



Trade Advice Notice

on cyclobutrifluram in the product VANIVA 450SC TYMIRIUM technology Nematicide for use on fruiting vegetables and cucurbits

APVMA product number 91437

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Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601, Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

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 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 VANIVA 450SC TYMIRIUM technology Nematicide 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 2 September 2025 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 <u>public consultation coversheet</u>).

Please lodge your submission using the <u>public consultation coversheet</u>, 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 574 Canberra ACT 2601, Australia

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 APVMA has before it an application from Syngenta Australia Pty Ltd to register the product VANIVA 450SC TYMIRIUM technology Nematicide for use on fruiting vegetables and cucurbits. The product contains 450 g/L cyclobutrifluram as the only active constituent.

The product Trefinti Turf Nematicide (P91438, 450 g/L cyclobutrifluram), was recently registered for use on turf. The Public Release Summary for this product¹ contains discussion concerning metabolism in plants (wheat, soybeans, potatoes and rotational crops) and animals (hens and goats) and the establishment of appropriate residue definitions for plant and animal commodities for enforcement and dietary exposure assessment.

In addition, the product VICTRATO TYMIRIUM technology Seed Treatment (P91436, 200 g/L cyclobutrifluram) was recently registered for treatment of wheat and barley seed. The Trade Advice Notice for this product² contains discussion concerning residues in barley and wheat grain, straw and forage and recommended MRLs for these matrices and for animal commodities. In addition, based on the results of a confined rotational study, an All other foods MRL was recommended at 0.05 mg/kg and a Table 4 MRL was recommended for Primary feed commodities {except Barley forage; Wheat forage} at 1 mg/kg.

¹ Australian Pesticides and Veterinary Medicines Authority, <u>Public Release Summary on the evaluation of the new active cyclobutrifluram in the product TREFINTI Turf Nematicide</u>, APVMA website, 2024, accessed 21 July 2025.

² Australian Pesticides and Veterinary Medicines Authority, <u>Trade Advice Notice on cyclobutrifluram in the product Victrato Tymirium technology Seed Treatment for use on wheat and barley</u>, APVMA website, 2024, accessed 21 July 2025.

Trade considerations

Commodities exported

The proposed use does not involve direct treatment of major trade commodities, however finite residues may occur in grain and livestock feeds produced from crops grown in rotation with fruiting vegetables and cucurbits treated with the proposed use. A 15 months plant back interval is recommended for cereals, oilseeds and pulses as rotational crops after the proposed use of VANIVA 450SC TYMIRIUM technology Nematicide on fruiting vegetables or cucurbits, to ensure that there are no quantifiable residues in the major export commodities of cereal grains, pulses or oilseeds.

No changes are required to the mammalian and poultry animal commodity MRLs recommended at the time of the residues evaluation for the wheat and barley seed treatment application (VICTRATO TYMIRIUM technology Seed Treatment - P91434).

Proposed Australian use pattern

Table 1: Proposed use pattern – VANIVA 450SC TYMIRIUM technology Nematicide

Crop	Pest	Rate/concentration	Critical comments
Fruiting vegetables (field and protected cropping): including tomato,	Root-knot Nematode (<i>Meloidogyne</i>	550 mL/ha (= 247.5 g ai/ ha)	Apply VANIVA Nematicide as a single trickle/drip application within 3 days of transplanting seedlings or planting seeds.
capsicum, chilli, eggplant Cucurbits (field and protected cropping): including cucumber, zucchini, rockmelon,	eld and pping): umber, kmelon, melon,		Only apply VANIVA where pre-planting soil counts or paddock history indicate that the root-knot nematode population density is above the economic threshold and significant yield loss is expected.
melon, watermelon, pumpkin, Asian melon)			Application placement is important and trickle/drip irrigation tape should be positioned no greater than 12 cm from the plant. VANIVA application through the trickle irrigation should occur in the second quarter of the irrigation cycle after the soil has been partially wetted up.
			Refer to Mixing and Application under General Instructions for detailed information on application methods.
			Best results will be obtained where VANIVA is used as part of an integrated program aimed at reducing overall nematode populations. An application of VANIVA does not provide season long control nor guarantee crops free from nematode root damage at harvest.
			This use may be subject to a CropLife Australia Nematicide and/or Fungicide Resistance Management strategy.

Withholding periods:

Harvest: Not required when used as directed.

Restraints: DO NOT apply more than one application per crop.

DO NOT apply to dry soil.

DO NOT apply to waterlogged soils.

DO NOT apply via flood irrigation or overhead irrigation systems.

VANIVA will control nematodes that are active in the soil.

DO NOT make applications of VANIVA when the soil temperatures do not allow nematode activity.

MINIMUM RECROPPING PERIODS – PLANT BACK PERIODS FOR CROPS FOLLOWING THE APPLICATION OF VANIVA 450SC TYMIRIUM technology Nematicide AT 550 mL/ha

Crop	Months
Cereals, oilseeds and pulses	15

Results from residues trials presented to the APVMA

Rotational crops

A confined rotational study was submitted for the application for the proposed use on wheat and barley seed and the approval of cyclobutrifluram (91436/132222), however field rotational crop studies for cyclobutrifluram have not been submitted to the APVMA.

In the confined rotational crop study, the uptake, distribution and metabolism of [14C]-SYN549522 (cyclobutrifluram) was investigated in representative succeeding crops (*e.g.* spinach, spring wheat and radish). The crops were sown 30, 120 and 273 days after application (DAA) of the test item to a sandy loam soil at a nominal rate of 500 g ai/ha. The actual application rates were approximately 523 g ai/ha for both the [phenyl-U-14C]-SYN549522 and the [pyridinyl-2-14C]-SYN549522 treatments. The radiochemicals were dissolved in aqueous acetonitrile and applied to the soil as a single spray application. The soil containers were maintained outdoors until 28 days after application when they were moved into a glasshouse for the remainder of the crop growth phase.

At each rotational interval, seeds of representative cereal (spring wheat), leafy vegetable (spinach) and root vegetable (radish) crops were sown. Crops were harvested at appropriate immature and mature growth stages and separated into commodities representative of food and feed items (wheat: forage, hay, straw and grain; spinach: immature and mature foliage; radish: foliage and roots).

Noting that the current proposal is for use on fruiting vegetables and cucurbits which are rotational crops, the possibility of quantifiable residues of cyclobutrifluram and metabolites in succeeding crops as a result of the proposed use needs to be considered.

The actual application rates in the confined rotational study are approximately 2.1× the proposed rate per hectare for fruiting vegetables and cucurbits (247.5 g ai/ha).

The following highest residues (at any plant back interval) were observed in the confined rotational study:

Table 2: Residues of parent and metabolites observed in the confined rotational study

Matrix	Residues (mg/kg)			
		nt definition YN549522	Risk assessment definition Parent SYN549522 + SYN510275 + SYN549104 + SYN552202 as parent equivalents	
	From study	1×	From study	1×
Wheat				
Wheat forage	0.364, 0.239, 0.529, 0.384, 0.548, 0.856	0.173, 0.125, 0.251, 0.182, 0.260, 0.406	0.400, 0.465, 0.672, 0.777, 0.587, 1.318	0.190, 0.220, 0.318, 0.368, 0.278, 0.625
Wheat hay	1.230, 1.765, 1.006, 0.910, 1.549, 2.611	0.583, 0.836, 0.477, 0.431, 0.734, 1.237	2.394, 3.143, 1.236, 2.075, 1.779, 3.674	1.13, 1.49, 0.586, 0.983, 0.843, 1.74
Wheat straw	1.152, 1.289, 2.222, 2.089, 1.145, 2.330	0.546, 0.611, 1.053, 0.990, 0.543, 1.104	4.007, 7.49, 3.571, 4.361, 1.813, 5.44	1.90, 3.55 , 1.69, 2.07, 0.859, 2.58
Wheat grain	0.034, 0.053, 0.044, 0.052, 0.023, 0.030	0.016, 0.025 , 0.021, 0.025, 0.011, 0.014	0.043, 0.098, 0.055, 0.078, 0.032, 0.057	0.020, 0.046 , 0.026, 0.037, 0.015, 0.027
Spinach		•		
Immature spinach	0.008, 0.005, 0.008, 0.010, 0.044, 0.016	0.004, 0.002, 0.004, 0.005, 0.021 , 0.008	0.016, 0.084, 0.065, 0.277, 0.318, 0.557	0.008, 0.040, 0.031, 0.131, 0.151, 0.264
Mature spinach	0.018, 0.024, 0.022, 0.021, 0.021, 0.009	0.009, 0.011 , 0.010, 0.010, 0.010, 0.010, 0.004	0.117, 0.327, 0.168, 0.428, 0.129, 0.642	0.055, 0.155, 0.080, 0.203, 0.061, 0.304
Radish				
Radish foliage	0.163, 0.239, 0.121, 0.114, 0.117, 0.169	0.077, 0.113 , 0.057, 0.054, 0.055, 0.080	0.264, 0.680, 0.173, 0.526, 0.130, 0.679	0.125, 0.322 , 0.082, 0.249, 0.062, 0.322
Radish root	0.030, 0.031, 0.017, 0.015, 0.025, 0.032	0.014, 0.015, 0.008, 0.007, 0.012, 0.015	0.036, 0.058, 0.023, 0.035, 0.027, 0.050	0.017, 0.027 , 0.011, 0.017, 0.013, 0.024

1× represents the residue scaled to the proposed application rate per hectare for fruiting vegetables and cucurbits (247.5 g ai/ha)

The highest observed parent cyclobutrifluram residues in rotational food commodities after application at approximately 1× the proposed rate, was in radish foliage (greens) at 0.113 mg/kg. An All other foods MRL at 0.2 mg/kg is necessary to cover residues in food commodities grown after treatment of a primary crop. It is

noted that this recommendation for an All other foods MRL at 0.2 mg/kg supersedes the All other foods MRL established at 0.05 mg/kg for the registered use of cyclobutrifluram on wheat and barley seed.

Further consideration to residues which may occur in grain from rotational sources is required, given that cereals, oilseeds and pulses are major export commodities and international MRLs have not been established for cyclobutrifluram. Wheat is representative of all cereals, pulses and oilseeds in the confined rotational crop guideline and scaled calculations indicate expected residues of 0.011-0.025 mg/kg in wheat grain, across both labels and the three plant back intervals (30, 120 and 273 days after application). At the last plant back interval scaled residues for the two labels were 0.011 and 0.014 mg/kg. Residues for both labels were seen to decline from the 120 DAA samples to the 273 DAA samples. The table below calculates approximately how long residues in wheat grain as a secondary crop would take to reduce to 0.01 mg/kg noting that no cyclobutrifluram MRLs are established in overseas markets for cereal, oilseed or pulse crops.

Table 3: Calculated time for residues in wheat grain as a secondary crop to be $<0.01\,\text{mg/kg}$

Label	Scaled residue in wheat grain at plant back interval of 120 DAA	Scaled residue in wheat grain at plant back interval of 273 DAA	Half-life of residues from plant back intervals of 120 DAA to 273 DAA	Time for residues to decay to 0.010 mg/kg	Total time for residues to decay to 0.010 mg/kg
Phenyl	0.021	0.011	164 days	22.6 days	296 days
Pyridinyl	0.025	0.014	183 days	88.8 days	362 days

Scaled calculations from residues and half-lives observed in the confined rotational crop study for cyclobutrifluram indicate that 362 days (12 months) may be required for residues in to be <0.01 mg/kg in wheat grain in crops grown as a secondary crop. It is however considered that some conservatism is required for a plant back interval for cereals, oilseeds and pulses, given that only a confined rotational crop study (and not field rotational crop studies) are available, as the only grain crop addressed was wheat, and because the use of both scaling and half-life calculations was required.

It is also noted that no residues were detected in harvested barley or wheat grain in 20 Australian cereal trials, including 4 conducted at the 2× application rate (for the cereal use) of approximately 160 g ai/ha which is approximately 0.65× the scaled rate (247.5 g ai/ha) in the confined rotational study which showed residues of 0.011 and 0.014 mg/kg after a plant back interval of 273 DAA (91436/132222). Cereal trials (as a primary crop) however do not address the proposed seasonal rate per hectare for rotational crops (fruiting vegetables and cucurbits) of 247.5 g ai/ha.

A 15 months plant back interval is recommended for cereals, oilseeds and pulses as rotational crops after the proposed use of VANIVA 450SC TYMIRIUM technology Nematicide on fruiting vegetables or cucurbits to ensure that there are no quantifiable residues in the major export commodities of cereal grains, pulses or oilseeds.

The highest observed parent cyclobutrifluram residues in the wheat animal feeds after application at approximately 1× the proposed maximum rate were in wheat forage at 0.406 mg/kg, which consists of 25% dry matter (DM)³, to give a dry weight residue of 1.62 mg/kg,

in wheat hay at 1.237 mg/kg (88% DM)³, to give a dry weight residue of 1.41 mg/kg, and

in wheat straw at 1.104 mg/kg (88% DM)³ to give a dry weight residue of 1.25 mg/kg.

It is noted that the highest residues in wheat forage, hay and straw in the confined rotational crop study were observed from the 273 days plant back interval and therefore residues in forage and fodder of cereals, oilseeds and pulses grown in rotation with treated fruiting vegetables or cucurbits may occur following the recommended 15 months plant back interval.

An MRL for Primary feed commodities at 2 mg/kg would be required to cover residues in animal feeds grown after treatment of a primary crop. It is noted that this recommendation for a Primary feed commodities {except Barley forage; Wheat forage} MRL at 2 mg/kg supersedes the Primary feed commodities {except Barley forage; Wheat forage} MRL at 1 mg/kg, established for the registered use of cyclobutrifluram on wheat and barley seed.

Overseas registration and approved label instructions

The Applicant has indicated that cyclobutrifluram is registered for various uses in a number of African (Zambia and Zimbabwe), Asian (China, India, Oman, Pakistan, Philippines, South Korea, United Arab Emirates and Vietnam), Central American (Belize, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua), European (Belarus) and South American (Argentina, Chile, Colombia, Ecuador, Paraguay and Peru) countries.

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. Cyclobutrifluram has not been considered by Codex.

³ Organisation for Economic Co-operation and Development (OECD), <u>Guidance Document on Residues in Livestock</u>, OECD website, 2013, accessed 21 July 2025.

Current and proposed Australian MRLs for cyclobutrifluram

Table 4: Current MRL Standard - Table1

Comp	oound	Food	MRL (mg/kg)
Cyclo	butrifluram		
		All other foods	0.05
МО	0105	Edible offal (mammalian)	0.5
PE	0112	Eggs	*0.03
MM	0095	Meat (mammalian)	0.05
ML	0106	Milks	0.05
РМ	0110	Poultry meat	*0.03
РО	0111	Poultry, edible offal of	*0.03

Table 5: Proposed MRL Standard - Table1

Compound	Food	MRL (mg/kg)
Cyclobutrifluram		
Delete:		
	All other foods	0.05
Add:		
	All other foods	0.2
VO 0045	Fruiting vegetables, cucurbits	0.1
VO 0050	Fruiting vegetables, other than cucurbits	*0.01

Table 6: Current MRL Standard - Table4

Compound	Food	MRL (mg/kg)
Cyclobutrifluram		
	Barley forage	10
	Primary feed commodities {except Barley forage; Wheat forage}	1
	Wheat forage	10

Table 7: Proposed MRL Standard - Table4

Compound	Food	MRL (mg/kg)
Cyclobutrifluram		
Delete:		
	Primary feed commodities {except Barley forage; Wheat forage	1
Add:		
	Primary feed commodities {except Barley forage; Wheat forage	2

Potential risk to trade

All other foods

The highest observed parent cyclobutrifluram residues in rotational food commodities after application at approximately 1× the proposed rate, was in radish foliage (greens) at 0.113 mg/kg. An All other foods MRL at 0.2 mg/kg is necessary to cover residues in food commodities grown after treatment of a primary crop.

The scaled calculations of residues observed in the confined rotational crop study indicate expected residues of 0.011-0.025 mg/kg in wheat grain, across both radiolabels and the three plant back intervals (30, 120 and 273 days after application). A 15 months plant back interval is recommended for cereals, oilseeds and pulses as rotational crops after the proposed use of VANIVA 450SC TYMIRIUM technology Nematicide on fruiting vegetables or cucurbits, to ensure that there are no quantifiable residues in major export commodities, noting that no residues were detected in harvested barley or wheat grain in 20 Australian cereal trials (91436/132222), including 4 conducted at the 2× application rate of approximately 160 g ai/ha, which is approximately 0.65× the proposed application rate.

Conclusion

Syngenta Australia Pty Ltd has applied to register the product VANIVA 450SC TYMIRIUM technology Nematicide for use on fruiting vegetables and cucurbits. Comment is sought on the potential for the proposed use to pose a risk to Australian trade.