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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: 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 Regulation 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 medically relevant 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 claims 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 interpretation 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 that 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). Leverage 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,

Dr Charmian Bennett

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 antimicrobial 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 or 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) growth 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 necessary 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 that 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.

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Veterinary Medicines
Head of Unit

Brussels
SANTE.D.4/ (2024)2579256

Sent by e-mail only

Dear Dr Somerville,

We thank you for your letter sent on 21 March 2024, which we have carefully examined and we are pleased to reply to your questions as follows.

Article 118(1) refers to Article 107(2) of Regulation (EU) 2019/6, which requires that no antimicrobial medicinal product shall be used for the purpose of promoting growth or to increase yield.

Therefore, following Article 107(2) of Regulation (EU) 2019/6, an animal treated by ionophores for therapeutic reason 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.

Moreover, if an ionophore product label explicitly indicates its exclusive use for growth promotion, animals treated with this product are ineligible for export to the Union.

We hope that the responses conveyed clarify the raised concerns.

Yours sincerely,

(e-signed)

c.c.: Mr D. MacLachlan, Dr K. Jeevan, Ms R. Schipp (Australian Government)
Mr P. Creaser (Australian Mission to the EU)
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