



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



TRADE ADVICE NOTICE

on Coumaphos and Diazinon in the product
CO-RAL[®] Plus Insecticide Cattle Ear Tags

APVMA Product Number 60662

MARCH 2010

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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 the APVMA's publication *Vet 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 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.

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: <http://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 CO-RAL[®] Plus Insecticide Cattle Ear Tags 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 **27/04/2010** 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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 public release summaries can be found on the APVMA website:

<http://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 Bayer Australia Limited (Animal Health) for the registration of a new product, *CO-RAL[®] Plus Insecticide Cattle Ear Tags*, which contains 200 g/kg coumaphos (2.6 g/ear tag) and 200 g/kg diazinon (2.6 g/ear tag). The ear tags are to be applied to beef and dairy cattle for the control of organophosphate-susceptible strains of buffalo fly (*Haematobia irritans exigua*), including synthetic pyrethroids resistant strains, for up to 4 months.

The application involves the establishment of permanent Australian Maximum Residue Limits (MRLs) for coumaphos residues in cattle commodities (liver, kidney, muscle, fat and milk). Additionally, the application requires the setting of meat and milk withholding periods (WHPs), establishment of an export slaughter interval (ESI), and approval of the proposed product label.

2 RESIDUES IN LIVESTOCK

2.1 Proposed Australian use pattern

The proposed Australian use-pattern for *CO-RAL® Plus Insecticide Cattle Ear Tags* is provided in Table 1.

Table 1: Proposed use pattern - *CO-RAL® Plus Insecticide Cattle Ear Tags*

HOST	PURPOSE	DOSE RATE	CRITICAL COMMENTS
Cattle (Beef and dairy)	For the control of organophosphate-susceptible strains of buffalo fly (<i>Haematobia irritans exigua</i>), including synthetic pyrethroids resistant strains, for up to 4 months.	Nominal Two (2) ear tags per animal, one tag in each ear	All mature animals in the herd should be tagged.
		Maximum As above	Replace tags as necessary. Calves less than 3 months should not be tagged, as ear damage may result. Remove tags at end of fly season or prior to slaughter.

Withholding periods

MEAT: Nil

MILK: Nil

Trade advice

EXPORT SLAUGHTER INTERVAL (ESI): The minimum time between removal of the ear tags and slaughter for export is zero (0) days.

2.2 Withholding periods and maximum residue limits

In support of the application, Bayer Australia Limited (Animal Health) provided details of two (2) Australian tissue residues trials and one (1) Australian milk residues trial conducted with *CO-RAL® Plus Insecticide Cattle Ear Tags* in cattle.

Meat

In the first tissue residues trial, beef cattle (n=10) were administered two *CO-RAL® Plus Insecticide Cattle Ear Tags*, one in each ear (equivalent to 1× the maximum proposed label rate). Groups of animals (n=5) were sacrificed at 21 and 42 days after insertion of the ear tags, and samples of muscle, liver, kidney, subcutaneous fat and peri-renal fat were collected and stored frozen until analysed for their content of diazinon and coumaphos residues.

In the second tissue residues trial, beef cattle (n=30) were administered two *CO-RAL® Plus Insecticide Cattle Ear Tags*, one in each ear (equivalent to 1× the maximum proposed label rate). Groups of animals (n=5)

were sacrificed at 94 days (3 months) and 122 days (4 months) after insertion of the ear tags, and at 7, 14, 28 and 42 days after removal of ear tags that had been in place for 4 months. Samples of subcutaneous fat and peri-renal fat were collected and stored frozen until analysed for their content of diazinon and coumaphos residues.

Fat was identified as the “target tissue” for both diazinon and coumaphos residues in treated cattle, and it is the decline of residues in fat that governs the length of the WHP and ESI that is to be assigned to the new product.

Diazinon: The highest diazinon residues in subcutaneous fat (0.15 mg/kg) and peri-renal fat (0.11 mg/kg) occurred in the first tissue residues trial at 42 days after insertion of the ear tags. The available residues data indicate that diazinon residues in fat are likely to comply with the existing MRL of 0.7 mg/kg for mammalian meat [in the fat] at all times after application of the ear tags, and support the Applicant’s proposal for a nil meat WHP.

Diazinon residues in liver and kidney were reported to range from <0.02 to <0.1 mg/kg, indicating that residues in liver and kidney will comply with the existing diazinon MRL of 0.7 mg/kg for mammalian offal. However, as part of the Diazinon Chemical Review, it has been recommended that the diazinon MRL for mammalian offal be reduced to 0.03 mg/kg. Further examination of the data for liver and kidney shows that most of the samples (>80%) did not contain detectable levels of diazinon residues (<0.02 mg/kg). The remaining 20 % of samples were reported as being <0.1 mg/kg, which was the LOQ of the analytical method used to quantify residues in these samples. Thus, results of <0.1 mg/kg are also likely to be <0.02 mg/kg, if a more sensitive analytical method had been employed. Therefore, it is concluded that use of the cattle ear tags (with a nil meat WHP) is unlikely to result in violations of the revised diazinon MRL for mammalian offal.

Coumaphos: Coumaphos residues in subcutaneous fat and peri-renal fat (target tissues) were below the method LOQ (<0.2 mg/kg) at all sampling times in the first tissue residues trial, and below the method LOD (<0.01 mg/kg) at all sampling times in the second residues trial. The available residues data support the (re)-establishment of a coumaphos MRL of *0.02 mg/kg (ie at or about the method LOQ) for cattle fat, and the assignment of a nil meat WHP to the new product.

Coumaphos residues in liver, kidney and muscle from treated cattle were all non-detectable at all sampling times. Thus, the available data support the (re)-establishment of coumaphos MRLs at the level of the method LOQ (*0.02 mg/kg) for cattle muscle, cattle liver and cattle kidney.

Meat WHP

Thus, a nil meat WHP is recommended for the use of *CO-RAL® Plus Insecticide Cattle Ear Tags* in cattle.

Meat MRLs

The following coumaphos MRLs are recommended to cover the occurrence of coumaphos residues in edible cattle tissues when the nil meat WHP is observed:

cattle fat: *0.02 mg/kg;

cattle muscle: *0.02 mg/kg;

cattle liver: *0.02 mg/kg;

cattle kidney: *0.02 mg/kg.

No changes to the existing Australian MRLs for diazinon are required to cover the use of *CO-RAL® Plus Insecticide Cattle Ear Tags* in cattle.

Milk

In the milk residues trial, lactating dairy cows (n=12) were administered two *CO-RAL® Plus Insecticide Cattle Ear Tags*, one in each ear (equivalent to 1× the maximum proposed label rate). Samples of milk were collected twice daily on days 1, 7, 14, 28, 42 and 49 after insertion of the ear tags. The ear tags were removed after 42 days, and the milk samples collected on day 49 represent a withdrawal period of 7 days. Milk samples were refrigerated (2-6 °C) after collection, and sent directly to the laboratory for analysis of diazinon and coumaphos residues.

Diazinon: Diazinon residues in milk butterfat ranged from <0.03 to 0.41 mg/kg throughout the treatment period (ie while the ear tags were attached), and ranged from <0.01 to 0.20 mg/kg at 7 days after removal of the ear tags. These results comply with the existing diazinon MRL of 0.5 mg/kg for milks [in the fat]. However, as part of the Diazinon Chemical Review, it has been recommended that the diazinon MRL for milks [in the fat] be changed to 0.02 mg/kg for milks (whole milk). The concentrations of diazinon residues in whole milk were estimated by multiplying the results for butterfat by the percentage fat content of each sample. The estimated concentrations of diazinon residues in whole milk ranged from <0.001 to 0.007 mg/kg throughout the treatment period, and ranged from <0.001 to 0.006 mg/kg at 7 days after removal of the ear tags. These data indicate that milk from cows treated with *CO-RAL® Plus* ear tags will comply with the recommended diazinon milk MRL of 0.02 mg/kg, and support the proposed nil milk WHP.

Coumaphos: Coumaphos residues in milk butterfat ranged from <0.02 to 0.08 mg/kg throughout the treatment period (ie while the ear tags were attached), and ranged from <0.02 to <0.06 mg/kg at 7 days after removal of the ear tags. These data indicate that coumaphos residues in milk butterfat would comply with the previously established MRL of 0.1 mg/kg for coumaphos residues in milks [in the fat]. The available data support the (re)-establishment of a coumaphos MRL of 0.1 mg/kg for cattle milk fat, and the assignment of a nil milk WHP to the new product.

The concentrations of coumaphos residues in whole milk were estimated by multiplying the results for butterfat by the percentage fat content of each sample. The estimated concentrations of coumaphos residues in whole milk ranged from <0.001 to 0.004 mg/kg throughout the treatment period, and ranged from

<0.001 to <0.004 mg/kg at 7 days after removal of the ear tags. These data support the establishment of a coumaphos MRL of *0.01 mg/kg for cattle milk, and the assignment of a nil milk WHP to the new product.

Note that the recommendation to set coumaphos MRLs for both cattle milk and cattle milk fat is consistent with the JECFA approach (decided at the 66th meeting of JECFA).

Milk WHP

Thus, a nil milk WHP is recommended for the use of *CO-RAL® Plus Insecticide Cattle Ear Tags* in dairy cattle.

Milk MRLs

The following coumaphos MRLs are recommended to cover the occurrence of coumaphos residues in cattle milk tissues when the nil milk WHP is observed:

cattle milk: *0.01 mg/kg;

cattle milk fat: 0.1 mg/kg.

No changes to the existing Australian MRLs for diazinon are required to cover the use of *CO-RAL® Plus Insecticide Cattle Ear Tags* in dairy cattle.

3 RESIDUES-RELATED ASPECTS OF TRADE

3.1 Commodities exported

Australian exports of beef/veal, live cattle and dairy produce could be affected by the use of CO-RAL[®] Plus Insecticide Cattle Ear Tags.

3.2 Destination and value of exports

Beef/veal exports

Australia exported 957.5 ktonne of beef and veal during 2008, which was valued at \$AUS 4.78 billion. Details of the top 7 export markets for Australian beef are provided below.

Table 2: Beef and Veal Exported in 2008

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (ktonne)	VALUE (\$ AUS MILLION)	CUMULATIVE TOTAL (%)
1	Japan	264.3	2009.2	42.0
2	USA	234.8	1039.2	63.7
3	Republic of Korea	127.2	636.3	77.0
4	CIS ^ψ	72.2	293.3	83.2
5	Chinese Taipei	27.1	123.8	85.8
6	European Union [†]	11.9	117.0	88.2
7	Indonesia	33.0	113.1	90.6
Total		957.5	4782.7	

[†] Regarded as 27 countries

^ψ Commonwealth of Independent States

Source: ABARE 2009

Live cattle exports

Australia exported around 870,000 head of live cattle during 2008, which were valued at approximately \$AUS 526 million. Details of the top 5 export markets for Australian live cattle are provided below.

Table 3: Live Cattle Exported in 2008

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (‘000 OF ANIMALS)	VALUE (\$ AUS MILLION)	CUMULATIVE TOTAL (%)
1	Indonesia	644.6	409.5	77.8
2	Israel	51.7	30.2	83.5
3	Libya	--	19.3	87.2
4	Japan	19.8	17.4	90.5
5	Malaysia	18.4	13.9	93.1
Total		868.5	526.4	

Source: ABARE 2009

Dairy produce exports

In 2008/2009, Australia exported \$AUS 2.675 billion of dairy products, including cheese, butter and butterfat, skin and whole milk powder. Details of the export destinations are provided in the following table.

Table 4: Dairy Product Exports in 2008-2009

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (KTONNE)	VALUE (\$AUS MILLION)
CHEESE			
1	Japan	74.4	398.9
2	USA	10.6	59.7
3	Saudi Arabia	5.4	30.6
Total		146.4	796.1
BUTTER AND BUTTERFAT			
1	Egypt	8.5	22.0
2	Singapore	5.1	20.2
3	Malaysia	3.7	14.0
Total		70.4	232.1

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (KTONNE)	VALUE (\$AUS MILLION)
SKIM MILK POWDER			
1	Philippines	25.4	99.7
2	Singapore	17.1	54.0
3	Malaysia	14.9	49.0
Total		162.3	552.9
CASEIN			
1	Japan	2.3	43.6
2	USA	2.4	29.5
Total		7.6	107.5
WHOLE MILK POWDER			
1	Singapore	17.0	77.0
2	Malaysia	3.2	14.9
3	Thailand	3.4	14.6
Total		116.3	475.3
OTHER PRODUCTS			
Fresh milk		69.2 ML	102.1
Other fresh products		0.2 ML	0.4
Condensed milk		81.4	158.9
Other powders		51.4	249.7
Total			511.1

3.3 Overseas registrations

Bayer Australia Limited (Animal Health) has advised that CO-RAL[®] Plus Insecticide Cattle Ear Tags are currently registered for use in the USA.

3.4 Comparison of the (proposed) Australian MRLs with Codex 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. Diazinon has been considered by Codex, and diazinon MRLs/tolerances have been established by a number of overseas countries, and these are tabulated below along with the proposed Australian MRLs. In contrast, coumaphos has not been considered by Codex, nor have MRLs for coumaphos been established in any of the overseas countries, except the USA.

Table 5: Comparison of Australian and Overseas MRLs/Tolerances for Diazinon and Coumaphos (Values in parenthesis are MRLs recommended as part of the Chemical Review for Diazinon).

COMPOUND	OVERSEAS MRL/TOLERANCE (mg/kg)				MRL(mg/kg)
	CODEX	EU	USA	JAPAN	
COUMAPHOS					
Cattle liver	--	--	--	--	*0.02
Cattle kidney	--	--	--	--	*0.02
Cattle muscle	--	--	--	--	*0.02
Cattle meat	--	--	1.0	--	--
Cattle meat byproducts	--	--	1.0	--	--
Cattle fat	--	--	1.0	--	*0.02
Cattle milk	--	--	--	--	*0.01
Cattle milk fat	--	--	0.5	--	0.1
DIAZINON					
Edible offal (mammalian)	--	--	--	--	0.7 (0.03)
Meat (mammalian) [in the fat]	--	--	--	--	0.7
Milks [in the fat]	--	--	--	--	0.5
Milks	0.02	0.02	--	0.02	(0.02)
Cattle muscle	--	0.02	--	0.02	
Cattle fat	--	0.7	0.7	2	--
Cattle liver	0.03	0.02	--	0.03	--

COMPOUND	OVERSEAS MRL/TOLERANCE (mg/kg)				MRL(mg/kg)
	CODEX	EU	USA	JAPAN	
Cattle kidney	0.03	0.02	--	0.03	--
Cattle meat [in the fat]	2	--	--	--	--
Cattle, Edible offal	--	--	--	0.7	--

* MRL set at or about the limit of quantification for the analytical method

3.5 Potential risk to trade

Export of treated produce containing finite (measurable) residues of diazinon or coumaphos 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.

3.5.1 Meat

Markets for consideration in export slaughter interval determination

In June 2009, the APVMA published a document titled “*Markets for Consideration in Export Slaughter Interval Determination*” which defined the major markets that are to be considered when establishing ESIs for cattle, pig and sheep commodities over the next five (5) years (see the Operational Notices section of the APVMA website – www.apvma.gov.au).

On the basis of economic and strategic value, the standards of the following export markets for Australian beef/veal and live cattle exports are to be considered, in conjunction with Codex CXLs, when determining ESIs for products that are to be used in cattle: CIS, EU, Japan, Republic of Korea, Taiwan and USA.

It is noted that consideration of the standards of the above markets will also mitigate trade risks in other markets that have similar standards.

Determination of the export slaughter interval (ESI) endpoint

Diazinon: Codex CXLs have been established for diazinon residues in edible cattle commodities. Similarly, the USA, EU and Japan have established MRLs/tolerances for diazinon residues in cattle commodities, and these MRLs/tolerances are either the same as, or higher than, the corresponding Australian MRLs. The Republic of Korea, Taiwan and CIS are expected to adopt the Codex CXLs for diazinon. Thus, the appropriate “endpoint” for the ESI determination is the Australian MRL of 0.7 mg/kg for mammalian meat [in the fat]. It is concluded that the available residues data support the Applicant’s proposal for a nil ESI.

Coumaphos: US tolerances have been established for coumaphos residues in cattle tissues. However, there are no Codex CXLs, or MRLs for coumaphos set in Japan or the EU. Thus, the appropriate “endpoint” for the ESI determination is the method LOQ (0.02 mg/kg). Given that coumaphos residues in all tissues

from treated cattle are expected to be non-detectable (<0.02 mg/kg) at all times after application of the ear tags, the Applicant's proposal for a nil ESI is supported.

3.5.2 Milk

Diazinon: A Codex CXL has been established for diazinon residues in milks. Similarly, the EU and Japan have established MRLs for diazinon residues in milk which are equivalent to the recommended Australian milk MRL. However, the USA has not established a tolerance for diazinon in milk. Thus, the appropriate "endpoint" for trade considerations is the LOQ of the analytical method (0.01 mg/kg). The available milk residues data show that diazinon residues in whole milk from cows treated with *CO-RAL[®] Plus Insecticide Cattle Ear Tags* are likely to be below the method LOQ (<0.01 mg/kg) at all times.

Coumaphos: A US tolerance has been established for coumaphos residues in milk fat (0.5 mg/kg). However, a Codex CXL has not been set for milk; nor have MRLs been established for coumaphos in milk by Japan and the EU. Thus, the appropriate "endpoint" for the trade considerations is the method LOQ (*0.01 mg/kg). The available milk residues data show that coumaphos residues in whole milk from cows treated with *CO-RAL[®] Plus Insecticide Cattle Ear Tags* are likely to be below the method LOQ (<0.01 mg/kg) at all times.

3.6 Trade advice statements

The following trade advice statement is to be included on the product label:

EXPORT SLAUGHTER INTERVAL (ESI): The minimum time between removal of ear tags and slaughter for export is zero (0) days.

4 CONCLUSIONS

The risk to Australia's export trade in cattle commodities (tissues and dairy produce), arising from the use of *CO-RAL[®] Plus Insecticide Cattle Ear Tags* is considered to be low when the recommended nil ESI is observed.

However, the APVMA is seeking comment from relevant industry groups and stakeholders in relation to whether the proposed use of coumaphos and diazinon in the product *CO-RAL[®] Plus Insecticide Cattle Ear Tags* poses an undue prejudice to Australia's export trade in beef/veal, live cattle and dairy commodities.

The APVMA also welcomes comment on any residues aspects of trade.