



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



Trade Advice Notice

on Lasalocid in the product BOVATEC 20CC SODIUM PREMIX in Poultry

APVMA product number 60761

OCTOBER 2019

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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.

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 trade advice notice 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 **BOVATEC 20CC LASALOCID SODIUM PREMIX** 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 **31 October 2019** 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)
- submission date.

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:

Residues and Trade
Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
PO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

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: 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 ZOETIS AUSTRALIA PTY LTD, to vary the registration of BOVATEC 20CC LASALOCID SODIUM PREMIX (containing 200 g/kg lasalocid sodium) for chickens. The proposal is to harmonise the current Australian lasalocid MRLs for poultry tissues where appropriate with Codex MRLs and to reduce the meat withholding periods for chickens from three days to one day.

An increase to the current Australian lasalocid MRLs for poultry tissues is recommended therefore the proposed reduction in meat withholding period may have the potential to unduly prejudice Australia's export trade in markets where no or lower MRLs have been established for poultry meat.

No change to poultry eggs MRL is proposed therefore residues aspects relating to poultry eggs are not discussed in this trade advice notice as the risk to international trade remains unchanged.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Poultry meat and offal are currently considered to be major export commodities²

2.2 Destination and value of exports

Approximately 36 kilo tonne of chicken meat was exported from Australia for the 2016 financial year. Australian chicken meat export was valued by ABARES at A\$54.1 M for the 2016–17 period and is been forecast to rise to \$63.6 M (39.8 kt) for 2017–18³.

2.3 Australian use-pattern

BOVATEC 20CC LASALOCID SODIUM PREMIX is currently approved for use in poultry (broiler, replacement pullet and turkey only)⁴. The only proposed change to the current label is for a reduction in the meat withholding period for chickens from three days to one day. No change to the current meat withholding period for turkey (zero days) is proposed.

The proposed use pattern is summarised below:

Species	Claims	Dosage
Poultry (broiler, replacement pullet and turkey only)	As an aid for the prevention of coccidiosis in broilers, in rearing replacement pullets and in turkeys	Broilers and replacement pullets: Use continuously in the feed—mix 375–500g BOVATEC® 20CC premix per tonne of feed to provide 75–100ppm of Lasalocid Sodium in complete feed. Under conditions of average exposure to coccidial infection, 450g of BOVATEC® 20CC premix per tonne of feed has been demonstrated to be efficacious for broilers and replacement pullets. For broilers, medicated feed should be fed continuously throughout life. Growing turkeys: Use continuously in feed—mix 450–625 g Bovatec 20CC premix tonne of feed to provide 90–125 ppm of Lasalocid Sodium in complete feed.

Withholding periods:

Broilers & Replacement Pullets:

MEAT: One day **{REDUCED FROM THREE DAYS}**

² APVMA Guideline: Veterinary drug residues in food commodities and overseas trade: apvma.gov.au/node/669

³ Australian Chicken Meat Federation (2019), Facts and Figures, chicken.org.au/facts-and-figures/#Exports

⁴ Current label: websvr.infopest.com.au/LabelRouter?LabelType=L&Mode=1&ProductCode=60761

EGGS: DO NOT USE in laying birds within 14 days of laying where eggs or egg products are to be used for human consumption or processing.

Turkeys:

MEAT: Zero (0) days

2.4 Results from residues trials presented to the APVMA

The proposal is to reduce the chicken meat withholding period from three days to one day and to harmonise the current Australian MRLs where appropriate for poultry tissues with Codex MRLs based on the comprehensive residues data package supplied that has also been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2013 and 2015⁵.

The critical residues depletion study was conducted with 48 healthy one-day old chickens fed 130 mg/kg lasalocid sodium. Birds were sacrificed at zero hour (on-feed), one, two and three days after dose administration. Tissue concentrations of lasalocid were determined in chicken kidney, liver, muscle and skin+fat after the proposed treatment are discussed below.

Liver: The current lasalocid MRL for liver is 400 µg/kg and the proposal is to harmonise this MRL by increasing it to the Codex MRL of 1200 µg/kg. Residue levels of lasalocid ranged from 1360–2802 µg/kg at day zero; 40–1039 µg/kg at day one; 39–444 µg/kg at day two and 23–194 µg/kg at day three after treatment. Statistical analysis indicates that a withdrawal period of one days is required for residues to comply with the proposed MRL of 1200 µg/kg.

Kidney: The current lasalocid MRL for kidney is 400 µg/kg, lower than the Codex MRL of 600 µg/kg. Residue levels of lasalocid ranged from 664–1667 µg/kg at day zero; 18–633 µg/kg at day one; 22–274 µg/kg at day two and 16–45 µg/kg at day three after treatment. Statistical analysis indicates that a withdrawal period of one days is required for residues to comply with the recommended MRL of 700 µg/kg.

Muscle: The current lasalocid MRL for meat is 100 µg/kg and the proposal is to harmonise this MRL by increasing it to the Codex MRL of 400 µg/kg. Residue levels of lasalocid ranged from 282–774 µg/kg at day zero; 8–294 µg/kg at day one; 9–84 µg/kg at day two and 5–14 µg/kg at day three after treatment. Statistical analysis indicates that a withdrawal period of one days is required for residues to comply with the proposed MRL of 400 µg/kg.

Skin/fat: The current lasalocid MRL for skin/fat is 1000 µg/kg and the proposal is to harmonise this MRL by decreasing it to the Codex MRL of 600 µg/kg. Residue levels of lasalocid ranged from 577–1492 µg/kg at day zero; 17–554 µg/kg at day one; 9–192 µg/kg at day two and <5–20 µg/kg at day three after treatment. Statistical analysis of this contemporary dataset indicates that a withdrawal period of one day is required for residues to comply with the proposed MRL of 600 µg/kg.

⁵ Monograph of the 81st Joint FAO/WHO Expert Committee on Food Additives (JECFA) meeting, 2015: fao.org/3/a-bp387e.pdf

The applicant has not proposed a change to the current zero day meat withholding period for turkeys. The residues depletion study considered by JECFA found that following zero hours of withdrawal, mean residues of lasalocid were highest in skin plus fat (159 µg/kg), followed by liver (155 µg/kg), kidney (108 µg/kg) and muscle (25 µg/kg). These observed residues were within the proposed MRLs for poultry tissues. It is concluded that the current zero day withholding period for turkey meat remains appropriate and that the recommended poultry MRLs will cover the approved use on turkey.

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 Veterinary Practice (GVP) employed by various countries. Some countries may accept Codex CXLs when importing foods. The relevant Codex and international MRLs are presented in Table 1 below.

Table 1: Comparison of proposed Australian MRLs with Codex, the USA and EU

Poultry tissue	Established MRL (mg/kg)			
	Australia (proposed)	Codex/JECFA	USA	EU
Muscle	0.4	0.4	-	0.06
Skin/fat	0.6	0.6	1.2	0.3
Kidney	0.7	0.6	-	0.15
Liver	1.2	1.2	0.4	0.3

2.6 Current and proposed Australian MRLs for lasalocid

Table 2: Current MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
LASALOCID		
PO 0111	Poultry, edible offal of	0.4
PM 0110	Poultry meat	0.1
	Poultry skin/fat	1

Table 3: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
LASALOCID		
DELETE:		
PO 0111	Poultry, edible offal of	0.4

COMPOUND	FOOD	MRL (mg/kg)
PM 0110	Poultry meat	0.1
	Poultry skin/fat	1
ADD:		
	Poultry kidney	0.7
	Poultry liver	1.2
	Poultry muscle	0.4
	Poultry skin/fat	0.6

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of lasalocid 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 eggs are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Finite residues of lasalocid in chicken meat tissues after observing a one day meat withholding period are expected, therefore the proposed use has the potential to unduly prejudice Australia's export trade in chicken meat. Noting that the proposed MRLs are similar to those established by Codex, the potential risk to international trade associated with this proposed label variation is considered to be low.

3 CONCLUSION

Comments are sought on the potential risk to trade in chicken tissues from the proposed use and the ability of the industry to manage any potential risk.