Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Trinexapac-ethyl in the Product Moddus Evo Yield & Quality Enhancer

APVMA Product Number 67695

APRIL 2013

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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 (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

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of **Moddus Evo Yield & Quality Enhancer** 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 **27 May 2013** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

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:

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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 Syngenta Crop Protection Pty Ltd, to register Moddus Evo Yield & Quality Enhancer for increasing grain yield in wheat, barley and oats by reducing lodging, reducing excessive crop biomass and enhancing general crop development.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Wheat, barley and oat grain, and oaten hay are exported, and are considered major export commodities in Appendix 1 of Part 5B of Manual of Requirements and Guidelines for Agricultural Products. Mammalian or poultry animal commodities derived from stock fed grain, grain byproducts, forage or fodder from treated cereal crops may be exported. As no changes are required to existing MRLs for mammalian animal commodities, these are not discussed further. New MRLs are proposed for cereal grains and bran, and poultry meat, offal and eggs.

2.2 Destination and value of exports of cereal products

Exports of Australian wheat, barley and oats, are detailed below (Agricultural Commodity Statistics 2012, Australian Bureau of Agriculture and Resource Economics and Sciences, Commonwealth of Australia).

Total exports of barley were 6568 kilotonnes in 2011/12, valued at $1.675 billion.

Total exports of wheat (including flour) were 23038 kilotonnes in 2011/12, valued at $6.381 billion.

Total exports of oats in 2011/12 were 163 kilotonnes, valued at $47 million.

Table 1 – Major destinations for Australian wheat and barley exports

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

Approximately 720 kilotonne of hay is exported from Australia, to the value of ~$230–250 million, per annum.[2] Approximately 85% of exports are oaten hay, while 10% is straw and the balance is predominantly lucerne hay and chaff. Approximately 85% of Australian export hay is destined for Japan, while the volume of hay exported to China and the UAE is increasing.

2.3 Destination and value of exports of animal products

Poultry meat exports in 2010/11 were 31 kilotonnes (worth $38 million), compared with the previous year when 28 kilotonnes were exported, worth $36 million.

[2] Personal communication, AFIA, August 2010

2.4 Proposed Australian use-pattern

Table 2 - Proposed use pattern

CROP	USE	RATE	CRITICAL COMMENTS
Barley	Increase grain yield by reducing lodging, reducing excessive crop biomass, enhancing general crop development.	300–400 mL/ha (75–100 g ai/ha)	Apply to actively growing healthy crops. Apply at the beginning of stem elongation (GS 30/32) when the 2nd node is detectable on the main tiller and the majority of other tillers have the 1st node above ground level. Use the higher rate when plant populations, soil moisture and nutritional levels favour high biomass crop development. In some situations, crop development may be delayed by up to 7–10 days at anthesis but total days to maturity will not generally be affected.
		200–400 mL/ha (50–100 g ai/ha)	Where conditions favour crop growth compensation (bounce back), an additional application can be made at GS 37–39 (flag leaf just visible to flag leaf fully emerged stage). Apply to actively growing, health crops. Use the higher rates when plant populations, soil moisture and nutritional levels favour high biomass crop development. In some situations, crop development may be delayed by up to 7–10 days at anthesis but total days to maturity will not generally be affected.
Oats		300–400 mL/ha (75–100 g ai/ha)	Apply to actively growing healthy crops. Apply at the beginning of stem elongation (GS 30/32) when the 2nd node is detectable on the main tiller and the majority of other tillers have the 1st node above ground level. Use the higher rate when plant populations, soil moisture and nutritional levels favour high biomass crop development. In some situations, crop development may be delayed by up to 7–10 days at anthesis but total days to maturity will not generally be affected.
Wheat		300–400 mL/ha (75–100 g ai/ha) OR 200 mL/ha (50 g ai/ha) + 1000 to 1300 mL/ha chlormequat chloride (528 g/L formulation)	Apply to actively growing healthy crops. Apply at the beginning of stem elongation (GS 30/32) when the 2nd node is detectable on the main tiller and the majority of other tillers have the 1st node above ground level. Use the higher rate when plant populations, soil moisture and nutritional levels favour high biomass crop development. In some situations, crop development may be delayed by up to 7–10 days at anthesis but total days to maturity will not generally be affected.

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

Restraints: DO NOT apply to crops under stress, suffering from nutrient deficiency, disease, drought stress, insect or nematode damage, herbicide effects or frost.

Withholding periods:
Harvest: Not required when used as directed.
Grazing: DO NOT graze or cut for stock food for 6 weeks after application.

2.5 Results from residues trials presented to the APVMA

Cereals:

The proposed GAP for wheat and oats is 1 × 100 g ai/ha application made at BBCH stage 30-32, while the proposed GAP for barley is 2 × 100 g ai/ha, with applications at BBCH stages 30–32 and 37–39. Harvest withholding periods are not required when the product is used as directed, while a grazing withholding period of 6 weeks is proposed for wheat, barley and oats.

Australian trials

A series of fourteen residue trials was conducted in cereal crops in Australia (eight in wheat, two in barley and four in oats).

For wheat, two applications were made at 50 or 100 g ai/ha, giving individual rates of 0.5× and 1× the proposed GAP for wheat, and seasonal rates of 1× and 2× the proposed GAP respectively. The two applications were timed for GS 24–28 (4–8 tillers detectable) and 30–32 respectively.

For barley and oats, two applications were made at 100, 150 or 200 g ai/ha, at GS 31 and 39 for barley, and at GS 24–28 and 30–32 for oats. The trial individual and seasonal rates for barley respectively correspond to 1×, 1.5× and 2× the proposed GAP for barley. For oats, the trial individual rates correspond to 1×, 1.5× and 2× the proposed GAP, while the trial seasonal rates correspond to 2×, 3× and 4 × the proposed GAP.

European trials

Eight trials in wheat, and 11 in barley, were conducted in Europe (UK, Spain, Germany, and north and south France). In all of these trials, a single application of trinexapac-ethyl was made, using the proposed formulation for Australia, at GS 37–39 (flag leaf just visible to flag leaf fully unrolled) or 45–49 (late boot stage to first awns visible). An application of 75 g ai/ha was made to the wheat crops (0.75× the proposed maximum rate for wheat and oats), while an application of 150 g ai/ha was made to the barley crops (1.5× the proposed maximum individual rate and 0.75× the proposed maximum seasonal rate for barley). Wheat and barley grain and straw were sampled at harvest.

US trials

A series of twenty trials in wheat and twelve in barley were conducted in the USA. A single application of trinexapac-ethyl was made at a target rate of approximately 130 g ai/ha (1.3× the proposed maximum individual and seasonal rate for wheat and oats, and 1.3x the proposed individual rate and 0.65x the proposed seasonal rate for barley), with two plots being treated at each site. One application was timed for the forage stage (around GS 30–39) for generation of forage and hay data, with the second plot being

treated approximately six weeks before the scheduled harvest (typically around GS 61–65) for generation of grain and straw data. Due to the much later application timing in these trials than proposed for the product, the grain, forage and fodder residue were not relied on, however processing data generated as part of these studies is considered below.

Residues of trinexapac in wheat, barley and oats are summarised in the table below:

Table 3 – Residues of trinexapac in wheat, barley and oat grain

GRAIN	TRINEXAPAC RESIDUE (MG/KG)
Wheat	<0.01, 0.01, 0.02 (2), 0.03 (2), 0.04 (4), 0.05 (2), 0.08, 0.09, 0.10 (2)
Barley	<0.005, 0.02 (2), 0.03 (3), 0.04 (3), 0.06 (2), 0.08, 0.09
Oats	0.02 (2), 0.03, 0.05

The combined data set for residues of trinexapac in cereal grains is: <0.005, <0.01, 0.01, 0.02 (6), 0.03 (6), 0.04 (7), 0.05 (3), 0.06 (2), 0.08 (2), 0.09 (2), and 0.10 (2) mg/kg (Supervised Trials Median Residue - STMR = 0.04 mg/kg).

A group MRL of 0.2 mg/kg is therefore recommended for trinexapac in cereal grains, with a withholding period not being required when the product is used as directed.

The combined data set for residues in cereal forage collected 6 weeks after application is 0.10, 0.17 (2), <0.20 (4), 0.29, 0.38, 0.52, 0.67, and 0.74 mg/kg (dry weight basis).

An MRL of 2 mg/kg is recommended for trinexapac-ethyl in forage of cereal grains (green), in conjunction with a 6 week grazing withholding period.

The combined data set for residues in cereal straw collected at harvest is <0.005 (2), <0.01 (4), 0.01 (7), 0.02 (9), 0.03 (7), 0.04, 0.05, and 0.07 (2) mg/kg

Residues in wheat hay 6 weeks after application were <0.06 (3), 0.20, and 0.23 mg/kg (dry weight basis).

An MRL of 0.5 mg/kg is recommended for straw and fodder (dry) of cereal grains, in conjunction with a 6 week grazing/cutting for stockfood withholding period for hay.

Grain from two of the US wheat trials and two of the USA barley trials was processed using simulated commercial processes into wheat aspirated grain fractions, wheat bran, wheat flour, wheat middlings, wheat shorts and wheat germ, and pearl barley, barley flour and barley bran. Residues of trinexapac concentrate in wheat and barley bran with the highest processing factor of 2.5. Using the highest residue value of 0.10 mg/kg for trinexapac in cereal grains (a wheat result), and the highest processing factor of 2.5 (for wheat bran), an HR-P value of 0.25 mg/kg is calculated for cereal bran. An MRL of 0.5 mg/kg is therefore proposed for trinexapac-ethyl in bran, unprocessed of cereal grain. The calculated STMR-P value for cereal bran is 2.5 × 0.04 mg/kg = 0.1 mg/kg. Residues of trinexapac appear to concentrate slightly in pearl barley, with the highest processing factor at 1.5. Multiplying this by the highest residue for barley (0.09 mg/kg) gives an HR-P value of 0.135 mg/kg, below the proposed MRL of 0.2 mg/kg for cereal grains. A separate MRL for pearl barley is not proposed.

Animal Commodities:

No MRLs for trinexapac-ethyl in poultry meat, offal or eggs are currently established. Cereal grain can be fed to poultry at up to 70% of the diet, while cereal bran can be fed to poultry at up to 20% of the diet. The dietary burden for poultry is estimated in the table below.

Table 4 - Dietary burden modelling for trinexapac-ethyl in poultry- 2 kg bw, 0.15 kg DM/day

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, MG/KG	% DM	LIVESTOCK DIETARY EXPOSURE		
						MG/ANIMAL	PPM	MG/KG BW
Cereal grains	Wheat grain	70	0.105	0.10	89	0.0169	0.112	0.00843
Cereal byproducts	Bran	20	0.03	0.10	88	0.00341	0.0227	0.00170
TOTAL		90				0.0203	0.135	0.0101

In a poultry feeding study, groups of laying hens were dosed with trinexapac (in the acid form) at levels of 3.3, 9.9 and 33 ppm dry weight in feed daily for 28 days. No residues were found above the limit of quantitation (LOQ) in eggs of birds from the 9.9 ppm feeding group, while only one egg sample from the 33 ppm feeding group contained residues of trinexapac at the LOQ (0.01 mg/kg). For muscle, no samples contained residues above the LOQ, even for the highest feeding level. Fat and liver samples from the 9.9 ppm feeding group did not contain residues above the LOQ, while low levels (up to 0.03 and 0.02 mg/kg respectively) were found in fat and liver from the 33 ppm feeding group. The Maximum Feeding Level for trinexapac in poultry is therefore 0.135 ppm. As no residues were found above the LOQ in eggs, fat or liver at a feeding level of 9.9 ppm, or in muscle at a feeding level of 33 ppm, residues of trinexapac are not expected to be found in the eggs, meat or offal of poultry consuming treated cereal grains or cereal grain byproducts such as bran.

Therefore, residues of trinexapac-ethyl in poultry meat, offal and eggs are expected to be below the LOQ. The following new MRLs at the LOQ are therefore proposed for trinexapac-ethyl in poultry commodities:

PE 0112	Eggs	*0.01 mg/kg
PO 0111	Poultry, edible offal of	*0.01 mg/kg
PM 0110	Poultry meat (in the fat)	*0.01 mg/kg

2.6 Overseas registrations

The applicant indicated that trinexapac-ethyl products are registered for use on cereal crops, variously including barley, oats and wheat in Argentina, Belarus, Belgium, Brazil, Chile, Croatia, the Czech Republic, Denmark, Estonia, Finland, Germany, Kazakhstan, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Pakistan, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Switzerland, Turkey, the UK and Ukraine.

2.7 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.

Trinexapac-ethyl is scheduled for evaluation by the Joint Meeting on Pesticide Residues (JMPR) in 2013, however Codex limits have not yet been established.

* Denotes that the maximum residues limit (MRL) has been set ‘at or about the limit of analytical quantification.

The following relevant residue tolerances for trinexapac-ethyl in cereal and poultry commodities have been established:

Table 5 - Proposed Australian and overseas MRLs/tolerances for trinexapac-ethyl

COUNTRY	COMMODITY	TOLERANCE, MG/KG	REFERENCE
Australia	Cereal grains	0.2 (HR = 0.1)	This evaluation.
	Cereal bran	0.5 (HR-P = 0.25)	
	Eggs	*0.01	
	Poultry meat	*0.01	
	Poultry edible offal	*0.01	
Japan	Wheat	0.6	Japan Food Chemical Research Foundation, Japan Ministry of Health, Labour and Welfare, Food and Agricultural Materials Inspection Centre.
	Barley		
	Rye		
	Other cereal grains		
Russia	Cereal grains	0.2	www.mrldatabase.com
USA	Barley bran	2.5	US Code of Federal Regulations Title 40, Chapter I, subchapter E, Part 180, Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food, 8 January 2013 (www.gpoaccess.gov/cfr/index.html)
	Barley grain	2.0	
	Barley hay	0.8	
	Barley straw	0.4	
	Oat forage	1.0	
	Oat grain	4.0	
	Oat hay	1.5	
	Oat straw	0.9	
	Wheat bran	6.0	
	Wheat forage	1.0	
	Wheat grain	4.0	
	Wheat hay	1.5	
	Wheat middlings	10.5	
	Wheat straw	0.9	

COUNTRY	COMMODITY	TOLERANCE, MG/KG	REFERENCE
EU	Cereal grains	0.5	EU Pesticides Database.
	Poultry meat	*0.05	
	Poultry fat	*0.05	
	Poultry liver	*0.05	
	Poultry kidney	*0.05	
	Poultry edible offal	*0.05	
	Poultry, other products	*0.05	
	Eggs (chicken, duck, goose, quail and others)	*0.05	
New Zealand	Cereal grains	*0.05	New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012

2.8 Current and proposed Australian MRLs for trinexapac-ethyl

The Australian residue definition for trinexapac-ethyl is:4-(Cyclopropyl-α-hydroxy-methylene)-3,5-dioxocyclohexanecarboxylic acid.

Table 6 - Current food MRLs in the maximum Residue Limit Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Trinexapac-ethyl	GC 0640	Barley	T0.3
	MO 0105	Edible offal (Mammalian)	0.05
	MM 0095	Meat (mammalian)	*0.02
	ML 0106	Milks	*0.005
	GC 0647	Oats	T0.3
	SO 0088	Poppy seed	7
	GS 0659	Sugar cane	T0.2
	GC 0654	Wheat	T0.3

Table 7 - Current animal feed commodities in the maximum Residue Limit Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Trinexapac-ethyl	AF 0081	Forage of cereal grains	T0.2
	AS 0162	Hay or fodder (dry) of grasses	3
	AM 0659	Sugar cane fodder	1
	AV 0659	Sugar cane forage	1

Table 8 - Proposed changes for Moddus Evo Yield and Quality Enhancer in the Maximum Residue Limit Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Trinexapac-ethyl			
DELETE:	GC 0640	Barley	T0.3
	GC 0647	Oats	T0.3
	GC 0654	Wheat	T0.3
ADD:	CM 0081	Bran, unprocessed of cereal grains	0.5
	GC 0080	Cereal grains	0.2
	PE 0112	Eggs	*0.01
	PO 0111	Poultry, edible offal of	*0.01
	PM 0110	Poultry meat	*0.01

Table 9 - Proposed changes for Moddus Evo Yield and Quality Enhancer in the Maximum Residue Limit Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Trinexapac-ethyl			
DELETE:	AF 0081	Forage of cereal grains	T0.2
ADD:	AF 0081	Forage of cereal grains	2
	AS 0081	Straw and fodder (dry) of cereal grains	0.5

2.9 Potential risk to trade

Export of treated produce containing finite (measurable) residues of trinexapac-ethyl 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.

Cereals

There is a possible risk to trade in cereal grains as detectable residues of trinexapac-ethyl may be found in grain. In trials in accordance with the proposed GAP, the highest residue for trinexapac-ethyl was 0.10 mg/kg (STMR 0.04 mg/kg; proposed MRL = 0.2 mg/kg). Codex and a number of major export markets for cereal grains do not have established MRLs for trinexapac-ethyl (e.g. China, Taiwan, and various countries in the Middle East and Southeast Asia). There are no entries for trinexapac-ethyl in the Ordinance of the Standards of Feed and Feed Additives of the Japan Food and Agricultural Materials Inspection Center.

Stakeholders are requested to provide comment on the potential risks to trade in cereal grains and oaten hay.

Animal commodities derived from livestock that have been fed treated cereal grains, processed fractions, forage, and fodder

Feeding of cereal forage, fodder, grains, or grain byproducts to mammalian livestock is not expected to result in residues of trinexapac-ethyl in mammalian meat, milk or offal at levels above those arising from existing registered uses. Therefore, there is not expected to be no change in risk to exports of mammalian meat or dairy products.

Exports of poultry products are relatively small and finite residues of trinexapac-ethyl are not expected to arise in poultry products as a result of the proposed use. Proposed MRLs for trinexapac-ethyl in poultry meat, offal and eggs are at the LOQ of 0.01 mg/kg.

3 CONCLUSIONS

Comments are sought on the potential for Moddus Evo Yield & Quality Enhancer to unduly prejudice Australian export trade in cereal grains and oaten hay when it is used on wheat, barley and oats for increasing grain yield in wheat, barley and oats by reducing lodging, reducing excessive crop biomass and enhancing general crop development.