Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on meloxicam in the product Metacam 20 mg/ml Solution for Injection

APVMA Product Number 54061

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This publication is available from the APVMA website: www.apvma.gov.au.

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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 Metacam 20 mg/ml Solution for Injection 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 18 March 2016 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)*[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:

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

Phone: +61 2 6210 4701
Email: 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.

[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 Boehringer Ingelheim Pty Limited, to vary the registration of Metacam 20 mg/ml Solution for Injection to include a new use in sheep for the alleviation of pain and inflammation.

2 RESIDUES IN LIVESTOCK

2.1 Proposed Australian use pattern

Table 1: Proposed use pattern

HOST	PURPOSE	DOSE RATE
Sheep	For the alleviation of pain and inflammation.	SINGLE USE ONLY by subcutaneous injection high on the neck behind the ear. 1.0 mg meloxicam/kg bodyweight (ie 1.0 ml/20 kg bodyweight).

Withholding periods

Sheep meat: DO NOT USE less than 11 days for sheep before slaughter for human consumption.

DO NOT USE in ewes which are producing or may in the future produce milk that may be used or processed for human consumption'.

Trade advice

Sheep: DO NOT slaughter for export less than 11 days after final treatment.

3 RESIDUES—RELATED ASPECTS OF TRADE

3.1 Commodities exported

Sheep are considered to be major export commodity. Meloxicam residues in sheep commodities resulting from the use of Metacam 20 mg/ml Solution for Injection may have the potential to unduly prejudice trade.

3.2 Destination and value of exports

Sheep exports

In 2014–15, Australian exported 242 kt of lamb ($1,696 million) and 169 kt of mutton ($778 million).

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). Significant markets for trade considerations for sheep include Codex, China, the European Union, Japan, Russia, Saudi Arabia, the United Arab Emirate and the United States.

3.3 Overseas registrations

The extension of Metacam 20 mg/ml Solution for Injection into sheep is being considered as part of joint review between Canada, New Zealand and Australia. The same use pattern has been proposed in each country.

The applicant indicated that other than the current proposal for the use of meloxicam in sheep in Australia, New Zealand and Canada, meloxicam has not been approved for use in sheep by any country.

3.4 Comparison of the (proposed) Australian MRLs with Codex and overseas MRLs

It is proposed that Australian MRLs for sheep fat, liver, kidney and meat be established at 0.01 mg/kg.

Meloxicam MRLs for sheep tissues are expected to be established in Canada and New Zealand.

Meloxicam MRLs for sheep commodities have not been established by Codex, the USA, the EU, China, Japan or Russia.

3.5 Potential risk to trade

Sheep exports

As major export markets have not established meloxicam MRLs for sheep commodities, residues of meloxicam must be below the LOQ to prevent an undue risk to international trade. The validated LOQ of 0.005 mg/kg for fat, liver, kidney and meat is therefore considered to be a suitable endpoint for ESI determination.

A residue depletion study found that a single subcutaneous injection of meloxicam at 3.5 mg ai/kg bw (3.5 X the proposed dose of 1 mg ai/kg bw) resulted in meloxicam residues below the LOQ of 0.005 mg/kg in all tissues of all six animals sacrificed 10 days after treatment. The data therefore indicates that residues above the LOQ of 0.005 mg/kg, which may result in an undue risk to trade, should not occur in tissues of sheep treated with the proposed use of meloxicam at the proposed Export Slaughter Interval of 11 days.

3.6 Trade advice statements

A 11 day Export Slaughter Interval (ESI), which is the same as the proposed withholding period, is to be associated with the proposed use of Metacam 20 mg/ml Solution for Injection in sheep.

4 CONCLUSIONS

Key export markets of Australian lamb and mutton have not established meloxicam MRLs for sheep commodities. The risk to Australia's export trade in sheep meat is however considered to be low and acceptable when the proposed ESI of 11 days is observed for Metacam 20 mg/ml Solution for Injection, as meloxicam residues in edible tissues from treated sheep are likely to have declined to below 0.005 mg/kg.