



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



TRADE ADVICE NOTICE

on spiroxamine in the Product Prosper 500 EC Fungicide for use on barley

APVMA Product Number 52817

MAY 2018

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Department of the Environment and Energy, and State Departments of Primary Industry.

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 is a Trade Advice Notice.

It 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 vary the registration of Prosper 500 EC Fungicide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the **trade implications** of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **Wednesday, 20 June 2018** 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 Group name (if relevant)
- Postal Address
- Email Address (if available)
- The date you made the submission.

All personal and confidential commercial information (CCI)¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609
Phone: +61 2 6210 4701
Email: enquiries@apvma.gov.au

Further information

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

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

¹ A full definition of "confidential commercial information" is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from, Bayer Cropscience Pty Ltd, to vary the registration of Prosper 500 EC Fungicide containing spiroxamine to include a new use on barley.

A similar use was previously allowed under minor use permits: PER 13482 (27 July 2012–31 March 2013) and PER14012 (1 April 2013 – 31 March 2017) for Western Australia only.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Barley is considered to be major export commodity², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated barley grain, forage and straw and fodder. Residues in these commodities resulting from the use of PROSPER 500 EC FUNGICIDE may have the potential to unduly prejudice trade.

MRLs for barley forage and fodder are proposed at 5 and 1 mg/kg respectively and it is calculated that current mammalian commodity MRLs remain appropriate. As no changes are proposed to the current mammalian animal commodity MRLs, the risk to the export trade in animal commodities is unchanged and will not be considered further. MRLs for poultry commodities are proposed at LOQ (*0.02 and *0.05 mg/kg). The trade risk to poultry commodities is considered to be low as finite residues are not expected.

2.2 Destination and value of exports

Australian exports of barley grain totalled 9 537 kt (value \$ 2.4 billion) in 2016-17³.

The major export markets for barley grain in 2016-17 included China, Japan, Republic of Korea, Philippines, Taiwan, Thailand, Vietnam, Kuwait, Saudi Arabia, and United Arab Emirates.

2.3 Proposed Australian use-pattern

Prosper 500 ec fungicide (500 g/L Spiroxamine)

CROP	PEST	RATE/ CONCENTRATION	CRITICAL COMMENTS
Barley	Powdery mildew	600 ml/ha (300 g spiroxamine / ha)	Monitor crops from mid-tillering. Apply at the first sign of disease. Apply a maximum of 2 sprays with a minimum of 7 days between consecutive sprays. Do not apply the last application later than GS32 (node 2 at least 2 cm above node 1).

Restrains: DO NOT apply Prosper by aircraft.

Withholding periods:

Harvest: NOT REQUIRED when used as directed.

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

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

³ [Australian Commodity Statistics 2016-17 - ABARES](#)

Trade advice: Growers should note that suitable MRLs or import tolerances may not exist in all markets for produce treated with Prosper. If you are growing produce for export, please check with Bayer for the latest information on MRLs and import tolerances and for advice on any potential trade issues and their management.

2.4 Results from residues trials presented to the APVMA

The proposed use of Prosper 500 EC Fungicide on barley is for 2 sprays at 600 m/lha (300 g spiroxamine/ha) in conjunction with a harvest withholding period of 'NOT REQUIRED when used as directed' and a 6 weeks grazing withholding period.

Barley grain

Australian trials conducted in 2015-16 involved two applications of spiroxamine at 1x or 2x the proposed rate at BBCH 29 and 32. Spiroxamine residues in barley grains at harvest at 1x the proposed rate at 86-114 days PHI were <0.01 (3) and 0.02 mg/kg (LOQ = 0.01 mg/kg). At 2x the proposed rate residues were <0.01 (3) and 0.03 mg/kg.

European trials conducted in 2007 used two applications of spiroxamine at 1.25x the proposed rate at BBCH 37 and 61. Spiroxamine residues in barley grains at harvest, 35-96 days PHI were: <0.01, 0.01 (5) and 0.02 (2) mg/kg (LOQ = 0.01 mg/kg).

In 2005 European trials spiroxamine was applied at 1.04x the proposed rate at BBCH 47 and 61. Spiroxamine residues in barley grains at all trial sites at harvest were: <0.05 (6) mg/kg (LOQ = 0.05 mg/kg).

The combined dataset suitable for MRL estimation from the four 2015 Australian trials and the eight 2007 European trials that had an LOQ of 0.01 mg/g is, in rank order, <0.01 (4), 0.01 (5) and 0.02 (3). The OECD MRL calculates an MRL of 0.03 mg/kg (STMR = 0.01 mg/kg).

Based on the available information an MRL of 0.03 mg/kg is considered appropriate for barley grain in conjunction with a harvest withholding period of 'NOT REQUIRED when used as directed' and the proposed 'DO NOT apply the last application later than GS 32 (node 2 at least 2 cm above node 1)' label statement.

2.5 Overseas registration and approved label instructions

The applicant indicated that spiroxamine products are registered in many countries for use in barley, including European countries (e.g. France Germany, Luxembourg, United Kingdom and Switzerland), New Zealand and South Africa.

2.6 Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Spiroxamine has not been considered by Codex.

Table 1: Current and proposed Australian and overseas MRLs/tolerances for spiroxamine

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF SPIROXAMINE (mg/kg)						
	AUSTRALIA	EU ⁴	USA	JAPAN	KOREA	CHINA	TAIWAN
Residue Definition	Commodities of plant origin: Spiroxamine Commodities of animal origin: Spiroxamine carboxylic acid	Spiroxamine (sum of isomers)	Spiroxamine	Spiroxamine	-	Not established	Not established
Barley	Current: T*0.05 (Proposed: 0.03)	0.05	Not established for barley	0.3	Not established for barley	Not established	Not established

2.7 Current and proposed Australian MRLs for spiroxamine

Table 2: Current MRL Standard - Table1 - Spiroxamine

COMPOUND	FOOD	MRL (MG/KG)
Spiroxamine		
GC 0640	Barley	T*0.05
MO 0105	Edible offal (Mammalian)	0.5
MF 0100	Mammalian fats (except milk fats)	0.05
MM 0095	Meat [Mammalian]	0.05
ML 0106	Milks	0.05

Table 3: Current MRL Standard - Table 4 - Spiroxamine

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Spiroxamine		
	Barley forage	T1
AS 0640	Barley straw and fodder, dry	T1
AB 0269	Grape pomace	10
AL 0528	Pea vines (green)	T7

⁴ <http://ec.europa.eu>

Table 4: Proposed MRL Standard - Table1 - Spiroxamine

COMPOUND	FOOD	MRL (MG/KG)
SPIROXAMINE		
DELETE:		
GC 0640	Barley	T*0.05
ADD:		
GC 0640	Barley	0.03
PE 0112	Eggs	*0.02
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry, Meat	*0.05

Table 5: Proposed MRL Standard - Table 4 - Spiroxamine

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
SPIROXAMINE		
DELETE:		
	Barley forage	T1
AS 0640	Barley straw and fodder, dry	T1
ADD:		
	Barley forage	5
AS 0640	Barley straw and fodder, dry	1

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of spiroxamine 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 use involves treatment of barley which is a major trade commodity. A similar use was previously approved under minor use permit in Western Australia from 2012–2017. Spiroxamine has been included in the National Residues Survey's barley program since 2014 and no detections above 0.01 mg/kg have been observed.

The proposed level of MRL for barley grain is at 0.03 mg/kg. An observed high residue of 0.02 mg/kg was above the LOQ of 0.01 mg/kg. The proposed MRL of 0.03 mg/kg is lower than that established by the EU (0.05 mg/kg) and Japan (0.3 mg/kg), but Codex and other countries have not established relevant MRLs noting that a residue above the LOQ of 0.01 mg/kg was observed in 1 of 4 Australian trials and in 3 of 12 trials in the overall dataset, the likelihood of finite residues occurring in exported barley following bulking and blending is considered to be low.

3 CONCLUSIONS

Bayer CropScience Pty Ltd have made an application to vary the registration of Prosper 500 EC Fungicide containing spiroxamine. Bayer propose adding a use on barley which will require the establishment of permanent MRLs for spiroxamine on barley.

Comment is sought on the potential for Prosper 500 EC Fungicide to prejudice Australian trade when used on barley according to the proposed label directions.