Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Submissions received

January 2025

EUROGROUP FOR ANIMALS

30/01/2025

Director, Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra, ACT, 2601

Via email: chemicalreview@apvma.gov.au

Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Thank you for the opportunity to provide feedback on the proposed amendments to labels of products containing flavophospholipol, monensin, lasalocid, narasin and salinomycin for use in cattle and sheep. Eurogroup for Animals, the pan-European animal protection organisation, wishes to contribute to this consultation in the context of the European Union's forthcoming prohibition on imports of edible animal products derived from animals fed antimicrobials for growth promotion purposes.

We welcome the Australian Government's recognition of the EU's Regulation (EU) 2019/6 and Regulation (EU) 2024/399, which prohibit the use of antimicrobials for growth promotion and extend this prohibition to imported animal products starting September 2026. However, we urge a more comprehensive and systemic response to address this matter beyond the proposed amendments to antimicrobial product labels.

While the removal of growth promotion claims from product labels may align with EU trade requirements, it is not an adequate substitute for robust national legislation prohibiting such practices. Simply amending product labels does not alter the use, purpose, or effects of these antimicrobials in practice. As noted in the Trade Advice Notice, the same antimicrobials could continue to be used for growth promotion under other circumstances, undermining the intent of EU legislation.

To ensure compliance with EU legislation and provide equitable protections for Australian citizens and animals, Australia should adopt national legislation explicitly prohibiting the use of antimicrobials for growth promotion and prophylactic purposes across all animal production sectors. This would (1) align Australia's domestic practices with EU import requirements, ensuring consistency and minimising risks of non-compliance or fraud within segregated supply chains; (2) provide equal protection to Australian consumers and animals, reducing the risk of antimicrobial resistance (AMR), a critical global health challenge; and (3) strengthen Australia's reputation as a responsible trading partner.

The proposed reliance on segregated supply chains, while feasible for the beef sector, poses significant challenges for the dairy and sheep industries. Segregation systems are complex and resource-intensive. These challenges highlight the need for a uniform national approach

that prohibits antimicrobials for growth promotion and prophylactic use altogether, removing the need for segregation and ensuring compliance across all production sectors.

The routine use of antimicrobials for growth promotion often correlates with intensive farming systems that compromise animal welfare. Eurogroup for Animals believes that antimicrobials should be used responsibly solely when animals genuinely require it (e.g. to treat bacterial infections). We encourage the Australian Government to opt for high-welfare farming practices to reduce and phase out the use of antimicrobials for growth promotion.

We strongly urge the Australian Government to consider national legislation prohibiting the use of antimicrobials for growth promotion and prophylactic purposes across all animal production sectors. This approach would ensure alignment with EU regulations, address public health concerns associated with AMR, and promote higher standards of animal welfare and farming sustainability. Amending product labels alone is insufficient and risks exacerbating current practices without meaningful change.

Thank you for considering our input. We remain available for further discussions and collaboration on this matter.

Yours sincerely,

[redacted]

[redacted]
Trade and Animal Welfare Officer
Eurogroup for Animals

RSPCA
for all creatures great & small

30 January 2025

Director, Chemical Review
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Via email: chemicalreview@apvma.gov.au

Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Thank you for the opportunity to provide feedback on the label amendments proposed for registered antimicrobial products containing flavophospholipol (bambermycin), lasalocid, monensin, narasin and salinomycin for use in cattle and sheep

RSPCA Australia opposes the removal of growth promotion and yield increase claims from these antimicrobials and urges the dairy, beef, and sheep industries to work towards achieving housing, husbandry, and management practices that promote good animal health and welfare without the routine prophylactic use of antimicrobials.

The RSPCA is Australia's most trusted animal welfare charity. We have worked alongside government and policy makers for many years to improve animal welfare in Australia through contemporary animal welfare science.

The RSPCA understands that European Regulation 2019/6 prohibits the use of antimicrobials that are reserved for treatment of infections in humans as well as the use of antimicrobials that claim to promote growth or increase yield in farmed animals. In European Regulation 2024/399, it states that, from 3 September 2026, this prohibition will extend to certain animals and animal products entering the European Union (EU) thus affecting Australian beef and dairy cattle and sheep products exported to the EU as these sectors have access to and use antimicrobials that are registered with such claims.

The RSPCA understands that the Australian beef cattle industry can segregate supply of beef to the EU so that it complies with the prohibition on antimicrobials that promote growth or increase yield in beef cattle. However, the sheep and dairy sector claim that they are unable to set up a segregated supply chain and therefore wish to see growth promotion and yield increasing claims removed from the label of certain antimicrobials used in these sectors.

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The RSPCA believes antimicrobials should be used responsibly, particularly those important for human medicine. The use of low dose antibiotics for growth promotion has emerged with the intensification of livestock production. Routine use of antimicrobials for growth promotion or to prevent infections (prophylaxis), especially antibiotics and ionophores, undermines the key focus of farm animal management which must be on creating an optimal environment to meet the animals' behavioural and physical needs. Prevention of disease and reduction in antimicrobial usage can be achieved by, for example: low-stress stock handling; reducing stocking density; implementing an all-in all-out system; vaccination; effective shed design and ventilation for indoor systems; appropriate feeding; avoiding mixing unfamiliar animals; and breeding for robustness. The RSPCA does not oppose the responsible use of antimicrobials to treat disease (e.g. antibiotics to treat bacterial infections).

It is highly disappointing that the APVMA is considering the removal of any growth promotion and yield increase claims from antimicrobials registered for use in dairy cattle and/or sheep. The Trade Advice Notice also proposes alterations to labels on products for use in beef cattle, so we assume that beef cattle will be included in the suite of antimicrobials being considered for label amendments.

Ionophore antimicrobials (e.g. lasalocid, monensin, narasin, salinomycin) have a common mode of action in the rumen against a range of pathogens and are added to animal feed to prevent coccidiosis as well as improve feed efficiency and liveweight gain (i.e. growth promotion). Non-ionophore antimicrobials (e.g. the antibiotic flavophospholipol) modify select microbial populations in the gut and are added to animal feed to improve feed efficiency and fight low-level infections and have similar growth-promoting outcomes as ionophores. In other words, the current claims on the labels of the registered antimicrobials proposed for amendment by the APVMA are valid claims.

Removing such claims from a product label does not change the active constituent of that product nor the purpose or effect of its use. In fact, removing growth promotion and yield increasing claims from the labels of the proposed antimicrobials could be seen as misleading as it would likely see the same antimicrobials continuing to be used in cattle and/or sheep, for the same purpose, and with the same effect, and their products continuing to be exported to the EU.

The routine prophylactic use of antimicrobials in farmed animals should be more closely scrutinised with a view to phasing out their use in favour of housing, husbandry, and management practices that promote good animal welfare, including animal health. Removing valid claims from product labels is disingenuous and should not occur.

Yours sincerely

[redacted]

[redacted]
Senior Scientific Officer (Farm Animals)
RSPCA Australia

31 January 2025

Gaye Weller, Director
Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 574
Canberra ACT 2601

By email only: chemicalreview@apvma.gov.au

Dear Ms. Weller,

Re: APVMA Trade Advice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Phibro Animal Health Corporation (Phibro) is a global manufacture of animal health products including ionophores approved for administration to ruminants.

Phibro is committed to supporting sustainable food production, promoting antimicrobial stewardship and ensuring the health and well-being of animals. Phibro also recognizes the complexity of internation trade and the importance of science-based trade standards to support a fair market for both exporters and importers.

Phibro appreciates the work of the Australian Pesticides and Veterinary Medicines Authority (APVMA) in combatting antimicrobial resistance, however, we do have concerns about the removal of production claims from product labels of non-medically important ionophores containing products to accommodate the social policy of a single market.

Phibro is a member of Animal Med cines Australia (AMA) and endorses the AMA comments to the APVMA on this Trade Advice Notice (TAN).

While our comments are reflected in the AMA submission, we respectfully highlight the following points for your consideration:

- This TAN will have most impact on farmers using ionophores in cattle.
- EU Delegated Regulation (2023/905) is the key regulatory driver for the EU objection to the use of antimicrobials to “promote growth or to increase yield”. This regulation addresses the threat posed by antimicrobial resistance to human health. Ionophores are not used in human medicine, nor do they select for cross-resistance to antimicrobials used in human medicine. The EU’s own AMEG panel did not classify ionophore compounds as medically important. The WHO specifically classifies ionophores as animal only compounds that are not medically important. We believe the EU is going beyond the key intent EU 2023/905 by attempting to apply this regulation to the control of use of non-medically important antimicrobials in third countries.

- The use of ionophores to improve the efficiency and lower the environmental impact of beef and dairy production is an important tool for farmers and Australian exporters who currently compete very effectively in global markets. The loss of efficiency will potentially have negative ramifications for volume or profitability of these exports.
- Phibro believes the EU has overstepped accepted international trade practice that control of use of veterinary drugs is a domestic sovereign matter in the absence of a scientifically demonstrated negative safety impact to the traded produce.
- The APVMA proposal to develop market specific label restraints is a potentially problematic precedent for other trading partners, however, Phibro recognizes that the segmented production approach taken for the "beef labels" could provide flexibility for producers able to conform. Accordingly, Phibro notes that the same flexibility could be provided for dairy producers who may currently or in future limit their production for non-EU markets.

Phibro thanks the APVMA for the opportunity to participate in this regulatory process and remains available for future engagement on this matter.

[redacted]

[redacted]

[redacted]

VP, Scientific and Regulatory Affairs

Phibro Animal Health Corporation

CC: [redacted], Managing Director, Australia & New Zealand

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30 January 2025

Director, Chemical Review
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Dear Director, Chemical Review,

Trade Advice Notice
on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

The proposed label changes by APVMA as set out in the Trade Advice Notice (TAN) are not based on scientific evidence and are presented by APVMA as one means to satisfy the demands of a single market, the EU. What is proposed in the TAN sets an unwelcome, unnecessary and unreasonable trade precedent.

We propose an alternative approach that is practical and readily implemented and one that **does not deny Australian agriculture access to important animal health tools for legitimate uses that are completely acceptable in other valuable markets.**

The EU regulation (Commission Delegated Regulation (EU) 2023/905 of 27 February 2023) that forms the basis of the APVMA TAN includes the following restrictions on use:

4.5.2023 | EN | Official Journal of the European Union | L 116/1

COMMISSION DELEGATED REGULATION (EU) 2023/905

of 27 February 2023

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 3

Restrictions on the use of certain antimicrobial medicinal products in animals or products derived therefrom entering the Union

Animals or products referred to in Article 1(2) that are exported from third countries into the Union shall not have been administered, or originate from animals that have been administered any of the following:

(a) an antimicrobial medicinal product used for the purpose of promoting growth or to increase yield;

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) 2022/1255.

We propose two complementary actions.

The **Livestock Production Assurance National Vendor Declarat on** can appropriately respond to this EU concern by documenting all feed additive antibiotics used in the production cycle and their purpose for use. The Livestock Production Assurance program utilising National Vendor Declarations completed by the producer is a legal document describing every animal movement through the supply chain This document captures all information relating to food safety and treatment status of every animal.

Furthermore, the **TRADE ADVICE** section of each product label could include a statement alerting the user to the particular export requirements of products intended for the EU. (As per Section 13 of the APVMA Labelling Code)

Rumen modifiers – ionophores (monensin) and flavophospholipol are used in the Australian cattle industry to improve feed digestion, not "for the purpose of promoting growth or to increase yield". Their use focuses on metabolic efficiency of rumen microbiota, resource utilisation (fibre, starch, and byproducts), economic and environmental sustainability. The benefit is improved feed utilisation with associated enhanced capture of plant nutrients, digestibility, animal health and welfare. **Better feed conversion efficiency results in a healthier animal, reduces greenhouse gas emissions and supports productivity with reduced adverse environmental impact.** Their ability to positively change volatile fatty acid profiles, support metabolic health (reduced incidence of bloat and ketosis) while providing a positive ruminal environment for beneficial bacteria to proliferate is essential for sustainable protein production.

The EU restrictions on use are driven by the EU concern over the rise of Antimicrobial Resistance. The World Health Organisation – Medically Important Antimicrobials (MIA) for Human Medicine – 2024 classifies polyether ionophores and phosphoglycolipids as not authorized for use in humans and not medically important for humans.

Table 4. Categorization of antimicrobials not authorized for use in humans

NOT AUTHORIZED FOR USE IN HUMANS Not medically important for humans	
Aminocoumarins	novobiocin
Arsenicals	nitarsone, roxarsone
Bicyclomycins	bicozamycin
Halogenated 8-hydroxyquinolines	halquinol
Ionophores (including polyethers)	laidlomycin lasalocid maduramicin monensin narasin salinomycin semduramicin
Orthosomycins	avilamycin
Phosphoglycolipids	bambermycin (= flavomycin) flavophospholipol moenomycin
Quinoxalines	carbadox, olaquindox

The Australian position on the importance of antibacterial agents in humans and animals is set out by the Australian Strategic and Technical Advisory Group on Antimicrobial Resistance (ASTAG) in the document entitled "**Importance Ratings and Summary of Antibacterial Uses in Human and Animal Health in Australia, Version 1.0 (2018)**".

Ionophores						
Lasalocid Maduramicin	Low	Not used in humans	Not used in humans.	Yes	Maduramicin and semduramicin approved as anticoccidial agents for	Laidlomycin

Antibacterial class and antibacterial	Australian Importance Rating[1]	Human health uses P, T, R	Brief comments on human use[2]	APVMA registered	Brief comments on animal use[5]	Not registered in Australia by TGA or APVMA for any purpose
Monensin Narasin Salinomycin Semduramicin					use in meat chickens (broilers). The other ionophores are approved as anticoccidial agents for meat chickens (broilers), replacement pullets, turkeys and cattle, and as growth promoters in cattle, sheep, pigs and goats. No cross resistance to human agents.	

Bambermycins						
Flavophospholipol (bambermycin)	Low	Not used in humans	Not used in humans.	Yes	Approved for growth promotion in cattle, pigs, meat chickens (broilers), layers and turkeys. No cross resistance with human medicines.	

The ionophore class (which includes monensin) and the bambermycin class (which includes the single agent flavophospholipol) are assigned an importance rating of LOW – the lowest category available, with a note that they are not used in humans and there is no cross resistance with human medicines. There is clearly no public health concern associated with the non-human use of these classes of antibacterial agents.

Many of the current labels of products included in the TAN are approximately 40 years old. If Australia is the only country to restrict these very important tools in cattle production, Australia will be disadvantaged. We strenuously advocate and defend the prudent and responsible use of non-medically important additives in Australian beef and sheep production, especially for feed efficiency. We need to work with other major trading countries to discuss and collaborate as to how they will address this trade issue. If Australia is the only country to restrict these very important tools in cattle production, Australia will be disadvantaged.

Monensin and flavophospholipol are efficient and practical additive tools to improve feed digestion and reduce methane production. The Australian beef pastoral industry supplement cattle with mineral licks during dry and drought conditions. Monensin and flavophospholipol are included to help digestion of dry poor-quality feed.

An existing and well understood and implemented system of NVDs can be readily adapted to meet the EU requirements. The addition of appropriate TRADE ADVICE adds further assurance of compliance with the EU restrictions on use.

We strongly encourage APVMA to consider the multiple options available that satisfy EU legislation and to accept the Trade Advice plus NVD option, which is well tested, practical and will have the least adverse impacts and consequences for Australian agriculture.

Yours faithfully,

[redacted]

[redacted]
Nutriment Health Pty Ltd

Director, Chemical Review
Australian Pesticides and Veterinary Medicines Authority
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Canberra, ACT, 2601

09.01.2025

Submission Supporting Proposed APVMA Changes to Antimicrobial Labels

Dear Director,

The Australian Meat Industry Council (AMIC) appreciates the opportunity to provide this submission in response to the Trade Advice Notice issued by the Australian Pesticides and Veterinary Medicines Authority (APVMA) regarding proposed changes to the labels of veterinary products containing antimicrobials used for growth promotion in cattle (beef and dairy) and sheep.

AMIC is the peak industry body representing 2,000 post-farm gate red meat businesses. AMIC members include meat processors, smallgoods manufacturers, boning rooms, cold stores, wholesalers and distributors, through to exporters and independent retail butchers.

AMIC would like to express its support of the proposed amendments to ensure continued compliance with European Union (EU) importing country requirements for exported meat and meat products from Australia. As a sector that is highly reliant on international trade, AMIC recognises the importance of adherence to the regulations of key trading partners for maintaining market access. As outlined in the TAN, the EU represents a significant export destination for Australian sheepmeat and beef.

AMIC notes we have been involved in and supported the cross-supply chain working groups that have led to the current proposal as outlined in the TAN. AMIC has also specifically consulted with its members on the aspects outlined in the TAN and has gained support for the proposed changes and recognition that the removal of antimicrobial growth promotion claims from product labels is an important step in ensuring continued trade in red meat with the EU.

We appreciate the APVMA's proactive approach in addressing this issue and would welcome continued engagement on this matter where valuable.

Please do not hesitate to get in contact should you require any additional information.

Yours sincerely,

[redacted]
General Manager, Trade and Technical Affairs
Australian Meat Industry Council

[redacted]

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31 January 2025

Director, Chemical Review
Australian Pesticides and Veterinary Medicines Authority
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By email: chemicalreview@apvma.gov.au

Dear Director

RE: Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Thank you for the opportunity to respond to your organisation's *Trade Advice Notice* [TAN] *on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets.*

The details of proposed label changes enunciated within the TAN are fundamentally consistent with Australian Dairy Farmers' (ADF) policy on this issue (see attached letter to the Department of Agriculture, Fisheries and Forestry (DAFF) dated 8 August 2024); however, ADF wishes to draw to your attention one significant difference.

In the attached letter to DAFF, ADF accepted – albeit reluctantly – the need for certain antimicrobial (including ionophore) product labels being amended in response to the European Commission's Regulations 2019/6 and 2023/905. ADF anticipated these amendments to comprise the removal of reference to growth promotion, production efficiency and the like, thus avoiding a possible impediment to ongoing dairy-product access to the EU market from late 2026 onwards.

It appears from the TAN APVMA is recommending not just the removal of reference to growth promotion, etc., but the addition of the following: *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*** [ADF's emphasis]. This goes beyond ADF's level of support, as it effectively puts a total ban on future use of the named compounds (other than for therapeutic reasons) for all producers, whether they have an interest in the EU market or not.

An alternate set of words for consideration would be: *Dairy cattle: DO NOT USE for growth promotion, improved feed efficiency, milk production, weight gain, reproductive performance in heifers or cows that are producing or may in the future produce milk or milk products that may be ~~used or processed for human consumption~~ exported to markets that prohibit such uses (e.g., the EU).*

While the difference may appear semantic, it is far from it. Prohibiting use of products for reasons relating to "human consumption" (as drafted) is inappropriate given the current scientific evidence and long-running experience supporting the safety of these products. On the other hand, prohibiting use in response to market demands, while seemingly unscientific, is something industry must bear to maintain access to those markets; hence ADF's suggested rewording.

One other aspect has come to ADF's attention that lends weight to avoiding the notion of a total prohibition (as drafted).

In its letter to DAFF, ADF stated the dairy sector lacks a product-separation mechanism akin to the EUCAS (European Union Cattle Assurance Scheme) used by the beef sector. This is true; however, unlike the beef sector where cattle producers are often unable to predict where products from their cattle may be sent, dairy farmers are locked into contracts with specific processing companies that have complete knowledge of where their dairy products are to be sent.

This leads ADF to believe a separation system, based on individual processor commitments, may be feasibly developed in short time to enable DAFF the capacity to certify dairy products to the level of assurances required by the EU. ADF's suggested rewording above would allow for such a circumstance.

With the above in mind, ADF respectfully requests a short pause in APVMA proceedings around relabelling of antimicrobials to allow further investigation of potential options that may provide dairy farmers ongoing access to scientifically safe compounds for production and environmental purposes while assuring DAFF that dairy products from treated animals remain clear of the EU and other sensitive markets should any develop.

Yours sincerely

[redacted]

[redacted]
President

Att: ADF letter to DAFF, dated 8 August 2024

CC: Department of Agriculture, Fisheries and Forestry

ATTACHMENT

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8 August 2024

Dr Anna Somerville
Assistant Secretary
Export Standards Branch
Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry
CANBERRA ACT 2600

By email: Anna.Somerville@aff.gov.au

Dear Dr Somerville

RE: Australian response to EU and UK antimicrobial controls applicable to third countries

Thank you for your letter of 18 June 2024 in which you set out the details to be considered regarding the above topic.

As the national representative body for dairy farmers across the six dairying States, Australian Dairy Farmers' (ADF) response has been developed following widespread consultation across the sector and discussions with your Department and with peak industry bodies representing other affected sectors.

ADF strongly supports initiatives designed to reduce the potential impact of antimicrobial resistance among the human and animal populations of the world. ADF believes the dairy sector is a responsible user of antimicrobials and deliberately avoids administering compounds of importance to human health, except where they are essential for therapeutic treatments by veterinarians. This commitment to antimicrobial stewardship is documented within the *Australian Dairy Sustainability Framework* such that the dairy industry uses antibiotics responsibly, as little as possible, as much as necessary, to protect the health and welfare of the animals in its care. The industry, via its research and development corporation, Dairy Australia, continues to invest heavily in initiatives to support farmers and dairy cattle veterinarians in implementing sound antimicrobial stewardship practices.

Regarding the European Commission's regulation 2019/6 on antimicrobial labelling, and subsequent delegated regulations (particularly (EU) 2023/905[1] that "prohibits the use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union"), ADF has considered the options you've presented in your letter and on which you seek advice as to each affected livestock sector's preferred response.

[1] http://data.europa.eu/eli/reg_del/2023/905/oj

In this context, ADF notes from your letter:

> *The EC require that:*
> - *Australia confirms that antimicrobial medicinal products are not authorised for the purpose of promoting growth or increasing yield in food-producing animals,*
> - *OR Australia creates a segregated system for each commodity to ensure that products from treated animals are not exported to the EU.*

There has been some delay for industry in its consideration of this matter because of confusion around whether ionophores are covered by EC2019/6. ADF thanks DAFF for eliciting a definitive answer from the EU, which you attached to your letter. Clearly, ionophores appear to be included within EC2019/6 and it is DAFF's understanding that the EU considers them antimicrobial medicinal products for the purposes of the regulation.

To reiterate the options and related comments contained in your letter:

1. *NO ACTION: If no action is taken, Australia will be unable to comply with the EU requirements for the commodity. Access to the EU market for affected commodity/s will be lost.*
2. *SEGREGATED SYSTEM: Confirm the ability of the industry to set up a segregated production system. Note that both the EU and the UK have adopted Regulation 2019/6.*
3. *INFORM APVMA OF TRADE RISK: Provide formal advice to the APVMA on the identified risks to trade and request an expedited review of affected label claims based on risk to trade.*
    a. *Advise the APVMA that all growth promotion claims, yield increase, increased weight gains and feed efficiency claims present an unmanageable risk to trade.*
    b. *Option 3a as outlined above BUT provide your support to retain certain claims where there may be a degree of uncertainty [e.g.,] "reproductive efficiency", "increased milk production", "feed efficiency" or "improved feed conversion". …Strong justification would be required if you wish to retain these uses as part of Option 3. Note that there is a risk that the EC may disagree and find that, for example, "feed efficiency" and "improved feed conversion" are NOT permitted uses. The EC may impose trade restrictions or refuse to list Australia as being suitable to export edible animal products until such a situation is resolved.*

Of the options presented, ADF prefers 3(a), for the following reasons:

1. Option 1 is untenable. Although the EU market for Australian dairy products is currently relatively small, EU regulations often have a significant influence on the importing requirements of Australia's key trading partners in Greater China, Singapore, Japan,

Malaysia and Indonesia. Ensuring compliance with EU trade-related directives should therefore be viewed in this broader context.

2. Option 2 is unachievable for the dairy sector. Aggregation of milk across farms for transportation and processing makes it near impossible – certainly in the short term – to devise a workable system for segregating milk based on use or non-use of antimicrobials with non-compliant labels.
3. Option 3(a) – ADF's preferred option – offers ongoing access for Australian dairy products to the EU market, provided steps can be taken for DAFF to have sufficient confidence for certifying product as being compliant with EU requirements.
4. Option 3(b) appears to ADF as having too high a risk of EU rejection, leading to inevitable market disruption until a more acceptable system (like under Option 3(a)) can be installed. This concern is underpinned by text in the delegated regulation EU2023/905: "The use of antimicrobial medicinal products to promote growth **or to increase yield** [emphasis added] is neither prudent nor responsible" [Cl. 2]

While offering its preference as Option 3(a), ADF still has a significant concern: If, as you have stated in your letter, "**these prohibitions are for the life of the animal**, so measures need to be put into place soon to guarantee continued access after September 2026", what is to be done with 'pipeline product'?

Put another way, treated dairy cows currently in production may still be producing milk for processing and export at the time of the prohibition, making it difficult for DAFF to certify the product coming from animals *never treated in their lifetime* with antimicrobials (including ionophores) that have non-compliant labels.

ADF's acceptance of Option 3(a) is contingent on this potential problem being resolved as a matter of urgency.

ADF is comfortable for you to copy this letter to APVMA as evidence of the dairy sector's support for urgent changes to relevant labels to prevent an inevitable breakdown in trade with the EU should no changes be made.

Yours sincerely

[redacted]

[redacted]
President

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31 January 2025

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Dear Ms Weller,

Re: Trade Advice Notice on products containing antimicrobials for growth promotion on cattle and sheep destined for European markets

Thank you for the opportunity to comment on the Trade Advice Notice issued by APVMA for products containing antimicrobials for growth promotion on cattle and sheep destined for European markets.

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. Our member companies are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

Animal Medicines Australia seeks to ensure that Australia's approach to veterinary medicine regulation by the European Union (EU):

- protects Australian access to the EU market for animal products, and
- facilitates livestock industries' access to effective products that protect animal health and welfare, and that enhance sustainability, productivity and the economic competitiveness of Australian agricultural production.

In seeking these outcomes, AMA seeks to ensure that Australia's approach remains consistent with other trading economies that also export to the EU.

Ensuring that the correct policy settings are reached requires an accurate understanding of the scope and applicability of EU's relevant veterinary medicine regulatory scheme. We recognize that considerable effort has been expended by the Department of Agriculture, Fisheries and Forestry, and many industry stakeholders, to evaluate mechanisms by which Australia could satisfy the new EU requirements for antimicrobial growth promotant use.

AMA is pleased to provide the following comments for your consideration. Part 1 of our submission presents analysis of the EU legislation that demonstrates that ionophores are excluded from EU Regulation 2019/6 by definition. As such, Australia is already compliant with the EU requirements and no label changes are necessary. Part 2 notes AMA's concerns to the specific label changes proposed in the Trade Advice Notice.

Part 1 – Issue Analysis

AMA has worked closely with our international colleagues to interpret the EU legislation and understand the approaches being taken by other countries who also supply the EU market. AMA notes that other similar trading markets have arrived at a different conclusion to Australia on how to interpret and apply the EU legislation.

Careful analysis of the EU legislation reveals that ionophores are explicitly excluded from the new EU requirements (primarily Regulation 2019/6 on veterinary medicinal products). Ionophores are regulated as feed additives in the EU under separate legislation (Regulation 1831/2003), not as antimicrobials or growth promotants Specific growth promotion claims on EU-registered products were removed when Regu ation 1831/2003 came into force in 2003, but ionophores remain available for use by EU producers.

The **only** clause of Regulation 2019/6 that is applicable to veterinary antimicrobial use in third countries, including Australia, is described in Article 118(1):

> *"1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union."*
>
> where Article 107(2) states
>
> "*Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield"*
>
> and Article 37(5) states
>
> "*The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans."*

Australia is already compliant with these two requirements:

1. This regulation only applies to antimicrobial *veterinary medicinal products* (VMPs). Under EU legislation, ionophores are not considered to be *veterinary medicinal products*[1], and are not *antibiotics*[2]. They are therefore excluded from Regulation 2019/6 by definition, regardless of label claims.

   Ionophore coccidiostats are regulated in the EU as feed additives under Regulation 1831/2003, which is not applicable in third countries such as Australia.

   Article 107(2) does not ban the use of non-antibiotic *feed additives* for growth promotion, which can continue to be used by producers in EU member states and in third countries.

2. None of the antimicrobials identified in the reserved list are currently registered in Australia for use in any animal species. It is relevant to note that there are no medically-relevant antibiotics registered for growth promotion in Australia - Australian companies voluntarily removed all growth promotion claims from medica ly re evant antibiotics in 2017.

Therefore, Australia is already compliant with the new EU regulations and **label changes to remove growth promotion use patterns from Australian-registered ionophore products are not required** to meet the EU requirements on antimicrobial use in third countries.

The presence of growth promotion or production c aims on labels is still permitted on veterinary products. The EU requirement relates to the *reason for use* in animals destined for the EU market, not the claims that may be registered for such products in third countries.

AMA's analysis is consistent with that of other major producer countries exporting to the EU, which concur that ionophores, regardless of their label claims, are excluded by definition from EU Regulation 2019/6 and its subordinate regulations.

Australia's unique interpre ation of, and response to, the EU legislation will put Australian producers out of step with other equivalent production countries that also supply the EU market. It will undermine Australia's efforts to produce more food, more sustainably, whilst simultaneously using less land and resources, and reducing greenhouse gas emissions in food production systems. In particular, it will deny producers access to proven, safe and efficacious production tools for major non-EU markets where their use is entirely legal and beneficial. The blanket removal of growth promotion label claims in response to demands from a single export market will set a non-scientific trade precedent, confer unnecessary costs on industry, producers, exporters and consumers, and lead to unacceptable animal health and welfare concerns.

[1] With the exception of one ionophore (monensin) registered as a VMP for treating ketosis in lactating cows.
[2] It is noted that some ionophores can exhibit antibacterial activity and may be classed as antibiotics in some jurisdictions. However the definition of relevance here is the EU definition, in which ionophores are clearly *excluded* from their definition of antibiotics.

Legislative analysis

AMA offers the following legal justification on why EU veterinary medicines legislation, namely Regulation 2019/6 and Delegated Regulation 2023/905, does not prohibit Australian producers from using ionophore growth promotant products in animals destined for the EU market.

A detailed analysis of EU Regulations 2019/6, 2023/905 and 1831/2003 is presented in Attachment 1 & further information on the history and context of Regulation 2019/6 is provided in Attachment 2.

The governing legislation is EU 2019/6, with regulation 2023/905 being subordinate legislation to implement 2019/6. 2019/6 specifies ionophores are out of scope, as defined by EU Regulations 2019/4 and 1831/2003 (Article 2(2) and Article 5(3)), where coccidiostats are identified as feed additives, not medicinal products. 2019/6 is understood to be the dominant legislation, and exclusions provided under 2019/6 therefore also apply to any subordinate implementing regulations, such as 2023/905. Anticoccidials are regulated in the EU by the European Food Safety Authority under Regulation 1831/2003 and are out of scope of both 2019/6 and 2023/905.

EU Regulation 2019/6 relates to the regulation of *veterinary medicinal products* (VMPs) only. Articles 118 and 107(2) in that Regulation relate to "*antimicrobial medicinal products*". For third countries and for EU member states, **this regulation only applies to antimicrobial veterinary medicinal products (VMPs)**. This excludes ionophores as these are regulated in the EU as feed additives and not veterinary medicines.

Ionophores (whether registered as cocciodiostats, histomonostats or growth promotants) are out of scope of 2019/6 as the EU does not define them as *veterinary medicinal products* or *antibiotics*:

- Ionophores registered for growth promotion do not fulfill any of the conditions to be regulated as VMPs as defined in Article 4(1) of Regulation 2019/6. They are out of scope of Regulation 2019/6 by definition.
- Coccidiostat ionophores are regulated by the EU as feed additives under Regulation 1831/2003, *which is not applicable in third countries*. Coccidiostat ionophores are out of scope of EU Regulation 2019/6 by definition and Regulation 1831/2003 is not applicable outside the EU
- Ionophores registered as growth promotants are not considered to be antibiotics (Article 4(14)) because they are not used for treatment or prevention of infections or infectious diseases. They are out of scope of Regulation 2019/6 by definition.
- Ionophores remain available for use both in the EU and in other countries exporting animal products to the EU. The molecules themselves are not prohibited.

In 2020, the European Commission expressly confirmed to third countries (including Australia), in writing, that ionophores (regardless of label claims) are not in scope of Regulation 2019/6 (as highlighted in Attachment 3). In response to questions posed by a group of producer countries about Regulation 2019/6 and the status of ionophores used for growth promotion in third countries, EC Sante responded:

> "*ionophores would not be included in the list of antimicrobials to be reserved to human use, nor would their use be forbidden as regards animals or products of animal origin to be imported in the EU from Third Countries.*"

The EC has been very clear from the beginning that ionophore products were **not** intended to be captured by these new EU regulations.

The Importance of Ionophores

While global concerns over the rise in antimicrobial resistance in both humans and animals have led to the EU's decision to ban the import of edible animal products derived from animals fed antimicrobial compounds for growth promotion starting in September 2026, there is limited evidence that non-medically important antimicrobials pose significant risks.

The World Health Organization (WHO) recommends that non-medically important antibiotics should not be used for growth promotion unless their potential risks to human health have been assessed through risk evaluation.[3] This approach ensures that risk management decisions are based on solid evidence rather than speculative or nonexistent data. Although research supporting the growth promotion claims for non-medically important antimicrobials is limited, it suggests that these antimicrobials do not pose significant risks that warrant extensive study. Consequently, any proposal to remove growth promotion indications for non-medically important antimicrobials without conducting risk assessments lacks scientific evidence of benefit to public or animal health.

Ionophores have no role in human medicine or impact on the prevalence of antimicrobial resistance, but significant environmental benefits from using ionophores will be lost if access is restricted. Ionophores are a critical tool in reducing methane emissions from livestock production. Ionophores cause the ruminant gut to produce more volatile fatty acids, which are glycogenic precursors that make energy more readily available to the growing animal whilst reducing methane production; growth benefits result from this more efficient conversion of food to energy by the animal. The use of ionophores has no impact on the quality of the resultant commodity, nor its safety for human consumption.

Restrictions on the use of ionophores directly undermine global efforts to address climate change and agricultural sustainability, and contribute to feeding a growing world population by producing more food, more sustainably, whilst simultaneously using less land and resources, and reducing greenhouse gas emissions from livestock food production systems. Ionophores have no role in human medicine or impact on the prevalence of antimicrobial resistance, but significant environmental benefits from using ionophores will be lost if access is restricted.

Australia’s regulation of veterinary medicines for food-producing species is based on scientific evidence and conservative risk assessments in order to protect the health of both Australian consumers and those in our export markets. Australia’s competency in robust and evidence-based regulation of all antimicrobials in food-producing species should be recognised. Australia has strong internal controls on access to and use of antimicrobial medicines in food-producing animals, alongside a proven history of trade of high quality agricultural products with the EU.

[3] WHO guidelines on use of medically important antimicrobials in food-producing animals. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO

International Response

There has been strong global pushback on Regulation 2019/6 since it was first announced by the EU. International commentary has specifically noted the following concerns:

- Regulation 2019/6 contravenes the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) and Sanitary & Phytosanitary (SPS) regulations (of which the EU is also a signatory). This regulation represents a prohibition on *uses*, not an active ingredient or product.

- Regulation 2019/6 represents a trade barrier that is not based on science or health impacts.

- Regulation 2019/6 is not scientifically justified as ionophores are not used in human medicine and do not affect the development or dissemination of antimicrobial resistance of relevance to human therapeutics.

- Ionophores meet important veterinary therapeutic needs and to remove or lose them from production systems would confer unacceptable animal health and welfare risks.

- Claims that could be interpreted as growth or production claims on ionophore products contribute significant environmental benefits that support safe and sustainable food production in a climate-changed world.

The EU has attempted to avoid potential trade challenges in the WTO by seeking voluntary compliance to its requests for exports from third countries, especially Australia and New Zealand. If successful, this would set a precedent for EU supply by other countries. It is unclear whether Australia has challenged the validity or legality of the EU request under established global trade principles, nor if the economics of the EU request have been fully explored.

Restrictions on the legitimate use of a registered veterinary medicine in a third country that are not based on established risks conferred to the traded commodity and delineated by science-based Maximum Residue Levels (MRLs) is highly questionable. It is unacceptable for one jurisdiction to unilaterally impose an unscientific regulatory restriction on other countries that undermines our sovereign authority to determine what, and how, veterinary medicines can be used in Australia to meet the health and welfare needs of animals in our care.

Part 2 – Response to proposals in the Trade Advice Notice

AMA notes that two fundamental questions have never been clarified:

1. <u>The actual trade risk has not been identified, noting that the molecules themselves are not banned.</u>

AMA notes that it is the *reason for use* that is of concern to the EU, not the molecules themselves (as clarified in correspondence from the EU to Australia, Attachment 4). Therapeutic uses of these products is outside the scope of the EU regulations and will continue to be permitted.

It is unclear how the EU intends to assess compliance with the regulations when the molecules themselves are not banned. Even if residues were detected in EU-bound products, these could not be attributed to use of that product for growth promotion, as opposed to a therapeutic use.

The registration of a growth promotant product in Australia, or the presence of a growth or production claim on an Australian-registered product label in addition to therapeutic claims, should not preclude its legitimate use in animals destined for domestic or non-EU export markets.

Removing growth promotion claims from labels to appease one market sets a dangerous precedent, potentially forcing other international markets to adapt to EU policies without regard for their own regulatory frameworks or market needs. Such adaptation not only undermines the sovereignty and regulatory autonomy of these markets, but could also lead to broader market disruptions and increased compliance costs across the global supply chain. Additionally, it risks marginalizing the significant benefits of growth promotion products in markets where they are entirely legal and beneficial, thereby stifling innovation and efficiency in agricultural practices. Balanced and market-specific approaches are essential to protect the diversity and stability of international trade.

2. Clarity on the exact terminology that would be considered to be growth promotion or production claims has never been established.

There are multiple words and phrases on current labels that could potentially be interpreted as providing a growth or production benefit. If a broad interpretation of growth promotion or production is taken, more than 94% of all ionophore products registered in Australia will be captured.

This lack of clarity has facilitated a unique interpretation of the regulation by Australia and resulted in the development of an overly conservative approach that will inappropriately remove access to important animal health tools for legitimate use to supply other markets.

Appropriateness of proposed changes to use patterns and labels to address trade risks

AMA has significant concerns about setting a precedent through the proposed removal of growth promotion claims from registered labels to satisfy a single market. The proposed label changes outlined in the Trade Advice Notice will deny the use of safe and beneficial growth promotants by producers who supply the majority of Australia's trade markets, including the domestic market.

AMA notes that it is the *reason for use* that is of concern to the EU, not the molecules themselves, nor the words on the label. Use of these products for therapeutic purposes is outside the scope of the EU regulations and will continue to be permitted in animals destined for the EU market. The presence of a growth promotion claim on a label (alongside a therapeutic claim) is not of concern to the EU. The blanket removal of all growth promotion claims is unnecessary and will inappropriately remove access to important production benefits for the majority of Australian producers who supply Australia's non-EU and domestic markets.

Similarly, the addition of restraint statements to labels (as noted in Tables 1-5 in the Trade Advice Notice) will inappropriately restrict the use of these products in dairy cattle and sheep destined for *any* market, not just the EU. AMA notes that these products can legitimately be used in animals destined for non-EU markets, including domestic supply chains. It is *only* the EU that is

imposing this restriction. Any new restraints on use in dairy cattle and sheep must therefore be confined to the EU market.

Therefore, AMA considers that a more appropriate and proportionate regulatory response to demonstrate compliance with the new EU requirements, and therefore maintain EU market access, would be a producer or veterinarian declaration, made *at the point of use,* to confirm that the use of any ionophore products during production was for therapeutic purposes and not growth promotion (where that product has both therapeutic and growth promotion or production claims on the registered label).

The existing National Vendor Declaration Scheme (NVDS) was developed to provide legal assurances underpinning market access for Australia's red meat industry. National Vendor Declarations (NVDs) assure traceability and market access by communicating the food safety and treatment status of every animal as it moves through the supply chain.[4] Health declarations and other statutory declarations can already be attached to NVDs, providing a cost-effective mechanism for producers to legally declare that growth promotants were not used. Leveraging this existing on-farm, point-of-use system would provide assurance to the EU that its requirements are being met, whilst ensuring that producers can continue to have access to products carrying growth promotion or production indications in order to support both domestic and non-EU export market access.

It is critical that any regulatory responses are market-specific in order to safeguard broader production and animal health needs. A strategic balance between regulatory compliance and market viability is essential to protect valuable non-EU export markets, as well as the domestic supply chain.

Implications of label changes

Label changes are complex, costly and time-consuming for both the regulator and the registrant. Changes to physical labels on products typically take several years to implement – from application, assessment and approval, to implementation in globally integrated production lines and distribution through international and national supply chains onto farms. Packaging and label changes have considerable global implications, as packaging is often produced separately to the product itself and the same packaging may be registered in multiple jurisdictions.

The removal of claims risks the commercial viability of products. Every claim registered and present on a product label must be supported by scientific evidence. Companies expend considerable resources to generate data to support label claims, therefore every registered label claim represents significant economic value to the registrant. The logistical costs of removing a label claim are amplified by the loss of market value associated with that claim.

The financial and logistical implications associated with label changes to satisfy a single market pose a genuine risk that registrants will choose to remove those products from the Australian marketplace, rather than changing the labels. Many ionophore products are now off-patent and generic versions are in the marketplace. This is a significant disincentive for registrants to invest in label changes.

[4] https://www.integritysystems.com.au/on-farm-assurance/national-vendor-declaration-nvd/

The loss of any ionophore products will pose unacceptable risks to animal health and welfare. The range of ionophore products available to Australian producers is already limited, and most ionophore products have critically important therapeutic uses. The loss of an ionophore from the Australian market could result in a disproportionate increase in animal illness and poor welfare outcomes, especially where there are few effective alternatives (especially for sheep).

For example, dairy producers have noted they expect a significant impact to their cost of production and efficient rumen health management should ionophores become unavailable through a blanket loss of dairy label production claims. Whilst dairy exports to the EU are small (typically around 5-6% of total dairy exports[5]), Australia's dairy exports have historically been very cost competitive relative to other global dairy export nations. A general increased cost of production can and would be expected be absorbed by Australian consumers, as well as significant non-EU markets (primarily Asia). An increased cost of production is also likely to lead to an unfavorable impact on export volumes of ruminant commodities to non-EU markets.

Practical considerations

The Trade Advice Notice does not indicate if any proposed label changes would be processed under a fee waiver or minimal fee arrangement, or if full fees will be applicable. There is also no indication on timelines for the proposed changes (except hat the EU regulations will come into force from September 2026).

As noted above, changes to physical labels and packaging typically take several years to implement and have global implications. The financial and logistical implications associated with label changes for one market would likely require approval by global headquarters. Australia is a small market (approximately 3% of global sales). Significant costs to market access with limited return-on-investment opportunities creates a genuine risk that products would be removed from the Australian marketplace, rather than changing the labels. This would have significant adverse impacts on the health and welfare of Australian livestock, especially where there are few effective alternatives to address known therapeutic needs.

Many of the proposed label changes involve the addition of considerable amounts of new information, particularly the proposed new Restraint statements. Australian labels already contain a significant amount of information and the physical space available to present that information is constrained by the container size and/or packaging material. The packaging is assessed as part of the registered product, and packaging sizes and materials cannot easily be changed by registrants. The addition of significant amounts of new text on labels may literally be impossible for some products where space is already at a premium. Product variations to register larger pack sizes (to obtain correspondingly larger labels) would require considerable investment by registrants that far exceed those for label changes and would be commercially unviable, with product withdrawal likely to result.

[5] In Focus 2024, Dairy Australia

Summary

Animal Medicines Australia seeks to ensure that the correct policy approaches are reached in response to the EU's new requirements in order to protect market access for Australian producers, and support access to safe and effective veterinary products that protect animal health and welfare, agricultural sustainability and productivity, and the competitiveness of Australian producers in a global market.

Detailed analysis of the EU legislation demonstrates that ionophores carrying growth promotion or production claims in Australia are *excluded by definition* from Regulation 2019/6 and its subordinate legislation. Australia is already compliant with the only new requirements of third countries – that medically-relevant antibiotics are not used for growth promotion, and that certain antimicrobials reserved for human treatment are not used in production animals – without any label changes being required.

AMA is concerned that the proposed label changes and new Restraint statements will inappropriately remove access to critically important veterinary products for producers who choose to supply other (non-EU) markets and the domestic supply chain. Any changes to or restraints on use must be confined to the EU market. AMA considers that the blanket removal of all growth promotion and production claims to satisfy a single market is an inappropriate and disproportionate regulatory response that is likely to create an unwanted precedent in international trade regulation.

AMA recommends that the regulatory response is more appropriately directed at the point of use of these products, where the reason for use can be declared by the producer and/or the prescribing veterinarian (similar to the requirements already in place to meet the trade requirements of other countries). Leve age of the existing NVDS is a more appropriate approach to provide such assurances.

I would be pleased to discuss this submission or provide further information at any time.

Yours sincerely,

[redacted]

Director, Science and Policy

ATTACHMENT 1 – analysis of EU Regulations 2019/6, 2023/905 and 1831/2003

Defining the scope of Regulation 2019/6

The governing regulation is Regulation **2019/6** on veterinary medicinal products.[6]

Regulation 2019/6 provides three relevant definitions that define the scope of its application. These are:

> Article 4(1): "*'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:*
> *(a) it is presented as having properties for treating or preventing disease in animals;*
> *(b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;*
> *(c) its purpose is to be used in animals with a view to making a medical diagnosis;*
> *(d) its purpose is to be used for euthanasia of animals"*
>
> Article 4(12): "*'antimicrobial' means any substance with a direct action on microorganisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals.*"
>
> Article 4(14): "*'antibiotic' means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases"*

Regulation 2019/6 applies only to *veterinary medicinal products (*VMPs*)*. Ionophores, when registered and used as growth promotants, do not fulfil any of the criteria to be regulated as VMPs (Article 4(1)).

Ionophores are not *antibiotics* (Article 4(14). They may have antibacterial activity, but are registered and used as growth promotants, not antibacterial agents.

Ionophores may be registered as coccidiostats and thus understood to be *antimicrobials* by Article 4(12). These products are regulated as *feed additives* under separate EU legislation (EU Regulation 1831/2003, not 2019/6). Article 2(7) specifically excludes *feed additives* from the scope of 2019/6:

> *7. This Regulation shall not apply to:*
> *(a) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;*
> *(b) veterinary medicinal products based on radio-active isotopes;*
> ***(c) feed additives as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (19);***
> *(d) veterinary medicinal products intended for research and development;*
> *(e) medicated feed and intermediate products as defined in points (a) and (b) of Article 3(2) of Regulation (EU) 2019/4.*

[6] EUR-Lex - 32019R0006 - EN - EUR-Lex (europa.eu)

where EU 1831/2003[7] Article 2(2(a)) states that:

"'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3)",

And where EU1831/2003[8] Articles 5(3) states that:
"The feed additive shall:
(a) favourably affect the characteristics of feed,
(b) favourably affect the characteristics of animal products,
(c) favourably affect the colour of ornamental fish and birds,
(d) satisfy the nutritional needs of animals,
(e) favourably affect the environmental consequences of animal production,
(f) ***favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs, or***
(g) ***have a coccidiostatic or histomonostatic effect****."*

The **only** clause of 2019/6 that is applicable to veterinary antimicrobia use in third countries is described in Article 118(1):

"1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union."

where Article 107(2) states "*Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield"*

and Article 37(5) states "*The Commission shall, by means of implementing acts, designate antimicrobials o groups of antimicrobials reserved for treatment of certain infections in humans."*

For third countries and for EU member states, **this regulation only applies to antimicrobial veterinary medicinal products (VMPs)**. Ionophores are not *VMPs* and are not *antibiotics* and are thus excluded from the scope of Regulation 2019/6. Further, Article 107(2) does not ban the use of *feed additives* (EU Regulation 1831/2003 Article 5(3)) for growth promotion.

None of the antimicrobials, or groups of antimicrobials, identified by the European Commission as reserved for use in humans are currently registered for animal use in Australia.

Subordinate nature of Regulation 2023/905

Commission Delegated Regulation **2023/905** supplementing Regulation 2019/6 as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union.[9]

[7] EUR-Lex - 32003R1831 - EN - EUR-Lex (europa.eu)
[8] EUR-Lex - 32003R1831 - EN - EUR-Lex (europa.eu)
[9] EUR-Lex - 32023R0905 - EN - EUR-Lex (europa.eu)

This regulation is part of the implementing legislation of Regulation 2019/6. It is subordinate to 2019/6 (it is not a stand-alone instrument) and uses the definitions of Regulation 2019/6 to define its scope.

As products containing ionophores (as coccidiostats or as growth promotants) are excluded by definition from Regulation 2019/6, Australia remains compliant with Regulation 2023/905 and no changes to Australian labels are required.

EU regulation of ionophores as feed additives

The EU identifies ionophore coccidiostats and growth promotants as '*feed additives*', not '*medicinal products*' or '*antibiotics*'. Feed additives are regulated by Regulation **1831/2003** on additives for use in animal nutrition[10].

Article 2(2(a)): "*'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3)"*

where Article 5(3) states:

"The feed additive shall:
(a) favourably affect the characteristics of feed,
(b) favourably affect the characteristics of animal products,
(c) favourably affect the colour of ornamental fish and birds,
(d) satisfy the nutritional needs of animals
(e) favourably affect the environmental consequences of animal production,
(f) ***favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs, or***
(g) ***have a coccidiostatic or histomonostatic effect****."*

and Article 5(4) states:

4. ***Antibiotics****, other than coccidiostats or histomonostats, shall not be authorised as feed additives*

Ionophores with growth promotant label claims meet the definition provided in 5(3(f)) as they favourably affect animal production and performance by affecting the gastrointestinal flora and feed efficiency.

Ionophores with coccidiostat label claims meet the definition provided in 5(3(g)) by having a coccidiostatic effect.

Ionophores, regardless of label claim, are not *antibiotics*, which satisfies Article 5(4) that antibiotics may not be used as feed additives.

[10] EUR-Lex - 32003R1831 - EN - EUR-Lex (europa.eu)

IN CONCLUSION:

The European Commission has clearly stated that Regulation 2019/6 and Delegated Regulation 2023/905 do not apply to ionophore products registered and used in Australia in animals destined for the EU market, including ionophores that carry a growth promotion claim on the label:

- Regulation 2019/6 specifically applies to '*veterinary medicinal products'*. Ionophores are not considered to be '*veterinary medicinal products'* by the EU, therefore neither Regulation 2019/6 nor Delegated Regulation 2023/905 are applicable.
- Ionophores are not considered to be '*antibiotics*' and are thus excluded from the specific requirements imposed on third countries under Article 118 of Regulation 2019/6.
- Non-antibiotic feed additives are not prohibited by Regulation 2019/6 and can still be used by producers in EU member states and third countries supplying to the EU.

The *only* restrictions imposed by the EU regulations on antimicrobial use in Australia are associated with Article 118 of Regulation 2019/6, which stipulates that producers in third countries:

(1) do not use antimicrobial medicinal products as growth promotants, and
(2) do not use antimicrobials that are identified as reserved for human use only.

Article 118 does not apply to ionophores, irrespective of label claims, because:

- Ionophores are not *veterinary medicinal products* and are therefore out of scope of Regulation 2019/6.
- Ionophore coccidiostats are regulated as feed additives under Regulation 1831/2003, which is not applicable to third countries such as Australia.
- Non-antibiotic (ionophore) grow h promotants are not prohibited by Regulation 2019/6 and may still be used by producers in EU member states and in third countries.

Further, none of the antimicrobials identified in the reserved list are currently registered in Australia for use in any animal species, therefore no action is required in Australia to meet this condition either. It is also relevant to note that Australian companies voluntarily removed all growth promotion claims from medically relevant antibiotics in 2017.

This means that Australia already meets the EU requirements for antimicrobial use in third countries described in Article 118. Animal Medicines Australia concurs with other major markets exporting to the EU that **Regulation 2019/6 and Delegated Regulation 2023/905 clearly exclude products containing ionophores** and therefore **label changes to remove growth promotion or production claims from Australian-registered products containing ionophores are not required** to meet the requirements of the EU on antimicrobial use in third countries.

Article 118 and 107(2) are about "*antimicrobial medicinal products*": words matter and there is a need to clarify. For third countries and for EU member states, **this regulation only applies to antimicrobial veterinary medicinal products (VMPs)**. This excludes ionophores as these are regulated in the EU as feed additives and not veterinary medicines.

- Until 1st of January 2006, some feed additives antimicrobials were licensed and marketed for growth promotion in the EU. *They were regulated as feed additives*. Those products were banned since the entry in force of Regulation 1831/2003. However Regulation 1831/2003 makes **no** reference to third countries. In other words, *EU regulation 1831/2003 does not apply to third countries*.

- So why did the EU include Article 107(2) in its VMP regulation?
    - Because there are **antimicrobials** that are licensed as VMPs (eg: colistin, tetracycline) that **could be misused** for growth promotion The intent of Article 107(2) is to remind EU farmers that antimicrobials approved as VMPs should only be used for therapeutic purposes (treatment, metaphylaxis or prophylaxis). **Article 107(2) applies first and foremost to EU member states** (where there are no antimicrobial medicinal products registered for growth promotion). It does not fit with the definition of antimicrobial VMPs.
    - **Article 107(2) does not ban the use of feed additives for growth promotion** because Article 107(2) is part of VMP regulation.

Why products containing ionophores that are currently registered in Australia are not in scope of Article 118 of EU Regulation 2019/6

Products containing ionophores and registered in Australia have 3 kinds of claims:

- Prevention of metabolic diseases: "aid in the control of bloat" or "aid in reducing the severity of non-clinical ketosis"
    - Under EU regulation, those products would be registered as VMPs. They fall under Regulation 2019/6 but are not antimicrobial medicinal products. → **Out of Scope**
- Growth promotion: "improved feed efficiency", "increased milk production", "improved weight gains"
    - Those products could not be registered in the EU as VMPs under Regulation 2019/6 as those claims do not fit the definition of VMPs (Article 4.1 of Regulation 2019/6). Such products are registered as feed additives. → **Out of Scope**
- Prevention of coccidiosis: "aid in the prevention of coccidiosis"
    - Despite the fact that the EU antimicrobial definition includes anti-protozoals, ionophore coccidiostats are regulated in the EU as **feed additives** under EU Regulation 1831/2003. The EU definition of coccidiostats is that they "kill or inhibit protozoa" (Article 2(2(k))) of Regulation 1831/2003). They are not VMPs → **Out of Scope**

In summary: products containing ionophores currently registered in Australia are **not** antimicrobial medicinal products/VMPs, and ionophores are not identified as reserved for human use. As such, it will be possible for Australia, as a third country operator, to provide an official certificate attesting that the consignment complies with the requirements in Article 3 of Regulation 2023/905.

Third country questions sent to EC Sante on 25 September 2020 [highlights added]. **Reply received by email from DG EC (to US Agricultural Trade attaché) on 24 November 2020 and shared with other third countries, including Australia.**

1. How will the Commission define the range, or priority order of inclusion, of products of animal origin subject to the import restriction? If products not for human consumption are included, the import restrictions would be indeed far-reaching. Thus, we would request that DG SANTE give us an early clarification of the criteria for products subject to the import restriction together with the scientific rationales.

   Reply:

   DG SANTE plans to mirror the scope of Regulation 2017/625 on official controls, which uses EU law's existing definition of products of animal origin in food hygiene legislation. This definition is contained in Point 8.1 of Annex I to Regulation (EC) 853/2004. *"'Products of animal origin' means:*
   - *food of animal origin, including honey and blood;*
   - *live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;*
   - *other animals destined to be prepared with a view to being supplied live to the final consumer.")*

2. Would the Commission take into consideration the sanitary status/epidemiological situation of third countries when applying Article 118 for the prohibition of the use of antimicrobials? How would the sanitary status be considered?

   Reply:

   Regulation 2019/6 promotes prudent use of antimicrobials through a number of measures, including by banning their use for the purposes of growth promotion and yield increase. Moreover, work is ongoing on establishing a list of antimicrobials to be reserved for human use. Both of the above apply within the EU and to certain imports.

   The Commission has tasked the European Medicines Agency ("the Agency") to provide scientific advice on:
   1) the criteria necessa y to designate antimicrobials to be reserved for treatment of certain infections in humans and
   2) the list of such antimicrobials itself. The criteria proposed by the European Medicines Agency to the Commission were presented to the US and other Third Countries during the meeting organised by the Commission in January 2020. They were established taking into account other criteria existing worldwide, including those of international organisations such as WHO and OIE and those used by certain third countries. Advice from the Agency on the list of antimicrobials reserved for human use is expected by January 2021.

3. What would be the mechanism for control of compliance with Article 118, both with regards to Article 107(2) and to antimicrobials referred to in Article 37(5)?

   Reply:
   The exact control mechanism for control of compliance with Article 118 is still under development; however, it is intended to refer to the control mechanisms already established for similar control purposes under Regulation 2017/625 on official controls. Detailed rules will be laid down in a delegated act to be adopted by 27 January 2022.

4. As Article 37(5) is an implementing act, can the Commission provide more details on which Standing Committee(s) will be consulted?

   Reply:

   As previously specified in our response of 15 October 2019 to you, the Commission will consult the Standing Committee on Veterinary Medicinal Products on the draft implementing act to be adopted under Article 37(5).

5. If there is an antimicrobial of exclusive use in humans, and the veterinarian does not identify any other therapeutic alternative to treat an animal, would the Commission allow a derogation from Article 118, in the same way of derogations established in Articles 113 and 114?

   Reply:

   Article 118 does not provide for the possibility of any derogations. In relation to the use of medicinal products outside the terms of a marketing authorisation in the EU, the derogations allowed under Articles 112, 113 and 114, Article 107(5) of Regulation (EU) 2019/6 provides tha those antimicrobials listed as reserved for treatment of certain human infections cannot benefit from these derogations.

6. Given that some antimicrobials may have multiple indications including both therapeutic and production authorizations, how will the Commission make a distinction in the implementation of Article 118 with respect to Article 107(2)? Here therapeutic means veterinary medical use for prevention/prophylaxis, control/metaphylaxis, and treatment as defined by OIE.

   Reply:

   The Commission will lay down the detailed rules as regards the implementation of Article 118 in the delegated act to be adopted by 27 January 2022. See replies to questions 2 and 3.

7. Did the Commission conduct an impact assessment on the implementation of Article 118 with respect to the importation of animals or products of animal origin to the EU and its impact on EU business operators?

   Reply:

   Article 118 reflects the global recognition that the widespread use of antimicrobials for growth promotion is neither a prudent, nor a responsible use of antimicrobials. An extensive body of scientific literature has been developed over the last decades, showing that the use of antimicrobials for growth promotion can trigger antimicrobial resistance and that therefore such use cannot be considered as responsible. This has led international organisations and many countries around the world to start ruling out or restricting such use. The use of antibiotics for growth promotion as feed additives is banned in the EU since 2006. Regulation (EU) 2019/6 expands this ban to antimicrobial medicinal products.

   Article 118 also reflects that there is growing evidence at international level that strong measures need to be taken quickly to preserve the efficacy of certain antimicrobials used for treatment of infections in humans, especially those considered 'last resort' treatments. Regulation (EU) 2019/6 seeks to implement this principle by reserving certain crucial antimicrobials for the treatment of diseases in humans.

8. Given that animal disease conditions and therapeutic approaches vary across the globe, will the Commission consider the impact of extraterritorial application of EU risk management measures on international animal health?

Reply:
This is a very broad question. With regard to the provisions of Article 118, it cannot be expected that a ban of the use of antimicrobials for growth promotion and yield increase negatively affects animal health internationally. Likewise, reserving certain antimicrobials for human use will only apply to animals and products of animal origin intended to be exported to the Union, which always leaves the opportunity to direct treated animals (provided their consumption is deemed safe) to other markets or purposes. In any event prudent use of antimicrobials will also safeguard their efficacy also for the treatment of animal diseases.

9. The EU requirements only apply to animals and produces of animal origin intended to be exported to the Union. Regulation 2019/6 promotes prudent use by banning the use of antimicrobials for the purposes of growth promotion and yield increase as well as those to be reserved for human use as explained in the replies to previous questions. The Delegated Act, stipulating the rules on imports from third countries to be established according to Article 118 of EU regulation 2019/6 should consider both the relevant science-based international standards as well as international trade agreements adopted by Members. In this context, we ask the EU to warrant its commitment to respect the obligation of the SPS Agreement in drafting the Delegated Act, duly taking into account comments from WTO Members.

   Reply:

   The Commission remains committed to engage with its trading partners and other countries, both in the context of multilateral international fora and bilaterally, to promote and support effective strategies to prevent and contain the global threat of AMR.

   The Commission intends to notify the draft delegated act under Article 37(4), the draft implementing act under Article 37(5) and the draft delegated act under Article 118(2) of Regulation 2019/6 to the WTO SPS Committee before adoption. In this context, Third Countries will have an opportunity to provide feedback on the draft acts.

   Third Countries will also have the opportunity to provide input during the "feedback mechanism", as foreseen under the Commission's Better Regulation agenda, for a period of 4 weeks. Legal acts subject to the feedback mechanisms are published at regular intervals on the 'Have your say' webpage of the Commission's website[11] and open to citizens and stakeholders for feedback.

10. We understand that the Delegated Act, which states criteria for the designation of antimicrobials reserved for human use will be published by September 2021 and that the list of such antimicrobials will be published by 27 January 2022 (the date it becomes applicable). We ask that the EU explain the progress of its investigations concerning the setting of a transition period, which transition period should take into account production periods of relevant animals and the products range (which is yet to be disclosed) as well as the preparation period for producers and exporters. We note that the transition period for full implementation should account for the various production times around the world.

    Reply:

    The preparation of the draft legal acts will continue to follow its course, according to the institutional process and legal deadlines set in the Regulation.

11. Article 107(2) of EU regulation 2019/6 prescribes that "antimicrobials medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield". We understand that a certain antimicrobial class of polyether, also known as "ionophore", is used in the EU as a feed additive for "preventing coccidiosis" and that this is done with neither veterinary examination nor veterinary prescription, while the same ionophore is used elsewhere for the purpose of promoting

[11] https://ec.europa.eu/info/law/better-regulation/have-your-say

growth. We ask the EU to clarify whether it includes ionophore among antimicrobial feed additives to be banned only in cases where its nominal purpose is growth promotion rather than preventing coccidiosis. If so, please provide a scientific rationale for banning a substance for reasons other than the chemical properties of such substance.

Reply:

Coccidiostats and histomonostats used as feed additives do not fall under the scope of the Regulation on veterinary medicinal products, but fall under Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)). In this setting, ionophores would not be included in the list of antimicrobials to be reserved to human use, nor would their use be forbidden as regards animals or products of animal origin to be imported in the EU from Third Countries.