



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



## TRADE ADVICE NOTICE

*ELANCO AF1404 Rumensin 100 Monensin Sodium*

APVMA Product Number 47359

FEBRUARY 2011

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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 *ELANCO AF1404 Rumensin 100 Monensin Sodium* 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 **Friday, 4 March 2011** 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.

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:

Linden Moffatt  
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Veterinary Medicines Program  
Australian Pesticides and Veterinary Medicines Authority  
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**Phone:** (02) 6210 4789

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**Email:** [vetmedicines@apvma.gov.au](mailto:vetmedicines@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: <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 Elanco Animal Health to vary the registration of *ELANCO AF1404 Rumensin 100 Monensin Sodium*, which contains 100 g/kg of monensin as monensin sodium. The product is added to feed for the prevention of ovine coccidiosis as well as to improve weight gain and feed efficiency.

The application involves consideration of the proposal to extend the use of monensin to a new food-producing animal species (sheep), along with the establishment of Australian Maximum Residue Limits (MRLs) for monensin in sheep commodities (muscle, fat, liver and kidney). 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 *ELANCO AF1404 Rumensin 100 Monensin Sodium* is given below.

*Table 1: Proposed use pattern for ELANCO AF1404 Rumensin 100 Monensin Sodium*

HOST	PURPOSE	DOSE RATE
Sheep	For the prevention of ovine coccidiosis.	Complete feed: 5-20 mg monensin/kg feed
	For improved weight gain and feed efficiency.	Supplementary: 5-40 mg monensin/head/day

#### RESTRAINT

DO NOT use in sheep which are producing or may in the future produce milk where the milk or milk products may be used for human consumption.

#### WITHHOLDING PERIODS

MEAT: DO NOT USE less than 24 hours before slaughter for human consumption.

MILK: DO NOT USE in sheep which are producing or may in the future produce milk where the milk or milk products may be used for human consumption.

#### TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 7 days before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from Elanco Animal Health on 1800 226 324 or the APVMA website ([www.apvma.gov.au/residues/ESI.shtml](http://www.apvma.gov.au/residues/ESI.shtml)).

### 2.2 Residues trials

In support of their application, Elanco Animal Health submitted details of one contemporary residues trial conducted with *ELANCO AF1404 Rumensin 100 Monensin Sodium*. Sheep were administered a daily oral drench of 40 mg/head (ie 1x maximum dose rate) for 10 consecutive days. Groups of animals were sacrificed at specific times ranging from 6 to 168 hours after the last treatment. Samples of fat, muscle, liver and kidney were collected and analysed for their concentrations of monensin residues.

## MRL recommendations

The following monensin MRLs are recommended to cover the occurrence of monensin residues in edible sheep tissues after the recommended WHP has been observed: sheep liver - 0.2 mg/kg; sheep kidney - 0.015 mg/kg; sheep muscle - 0.005 mg/kg; sheep fat - 0.07 mg/kg.

## Withholding period - Meat

Statistical analyses of the residues data indicate that 24 hours after treatment monensin residues in all edible sheep tissues have declined to below the recommended Australian monensin MRLs. Therefore, a meat WHP of 24 hours is recommended for the use of *ELANCO AF1404 Rumensin 100 Monensin Sodium* in sheep.

## Withholding period - Milk

In the absence of any milk residues data, the following milk WHP is recommended: *“DO NOT USE in sheep which are producing or may in the future produce milk where the milk or milk products may be used for human consumption”*.

## Re-treatment interval

The use-pattern of *ELANCO AF1404 Rumensin 100 Monensin Sodium* in sheep is a 'long-term' treatment. Therefore, a re-treatment interval is not considered necessary.

### 3 RESIDUES-RELATED ASPECTS OF TRADE

#### 3.1 Commodities exported

Australian exports of mutton/lamb and live sheep could be affected by the use of *ELANCO AF1404 Rumensin 100 Monensin Sodium*.

#### 3.2 Destination and value of exports

##### Mutton/lamb exports

Australia exported ~316 ktonne of mutton and lamb during 2008, which was valued at approximately \$AUS 1.3 billion. Details of the top export markets for Australian lamb/mutton are provided below.

*Table 2: Mutton and lamb exports in 2008*

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (KTONNE)	VALUE (\$ AUS MILLION)
1	USA	49.3	335.2
2	European Union†	21.9	138.1
3	Japan	16.7	93.9
4	United Arab Emirates	13.3	65.6
5	Saudi Arabia	20.6	59.9
6	China	24.3	48.9

† Regarded as 25 countries

Source: ABARE 2009

##### Live sheep exports

Australia exported ~4.2 million head of live sheep during 2008, which were valued at \$AUS 320 million. Details of the top export markets for Australian live sheep are provided below.

*Table 3: Live sheep exports in 2008*

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (KTONNE)	VALUE (\$ AUS MILLION)
1	Kuwait	956	68
2	Saudi Arabia	874	68
3	Oman	741	57

RANK (BY \$ VALUE)	IMPORTING COUNTRY	QUANTITY (KTONNE)	VALUE (\$ AUS MILLION)
4	Bahrain	716	56
5	Qatar	269	27
6	Jordan	384	26

Source: ABARE 2009

### 3.3 Comparison of the proposed Australian MRLs with Codex and overseas MRLs/tolerances

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. The use of monensin in sheep has been considered by Codex, and monensin MRLs have been established by a number of overseas countries. A comparison of Australian and overseas MRLs/tolerances for monensin are tabulated below.

Table 4: Comparison of Australian and Overseas MRLs/tolerances

COMPOUND	OVERSEAS MRL/TOLERANCE (MG/KG)						PROPOSED AUSTRALIAN MRL (MG/KG)
	CODEX	EUROPE	USA	CHINA	CIS	JAPAN	
Other terrestrial mammals, muscle	--	--	--	--	--	0.05	--
Other terrestrial mammals, kidney	--	--	--	--	--	0.05	--
Other terrestrial mammals, liver	--	--	--	--	--	0.05	--
Sheep muscle	0.01	--	--	0.05	--	--	0.005
Sheep liver	0.02	--	--	0.05	--	--	0.2
Sheep kidney	0.01	--	--	0.05	--	--	0.015
Sheep fat	0.1	--	--	0.05	--	--	0.07

### 3.4 Markets for consideration in Export Slaughter Interval (ESI) 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.

On the basis of economic and strategic value, the standards of the following export markets for Australian mutton/lamb and live sheep exports are to be considered, in conjunction with Codex Maximum Residue Limits (CXLs), when determining ESIs for products that are to be used in sheep: Commonwealth of Independent States (CIS), European Union, Japan, China, Saudi Arabia, United Arab Emirates (UAE) and USA. Consideration of the standards of these markets will also mitigate trade risks in other markets that have similar standards.

### 3.5 Potential risk to trade

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

#### Identification of the appropriate ESI “endpoint”

Codex, Japan and China have established MRLs for monensin residues in sheep. However, in the absence of monensin MRLs/tolerances for sheep commodities in Europe, CIS and USA, the ESI “endpoint” is considered to be the method LOQ (ie 0.001 mg/kg).

#### Estimation of the ESI

Statistical analysis of the residues data indicates that monensin residues in all edible tissues are expected to be less than 0.001 mg/kg 7 days after the last treatment. Therefore, an ESI of 7 days is recommended for *ELANCO AF1404 Rumensin 100 Monensin Sodium* when used in sheep.

### 3.6 Trade advice statements

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

#### TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 7 days before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from Elanco Animal Health on 1800 226 324 or the APVMA website ([www.apvma.gov.au/residues/ESI.shtml](http://www.apvma.gov.au/residues/ESI.shtml)).

## 4 CONCLUSIONS

The APVMA has considered whether use of *ELANCO AF1404 Rumensin 100 Monensin Sodium*, in accordance with the proposed label instructions, could potentially unduly prejudice trade and commerce between Australia and places outside Australia, as per Section 14(3)(e)(iv) of the Agvet Codes.

The risk to Australia's export trade in sheep meat and live sheep is considered to be low when the recommended ESI of 7 days is observed for *ELANCO AF1404 Rumensin 100 Monensin Sodium*, as residues in edible tissues from treated sheep are likely to have declined to below the standards applied by the importing countries.

The APVMA is seeking comment from relevant industry groups and stakeholders in relation to the perceived level of risk to Australia's export trade in sheep meat and live sheep.