Australian Government

Australian Pesticides and Veterinary Medicines Authority

Consideration of submissions received on the Trade Advice Notice of antimicrobial products

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Comments and enquiries regarding copyright:

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This publication is available from the APVMA website.

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1 Submissions received

The Australian Pesticides and Veterinary Medicines Authority (APVMA) published a Trade Advice Notice (TAN) on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets. The APVMA invited comments in relation to the TAN between 10 December 2024 and 31 January 2025 and received 10 submissions. The APVMA was given permission to publish 8 of these submissions, which are available on apvma.gov.au. The remaining 2 submissions have been considered but not published.

The submissions received by the APVMA are listed in Table 1 and the APVMA's consideration of the information received is summarised in Section 2 below. Where applicable, the APVMA consulted with the Department of Agriculture, Fisheries and Forestry (DAFF) to seek clarification from the European Union (EU) on some questions raised in the submissions below.

Table 1. Submissions in response to the Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

	Submitter	Comments
1	Australian Meat Industry Council (AMIC)	The AMIC provided a submission supportive of proposed amendments to antimicrobial veterinary products and noting the importance of maintaining market access for Australian beef and sheep meat to the EU.
2	Royal Society for the Prevention of Cruelty to Animals, Australia (RSPCA)	The RSPCA provided a submission that was not supportive of the proposed amendments, calling on dairy, beef, and sheep industries to phase out the routine prophylactic use of antimicrobials.
3	Nutriment Health	Nutriment Health provided a submission that was not supportive of the proposed amendments. The submission proposed that the risk to EU trade could be addressed by a segregated system via the National Vendor Declaration Scheme and trade advice statements rather than removal of use patterns. The submission also noted the importance of feed conversion efficiency uses to Australian farmers and that the antimicrobial compounds considered were not important in human medicine.
4	Eurogroup for Animals	Eurogroup for Animals provided a submission that was not supportive of the proposed amendments, calling on Australia to restrict the use of antimicrobials for prophylactic or growth promotion purposes across all animal production sectors.
5	Animal Medicines Australia (AMA)	Animal Medicines Australia (AMA) provided a submission that was not supportive of the proposed amendments. AMA presented an argument that ionophores are excluded from EU Reg 2019/6 as they are 'feed additives' rather than 'veterinary medicinal products' and therefore removal of growth promotion uses is unnecessary. They also argued that the proposed changes will disadvantage Australian producers. The submission proposed that the risk to EU trade could instead be addressed by a segregated system via the National Vendor Declaration Scheme and inclusion of trade advice statements on product labels rather than removal of use patterns. The submission also sought clarification on affected use patterns and noted the potential financial impacts of the proposed label updates to industry.

	Submitter	Comments
6	Phibro Animal Health Corporation	Phibro Animal Health Corporation provided a submission that was not supportive of the proposed amendments and endorsed the position of the AMA. The submission noted the importance of feed conversion efficiency uses to Australian farmers and the environment. It also noted that the antimicrobial compounds considered were not important in human medicine and argued that they would not contribute to antibiotic resistance. The submission noted the impact on cattle producers and suggested that a segregated system could also be implemented for dairy cattle in order to retain growth promotion use patterns on the label.
7	Australian Dairy Farmers Ltd – Initial submission	Australian Dairy Farmers initially provided a submission requesting that decisions on label amendments be paused to allow the dairy industry to consider if segregation of EU and other markets was possible. The submission also proposed a modified label restraint for dairy cattle. The follow up submission, provided to DAFF and the APVMA, indicated that a segregated production system would not be feasible for the dairy industry; that access to the EU market was important for dairy producers; and that they were supportive of the approach to remove relevant use patterns. This submission also proposed a simplified label restraint for dairy cattle.
8	Australian Dairy Farmers Ltd - Follow up submission	
9	Confidential	A confidential submission supportive of the proposal to modify products and labels and providing information about the ability of industry to segregate for different markets. The submission also noted the importance of therapeutic uses of antimicrobials for coccidiosis control.
10	Confidential	A confidential submission providing information about the ability of industry to segregate for different markets and raising concerns about the proposed restriction of feed efficiency/feed conversion uses.

2 APVMA's consideration of submissions

2.1 Information regarding the ability of industry to establish a segregated system

Submissions by Australian Meat Industry Council, Dairy Australia, and anonymous parties provided information on the ability of industries to segregate between the EU market and domestic and other international markets. This information confirms that the beef cattle industry would be able to use the existing European Union Cattle Accreditation Scheme (EUCAS) to ensure that beef supplied to the EU is compliant with Regulation (EU) 2019/6. The dairy industry initially requested a pause to consider whether a segregated system would be possible for their industry but later confirmed that a segregated system would not be possible. Information received indicated that a segregated system would not be feasible for the sheep industry. Several submissions also provided information on the importance of the EU market for export of Australian beef, dairy, and sheep meat products.

APVMA response: The APVMA sought and received confirmation that a segregated system would be feasible for beef cattle, but not for dairy cattle or sheep. The label variations proposed in the TAN — where growth promotion use patterns for sheep and dairy cattle are removed and growth promotion use patterns for beef cattle are retained with restraints and trade advice statements — were based on initial information provided by DAFF and have now been confirmed by the APVMA's consultation on the TAN. The APVMA notes submissions indicated that the EU is an important market for beef, dairy, and sheep producers.

2.2 Submissions advocating phase out of antimicrobials for prophylactic and growth promotion uses

Submissions received from the RSPCA and Eurogroup for Animals did not support the approach outlined in the TAN and instead proposed that Australian animal production sectors should phase out the use of antimicrobials for growth promotion and for prophylactic use.

APVMA response: The APVMA has reviewed the submission received from RSPCA and Eurogroup for Animals and considers that it does not include information relevant to consideration of the trade risk with the EU.

2.3 Concerns about making changes to Australian veterinary product labels to satisfy the EU market

Several submissions (Animal Medicines Australia, Phibro Animal Health, Nutriment Health) raised concerns about making changes to Australian veterinary product labels to satisfy the requirements of the EU market. Some submissions proposed a segregated system via the National Vendor Declaration Scheme and the addition of trade advice statements to labels. Several submissions noted that flavophospholipol and the ionophores were not medically important for humans and argued that they would not contribute to antibiotic resistance.

APVMA response: Under the Agricultural and Veterinary Chemicals Code Act 1994, a product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

Cattle, cattle dairy products, and sheep are considered major export food commodity groups by the APVMA, and the EU is a significant market for export of these commodities. Submissions discussed in this document (Section 2.1) reiterate the importance of the EU market to producers. DAFF has indicated that to maintain EU market access Australia must either:

- confirm that antimicrobial veterinary products are not authorised to promote growth or increase yield in specific food-producing animals; OR
- demonstrate that a system can be set up to segregate food producing animals destined for the EU from those destined for other markets (including domestic).

Consultation with industry peak bodies has indicated that it is possible to segregate beef cattle destined for the EU using the current EUCAS system, but that it is not possible to segregate dairy cattle or sheep (section 2.1). As a result, the APVMA is proposing to retain use patterns relating to growth promotion in beef cattle with the inclusion of additional trade advice statements advising users of the EU trade risks. As dairy cattle and sheep cannot feasibly be segregated at this time, the APVMA proposes to remove use patterns relating to growth promotion for these animals to protect trade with the EU. No changes to therapeutic use patterns are proposed as these will not impact EU market access.

The APVMA notes that the antimicrobial compounds included in the TAN are not medically important for humans; however this consideration is not relevant to the potential trade risk posed by the EU decision.

2.4 Argument concerning the inclusion of ionophores in the response to the EU decision

Animal Medicines Australia, provided an extensive submission (endorsed by Phibro Animal Health and supported by Nutriment Health), arguing that ionophores are excluded from EU Regulation 2019/6, which states that '*Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield*' as they are considered feed additives rather than veterinary medicinal products. The APVMA requested information from DAFF on this matter. DAFF confirmed with the EU that the requirements of EU 2019/6 apply to ionophores, with the EU stating in correspondence to DAFF that *'an animal treated by ionophores for therapeutic reasons is eligible for export to the Union. However, if this ionophore is used for growth promoting purposes, it renders the treated animal ineligible for export to the Union.'*

APVMA response: The APVMA seeks to address the risk to trade posed by the use of products containing antimicrobial compounds (including ionophores), for growth promotion in animals and resultant animal products that may be exported to the EU. DAFF has advised that the EU has taken the position that ionophores are captured by EU Regulation 2019/6. As a result, to address the risk to trade, the APVMA is considering ionophores to be antimicrobial medicinal products that require amendment.

2.5 Argument about the inclusion of 'feed efficiency' in the EU definition of growth promotion or yield increase

Submissions by Animal Medicines Australia, Australian Dairy Farmers, and anonymous submitters highlighted the importance of feed efficiency/improved feed conversion and related uses of antimicrobials in animal production in

Australia and questioned whether they should be included in the EU definition of growth promotion and yield increase. Submissions also argued that these uses should be retained as they support sustainable meat production and reduced methane emissions.

APVMA response: The APVMA is considering the potential trade risk posed by use of antimicrobials for growth promotion in animals and resultant animal products that may be exported to the EU. To this end, the APVMA requested information from DAFF on this matter.

DAFF advised that the EU clarified the status of feed efficiency with regards to EU Regulation 2019/6 as follows; *"While the concept of the 'use of antimicrobials to reduce feed wastage' is not specifically defined in your correspondence, it is implied that such use aims at increasing efficiency in the farming of animals ("improved feed conversion efficiency"). On this basis, it is not possible to draw a clear distinction between this use and growth promotion."*

On this basis, the APVMA considers that uses for 'improved feed conversion efficiency' present a trade risk under EU Regulation 2019/6.

The APVMA notes the argument around the potential sustainability and methane reduction benefits of flavophospholipol and the ionophores, however such a cost benefit analysis is outside the legislative provisions of the APVMA.

2.6 Information about the importance of therapeutic uses of antimicrobials

A confidential submission highlighted the therapeutic importance of antimicrobials discussed in the TAN, particularly monensin and lasalocid for coccidiosis treatment. Animal Medicines Australia also highlighted the importance of ionophores to animal health and welfare.

APVMA response: The proposed label variations outlined in the TAN do not impact therapeutic uses of antimicrobials such as control of coccidiosis, ketosis/mastitis or bloat. Australian livestock treated with antimicrobials products for therapeutic uses are outside the scope of the EU restrictions and do not pose a trade risk.

2.7 Feedback on wording of dairy restraints

A submission from Dairy Australia requested modification of the proposed restraint below, arguing that the wording suggested that the use of antimicrobial products is inappropriate for human consumption due to human health risks:

Dairy cattle: *DO NOT USE for growth promotion, improved feed efficiency, milk production, weight gain, reproductive performance in heifers or cows which are producing or may in the future produce milk or milk products which may be used or processed for human consumption.*

APVMA response: The APVMA has considered this feedback and determined that the proposed alternative restraint presented below effectively addresses the risk to trade. The intent of the restraint is to avoid antimicrobials being administered to animals for growth promotion purposes that currently or in the future may

produce milk destined for the EU market. This intends to capture calves or heifers that are not currently producing milk but may do so in the future as the EU prohibition is for the life of the animal and are retrospective.

Dairy cattle: *DO NOT USE for any purpose other than to prevent or control disease.*

2.8 Impact of label changes

Animal Medicines Australia highlighted the financial impact of label changes on holders of veterinary products that contain flavophospholipol or ionophores and end users of these products.

APVMA response: The proposed changes to labels are intended to address the risk to trade posed by the ongoing use of products containing antimicrobial compounds (including ionophores), for growth promotion in animals and resultant animal products that may be exported to the EU. There are no legislative provisions that allow the APVMA to consider a cost/benefit analysis on the use of an Agricultural or Veterinary chemical, nor for the APVMA to consider factors such as the cost to industry.