Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on fluroxypyr for use on rice

Permit PER90025

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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 concerning the use of a proposed agricultural 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 for a permit for use of fluroxypyr on rice 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 17 February 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 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 APVMA has before it a permit application from Rice Extension for the use of fluroxypyr on rice, for the control of various weeds.

The use of fluroxypyr on rice has not been previously assessed by the APVMA.

The proposed permit is for use in Queensland and New South Wales only, for a period of 3 to 5 years.

Trade considerations

Commodities exported

Cereal grains (including rice) are major export commodities[1], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated rice. Residues in these commodities resulting from the use of fluroxypyr on rice may have the potential to unduly prejudice trade.

As no changes are required to the animal commodity MRLs, the risk to trade with respect to animal commodities is considered to be low and does not require further consideration. The risk to trade with respect to rice grain is considered below.

Destination and value of exports

Australia exported an average of 350,000 tonnes per year of rice between 2010–11 and 2019–20[2].

In recent years, around 74% of the Australian rice crop was exported, but this percentage varies from season to season. Australia is a small exporter of mostly medium grain rice, representing around 5% of global medium and short grain rice exports and 0.4% of total global rice exports in 2019. Globally, Australia competes primarily with China and the United States in medium grain rice markets. The main export destinations are the Middle East and Oceania.

[1] Australian Pesticides and Veterinary Medicines Authority, APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B), APVMA website, 20 July 2020, accessed 9 December 2021.

[2] https://www.agriculture.gov.au/abares/research-topics/agricultural-outlook/rice#:~:text=Australia%20exports%20most%20of%20its,varies%20from%20season%20to%20season, accessed 9 December 2021.

Proposed Australian use pattern

Table 1: Proposed use pattern being considered by the APVMA

Starane Advanced Herbicide (containing 333 g/L fluroxypyr as the methyl heptyl ester as the only active constituent and all other similar registered products)

Crop	Pest	Rate	Critical comments
Rice (field grown)	Pigweed, Blackberry nightshade, Bathurst burr, Bindweed and Sesbania (*Portulaca oleracea*, *Solanum nigrum*, *Xanthium spinosum*, *Convolvulus arvensis* and *Sesbania cannabina*)	900 mL/ha (=300g a.i./ha)	Apply a maximum of one foliar application per crop from 3 leaf to tillering growth stages using a boom spray. Apply with the addition of uptake oil at 1L/ 100L. a. Ground application (boom), in at least 50 L/ha water. Flat fan nozzles applying a medium quality spray (ASAE-S572) are recommended. Set the boom at a height to ensure a double overlap of the nozzle patterns. b. Aerial application - Apply in a minimum volume of at least 35 L/ha water. Use equipment calibrated to produce a coarse quality spray (ASAE-S572). DO NOT apply when the temperature is above 30°C, when there is no wind or when the wind is blowing toward susceptible crops. DO NOT spray when wind speed is less than 3 km/hr or more than 20 km/hr.

Withholding periods

Harvest: Not required when used as directed.

Grazing: DO NOT graze or cut for stock food for 7 days after application.

Results from residues trials presented to the APVMA

The proposed use for fluroxypyr on field grown rice is for a maximum of one application at 300 g a.i./ha per crop from 3 leaf (BBCH 13) to tillering growth stages (which are from BBCH 21-29). The proposed harvest withholding period (WHP) is “Not required when used as directed” with a proposed grazing WHP of “DO NOT graze or cut for stock food for 7 days after application”.

Grain

Summary details of four non-GLP Central or South American trials on rice and full details of a GLP study containing details of two relevant trials conducted in the USA on rice were considered.

The combined dataset considered suitable for MRL estimation for the proposed use on rice is in rank order:

0.016, <0.05 (4) and 0.087 mg/kg (n=6, STMR= 0.05 mg/kg). The OECD MRL calculator estimates an MRL of 0.15 mg/kg based on this dataset.

The established MRL for GC 0080 cereal grains at 0.2 mg/kg is considered appropriate to cover residues arising in rice grain from the proposed use pattern.

Processing

Based on the highest residue (HR) in rice grain at 0.087 mg/kg and the highest processing factor (PF) of 3.15 in rice bran determined in the USA residues study, the HR-P in rice bran is calculated to be 0.27 mg/kg. A fluroxypyr TMRL at T0.3 mg/kg is recommended for CM 1206 Rice bran, unprocessed.

In rice hulls, which are an animal feed, based on the HR in rice grain of 0.087 mg/kg and the highest PF of 2.70 in rice hulls determined in the USA residues study, the HR-P in rice hulls is calculated to be 0.23 mg/kg. A fluroxypyr TMRL at T0.3 mg/kg is recommended for rice hulls in Table 4 of the MRL Standard.

Animal feeds

No residues data addressing residues of fluroxypyr in rice straw and fodder has been submitted or is available. Noting that use on other cereal grain crops (sorghum, maize, sweet corn, millets, wheat, barley, oats and triticale) is allowed up to the same application rate and with a 7 day grazing WHP as proposed for use on rice, it can be concluded that residues in rice animal feeds (fodder/ straw) will be covered by the relevant Table 4 MRLs for straw/ fodder for those other cereal crops.

Overseas registration

The applicant noted that fluroxypyr is registered for use on rice in Argentina and Columbia.

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. Fluroxypyr has not been considered by Codex. The following relevant Codex CXL and overseas MRLs have been established for fluroxypyr.

Table 2: International MRLs

Commodity	Tolerance for residues arising from the use of fluroxypyr (mg/kg)				
	Australia[3]	EU[4]	Japan[5]	USA[6]	China[7]
Definition	Parent	Sum of fluroxypyr, its salts, its esters, and its conjugates, expressed as fluroxypyr	Parent	Sum of fluroxypyr 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5,dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] calculated as fluroxypyr	Parent
Rice	0.2 (cereal grains)	*0.01	0.1 (brown rice) 0.3 (other cereal grains)	1.5	0.2

Relevant MRLs are not established in either the Republic of Korea or Taiwan.

[3] Australian Government, Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019, Federal Register of Legislation, accessed 16 November 2021.

[4] European Commission, Pesticide residue(s) and maximum residues levels (mg/kg), European Commission website, accessed 16 November 2021.

[5] Japanese Food Chemistry Research Promotion Foundation, Table of MRLs for Agricultural Chemicals, JFCRPF website, accessed 16 November 2021.

[6] Electronic Code of Federal Regulations, USA Electronic Code of Federal Regulations, ECFR website, accessed 16 November 2021.

[7] United States Department of Agriculture, China: Maximum Residue Limits for Pesticides in Foods, Global Agricultural Information Network report, 24 August 2021, accessed 16 November 2021.

Current MRLs for fluroxypyr

Table 3: Current relevant MRLs in Table 1 of the MRL Standard

Compound		Food	MRL (mg/kg)
FLUROXYPYR			
GC	0080	Cereal grains	0.2
MO	0105	Edible offal (mammalian) [except kidney]	0.1
PE	0112	Eggs	*0.01
		Kidney (mammalian)	1
MM	0095	Meat (mammalian) [in the fat]	0.1
ML	0106	Milks	0.1
PM	0110	Poultry meat	*0.05
PO	0111	Poultry, edible offal of	*0.05

Table 4: Current relevant MRLs in Table 4 of the MRL Standard

Compound		Animal feed commodity	MRL (mg/kg)
FLUROXYPYR			
AF	0161	Forage of cereal grains and other grass-like plants	100
AS	0161	Straw and fodder (dry) and hay of cereal grains and other grass-like plants	100

Proposed amendments to the MRL Standard for fluroxypyr

Table 5: Amendments to Table 1 of the MRL Standard

Compound		Food	MRL (mg/kg)
FLUROXYPYR			
ADD:			
CM	1206	Rice bran, unprocessed	T0.3

Table 6: Amendments to Table 4 of the MRL Standard

Compound	Animal feed commodity	MRL (mg/kg)
FLUROXYPYR		
ADD:		
	Rice hulls	T0.3

Potential risk to trade

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

Residues in rice grain from the proposed use are covered by the existing fluroxypyr MRL at 0.2 mg/kg for cereal grains. This MRL is lower than the USA MRL for rice (1.5 mg/kg), although the USA residue definition includes fluroxypyr-meptyl, and the same as the China MRL (0.2 mg/kg). In Japan the MRL for brown rice (0.1 mg/kg) is lower than the Australian MRL, while the MRL for other cereal grains (0.3 mg/kg) is higher.

The proposed use may present a risk to trade to markets such as the EU which has a rice MRL at *0.01 mg/kg, the Republic of Korea and Taiwan where relevant MRLs are not established and the major markets in Oceania and the Middle East which refer to Codex MRLs, which have not been established for fluroxypyr.

It is noted however, that the HR of 0.087 mg/kg and the STMR of 0.05 mg/kg are less than all established MRLs for rice except that from the EU and that the only observations with finite residues were from trials conducted with two applications of fluroxypyr, the second of which was at a growth stage (just) after the proposed use up to the end of tillering.

Conclusion

Rice Extension has applied for a minor use permit for the use of fluroxypyr on rice.

Comment is sought on the potential for the proposed use to prejudice Australian trade of rice and the ability of industry to manage any potential trade risk.