



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



**Trade Advice Notice**

on dicamba in the products XtendiMax 2 Herbicide with  
VapourGrip Technology for use on XtendFlex cotton

88630

October 2023

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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.

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 APVMA is considering an application concerning the use of a proposed agricultural 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 for a research permit for use of dicamba on XtendFlex cotton 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 22 November 2023** 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 organisation name (if relevant)
- email or postal address (if available)

- the date you made the submission.

**Please note:** submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, 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](mailto:enquiries@apvma.gov.au).

## Further information

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

Further information on Trade Advice Notices can be found on the APVMA website: [apvma.gov.au](http://apvma.gov.au).

## Introduction

The APVMA has before it an application from Monsanto Australia Pty Ltd for the use of dicamba on XtendFlex cotton, for the control of various weeds. XtendFlex cotton is tolerant to dicamba.

The use pattern includes tank mix directions for glyphosate. No changes are required to the current glyphosate cotton seed MRL or animal commodity MRLs therefore the risk to trade is unchanged and no further consideration is necessary with respect to glyphosate.

## Trade considerations

### Commodities exported

Cotton seed, cotton seed oil and cotton seed meal are considered to be major export commodities<sup>1</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 cotton seed and cotton seed meal. Residues in these commodities resulting from the use of XtendiMax 2 Herbicide with VapourGrip Technology may have the potential to unduly prejudice trade.

### Destination and value of exports

Australian exports of cotton seed and cotton seed oil totalled approximately 306 kt and 9 kt, respectively, in 2021 to 2022<sup>2</sup>. The major export markets for cotton seed were China, Japan and the Republic of Korea.

Cottonseed meal was not exported in 2021 to 2022<sup>3</sup>, although previous markets included New Zealand and the Republic of Korea.

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<sup>1</sup> Australian Pesticides and Veterinary Medicines Authority, [APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade \(Part 5B\)](#), APVMA website, 20 July 2020, accessed October 2023.

<sup>2</sup> [Australian Bureau of Agricultural and Resource Economics and Sciences](#), accessed October 2023.

<sup>3</sup> [Australian Oilseeds Federation Annual Report 2021-2022](#), accessed October 2023.

## Proposed Australian use pattern

The proposed new uses/amendments to the XtendiMax 2 label are presented in purple font in Table 1.

**Table 1: Proposed use pattern being considered by the APVMA**

XtendiMax 2 Herbicide with VapourGrip Technology (480 g/L dicamba present as the monoethanolamine salt)		
Weeds controlled	Rate	Critical comments
Peach Vine	1.17 L/ha (=561.6 g dicamba/ha) + 1% v/v VapourGrip Xtra Agent	Apply when weeds have 2 to 6 leaves. Improved levels of control can be achieved by tank-mixing with 1.9 L/ha of Roundup Ready® PL Herbicide with Plantshield® Technology, especially where weeds are more developed
Fleabane	1.17 L/ha (=561.6 g dicamba/ ha) + 1.9 L/ha of Roundup Ready PL Herbicide with Plantshield Technology (=1026 g glyphosate/ha) + 1% v/v VapourGrip Xtra Agent	Tank mix with Roundup Ready PL Herbicide with Plantshield Technology, applied at 1.9 L/ha. Apply when weeds have 2 to 6 leaves.
Annual gooseberry, annual ground cherry, Bathurst and noogoora burrs, bellvine, blackberry nightshade, caltrop (yellow vine), climbing buckwheat (black bindweed), cobbler's pegs, common sowthistle, double gee (3-cornered Jack, spiny emex), dwarf amaranth, fat hen, field bindweed, green amaranth, lucerne, mintweed, New Zealand spinach, parthenium weed, pigweed, redroot amaranth, redshank, seedling khaki weed, seedling perennial gooseberry sunflower, thornapple (datura), wireweed	335 mL to 1.17 L/ha (=160.8 - 561.6 g dicamba/ha) + 1% v/v VapourGrip Xtra Agent	Apply when weeds have at least 3 to 5 true leaves. DO NOT treat weeds which are beyond the rosette stage. Use higher rate on larger weeds and where amaranthus, blackberry nightshade and mintweed are the major problems or where annual and perennial gooseberry are present. May be tank-mixed with 1.9 L/ha of Roundup Ready PL Herbicide with Plantshield Technology to improve the spectrum of weeds controlled.

### RESTRAINTS

**DO NOT** spray with aircraft.

**DO NOT** spray when rain seems likely to occur within 4 hours.

**DO NOT** spray when weeds are wet with dew or rain or under stress from drought, low soil fertility, extreme cold or water logging.



**DO NOT** spray outside recommended crop growth stages as crop damage may result.

**DO NOT** apply to crops undersown with clover, lucerne or medics.

#### Additional Restraints for Conservation Tillage

When grass and broadleaf weeds are present, use a mixture of XTENDIMAX 2 HERBICIDE WITH VAPOURGRIP TECHNOLOGY and Roundup Ready® PL Herbicide with Plantshield® Technology.

**DO NOT** disturb treated weeds by cultivation, sowing or grazing for one day after treatment of annual weeds and 7 days for perennial weeds.

**DO NOT** treat weeds heavily covered with dust or silt.

**DO NOT** apply if rainfall is likely within 6 hours of application.

Observe plant back periods listed under General Instructions.

When applying to dry soil surfaces, at least 15 mm rainfall is required before the plant back.

#### Additional restraint for XtendFlex cotton

**DO NOT** apply more than 1 application per season.

Withholding period

Harvest: DO NOT harvest for 7 days after application.

Grazing: DO NOT feed cotton fodder, stubble or trash to livestock.

Trade Advice:

EXPORT OF TREATED PRODUCE: Growers should note that MRLs or import tolerances may not exist in all markets for cotton seed treated with XtendiMax 2 Herbicide with VapourGrip Technology. If you are growing cotton for seed export, please check with Bayer Crop Science for the latest information on MRLs and import tolerances before using XtendiMax 2 Herbicide with VapourGrip Technology.

## Metabolism and residue definition

The APVMA residue definition for dicamba was revised under the research permit PER91044 – 7 September 2021 to 1 December 2021 to allow the use of dicamba in dicamba tolerant (DT) cotton. Further information on the metabolism of dicamba in dicamba tolerant (DT) cotton can found within the Trade Advice Notice on

dicamba in the product XtendiMax 2 Herbicide with VapourGrip Technology for use on XtendFlex cotton published in July 2021<sup>4</sup>. No further consideration of the metabolism or residue definition was necessary.

## Results from residues trials presented to the APVMA

### Cotton

The proposed use of XtendiMax 2 Herbicide with VapourGrip Technology (88630 / 138083) involves a maximum of one application/season at a maximum single rate of 560 g ai/ha dicamba (plus 1% VapourGrip Xtra Agent) Over-The-Top of XtendFlex cotton varieties for control of numerous weeds including fleabane and peach vine, in conjunction with a harvest withholding period of 7 days and a grazing restraint, 'DO NOT feed cotton fodder, stubble or trash to livestock'.

The applicant has re-submitted 7 Australian and 13 USA GLP residue trials in support of the proposed use in XtendFlex cotton.

In the 2016 to 2017 Australian trials, no quantifiable residues of dicamba or its metabolites were detected in undelinted cotton seeds at 7 days PHI, following 4 different treatment regimens comprising 4 applications at a nominal application rate of 560 g dicamba/ha (approximately 1× the proposed rate) [i.e., total dicamba residues for enforcement (MRL estimation) = sum of dicamba plus DCSA were <0.02 mg/kg (n=3)].

In the 2015 to 2016 Australian trials, the highest total dicamba residues in undelinted cotton seeds at 7 days PHI, following 3 different treatment regimens comprising 4 applications at a nominal application rate of 560 g dicamba/ha, were in rank order: 0.32, 0.33, 0.44 and 0.68 mg/kg (n=4).

In the USA trials, the highest total dicamba residues in undelinted cotton seeds at 6 to 8 days PHI, following 2 different treatment regimens comprising 4 applications at a nominal application rate of 560 g dicamba/ha, at 6 to 8 days PHI were, in rank order: 0.19 (2), 0.29, 0.47, 0.52, 0.57, 0.83, 0.85, 0.90, 1.20, 1.23, 1.41 and 1.83 mg/kg (n=13).

The combined dataset suitable for MRL estimation is, in rank order: <0.02 (3), 0.19 (2), 0.29, 0.32, 0.33, 0.44, 0.47, 0.52, 0.57, 0.68, 0.83, 0.85, 0.90, 1.20, 1.23, 1.41 and 1.83 mg/kg (n=20, STMR = 0.495 mg/kg).

The OECD MRL calculator estimates an MRL of 3 mg/kg. Based on the available information, a MRL of 3 mg/kg for Cotton seed [SO 0691] is considered appropriate for the proposed use. It is noted that the proposed dicamba MRL of 3 mg/kg is likely to be conservative given the trials involved 4 applications and the proposed use is limited to 1 application per season.

The combined dataset for dietary exposure estimation from the same Australian and USA trials [i.e. total dicamba residues for dietary exposure = dicamba plus DCSA plus DCGA] is in rank order:

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<sup>4</sup> Australian Pesticides and Veterinary Medicines Authority, [Trade Advice Notice on dicamba in the product XtendiMax 2 Herbicide with VapourGrip Technology for use on XtendFlex cotton](#), APVMA website, 20 July 2021, accessed October 2023.

<0.03 (3), 0.22, 0.25, 0.32, 0.34, 0.35, 0.45, 0.55, 0.56, 0.61, 0.71, 0.86, 0.88, 0.98, 1.23, 1.25, 1.49 and 2.00 mg/kg (n=20, STMR = 0.555 mg/kg).

Dicamba cotton processing studies conducted as part of the USA study showed that total dicamba residues did not concentrate in oil, hulls or cotton seed meal. Mean processing factors were 0.06× for refined oil, 0.67× for hulls and 0.20× for meal. As dicamba residues did not concentrate in these commodities, it is not necessary to establish separate MRLs.

### Animal transfer studies and animal commodity MRLs

For consideration of mammalian animal transfer, a lactating dairy cattle transfer study, in which the animals were dosed with dicamba twice daily at 40, 120 and 400 ppm in the feed for 30 days, was considered. Residues of dicamba plus DCSA after dosing with dicamba at 40 ppm were up to 0.03 mg/kg in milk, <0.01 mg/kg in muscle, 0.029 mg/kg in liver, 0.174 mg/kg in kidney and 0.046 mg/kg in fat. Cotton seed (maximum of 30% of the diet for beef cattle and 20% dairy cattle), meal (30% beef cattle and 15% dairy cattle) and hulls (20% beef cattle and 10% dairy cattle) may be fed to livestock. Feeding beef cattle on cotton seed, hulls and meal from treated crops with a dietary burden of up to 0.332 ppm (beef cattle) or 0.194 ppm (dairy cattle) should not give quantifiable residues in tissues or milk.

No changes are required to the current animal commodity MRLs for dicamba [edible offal (mammalian) at 0.05 mg/kg, meat (mammalian) at 0.05 mg/kg and milks at 0.1 mg/kg] as a result of the proposed use in DT cotton.

For consideration of poultry transfer, a laying hen transfer study, in which the hens were dosed with dicamba daily at 2, 6 and 20 ppm in the feed for 28 days, was considered. The maximum poultry dietary burden is from the consumption of cotton seed meal at 10% of the diet. As no residues above the LOQ were found in eggs or tissues after feeding at 2 or 6 ppm in the study, except in liver after feeding at 6 ppm (up to 0.023 mg/kg), feeding poultry on cotton seed meal from treated crops with a dietary burden of 0.018 ppm, should not result in quantifiable residues in tissues or eggs.

No changes to the current poultry commodity MRLs for dicamba, which are established at \*0.05 mg/kg for eggs, poultry meat and poultry, edible offal of, are required.

## Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Dicamba has been considered by Codex. The following relevant Codex CXL and overseas MRLs have been established for dicamba.

**Table 2: International MRLs**

Commodity	Tolerance for residues arising from the use of dicamba (mg/kg)					
	Australia	EU <sup>5</sup>	Codex <sup>6</sup>	Japan <sup>7</sup>	Korea <sup>8</sup>	USA <sup>9</sup>
Cotton seed	T3 3 (proposed)	*0.05	3	3	3	3

The current Australian residue definition for dicamba, for commodities of plant origin for compliance, is the sum of dicamba and DCSA (free and conjugated), expressed as dicamba. The current definition for commodities of plant origin for dietary exposure, is the sum of dicamba, DCSA (free and conjugated) and DCGA (free and conjugated), expressed as dicamba. The definition for animal commodities is dicamba, only.

The 2019 extra JMPR meeting revised the dicamba residues definition as follows. For compliance with the MRL for plant commodities, the definition for soya bean, maize and cotton is the sum of dicamba and DCSA (free and conjugated) expressed as dicamba, and for all other plant commodities, dicamba. For dietary risk assessment for plant commodities, the definition for soya bean, maize and cotton is the sum of dicamba, 5-OH dicamba, DCSA and DCGA expressed as dicamba, and for all other plant commodities, the sum of dicamba and 5-OH dicamba expressed as dicamba. The residue definition for animal commodities for compliance with the MRL and for estimation of dietary intake is the sum of dicamba and DCSA expressed as dicamba. As the decisions of the 2019 JMPR have not yet been ratified by the CCPR, the Codex Pesticides website<sup>10</sup>, gives the residue definition as '*For compliance with the MRL for plant commodities: Dicamba. For estimation of dietary intake for plant commodities: sum of dicamba and 5-OH dicamba expressed as dicamba. For compliance with the MRL and for estimation of dietary intake for animal commodities: Sum of dicamba and DCSA expressed as dicamba*', and the cotton seed MRL as 3 mg/kg.

<sup>5</sup> [European Commission - Pesticide Residue\(s\) and Maximum Residue Levels \(mg/kg\)](#), accessed, October 2023.

<sup>6</sup> [Codex Alimentarius - International Food Standards](#), accessed, October 2023.

<sup>7</sup> [Japanese MRL Database – Japan Food Chemistry Research Promotion Foundation](#), accessed October 2023.

<sup>8</sup> [Korean MRL database - Food Safety Korea](#), accessed October 2023

<sup>9</sup> [USFDA - Code of Federal Regulations](#), accessed October 2023.

<sup>10</sup> Codex Alimentarius, [Pesticides Database Search](#), FAO website, accessed October 2023.

In Japan, the residue definition for soybeans (dry) and animal commodities is the sum of dicamba, the metabolite B (5-OH dicamba) and the conjugate of the metabolite B, and for other crops (except for soybeans dry), dicamba.

In the USA, the residue definition for cotton and soybean is the sum of dicamba and its metabolites DCSA, and 5-OH dicamba. The definition for other plant commodities is the sum of dicamba and 5-OH dicamba, and for animal commodities, the sum of dicamba and DCSA.

In the EU<sup>11</sup> and Korea, the current residue definition for dicamba is dicamba, only.

## Current MRLs and proposed MRLs for dicamba

**Table 3: Current MRL Standard – Table 1**

Compound	Food	MRL (mg/kg)
<b>Dicamba</b>		
SO 0691	Cotton seed	T3
MO 0105	Edible offal (mammalian)	0.05
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian)	0.05
ML 0106	Milks	0.1
PM 0110	Poultry meat	*0.05
PO 0111	Poultry, edible offal of	*0.05

No changes are required to the current residue definition of dicamba.

**Table 4: Current Residue definition – Table 3**

Compound	Residue
<b>Dicamba</b>	<p>Commodities for plant origin for enforcement: sum of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated), expressed as dicamba.</p> <p>Commodities of plant origin for dietary exposure: sum of dicamba, 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated) and 2,5-dichloro-3,6-dihydroxybenzoic acid (DCGA; free and conjugated), expressed as dicamba.</p> <p>Commodities of animal origin: dicamba.</p>

<sup>11</sup> [European Commission - Pesticide Residue\(s\) and Maximum Residue Levels \(mg/kg\)](#), accessed, October 2023.

Note: There is an ongoing periodic re-evaluation in the EU

Table 5: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
DELETE:		
Dicamba		
SO 0691	Cotton seed	T3
ADD:		
Dicamba		
SO 0691	Cotton seed	3

### Potential risk to trade

Export of treated produce containing finite (measurable) residues of dicamba 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.

All dicamba residue values in cotton seed from 7 Australian trials (HR = 0.68 mg/kg, STMR = 0.32 mg/kg) and 13 USA trials (HR = 1.83 mg/kg, STMR = 0.83 mg/kg) were lower than the MRLs of 3 mg/kg established by various overseas markets, with the exception of Europe.

The European MRL at \*0.05 mg/kg is lower than the supported MRL at 3 mg/kg and therefore there may be a potential risk to trade to European markets. Europe however has not recently been a major market for Australian cotton seed.

The applicant has proposed the following trade advice on the proposed label which is considered appropriate and acceptable from the Residues and Trade perspective.

Trade Advice:

EXPORT OF TREATED PRODUCE: Growers should note that MRLs or import tolerances may not exist in all markets for cotton seed treated with XtendiMax 2 Herbicide with VapourGrip Technology. If you are growing cotton for seed export, please check with Bayer Crop Science for the latest information on MRLs and import tolerances before using XtendiMax 2 Herbicide with VapourGrip Technology.

## Conclusion

Monsanto Australia Pty Ltd has applied for registration for the use of dicamba on XtendFlex cotton.

Comment is sought on the potential for the proposed use to cause undue risk to Australian trade of cotton seed (including oil and meal) and the ability of industry to manage any potential trade risk.