



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



# TRADE ADVICE NOTICE

on Glyphosate in the product DuPont Glyphosate Herbicide

APVMA Product Number 80641

**FEBRUARY 2016**

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ISSN 1443-1335 (electronic)

ISBN 978-1-925390-22-3 (electronic)

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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, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 DuPont Glyphosate 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 16 March 2016 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)*<sup>1</sup> 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:

Scientific Assessment and Chemical Review  
Residues and Trade  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Symonston ACT 2609

**Phone:** +61 2 6210 4701  
**Fax:** +61 2 6210 4776  
**Email:** [enquiries@apvma.gov.au](mailto: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](http://www.apvma.gov.au).

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<sup>1</sup> 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 DuPont (Australia) Pty Ltd, to register DuPont Glyphosate Herbicide for use on *Optimum*<sup>®</sup> *GLY canola varieties*. *Optimum*<sup>®</sup> *GLY canola* has been genetically modified to express the GAT4621 protein (glyphosate acetyltransferase) which confers tolerance to glyphosate containing herbicides by acetylating glyphosate and thereby rendering it non-phytotoxic.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Canola is considered to be a major export commodity<sup>2</sup>, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated canola. Residues in these commodities resulting from the use of *DuPont Glyphosate Herbicide* may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

Australian exports of canola grain, oil and meal totalled 2445 kt (value \$1349 million), 159 kt and 36.9 kt respectively in 2014–15<sup>3</sup>

The major export markets for canola grain in 2014–15 included Bangladesh, Belgium, China, France, Germany, Japan, The Netherlands and Pakistan. Destinations for canola oil included China, Japan, the Republic of Korea, Malaysia and New Zealand. The major market for Canola meal in 2014/15 was New Zealand.

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).

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<sup>2</sup> APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

<sup>3</sup> Australian Commodity Statistics 2015

## 2.3 Proposed Australian use-pattern

DuPont Glyphosate Herbicide (360 g/L Glyphosate, present as the isopropylamine and mono-ammonium salts)

### SITUATION–OPTIMUM™ GLY CANOLA VARIETIES

Before application, users should consult the Optimum™ GLY Crop and Resistance Management Plan (CRMP) which has been designed to minimise the development of glyphosate resistance in weed populations.

WEEDS CONTROLLED	GROWTH STAGE OF CROP	RATE	CRITICAL COMMENTS
Annual ryegrass Amsinckia (Amsinckia spp) Barley grass Black pigweed Brome grass Canary grass Capeweed Deadnettle Dock (seedling) ( <i>Rumex</i> spp) Doublegee (spiny emex) Fumitory Milk (sow) thistle Mintweed Paradoxa grass Patersons curse Pigweed Saffron thistle Scotch thistle Silver grass Skeleton weed – fully emerged rosettes (NSW only) Sorrel Soursob Spear thistle Sub clover Turnip weed Volunteer cereals Volunteer lupins Variegated thistle Wild mustard Wild oats Wild radish Wild turnip Winter grass Wireweed	Cotyledon (BBCH10– Cotyledons completely unfolded) to early bloom (BBCH 61–10% of flowers on main raceme open, main raceme elongating)	1.7 to 3 L/ha  (0.61–1.08 kg ai/ha)	DO NOT apply after BBCH 61. Apply treatments to weeds which have at least one true leaf (broadleaf weeds) or two leaves (grasses) to provide an adequate surface area for herbicide uptake.  Repeat applications may be required if a second flush of weeds germinates but do not apply after the crop reaches 10% flowering. For sequential applications, applications must be at least 14 days apart.  Apply up to 3 applications only, in any one crop. Each application must be a minimum of 1.7 L/ha and a maximum of 3 L/ha.  Annual weeds may be sprayed anytime they are actively growing. Use the lower rate on weeds up to 15 cm tall; increase to the higher rate where weeds are over 15 cm tall and/or high density weed populations. The effects of this product may not be apparent for 3 to 7 days (annual weeds) or 2 to 3 weeks (perennial weeds) or longer under cool, cloudy conditions. This product will control emerged weeds only, and provides no residual control.

Withholding periods:

Harvest: Not required when used as directed

Grazing: Do not graze or cut for stock food for 7 days after application.

Trade advice information:

Import tolerances for canola treated with DuPont Glyphosate herbicide may be pending in some countries. Consult with your exporter or DuPont before applying DuPont Glyphosate herbicide to export crops.

## 2.4 Results from metabolism studies and residues trials presented to the APVMA

### Metabolism in canola and proposed residue definition

The variety of canola which will be treated has a new mechanism of tolerance or detoxification to glyphosate which involves formation of *N*-acetyl-glyphosate. In a canola metabolism study involving the application of <sup>14</sup>C-glyphosate to the new variety of canola, *N*-acetyl-glyphosate was the major residue in all matrices at 89.5% TRR (5.351 ppm) in immature foliage, 93.0% TRR (1.442 ppm) in preharvest foliage, 79.6% (1.013 ppm) in preharvest pods (with seed), and 51.1% TRR (1.101 ppm) in mature seed. It is appropriate to include *N*-acetyl-glyphosate in the residue definition of glyphosate for plant commodities for compliance with MRLs.

Given that *N*-acetyl-glyphosate is the major residue in feeds and therefore livestock consuming feeds arising from glyphosate treated Optimum® GLY canola, the recommended residue definition for animal commodities for compliance with MRLs is the same as that for plants.

As the *N*-acetyl-glyphosate metabolite is only a major component in plants with the GAT trait, current glyphosate MRLs for other crops will remain appropriate when the recommended change in residue definition comes into force.

### Residue trials—canola seed

Twelve GLP trials conducted on canola containing the GAT trait were considered. Total residues of glyphosate, AMPA and *N*-acetyl-glyphosate (expressed as glyphosate) in canola seed at harvest after 3 applications at the target rate of 1080 g ai/ha (1×) at up to 10% flowering (or later) were 0.02, 0.04, 0.05, 0.05, 0.06, 0.07, 0.08, 0.18, 0.38, 0.83, 0.93 and 1.25 mg/kg. Residues in canola seed are therefore expected to remain within the current MRL of 20 mg/kg for glyphosate on SO 0495 Rape Seed.

### Residue trials—canola forage

Total residues of glyphosate, AMPA and *N*-acetyl-glyphosate (expressed as glyphosate) in canola forage at 7 days after the last of 2 applications at the target rate of 1080 g ai/ha (1×) were 61, 66, 70, 145, 147 and 155 mg/kg dry weight. At 7 days after the last of 3 applications residues were 18, 25 and 85 mg/kg. Residues in canola forage are therefore expected to remain within the current MRL of 200 mg/kg for glyphosate on Primary feed commodities if a 7 day grazing WHP is observed.

### Residue trials—canola straw / trash

Total residues of glyphosate, AMPA and *N*-acetyl-glyphosate (expressed as glyphosate) in canola trash/straw at harvest after 3 applications at the target rate of 1080 g ai/ha (1×) at up to 10% flowering (or later) were 0.03, 0.06, 0.08, 0.10, 0.15, 0.18, 0.20, 0.83, 1.1, 2.3, 2.7 and 4.0 mg/kg. Residues in canola trash/straw are therefore expected to remain well within the current MRL of 200 mg/kg for glyphosate on Primary feed commodities.

## Processing—oil

A processing study indicated that residues do not concentrate in oil. Average processing factors for glyphosate, *N*-acetyl-glyphosate, AMPA, and *N*-acetyl AMPA in refined oil from both the cold press and solvent extraction processes were <0.03x, <0.05x, <0.4x, and <0.1x. It is not necessary to establish a separate MRL for canola oil.

## Processing—meal

In cold-pressed and solvent-extracted meal, respectively, concentration factors (and averages) were 1.0–1.9x (1.5x) and 0.5-1.4x (1.1x) for *N*-acetyl-glyphosate. Average processing factors were 0.6–0.8x for glyphosate. Residues of AMPA did not concentrate in meal from either process (average processing factor of <0.4x).

Given the observed processing factors for glyphosate, *N*-acetyl-glyphosate and AMPA and an STMR of 0.075 mg/kg in canola seed from the proposed use pattern it is anticipated that residues in canola meal will be covered by the current MRL of 15 mg/kg for canola meal.

## Animal commodities

The highest combined residue of glyphosate, AMPA and *N*-acetyl-glyphosate in canola forage from the proposed use was 155 mg/kg. The overall dietary exposure is unchanged as a result of the proposed use, although crops containing the GAT trait may contain some *N*-acetyl-glyphosate. The applicant has provided details of a dairy cattle feeding study which involved dosing with *N*-acetyl-glyphosate in support of their application.

Residues in whole milk were below the LOQ (0.025 mg/kg) for *N*-acetyl-glyphosate and glyphosate at all dose levels (up to 1179 ppm). The highest total residues in tissues after dosing with *N*-acetyl-glyphosate at 437 ppm together with the estimated residues following exposure at 155.4 ppm (assume all *N*-acetyl-glyphosate as a worse case) are summarised below:

### Cattle

FEEDING LEVEL (ppm)	MILK	MUSCLE	LIVER	KIDNEY	FAT
	TOTAL RESIDUE (mg/kg)				
437	<0.025	<0.025	0.12	0.79	0.054
155.4–beef, estimated burden	<0.025	<0.025	0.04	0.28	0.02
Established MRLs	*0.1 (milks)	*0.1 (meat)	2 (offal)		-
Recommended MRLs	No change	No change	No change		No change

No changes are required to the current mammalian animal commodity MRLs for glyphosate to account for any potential exposure from *N*-acetyl-glyphosate in crops containing the GAT trait.

## Poultry

In the residue trials provided in support of this application the STMR for canola seed was 0.075 mg/kg. The average processing factor from seed to meal for *N*-acetyl-glyphosate was 1.3× giving a maximum STMR-P for *N*-acetyl-glyphosate of 0.0975 mg/kg. At 5% of the diet for canola meal, the maximum dietary exposure to *N*-acetyl-glyphosate is 0.005 ppm.

The overall dietary exposure is unchanged as a result of the proposed use, although crops containing the GAT trait may contain some *N*-acetyl-glyphosate. The applicant has provided details of a laying hen feeding study which involved dosing with *N*-acetyl-glyphosate in support of their application.

The highest total residues in tissues after dosing with *N*-acetyl-glyphosate at 22 ppm together with the estimated residues following exposure at 0.005 ppm (assume all *N*-acetyl-glyphosate as a worse case) are summarised below:

## Poultry

FEEDING LEVEL (ppm)	EGGS	MUSCLE	LIVER	FAT
	TOTAL RESIDUE (mg/kg)			
22	0.025	0.036	0.21	0.13
0.005—broilers, estimated burden	<0.025	<0.05	<0.05	<0.05
Established MRLs	*0.05 (eggs)	*0.1 (meat)	1 (offal)	-
Recommended MRLs	No change	No change	No change	No change

Detectable residues of glyphosate and its metabolites are not expected to occur in poultry as a result of consumption of canola meal containing residues of *N*-acetyl-glyphosate from the proposed use. No changes are required to the current glyphosate poultry commodity MRLs to account for the additional use of glyphosate on canola containing the GAT trait.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that glyphosate products are registered for use on canola with the GAT trait in the USA and Canada.

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

Table 1: Codex and overseas MRLs

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF GLYPHOSATE (mg/kg)						
	AUSTRALIA	EU	JAPAN	KOREA	TAIWAN	USA	CODEX
Residue Definition	Current: Sum of glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate  Proposed: Sum of glyphosate, <i>N</i> -acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	Glyphosate	Glyphosate	-	-	Glyphosate ( <i>N</i> -phosphonomethyl) glycine and its metabolite <i>N</i> -acetyl-glyphosate ( <i>N</i> -acetyl- <i>N</i> -phosphonomethyl)glycine; calculated as the stoichiometric equivalent of glyphosate  (for canola and animal commodities)	For compliance with MRL for plant commodities - for soya bean, maize and rape: sum of glyphosate and <i>N</i> -acetyl-glyphosate, expressed as glyphosate for other crops: glyphosate. For compliance with MRL for animal commodities: sum of glyphosate and <i>N</i> -acetyl-glyphosate, expressed as glyphosate.
Rape seed (canola)	20	10	10	-	-	20	30
Edible offal (Mammalian)	2	2 (bovine kidney)	2 (cattle kidney, liver)	2 (cattle by-product)	2 (cattle)	5 (cattle meat byproducts)	5
Meat [mammalian]	*0.1	*0.05 (bovine muscle)	0.1 (cattle muscle)	0.1 (cattle meat)	0.1 (cattle, muscle)	-	0.05
Milks	*0.1	*0.05	0.1	0.1 (cow's milk)	0.1 (cattle milk)	-	0.05

MRLs for glyphosate on canola are not established in Korea or Taiwan.

## 2.7 Current and proposed Australian MRLs for glyphosate

Table 2: Current MRL Standard—Table1, 3 and 4

TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
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
SO 0495	Rape Seed	20

TABLE 3

COMPOUND	RESIDUE
GLYPHOSATE	Sum of glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate

TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
GLYPHOSATE		
	Canola meal	15
	Primary feed commodities [other than cotton forage, soya bean hulls and soya bean aspirated grain fractions]	200

Table 3: Proposed MRL Standard—Table3

COMPOUND	RESIDUE
DELETE:	
GLYPHOSATE	Sum of glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate
ADD:	
GLYPHOSATE	For enforcement: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate  For dietary risk assessment: Sum of glyphosate, N-acetyl-glyphosate, aminomethylphosphonic acid (AMPA) and N-acetyl-aminomethylphosphonic acid (N-acetyl AMPA), expressed as glyphosate

There are no proposed changes to Table 1 and Table 4 of the MRL Standard.

## 2.8 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.

It is proposed to include the N-acetyl-glyphosate metabolite in the residue definition for glyphosate as this is a significant metabolite in canola with the GAT trait. This metabolite is included in the residue definition for canola by Codex and in the USA.

A change in the residue definition does not require any changes to the current MRLs for glyphosate on canola or animal commodities as a result of the proposed new use on GM canola with the GAT trait. From the available residue trials the HR and STMR in canola seed are 1.25 mg/kg and 0.075 mg/kg respectively, considerably below the current MRL of 20 mg/kg for glyphosate on Rape seed (canola). The HR in kidney from livestock consuming 100% canola forage with the GAT trait is estimated to be 0.28 mg/kg, considerably below the current MRL of 2 mg/kg for glyphosate in Edible offal (Mammalian).

## 3 CONCLUSIONS

DuPont (Australia) Pty Ltd have applied to register the new product DuPont Glyphosate Herbicide for use on Optimum® GLY canola varieties. The APVMA proposes to be satisfied that the risk to trade associated with this new product is manageable under established industry systems. Comment is sought on the potential for DuPont Glyphosate Herbicide to prejudice Australian trade when used on Optimum® GLY canola varieties.