Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on methoxyfenozide and spinetoram in the product Intrepid Edge Insecticide for use on cotton, chickpeas, mung beans, soybeans and maize

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This publication is available from the APVMA website.

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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 Trade Advice Notice indicates that the 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 Intrepid Edge Insecticide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider 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 27 October 2022 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 considered 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.

Introduction

The APVMA has before it an application from Corteva Agriscience Australia Pty Ltd to register Intrepid Edge Insecticide for use on cotton, chickpeas, mung beans, soybeans and maize. Intrepid Edge Insecticide is a suspension concentrate (SC) formulation that contains methoxyfenozide and spinetoram as its only active ingredients.

Use of methoxyfenozide on cotton was previously approved under the product Prodigy 240 SC Insecticide, which is no longer registered. Methoxyfenozide was registered in cotton in 2002 at up to 600 g ai/ha, with up to 3 sprays, 10 days apart, with a 4-week harvest WHP and a grazing restraint for cotton stubble and trash[1]. The Maximum Residue Limit (MRL) for cottonseed was set at 3 mg/kg and is still in place. The cotton claim on the Prodigy label was subsequently removed in late 2006 for reasons not related to residues and trade.

Similar uses to those proposed for spinetoram on cotton, chickpeas, mung beans and soybeans are already registered (see label for Success Neo Jemvelva Insecticide P64109). There is also a current emergency permit for use of spinetoram on maize cereals to control Fall Army Worm (PER89390, expires 30 April 2023).

[1] Australian Pesticides and Veterinary Medicines Authority (APVMA), 2015. *Public Release Summary on methoxyfenozide in the product Prodigy 240 SC Insecticide*, APVMA website, accessed August 2022.

Trade considerations

Commodities exported

Cotton seed (including derived oils and meals), chickpeas, mung beans and maize are major export commodities[2], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated pulse and maize crops. Residues in these commodities resulting from the use of Intrepid Edge Insecticide may have the potential to unduly prejudice trade. Soybeans are not considered to be a major export commodity so do not require consideration with respect to trade except in regard to feeding grain, forage and fodder to livestock.

Quantifiable residues are not expected to occur in maize grain from the proposed uses so the risk to trade in maize grain is low, but consideration is given to feeding maize forage and fodder to livestock. In addition, no changes are required to the methoxyfenozide milk MRL or to the spinetoram pulse and animal commodity MRLs. Overseas spinetoram animal commodity MRLs will only be considered in relation to the proposed export slaughter intervals.

Destination and value of exports

In the 2020 fiscal year Australia exported 35.2 kt of cotton seed 15.0 kt of cotton seed oil and 0.01 kt of cotton seed meal. Major export destination for cotton seed were Korea and Japan (ABARES Agricultural Commodity Statistics)[3].

In the 2020 fiscal year Australia exported 764.7 kt of chickpeas valued at $543 million (ABARES Agricultural Commodity Statistics.3 Export figures for mung beans were not recorded by ABARES. Export destinations for Australian pulses include Asia, North Africa, the Middle East and the Indian sub-continent[4].

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B).

[2] Australian Pesticides and Veterinary Medicines Authority (APVMA), 2014. *APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B)*, APVMA website, accessed August 2022.

[3] Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), 2021. *Agricultural commodities and trade data 2021*, ABARES website, accessed August 2022.

[4] Pulse Australia, 2015. *Pulse Australia – Australian Pulse Bulletin: Marketing Pulses*, Pulse Australia website, 20 November 2015, accessed August 2022.

Proposed Australian use pattern

Intrepid Edge Insecticide (300 g/L methoxyfenozide, 60 g/L spinetoram).

Table 1: Proposed use pattern

Crop	Pest	Rate (mL/ha)	Critical comments
Chickpea	Heliothis (*Helicoverpa spp.*) Cotton bollworm (*Helicoverpa armigera*) Native budworm (*Helicoverpa punctigera*)	300 to 350 (up to 105 g methoxyfenozide+ 21 g spinetoram/ha)	Product can be applied twice up to early pod development.
Cotton	Fall armyworm (*Spodoptera frugiperda*)	500 (150 g methoxyfenozide+ 30 g spinetoram/ha)	Product can be applied either twice to the crop during flowering or once at flowering and once up to 28 days before harvest. When targeting western flower thrips, use this product as part of the western flower thrips resistance management strategy (see end of table for details).
	Western flower thrips	800 mL/ha + wetter (240 g methoxyfenozide+ 48 g spinetoram/ha)	
Maize	Fall armyworm (*Spodoptera frugiperda*)	500 (150 g methoxyfenozide+ 30 g spinetoram/ha)	Product can be applied twice, 7 days apart. Maize: Apply when fall army worm exceed spray thresholds anytime during crop development up to 28 days prior to harvest.
Mung bean Soybean	Heliothis (*Helicoverpa spp.*) Cotton bollworm (*Helicoverpa armigera*) Native budworm (*Helicoverpa punctigera*) Loopers (*Chrysodeixis spp.*) Soybean looper (*Thysanoplusia orichalcea*)	400 to 600 (up to 180 g methoxyfenozide+ 36 g spinetoram/ha)	Mung beans: Product can be applied twice up to early pod development. Soybeans: Product can be applied either twice to the crop during flowering or once at flowering and once up to 14 days before harvest. Use the low rate against light Heliothis infestations and the higher rate when infestations are heavy.
	Fall armyworm (*Spodoptera frugiperda*)	500 (150 g methoxyfenozide+ 30 g spinetoram/ha)	

Restraints

DO NOT apply to chickpeas and mung beans after early pod development.

Withholding periods

Harvest:

Chickpeas, mung beans – NOT REQUIRED WHEN USED AS DIRECTED

Cotton and Maize – DO NOT HARVEST FOR 28 DAYS AFTER APPLICATION

Soybeans – DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION

Grazing

Chickpeas and mung beans:

Grazing or cutting for meat production – DO NO GRAZE OR CUT FOR STOCKFEED FOR 14 DAYS AFTER APPLICATION.

Restraint – Grazing or cutting for milk production (forage): DO NOT FEED OR ALLOW LACTATING DAIRY ANIMALS PRODUCING MILK FOR HUMAN CONSUMPTION TO GRAZE TREATED PULSE OR LEGUME VEGETABLE FORAGE.

Grazing or cutting for milk production (fodder, i.e. hay or straw) – DO NOT GRAZE OR CUT FODDER FOR STOCKFEED FOR LACTATING DAIRY ANIMALS FOR 14 DAYS AFTER APPLICATION.

Soybeans:

Grazing or cutting for meat production – DO NO GRAZE OR CUT FOR STOCKFEED FOR 14 DAYS AFTER APPLICATION.

Restraint – Grazing or cutting for milk production (forage): DO NOT FEED OR ALLOW LACTATING DAIRY ANIMALS PRODUCING MILK FOR HUMAN CONSUMPTION TO GRAZE TREATED PULSE OR LEGUME VEGETABLE FORAGE.

Grazing or cutting for milk production (fodder, i.e. hay or straw) – DO NOT GRAZE OR CUT FODDER FOR STOCKFEED FOR LACTATING DAIRY ANIMALS FOR 14 DAYS AFTER APPLICATION.

Restraint – Cotton: DO NOT GRAZE OR CUT TREATED COTTON CROPS, STUBBLE OR GIN TRASH.

Maize – DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 14 DAYS AFTER APPLICATION.

Trade advice

TRADE ADVICE: Intrepid Edge® may leave detectable chemical residues in harvested produce. Overseas markets may not have appropriate residue tolerances in place or may have established tolerances which are

lower than Australian maximum residue limits. Some crops for export to these destinations may require a longer harvesting withholding period. If you are using this product on crops destined for export, please contact your exporter for advice.

Livestock destined for export markets

To ensure compliance with residue standards in export markets, comply with the above grazing withholding periods and then ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

Export Slaughter Interval:

Chickpeas, mung beans, soybeans – 7 days

This means that livestock that have grazed on or were fed treated crops should be placed on clean feed for at least the periods stated above prior to slaughter.

Results from residues trials presented to the APVMA

Cotton

Use of methoxyfenozide on cotton was previously supported at higher rates and the MRL is still in place[5]. The previously submitted Australian trials and the US trials (results scaled to a 600 g ai/ha rate) were considered as a single population, giving residues of methoxyfenozide in cotton seed 28 days after last application of <0.05, <0.05, <0.05, <0.05, 0.47, 0.50, 0.87, 1.13 and 1.79 mg/kg. Residues scaled to the proposed 240 g ai/ha rate would be <0.05 (4), 0.19, 0.20, 0.35, 0.45 and 0.72 mg/kg. The OECD6 MRL calculator recommends an MRL of 1.5 mg/kg (n=9, STMR[7]=0.19 mg/kg). It is recommended that the current methoxyfenozide MRL of 3 mg/kg for SO 0691 Cotton seed be reduced to 2 mg/kg to reflect the new supported use pattern for methoxyfenozide given that the previously considered use pattern is no longer registered.

Spinetoram is currently registered on cotton with a similar use pattern as proposed. No changes are required to the current MRL of *0.01 mg/kg for spinetoram on SO 0691 Cotton seed.

Chickpeas

Residues of methoxyfenozide in chickpea grain at harvest in Australian GLP trials conducted in 2019 and 2020, after 2 applications with the first application being made at BBCH[8] 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 90 g ai/ha (0.6× proposed), were 0.016, 0.017, 0.025, 0.20 and 0.51 mg/kg. Scaled for application rate residues were 0.027, 0.028, 0.042, 0.33 and 0.85 mg/kg. The OECD MRL Calculator recommends an MRL of 2 mg/kg (STMR=0.042 mg/kg, n=5), noting a high uncertainty due to the small dataset. An MRL of 2 mg/kg is recommended for methoxyfenozide on VD 0524 Chick-pea (dry). To ensure the proposed withholding period of “Not required when used as directed” is appropriate the following restraint is proposed: “DO NOT apply to chickpeas after early pod development”. It is noted that the last application in 3 of the 5 trials was later than early pod development but that the second application in the trial that reported the high residue (HR) was made just prior to early pod development (BBCH 69).

Residues of methoxyfenozide in chickpea forage at 14 days after the last of 2 applications with the first application being made at BBCH 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 90 g ai/ha (0.6× proposed) were 1.8, 9.4, 10, 13 and 17 mg/kg on a dry weight basis. Scaled for application rate residues were 3.0, 15.7, 16.7, 21.7 and 28.3 mg/kg. The OECD MRL calculator recommends an MRL of 60 mg/kg (unrounded 54 mg/kg,

[5] Australian Pesticides and Veterinary Medicines Authority (APVMA), 2015. *Public Release Summary on methoxyfenozide in the product Prodigy 240 SC Insecticide*, APVMA website, accessed August 2022.

[6] OECD= Organisation for Economic Co-operation and Development

[7] STMR= Supervised trial median residue

[8] BBCH= Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie (growth scale)

STMR=16.7, n=5), noting a high uncertainty due to the small dataset. An MRL of 50 mg/kg is recommended on Chick-pea forage in conjunction with a 14-day grazing withholding period.

Residues of methoxyfenozide in chickpea straw at harvest after 2 applications with the first application being made at BBCH 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 90 g ai/ha (0.6× proposed) were 2.1, 2.4, 2.7, 2.9 and 3.2 mg/kg. Scaled for application rate residues were 3.5, 4.0, 4.5, 4.8 and 5.3 mg/kg. The OECD MRL calculator recommends an MRL of 15 mg/kg (STMR=4.5 mg/kg, n=5), noting a high uncertainty due to the small dataset. An MRL of 15 mg/kg is recommended for AL 0524 Chick-pea fodder.

Residues of spinetoram in chickpea grain at harvest after 2 applications with the first application being made at BBCH 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 18 g ai/ha (0.6× proposed) were <LOD (Limit of detection=0.006 mg/kg for total, n=5). No changes are required to the current MRL of 0.01 mg/kg for spinetoram on VD 0070 Pulses which covers current registrations (P64109 allows application of spinetoram to chickpeas either twice during flowering or once at flowering and once up to 14 days before harvest at 24 g ai/ha).

Residues of spinetoram in chickpea forage at 14 days after the last of 2 applications with the first application being made at BBCH 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 18 g ai/ha (0.6× proposed) were <LOQ (2), 0.064, 0.078 and 0.097 mg/kg on a dry weight basis. Scaled for application rate residues were <0.03 (2), 0.11, 0.13 and 0.16 mg/kg, noting it is not usually appropriate to scale up results that are <LOQ (limit of quantitation). The OECD MRL calculator recommends an MRL of 0.4 mg/kg (STMR=0.11 mg/kg, n=5), noting a high uncertainty due to the small dataset.

Residues of spinetoram in chickpea straw at harvest after 2 applications with the first application being made at BBCH 65 to 71 and the second was approximately 21 days later (BBCH 69, 73 to 74, 79, 79 to 82 and 82 to 86) at approximately 18 g ai/ha (0.6× proposed) were <LOQ (4) and 0.039 mg/kg. Scaled for application rate the HR is 0.065 mg/kg.

No changes are required to the current MRL of 1 mg/kg for spinetoram on AL 0157 Legume animal feeds.

Mung beans

Residues of methoxyfenozide in mung bean grain at harvest in Australian GLP trials conducted in 2020 and 2021, after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 90 to 180 g ai/ha (0.5 to 1× proposed), were 0.006, 0.016, 0.066 and 0.12 mg/kg. Scaled for application rate residues were 0.012, 0.032, 0.066 and 0.24 mg/kg. The OECD MRL calculator recommends an MRL of 0.5 mg/kg (STMR=0.049 mg/kg, n=4), noting a high uncertainty due to the small dataset. An MRL of 0.5 mg/kg is recommended for methoxyfenozide on VD 0536 Mung bean (dry). To ensure the proposed withholding period of “Not required when used as directed” is appropriate the following restraint is proposed: “DO NOT apply to mung beans after early pod development”. It is noted that the last application in 2 of the 4 trials was later than early pod development but that the second application in the trial that reported the high residue (HR) was made during early pod development (BBCH 71 to 72).

Residues of methoxyfenozide in mung bean forage at approximately 14 days after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 90 to 180 g ai/ha (0.5 to 1× proposed) were 3.9, 11, 13 and 21 mg/kg on a dry weight basis. Scaled for application rate 7.8, 21, 22 and 26 mg/kg. The OECD MRL calculator recommends an MRL of 60 mg/kg (STMR=21.5 mg/kg, n=4), noting a high uncertainty due to a small dataset. An MRL of 50 mg/kg is recommended on Mung bean forage in conjunction with a 14-day grazing withholding period.

Residues of methoxyfenozide in mung bean straw at harvest after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 90 to 180 g ai/ha (0.5 to 1× proposed) were 0.19, 3.3, 6.4 and 17 mg/kg. Scaled for application rate residues were 0.38, 6.6, 12.8 and 17 mg/kg. The OECD MRL calculator recommends an MRL of 40 mg/kg (STMR=9.7 mg/kg, n=4), noting a high uncertainty due to the small dataset. An MRL of 30 mg/kg is recommended for Mung bean fodder.

Residues of spinetoram in mung bean grain at harvest after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 18 to 36 g ai/ha (0.5 to 1× proposed) were <LOD (<0.006 and <0.006 (3) mg/kg). While it is not possible to scale up residues below the LOD for application rate, spinetoram is already registered for use on mung beans at rates up to 36 g ai/ha. P64109 allows application of spinetoram to mung beans either twice during flowering or once at flowering and once up to 14 days before harvest. The registered use of spinetoram on mung beans therefore has a higher residue potential than the use supported here. No changes are required to the current MRL of 0.01 mg/kg for spinetoram on VD 0070 Pulses.

Residues of spinetoram in mung bean forage at approximately 14 days after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 18 to 36 g ai/ha (0.5 to 1× proposed) were 0.01, 0.03, 0.18 and 0.18 mg/kg on a dry weight basis. Scaled for application rate 0.02, 0.06, 0.18 and 0.36 mg/kg. The OECD MRL calculator recommends an MRL of 0.8 mg/kg (STMR=0.12 mg/kg, n=4), noting a high uncertainty due to a small dataset.

Residues of spinetoram in mung bean straw at harvest after 2 applications with the first application being made at BBCH 64 to 67 and the second was approximately 21 days later (BBCH 71, 71 to 72, 78 to 81 and 78 to 81) at approximately 18 to 36 g ai/ha (0.5 to 1× proposed) were <LOD (2), 0.047 and 0.051 mg/kg. Scaled for application rate the finite residues were 0.047 and 0.102 mg/kg.

No changes are required to the current MRL of 1 mg/kg for spinetoram on AL 0157 Legume animal feeds for the use supported here on mung beans.

Soybeans

Residues of methoxyfenozide in soybean seed in North American trials at 14 to 15 days after the last of 4 applications at 280 g ai/ha (1.6× proposed) were 0.026, 0.033, 0.033, 0.044, 0.052, 0.057, 0.070, 0.073, 0.092, 0.10, 0.11, 0.14, 0.22, 0.45 and 1.2 mg/kg. Scaled for the proposed application rate residues were 0.016, 0.021, 0.021, 0.028, 0.033, 0.036, 0.044, 0.046, 0.058, 0.063, 0.069, 0.088, 0.14, 0.28 and 0.75 mg/kg. The OECD MRL calculator recommends an MRL of 0.9 mg/kg (STMR=0.046 mg/kg, n=15).

An MRL of 0.9 mg/kg is recommended for methoxyfenozide on VD 0541 Soya bean (dry) in conjunction with the proposed 14-day harvest withholding period.

Only 2 trials sampled soybean forage at the proposed 14-day grazing withholding period when residues were 2.2 and 2.5 mg/kg. In the available Australian mung bean trials, scaled (for a 180 g ai/ha rate) residues in mung bean forage at 14 days after the last application were 7.8, 21, 22 and 26 mg/kg. The combined dataset relevant to soybean forage is 2.2, 2.5, 7.8, 21, 22 and 26 mg/kg. The OECD MRL calculator recommends an MRL of 60 mg/kg (STMR=14.4 mg/kg, n=6). An MRL of 50 mg/kg is recommended for methoxyfenozide on AL 1265 Soya bean forage and fodder in conjunction with the proposed 14-day grazing withholding period.

Spinetoram is already registered for use on soybeans at rates up to 36 g ai/ha (1× proposed). Product 64109 allows application of spinetoram to soybeans either twice during flowering or once at flowering and once up to 14 days before harvest. The registered harvest and grazing withholding periods for soybeans are each 14 days. No changes are required to the current MRL of 0.01 mg/kg for spinetoram on VD 0070 Pulses or to the current MRL of 1 mg/kg for spinetoram on AL 0157 Legume animal feeds for the use supported here on soybeans.

Maize

Residues of methoxyfenozide in maize grain in North American trials at 28 days after the last of 4 applications at 280 g ai/ha (1.9× proposed) were <0.02 mg/kg (n=2). Scaled for application rate residues would still be <0.02 mg/kg (n=2). Residues of methoxyfenozide in maize grain in European trials at approximately 28 days after the last of 3 applications at around 130 to 150 g ai/ha (~1× proposed) were <0.01 (8) and <0.02 (18) mg/kg. The combined dataset for maize grain is <0.01 (8) and <0.02 (20) mg/kg. An MRL of *0.02 mg/kg is recommended for methoxyfenozide on GC 0645 Maize in conjunction with the proposed 28-day harvest withholding period.

Residues of methoxyfenozide in maize forage in North American trials at 14 days after the last of 4 applications at 280 g ai/ha (1.9× proposed) were 3.03 and 5.42 mg/kg. Scaled for application rate residues were 1.59 and 2.85 mg/kg. Residues of methoxyfenozide in maize whole plants in European trials at approximately 14 days after the last of 3 applications at around 130 to 150 g ai/ha (~1× proposed) were 0.287, 0.375, 0.410, 0.948, 1.142, 2.104, 2.126 and 6.819 mg/kg.

The combined dataset for maize forage/whole plants is 0.287, 0.375, 0.410, 0.948, 1.142, 1.59, 2.104, 2.126, 2.85 and 6.819 mg/kg, assume fresh weight. The OECD Livestock Feed Calculator indicates that corn forage contains 40% dry matter. On a dry weight basis residues were 0.72, 0.94, 1.03, 2.37, 2.86, 3.98, 5.26, 5.32, 7.13 and 17.05 mg/kg (dry weight). The OECD MRL Calculator recommends an MRL of 30 mg/kg (STMR=3.42 mg/kg, n=10). An MRL of 30 mg/kg is recommended for methoxyfenozide on AF 0645 Maize forage in conjunction with the proposed 14-day grazing withholding period.

Residues of methoxyfenozide in maize stover in North American trials at 28 days after the last of 4 applications at 280 g ai/ha (1.9× proposed) were 6.13 and 13.3 mg/kg. Scaled for application rate residues would be 3.23 and 7.0 mg/kg. Residues of methoxyfenozide in maize rest of plant in European trials at approximately 28 days after the last of 3 applications at around 130 to 150 g ai/ha (~1× proposed) were 0.055, 0.220, 0.338, 1.736, 1.774, 1.883, 2.098 and 5.650 mg/kg. The combined dataset for maize stover/rest of plant is 0.055, 0.220, 0.338, 1.736, 1.774, 1.883, 2.098, 3.23, 5.650 and 7.0 mg/kg, assume

fresh weight. The OECD Livestock Feed Calculator indicates that corn stover contains 83% dry matter. On a dry weight basis residues were 0.066, 0.27, 0.41, 2.09, 2.14, 2.27, 2.53, 3.89, 6.81 and 8.43 mg/kg (dry weight). The OECD MRL calculator recommends an MRL of 15 mg/kg. An MRL of 15 mg/kg is recommended for AS 0645 Maize fodder in conjunction with the proposed 28-day harvest withholding period.

Residues of spinetoram in maize grain in European trials at 19 to 33 days after the last of 3 applications at 50 g ai/ha (1.7× proposed) were <0.02 mg/kg (n=4, all residue below LOD of 0.003 mg/kg for each component). Residues were also <LOD (0.003 mg/kg) at approximately 30 days after the last of 3 applications at around 15 g ai/ha (0.5× proposed) in 3 Argentinian trials. Given the European trials involved application at higher rates than proposed it is recommended that the current MRL of T*0.01 mg/kg for spinetoram on GC 2091 Maize cereals be made permanent (this MRL covers the use of spinetoram on maize cereals under emergency permit 89390).

Residue data for spinosad have been provided in relation to residues in maize forage. It has previously been accepted that data from spinosad trials can be used to assess residues potential for spinetoram given the similarities in structure and metabolism.[9]

Residues of spinosad in corn forage from European trials at 14 days after the last of 1 to 2 applications at approximately 100 g ai/ha (3.3× proposed) were <0.01, <0.01, 0.014, 0.018, 0.019, 0.019, 0.021, 0.022, 0.024, 0.028, 0.033, 0.050, 0.080 and 0.108 mg/kg. Scaled for application rate residues were <0.01, <0.01, 0.004, 0.005, 0.006, 0.006, 0.006, 0.007, 0.007, 0.008, 0.010, 0.015, 0.024 and 0.033 mg/kg assume fresh weight. The OECD Livestock Feed Calculator indicates that maize forage contains 40% dry matter. On a dry weight basis residues were <0.01, <0.01, 0.011, 0.014, 0.014, 0.014, 0.016, 0.017, 0.018, 0.021, 0.025, 0.038, 0.061 and 0.082 mg/kg dry weight. The OECD MRL Calculator recommends an MRL 0.15 mg/kg (STMR=0.017 mg/kg, n=14).

Residue data relevant to maize fodder at harvest have not been provided but would be expected to have a lower residue potential than maize forage at a 14-day grazing withholding period.

The current temporary MRLs of T1 and T3 mg/kg for Maize cereals fodder and Maize cereals forage respectively were set for emergency permit 89390 (24 April 2020 to 30 April 2023). The permit allows 2 applications of spinetoram each at 36 g ai/ha (1.2× the proposed rate for Intrepid) with a 14-day grazing withholding period. The MRLs were based JMPR data for spinetoram and spinosad on sweet corn forage and fodder. However, the PHIs in the JMPR trials were 3 to 7 days, considerably less than the 14-day grazing withholding period which is associated with the permit and is proposed for this product.

It is recommended that the current temporary MRLs of T1 and T3 mg/kg for spinetoram on Maize cereals fodder and Maize cereals forage be replaced with a permanent MRL of 0.3 mg/kg for Maize cereals forage and fodder in conjunction with the proposed 14-day grazing withholding period based on the data considered here. This recommended MRL will cover residues expected from the emergency permit use based on the new data submitted with this application.

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[9] Australian Pesticides and Veterinary Medicines Authority (APVMA), 2015. *Public Release Summary on spinetoram in the product Delegate Insecticide*, APVMA website, accessed August 2022.

Australian Pesticides and Veterinary Medicines Authority (APVMA), 2015. *Trade Advice Notice on spinetoram in the product Success Neo Insecticide*, APVMA website, accessed August 2022.

Animal commodities

Methoxyfenozide

The highest methoxyfenozide residue in an animal feed from cotton, chickpeas, mung beans, soybeans and maize following the proposed use was 28.3 mg/kg in chickpea forage. According to the OECD Livestock Feed Calculator soybean forage can form 100% of the diet for beef cattle in Australia and 40% for dairy cattle. The APVMA Part 5B guideline indicates that forage from legumes can also form 100% of the diet for cattle in Australia. The maximum mammalian livestock dietary burden for methoxyfenozide will be taken as 28.3 ppm.

It is noted that the current temporary methoxyfenozide MRLs of T200 mg/kg for Pea vines (green) and Sweet corn forage and fodder are associated with permits (80954 and 84531) which have slaughter intervals to ensure current mammalian commodity MRLs remain appropriate.

Estimated methoxyfenozide residues in tissues and milk for a dietary burden of 28.3 ppm (extrapolated from the available animal transfer study involving dosing at 45 ppm) and required MRLs are summarised below:

Table 2: Estimated methoxyfenozide residues in cattle tissues and milk

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
	Methoxyfenozide residue (mg/kg)				
45 (feeding study)	0.0076	<LOD	0.0305	0.038	0.082
28.3 – beef, estimated burden	-	<LOD	0.019	0.024	0.052
28.3 – dairy, estimated burden	0.0048	-	-	-	-
Established MRLs	*0.01 (milks)	*0.01 (meat in fat)	*0.01 (offal)		-
Recommended MRLs	No change	0.1 (fat)	0.05 (offal)		

The following methoxyfenozide mammalian commodity MRLs are recommended:

MO 0105 Edible offal (mammalian): 0.05 mg/kg (increase)

MM 0095 Meat (mammalian)[in the fat]: 0.1 mg/kg (increase)

ML 0106 Milks: *0.01 mg/kg (no change)

Spinetoram

A Maize cereals forage and fodder MRL has been proposed for spinetoram at 0.3 mg/kg which is less than the currently established MRL for Legume animal feeds at 1 mg/kg. As legume animal feeds can form 100% of the diet for mammalian livestock the maximum livestock dietary burden is unchanged and current mammalian commodity MRLs should remain appropriate noting that the following grazing withholding periods/restraints have been proposed with respect to dairy cattle for chickpea, mung bean and soya bean forage and fodder:

Grazing or cutting for milk production (forage): DO NOT FEED OR ALLOW LACTATING DAIRY ANIMALS PRODUCING MILK FOR HUMAN CONSUMPTION TO GRAZE TREATED PULSE OR LEGUME VEGETABLE FORAGE.

Grazing or cutting for milk production (fodder, i.e. hay or straw): DO NOT GRAZE OR CUT FODDER FOR STOCKFEED FOR LACTATING DAIRY ANIMALS FOR 14 DAYS AFTER APPLICATION.

These are the same as on the current label for Success Neo Jemvelva Active Insecticide (P64109) for similar uses and should ensure that the spinetoram milk and milk fats MRLs remain appropriate.

It is noted that maize forage with a spinetoram HR of 0.082 mg/kg dry weight would not be expected to give quantifiable residues in milk. Separate grazing withholding periods/restraints for dairy cattle are not required for maize.

Poultry

Poultry commodity MRLs have not been established for methoxyfenozide and were not required for the previous use on cotton. The current MRL of 3 mg/kg for methoxyfenozide on cotton seed will be reduced to 2 mg/kg. Quantifiable residues are not expected to occur in maize grain from the proposed use. APVMA Guidelines indicate that pulses can form 100% of the diet for poultry. Based on the HR of 0.85 mg/kg in chickpea seed as a worst case and a dry matter content of 89% the dietary burden associated with pulse crops is 0.96 ppm.

Estimated methoxyfenozide residues in poultry eggs and tissues from feeding at 0.96 ppm from the proposed use on pulses are summarised below (extrapolated from the available animal transfer study involving dosing at 2 ppm):

Table 3: Estimated methoxyfenozide residues in poultry tissues and eggs

Feeding level (ppm)	Eggs	Muscle	Liver	Kidney	Fat
					Methoxyfenozide residue (mg/kg)
2 (feeding study)	<0.003	<0.003	<0.003	-	<0.003
0.96 – estimated burden	<0.003	<0.003	<0.003	-	<0.003
Established MRLs	- (milks)	- (meat)		- (offal)	-
Recommended MRLs	*0.01	*0.01 (meat in fat)		*0.01	-

The following poultry commodity MRLs are recommended for methoxyfenozide:

PE 0112 Eggs: *0.01 mg/kg

PM 0110 Poultry meat [in the fat]: *0.01 mg/kg

PO 0111 Poultry, edible offal of: *0.01 mg/kg

Quantifiable residues of spinetoram are not expected to occur in maize grain from the proposed use. The proposed uses on pulses are similar to those already registered. The current poultry commodity MRLs for spinetoram should remain appropriate.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Methoxyfenozide and spinetoram have been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for methoxyfenozide and spinetoram.

Table 4: International MRLs for methoxyfenozide

Commodity	Tolerance for residues arising from the use of methoxyfenozide (mg/kg)						
	Australia	Codex[10]	EU[11]	Japan[12]	Korea[13]	Taiwan[14]	USA[15]
Residue Definition	Methoxyfenozide	Methoxyfenozide	Methoxyfenozide	Methoxyfenozide	-	-	Methoxyfenozide (or methoxyfenozide and its glucuronide metabolite (liver and meat byproducts)
Edible offal (mammalian)	*0.01 (current) 0.05 (proposed)	0.2	0.2 (bovine, sheep)	0.2 (cattle)	0.2 (mammalian by-product)	-	0.40 (Cattle liver) 0.10 (Cattle, meat byproducts, except liver)
Meat (mammalian)[in the fat]	*0.01 (current) 0.1 (proposed)	0.3 (Meat (from mammals other than marine mammals)(fat))	0.01* (bovine, sheep muscle) 0.3 (bovine, sheep fat)	0.2 (cattle muscle) 0.3 (cattle fat)	0.02 (mammalian meat) 0.3 (mammalian fat)	-	0.02 (cattle meat) 0.50 (cattle fat)

[10] Food and Agriculture Organisation of the United Nations (FAO), 2022. *Codex Alimentarius, International Food Standards,* FAO website, accessed August 2022.

[11] European Commission (EC), 2015. *EU Pesticide residue(s) and maximum residue levels (mg/kg),* EC website, accessed August 2022.

[12] Japanese Food Chemistry Research Foundation (JFCRPF), 2022. *Table of MRLs for Agricultural Chemicals,* JFCRPF website, accessed August 2022.

[13] Ministry of Food and Drug Safety Korea, 2015. *MRLs in Pesticides*, Ministry of Food and Drug Safety Korea website, accessed August 2022.

[14] Taiwan Food and Drug Administration, 2015. *Standards for Pesticide Residue Limits in Foods*, Taiwan FDA website, accessed August 2022.

[15] Electronic Code of Federal Regulations (eCFR), 2022. *Part 180 – Tolerances and exemptions for pesticide chemical residues in food,* eCFR website, accessed August 2022.

Commodity	Tolerance for residues arising from the use of methoxyfenozide (mg/kg)						
	Australia	Codex[10]	EU[11]	Japan[12]	Korea[13]	Taiwan[14]	USA[15]
Chick-pea (dry)	2 (proposed)	5 (Peas (dry)) (Pisum spp.; Vigna spp. based on Codex classification)	5 (Peas)	5 (Peas) 5 (other legumes/pulses)	0.2 (pea)	5 (Pea, (dry))	0.5 (Pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed)
Mung bean (dry)	0.5 (proposed)	0.5 (Beans (dry))	0.5 (Beans)	5 (Beans, dried) 5 (other legumes/pulses)	0.05	0.5 (other dry beans, except soybean)	0.5 (Pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed)
Soybean (dry)	0.9 (proposed)	0.5 (Beans (dry))	0.5 (Beans)	0.5	0.5	1.0	1.0
Cotton seed	3 (current) 2 (proposed)	7	7	7	-	7	2

Table 5: International MRLs for spinetoram

Commodity	Tolerance for residues arising from the use of spinetoram (mg/kg)							
	Australia	Canada	Codex	EU (proposed)*	Japan	Korea	Taiwan	USA
Residue Definition	Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L	XDE-175-J and XDE-175-L including the metabolites N-demethyl-175-J and N-formyl-175-J	Spinetoram	Spinetoram	Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L	-	-	Spinosyn-J, spinosyn-L, N-demethyl spinosyn-J and N-formyl spinosyn-J
Edible offal (mammalian)	0.2 (current)	0.6 (Meat byproducts of cattle except liver)	0.1	0.1 (Except liver and kidney)	0.1	0.01	0.6 (Except liver)	0.60 (Meat byproducts except liver)
Fat of cattle		5.5		0.2	1	0.2	5.5	5.5
Kidney of cattle				0.1	0.1			
Liver of cattle		0.85		0.1	0.1		0.85	0.85
Meat (mammalian) [in the fat]	2 (current)		1 (Mammalian fats except milk fats)					
Meat of cattle		0.2	1 (Meat from mammals other than marine mammals) (fat)	*0.01	1	0.01	0.2	0.20
Milk	0.01 (current)	0.3	0.02	*0.01	0.02	0.01 (Fat)	0.3	0.30

Commodity	Tolerance for residues arising from the use of spinetoram (mg/kg)							
	Australia	Canada	Codex	EU (proposed)*	Japan	Korea	Taiwan	USA
Milk fats	0.2 (current)	7.5	0.15				7.5	7.5

Note: XDE-175-J = ethyl-spinosyn-J and XDE-175-L = ethyl-spinosyn-L;

*Information about proposed MRLs in Europe is from the Applicant, currently the EU animal commodity MRLs are all set at *0.02 mg/kg

Current and proposed Australian MRLs for methoxyfenozide and spinetoram

Table 6: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Methoxyfenozide		
SO 0691	Cotton seed	3
MO 0105	Edible offal (mammalian)	*0.01
MM 0095	Meat (mammalian) [in the fat]	*0.01
ML 0106	Milks	*0.01
Spinetoram		
MO 0105	Edible offal (mammalian)	0.2
PE 0112	Eggs	*0.01
GC 2091	Maize cereals	T*0.01
MM 0095	Meat (mammalian) [in the fat]	2
FM 0183	Milk fats	0.2
ML 0106	Milks	0.01
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	*0.01
VD 0070	Pulses	0.01

Table 7: Current MRL Standard – Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Methoxyfenozide		
	Almond hulls	50
AB 0226	Apple pomace, dry	3
AB 0001	Citrus pulp, dry	10
AB 0269	Grape pomace, dry	3
AL 0528	Pea vines (green)	T200
	Sweet corn forage and fodder	T200
Spinetoram		
AL 0157	Legume animal feeds	1
	Maize cereals fodder	T1
	Maize cereals forage	T3
	Sorghum grain and millet forage and fodder	T0.2

Table 8: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Methoxyfenozide		
Delete:		
SO 0691	Cotton seed	3
MO 0105	Edible offal (mammalian)	*0.01
MM 0095	Meat (mammalian) [in the fat]	*0.01
Add:		
VD 0524	Chick-pea (dry)	2
SO 0691	Cotton seed	2
MO 0105	Edible offal (mammalian)	0.05
PE 0112	Eggs	*0.01
GC 0645	Maize	*0.02
MM 0095	Meat (mammalian) [in the fat]	0.1
VD 0536	Mung bean (dry)	0.5
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat [in the fat]	*0.01
VD 0541	Soya bean (dry)	0.9
Spinetoram		
Delete:		
GC 2091	Maize cereals	T*0.01
Add:		
GC 2091	Maize cereals	*0.01

Table 9: Proposed MRL Standard – Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Methoxyfenozide		
Add:		
AL 0524	Chick-pea fodder	15
	Chick-pea forage	50
AS 0645	Maize fodder	15
AF 0645	Maize forage	30
AL 0536	Mung bean fodder	30
	Mung bean forage	50
AL 1265	Soya bean forage and fodder	50
Spinetoram		
Delete:		
	Maize cereals fodder	T1
	Maize cereals forage	T3
Add:		
	Maize cereals forage and fodder	0.3

Potential risk to trade

Export of treated produce containing finite (measurable) residues of methoxyfenozide and spinetoram 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 proposed methoxyfenozide offal and meat (fat) MRLs are lower than those established by Codex and by the majority overseas markets, although no animal commodity MRLs are established for methoxyfenozide in Taiwan. However, the proposed 7-day ESI which is required for spinetoram will also ensure that there will be no quantifiable residues of methoxyfenozide in animal commodities for export (the methoxyfenozide animal transfer study indicated that residues in tissues were <0.01 mg/kg after 7 days on clean feed when initially dosed at 150 ppm).

The proposed ESIs are the same as required for similar uses on pulse crops for spinetoram for Success Neo Jemvelva Active Insecticide (P64109) and should ensure spinetoram residues in animal commodities are within the MRLs established by most major export markets.

A reduction has been proposed to the current methoxyfenozide cotton seed MRL which remains lower than most of the tolerances established overseas, noting that Korea has not established a relevant MRL.

The proposed methoxyfenozide chick-pea (dry) MRL at 2 mg/kg is lower than the dried pea MRLs established by the EU, Japan and Taiwan, and higher than those established in Korea and the USA. While there is a Codex MRL established for ‘Peas (dry)’ at 5 mg/kg, this is not expected to cover chickpea (Cicer arietinum L).

The proposed methoxyfenozide mung bean (dry) MRL at 0.5 mg/kg is at the same level as the dried beans MRLs established by Codex, the EU, Taiwan and the USA and lower than that for Japan.

Conclusion

The APVMA has before it an application from Corteva Agriscience Australia Pty Ltd to register Intrepid Edge Insecticide for use on cotton, chickpeas, mung beans, soybeans and maize. Comment is sought on the potential for the proposed uses to prejudice Australian trade on chickpeas, mung beans and animal commodities.