

**Trade Advice Note
on**

Glyphosate

in the product

**Roundup Ready Herbicide by Monsanto
(APVMA Product Number 54112)**

**Australian Pesticides and Veterinary
Medicines Authority**

For further information contact:

**Jay Kottege
Manager, Herbicides
Pesticides Program**

Ph: 02 6272 5208

Fax: 02 6272 3218

Email: jay.kottege@apvma.gov.au

DRAFT

Trade Advice Note on the Product

Roundup Ready Flex Herbicide by Monsanto (690 g/kg glyphosate)

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Monsanto Australia Limited to extend the existing Roundup Ready herbicide label to include use on a new generation of glyphosate-tolerant cotton, known as Roundup Ready Flex cotton. The extension involves a new section to the label where three specific application timings are indicated. As a result of the residues evaluation of the revised use, an increase to the cottonseed MRL is recommended to reflect residues occurring from the pre-harvest use of the above product.

The APVMA invites any person to submit a relevant written submission with respect to whether the proposed new use is likely to unduly prejudice trade or commerce between Australia and Australia's trading partners. Please provide your submission to the APVMA by 4 August 2006. Any submissions provided after this date may be unable to be considered before the regulatory decision is made. All submissions should be addressed to the contact stated on the title page.

Trade Considerations

1. Commodities exported

Cottonseed, and its derived oils and meals are considered major export commodities, as listed in Appendix 1 of Part 5B of the APVMA Ag Manual of Requirements and Guidelines.

2. Destination and Value of Exports

The volume of total exports of Australian cottonseed and related products are: 214.35 kt seed, 2.19 kt of oil and 6.24 kt of meal (including sunflower seed meal).

Over the 2004-2005 period, Australia exported \$A 771 million of cottonseed and products. The major markets were Indonesia, Thailand, the Republic of Korea, Japan and China.¹

The largest export markets for Australian cottonseed by volume are shown below (Australian Commodity Statistics (2005)).

Destination	Volume (kt)
Chinese Taipei	0.61
Japan	144.67
Republic of Korea	56.04
Saudi Arabia	10.58
USA	1.00
Other	1.47
TOTAL	214.35

The largest export markets for Australian cottonseed and sunflowerseed meal by value are shown below (Australian Commodity Statistics (2005)).

¹ <http://www.dfat.gov.au/facts/affaoverview.html>

DRAFT

Destination	Volume (kt)
Republic of Korea	4.28
New Zealand	0.43
Other	1.72
TOTAL	6.42

Australia is an importer of cottonseed oil, importing 3.16 kt over the 2004-2005 fiscal year.

3. Proposed use pattern

The proposed use pattern for glyphosate as applied to Roundup Ready Flex cotton is presented below:

Roundup Ready Herbicide by Monsanto (690 g/kg glyphosate)

Crop	Pest	Rate	Critical Comments
Cotton with Roundup Ready Flex Technology (in crop up to 16 nodes) NO MORE than 3 applications are permitted in crop up to 16 nodes. Any single application in crop up to 16 nodes MUST NOT exceed 1.5 kg/ha. Total of all applications in crop through all growth stages MUST NOT exceed 6.0 kg/ha	As listed on the label	520 g-1.5 kg/ha (358.8 g – 1.035 kg a.i./ha)	Rate Selection: Use the lower rates on young weeds and increase to the higher rate where weeds are dense or well developed. Dense infestations of some weeds e.g. Barnyard grass, Liverseed (Urochloa) grass may need follow up treatments for complete control.
		980 g-1.5 kg/ha (676.2 g-1.035 kg a.i./ha)	Use the higher rate on plants at the flowering/seed head stage. For Johnson grass apply to plants with a minimum of 30 cm new growth. For long term control of Couch and Johnson grass, repeat applications will be required.
		1.5 kg/ha followed by 1.5 kg/ha (1.035 kg a.i./ha)	Make first application to actively growing plants when the majority of nutgrass plants have reached at least the 6-8 leaf stage but preferably later. Allow for maximum re-emergence before retreating.
Cotton with Roundup Ready Flex Technology (in crop between 16 and 22 nodes) ONLY ONE (1) application is permitted between 16 and 22 Nodes. This application MUST BE DIRECTED, and MUST NOT exceed 1.0 kg/ha. The total of all applications in crop through all growth stages MUST NOT exceed 6.0 kg/ha	As listed on the label.	520g-1.0 kg/ha (358.8-690 g a.i./ha)	Rate Selection: Use the lower rates on young weeds and increase to the higher rate where weeds are dense or well developed. Directed applications should be made using nozzle type and configuration that achieves adequate coverage for target weed species. For best results, applications should be made while weeds are small (less than 8 cm).
Cotton with Roundup Ready Flex Technology (in crop between 60% Boll open stage and Harvest) Do not use on crops intended for seed production. Application made between 60% open stage and harvest MUST NOT exceed 1.0 kg/ha and total of all applications in crop through all growth stages MUST NOT exceed 6.0 kg/ah.	As listed on the label	710 g-1.0 kg/ha (489.9-690 g a.i./ha)	Use the lower rate on light infestations of small weeds, where the crop canopy allows adequate spray coverage of the weeds. Increase to the higher rate when the crop canopy may limit spray coverage, when treating dense infestations, or when treating larger weeds. Apply alone or in tank mixtures with Dropp* for Harvade*. Apply when at least 60% of bolls are open and immature bolls cannot be easily cut with a sharp knife. Alternatively where the seed coat in bisected bolls is black in colour.

DRAFT

Crop	Pest	Rate	Critical Comments
			Where a leafy canopy limits spray coverage, reduced weed control can be expected. For best results under these conditions, delay application until canopy re-opens following initial conditioning treatment.

Withholding periods:

Harvest: NOT REQUIRED when used as directed.

4. Results from trials presented to the APVMA

When glyphosate was applied as per the use pattern above, residues in cottonseed at the time of normal harvest ranged from 0.14 to 12.08 mg/kg. On the basis of the Australian data provided, an MRL of 15 mg/kg is recommended.

5. Overseas Registration & Use Pattern

Glyphosate is approved for use in many overseas countries on many crops, including genetically modified cotton, however full details of overseas use patterns were not available.

6. Codex Alimentarius Commission and overseas MRLs

Country/status	Commodity	Tolerance, mg/kg	Reference
USA	Cotton, gin byproducts	175	http://ecfr.gpoaccess.gov
	Cotton, undelinted seed	35	
Japan	Cotton seeds	10	http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/r02.pdf
	Cottonseed oil (limited to refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	0.05	http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/n03.pdf
	Cottonseed oil (except refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	0.05	
Korea	Cottonseed	0.5	MRLs for Pesticides in Foods, Korea Food and Drug Administration.

CODEX MRLs are established for cottonseed (10 mg/kg), cottonseed oil crude (*0.05 mg/kg) and cottonseed oil edible (*0.05 mg/kg). An increase in the glyphosate CXL from 10 mg/kg to 40 mg/kg in cottonseed was considered by the Codex Committee on Pesticide Residues (CCPR) at the 2006 Meeting and was advanced to Step 5/8. .

7. Current and Proposed Australian MRLs for glyphosate relevant to cottonseed:

Code	Food	MRL, mg/kg	
		Current	Proposed
SO 0691	Cotton seed	10	15

DRAFT

For full details of glyphosate MRLs, please refer to the APVMA website <http://www.apvma.gov.au> and follow the Residues link.

The dietary burden of livestock to glyphosate residues will not increase as a result of the increase in MRL for cottonseed since residues in cottonseed and processed commodities will be much less than the current Primary feed commodities MRL of 150 mg/kg. No changes to the current animal MRLs are required and therefore there are no additional trade risks to consider. In relation to poultry, processing studies show that residues decrease by a factor of 0.11 when compared to the cottonseed MRL. This feeding level is not likely to result in exceedance of the current poultry MRLs when poultry are fed on treated cottonseed meal.

On the basis that revision of the existing CXL is being considered by CODEX through CCPR and MRLs/tolerances are in place in two of Australia's major trading partners, it is concluded that the proposed increase in MRL is unlikely to present an undue risk to Australian trade.

8. Potential Risk to Trade:

Export of treated produce containing finite 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.

Although residues of glyphosate are expected to occur in treated cottonseed, CODEX and Australia's major trading partners for cottonseed commodities have established adequate tolerances. It is considered that the proposed increase in the MRL from 10 to 15 mg/kg is unlikely to pose an undue prejudice to trade, however comment is sought as a part of this Trade Advice Process.

In relation to residues of glyphosate in animal commodities such as meat, milk, offal and eggs, the dietary burden for livestock remains unchanged from feeding of seed, meal and forage and therefore no amendment to existing animal commodity MRLs is required. The risk to trade in these commodities is therefore unchanged.

9. Conclusions

Australian data indicate that glyphosate residues in cottonseed will be below 15 mg/kg when the product is used according to the proposed label directions. Residues in commodities that are used as livestock feeds are unlikely to exceed currently established MRLs in both Tables 1 and 4 of the *MRL Standard*.

The APVMA welcomes comment with regard to whether the proposed use of glyphosate as a herbicide for Roundup Ready Flex cotton poses an undue prejudice to Australia's trade in cottonseed, and in animal commodities.