



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



Trade Advice Notice

on Glyphosate in the product Roundup Ultra Max Herbicide for use on barley

APVMA product number 68506

February 2020

© Australian Pesticides and Veterinary Medicines Authority 2020

ISSN 2200-3894 (electronic)

Ownership of intellectual property rights in this publication

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Creative Commons licence

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 4.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.



A [summary of the licence terms](#) and [full licence terms](#) are available from Creative Commons.

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

Source: Licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 4.0 Australia Licence.

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as the author, publisher and copyright owner.

Cover image: iStockphoto (www.istockphoto.com)

iStockphoto images are not covered by this Creative Commons licence.

Use of the Coat of Arms

The terms under which the Coat of Arms can be used are set out on the [Department of the Prime Minister and Cabinet website](#).

Disclaimer

The material in or linking from this report may contain the views or recommendations of third parties. Third party material does not necessarily reflect the views of the APVMA, or indicate a commitment to a particular course of action. There may be links in this document that will transfer you to external websites. The APVMA does not have responsibility for these websites, nor does linking to or from this document constitute any form of endorsement. The APVMA is not responsible for any errors, omissions or matters of interpretation in any third-party information contained within this document.

Comments and enquiries regarding copyright:

Assistant Director, Communications

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au

This publication is available from the [APVMA website](#).

CONTENTS

PREFACE	1
About this document	1
Making a submission	1
Further information	2
1 INTRODUCTION	3
2 TRADE CONSIDERATIONS	3
2.1 Commodities exported	3
2.2 Destination of exports	3
2.3 Proposed Australian use-pattern	4
2.4 Results from residues trials presented to the APVMA	4
2.5 Codex Alimentarius Commission and overseas MRLs	5
2.6 Current and proposed Australian MRLs for glyphosate	7
2.7 Potential risk to trade	7
3 CONCLUSION	8

LIST OF TABLES

Table 1: Proposed use pattern— <i>Roundup Ultra Max Herbicide</i> (570 g/L glyphosate present as the potassium salt as its only active constituent)	4
Table 2: Overseas MRLs	6
Table 3: Current MRL Standard—Table1	7
Table 4: Proposed MRL Standard—Table1	7

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 vary the registration of **Roundup Ultra Max Herbicide** 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 **27 March 2020** 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)
- submission date.

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

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

1 INTRODUCTION

The APVMA has before it an application from Monsanto Australia Pty Ltd to register the use of Roundup Ultra Max Herbicide on barley (except malting barley). The product contains 570 g/L glyphosate as its active ingredient.

The use pattern proposed for registration is equivalent to that allowed under permit 82594 (valid from 2 November 2016 to 30 April 2020)².

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Barley is considered to be a major export commodity, 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. Residues in these commodities resulting from the use of Roundup Ultra Max Herbicide may have the potential to unduly prejudice trade.

As the mammalian and poultry dietary burdens through consumption of barley forage, fodder or grain derived from treated barley should be no greater than previously considered, no changes are required to the established animal commodity MRLs for glyphosate. The risk to trade in animal commodities is unchanged and does not require further consideration.

2.2 Destination of exports

Australian exports of barley were estimated to be 4683 kt and valued at \$1836 m in 2018-2019³. Major export markets for Australian barley in 2018–19 were in Asia (China, Japan, Vietnam, Thailand, Rep. of Korea, Philippines and Taiwan), and in the Middle East (Saudi Arabia, United Arab Emirates and Kuwait).

² permits.apvma.gov.au/PER82594.PDF

³ agriculture.gov.au/abares/research-topics/agricultural-commodities/agricultural-commodities-trade-data#2019

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern—Roundup Ultra Max Herbicide (570 g/L glyphosate present as the potassium salt as its only active constituent)

Crop	Weeds controlled	Rate	Critical comments
PRE-HARVEST APPLICATION	Annual weeds	1.65 L/ha (=940.5 g a.i./ha)	Apply to mature crops from late dough stage (28% moisture) onwards.
As harvest aid and weed control			DO NOT apply more than one (1) treatment per crop.
Barley (except malting barley) (<i>Hordeum vulgare</i> L.)			DO NOT apply if heavy rains are imminent. DO NOT use on crops intended for seed or sprouting.

Withholding period:

Harvest: DO NOT harvest for 7 DAYS after application.

Grazing: DO NOT graze or cut for stockfood for 7 DAYS after application.

Trade advice information:

EXPORT OF TREATED PRODUCE

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Roundup Ultra MAX Herbicide. If you are growing produce for export, please check with Monsanto Australia Pty Ltd for the latest information on MRLs and import tolerance before using Roundup Ultra MAX Herbicide.

2.4 Results from residues trials presented to the APVMA

In eight glyphosate residue trials conducted on barley in Australia in 2017 and 2018 (four per season), one application was made at 901–1254 g a.i./ha. Residues observed in barley grain in these Australian trials (converted to expected residues at the 1x application rate of 940 g a.i./ha) at a seven-day harvest WHP are in rank order:

0.60, 0.83, 6.4, 7.1, 9.9, 10.5, 11.2 and 14.1 mg/kg (n = 8, STMR = 8.5 mg/kg).

Relevant European residue studies that are available in the 2005 JMPR evaluation, which were previously considered as part of the residues assessment for PER82594, were considered for MRL estimation. The STMR and HR were 3.5 and 8.5 mg/kg respectively, in 26 relevant trials, after conversion to expected residues at the 1x application rate.

The combined dataset of submitted Australian trials and European JMPR data suitable for MRL estimation is, in rank order:

0.60, 0.67, 0.83, 0.90, 0.94, 1.3, 1.3, 1.4, 2.4, 2.6, 2.8, 3.0, 3.0, 3.2, 3.3, 3.7, 3.8, 3.8, 4.1, 4.3, 5.8, 5.9, 6.0, 6.4, 7.1, 7.4, 8.1, 8.1, 8.5, 8.5, 9.9, 10.5, 11.2 and 14.1 mg/kg (STMR = 3.8 mg/kg, n = 34).

The OECD MRL calculator recommends an MRL of 20 mg/kg based on this combined dataset.

Based on the available residues data including contemporary Australian trials that address the proposed use pattern, a glyphosate MRL of 20 mg/kg is recommended for GC 0640 Barley, in conjunction with a seven day WHP.

2.5 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. Glyphosate has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for glyphosate.

Table 2: Overseas MRLs

Commodity	Australia	Tolerance for residues arising from the use of glyphosate (mg/kg)					
		EU	Japan	Codex	Canada	USA	Korea
Residue definition	For enforcement: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	Glyphosate	Glyphosate (soybean, corn and rapeseed excluded)	For compliance with MRL for plant commodities—for soya bean, maize and rape: sum of glyphosate and N-acetylglyphosate, expressed as glyphosate. For other crops: glyphosate. For compliance with MRL for animal commodities: sum of glyphosate and N-acetylglyphosate, expressed as glyphosate.	All food crops except dry soybeans, rapeseeds (canola), and field corn N-(phosphonomethyl)glycine, including the metabolite aminomethylphosphonic acid	Glyphosate (N-(phosphonomethyl) glycine and its metabolite N-acetyl-glyphosate (N-acetyl-N-(phosphonomethyl)glycine; calculated as the stoichiometric equivalent of glyphosate	Compliance: glyphosate
Cereal grains				30 (except maize and rice)		30	
Barley	20 (proposed) Current 10	20	30		10		20

Note: Barley MRLs are not established for either China, Taiwan or Kuwait.

2.6 Current and proposed Australian MRLs for glyphosate

Table 3: Current MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
GC 0640	Barley	10
MO 0105	Edible offal (mammalian)	2
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian)	*0.1
ML 0106	Milks	*0.1
PO 0111	Poultry, edible offal of	1
PM 0110	Poultry meat	*0.1

Table 4: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
DELETE:		
GC 0640	Barley	10
ADD:		
GC 0640	Barley	20

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of glyphosate 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 pattern is equivalent to that approved under permit (PER82594). Based on the assessment of new Australian residues data (HR of 14.1 mg/kg), an increase to the current MRL for barley is proposed, from 10 mg/kg to 20 mg/kg.

All residues values considered for MRL establishment were within the barley MRLs of 20 mg/kg set by the EU and Korea and 30 mg/kg set by Codex, Japan and the United States. China, Taiwan and Kuwait however have not set a glyphosate MRL for barley.

It is noted that the Australian barley industry have been successfully managing the trade risk equivalent to that associated with the proposed use, resulting from use of glyphosate on barley under the permit which commenced in November 2016.

The Applicant has proposed the following Trade advice information to mitigate the risk to trade in barley:

EXPORT OF TREATED PRODUCE

Growers should note that MRLs or import tolerances DO NOT exist in all markets for produce treated with Roundup Ultra MAX Herbicide. If you are growing produce for export, please check with Monsanto Australia Pty Ltd for the latest information on MRLs and import tolerance before using Roundup Ultra MAX Herbicide.

3 CONCLUSION

Monsanto Australia Pty Ltd have made an application to register the use of Roundup Ultra Max Herbicide on barley requiring an increase of the permanent MRL for barley from 10 to 20 mg/kg.

Comment is sought on the potential for Roundup Ultra Max Herbicide to prejudice Australian trade when used on barley according to the proposed label directions.