



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



Trade Advice Notice

on cyclobutrifluram in the product Victrato Tymirium technology Seed Treatment
for use on wheat and barley

APVMA product number 91436

December 2024

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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 Victrato Tymirium technology Seed Treatment 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 24 January 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 [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 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 Victrato Tymirium technology Seed Treatment for use on wheat and barley. The product contains 200 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.

¹ Australian Pesticides and Veterinary Medicines Authority, [Public Release Summary on the evaluation of the new active cyclobutrifluram in the product TREFINTI Turf Nematicide](#), APVMA website, 2024, accessed 3 December 2024.

Trade considerations

Commodities exported

Wheat and barley are considered to be major export commodities², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated wheat and barley. Residues in these commodities resulting from the use of Victrato Tymirium technology Seed Treatment may have the potential to unduly prejudice trade.

Destination and value of exports

In 2022–23 Australia exported 32304 kilotonnes (kt) of wheat grain valued at \$16,738 million³. In 2023–24 Australia exported 22454 kt of wheat grain valued at \$9,869 million³.

The 10 largest export markets for Australian wheat in 2023-2024 (in kt) are shown below, with lower quantities going to numerous other countries including (in order of increasing tonnage) United Republic of Tanzania, Egypt, Bangladesh, Saudi Arabia, Mozambique, Singapore, India, Iraq, Oman, Fiji, Taiwan, South Africa, Myanmar, Papua New Guinea, United Arab Emirates and Kuwait³.

Table 1: Largest export markets by tonnage for wheat in 2023–2024

Destination	Amount (kt)
China	4934
Indonesia	4106
Philippines	2591
Vietnam	1465
Yemen	1450
Republic of Korea	1401
Japan	1158
Malaysia	858
New Zealand	632
Thailand	595
Total (including other markets)	22454

² APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

³ Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), [Agricultural commodities and trade data - ABARES](#), ABARES website, 24 September 2024, accessed 3 December 2024.

In 2022–23 Australia exported 7623 kt of barley grain valued at \$3,332 million. In 2023–24 Australia exported 8323 kt of barley grain valued at \$3,320 million³.

The largest export markets for Australian barley in 2023-2024 (in kt) are shown below³.

Table 2: Largest export markets by tonnage for barley in 2023–2024

Destination	Amount (kt)
China	5917
Japan	1078
Thailand	266
Vietnam	226
Republic of Korea	141
Philippines	140
Taiwan	25
United Arab Emirates	15
Saudi Arabia	<<1
Total (including other markets)	8323

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

Proposed Australian use pattern

Table 3: Proposed use pattern – Victrato Tymirium technology Seed Treatment (200 g/L cyclobutrifluram as the only active constituent)

Crop	Pest	Rate	Critical comments
Wheat, Barley	Crown Rot (<i>Fusarium pseudograminearum</i> , <i>F. culmorum</i>) - Suppression	200- 400 mL/ 100 kg seed (=40-80 g a.i./ 100 kg seed)	<p>Apply in slurry with water to clean healthy seed before sowing. Total application volume should be determined through equipment calibration to provide good coverage of all seed. Even coverage of all seeds is essential. Allow seed to dry before bagging or sowing.</p> <p>Crown Rot VICTRATO will significantly reduce the symptoms of Crown Rot, including basal browning and white head expression, assisting in the improvement of crop yields when seasonal growing conditions favour disease development. Use higher rate where soil/stubble testing suggests high inoculum levels are present.</p> <p>VICTRATO should not be used in isolation but as part of a fully integrated management strategy for respective targets. Refer to current industry guidelines for further information.</p> <p>The use of VICTRATO may be subject to CropLife resistance management strategies and should be incorporated into associated management programs.</p> <p><u>Note:</u> Victrato will only control those seed and soil borne diseases listed on the label. For control of other diseases, Victrato should be used in conjunction with a registered seed treatment (eg Vibrance)</p>

Restrains:

PRECAUTIONS

DO NOT use treated seed for animal or human consumption.

DO NOT use treated seed for meal.

DO NOT allow treated seed to contaminate grain or other seed intended for animal or human consumption.

When treated seed is stored it should be kept apart from other grain and the bags or other containers should be clearly marked to indicate the contents have been treated.

Bags which have held treated seed should not be used for any other purpose.

Withholding periods:

Harvest: Not required when used as directed.

Grazing: DO NOT graze treated crops or cut for stock food for 6 weeks after application.

Results from residues trials presented to the APVMA

Barley and wheat grain

As no detectable residues were observed in 20 relevant Australian cereal trials (10 wheat, 6 barley and 4 oats) conducted in 2019 and 2020-2021, including 4 trials conducted at 2× the maximum proposed application rate for barley and wheat, cyclobutrifluram MRLs at *0.01 mg/kg for GC 0640 Barley and GC 0654 Wheat are recommended for the proposed use on barley and wheat, in conjunction with the proposed harvest WHP of “Not required when used as directed”.

Barley and wheat straw

The combined dataset of wheat, barley and oat straw dry weight residues observed at harvest (139-198 DAS) after one seed treatment application of cyclobutrifluram at 79.2-80.5 g a.i./100 kg seed (1× the maximum proposed application rate for barley and wheat) is, in rank order: <0.01 (8), 0.01 (3), 0.02 (3), 0.04 (2), 0.05, 0.08, 0.14 and 0.16 mg/kg (STMR = 0.01 mg/kg, n = 20).

The OECD MRL calculator estimates an MRL of 0.3 mg/kg. Cyclobutrifluram MRLs at 0.3 mg/kg would be appropriate for AS 0640 Barley straw and fodder, dry and AS 0654 Wheat straw and fodder, dry.

Barley and wheat forage

The combined dataset of wheat, barley and oat forage dry weight residues approximately 6 weeks after sowing after one seed treatment application of cyclobutrifluram at 79.2-80.5 g a.i./100 kg seed (1× the maximum proposed application rate for barley and wheat) is, in rank order: 0.63, 1.32, 1.67, 2.28, 2.38, 3.01, 3.49, 3.56, 3.82, 4.27, 4.60 and 5.92 mg/kg (STMR = 3.25 mg/kg, n = 12).

The OECD MRL calculator estimates an MRL of 10 mg/kg. Cyclobutrifluram MRLs at 10 mg/kg are recommended for Barley forage and Wheat forage in conjunction with the proposed WHP of “DO NOT graze treated crops or cut for stock food for 6 weeks after application”.

Rotational crops

The highest observed parent cyclobutrifluram residues in rotational food commodities after application of [¹⁴C]-cyclobutrifluram to soil at approximately 1× the proposed maximum rate (based on an estimated seeding rate of 100 kg seed/ha) were in radish foliage (greens) at 0.037 mg/kg. An “All other foods” MRL at 0.05 mg/kg is necessary to cover residues in food commodities grown after treatment of a primary crop.

The highest observed parent cyclobutrifluram residues in the wheat animal feeds after application of [¹⁴C]-cyclobutrifluram to soil at approximately 1× the proposed maximum rate (based on an estimated seeding rate of 100 kg seed/ha) were in wheat forage at 0.132 mg/kg which consists of 25% dry matter (DM), to give a dry weight residue of 0.53 mg/kg, in wheat hay at 0.402 mg/kg (88% DM), to give a dry weight residue of 0.46 mg/kg, and in wheat straw at 0.358 mg/kg (88% DM) to give a dry weight residue of 0.41 mg/kg.

An MRL for Primary feed commodities {except Barley forage; Wheat forage} at 1 mg/kg would be required to cover residues in animal feeds grown after treatment of a primary crop and will also cover residues in wheat and barley straw and fodder, dry from primary crops.

Animal commodities

Based on the wheat forage highest residues (HR) (5.92 mg/kg) and the barley forage HR (4.27 mg/kg) the anticipated dietary burdens of cyclobutylfluram of livestock (beef and dairy cattle) for the purposes of MRL estimation are calculated below:

Table 4: Estimated livestock dietary burden for beef cattle

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)	Residue contribution (ppm)
Wheat forage	AF/AS	5.92	HR	100	5.92	100	5.92
Total						100	5.92

Table 5: Estimated livestock dietary burden for dairy cattle

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)	Residue contribution (ppm)
Wheat forage	AF/AS	5.92	HR	100	5.92	60	3.55
Barley forage	AF/AS	4.27	HR	100	4.27	40	1.71
Total						100	5.26

The estimated residues in tissues and milk from feeding at 5.92 ppm for beef cattle and 5.26 ppm for dairy cattle are calculated below based on extrapolation from observed high residues in lactating dairy cows following feeding at 7.0 ppm in the diet, together with the required MRLs.

Table 6: Estimated residues in cattle tissues and milk and recommended MRLs

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
	Parent + SYN510275 residues as parent equivalents (mg/kg)				
7.0 (observed)	0.0459	0.0395	0.250	0.0449	<0.0305
5.92 – beef, estimated burden	–	0.033	0.21	0.038	<0.026
5.26 – dairy, estimated burden	0.034	–	–	–	–
Established MRLs	–	–	–	–	–
Recommended MRLs	0.05 (Milks)	0.05 (meat)	0.5 (edible offal)		–

MWt of parent cyclobutrifluram = 389.20 g/mol.

MWt of SYN510275 = 190.12 g/mol. Conversion to parent equivalent = $\times 2.05$.

Residues of parent in muscle, kidney and fat were not analysed for in the lactating dairy cow feeding study.

Based on the goat metabolism study, where residues of parent were not detected in goat kidney, parent residues are not expected in kidney at a feeding level of 7.0 ppm and are assigned a value of 0.01 mg/kg (the LOQ) above.

Residues of parent in muscle in the goat metabolism study were present at 0.7% TRR (0.001 mg/kg) for the phenyl label and not detected for the pyridinyl label where residues of SYN510275 were present at 33.6% TRR (0.360 mg eq./kg). Residues of parent in muscle are assigned a value of 0.01 mg/kg above.

Residues of parent in skin and fat in the goat metabolism study were present at 3.1% TRR (0.006 mg/kg) for the phenyl label and 1.8% TRR (0.006 mg/kg) for the pyridinyl label where residues of SYN510275 were present at 41.9% TRR (0.144 mg eq./kg). As residues of SYN510275 were not quantifiable (0.0205 mg eq./kg) after feeding at 7.0 ppm, residues of parent in fat are assigned a value of 0.01 mg/kg above.

The above calculations indicate that quantifiable residues of the parent + metabolite SYN510275 as parent equivalents (which is the residue definition for enforcement for animal commodities in Australia) will be present in milk, muscle, liver and kidney after feeding for 28 consecutive days.

The following MRLs are recommended:

MO 0105	Edible offal (mammalian)	0.5 mg/kg
MM 0095	Meat (mammalian)	0.05 mg/kg
ML 0106	Milks	0.05 mg/kg.

No Codex MRLs are established for cyclobutrifluram. In addition, no animal commodity MRLs are established in major export markets, so the endpoint for an Export Slaughter Interval (ESI) will be taken as the LOQ.

The residue definition for enforcement for animal commodities is "Sum of cyclobutrifluram and 2-trifluoromethyl-nicotinamide (SYN510275), expressed as cyclobutrifluram". As the validated LOQs for parent cyclobutrifluram and the metabolite SYN510275 are 0.01 mg/kg and the conversion factor from SYN510275 to parent equivalents is $\times 2.05$, the overall LOQ is 0.03 mg/kg as parent equivalents.

Liver was the tissue with the highest residues and is the driver for consideration of an ESI. At 7 days post-dosing, total (parent + SYN510275) residues of 0.252 mg/kg (as parent) were observed in liver after feeding at 70 ppm (0.021 mg/kg based on expected residues after feeding at 5.92 ppm). By 14 days post-dosing, no residues of parent or SYN510275 were detected in liver.

A 14 days ESI would therefore be required to ensure residues of cyclobutrifluram in the liver of livestock for export (and in other tissues), which were previously fed on wheat and/or barley forage (or rotational primary feed commodities), will be below the LOQ of 0.03 mg/kg (as parent equivalents).

The following Export slaughter interval should be added to the draft label under the Trade Advice heading:

LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

Export slaughter interval (ESI) - 14 days

Livestock that has been grazed on or fed treated crops should be placed on clean feed for 14 days prior to slaughter.

No poultry transfer studies have been submitted with the current application. There is no need to conduct animal transfer studies if the dietary consumption level for animals is less than 0.1 mg/kg. As no quantifiable residues are expected in wheat or barley grain arising from the proposed uses, or in processed products of wheat or barley, there is no necessity for poultry transfer studies.

The likelihood of detectable residues occurring in poultry commodities as a result of the proposed use is therefore low. It is appropriate to establish poultry commodity MRLs at the total (parent + SYN510275) LOQs in the analytical methods, to satisfy the proposed residue definition for animal commodities. As the validated LOQs for parent and the metabolite SYN510275 in tissues and eggs are 0.01 mg/kg (0.02 mg/kg as parent equivalents for SYN510275), the following MRLs are recommended:

PE 0112	Eggs	*0.03 mg/kg
PO 0111	Poultry, Edible offal of	*0.03 mg/kg
PM 0110	Poultry meat	*0.03 mg/kg.

Overseas registration and approved label instructions

The Applicant has indicated that cyclobutryfluram is registered for various uses in a number of African (Zambia and Zimbabwe), Asian (China, Philippines, South Korea and Vietnam), Central American (Belize, El Salvador, Guatemala and Honduras) and South American (Argentina, Chile, Colombia and Paraguay) 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. Cyclobutryfluram has not been considered by Codex. The Applicant has advised that an MRL is not yet established in China for a registered use as a seed treatment on wheat.

Proposed Australian MRLs for cyclobutrifluram

Table 7: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Add:		
Cyclobutrifluram		
	All other foods	0.05
GC 0640	Barley	*0.01
MO 0105	Edible offal (mammalian)	0.5
PE 0112	Eggs	*0.03
MM 0095	Meat (mammalian)	0.05
ML 0106	Milks	0.05
PM 0110	Poultry meat	*0.03
PO 0111	Poultry, edible offal of	*0.03
GC 0654	Wheat	*0.01

Table 8: Proposed MRL Standard – Table 4

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

Potential risk to trade

Export of treated produce containing finite (measurable) residues of cyclobutrifluram 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.

Barley and wheat grain

Quantifiable residues of cyclobutrifluram are not expected to arise in barley or wheat grain as a result of the proposed use and MRLs for barley and wheat are proposed at the LOQ of 0.01 mg/kg. The risk to the export trade in barley and wheat grain is considered to be low.

All other foods

The highest observed parent cyclobutrifluram residues in rotational food commodities after application at approximately 1× the proposed maximum rate (based on an estimated seeding rate of 100 kg seed/ha) were in radish foliage (greens) at 0.037 mg/kg. An “All other foods” MRL at 0.05 mg/kg is necessary to cover residues in food commodities grown after treatment of a primary crop. Although the scaled calculations indicate expected residues of 0.005–0.008 mg/kg in wheat grain, noting that:

- 1) the confined rotational study involved a worst-case scenario of application to bare soil rather than a primary crop,
- 2) the calculation of expected residues was based on extrapolation from using a seeding rate of 100 kg seed/ha which is at the higher end of common practice seeding rates for barley and wheat, and
- 3) no residues were detected in harvested barley or wheat grain in 20 relevant Australian cereal trials, finite residues are not expected in the major trade commodities cereal grains, oilseed and pulses grown as secondary crops.

Animal commodities

Finite MRLs for animal commodities are proposed at 0.5 mg/kg for mammalian edible offal, 0.05 mg/kg for mammalian meat and 0.05 mg/kg for milks, leading to a potential risk to trade in these commodities, as most export markets do not have established MRLs.

The proposed 14 days ESI should however ensure that residues of cyclobutrifluram in the tissues of livestock for export, which were previously fed on wheat or barley forage and/or fodder and byproducts, will be below quantifiable levels.

Conclusion

Syngenta Australia Pty Ltd has applied to register the product Victrato Tymirium technology Seed Treatment for use on wheat and barley. Comment is sought on the potential for the proposed use to pose a risk to Australian trade.