Australian pulses include Asia, North Africa, Middle East and the Indian sub-continent⁴.

¹ Australian Pesticides and Veterinary Medicines Authority, [Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website, 20 July 2020, accessed 23 February 2021.

² ABARES, [Agricultural commodity statistics 2020 rural commodities – oilseeds](#), 2020, accessed 23 February 2021.

³ ABARES, [Agricultural commodity statistics 2020 rural commodities – pulses](#), 2020, accessed 23 February 2021.

⁴ Pulse Australia, [Pulses: Understanding Global Markets](#), *Australian Pulse Bulletin*, 20 November 2015, accessed 23 February 2021.

Proposed Australian use pattern

Miravis Star Atepidyn Technology Fungicide (150 g/L fludioxonil and 100 g/L pydiflumetofen).

Table 1: Proposed use pattern

Crop	Pest	Rate/ha	Critical comments
Canola	Blackleg (<i>Leptosphaeria maculans</i>)	600 to 750 mL/ha (90 to 112.5 g fludioxonil/ha and 60 to 75 g pydiflumetofen/ha)	Apply up to 20% flowering. DO NOT apply more than one application per crop. If targeting early season seedling blackleg, for best results apply at 4 to 6 leaf stage. Use lower rate range when used in combination with an effective seed treatment/in-furrow product. Fungicide application should reduce dodging, improve adult plant survival and stem canker from blackleg. For late season upper canopy blackleg, target application from 20 cm stem elongation to 20% flowering. Use the higher rate in higher yielding crops where disease risk is high.
	White leaf spot (<i>Pseudocercospora capsellae</i>)		
	Sclerotinia (<i>Sclerotinia sclerotiorum</i>)	750 to 1000 mL/ha (112.5 to 150 g fludioxonil/ha and 75 to 100 g pydiflumetofen/ha)	Application for sclerotinia will also result in control of: <ul style="list-style-type: none"> • Alternaria Leaf Spot (<i>Alternaria</i> spp.) • Blackleg (<i>Leptosphaeria maculans</i>) • White leaf spot (<i>Pseudocercospora capsellae</i>) • Powdery mildew (<i>Erysiphe</i> spp.)
Pulse crops including lentils, chickpeas and faba beans	Ascochyta blight (<i>Ascochyta</i> spp.)	250 to 1000 mL/ha (37.5 to 150 g fludioxonil/ha and 25 to 100 g pydiflumetofen/ha)	Apply up to the end of flowering. DO NOT apply more than 2 applications per crop.
	Chocolate spot and botrytis rot (<i>Botrytis</i> spp.)		Apply at first sign of disease. A second application maybe required at 14 to 42 days after initial application if disease conducive conditions continue. Under very vigorous growing conditions, use the shorter application interval and/or the higher application rate. Under extended conditions of high disease risk and for susceptible lines, further fungicide applications may be required. In these conditions rotate with a non-cross resistant mode of action fungicide. A maximum of 2 applications may be made per crop with a minimal retreatment interval of 14 days.
	Rust (<i>Uromyces vicia-fabae</i>)		
	Cercospora leaf spot (<i>Cercospora</i> spp.)		
	Sclerotinia (<i>Sclerotinia sclerotiorum</i>)		DO NOT apply after crop growth stage BBCH 69 (end of flowering). This use pattern is subject to a CropLife resistance strategy.

Withholding periods (WHP):

Harvest: Canola and pulses: Not required when used as directed.

Grazing: Canola and pulses: DO NOT graze or cut for stock food for 6 weeks after application.

Restrains:

DO NOT apply by a vertical sprayer.

Canola: DO NOT apply more than one application per crop. DO NOT apply after crop growth stage BBCH 62 (20% flowering).

Pulses: DO NOT apply more than 2 applications per crop. DO NOT apply after crop growth stage BBCH 69 (end of flowering).

Results from residues trials presented to the APVMA

Canola

The proposed critical GAP on canola involves a single application at up to 1000 mL product/ha (150 g fludioxonil/ha and 100 g pydiflumetofen/ha) applied up to 20% flowering (BBCH 62) by ground or aerial application in conjunction with a harvest WHP of 'Not Required when used as directed' and a grazing WHP of 6 weeks.

Canola seed – fludioxonil

In 4 Australian canola trials, following a single application at 20% flowering (BBCH 62) at a nominal rate of 150 g ai/ha (matching the proposed GAP), residues of fludioxonil in canola seed at harvest (73-107 DAA) were <0.01 mg/kg (LOD) (n=4). In Canadian trials, following a single application at BBCH 55–67 at a nominal rate of 250 g ai/ha (231-260 g ai/ha, ~1.7× proposed), no residues of fludioxonil were observed above the LOQ of <0.01 mg/kg (n=16) in seed (35–57 DAA).

Based on the available data, finite residues of fludioxonil are not expected in canola seed from the proposed use. A fludioxonil MRL of *0.01 mg/kg for SO 0495 rape seed [canola] is recommended for the proposed use when applied up to 20% flowering (BBCH 62) with a harvest WHP of 'Not required when used as directed'.

Canola forage – fludioxonil

From European trials, at 38–42 DAA, following a single application at 50% flowering (BBCH 69) at 375 g ai/ha (2.5× proposed), residues of fludioxonil in canola (whole plant) were 0.01, 0.03, 0.05, 0.10, 0.12, 0.14, 0.15 and 0.41 mg/kg (n=8). Scaled and corrected for dry weight, assumed 30% DM, the dataset suitable for MRL estimation is, in rank order, 0.01, 0.04, 0.07, 0.13, 0.16, 0.19, 0.20 and 0.55 mg/kg (n=8). It is recommended that fludioxonil MRL for rape seed [canola] forage (fresh weight) at *0.01 mg/kg should be replaced by an MRL for rape seed [canola] forage at 1 mg/kg and is considered appropriate for the propose use in conjunction with the proposed GWHP of 6 weeks.

Canola straw and fodder – fludioxonil

Based on the Australia trials (matching the proposed GAP), no finite residues of fludioxonil were observed (<0.02 mg/kg, n=4). The existing fludioxonil MRL of *0.02 mg/kg for rape seed [canola] straw and fodder, dry is considered appropriate for the proposed use, noting the data set is small.

Canola seed – pydiflumetofen

From the Australian trials (matching the proposed GAP), following a single application at 20% flowering (BBCH 62) at a nominal rate of 100 g ai/ha, residues of pydiflumetofen in seed at harvest (73–107 DAA) were <0.005 mg/kg (LOD) (n=4).

From the EU trials, following a single application at BBCH 65–71 (46 to 85 days before harvest) at a nominal rate of 200 g ai/ha (189-214 g ai/ha, ~2× proposed) residues in the seed were <0.01 (6), 0.01 (2), 0.02, 0.03, 0.04 and 0.05 mg/kg (n=12). Scaled for the proposed application rate of 100 g ai/ha residues in the EU trials were <0.01 (8), 0.01, 0.02 (2) and 0.03 mg/kg, noting the later application timing.

Based on the available data, a pydiflumetofen MRL of 0.05 mg/kg for SO 0495 rape seed [canola] is considered appropriate for the proposed use when applied up to 20% flowering (BBCH 62) with a harvest WHP of 'Not required when used as directed'. The proposed MRL is consistent with the recommended MRL for the registered use on canola under Miravis Adepidyn Active Fungicide (82484)⁵. The MRL is likely to be conservative as the EU data involves application at a later growth stage than proposed.

Canola forage – pydiflumetofen

From the Australian trials (matching the proposed GAP), at 42 DAA (the proposed GWHP), following a single application at the 4 to 6 leaf growth stage at a nominal rate of 100 g ai/ha (~1× proposed), residues of pydiflumetofen in canola foliage were 0.83 (2), 1.09 and 1.38 mg/kg (n=4) (dry weight).

From the EU trials, at 38–42 DAA, following a single application at BBCH 65–71 at a nominal rate of 200 g ai/ha, (~2× proposed), residues of pydiflumetofen in canola (whole plant) were 0.07, 0.11, 0.17, 0.18 (2), 0.23, 0.25 and 0.48 mg/kg (n=8). Scaling to the proposed rate of 100 g ai/ha and correcting for an assumed dry matter content of 30%, residues would be 0.12, 0.18, 0.28, 0.30, 0.30, 0.38, 0.42 and 0.80 mg/kg.

Based on the available data, the existing pydiflumetofen MRL for rape seed [canola] forage at 3 mg/kg remains appropriate for the proposed use in conjunction with the proposed GWHP of 6 weeks.

Canola straw and fodder – pydiflumetofen

From the Australian trials (matching the proposed GAP), following a single application at 20% flowering (BBCH 62) at a nominal rate of 100 g ai/ha, residues of pydiflumetofen in canola straw at harvest (73–107 DAA) were <0.005, <0.01, 0.01 and 0.08 mg/kg (n=4) (dry weight). It is recommended that rape

⁵ Australian Pesticides and Veterinary Medicines Authority, [Public Release Summary – Miravis Fungicide](#), APVMA website, 27 February 2018, accessed 26 February 2021.

seed [canola] straw and fodder will be covered by a primary feed commodities {except pulse forage and fodder; rape seed [canola] forage} MRL at 0.2 mg/kg, noting the data set is small.

Pulses

The proposed use on pulses involves up to 2 applications at 1000 mL product/ha (150 g fludioxonil/ha and 100 g pydiflumetofen/ha) applied up to the end of flowering (BBCH 69) via ground or aerial application in conjunction with a harvest WHP of 'Not Required when used as directed' and a grazing WHP of 6 weeks.

Pulse grain – fludioxonil

From the Australian trials, selecting the data points from each trial closest to the last application of BBCH 69, or earlier if higher, following 2 applications at 150 g ai/ha (final application at BBCH 61/65 – 74/78), residues of fludioxonil in pulse grain were <0.02 (7), 0.06 and 0.08 mg/kg (n=9).

From the EU trials, 4 dried pea trials involved a final application timing applicable to BBCH 69. At 28–49, following 2 applications to dried peas at 250 g ai/ha (~1.7× proposed) (last application timings at BBCH 69/71 – BBCH 73/75), residues of fludioxonil in dried peas were <0.02, 0.02, 0.05 and 0.08 mg/kg (n=4). Scaled to the proposed rate of 150 g ai/ha residues would be expected to be <0.02 (2), 0.03 and 0.05 mg/kg.

The combined dataset suitable for MRL estimation is, in rank order, <0.02 (9), 0.03, 0.05, 0.06 and 0.08 mg/kg (n=13). The STMR was 0.02 mg/kg. It is recommended that the existing fludioxonil MRL for VD 0070 pulses at 0.1 mg/kg should be replaced by a permanent MRL at 0.1 mg/kg and is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed' and the restraint statement 'DO NOT apply after crop growth stage BBCH 69 (end of flowering)'.

Pulse forage and fodder – fludioxonil

From the Australian trials, at 42–43 DALA (6 weeks), following 2 applications at 150 g ai/ha, residues of fludioxonil in pulse forage were 0.59, 0.67, 1.28 and 3.39 mg/kg (n=4) (dry weight).

From European bean and pea trials, at 28–43 DALA, following 2 applications at a nominal rate of 250 g ai/ha (~1.7× proposed), residues of fludioxonil in bean and pea forage were 0.24, 0.31, 0.88, 1.02, 1.25, 1.42, 1.44, 1.59, 1.78, 2.25, 2.7, 3.4, 4.5, 4.5 and 5.87 mg/kg (n=15). Scaled and corrected for dry weight (assumed 25% DM for pea vines and 35% DM for bean vines), residues would be expected to be 0.58, 0.74, 1.75, 2.11, 2.14, 2.43, 2.47, 2.73, 3.05, 3.86, 6.48, 8.16, 9.12, 10.1 and 10.8 mg/kg.

The combined dataset suitable for MRL estimation in pulse forage is, in rank order, 0.58, 0.59, 0.67, 0.74, 1.28, 1.75, 2.11, 2.14, 2.43, 2.47, 2.73, 3.05, 3.39, 3.86, 6.48, 8.16, 9.12, 10.1 and 10.8 mg/kg (n=19). The STMR was 2.47 mg/kg. The OECD MRL calculator estimates an MRL of 20 mg/kg. The existing fludioxonil MRL for AL 0157 legume animal feeds at 30 mg/kg will cover expected residues in pulse forage from the proposed use in conjunction with a GWHP of 6 weeks.

From the Australian trials, at 44–61 DALA, based on the final application timing at BBCH 69, following 2 applications at 150 g ai/ha (final application at BBCH 65/70 – 74/78), residues of fludioxonil in pulse straw were 0.15, 0.26, 0.28, 0.50, 0.68, 0.80, 1.03, 1.05 and 1.43 mg/kg (dry weight) (n=9). The STMR was

0.68 mg/kg. The OECD MRL calculator estimates an MRL of 3 mg/kg. The existing fludioxonil MRL for AL 0157 Legume animal feeds will cover the expected residues in pulse fodder.

It is recommended that the existing fludioxonil MRL for AL 0157 legume animal feeds at 30 mg/kg will cover the expected fludioxonil residues in pulse forage and fodder from the proposed use in conjunction with a GWHP of 6 weeks.

Pulse grain – pydiflumetofen

From the Australian trials, selecting the data points from each trial closest to the last application of BBCH 69, or earlier if higher, following 2 applications at 100 g ai/ha (final application at BBCH 61/65 – 74/78), residues of pydiflumetofen in pulse grain were <0.01 (3), 0.01, 0.03, 0.05, 0.10, 0.14 and 0.20 mg/kg (n=9).

From the Canadian trials, following 2 applications at 200 g ai/ha, selecting the 2 trials with a last application timing at BBCH 74/75 (dried beans) and BBCH 67/75 (dried peas), residues of pydiflumetofen were 0.02 and 0.03 mg/kg respectively. Scaled to the proposed rate of 100 g ai/ha residues of pydiflumetofen would be expected to be 0.01 mg/kg in dried beans and 0.02 mg/kg in dried peas.

The combined dataset suitable for MRL estimation is, in rank order, <0.01 (3), 0.01 (2), 0.02, 0.03, 0.05, 0.10, 0.14 and 0.20 mg/kg (n=11). The STMR was 0.02 mg/kg. The OECD MRL calculator estimates an MRL of 0.4 mg/kg. It is recommended that the existing pydiflumetofen MRL for VD 0070 Pulses at T0.5 mg/kg should be replaced by a permanent MRL at 0.4 mg/kg and is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed' and the restraint statement 'DO NOT apply after crop growth stage BBCH 69 (end of flowering)'.

Pulse forage and fodder – pydiflumetofen

From the Australian trials, at 42–43 DALA (6 weeks), following 2 applications at 100 g ai/ha, residues of pydiflumetofen in pulse forage were 1.67, 1.81, 1.82 and 5.24 mg/kg (n=4) (dry weight). The STMR was 1.82 mg/kg. The OECD MRL calculator estimates an MRL of 10 mg/kg.

From the Australian trials, at 44–61 DALA, based on the final application timing at BBCH 69, following 2 applications at 100 g ai/ha (final application at BBCH 65/70 – 74/78), residues of pydiflumetofen in pulse straw were 1.29, 1.70, 2.23, 2.49, 2.62, 2.30, 4.08, 5.99 and 6.12 mg/kg (dry weight) (n=9). The STMR was 2.49 mg/kg. The OECD MRL calculator estimates an MRL of 10 mg/kg.

It is recommended that a pydiflumetofen MRL for pulse forage and fodder should be established at 10 mg/kg in conjunction with a GWHP of 6 weeks.

Animal commodities

The OECD calculator indicates that canola forage may form up to 100% of the diet for beef cattle and 40% of the diet for dairy cattle. Canola meal may form up to 20% of the diet for beef cattle and 15% of the diet for dairy cattle. Bean forage may form 60% of the diet for beef cattle and 70% of the diet for dairy cattle. Dried beans may form up to 50% of the diet for beef cattle and 15% of the diet for dairy cattle. Pea hay can form 100% and 70% of the diet for beef and dairy cattle respectively while pea vines can form 60% and 40% respectively.

For fludioxonil, dairy cow feeding studies were provided previously. The estimated fludioxonil dietary burden for beef and dairy cattle was 20.3 ppm and 9.6 ppm respectively. Predicted residues and required MRLs are presented below in Table 2.

Table 2: Estimated residues of fludioxonil in animal commodities and required MRLs

Feeding level (ppm)	Milk	Muscle	Fat	Liver	Kidney
CGA192155 expressed as fludioxonil (mg/kg)					
20 (actual)	0.07	0.01	0.01	0.08	0.08
20.3 – beef, estimated burden	–	0.01	0.01	0.08	0.08
9.6 – dairy, estimated burden	<0.05	–	–	–	–
Established MRLs	0.05	0.05 (meat)	–	0.1 (edible offal)	
Recommended MRLs	0.05	0.05 (meat)	–	0.1 (edible offal)	

Based on the animal feeding studies and the maximum estimated dietary burdens, the established fludioxonil MRLs for ML 0106 milks, MM 0095 meat (mammalian) and MO 0105 edible offal (mammalian) of 0.05, 0.05 and 0.1 mg/kg respectively, remain appropriate for the proposed uses. The animal feeding studies indicate that there is no preferential accumulation of fludioxonil in fat.

For pydiflumetofen, a dairy cow feeding studies was provided previously. The estimated pydiflumetofen dietary burden for beef and dairy cattle is 7.5 ppm and 5.6 ppm respectively. Predicted residues and required MRLs are presented below in Table 3.

Table 3: Estimated residues of pydiflumetofen in animal commodities and required MRLs

Feeding level (ppm)	Milk	Muscle	Fat	Liver	Kidney
Pydiflumetofen (mg/kg)					
15 (actual)	<0.01	<0.01	0.02	0.02	<0.01
7.5 – beef, estimated burden	–	<0.01	0.01	0.01	<0.01
5.6 – dairy, estimated burden	<0.01	–	–	–	–
Established MRLs	*0.01	*0.01 (meat)		*0.01 (edible offal)	
Recommended MRLs	*0.01	0.02 (meat [in the fat])		0.02 (edible offal)	

Based on the animal feeding study and the maximum estimated dietary burden, no finite residues of pydiflumetofen are expected in milks and the MRL for ML 0106 milks at *0.01 mg/kg remains appropriate for the proposed uses. Finite residues of pydiflumetofen are not expected in muscle or kidney but may be expected in fat and liver at 0.01 mg/kg therefore it is recommended that the pydiflumetofen MRL for

MM 0095 Meat (mammalian) and MO 0105 edible offal at *0.01 mg/kg should be increase to 0.02 mg/kg. Noting that the pydiflumetofen residues are expected in the fat the meat MRL will be established in the fat.

Depuration data is not available for pydiflumetofen to allow for consideration of an Export Slaughter Interval (ESI).

For poultry, the OECD calculator indicates that dried beans may contribute up to 70% of the diet for broiler poultry and field peas (dry) and canola meal can contribute up to 5% of the diet each for broiler and layer poultry. The dietary burdens of fludioxonil and pydiflumetofen for poultry are low and are estimated at 0.02 ppm and 0.3 ppm respectively. The STMR values observed in canola and pulse grain from the proposed uses are at the LOQ for both actives therefore no increased poultry dietary burden is expected.

Fludioxonil MRLs were previously established for PE 0112 eggs, PO 0111 poultry, edible offal and PM 0110 poultry meat at T*0.01 mg/kg, it is recommended that these MRLs should be established as permanent MRLs for the proposed uses. No changes are required to the pydiflumetofen poultry commodity MRLs at *0.01 mg/kg.

Overseas registration and approved label instructions

The applicant indicated that Miravis Star is registered in the USA on celery, cucurbits, fruiting vegetables and leafy vegetables.

The applicant also mentioned that Miravis Prime (containing 250 g/L fludioxonil and 150 g/L pydiflumetofen) is registered in Argentina on grapes; in Canada on celery, leafy greens, and grapes (small fruit vine climbing except fuzzy kiwifruit); in Chile on blueberries, cherries, grapes, lettuces and tomatoes; in Israel on carrots, cucurbits, eggplant, grape, leafy greens, potatoes and solanaceae; and in the USA on cucurbits, fruiting vegetables, leafy vegetables, leaf petioles, peas and beans (dried and shelled except soybeans), potatoes, grapes (small fruit vine climbing except fuzzy kiwifruit), tomatoes and tuberous and corm vegetables.

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. Pydiflumetofen and fludioxonil have been considered by Codex. The relevant Codex CXLs in Table 4 have been established for fludioxonil and pydiflumetofen.

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

Commodity	MRLs/tolerances for residues arising from the use of fludioxonil (mg/kg)									
	Australia ⁶	Codex ⁷	USA ⁸	EU ⁹	Canada ¹⁰	Japan ¹¹	Korea ¹²	Taiwan ¹³	China ¹⁴	
Residue definition	Plant: Fludioxonil Animal: Sum of fludioxonil and oxidizable metabolites, expressed as fludioxonil.	Plant: Fludioxonil Animal: Sum of fludioxonil and metabolites determined as 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid, expressed as fludioxonil.	Plant: Fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1- <i>H</i> -pyrrole-3-carbonitrile). Animal: Sum of fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1- <i>H</i> -pyrrole-3-carbonitrile), and its metabolites converted to 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid, calculated as the stoichiometric equivalent of fludioxonil.	Fludioxonil	Fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1- <i>H</i> -pyrrole-3-carbonitrile).	Plant: Fludioxonil Animal: Sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.	–	–	Fludioxonil	

⁶ Australian Government, [Agricultural and Veterinary Chemicals Code \(MRL Standard\) Instrument 2019](#), Federal Register of Legislation, accessed 26 February 2021.

⁷ Food and Agriculture Organization of the United Nations, [Codex Alimentarius International Food Standards](#), FAO website, accessed 26 February 2021.

⁸ Electronic Code of Federal Regulations, [USA Electronic Code of Federal Regulations](#), ECFR website, accessed 26 February 2021.

⁹ European Commission, [Pesticide residue\(s\) and maximum residues levels \(mg/kg\)](#), European Commission website, accessed 26 February 2021.

¹⁰ Health Canada, [Maximum Residue Limits for Pesticides](#), Health Canada website, accessed 26 February 2021.

Commodity	MRLs/tolerances for residues arising from the use of fludioxonil (mg/kg)									
	Australia ⁶	Codex ⁷	USA ⁸	EU ⁹	Canada ¹⁰	Japan ¹¹	Korea ¹²	Taiwan ¹³	China ¹⁴	
Edible offal (mammalian)	0.1	0.1	0.05 Cattle, meat by-products.	0.2 Bovine kidney 0.1 Bovine kidney^ 0.2 Bovine liver 0.1 Bovine liver^	0.05 Cattle kidney 0.05 Cattle liver	0.05	–	0.05 (edible offal except pig)	–	–
Eggs	T*0.01 (*0.01 proposed)	0.02	–	0.05 0.02^	0.05	0.01	–	–	–	–
Meat (mammalian)	0.05	0.02	0.01 Cattle, meat 0.05 Cattle fat	0.04 Bovine muscle 0.02 Bovine muscle^ 0.2 Bovine fat 0.02 Bovine fat^	0.01 Cattle meat 0.05 Cattle fat	0.01 Cattle muscle 0.05 Cattle fat	–	0.05 (fat except pig)	–	–
Milks	0.05	0.04	0.01	0.04	0.01	0.01	–	–	–	–
Poultry meat	T*0.01 (*0.01 proposed)	0.01	–	0.01* Muscle 0.05* Fat 0.01* Fat^	0.01 Meat 0.05 Fat	0.01 Muscle 0.05 Fat	–	–	–	–

¹¹ Japanese Food Chemistry Research Promotion Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed 26 February 2021.

¹² Food Safety Korea, [Pesticide MRLs for agricultural commodities](#), FSK website, accessed 26 February 2021.

¹³ Food and Drug Administration Taiwan, [Standards for Pesticide Residue Limits in Foods](#), FDAT website, accessed 26 February 2021.

¹⁴ United States Department of Agriculture, [Maximum residue limits China](#), *Global Agricultural Information Network report*, 18 November 2019, accessed 26 February 2021.

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Commodity	MRLs/tolerances for residues arising from the use of fludioxonil (mg/kg)								
	Australia ⁶	Codex ⁷	USA ⁸	EU ⁹	Canada ¹⁰	Japan ¹¹	Korea ¹²	Taiwan ¹³	China ¹⁴
Poultry, edible offal of	T*0.01 (*0.01 proposed)	0.1	-	0.1 Kidney 0.1 Liver	0.05 Kidney 0.05 Liver	0.05	-	0.05 (liver, kidney)	-
Pulses	T0.1 (0.1 proposed)	0.5 Beans (dry) 0.3 Chick-pea (dry) 0.3 Lentils (dry) 0.07 Peas (dry) 0.2 Soya bean (dry)	0.4 Beans (dry)	0.5 Beans 0.4 Lentils 0.4 Peas 0.4 Lupins	0.5 (in all pulses listed except soybeans) 0.01 Dry soybeans	0.5 Beans, dried 0.5 Soybeans, dried 0.07 Peas 0.5 Broad beans 0.5 other legumes/pulses	0.4 Kidney bean 0.4 Soybean 0.3 Pea	0.3 (in all pulses except soybean) 0.02 Soybean	0.05 Soybean
Rape seed [canola]	T0.2 (*0.01 proposed)	0.02	0.01	0.01* 0.3^	0.01	0.02	0.05	0.02	0.02

[^] Applicable from 25 May 2021 – Reg (EU) 2020/1633.

Temporary Australian MRLs are established for fludioxonil and pydiflumetofen in canola and pulse grain under current research permits which contain restraints prohibiting the export of treated produce. Proposed MRL changes will not be actioned until the expiry of these permits.

Table 5: Current and proposed Australian and overseas MRLs/tolerances for pydiflumetofen

Commodity	MRLs/tolerances for residues arising from the use of pydiflumetofen (mg/kg)					
	Australia ¹⁵	Codex ¹⁶	USA ¹⁷	Canada ¹⁸	Japan ¹⁹	Korea ²⁰
Residue Definition	Pydiflumetofen	Pydiflumetofen	Pydiflumetofen (3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide)	–	Pydiflumetofen	–
Edible offal (mammalian)	*0.01 (0.02 proposed)	Not established (0.1 recommended by the 2019 JMPR)#	0.03 Cattle meat by-products	0.03 Cattle meat by-products	0.03	0.03 Cattle by-product
Eggs	*0.01	(0.02 recommended by the 2019 JMPR)#	–	0.01	–	–
Meat (mammalian)	*0.01 (0.02 proposed in the fat)	Not established (0.1 Meat and 0.1 Mammalian fats (except milk fat recommended by the 2019 JMPR))	0.01 Cattle, meat 0.03 Cattle fat	0.01 Cattle, meat 0.03 Cattle fat	0.01 Cattle, muscle 0.03 Cattle, fat	0.03 Cattle meat
Milks	*0.01	Not established (0.01 recommended by the 2019 JMPR)#	0.03	0.03	0.03	0.01 Cow' milk

¹⁵ Australian Government, [Agricultural and Veterinary Chemicals Code \(MRL Standard\) Instrument 2019](#), Federal Register of Legislation, accessed 26 February 2021.

¹⁶ Food and Agriculture Organization of the United Nations, [Codex Alimentarius International Food Standards](#), FAO website, accessed 26 February 2021.

¹⁷ Electronic Code of Federal Regulations, [USA Electronic Code of Federal Regulations](#), ECFR website, accessed 26 February 2021.

¹⁸ Health Canada, [Maximum Residue Limits for Pesticides](#), Health Canada website, accessed 26 February 2021.

¹⁹ Japanese Food Chemistry Research Promotion Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed 26 February 2021.

²⁰ Food Safety Korea, [Pesticide MRLs for agricultural commodities](#), FSK website, accessed 26 February 2021.

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Commodity	MRLs/tolerances for residues arising from the use of pydiflumetofen (mg/kg)					
	Australia ¹⁵	Codex ¹⁶	USA ¹⁷	Canada ¹⁸	Japan ¹⁹	Korea ²⁰
Poultry meat	*0.01	Not established (0.01 Meat and 0.01 Fat recommended by the 2019 JMPR)#	–	0.01 Meat of poultry 0.01 Fat of poultry	–	–
Poultry, edible offal of	*0.01	Not established (0.01 recommended by the 2019 JMPR)#	–	0.01 Meat by-products of poultry	–	–
Pulses	T0.5 (0.4 proposed)	Not established (0.4 Dry Beans VD 2065 and 0.4 Dry Peas VD 2066 recommended by the 2019 JMPR)#	0.4 Pea and bean, dried shelled except soybean, Subgroup 6C 0.4 Soybean, seed	0.4 (in all pulses listed)	0.4 Soybeans, dried 0.4 Beans, dried 0.4 Peas 0.4 Broad beans 0.4 Other legumes/pulses	0.4 Beans
Rape seed [canola]	T0.07 (0.05 proposed)	Not established (0.9 Small seed oilseeds SO 2090 recommended by the 2019 JMPR)#	0.9 Rapeseed Subgroup 20A	0.9 Rapeseeds (canola)	0.9 Rapeseeds	0.9

Pydiflumetofen has not been considered by China²¹, the EU or Taiwan.

MRLs have been recommended in the 2019 JMPR and are expected to be established in Codex in 2021 or 2022 noting that the 2020 CCPR Meeting was postponed due to COVID-19. Temporary Australian MRLs are established for fludioxonil and pydiflumetofen in canola and pulse grain under current research permits which contain restraints prohibiting the export of treated produce. Proposed MRL changes for canola and pulse grain will not be actioned until the expiry of these permits.

²¹ United States Department of Agriculture, [Maximum residue limits China](#), *Global Agricultural Information Network report*, 18 November 2019, accessed 26 February 2021.

Current and proposed Australian MRLs for fludioxonil and pydiflumetofen

The following relevant MRLs are currently established in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 for fludioxonil and pydiflumetofen. It is noted that temporary MRLs for pydiflumetofen in canola and pulse commodities are established for a use permitted under research permit only.

Table 6: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Fludioxonil		
MO 0105	Edible offal (mammalian)	0.1
PE 0012	Eggs	T*0.01
MM 0095	Meat (mammalian)	0.05
ML 0106	Milks	0.05
PM 0110	Poultry meat	T*0.01
PO 0111	Poultry, edible offal of	T*0.01
VD 0070	Pulses	T0.1
SO 0495	Rape seed [canola]	T0.2
Pydiflumetofen		
MO 0105	Edible offal (mammalian)	*0.01
PE 0012	Eggs	*0.01
MM 0095	Meat (mammalian)	*0.01
ML 0106	Milks	*0.01
PM 0110	Poultry meat	*0.01
PO 0111	Poultry, edible offal of	*0.01
VD 0070	Pulses	T0.5
SO 0495	Rape seed [canola]	T0.07

Table 7: Current MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Fludioxonil		
AL 0157	Legume animal feeds	30
	Rape seed [canola] forage (fresh weight)	*0.01
	Rape seed [canola] straw and fodder	*0.02
Pydiflumetofen		
	Primary feed commodities {except Rape seed [canola] forage; Rape seed [canola] straw and fodder, dry}	0.2
	Rape seed [canola] forage	3

Table 8: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Fludioxonil		
Delete:		
PE 0012	Eggs	T*0.01
PM 0110	Poultry meat	T*0.01
PO 0111	Poultry, edible offal of	T*0.01
VD 0070	Pulses	T0.1
SO 0495	Rape seed [canola]	T0.2
Add:		
PE 0012	Eggs	*0.01
PM 0110	Poultry meat	*0.01
P0 0111	Poultry, edible offal of	*0.01
VD 0070	Pulses	0.1
SO 0495	Rape seed [canola]	*0.01
Pydiflumetofen		
Delete:		
MO 0105	Edible offal (mammalian)	*0.01

Compound	Food	MRL (mg/kg)
MM 0095	Meat (mammalian)	*0.01
VD 0070	Pulses	T0.5
SO 0495	Rape seed [canola]	T0.07
Add:		
MO 0105	Edible offal (mammalian)	0.02
MM 0095	Meat (mammalian) [in the fat]	0.02
VD 0070	Pulses	0.4
SO 0495	Rape seed [canola]	0.05

Proposed MRL changes for canola seed will not be actioned until the expiry of current research permits.

Table 9: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Fludioxonil		
Delete:		
	Rape seed [canola] forage (fresh weight)	*0.01
Add:		
	Rape seed [canola] forage	1
Pydiflumetofen		
Delete:		
	Primary feed commodities {except Rape seed [canola] forage; Rape seed [canola] straw and fodder, dry}	0.2
	Rape seed [canola] straw and fodder, dry	0.1
Add:		
	Primary feed commodities {except Pulse forage and fodder; Rape seed [canola] forage}	0.2
	Pulse forage and fodder	10

Potential risk to trade

Export of treated produce containing finite (measurable) residues of fludioxonil and pydiflumetofen 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.

For SO 0495 rape seed [canola], a fludioxonil MRL at *0.01 mg/kg is proposed with international fludioxonil MRLs/tolerances established in most markets at *0.01 to 0.05 mg/kg. As finite residues of fludioxonil are not expected in canola seed, following treatment at the proposed GAP, the potential risk to Australian trade is considered to be low.

For VD 0070 pulses, a fludioxonil MRL 0.1 mg/kg is proposed, again international fludioxonil MRL/tolerances are established in most markets generally at between 0.4 to 0.5 mg/kg in most dried beans, 0.07 to 0.4 mg/kg in dried peas and 0.01 to 0.2 mg/kg in dried soya beans (soya beans are not listed as a major export commodity²²). It is noted that the STMR from the available pulse trial data was at the LOQ (0.02 mg/kg). Considering that there is generally appropriate international MRL/tolerance coverage for the proposed MRL for pulses, the potential risk to Australian trade is considered to be low.

Pydiflumetofen MRLs are proposed for SO 0495 rape seed [canola] at 0.05 mg/kg and VD 0070 pulses at 0.4 mg/kg. Codex MRLs are not currently established for pydiflumetofen in canola or pulses however the 2019 JMPR has recommended an MRL for SO 2090 small seed oilseeds at 0.9 mg/kg and for VD 2065 dried beans (subgroup 015A) and VD 2066 dried peas (subgroup 015B) at 0.4 mg/kg which will be considered for adoption by Codex in the CCPR meeting scheduled for 2021. The USA, Canada, Japan have established MRLs for the rapeseeds subgroup at 0.9 mg/kg and for pulses, either as subgroups or individually, at 0.4 mg/kg. Korea has a temporary MRL established for rape seed at 0.9 mg/kg and beans at 0.4 mg/kg. The EU, Taiwan and China have yet to establish MRLs for pydiflumetofen. The proposed pydiflumetofen MRL for SO 0495 rape seed [canola] at 0.05 mg/kg is consistent with the MRL recommended for the registered use of pydiflumetofen on canola under Miravis Adepidyn Active Fungicide. Potential risks to Australian trade were considered under that evaluation and are summarised in the Public Release Summary (PRS)²³. As residues pydiflumetofen in canola from the proposed use are expected to be similar to those previously considered and there is now improved international MRL coverage, the potential risk to Australian trade has not increased from that previously considered and is considered to be low.

Low finite residues of pydiflumetofen may occur in mammalian fat and liver as a result of the proposed use, therefore pydiflumetofen MRLs for MM 0095 meat (mammalian) [in the fat] and MO 0105 edible offal are proposed at 0.02 mg/kg. Codex MRLs are not currently established for pydiflumetofen in animal commodities however the 2019 JMPR has recommended pydiflumetofen MRLs for meat, mammalian fat and edible offal (mammalian) at 0.1 mg/kg. The USA, Canada, Japan have established MRLs for cattle meat at 0.01 mg/kg and for cattle fat and cattle by products at 0.03 mg/kg. Korea has provisional MRLs established for cattle

²² Australian Pesticides and Veterinary Medicines Authority, [Major export food commodity groups](#), *Pesticides: Overseas trade (Part 5B)*, APVMA website, 20 July 2020, accessed 27 February 2021.

²³ Australian Pesticides and Veterinary Medicines Authority, [Public Release Summary – Miravis Fungicide](#), APVMA website, 27 February 2018, accessed 26 February 2021.

meat and cattle by-products at 0.03 mg/kg. Again, the EU, Taiwan and China have yet to establish MRLs for pydiflumetofen.

Finite residues of pydiflumetofen are expected in canola, pulses and mammalian fat and liver. Established international MRLs/tolerances are above the proposed Australian MRL but not in all markets. Given that Codex, the EU, Taiwan and China have not yet established pydiflumetofen MRLs in pulses or animal commodities industry is invited to provide comment on how the potential risks might be managed particularly given the delays in the establishment of appropriate Codex MRLs for pydiflumetofen.

Conclusion

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Australia Pty Limited for registration of Miravis Star Adepidyn Technology Fungicide, containing fludioxonil and pydiflumetofen, for use on canola and pulses.

Comment is sought on the potential for Miravis Star Adepidyn Technology Fungicide to prejudice Australian trade when used on canola and pulses according to the proposed label directions.