



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



## TRADE ADVICE NOTICE

on Saflufenacil in the product Sharpen WG Herbicide for use on Wheat, Barley  
and Triticale

APVMA Product Number 62853

**AUGUST 2017**

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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 Sharpen WG 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 Monday 4 September 2017 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:

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

**Phone:** (02) 6210 4701

**Fax:** (02) 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 BASF Australia Ltd, to vary the registration of Sharpen WG Herbicide containing 700 g/kg saflufenacil. BASF wish to add late season uses on cereals (wheat, barley and triticale). This use was considered previously in a Trade Advice Notice published in June 2016. It was not supported at that time as appropriate MRLs were not established by Codex or in some major export markets. New MRLs for saflufenacil on cereals have now been established by Codex and Japan as detailed in section 2.6

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Wheat, barley and triticale 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 cereal crops. Residues in these commodities resulting from the use of Sharpen WG Herbicide may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

Total exports of barley were 5498 kilotonnes in 2015/16, valued at \$1.79 billion. Total exports of wheat (including flour) were 15777 kilotonnes in 2015/16, valued at \$5.12 billion (ABARES). Major export destinations are summarised below:

COMMODITY	MAJOR DESTINATIONS
Barley	China, Japan, Korea, Vietnam, the Philippines, Taiwan, Saudi Arabia, Kuwait, United Arab Emirates
Wheat	Indonesia, Korea, China, Japan, Thailand, Malaysia, Philippines, Egypt, Nigeria, Yemen, Kuwait, 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).

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

## 2.3 Proposed Australian use-pattern

### SHARPEN WG HERBICIDE (700 G/KG SAFLUFENACIL)

CROP	TARGET	RATE	CRITICAL COMMENTS
Late application in Wheat, Barley and Triticale	Wild Radish ( <i>Raphanus raphanistrum</i> ) – for the reduction of seed set and viability of weed seeds	34 g/ha (23.8 g ai/ha) plus 1 % Hasten or high quality MSO	<p><b>ALWAYS apply SHARPEN WG with 1% v/v Hasten Spray adjuvant or high quality methylated seed oil (MSO)</b></p> <p>DO NOT apply before growth stage Z71 (BBCH71) – watery ripe where first grains have reached half their final size.</p> <p>SHARPEN WG can be applied from watery ripe stage (Z71 / BBCH 71). Applications made to an earlier growth stage may results in yield penalties.</p> <p>Application should be made as soon as the crop reaches the watery milk maturity stage to maximise reduction of weed seed set and seed viability. Weeds will be desiccated however complete control may not occur and some regrowth may occur however significant reductions in seed set will be achieved.</p> <p>Following the application of SHARPEN WG minor scarring on wheat stems and grain heads may be visible but have been shown not to cause yield or quality reductions.</p> <p>In order to guarantee good coverage it is recommended to apply SHARPEN WG at minimum 100 L/ha volume.</p> <p>SHARPEN WG may have a negative effect on triticale germination.</p> <p>DO NOT apply after BBCH 83 (early dough)</p>

Withholding periods:

Harvest: Wheat, Barley, Triticale: Not required when used as directed.

Grazing: Wheat, Barley, Triticale: Do not graze or cut for stock food for 14 days after application.

#### LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

#### EXPORT SLAUGHTER INTERVAL (ESI) 30 DAYS

Livestock that has grazed on or been fed treated crops should be placed on clean feed for 30 days prior to export slaughter.

This ESI requirement must be declared on any Commodity Vendor Declaration accompanying traded fodder.

## 2.4 Results from residues trials presented to the APVMA

### *Cereal grains*

The applicant has provided details of Australian trials involving a single application at 23.8 – 34 g ai/ha (1x - 1.4 xproposed) at milky dough growth stage (BBCH 73 - 83) to wheat (11 trials), barley (3 trials) and oats (3 trials). Saflufenacil residues<sup>3</sup> in wheat, barley and oat grain from Australian trials at 27 – 68 days after treatment at 23.8 - 34 g ai/ha applied at BBCH 73 – 83 were <0.010 (5), <0.0174 (2), 0.010 (2), 0.011 (2), 0.012 (2), 0.014, 0.016, 0.051 and 0.11 mg/kg. It is proposed that the current MRL of \*0.03 mg/kg for saflufenacil on GC 0080 Cereal grains be increased to 0.2 mg/kg.

Processing studies have been provided for wheat and barley. Saflufenacil did not concentrate in any fractions except wheat germ (PF 0.8 and 1.4x), wheat bran (PF 1.0 and 1.4x) and barley bran (PF 1.6, 2.7, 3.1 and 3.5x).

Based on a HR of 0.11 mg/kg in cereal grains from the Australian use pattern with application at the milky dough stage, the HR-P for cereal bran is 0.385 mg/kg. An MRL of 0.5 mg/kg is proposed for saflufenacil on CM 0081 Bran, unprocessed of cereal grains.

### *Animal feeds*

#### *Cereal straw*

Saflufenacil residues in wheat, barley and oat straw at harvest from Australian trials at 27 – 68 days after treatment at 23.8 - 34 g ai/ha applied at BBCH 73 – 83 were 0.03, 0.037, 0.038, 0.08, 0.081, 0.11, 0.12, 0.13, 0.16, 0.16, 0.19, 0.20, 0.22, 0.23, 0.26, 0.45 and 0.74 mg/kg dry weight. The OECD MRL calculator recommends an MRL of 1 mg/kg. The HR is 0.74 mg/kg, the STMR is 0.16 mg/kg.

It is proposed that the current MRLs of \*0.1 mg/kg for saflufenacil on AS 0081 Straw and fodder (dry) of cereal grains and AF 0081 Forage of cereal grains (green) [fresh weight] be replaced with an MRL of 1 mg/kg for Forage and fodder of cereal grains.

### *Animal commodities*

The maximum livestock dietary burden is unchanged from that considered previously, noting that there is an MRL of 3 mg/kg established for saflufenacil on legume animal feeds which may form 100% of the diet for ruminants. A 30 day ESI, as currently on the Sharpen label for legume animal feeds, will ensure there are no detectable residues in animal commodities for export derived from livestock fed on treated cereal straw.

In a response to the previous TAN for this use pattern it was indicated that cereal straw is used as bedding in Australian pig production systems and that straw bedding could form up to 7% of the total diet of pigs housed

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<sup>3</sup> Residues are reported according to the Australian residue definition

in such systems. It was noted that it is not possible to observe an ESI as pigs are loaded for market directly from straw based shelters. At 7% of the diet, residues at the HR in cereal straw would be predicted to give residues in liver of 0.17 mg/kg. A Codex Edible offal (mammalian) MRL of 60 mg/kg, and a Japanese MRL of 0.8 mg/kg for pig liver, are established.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that the formulation BAS 800 01 H, registered as Sharpen WG Herbicide in Australia, is registered in over 30 countries globally. Global registrations of this formulated product in cereals include Canada, Mexico, Chile, Argentina, New Zealand and the USA.

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

TABLE 1: CODEX AND OVERSEAS MRLS FOR SAFLUFENACIL

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF SAFLUFENACIL (MG/KG)						
	AUSTRALIA	EU	JAPAN	KOREA	CODEX	TAIWAN	USA
Residue Definition	Plants: Sum of saflufenacil and 2 metabolites Animals: saflufenacil	Plants: Sum of saflufenacil and 2 metabolites Animals: saflufenacil	Saflufenacil		Saflufenacil		Plants: Sum of saflufenacil and 2 metabolites Animals: saflufenacil
Cereal grains	*0.03 (0.2 proposed)	0.03*	1 barley 0.6 wheat 0.03 others	0.03 wheat, barley	1 barley 0.7 triticale 0.7 wheat	0.03 wheat, barley	1 barley 0.6 wheat 0.03 others
Bran, unprocessed of cereal grains	- (0.5 proposed)				3 barley bran (unprocessed)		1.5 barley bran

Note: The Australian residue definition is the same as that established in the EU and USA.

Codex MRLs for wheat, barley and triticale were adopted by CAC in July 2017<sup>4</sup>

## 2.7 Current and proposed Australian MRLs for Saflufenacil

Table 2: Current MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
SAFLUFENACIL		
GC 0080	Cereal grains	*0.03
MO 0105	Edible offal (Mammalian)	7
PE 0112	Eggs	*0.01
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

Table 3: Proposed MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
SAFLUFENACIL		
OMIT:		
GC 0080	Cereal grains	*0.03
INSERT:		
GC 0080	Cereal grains	0.2
CM 0081	Bran, unprocessed of cereal grain	0.5

## 2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of saflufenacil may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing

<sup>4</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-49%252FREPORT%252FREp17\\_PRe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-49%252FREPORT%252FREp17_PRe.pdf)  
[http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-40%252FREPORT%252FREp17\\_CAC.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-40%252FREPORT%252FREp17_CAC.pdf)

country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

#### Cereals

Detectable residues are expected to occur from time to time in wheat, barley and triticale which are major export commodities. The STMR (0.011 mg/kg) in the available trials is approximately at the LOQ for the method. The proposed Australian cereals MRL is lower than those established in the USA and Japan for wheat and barley and is also lower than those MRLs recently established by Codex for barley (1 mg/kg) and wheat and triticale (both at 0.7 mg/kg). Comment is sought on the risk to trade due to the proposed new use pattern on wheat, barley and triticale.

### 3 CONCLUSIONS

BASF Australia Ltd have applied to vary the registration of Sharpen WG Herbicide containing Saflufenacil as active constituent. BASF wish to add late season uses on cereals (wheat, barley and triticale). Comment is sought on the potential for Sharpen WG Herbicide to prejudice Australian trade when used on wheat, barley and triticale as proposed.