Australian Government

Australian Pesticides and Veterinary Medicines Authority

# TRADE ADVICE NOTICE

## on Terbuthylazine in the Product Terbyne 750 WG Herbicide

APVMA Product Number P56973

**JUNE 2012**

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Email: communications@apvma.gov.au

ISSN: 1443-1335
ISBN: 978-0-9873529-0-3

This document is published by the APVMA. In referencing this document the APVMA should be cited as both author and publisher.

This publication is available from the APVMA website: www.apvma.gov.au

# CONTENTS



## List of tables

# PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator 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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

## 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 **Terbyne 750 WG Herbicide** containing the existing active constituent terbuthylazine 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. In relation to this document, these grounds relate to the **trade implications** of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **26th July 2012** 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)***[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:

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

**Phone:** (02) 6210 4748
**Fax:** (02) 6210 4776
**Email:** pesticides@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: www.apvma.gov.au

[1] 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 Sipcam Pacific Australia Pty Ltd to vary the registration of the product, *Terbyne 750 WG Herbicide*, containing 750 g/kg terbuthylazine, to extend the directions for use to include pre-sowing and pre and post-emergence use in sorghum for the control and suppression of various broadleaf and grass weeds. The proposed extensions of use require the establishment of permanent MRLs for terbuthylazine in sorghum.

The proposed use also involves the addition of 500-750 mL/ha of *Acclaim* (200g /L fluroxypyr). *Acclaim* is currently registered for use on sorghum at rates of 500-750 mL/ha from 8 leaf to boot stage and no further consideration of fluroxypyr residues is necessary.

Sorghum is exported along with animals that have been fed feeds containing residues arising from the proposed use. The potential for terbuthylazine residues in sorghum and animal commodities to unduly prejudice trade is discussed below.

# 2 TRADE CONSIDERATIONS

## 2.1 Commodities exported

Sorghum 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 feeding on treated animal feeds. Residues in these commodities resulting from the use of *Terbyne 750 WG Herbicide* have the potential to unduly prejudice trade.

## 2.2 Destination and value of exports

### Sorghum

Export volumes and values for cereals, are tabulated below.

**Table 1: Value of Australian Cereal Exports 2006-07 to 2010-11**

| COMMODITY | EXPORT VALUE ($ MILLION) | | | | |
|---|---|---|---|---|---|
| | 2006-07 | 2007-08 | 2008-09 | 2009-10 | 2010-2011 |
| Wheat (including flour) | 2315 | 3354 | 5116 | 3778 | 5867 |
| Barley (including malt) | 833 | 1496 | 1321 | 1093 | 1295 |
| Oats | 20 | 37 | 64 | 53 | 37 |
| **Sorghum** | **13** | **76** | **405** | **116** | **146** |
| Maize | 9 | 11 | 30 | 19 | 15 |
| Triticale | 44 | 113 | 93 | 120 | 149 |

Source: Australian Bureau of Agricultural and Resource Economics (ABARE), Australian commodity statistics, 2011

**Table 2: Major export markets for Australian sorghum, 2010-2011 financial year**

| EXPORT COMMODITY | KEY EXPORT MARKET | EXPORTS (KILO TONNE) |
|---|---|---|
| Sorghum | Japan | 409 |
| | New Zealand | 42 |
| | Papua New Guinea | 18 |
| | Chinese Taipei | 16 |

## Animal Commodities

The significant export markets for Australian meat, kidney and liver are listed in Appendix 3 of Part 5B of Ag MORAG. The destination and value of Australian dairy exports are summarised in Table 1 below.

**Table 3: Destination and value of Australian dairy exports**

| DESTINATION | VALUE OF AUSTRALIAN EXPORTS OF DAIRY PRODUCTS, BY DESTINATION ($ MILLION) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 |
| CHEESE | | | | | | | |
| Japan | 272.0 | 299.6 | 378.9 | 298.5 | 337.9 | 426.7 | 398.9 |
| Saudi Arabia | 98.9 | 69.0 | 81.5 | 103.5 | 86.7 | 89.7 | 30.6 |
| United States | 36.1 | 33.9 | 45.4 | 54.2 | 52.7 | 37.2 | 59.7 |
| Other | 393.3 | 336.7 | 370.9 | 381.0 | 346.9 | 414.8 | 306.9 |
| TOTAL | 800.3 | 739.2 | 876.7 | 837.2 | 824.2 | 968.4 | 796.1 |
| BUTTER AND BUTTER FAT | | | | | | | |
| Egypt | 18.9 | 6.4 | 10.5 | 12.5 | 13.9 | 5.0 | 22.0 |
| Malaysia | 12.7 | 13.5 | 11.6 | 15.8 | 11.0 | 17.4 | 14.0 |
| Singapore | 15.5 | 18.2 | 16.8 | 21.1 | 14.4 | 26.2 | 20.2 |
| Other | 176.9 | 144.8 | 149.6 | 175.3 | 139.3 | 146.0 | 175.9 |
| TOTAL | 224.0 | 182.9 | 188.5 | 224.7 | 178.6 | 194.6 | 232.1 |
| SKIM MILK POWDER | | | | | | | |
| Malaysia | 51.4 | 52.7 | 64.2 | 77.1 | 72.2 | 63.4 | 49.0 |
| Philippines | 71.8 | 60.1 | 49.4 | 72.0 | 46.1 | 64.1 | 99.7 |
| Singapore | 38.4 | 42.4 | 57.8 | 56.1 | 67.1 | 61.8 | 54.0 |
| Other | 246.9 | 232.3 | 248.7 | 323.7 | 319.6 | 343.9 | 350.2 |
| TOTAL | 408.5 | 387.5 | 420.1 | 528.9 | 505.0 | 533.2 | 552.9 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **CASEIN** | | | | | | | |
| Japan | 20.6 | 23.3 | 23.1 | 30.4 | 31.8 | 38.4 | 43.6 |
| United States | 81.4 | 68.8 | 56.6 | 27.3 | 32.4 | 42.2 | 29.5 |
| Other | 26.4 | 30.5 | 36.5 | 31.3 | 49.3 | 44.2 | 34.4 |
| TOTAL | 128.4 | 122.5 | 116.2 | 89.0 | 113.5 | 124.8 | 107.5 |
| **WHOLEMILK POWDER** | | | | | | | |
| Malaysia | 22.3 | 28.9 | 33.1 | 23.8 | 14.5 | 27.3 | 14.9 |
| Singapore | 25.2 | 21.4 | 30.9 | 44.6 | 41.4 | 88.9 | 77.0 |
| Taiwan | 44.9 | 40.0 | 31.5 | 22.8 | 13.5 | 11.8 | 9.3 |
| Other | 284.4 | 231.6 | 228.9 | 242.4 | 205.4 | 264.1 | 374.2 |
| TOTAL | 379.8 | 321.8 | 324.4 | 333.6 | 274.9 | 392.2 | 475.3 |
| **OTHER PRODUCTS** | | | | | | | |
| Fresh milk | 98.2 | 104.0 | 108.8 | 107.3 | 96.3 | 83.6 | 102.1 |
| Other fresh products | 5.6 | 9.6 | 9.1 | 6.3 | 11.8 | 12.0 | 0.4 |
| Condensed milk | 133.3 | 121.0 | 139.8 | 147.5 | 156.9 | 152.4 | 158.9 |
| Other powders | 274.4 | 257.3 | 248.3 | 241.5 | 211.0 | 247.4 | 249.7 |
| TOTAL | 511.5 | 492.0 | 506.0 | 502.6 | 476.0 | 495.5 | 511.1 |
| **TOTAL DAIRY PRODUCTS** | 2,453 | 2,246 | 2,432 | 5,516 | 2,372 | 2,709 | 2,675 |
| Source: ABARE, Australian commodity statistics 2009, Canberra | | | | | | | |

## 2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Terbyne 750 WG Herbicide* (750 g/kg terbuthylazine) in sorghum is summarised below.

### Table 4: Proposed use pattern

*Terbyne 750 WG Herbicide* (750 g/kg terbuthylazine)

**RESTRAINTS:**

DO NOT apply by air.
DO NOT apply to waterlogged soil.
DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast within two days of application.
DO NOT irrigate to the point of runoff for at least 2 days after application.
DO NOT use as a pre-emergence application in sorghum during the wet season in the Northern Irrigation areas of Western Australia.
DO NOT apply more than 1.4 kg/ha per crop.

| Crop | Situation | Weeds | Rate (kg/ha) | Critical Comments |
|---|---|---|---|---|
| Sorghum | Pre-Sowing AND Post-Sowing Pre-Emergence | Bladder ketmia, caltrop (yellow vine), dwarf amaranth, milk thistle (sow thistle) and pigweed | 1.4 | Apply to soil pre-sowing or post-sowing. Refer to the APPLICATION section below. Use only with sorghum treated with Concep* II Sorghum Seed Safener. |
| | Post-Emergence | Boggabri weed, noogoora burr, sow thistle (milk thistle), turnip weed, wild gooseberry. | 1.4 | Always add Hasten at 500 mL/100 L water. Apply up to the 5-7 leaf stage of sorghum. Refer to the Acclaim® label for complete directions and rate selection. |
| | | All weeds above plus-Annual ground cherry, apple of Peru, Bathurst burr, Bladder ketmia, caltrop (yellow vine), cow vine (peach vine), dwarf amaranth, giant (black) pigweed, pigweed (red), thorn apples (Datura spp) | 1.1 PLUS Acclaim (200 g/L fluroxypyr) at 500-750 mL/ha | |

**WITHHOLDING PERIODS:**

| Crop | Activity | WHP |
|---|---|---|
| All | Harvest | NOT REQUIRED WHEN USED AS DIRECTED |
| Sorghum | Grazing | DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION. |

## 2.4 Results from residues trials presented to the APVMA

### Sorghum

The proposed use of *Terbyne 750 WG Herbicide* involves application of terbuthylazine at up to 1.4 kg ai/ha per crop up until the 5-7 leaf stage of sorghum (GS 15-17). The applicant has proposed that a harvest withholding period is not required when used as directed. A grazing withholding period of 4 weeks has also been proposed.

At each trial site in the Australian trials, an application of *Terbyne* was made pre-emergent and a second application of *Terbyne* was made post emergent between the 4-8 leaf growth stage. This was done at two different rates for each trial site and involved either a pre-emergent spray at 1.05 kg ai/ha followed by a post emergent spray at 1.50 kg ai/ha (1.8× the proposed seasonal rate) or a pre-emergent spray at 1.50 kg ai/ha followed by a post emergent spray at 0.83 kg ai/ha (1.7× the proposed seasonal rate). Detectable residues (LOQ = 0.01 mg/kg, LOD = 0.005 mg/kg) of terbuthylazine were not observed in any grain sample (n = 10) at natural harvest, while residues of terbuthylazine in the stubble were <0.01 (×4) and <0.02 (×6) mg/kg. Residues of terbuthylazine in the forage 28 days after treatment were 0.043, 0.054, <0.06, 0.11, 0.26, 0.41, 0.78 and 2.98 mg/kg, on a dry weight basis.

The Spanish trials on sorghum involved a single application of terbuthylazine at a rate of 1.5 kg ai/ha (1.1× the proposed seasonal rate). At harvest, detectable residues (LOQ = 0.02 mg/kg) of terbuthylazine were not observed in any grain sample (n = 2).

Considering the available data, the proposed use of terbuthylazine on sorghum is supported from a residues perspective, provided that application is made no later than the 8 leaf growth stage (GS 18). The data support MRLs of *0.01 mg/kg for sorghum grain, *0.02 mg/kg for dry sorghum straw and fodder and 5 mg/kg for sorghum forage (green) to cover the proposed use of terbuthylazine on sorghum, in conjunction with a harvest withholding period not required when used as directed and a grazing withholding period of 4 weeks.

### Animal Commodities

Cattle may be exposed to terbuthylazine in the diet from consumption of sorghum forage at up the 100% of the dietary intake. It is estimated that the worst-case dietary exposure to terbuthylazine is 2.98 ppm in the feed.

The estimated worst-case livestock burden is 3 ppm terbuthylazine in the feed. Livestock feeding studies have previously been submitted which showed no detectable residues in the milk of dairy cattle given daily doses of terbuthylazine equivalent to 15 mg/kg in feed. Additionally, residues were only detected in the liver of one animal at the LOQ when beef cattle were given daily doses equivalent to 17.5 mg/kg in the feed. Therefore detectable residues of terbuthylazine are not expected to occur in the milk, meat or offal of mammalian animals.

A feeding or metabolism study for poultry is not available. However, terbuthylazine is not expected to bio-accumulate, and residues in grain are expected to be below the limit of quantitation. Therefore, quantifiable residues of terbuthylazine are unlikely to be found in the eggs, meat or offal of poultry given feed derived from terbuthylazine-treated crops.

## 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.

Terbuthylazine has not been considered by Codex. The EU has established an MRL of 0.1 mg/kg for terbuthylazine in sorghum. Residues of terbuthylazine are not expected in Australian sorghum following treatment according to the proposed use pattern. Additionally, detectable residues of terbuthylazine are not expected to occur in the tissue or milk of animals that have been fed sorghum forage or fodder treated according to the proposed use.

## 2.6 Current and proposed Australian MRLs for terbuthylazine

Current relevant MRLs and the residue definition for terbuthylazine are presented below. A full listing of MRLs can be found at www.apvma.gov.au/residues/standard.php.

**Table 5: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4**

MRL STANDARD: TABLE 1

| COMPOUND | | FOOD | MRL (mg/kg) |
|---|---|---|---|
| TERBUTHYLAZINE | | | |
| MO | 0105 | Edible offal (Mammalian) | *0.01 |
| PE | 0112 | Eggs | *0.01 |
| GC | 0645 | Maize | T*0.02 |
| MM | 0095 | Meat [mammalian] | *0.01 |
| ML | 0106 | Milks | *0.01 |
| PO | 0111 | Poultry, Edible offal of | *0.01 |
| PM | 0110 | Poultry meat | *0.01 |
| GC | 0651 | Sorghum | T*0.02 |

MRL STANDARD: TABLE 3

| COMPOUND | RESIDUE |
|---|---|
| TERBUTHYLAZINE | Terbuthylazine |

MRL STANDARD: TABLE 4

| COMPOUND | | ANIMAL FEED COMMODITY | MRL (mg/kg) |
|---|---|---|---|
| TERBUTHYLAZINE | | | |
| AS | 0645 | Maize fodder | T*0.1 |
| AF | 0645 | Maize forage | T*0.1 |
| AF | 0651 | Sorghum forage (green) | T*0.1 |
| AS | 0651 | Sorghum straw and fodder, dry | T*0.1 |

## The following changes are proposed to Australian terbuthylazine MRLs:

### Table 6: Proposed changes to the MRL Standard – Table1, Table 4

MRL STANDARD: TABLE 1

| COMPOUND | | FOOD | MRL (mg/kg) |
|---|---|---|---|
| TERBUTHYLAZINE | | | |
| DELETE: | | | |
| GC | 0651 | Sorghum | T*0.02 |
| ADD: | | | |
| GC | 0651 | Sorghum | *0.01 |

MRL STANDARD: TABLE 4

| COMPOUND | | FOOD | MRL (mg/kg) |
|---|---|---|---|
| TERBUTHYLAZINE | | | |
| DELETE: | | | |
| AF | 0651 | Sorghum forage (green) | T*0.1 |
| AS | 0651 | Sorghum straw and fodder, dry | T*0.1 |
| ADD: | | | |
| AF | 0651 | Sorghum forage (green) [dry weight] | 5 |
| AS | 0651 | Sorghum straw and fodder, dry | *0.02 |

## 2.7 Potential risk to trade

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

Terbuthylazine has not been considered by Codex, while the EU has established an MRL of 0.1 mg/kg for terbuthylazine in sorghum. Residues of terbuthylazine are not expected in Australian sorghum following application according to the proposed use pattern. Additionally, detectable residues of terbuthylazine are not expected to occur in the tissue or milk of animals that have been fed sorghum forage or fodder treated according to the proposed use. The risk to Australian trade from the proposed use of *Terbyne 750 WG Herbicide* on sorghum is considered to be very low.

# 3 CONCLUSIONS

It is proposed to establish permanent MRLs for terbuthylazine in sorghum. Comment is sought on the potential for terbuthylazine residues to prejudice Australian trade when *Terbyne 750 WG Herbicide* is used in sorghum for the control and suppression of various broadleaf and grass weeds and when treated feeds are fed to animals.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: 9.00am–5.00pm (EST) Monday to Friday