



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



## TRADE ADVICE NOTICE

on prohexadione-calcium in the product Nufarm Regalis Plant Growth Regulator

APVMA Product Number 61570

AUGUST 2010

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## CONTENTS

PREFACE	IV
<b>About this document</b>	<b>iv</b>
<b>Making a submission</b>	<b>iv</b>
<b>Further information</b>	<b>v</b>
<b>1 INTRODUCTION</b>	<b>6</b>
<b>2 TRADE CONSIDERATIONS</b>	<b>6</b>
<b>2.1 Commodities exported</b>	<b>6</b>
<b>2.2 Destination and value of exports</b>	<b>6</b>
<b>2.3 Proposed Australian use-pattern</b>	<b>7</b>
<b>2.4 Results from residues trials presented to the APVMA</b>	<b>7</b>
<b>2.5 Codex alimentarius commission and overseas MRLs</b>	<b>8</b>
<b>2.6 Current and proposed Australian MRLs for [active]</b>	<b>8</b>
<b>2.7 Potential risk to trade</b>	<b>10</b>
<b>3 CONCLUSIONS</b>	<b>11</b>

## LIST OF TABLES

Table 1: Largest Export markets by value for cherries in 2007-2008 financial year	6
Table 2: Proposed use pattern Nufarm Regalis Plant Growth Regulator (100 g/kg prohexadione-calcium)	7
Table 3: Codex CXLs and overseas residue MRLs/tolerances for prohexadione-calcium	8
Table 4: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4	9
Table 5: Proposed changes to the MRL Standard – Table1	9

## 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 **Nufarm Regalis Plant Growth Regulator** containing the existing active constituent prohexadione-calcium 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 **30 September 2010** 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:

Contact Officer  
Pesticides Program  
  
Australian Pesticides & Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604  
Australia  
  
Telephone: +61 2 6210 4748  
Fax: +61 2 6210 4776  
Email: AgProductsCoordinator@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:

<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 Nufarm Australia Limited to vary the registration of the product, Nufarm Regalis Plant Growth Regulator, containing 100 g/kg prohexadione-calcium, to add a use on cherries for shoot growth reduction. The proposed extension of use requires the establishment of a permanent MRL for cherries.

The potential for use of prohexadione-calcium in cherries to unduly prejudice trade is discussed below.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Stone fruit are considered to be major export commodities thus the presence of detectable residues has the potential to prejudice trade.

### 2.2 Destination and value of exports

Australia exported \$15.2 million worth of cherries in the 2007-2008 financial year. The major export markets and value of cherries exported to each country in the 2007-2008 financial year are shown below.

Table 1: Largest Export markets by value for cherries in 2007-2008 financial year

DESTINATION	VALUE , \$-MILLION)
Taiwan	4.41
Hong Kong	3.23
Singapore	1.71
Thailand	1.64
Netherlands	1.13
United Arab Emirates	0.56
United States	0.43
Malaysia	0.42
Other	1.69
TOTAL	15.2

Source of data: Australian Bureau of Statistics

## 2.3 Proposed Australian use-pattern

Table 2: Proposed use pattern Nufarm Regalis Plant Growth Regulator (100 g/kg prohexadione-calcium)

CROP	PEST	RATE/100L	CRITICAL COMMENTS
Cherries	Shoot growth reduction	100 g/100 L (10 g ai/100 L)	<p>Regalis is leaf absorbed and best suited to dilute application using medium to coarse droplets. Thorough coverage of leaves under slow drying conditions will aid uptake.</p> <p>Apply in water with a pH of 7 or less, use LI 700 to acidify alkaline water.</p> <p>Allow 6 hours from application for the product to become rainfast.</p> <p>Cherries:</p> <p>Apply in a program of two sprays 3 to 4 weeks apart commencing when terminal shoots are 5 cm in length</p>

### Restrains:

DO NOT apply by aerial application.

DO NOT apply REGALIS within 3 days of sprays containing calcium, ethylene or gibberellic acid.

DO NOT apply more than 2 sprays per season to cherries.

### WITHHOLDING PERIOD

*Harvest: Cherries: Do not harvest for 4 weeks after application.*

*Grazing: Do not graze or cut forage in treated orchards for stock food until 8 weeks after application.*

## 2.4 Results from residues trials presented to the APVMA

Six Australian residue trials were conducted in 2007/08. Cherries were treated with a single application of prohexadione-calcium at the nominal rates of either 15 g ai/100 L or 30 g ai/100 L. Two trials treated with one application at 15 g ai/100L following a 18 and 28 day PHI both resulted in residues of <0.01 mg/kg. The remaining four trials also resulted in residues of <0.01 mg/kg at PHIs ranging from 52 to 71 days.

A further 4 Australian residue trials were conducted in 2009. Cherries were treated with two applications (3 week interval) of prohexadione-calcium at 10.5 or 21 g ai/100L with cherry samples taken at 0, 7, 14, 21 or 28 days after the last application. Twenty eight days after the second application at 10 g ai/100L residues were <0.01 (3) mg/kg. Twenty eight days after the second application at 21 g ai/ha residues were 0.01 and <0.01 (2) mg/kg. The decline data from the trial treated at 10.5 g ai/100L shows a decrease in residues from 0.04 mg/kg directly after the last application to 0.01 mg/kg after 7 days, and <0.01 mg/kg after 14 days.

An MRL of \*0.01 mg/kg is recommended for use of prohexadione-calcium on FS 0013 Cherries in conjunction with a 4 week WHP.

## Animal Commodities

As cherries are not considered an animal feed and quantifiable residues are unlikely in fruit, the proposed use is unlikely to have any impact on the current animal commodity MRLs which remain acceptable.

The 8 week grazing withholding period currently required for treated apple orchards has been recommended for cherry orchards. No changes are required to animal commodity MRLs.

## 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. Prohexadione-calcium has not been considered by Codex. The following relevant overseas residue MRLs/ tolerances have been established for prohexadione-calcium:

Table 3: Codex CXLs and overseas residue MRLs/tolerances for prohexadione-calcium

COUNTRY/STATUS	COMMODITY	TOLERANCE (mg/kg)
Australia	Cherries	*0.01 (Proposed)
USA <sup>2</sup>	Cattle, kidney	0.1
	Cattle, meat by products, except kidney	0.05
	Fruit, pome, group 11	3
EU <sup>3</sup>	Pome fruit	*0.05
	Stone fruit	*0.05
	Bovine	*0.05

## 2.6 Current and proposed Australian MRLs for [active]

Current relevant MRLs and the residue definition for prohexadione-calcium are presented below. A full listing of MRLs can be found at <http://www.apvma.gov.au/residues/standard.php>.

<sup>2</sup> [http://edocket.access.gpo.gov/cfr\\_2007/julqtr/pdf/40cfr180.593.pdf](http://edocket.access.gpo.gov/cfr_2007/julqtr/pdf/40cfr180.593.pdf)

<sup>3</sup> [http://ec.europa.eu/food/plant/protection/pesticides/database\\_pesticide\\_en.htm](http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm)

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

## MRL Standard: Table 1

COMPOUND	FOOD	MRL (mg/kg)
PROHEXADIONE-CALCIUM		
FP 0226	Apples	*0.02
MO 0105	Edible offal (Mammalian)	*0.05
MM 0095	Meat (Mammalian)	*0.05
ML 0106	Milks	*0.01

## MRL Standard: Table 3

COMPOUND	RESIDUE
Prohexadione-calcium	Sum of the free and conjugated forms of prohexadione expressed as prohexadione

## MRL Standard: Table 4

COMPOUND	FOOD	MRL (mg/kg)
PROHEXADIONE-CALCIUM		
ADD:		
AB 0226	Apple pomace, (dry)	0.1

The following changes are proposed to Australian prohexadione-calcium MRLs:

Table 5: Proposed changes to the MRL Standard – Table 1

## MRL Standard: Table 1

COMPOUND	FOOD	MRL (mg/kg)
PROHEXADIONE-CALCIUM		
ADD:		
FS 0013	Cherries	*0.01

## **2.7    Potential risk to trade**

Export of treated produce containing finite (measurable) residues of prohexadione-calcium 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.

As detectable residues of prohexadione-calcium are not expected to occur in cherries after the harvest withholding period has been observed, the risk to Australia's export trade in cherries is considered to be very low.

The overall risk to export trade in animal commodities is also considered to be negligible as no quantifiable residues are expected.

### 3 CONCLUSIONS

It is proposed to establish a permanent MRL for prohexadione-calcium on cherries. Comment is sought on the potential for prohexadione-calcium in Nufarm Regalis Plant Growth Regulator to prejudice Australian trade when it is used on cherries for shoot growth reduction.

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: 9.00 - 5.00 (EST) Monday to Friday