



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



## TRADE ADVICE NOTICE

on Glyphosate in the Product Pintobi Attack™ Herbicide with IQ inside™

APVMA Product Number P66117

**MAY 2014**

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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 Ageing, Office of Chemical Safety (OCS), Department of Sustainability Environment, Water, Population and Communities (DSEWPac), 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 chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the APVMA's publication *Ag MORAG: Manual of Requirements and Guidelines*.

## About this document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an 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.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found on the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au)

## Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application for the extension of use of Pintobi *Attack*<sup>™</sup> *Herbicide* with IQ inside<sup>™</sup> containing the existing active constituent glyphosate 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 **25 June, 2014** 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:

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## Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

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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 Nufarm Australia Ltd to vary the registration of the product, *Pintobi Attack*<sup>™</sup> *Herbicide* containing 570 g/L glyphosate, for use on canola and wheat pre-harvest for the control of various annual weeds and as a desiccant. The proposal also includes instructions for application of *Pintobi Attack*<sup>™</sup> *Herbicide* at the time of windrowing using windrowers fitted with spray booms. This is the first consideration of such a use by the APVMA.

Canola and wheat grain, as well as meat and dairy products from animals that have been fed feeds containing residues arising from the use of *Pintobi Attack*<sup>™</sup> *Herbicide* may be exported. The potential for glyphosate residues arising from the proposed use on canola and wheat to unduly prejudice trade is discussed below.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Canola and wheat are considered to be major export commodities<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 and wheat. Residues in these commodities resulting from the use of *Pintobi Attack™ Herbicide* may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports of Cereal and Oilseed Products

The significant export markets for Australian beef, sheep, pig meat and offals are listed in Appendix 3 of Part 5B of Ag MORAG.

#### Canola

Australian exports of canola grain, oil and meal totalled 3488 kt (value \$2094 million), 116 kt and 41 kt respectively in 2012/13<sup>3</sup>

The major export markets for canola grain in 2012/13 included Bangladesh, Belgium, China, Japan, The Netherlands and Pakistan. Destinations for canola oil included China, Japan, the Republic of Korea, Malaysia and New Zealand. The major markets for Canola meal included New Zealand, Taiwan and Vietnam<sup>3</sup>.

#### Wheat

Total exports of wheat (including flour) were 21,265 kt (value \$6.8 billion) in 2012/13 with major markets including China, Indonesia, Iran, Iraq, Japan, the Republic of Korea, Vietnam and Malaysia<sup>3</sup>.

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<sup>2</sup> [www.apvma.gov.au/morag\\_ag/vol\\_3/part\\_05b\\_trade.php](http://www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php)

<sup>3</sup> Australian Commodity Statistics 2013

## 2.3 Proposed Australian use-pattern

Pintobi Attack™ Herbicide with IQ inside™ (containing 570 g/L glyphosate as the potassium salt)

Host	Pest	Rate	Critical comments
PRE-HARVEST/CUTTING APPLICATION as harvest aid and weed control on Canola ( <i>Brassica napus</i> ) including conventional, triazine tolerant, CLEARFIELD and Roundup Ready® varieties	Annual weeds	1.15 - 3.4 L/ha (656g - 1.94kg ai/ha)	<p>Apply to mature standing crop from early senescence (minimum of 20% of canola seeds as a random visual sample from various heights in the crop canopy from the main stem have changed to a dark brown/black colour) prior to windrowing or direct harvest. For further information on timing contact your Nufarm representative.</p> <p><b>Applications can also be made at the time of windrowing (windrow equipment fitted with spray booms). To avoid shatter losses from ground application; apply before complete senescence of the crop.</b></p> <p>Use higher rates when crops or weeds are dense and where faster desiccation is required.</p> <p><b>DO NOT harvest for 3 days after application to standing crops</b>  <b>DO NOT apply after completion of the windrowing process</b>  <b>DO NOT use on crops intended for seed</b>  <b>DO NOT overspray windrows</b>  <b>DO NOT direct spray at windrows</b>  <b>DO NOT apply to standing crops and again at the time of windrowing</b></p> <p>Speed of crop desiccation is dependent on crop stage, growing conditions and weather conditions during and after application.</p> <p>For application to standing crops a minimum water rate of 80L/ha is recommended to ensure adequate coverage of target weeds below the crop canopy.</p> <p>Any subsequent weed management strategies should involve an integrated weed management (IWM) approach to minimise development of glyphosate resistance.</p>
PRE-HARVEST/CUTTING APPLICATION as harvest aid and weed control on Wheat ( <i>Triticum aestivum</i> )	Annual weeds	1.15 - 3.4 L/ha (656g - 1.94 kg ai/ha)	<p>Apply to mature crop from late dough stage (28% moisture) onwards. The higher rates will be required when crops are heavy and leaf shading effects may occur.</p> <p>DO NOT harvest within 3 days after application.  DO NOT use on crops intended for seed or sprouting.</p> <p>Where wheat is grown in rotation with any herbicide tolerant crop, management should be consistent with implementation of any management plan for herbicide tolerant crops.</p>

### WITHHOLDING PERIODS

Canola:	Harvest: NOT REQUIRED WHEN USED AS DIRECTED Grazing: NOT REQUIRED WHEN USED AS DIRECTED
Wheat:	Harvest: DO NOT harvest for 3 days after application Grazing: DO NOT CUT OR GRAZE FOR STOCKFOOD FOR 3 DAYS AFTER APPLICATION

## 2.4 Results from residues trials presented to the APVMA

### Canola

Fourteen GLP trials conducted on canola in Australia were considered. A single foliar application of glyphosate was made to standing canola at 0.33x, 0.66x, 1x or 2x of the maximum proposed rate. Sampling interval ranged from 0 to 15 days after application. Only results from the 1x and 2x trials are reported here.

Immediately after application (or longer if higher residues were observed), the total residues of glyphosate (parent + AMPA) on canola grain following a single pre-harvest application at a rate approximately the maximum proposed were 2.1, 2.2<sup>RR</sup>, 3, 4.4, 4.5, 4.9, 4.9<sup>RR</sup>, 5.2, 5.4<sup>RR</sup>, 6.3<sup>RR</sup>, 7<sup>RR</sup>, 7.1, 7.7 and 18<sup>RR</sup> mg/kg (Roundup Ready trials denoted by <sup>RR</sup>). There are no grounds for discounting the high residue of 18 mg/kg. When application was made at twice the maximum proposed rate the high residue was 37<sup>RR</sup> mg/kg.

It is recommended that the current Table 1 entry of 2 mg/kg for SO 0495 Rape seed [canola] be amended to 20 mg/kg in conjunction with a harvest withholding period of NOT REQUIRED WHEN USED AS DIRECTED and a critical comment requiring at least 3 days between application to a standing crop and harvest.

### Wheat

Seven GLP trials conducted in Australia were considered. A single foliar application of glyphosate was made to standing wheat (hard dough stage or later) at 0.5x, 1x or 2x the maximum proposed rate. A harvest WHP of 3 days is proposed. Only results from the 1x and 2x trials are reported here.

At the proposed harvest WHP of 3 days, residues of glyphosate (parent + AMPA) on wheat grain following a single pre-harvest application at the maximum proposed rate were 1.2, 2, 2.1, 2.8, 2.8, 3.3 and 4.3 mg/kg. When application was made at twice the maximum proposed rate the high residue was 9.3 mg/kg.

It is recommended that the current Table 1 entry of 5 mg/kg for wheat (GC 0650) be amended to 7 mg/kg in conjunction with a harvest WHP of 3 days.

### Animal Feeds

#### *Canola forage and fodder*

Immediately after a single application according to the proposed use pattern glyphosate residues (parent + AMPA) on canola fodder were 2, 2, 5, 5, 5, 7, 12, 45, 61, 68, 79, 94, 145 and 154 mg/kg. When application was made at twice the maximum proposed rate the high residue was 346 mg/kg.

It is recommended that the current Table 4 entry of 50 mg/kg for rape seed forage be deleted and the residues in rape seed forage and fodder be covered by a new Primary Feed Commodities MRL of 200 mg/kg.

#### *Canola meal*

A processing factor of 2.4 was estimated for canola meal. The STMR-P is (5 × 2.4) 12 mg/kg. A Table 4 entry for canola meal of 15 mg/kg is recommended.

**Wheat straw**

Immediately after a single application according to the proposed use pattern glyphosate residues (parent + AMPA) on wheat straw were 2.6, 3.5, 5, 5, 5, 9.5 and 14 mg/kg. When application was made at twice the maximum proposed rate the high residue was 15 mg/kg.

The residues in wheat straw will be covered by newly recommended Primary Feed Commodities MRL of 200 mg/kg.

**Animal Commodities**

Animal transfer studies were considered for lactating cattle, pigs (swine) and poultry where the animals were dosed with glyphosate and AMPA at a ratio approximating that present in animal feeds for 28 days. The results of those studies and estimated livestock burdens are considered here.

For beef cattle the estimated maximum livestock burden for glyphosate is 154 ppm, based on a diet of 100% canola fodder. For dairy cattle the estimated maximum livestock burden for glyphosate is 65 ppm based on a diet of 40% canola fodder; 15% canola meal and 40% barley grain. The expected residues and established MRLs for ruminants are summarised as:

*Beef cattle, 500 kg bw (20 kg DM/day)*

DOSE (ppm)	MILK	MUSCLE	LIVER	KIDNEY	FAT
Glyphosate residue (mg/kg)					
400	Not detected	<0.05	0.39	4.21	<0.05
154 – beef, estimated burden	Not detected	<0.05	0.15	1.62	<0.05
65 – dairy, estimated burden	Not detected	-	-	-	-
Established MRLs	*0.1 (milks)	*0.1 (meat)		2 (offal)	-

For pigs (swine) the estimated maximum livestock burden for glyphosate is 4 ppm, based on a diet of 15% canola meal and 85% barley grain. The expected residues in pigs are summarised as:

*Pigs, 60 kg bw (2.5 kg DM/day)*

DOSE (ppm)	MUSCLE	LIVER	KIDNEY	FAT
Glyphosate residue (mg/kg)				
40	<0.05	<0.05	0.70	<0.05
4 – estimated burden	<0.05	<0.05	0.07	<0.05
Established MRLs	*0.1 (meat)		2 (offal)	

For poultry the estimated maximum livestock burden for glyphosate is 4 ppm, based on a diet of 70% sorghum grain, 25% soybean meal and 5% canola meal. The expected residues in poultry are summarised as:

*Poultry, 2 kg bw (150 g DM/day)*

DOSE (ppm)	MUSCLE	LIVER	KIDNEY	FAT
	Glyphosate residue (mg/kg)			
40	<0.05	0.11	0.32	<0.05
4 – estimated burden	<0.05	0.01	0.03	<0.05
Established MRLs	*0.1 (meat)	1 (offal)		

No changes are required to established glyphosate animal commodity MRLs and there is no significant change to the risk to trade in animal commodities associated with the proposed use. Residues in animal commodities will not be discussed further.

## 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.

The following relevant residue tolerances for glyphosate have been established:

### Current and proposed Australian and overseas MRLs/tolerances for glyphosate

Commodity	Tolerance for residues arising from the use of glyphosate (mg/kg)				
	Australia	EU <sup>4</sup>	Japan <sup>5</sup>	Codex <sup>6</sup>	USA <sup>7</sup>
Residue Definition	Sum of glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	Glyphosate	Glyphosate	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.	Plant commodities: glyphosate (N-(phosphonomethyl) glycine)
Wheat	5 (7 proposed)	10	5	30 (Cereal grains)	30 (Cereal grains)
Rape seed (canola)	2 ( 20 proposed)	10	10	20	20

<sup>4</sup> <http://ec.europa.eu>

<sup>5</sup> <http://www.m5.ws001.squarestart.ne.jp>

<sup>6</sup> <http://www.codexalimentarius.net>

<sup>7</sup> <http://www.ecfr.gov>

## 2.6 Current and proposed Australian MRLs for glyphosate

The Australian residue definition for glyphosate is the sum of glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate.

### Current relevant entries in the MRL Standard<sup>8</sup>

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
GC 0640	Barley	10
GC 0080	Cereal grains (except sorghum, wheat and barley)	T*0.1
SO 0691	Cotton seed	15
OC 0691	Cotton seed oil, crude	*0.1
SO 0693	Linseed	T5
SO 0088	Oilseed [except Cotton seed, Linseed; Peanut; Poppy seed; Rape seed; Sunflower seed]	T*0.1
SO 0698	Poppy seed	T20
SO 0495	Rape Seed	2
GC 0651	Sorghum	15
SO 0702	Sunflower seed	T20
GC 0650	Wheat	5
CM 0654	Wheat bran, unprocessed	20

MRL Standard: TABLE 3

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

<sup>8</sup> A full listing of glyphosate MRLs can be found at <http://www.comlaw.gov.au/Current/F2014C00249>

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
	Linseed meal	T7
	Primary feed commodities [other than rape seed forage, rape seed straw and fodder (dry), cotton forage, soya bean hulls and soya bean aspirated grain fractions]	150
	Rape seed forage	50
	Rape seed straw and fodder (dry)	1

The following changes are proposed to Australian glyphosate MRLs:

Proposed changes to the MRL Standard - Table 1

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
DELETE:		
SO 0495	Rape seed	2
GC 0650	Wheat	5
ADD:		
SO 0495	Rape seed [canola]	20
GC 0650	Wheat	7

## Proposed changes to the MRL Standard - Table4

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
GLYPHOSATE		
DELETE:		
	Primary feed commodities [other than rape seed forage, rape seed straw and fodder (dry), cotton forage, soya bean hulls and soya bean aspirated grain fractions]	150
	Rape seed forage	50
	Rape seed straw and fodder (dry)	1
ADD:		
	Primary feed commodities [other than cotton forage, soya bean hulls and soya bean aspirated grain fractions]	200
	Canola meal	15

## 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.

### 1. Residue Definitions

Australia includes the metabolite AMPA in the residue definition for glyphosate while it is not included in the relevant Codex residue definition or the residue definition of the EU, Japan or the USA. Where reported separately, residues of AMPA formed only a small proportion of the residue in non-Roundup Ready cultivars. In Roundup Ready cultivars, residues of AMPA in canola grain (glyphosate equivalents) in the 1× treatments did not exceed 0.5 mg/kg. The differences in residue definition are of limited significance when considering the uses proposed here for *Pintobi Attack™ Herbicide*.

### 2. Canola

#### a. Standing crop use

The proposed Australian MRL of 20 mg/kg for glyphosate is the same as the currently established Codex and US MRL of 20 mg/kg. The EU and Japan have a lower MRL established (parent glyphosate only) of 10 mg/kg. Residues of glyphosate only observed in the Australian trials (expressed according to the Australian residue definition) did not exceed the US and Codex MRL. The established EU and Japanese MRLs of 10 mg/kg were exceeded in 1 of 14 trials, where the residue was 18 mg/kg. At that site, residues had fallen to 4 mg/kg by 4 days after treatment, noting that harvest is not allowed in the 3 days following application. In the other trials, residues ranged from 2 to 8 mg/kg on the day of application and declined thereafter. Thus the risk to trade is considered to be low.

#### b. Windrower use

The use proposed here for application during the windrowing process is the first such use of any pesticide considered by the APVMA. The use allows application of glyphosate during the windrowing process using spray booms fitted to the windrower. The use does not allow the overspray of windrows, or application between or over windrows after the crop has been cut. It is expected that residues on canola grain and canola fodder arising from the use of glyphosate during the windrowing process, where the application is not directed at the crop or at the windrow, would be no higher than those present immediately after application to a standing crop. Label critical comments have been included on the label to clarify this specific use pattern (refer to section 2.3).

Comment is sought on whether the proposed label statements are appropriate to ensure that:

- the appropriate equipment is used,
- there is no direct overspray of the crop,
- there is no direct overspray of the windrow,
- application is limited to the windrowing process.

#### 3. Wheat

The proposed Australian MRL of 7 mg/kg for glyphosate is lower than those established by the EU, Codex and the USA. This proposed MRL of 7 mg/kg is higher than the Japanese MRL of 5 mg/kg.

Residues of glyphosate, expressed according to the Australian residue definition, did not exceed the established Japanese MRL of 5 mg/kg in any of the 7 trials conducted on wheat following the proposed use pattern. Thus the risk to trade is considered to be low.

## 3 CONCLUSIONS

The establishment of new glyphosate MRLs in rape seed (canola), wheat and primary animal feed commodities are proposed. Comments are sought on the potential for glyphosate in *Pintobi Attack™ Herbicide* to unduly prejudice Australian trade when it is used for the control of various annual weeds and as a pre-harvest desiccant as per the proposed label. Comment is also sought on the proposed label directions for the use of *Pintobi Attack™ Herbicide* at the time of windrowing.