Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on ractopamine in the product
Elanco AF0602 Paylean 20 Ractopamine Hydrochloride Premix
for use in turkeys

APVMA Product Number 54172

AUGUST 2016

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CONTENTS

LIST OF TABLES

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, Department of the Environment and Energy, 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 Elanco AF0602 Paylean 20 Ractopamine Hydrochloride 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 20 September 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. 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:

Residues and Trade
Scientific Assessment and Chemical Review
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 Elanco Animal Health, to vary the registration of Elanco AF0602 Paylean 20 Ractopamine Hydrochloride Premix to include a new use for turkeys. The product is currently registered for use in pigs only.

2 RESIDUES IN LIVESTOCK

2.1 Proposed Australian use pattern

The draft product label and directions for use relevant to final feed are presented in appendices 1 and 2 respectively. The proposed use pattern for *Elanco AF0602 paylean 20 Ractopamine Hydrochloride Premix* (20 g/kg ractopamine hydrochloride) in turkeys is tabulated below:

Table 1: Proposed use pattern

HOST	PURPOSE	DOSE RATE	CRITICAL COMMENTS
For use in finisher turkeys	To increase the rate of weight gain and improve feed conversion efficiency in finisher turkeys.	5–13 ppm in final feed for increased rate of weight gain and improved feed efficiency.	Feed complete ration containing ractopamine as the sole ration to finisher hen and tom turkeys for at least 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality.

Restraints

DO NOT ADMINISTER PAYLEAN TO SPECIES OTHER THAN PIGS AND TURKEYS.

Note to feed formulators:

Unintended inclusion of medication into animal feeds may result in residues that adversely impact trade access or the rules of professional competition. Use cleaning or flushing, or avoid sequencing feed for other species (in particular ruminant and horse feeds) immediately after manufacture of pig or turkey finisher feeds containing paylean.

A copy of directions for use relevant to final feed are required to be provided to the producers with each consignment of paylean treated feed. Contact Elanco Animal Health for further information.

NOT FOR USE IN BREEDING PIGS OR BREEDING TURKEYS.

FOR USE IN FINISHER PIG AND TURKEY FEEDS ONLY.

Withholding periods

TURKEYS: REMOVE ALL MEDICATED FEED 6 hours before slaughter for human consumption.

EGGS: DO NOT USE in turkey hens which are producing or may in the future produce eggs for human consumption or processing.

3 RESIDUES—RELATED ASPECTS OF TRADE

3.1 Commodities exported

In Australia, commercial production of turkeys is quite small, amounting to ~$200 million/year from almost 5 million birds processed[2]. While poultry meat is currently considered to be a major export commodity in the APVMA regulatory Guidelines[3], Australia's turkey meat goes primarily to the domestic market with very little entering the export market.

3.2 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 veterinary drugs and 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. Ractopamine has been considered by Codex, but CXLs for turkey tissues have not been promulgated. The recommended Australian MRLs as well as established international tolerances for ractopamine in turkey commodities are tabulated below:

Table 2: Comparison of overseas MRLs with the proposed Australian MRLs

COMPOUND	OVERSEAS MRL/TOLERANCE (MG/KG)				PROPOSED AUSTRALIAN MRL (MG/KG)
	CODEX	EU	USA	JAPAN	
Ractopamine					
Turkey muscle	--	--	0.1	--	0.02
Turkey liver	--	--	0.45	--	0.3
Turkey kidney	--	--	--	--	0.3
Turkey skin/fat	--	--	--	--	0.05

[2] Poultry hub (Turkey) www.poultryhub.org/species/commercial-poultry/turkey/

[3] APVMA Regulatory Guidelines—Data Guidelines: Veterinary drug residues in food commodities and overseas trade

3.3 Potential risk to trade

Australia does not export significant quantities of turkey meat so the risk to Australia's export trade is considered to be low and undue. There is the potential risk of carry-over residues of ractopamine arising in non-medicated feeds.

4 CONCLUSIONS

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

Comment is sought on the potential of the proposed use of ractopamine in turkeys to result in unacceptable residues in exported animal products and the ability of industry systems to effectively manage any identified risk.

5 APPENDIX 1: DRAFT LABEL

CAUTION
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY

ELANCO™ AF0602 PAYLEAN™ 20 RACTOPAMINE HYDROCHLORIDE PREMIX

Active constituent: 20 g/kg ractopamine hydrochloride (equivalent to 17.8 g/kg ractopamine)

For increased rate of weight gain, improved feed efficiency, increased carcass leanness and increased dressing percentage in finisher pigs and for increased rate of weight gain and improved feed efficiency in finisher turkeys.

10 kg NET

DIRECTIONS FOR USE:

Restraint:
DO NOT ADMINISTER PAYLEAN TO SPECIES OTHER THAN PIGS AND TURKEYS.

Note to feed formulators:
Unintended inclusion of medication into animal feeds may result in residues that adversely impact trade access or the rules of professional competition. Use cleaning or flushing, or avoid sequencing feed for other species (in particular ruminant and horse feeds) immediately after manufacture of pig or turkey finisher feeds containing Paylean.
A copy of directions for use relevant to final feed are required to be provided to the producers with each consignment of Paylean treated feed. Contact Elanco Animal Health for further information.

NOT FOR USE IN BREEDING PIGS OR BREEDING TURKEYS.
FOR USE IN FINISHER PIG AND TURKEY FEEDS ONLY.

Precaution
Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality.

Dosage and Administration:

Pigs
Recommended dosages of ractopamine hydrochloride:

- 5–20 ppm in final feed for increased rate of weight gain and improved feed efficiency
- 10–20 ppm in final feed for increased carcass leanness and increased carcass dressing percent

Mixing Directions:
PAYLEAN 20 PREMIX MUST BE THOROUGHLY MIXED INTO FEEDS BEFORE USE.
All calculations are based on 90% dry matter.

Ractopamine Concentration in Final Feed g/tonne (ppm)	Grams of Paylean 20 Premix to Add per Tonne of Final Feed
5	250
10	500
15	750
20	1000 (1 kg)

IMPORTANT—To ensure adequate mixing, it is recommended to pre-blend Paylean 20 Premix in a small quantity of feed before incorporation into the total amount of complete feed. Thoroughly mix the pre-blend into a nutritionally balanced pig ration to result in a final ration containing 5 to 20 ppm of ractopamine. Amino acid content of the ration may influence response to treatment. Dietary specifications should be determined in consultation with a recognised pig nutritionist in order to optimise Paylean benefits.

Feeding directions: Feed complete ration containing ractopamine continuously as the sole ration to finisher pigs for the last 28–42 days prior to slaughter.

Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (could also be referred to as leg weakness syndrome). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean.

Turkeys

The recommended dose for finisher hen and tom turkeys is 5–13 ppm for increased rate of weight gain and improved feed efficiency.
Mixing Directions:
PAYLEAN 20 PREMIX MUST BE THOROUGHLY MIXED INTO FEEDS BEFORE USE.

Ractopamine Concentration in Final Feed g/tonne (ppm)	Grams of Paylean 20 Premix to Add per Tonne of Final Feed
5	250
9	450
13	650

IMPORTANT—To ensure adequate mixing, it is recommended to pre-blend Paylean 20 Premix in a small quantity of feed before incorporation into the total amount of complete feed. Thoroughly mix the pre-blend into a nutritionally balanced turkey ration to result in a final ration containing 5 to 13 ppm.

Feeding directions: Feed complete ration containing ractopamine continuously as the sole ration to finisher turkeys for the last 14 days prior to slaughter

WARNING: Not for use in humans. Individuals with cardiovascular disease should exercise special caution to avoid exposure. The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist.

WITHHOLDING PERIODS:

PIGS: MEAT—DO NOT USE less than 12 hours before slaughter for human consumption.

TURKEYS: REMOVE ALL MEDICATED FEED 6 hours before slaughter for human consumption.

EGGS: DO NOT USE in turkey hens which are producing or may in the future produce eggs for human consumption or processing.

EXPORT TRADE ADVICE—TREATED STOCK: Exporters need to comply with the regulations/standards of importing countries with regard to the use of animal health products in livestock. Producers are advised to contact their export slaughter facility for information before giving pigs or turkeys feed to which this product has been added.

SAFETY DIRECTIONS: Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. Wash hands after use. When opening the container and preparing stock feed wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, elbow length PVC gloves and face shield or goggles. After each day's use, wash gloves and contaminated clothing

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 13 1126.

DISPOSAL OF BAGS: Shake and empty contents into medicated feed. Do not dispose of undiluted chemicals on site. Puncture or shred and bury empty bags in a local authority landfill. If not available bury the bag below 500mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty bags and product should not be burnt.

Additional information is in the Material Safety Data Sheet.

Manufactured in U.K. for:
ELANCO ANIMAL HEALTH
A division of Eli Lilly Australia Pty Limited A.B.N. 39 000 233 992
112 WHARF ROAD, WEST RYDE, N.S.W. 2114
TEL: Toll free 1800 226 324

APVMA Approval Number: 54172/50618

STORAGE: Store below 30°C (Room temperature) in a dry place.

For batch number and expiry date see reverse

USE NO HOOKS

Bar code 93 23829 00273 6

Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing should not be allowed out of the workplace.
IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

6 APPENDIX 2: DIRECTIONS FOR USE RELEVANT TO FINAL FEED

CAUTION
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

THIS STOCK FEED CONTAINS PAYLEAN PREMIX *
(5–20 PPM RACTOPAMINE HYDROCHLORIDE)

DIRECTIONS FOR USE:

Restraint:
DO NOT ADMINISTER PAYLEAN TO SPECIES OTHER THAN PIGS AND TURKEYS.

Note to feed formulators:
Unintended inclusion of medication into animal feeds may result in residues that adversely impact trade access or the rules of professional competition. Use cleaning or flushing, or avoid sequencing feed for other species (in particular ruminant and horse feeds) immediately after manufacture of pig or turkey finisher feeds containing Paylean.
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FOR USE IN FINISHER PIG AND TURKEY FEEDS ONLY.

Precaution
Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality.

Dosage and Administration:

Feeding directions for pigs:
Feed complete ration containing ractopamine continuously as the sole ration to finisher pigs for the last 28– 42 days prior to slaughter.

Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (could also be referred to as leg weakness syndrome). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean.

Feeding directions for turkeys: Feed complete ration containing ractopamine continuously as the sole ration to finisher turkeys for the last 14 days prior to slaughter

WARNING: Not for use in humans. Individuals with cardiovascular disease should exercise special caution to avoid exposure. The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist.

WITHHOLDING PERIODS:

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