Section 2: Competent authority statement/information – antimicrobials for growth promotion	**Commission assessment**
Statement 5: Antimicrobial medicinal products used for the purpose of promoting growth or increasing yield in food-producing animals are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	
(b) **not authorised** for use in food producing animal species in my country ☐	
If you have ticked (a) **(authorised for use)** please list those antimicrobial substances which are authorised for such use in your country and for which food-producing animal species listed in Box 5.	
Response:	
If you have ticked (a) **(authorised for use)** please carefully read each of the statements below and tick only those which apply.	
For those animal species or commodities listed in Box 5 and intended for export to the EU for human consumption, are these: Born and reared in your country? Yes ☐ No ☐ Not applicable ☐ Imported into your country from another third country? Yes ☐ No ☐ Not applicable ☐	
Observations, if any:	
Statement 6 on food-producing animals born and reared in your country and products derived therefrom which are intended to be exported to the EU, for human consumption	

There is a **system of regular official controls on food business operators in my country** which is either already in place or which will be put in place (**if so, please specify the date here**) to ensure that antimicrobials used for the purpose of promoting growth or increasing yield have **not** been administered to those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) which are intended for export to the EU for human consumption. ☐	
Statement 7 on food-producing animals or products derived therefrom which are imported into your country and which are intended to be exported from your country to the EU, for human consumption Regarding those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) imported into my country from another third country for the purpose of manufacture of food of animal origin for the EU market, **guarantees** have been received from that third country indicating that antimicrobials used for the purpose of promoting growth or increasing yield have **not** been used in those animals/products imported into my country for that purpose. ☐	
Statement 8 on measures to prevent non-compliant animals & animal products being exported to the EU for human consumption In the event that food business operators are found to have used antimicrobials for the purpose of promoting growth or increasing yield in food-producing animals intended for export to the EU for human consumption, neither the animals in question, nor the products derived therefrom will be exported to the EU and the operator in question will be prohibited from supplying such animals and products for the EU market until such times as they have rectified the problem and official controls have verified that they are compliant with the rules. ☐	
If you have ticked (b) **(not authorised for use)** please specify if the use is **explicitly prohibited** by national legislation and if so, please provide the name of the legislation and identify the provision giving effect to the prohibition on use in food-producing animals.	
Response:	

Section 3: Competent authority statement/information – traceability of food-producing animals/products	Commission assessment
Statement 9 on traceability of animals and products intended to be exported to the EU, for human consumption With regard to the objective of ensuring that the animal species (see Box 5) or commodities (see Box 5) which are intended for export to the EU for human consumption, have not been administered at any time in their lifetime either antimicrobials reserved for human use [1] or antimicrobials for the purpose of promoting growth or increasing yield: (a) **food business operators** already have in place or will have by date **[insert date]** systems to ensure **traceability at all stages** of the production chain in order to meet the above objective. ☐ (b) Official controls are (or will be from **[insert date]**) performed to verify the **appropriateness of food business operators' traceability systems** in meeting the above objective. ☐	
If you are not in a position to tick either of the above boxes, please explain below.	
Response:	

General information

The competent authority response and supporting documents should be e-mailed to: SANTE-VETERINARY-MEDICINES@ec.europa.eu in English

Box 1: Country		Box 2: Date of provision of information by the competent authority	
Box 3: Name of competent authority:			
Box 4: Name and position of person responsible for the information submitted in this document			

Box 3: **all the concerned Competent Authorities MUST be included in this box**

Box 5: Animal species and commodities intended for export to the EU for human consumption (please tick)	Bovine	Ovine/Caprine	Porcine	Equine	Aquaculture	Poultry	Milk	Eggs	Rabbit	Farmed Game	Honey	Casings
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

- **Tick the boxes for the goods that are intended to be exported**
- In order to export into the Union, the country of export, has also to be listed in other EU legislation (e.g. Regulation 2021/404, Regulation 2021/405, etc.) depending on the EU import requirements for the specific type of consignment.
- **After entry into application of Commission Delegated Regulation 2023/905 :** according to its Article 5, third countries, for products falling under the scope of this Delegated Regulation, will also have to be listed in the the list of approved third countries.
- **In order to export to the Union, Third Countries MUST be listed in all the relevant lists.**

NEW STATEMENTS IN THE EXPORT CERTIFICATES

- **Commission Implementing Regulation (EU) …/...of XXX amending Annex III to Implementing Regulation (EU) 2020/2235 and Annex II to Implementing Regulation (EU) 2021/403 as regards model certificates for entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals**

European Commission

Example of the possible wording of the new attestation/ Commission Regulation (EU) 2020/2235 (PAO)

DRAFT TEXT

PUBLIC HEALTH SECTION

‘(x) (xx) [II.x.xx. I, the undersigned [official veterinarian/certifying officer/ the undersigned] declare that, **I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2023/905** and hereby certify that [product] described in Part I was produced in accordance with these requirements, and in particular, that the animals from which the [*PRODUCT CONCERNED*] is derived **have not been administered antimicrobial medicinal products for growth promotion and/or yield increase or antimicrobials reserved for the treatment of certain infections in humans** laid down in Commission Implementing Regulation (EU) 2022/1255 and originates from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]’

;

(ii) in the Notes to Part II, the following footnote is inserted:

‘(xx) Applicable to consignments entering the Union as from [***Exact Date to be inserted by the Service responsible for the publication***].’

Commission Delegated Regulation (EU) 2023/905 shall apply as from 24 months after the day of application of the amended Commission Regulation (EU) 2020/2235

European Commission

Example of the possible wording of the new attestation/ Commission Regulation (EU) 2021/403 (ANIMALS)

DRAFT TEXT

‘(x) (xx) [II.x.x. fulfil the requirements provided for in **Article 3 of Commission Delegated Regulation (EU) 2023/905**, and in particular, that **the animals have not been administered antimicrobial medicinal products for growth promotion and/or yield increase or antimicrobials reserved for the treatment of certain infections in humans** laid down in Commission Implementing Regulation (EU) 2022/1255 and originates from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]’

;

(ii) in the Notes to Part II, the following footnote is inserted:

‘(xx) Applicable to consignments entering the Union as from [***Exact Date to be inserted by the Service responsible for the publication***].’

Commission Delegated Regulation (EU) 2023/905 shall apply as from 24 months after the day of application of the amended Commission Regulation (EU) 2021/403

European Commission

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 4 August 2023 5:48 PM
To: s. 47F(1) EOP/USTR; s. 47F(1) Geneva); s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii)
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

Lovely to be put in contact with you. My apologies for the delayed emails (I was off sick a couple of days).

s. 22(1)(a)(ii) and I are the officers in our team who are assessing all the EU regulations and our potential response. We would be delighted to discuss this issue with you. Usually an early morning AEST 8:00 / 8:30 works out as 6:00 pm 6:30 pm in Washington. However we can be flexible.

Our issue is with growth promotion or feed efficiency uses of ionophores – there are no growth promotion claims on the antimicrobials rated as medically important in Australia but the EU approach appears to cover antimicrobials with no likelihood of causing AMR issues.

I was relieved today when s. 22(1)(a)(ii) pointed out that the footnotes in the new certificate (as in the SPS Notice) mean that even though we have to have the attestations ready in the certificates by about ~June 2024 we do not have to use them until 30 months after the legislation is published. Not sure if my certification team will be as happy with us asking for temporary cross-outs.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, July 28, 2023 3:35 PM
To: s. 47F(1) EOP/USTR <s. 47F(1) @ustr.eop.gov>; Ls. 47F(1) Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Re: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Dear s. 47F(1)

Many thanks for this response. Apologies for my delay in getting back to you. I am on leave today for a week and have been racing to get out the door!

I would like to e-introduce you to my Canberra colleagues dealing with AMR and how Australia will manage our implementation of the EU's Art 118 requirements.

Dr s. 22(1)(a)(ii) (AMR) and Dr s. 22(1)(a)(ii) (EU meat market exports), cc'd to this email.

Given arranging a time that suits Washington and Canberra plus Brussels doesn't really work, I won't join the call.

Could you please nominate some times that would work for you to have a Teams call?

s. 22(1)(a)(ii) and s. 22(1)(a)(ii) will then be in touch to confirm.

Many thanks for taking the time to compare notes on implementation and action to meet these new rules.

Best
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Date: Tuesday, 25 July 2023 at 18:57:20
To: s. 22(1)(a)(ii) @dfat.gov.au>, s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Hi s. 22(1)
Thanks for your email and for following up.

I had a few conversations with folks here in DC about the issue and would be happy to speak with colleagues on your side about the issue.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, July 25, 2023 11:34 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

I am just following up on this inquiry. Potentially you have a technical colleague who I could put my Canberra colleagues in touch with?

Cheers
s. 22(1

From: s. 22(1)(a)(ii)
Sent: Thursday, 13 July 2023 11:01 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Not urgent. In the coming weeks would be welcome.

Many thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 11:00 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

I'll ask – when do you need a reply?

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:57 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1)

Thanks. Sorry I should have written coccidiostat products.

Colleagues have looked at label claims that apparently include some relevant 'improved feed efficiency', 'increased rate of weight gain' and 'increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)' claims on coccidiostat products.

Is there any thinking about changing the label?

Thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 10:47 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @state.gov>
Subject: [EXTERNAL] RE: Vet meds [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

Hi s. 22(1)
Thanks for your email.

s. 33(b)

Happy to discuss further if/as needed.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:42 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1) and s. 47F(1)

Do you have insight into whether labels are changing on the ionophores in the US to allow compliance with the vet meds rules?

As I understand it, as long as the label doesn't make a growth claim the product can be used. Likely labels in the US (like Aus) for these products make a range of label claims including relating to growth.

We are thinking about this as we consider the response to the EU re the listing process.

Welcome your advice or this is one of the team we should be talking to about this issue.

Cheers
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | >>>www.eu.mission.gov.au<<;<;
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, 8 August 2023 6:58 PM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) Dawr Brussels; s. 22(1)(a)(ii)
Subject: FW: [EXTERNAL] KIND REMINDER - Information for listing third countries - Commission Delegated Regulation (EU) 2023/905 [SEC=OFFICIAL]
Attachments: Annex to letter - TC requirements article.docx

Follow Up Flag: Follow up
Flag Status: Flagged

OFFICIAL

Dear s. 22(1)(a)(ii) and s. 22(1)(a)(ii)

Please see the email sent from SANTE today. I confirmed receipt of the original request and this email and noted that we are working on our response and note the timeframe.

Fyi

Cheers
s. 22(1

From: SANTE-VETERINARY-MEDICINES@ec.europa.eu <SANTE-VETERINARY-MEDICINES@ec.europa.eu>
Sent: Tuesday, 8 August 2023 9:36 AM
Cc: SANTE-VETERINARY-MEDICINES@ec.europa.eu
Subject: [EXTERNAL] KIND REMINDER - Information for listing third countries - Commission Delegated Regulation (EU) 2023/905

Dear Sir/Madam,

We hope this e-mail finds you well.

We would like to draw your attention to the communication from the European Commission sent end of May 2023 regarding the listing of third countries eligible for the export to the EU of food-producing animals and products derived therefrom intended for human consumption, in accordance with the requirements specified in Commission Delegated Regulation (EU) 2023/905.

The European Commission sent letters to third countries, including yours, as regard the above-mentioned listing. The letter included an annex in the form of a written declaration (here attached for ease of reference) in order to facilitate the provision of the guarantees of compliance with the requirements set in Article 3 of Delegated Regulation (EU) 2023/905. This written declaration should be completed and submitted by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu .

The submission of the required guarantees is of utmost importance. The Commission has set a 6-month period for all third countries to provide the necessary information. Failure to provide the required information within the 6-

month period could result in your country not being included in the above-mentioned list, potentially leading to restrictions on exporting consignments falling within the scope of Regulation (EU) 2023/905 to the EU.

The European Commission would like to emphasize that each country must submit only one written declaration. Therefore, in cases where different competent authorities are involved in compiling the required information, it is essential to coordinate and provide a single joint written declaration.

We kindly request an acknowledgement of receipt of this email to ensure that the communication has reached the appropriate authorities in your country.

Should you have any queries or need further clarification, please do not hesitate to reach out to us.

Thank you for your attention to this matter. Your prompt action in providing the necessary guarantees will contribute to maintaining smooth trade relations between your country and the European Union.

Best regards,

PS: This email has been sent to the same addressees of the intial letter and to the participants in the information meeting between the European Commission and third countries held on 8 June 2023 on the next steps concerning the implementation of Commission Delegated Regulation (EU) 2023/905.

SANTE VETERINARY MEDICINES

European Commission
Health and Food Safety Directorate General
Veterinary Medicines

s. 22(1)(a)(ii)

From: s. 47F(1) @ustr.eop.gov>
Sent: Wednesday, 9 August 2023 9:24 PM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii)
Subject: Re: Let's try tomorrow [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Sounds good - let's plan to at least have an initial conversation in eleven hours or so and we can go from there. Will send the Zoom link in a bit.

Thanks,
s. 47F(1)

On Aug 9, 2023, at 03:31, s. 22(1)(a)(ii) @aff.gov.au> wrote:

Dear s. 47F(1)

I have checked the time differences and it appears that 8 am here is 6pm in Washington.

Zoom appears to be the best option if Teams is not OK for you.
If you can set up a Zoom meeting, I can be available at 8 am (log in from home).
Otherwise we can work out a suitable time next week.

It would be great to share our thoughts on this.

Cheers,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Tuesday, August 8, 2023 11:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Thanks for your email – Wednesday PM should work for me.

Please send me your preferred method to connect – please either Zoom or Webex, not Teams.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Tuesday, August 8, 2023 3:31 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

My apologies – we cannot do this Tuesday pm USA / Wednesday am AUS

Is Wed / Thursday suitable?

Cheers,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Saturday, August 5, 2023 2:20 AM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Noce to hear from you, glad to connect.

Perhaps we could aim to speak either on Tuesday evening, which I believe would be Wednesday morning for you.

Please let me know if this works and I'll plan accordingly.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Friday, August 4, 2023 3:48 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

Lovely to be put in contact with you. My apologies for the delayed emails (I was off sick a couple of days).

s. 22(1)(a)(ii) and I are the officers in our team who are assessing all the EU regulations and our potential response.
We would be delighted to discuss this issue with you. Usually an early morning AEST 8:00 / 8:30 works out as 6:00 pm 6:30 pm in Washington. However we can be flexible.

Our issue is with growth promotion or feed efficiency uses of ionophores – there are no growth promotion claims on the antimicrobials rated as medically important in Australia but the EU approach appears to cover antimicrobials with no likelihood of causing AMR issues.

I was relieved today when s. 22(1)(a)(ii) pointed out that the footnotes in the new certificate (as in the SPS Notice) mean that even though we have to have the attestations ready in the certificates by about ~June 2024 we do not have to use them until 30 months after the legislation is published. Not sure if my certification team will be as happy with us asking for temporary cross-outs.

Cheers,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, July 28, 2023 3:35 PM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Re: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Dear s. 47F(1)

Many thanks for this response. Apologies for my delay in getting back to you. I am on leave today for a week and have been racing to get out the door!

I would like to e-introduce you to my Canberra colleagues dealing with AMR and how Australia will manage our implementation of the EU's Art 118 requirements.

Dr s. 22(1)(a)(ii) (AMR) and Dr s. 22(1)(a)(ii) (EU meat market exports), cc'd to this email.

Given arranging a time that suits Washington and Canberra plus Brussels doesn't really work, I won't join the call.

Could you please nominate some times that would work for you to have a Teams call?

s. 22(1)(a)(ii) and s. 22(1)(a)(ii) will then be in touch to confirm.

Many thanks for taking the time to compare notes on implementation and action to meet these new rules.

Best
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Date: Tuesday, 25 July 2023 at 18:57:20
To: s. 22(1)(a)(ii) r@dfat.gov.au>, s. 47F(1) (Geneva)" s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Hi s. 22(1)
Thanks for your email and for following up.

I had a few conversations with folks here in DC about the issue and would be happy to speak with colleagues on your side about the issue.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, July 25, 2023 11:34 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

I am just following up on this inquiry. Potentially you have a technical colleague who I could put my Canberra colleagues in touch with?

Cheers
s. 22(1

From: s. 22(1)(a)(ii)
Sent: Thursday, 13 July 2023 11:01 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) <s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Not urgent. In the coming weeks would be welcome.

Many thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 11:00 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

I'll ask – when do you need a reply?

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:57 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1)

Thanks. Sorry I should have written coccidiostat products.

Colleagues have looked at label claims that apparently include some relevant 'improved feed efficiency', 'increased rate of weight gain' and 'increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)' claims on coccidiostat products.

Is there any thinking about changing the label?

Thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 10:47 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] RE: Vet meds [SEC=OFFICIAL]

Hi s. 22(1)
Thanks for your email.

s. 33(b)

Happy to discuss further if/as needed.

Thanks,

Rob

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:42 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1) and s. 47F(1)

Do you have insight into whether labels are changing on the ionophores in the US to allow compliance with the vet meds rules?

As I understand it, as long as the label doesn't make a growth claim the product can be used. Likely labels in the US (like Aus) for these products make a range of label claims including relating to growth.

We are thinking about this as we consider the response to the EU re the listing process.

Welcome your advice or this is one of the team we should be talking to about this issue.

Cheers
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | >>>>>>www.eu.mission.gov.au<<;<;<;<;<;
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii)r@dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/s. 22(1)(a)(ii)

<image001.png>

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

EU Antimicrobial use restrictions on exporting countries

To: Anna Somerville
For discussion
Timing: 16 August 2023 : 2:30 pm

Subject: Discuss Australian response to the EU antimicrobial use restrictions on exporting countries

Situation

1. The EU is implementing restrictions on imported animal products for human consumption that may have been treated with antimicrobials reserved by the EU for human use or any antimicrobials used for growth promotion or increased yield. EU farmers have already been subject to restrictions on growth promotion use for many years. The reserved antimicrobials are not an issue for Australia as none of them are registered for food animal use. Australia does not have any growth promotion or yield increase uses approved for antimicrobials of medical importance to humans. However, other antimicrobials (the ionophores, avilamycin, olaquindox and flavophospholipol) have such uses permitted for cattle, sheep, pigs and poultry. Australia needs to demonstrate that cattle and sheep will not be given these compounds for growth promotion or yield increase to maintain access to the European market for products from cattle and sheep for human consumption.

Time frames

2. The initial regulation 2019/6 came into force on 28 January 2022, but is not fully implemented for imported products.
3. The EU will establish a list of countries permitted to export animal commodities – based on responses to a questionnaire. These responses are due 23 November 2023.
    a. For each animal commodity Australia must respond indicating either that no such uses are permitted – or that a segregated supply system has been / or will be established.
    b. Although domestic pigs and poultry are not exported to the EU, the growth promotion uses must be reported
4. The EU is also proposing to include an attestation on all health certificates for edible products from domestic animals. Comments on this proposal are due to the EU by 15 September 2023. The EU plans to publish this regulation in January 2024. If published on time, the changes to certificates must be implemented from June 2024 onwards, however the attestation will not apply until January 2026 (or later if publication is delayed).
    a. We have reservations about the wording of the attestation (implies lifetime non-use) and intend to comment. We could also use the comment process to question the scope of the ban.

Consultation

5. s. 22(1)(a)(ii) and members of the One Health team (now in the OCVO) have been involved in monitoring these developments, participating in EU information sessions and contributing to an ongoing Specific Trade Concern #244 regarding the EU proposed restrictions. s. 22(1 has also consulted with Posts from other countries and arranged a virtual meeting with a representative of the USA.

a. Australia has also commented on the implementing regulation SPS 605 in January 2023 and received clarifications from the EU regarding the status of coccidiostats (including ionophores)

6. This issue has been raised at Safemeat (paper presented xxxx) and discussed with dairy industry representatives.
7. The APVMA has been consulted and have advised that a review of products to remove label directions allowing growth promotion or yield increase can be carried out if justified due to risk to trade.
8. Animal Medicines Australia has also been consulted.
9. Overall, industry have indicated that removal of label directions is preferable to establishment of segregated systems. However, they have asked if this move by the EU is WTO compliant and whether it can be opposed.

Guidance sought on options

10. We recommend that a letter is sent to the APVMA requesting a review of affected product labels on the basis of a risk to trade. (Currently $305 million direct trade with an unknown value of trade via third countries such as China). The APVMA PUBCRIS record has been searched comprehensively to develop a list of affected products and their label claims.
11. However, we could seek clarification from the EU regarding two topics:

    i. Whether the ionophore antimicrobials are exempt from this regulation. Our reading of the regulations is that they are not, but there has been confusing advice from the EU.

    ii. Whether “feed efficiency” or “improved feed conversion” is included in the definition of growth promotion and yield increase.

12. We could also share our findings regarding the status of ionophores with the US representative who currently considers that ionophores are exempt from the ban on growth promotion uses.

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Monday, 28 August 2023 2:34 PM
To: s. 47F(1) EOP/USTR; s. 22(1)(a)(ii) (DFAT); s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: FW: EU AMR rules shared concerns and status of ionophores E: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]
Attachments: EU and UK Antimicrobials and claims.docx

Dear s. 47F(1)

Thank you very much for the conversation on 10 August.
I had promised to send you our search results for EU products (whether approved as veterinary medicines (EU) 2019/6 or feed additives (EC) 1831/2003. I searched for the ingredients of concern to us (we have access for cattle and sheep but not pigs or poultry) – none of them had any feed conversion efficiency claims records in those databases. (I also searched UK ones as they have similar regulations)

I agree that we also consider the proposed attestation for health certificates as published in SPS Notice G.SPS.N.EU.656 to be problematic:

- it is implies lifetime "non-use" when an animal might have been treated prior to the start of the EU regulations – It should state the date from which the prohibition of use applies
- It implies knowledge of the **intent** of animal managers "not been administered antimicrobial medicinal products **for** growth promotion or yield increase" whereas the EU member states just have to ensure that the use pattern is not approved – and do not have to sign any such attestation.
- the use of Note (16) to limit applicability to 30 months after the date of entry in force is confusing when the certificates must be amended by ~ June 2024 (two years of not being applicable but on the certifcate?)

Our industry is also very reluctant to set up any segregated EU supply chains.

However, we are not confident that the ionophores are exempt from the prohibition of any use for growth promotion or yield increase. (Thanks Jeevan for the following).

Apparently some stakeholders have been convinced that the EU classify the ionophores a feed additive, not as an antibiotic or anti-microbial. However, both (EU) 2019/6 and (EC) 1831/2003 have fairly consistent definitions of antimicrobial that include anti-protozoals

- Regulation 2019/6 Article 4 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals;
- Regulation 1831/2003 Article 2 'antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

Regulation 2019/6 – indicates that feed additives are excluded

- Article 2 (7) This Regulation shall not apply to (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

However this is only useful for the EU internally Feed additive regulation 1831/2003 – does not allow any antimicrobial to be used unless they are intended to kill or inhibit protozoa.

- Article 5(4) - Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.
- Article 2 Definitions (2) k - 'coccidiostats' and 'histomonostats' means substances intended to kill or inhibit protozoa

When questioned in our response to G.SPS.N.EU.605, the EC replied that "*Coccidiostats and histomonostats, including ionophores, when exclusively used as feed additives intended to kill or inhibit protozoa, do not fall under the scope of the Regulation on veterinary medicinal products, but fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)).*"

Hence, we understand that a coccidiostat such as an ionophore being used for another purpose - ie. growth promotion, yield increase or possibly feed conversion efficiency - is not excluded from 2019/6. Therefore, there are products in both Australia and the USA that contain active ingredients such as monensin, lasalocid, narasin and salinomycin may have uses that the EU regulations prohibit.

We are keen to get clear EU guidance on this – and also on the status of the use pattern "feed conversion efficiency".

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Wednesday, August 9, 2023 9:24 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>
Subject: Re: Let's try tomorrow [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Sounds good - let's plan to at least have an initial conversation in eleven hours or so and we can go from there. Will send the Zoom link in a bit.

Thanks,
s. 47F(1)

> On Aug 9, 2023, at 03:31, s. 22(1)(a)(ii) @aff.gov.au> wrote:
>
> Dear s. 47F(1)
>
> I have checked the time differences and it appears that 8 am here is 6pm in Washington.
>
> Zoom appears to be the best option if Teams is not OK for you.
> If you can set up a Zoom meeting, I can be available at 8 am (log in from home).
> Otherwise we can work out a suitable time next week.
>
> It would be great to share our thoughts on this.
>
> Cheers,
>
> s. 22(1)(a)(ii)
>
> **Dr** s. 22(1)(a)(ii) **(she / her)**

Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Tuesday, August 8, 2023 11:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Thanks for your email – Wednesday PM should work for me.

Please send me your preferred method to connect – please either Zoom or Webex, not Teams.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Tuesday, August 8, 2023 3:31 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva)
s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

My apologies – we cannot do this Tuesday pm USA / Wednesday am AUS

Is Wed / Thursday suitable?

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Saturday, August 5, 2023 2:20 AM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) Geneva)
s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT)
s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Noce to hear from you, glad to connect.

Perhaps we could aim to speak either on Tuesday evening, which I believe would be Wednesday morning for you.

Please let me know if this works and I'll plan accordingly.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Friday, August 4, 2023 3:48 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) <LeonardiEV@state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

Lovely to be put in contact with you. My apologies for the delayed emails (I was off sick a couple of days).

s. 22(1)(a)(ii) and I are the officers in our team who are assessing all the EU regulations and our potential response.
We would be delighted to discuss this issue with you. Usually an early morning AEST 8:00 / 8:30 works out as 6:00 pm 6:30 pm in Washington. However we can be flexible.

Our issue is with growth promotion or feed efficiency uses of ionophores – there are no growth promotion claims on the antimicrobials rated as medically important in Australia but the EU approach appears to cover antimicrobials with no likelihood of causing AMR issues.

I was relieved today when s. 22(1)(a)(ii) pointed out that the footnotes in the new certificate (as in the SPS Notice) mean that even though we have to have the attestations ready in the certificates by about ~June 2024 we do not have to use them until 30 months after the legislation is published. Not sure if my certification team will be as happy with us asking for temporary cross-outs.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, July 28, 2023 3:35 PM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Re: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Dear s. 47F(1)

Many thanks for this response. Apologies for my delay in getting back to you. I am on leave today for a week and have been racing to get out the door!

I would like to e-introduce you to my Canberra colleagues dealing with AMR and how Australia will manage our implementation of the EU's Art 118 requirements.

Dr s. 22(1)(a)(ii) (AMR) and Dr s. 22(1)(a)(ii) (EU meat market exports), cc'd to this email.

Given arranging a time that suits Washington and Canberra plus Brussels doesn't really work, I won't join the call.

Could you please nominate some times that would work for you to have a Teams call?

s. 22(1)(a)(ii) and s. 22(1)(a)(ii) will then be in touch to confirm.

Many thanks for taking the time to compare notes on implementation and action to meet these new rules.

Best
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Date: Tuesday, 25 July 2023 at 18:57:20
To: s. 22(1)(a)(ii) @dfat.gov.au>, s. 47F(1) (Geneva)" s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

Hi s. 22(1)
Thanks for your email and for following up.

I had a few conversations with folks here in DC about the issue and would be happy to speak with colleagues on your side about the issue.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, July 25, 2023 11:34 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

I am just following up on this inquiry. Potentially you have a technical colleague who I could put my Canberra colleagues in touch with?

Cheers
s. 22(1

From: s. 22(1)(a)(ii)
Sent: Thursday, 13 July 2023 11:01 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Not urgent. In the coming weeks would be welcome.

Many thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 11:00 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

I'll ask – when do you need a reply?

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:57 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1)

Thanks. Sorry I should have written coccidiostat products.

Colleagues have looked at label claims that apparently include some relevant 'improved feed efficiency', 'increased rate of weight gain' and 'increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)' claims on coccidiostat products.

Is there any thinking about changing the label?

Thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 10:47 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) (Geneva)

s. 47F(1) @state.gov>
Subject: [EXTERNAL] RE: Vet meds [SEC=OFFICIAL]

Hi s. 22(1)
Thanks for your email.

s. 33(b)

Happy to discuss further if/as needed.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:42 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1) and s. 47F(1)

Do you have insight into whether labels are changing on the ionophores in the US to allow compliance with the vet meds rules?

As I understand it, as long as the label doesn't make a growth claim the product can be used. Likely labels in the US (like Aus) for these products make a range of label claims including relating to growth.

We are thinking about this as we consider the response to the EU re the listing process.

Welcome your advice or this is one of the team we should be talking to about this issue.

Cheers
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | >>>>>>www.eu.mission.gov.au<<;<;<;<;<;
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels

Twitter: @AustraliaEU | https://twitter.com/@s. 22(1)(a)(ii)

<image001.png>

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

EU UK products containing active ingredients:

For cattle we have an issue with all five actives. For sheep only with lasalocid and monensin.

Flavophospholipol (not an ionophore – also known as bambermycin)
EU UPD medicines list – nil
EU Food and Feed list – nil
UK list nil

Lasalocid sodium
EU UPD medicines list – nil
EU Food and Feed list - 51763 Avatec 150 G *Turkeys, Game birds, Chickens for fattening Coccidiostat*
UK list – nil UK feed list same

Monensin
EU UPD Medicines list – 1
Kexxtone 32.4 intraruminal Cattle (cow) , heifer
For the reduction in the incidence of ketosis in the peri-parturient dairy cow/heifer which is expected to develop ketosis

EU Food and Feed list – 51776 Monensin/Nicarbazin *Turkeys, Chickens coccidiostat*
51701 Monensin Coxidin *Chickens coccidiosis*
E757 Elancoban G100 *Turkeys, Chickens coccidiostat*
UK lists – same as EU

Narasin
EU UPD medicines list – Nil
EU Food and Feed list - E765 Monteban G 100 Elanco *Chickens coccidiosis*
Narasin / Nicarbazin Maxiban G160 *Chickens coccidiosis*

Salinomycin
EU UPD medicines list – Nil
EU Food and Feed list – 51766 Sacox 120 Huvepharma *Chickens coccidiosis*
UK same as EU

EU websites

Home | UPD (europa.eu) list of vet medicines – eg monensin as a rumen bolus for info see Union Product Database | European Medicines Agency (europa.eu)

Food and Feed Information Portal Database | FIP (europa.eu) list of feed additives eg monensin – in feed uses, salinomycin (chickens only) – sadly does not seem to include label claims but does give the name

European Public Assessment Reports (EPAR) European Medicines Agency website

UK websites

Product Information Database - Currently authorised products (defra.gov.uk)

The register of feed additives sets out a list of feed additives permitted for use in Great Britain and provides reference to the individual feed additive legislation. The register does not replace retained EU Regulation 1831/2003 which is the legal basis for the placing on the market and use of individual feed additives.

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Thursday, 31 August 2023 6:06 PM
To: s. 22(1)(a)(ii) ; s. 47F(1) @international.gc.ca
Cc: s. 22(1)(a)(ii)
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

Dear s. 22(1 and s. 47F(1)

We are very concerned about s. 33(b)

However, we are also concerned about the ionophores and want to seek clarification from the Commission about this.
We are not confident that the ionophores are exempt from the prohibition of any use for growth promotion or yield increase. (Thanks s. 22(1)(a)(ii) for the following).

Apparently some of our dairy stakeholders have been convinced that the EU classify the ionophores a feed additive, not as an antibiotic or anti-microbial. However, both (EU) 2019/6 and (EC) 1831/2003 have fairly consistent definitions of antimicrobial that include anti-protozoals

- Regulation 2019/6 Article 4 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals;
- Regulation 1831/2003 Article 2 'antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

It is correct that Regulation 2019/6 – indicates that feed additives are excluded

- Article 2 (7) This Regulation shall not apply to (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

However, Regulation 1831/2003 prohibits the use of any antimicrobials unless they are intended to kill or inhibit protozoa. Yes 1831/2003 does not apply to exporting countries bu tit does not appear And as you note from the EU website "Antibiotics, other than coccidiostats or histomonostats, are not feed additives under European legislation"

- Article 5(4) - Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.
- Article 2 Definitions (2) k - 'coccidiostats' and 'histomonostats' means substances **intended** to kill or inhibit protozoa

Ionophores are antibiotics (originally derived from bacterial / fungal species). Yes 1831/2003 does not apply to exporting countries but neither does it appears to give a valid exemption for ionophores when they are not used to kill or inhibit protozoa.

The feed conversion or growth promotion effects are attributed to ionophore effects on bacteria (not just protozoa).

When questioned in our response to G.SPS.N.EU.605, the EC replied that *"Coccidiostats and histomonostats, including ionophores, **when exclusively used as feed additives intended to kill or inhibit protozoa**, do not fall under the scope of the Regulation on veterinary medicinal products, but fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b))."*

Hence, we understand that a coccidiostat such as an ionophore being used for another purpose - ie. growth promotion, yield increase or possibly feed conversion efficiency - is not excluded from 2019/6. Therefore, there are products in both Australia (and possibly Canada) that contain active ingredients such as monensin, lasalocid, narasin and salinomycin may have uses that the EU regulations prohibit.

From an internal EU point of view the exclusion of 'coccidiostats' and 'histomonostats' is significant because they are the only group of antimicrobials exempt from the prohibition of use for prophylaxis and the limits on use for metaphylaxis that apply to EU farmers but not to us. Perhaps this is why they have not given precise advice.

We are keen to get clear EU guidance on this – and also on the status of the use pattern "feed conversion efficiency".

The worst outcome for me is that we go ahead on the assumption that ionophores are exempt and then get the EU disagree and refuse to list Australia as having access or worse still do not react until the regulations come into force and then remove our access and cause trade disruptions.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, August 31, 2023 1:11 AM
To: s. 47F(1) @international.gc.ca
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

Many thanks.

Cheers
s. 22(1

From: s. 47F(1) @international.gc.ca>
Sent: Wednesday, 30 August 2023 4:55 PM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

Dear s. 22(1)

Yes, we did consider the label claims for coccidiostats. This is actually what triggered our concern in the first place.

However, as coccidiostats are considered feed additives, not VMPs in the EU, and are excluded from the VMP regulation (Regulation (EU) 2019/6), we think it is fairly clear that coccidiostats are not prohibited under Regulation (EU) 2019/6, regardless of the label claim.

There is also a statement on the Commission website concerning feed additives (Legislation on feed additives (europa.eu)), that provides further clarity:

"Antibiotics, other than coccidiostats or histomonostats, are not feed additives under European legislation."

Hope this helps.

s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: August 30, 2023 4:37 PM
To: Cs. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

Thanks for your response. I am not sure about s. 33(b) . My colleagues from Canberra can advise on that one.

We are grappling with the label claims for coccidiostats and whether labels that include growth or feed efficiency claims (in addition to the protozoa claim) would meet the EU's rules to be considered feed additives.

Is this factoring in to Canada's thinking?

Cheers
s. 22(1

From: s. 47F(1) @international.gc.ca>
Sent: Wednesday, 30 August 2023 3:32 PM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: [EXTERNAL] RE: Vet meds question [SEC=OFFICIAL]

Dear s. 22(1)(a)(ii)

Thank you very much for your email! I am doing well. Hope you have had a good summer too.

In Canada (Health Canada and CFIA), we have a similar concern regarding how coccidiostats are treated by the EU. From reading EU regulations on Feed Additives (Regulation (EC) No 1831/2003) and VMPs (Regulation (EU) 2019/6), it would seem that coccidiostats are not within the scope of VMPs, and therefore, are not implicated by Regulation (EU) 2019/6.

Regulation (EU) 2019/6
Article 2

……

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 ([1]);
(d) veterinary medicinal products intended for research and development;

……

s. 33(b)

Kind regards,

s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: August 30, 2023 1:53 PM
To: s. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

How are you going? How was your summer?

We are thinking thru the Vet meds issue and ionophores. I have a question as to how Canada is interpreting the rules.

Our understanding is that ionophores are classified as feed additives when **exclusively used as feed additives intended to kill or inhibit protozoa** (ie. there is no claim for growth promotion or increased yield).

Are these products used in Canadian dairy for more purposes than intending to kill or inhibit protozoa? Do you think this practice can continue and meet the Vet med rules?

Do you have any plans to make label changes to this set of products in order to comply with the vet meds rules?

Welcome your advice.

Thanks
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | www.eu.mission.gov.au
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/@s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 7 September 2023 4:54 AM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: RE: EU AMR rules shared concerns and status of ionophores E: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 22(1)(a)(ii)
Thanks for your email and the thorough analysis you shared.

There isn't too much that I want to put in email about this but I thought it might be worthwhile to share the following, as it underlines the importance and ubiquity of ionophore use in the EU:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9497773/

s. 33(b)

Regardless, I assume that Australia is planning to submit comments on G/SPS/N/EU/656. Aside from any of the issues noted above and in previous emails, I think it is in everyone's best interest to continue pushing for more time (including pushing back the adoption and publication date); while 30 months seems like a long transition period, it is only a fraction of the productive life of many animals covered under this new regulation and more are being born every day.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, August 28, 2023 12:34 AM
To: s. 47F(1) @ustr.eop.gov>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>
Subject: FW: EU AMR rules shared concerns and status of ionophores E: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

Thank you very much for the conversation on 10 August.
I had promised to send you our search results for EU products (whether approved as veterinary medicines (EU) 2019/6 or feed additives (EC) 1831/2003. I searched for the ingredients of concern to us (we have access for cattle and sheep but not pigs or poultry) – none of them had any feed conversion efficiency claims records in those databases. (I also searched UK ones as they have similar regulations)

I agree that we also consider the proposed attestation for health certificates as published in SPS Notice G.SPS.N.EU.656 to be problematic:

- it is implies lifetime "non-use" when an animal might have been treated prior to the start of the EU regulations – It should state the date from which the prohibition of use applies
- It implies knowledge of the **intent** of animal managers "not been administered antimicrobial medicinal products **for** growth promotion or yield increase" whereas the EU member states just have to ensure that the use pattern is not approved – and do not have to sign any such attestation.

- the use of Note (16) to limit applicability to 30 months after the date of entry in force is confusing when the certificates must be amended by ~ June 2024 (two years of not being applicable but on the certifcate?)

Our industry is also very reluctant to set up any segregated EU supply chains.

However, we are not confident that the ionophores are exempt from the prohibition of any use for growth promotion or yield increase. (Thanks Jeevan for the following).

Apparently some stakeholders have been convinced that the EU classify the ionophores a feed additive, not as an antibiotic or anti-microbial. However, both (EU) 2019/6 and (EC) 1831/2003 have fairly consistent definitions of antimicrobial that include anti-protozoals

- Regulation 2019/6 Article 4 'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals;
- Regulation 1831/2003 Article 2 'antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

Regulation 2019/6 – indicates that feed additives are excluded

- Article 2 (7) This Regulation shall not apply to (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

However this is only useful for the EU internally Feed additive regulation 1831/2003 – does not allow any antimicrobial to be used unless they are intended to kill or inhibit protozoa.

- Article 5(4) - Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.
- Article 2 Definitions (2) k - 'coccidiostats' and 'histomonostats' means substances intended to kill or inhibit protozoa

When questioned in our response to G.SPS.N.EU.605, the EC replied that "*Coccidiostats and histomonostats, including ionophores, when exclusively used as feed additives intended to kill or inhibit protozoa, do not fall under the scope of the Regulation on veterinary medicinal products, but fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)).*"

Hence, we understand that a coccidiostat such as an ionophore being used for another purpose - ie. growth promotion, yield increase or possibly feed conversion efficiency - is not excluded from 2019/6. Therefore, there are products in both Australia and the USA that contain active ingredients such as monensin, lasalocid, narasin and salinomycin may have uses that the EU regulations prohibit.

We are keen to get clear EU guidance on this – and also on the status of the use pattern "feed conversion efficiency".

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Wednesday, August 9, 2023 9:24 PM
To: s. 22(1)(a)(ii) @aff.gov.au>

Cc: s. 22(1)(a)(ii) @aff.gov.au>
Subject: Re: Let's try tomorrow [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Sounds good - let's plan to at least have an initial conversation in eleven hours or so and we can go from there. Will send the Zoom link in a bit.

Thanks,
Rob

On Aug 9, 2023, at 03:31, s. 22(1)(a)(ii) @aff.gov.au> wrote:

Dear s. 47F(1)

I have checked the time differences and it appears that 8 am here is 6pm in Washington.

Zoom appears to be the best option if Teams is not OK for you.
If you can set up a Zoom meeting, I can be available at 8 am (log in from home).
Otherwise we can work out a suitable time next week.

It would be great to share our thoughts on this.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Tuesday, August 8, 2023 11:51 PM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Thanks for your email – Wednesday PM should work for me.

Please send me your preferred method to connect – please either Zoom or Webex, not Teams.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Tuesday, August 8, 2023 3:31 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva)
s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

My apologies – we cannot do this Tuesday pm USA / Wednesday am AUS

Is Wed / Thursday suitable?

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @ustr.eop.gov>
Sent: Saturday, August 5, 2023 2:20 AM
To: s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)
Noce to hear from you, glad to connect.

Perhaps we could aim to speak either on Tuesday evening, which I believe would be Wednesday morning for you.

Please let me know if this works and I'll plan accordingly.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Friday, August 4, 2023 3:48 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] EU Vet meds restrictions [SEC=OFFICIAL]

Dear s. 47F(1)

Lovely to be put in contact with you. My apologies for the delayed emails (I was off sick a couple of days).

s. 22(1)(a)(ii) and I are the officers in our team who are assessing all the EU regulations and our potential response.
We would be delighted to discuss this issue with you. Usually an early morning AEST 8:00 / 8:30 works out as 6:00 pm 6:30 pm in Washington. However we can be flexible.

Our issue is with growth promotion or feed efficiency uses of ionophores – there are no growth promotion claims on the antimicrobials rated as medically important in Australia but the EU approach appears to cover antimicrobials with no likelihood of causing AMR issues.

I was relieved today when s. 22(1)(a)(ii) pointed out that the footnotes in the new certificate (as in the SPS Notice) mean that even though we have to have the attestations ready in the certificates by about ~June 2024 we do not have to use them until 30 months after the legislation is published. Not sure if my certification team will be as happy with us asking for temporary cross-outs.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, July 28, 2023 3:35 PM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Re: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Dear s. 47F(1)

Many thanks for this response. Apologies for my delay in getting back to you. I am on leave today for a week and have been racing to get out the door!

I would like to e-introduce you to my Canberra colleagues dealing with AMR and how Australia will manage our implementation of the EU's Art 118 requirements.

Dr s. 22(1)(a)(ii) (AMR) and Dr s. 22(1)(a)(ii) (EU meat market exports), cc'd to this email.

Given arranging a time that suits Washington and Canberra plus Brussels doesn't really work, I won't join the call.

Could you please nominate some times that would work for you to have a Teams call?

s. 22(1)(a)(ii) and s. 22(1)(a)(ii) will then be in touch to confirm.

Many thanks for taking the time to compare notes on implementation and action to meet these new rules.

Best
s. 47F

From: s. 47F(1) @ustr.eop.gov>
Date: Tuesday, 25 July 2023 at 18:57:20
To: s. 22(1)(a)(ii) @dfat.gov.au>, s. 47F(1) (Geneva)" s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

Hi s. 22(1)(
Thanks for your email and for following up.

I had a few conversations with folks here in DC about the issue and would be happy to speak with colleagues on your side about the issue.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, July 25, 2023 11:34 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

I am just following up on this inquiry. Potentially you have a technical colleague who I could put my Canberra colleagues in touch with?

Cheers
s. 22(1

From: s. 22(1)(a)(ii)
Sent: Thursday, 13 July 2023 11:01 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Not urgent. In the coming weeks would be welcome.

Many thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 11:00 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

I'll ask – when do you need a reply?

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:57 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) (Geneva) s. 47F(1) @state.gov>
Subject: RE: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1)

Thanks. Sorry I should have written coccidiostat products.

Colleagues have looked at label claims that apparently include some relevant 'improved feed efficiency', 'increased rate of weight gain' and 'increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)' claims on coccidiostat products.

Is there any thinking about changing the label?

Thanks
s. 22(1

From: s. 47F(1) @ustr.eop.gov>
Sent: Thursday, 13 July 2023 10:47 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] RE: Vet meds [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

Hi s. 22(1)
Thanks for your email.

s. 33(b)

Happy to discuss further if/as needed.

Thanks,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, July 13, 2023 4:42 AM
To: s. 47F(1) @ustr.eop.gov>; s. 47F(1) Geneva) s. 47F(1) @state.gov>
Subject: [EXTERNAL] Vet meds [SEC=OFFICIAL]

OFFICIAL

Hi s. 47F(1) and s. 47F(1)

Do you have insight into whether labels are changing on the ionophores in the US to allow compliance with the vet meds rules?

As I understand it, as long as the label doesn't make a growth claim the product can be used. Likely labels in the US (like Aus) for these products make a range of label claims including relating to growth.

We are thinking about this as we consider the response to the EU re the listing process.

Welcome your advice or this is one of the team we should be talking to about this issue.

Cheers
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | >>>>>>>www.eu.mission.gov.au<<;<;<;<;<;<;
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/@s. 22(1)(a)(ii)

<image001.png>

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

s. 22(1)(a)(ii)

From: SPS Contact Point - Australia
Sent: Friday, 15 September 2023 4:46 PM
To: sps@ec.europa.eu
Cc: s. 22(1)(a)(ii)
Subject: Australia's comments on G/SPS/N/EU/656. [SEC=OFFICIAL]
Attachments: Australia comments on G.SPS.N.EU.656.pdf

Dear European Commission SPS Contact Point

Please find attached Australian Government comments on WTO SPS Notification G/SPS/N/EU/656: *COMMISSION IMPLEMENTING REGULATION (EU) …/... amending Annex III to Implementing Regulation (EU) 2020/2235 and Annex II to Implementing Regulation (EU) 2021/403 as regards model certificates for the entry into the Union of consignments of certain products of animal origin and certain categories of animals*.

We look forward to the EU's response in due course.

Please acknowledge receipt of this email at your earliest convenience.

Kind regards,

s. 22(1)(a)(ii)
Australian SPS Contact Point

Department of Agriculture, Fisheries and Forestry

70 Northbourne Avenue, Canberra ACT 2600 Australia

GPO Box 858 Canberra ACT 2601 Australia

Email: SPS.Contact@aff.gov.au

agriculture.gov.au

Australian Government

Comments from the Australian Government to the European Union on Draft Commission Implementing Regulation (EU) …/... amending Annex III to Implementing Regulation (EU) 2020/2235 and Annex II to Implementing Regulation (EU) 2021/403 as regards model certificates for the entry into the Union of consignments of certain products of animal origin and certain categories of animals (G/SPS/N/EU/656).

1. General comments

Australia thanks the European Union (EU) for the opportunity to comment on the draft Implementing Regulation that amends the model certificates for the export to the Union of food-producing animals and products derived therefrom intended for human consumption to include the relevant attestations of compliance with the provisions set by Regulation (EU) 2019/6.

Australia would appreciate consideration by the Commission of the following specific comments.

2. Timing of certificate amendments described in SPS Notice G.SPS.N.EU.656

The proposed regulation made available in SPS Notice G.SPS.N.EU.656 states in Article 2 that the transitional period applies to certificates issued no later than 6 months from the date of entry into force of the regulation. After this period all certificates issued must include the proposed new attestation.

However, in the annexe, the relevant footnote for each certificate explains that the attestation is not applicable for a further 24 months. "*Applicable to consignments entering the Union as from… [30 months after the date of entry into force of this Regulation]*".

This will result in there being a period of 24 months between when the attestations must be included in the certificates and when those attestations apply.

Australia requests that the Commission clarify whether the attestation should be deleted or crossed out during that 24-month period when the attestation is not applicable.

To avoid confusion and multiple changes to certification procedures, Australia requests that the Commission extend the transition period for the issuing of certificates to align it more closely with the date of applicability of the attestation.

3. Wording of the proposed attestation G/SPS/N/EU/656

The proposed attestation includes the words *"and in particular, that the animals from which the meat is derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 ...."*

These words imply compliance with the regulations **prior to their date of publication or applicability**. This is of particular concern for longer lived animals such as dairy or beef cattle.

Australia requests that the Commission explain the legal basis for this apparent retrospective application of these legal requirements.

The Commission has assured third countries that they will be given sufficient time to comply with these new regulations. However, the proposed attestation implies compliance with these requirements for animals that may have been born prior to the commencement of this requirement.

We recommend that the attestation or its footnote be amended to either recognise the date of commencement of the required controls on treatment of animals or to link the requirement to the date of applicability of the regulations. The current footnote only gives the date of applicability for consignments entering the Union rather than for the time of treatment of animals.

We propose wording similar to that used for the residues guarantee:

The guarantees covering live animals and products thereof provided by the declaration of compliance submitted in accordance with Article 5 of Delegated Regulation (EU) 2023/905, are fulfilled and the concerned animals and products are included in the list of approved countries adopted by the Commission in accordance with Article 5 of Delegated Regulation (EU) 2023/905;

Conclusion

Australia welcomes the Commission's consideration of the concerns and points raised in this submission.

Key points / impacts on Australia

- The European position is to tightly control all antimicrobials (medically and non-medically important) to protect human health.
- The EU legislative changes on anti-microbial resistance (AMR) have implications for Australia's trade and market access and reduces Australia's ability to preserve the health and welfare of Australian animals.
- Australia and its animal industries need to retain the option to responsibly use antimicrobials that are essential to preserve the health and welfare of animals.
- Unilateral pursuit of AMR-related trade policies outside the international standard setting organisations has the potential to undermine collaborative global efforts, and the integrity and relevance of these organisations.
- Australia cannot lose access to ionophores (non-medically important antimicrobials), and this antimicrobial class should not be included in prescription requirements along with medically important antimicrobials.

EU Legislation

- Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products (the "**Vet Med Regulation**") became applicable in the EU as from 28 January 2022. In line with the EU Farm to Fork Strategy, the Vet Med Regulation aims to reduce overall EU sales of antimicrobials by 50% for farmed animals.
- As part of its implementation, the Vet Med Regulation required the European Commission to adopt delegated and implementing acts. For this purpose, the European Commission adopted:
    - Delegated Regulation (EU) 2021/1760 of 26 May 2021, establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans.
    - Implementing Regulation (EU) 2022/1255 of July 2022, 'designating antimicrobials or groups of antimicrobials to be reserved for the treatment of certain infections in humans' (the "Implementing Regulation on reserved antimicrobials"), which provides in its Annex, the **EU list of reserved antimicrobials**. The Regulation which was notified in its draft version to the WTO SPS Committee on 21 April 2022, has been applicable since 9 February 2023.
    - Delegated Regulation (EU) 2023/905 of 27 February 2023 on 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 (the '**Delegated Regulation'**).

Delegated Regulation (EU) 2023/905

- Under the Delegated Regulation, food-producing animals and products of animal origin intended for human consumption:
    - cannot enter the EU if they have been administered an antimicrobial medicinal product (Article 3 of the Delegated Regulation):
        - used for the purpose of promoting growth or improving yield or;
        - that contains an antimicrobial that is included in the EU list of reserved antimicrobials.
    - must meet the following cumulative conditions if they are to be exported to the EU:
        - originate from a **country which is on the EU list of approved countries** (Article 5 of the Delegated Regulation), which is to be drawn up by the Commission, and
        - be accompanied with an **official certificate and an attestation** (to be drawn up by the Commission) stating compliance with EU rules (Article 6 of the Delegated Regulation).

- by implication, operators that do not meet **both** these two conditions will not be able to export to the EU.

Next steps

- Third countries have until November 2023 to complete the information template that was sent by the Commission (DG SANTE) to assess third countries' eligibility to be part of the list of approved third countries. The list will be established by the Commission through a **revision of the EU Official Control Regulation** (Regulation (EU) 2017/625) on the basis of the warranties provided by third countries in the template.

- The Commission will adopt a **new Regulation** (*Commission Implementing Regulation (EU) …/ … of XXX amending Annex III to Implementing Regulations (EU) 2020/2235 and Annex II to Implementing Regulation 2021/403 as regard model certificates for entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals*) amending the relevant models of official certificates, so that a **new attestation model** certifying compliance with the Vet Med legislation can be added to those certificates.
  =>A draft of the implementing Regulation was notified to the WTO SPS Committee meeting on 18 July 2023 (G/SPS/N/EU/656). Entry into force of the Implementing Regulation is expected by the end of 2023/beg 2024.

- **Delegated Regulation (EU) 2023/905** will enter into force 24 months after the date of application of the Implementing Regulation amending the certificates – i.e., by the end of 2025/beg 2026.

Specific Trade Concern at the WTO

Australia has raised its Specific Trade Concern (STC) against the EU Vet Med legislation eleven times within the WTO SPS Committee (first raised July 2018) (see STC 446 and Cables on SPS Committee meetings, notably our July SPS Committee meeting Cable in the WTO file in the G-Drive) and intends continuing doing so at next SPS Committee meetings.

The ionophore issue

Australia is currently discussing with s. 33(b) to see if ionophores should be de facto excluded from the scope of the EU Vet Med legislation s. 33(b) which are excluded from the scope of the Vet Med legislation. For Australia, a no-risk approach would imply relabelling ionophores in Australia to allow the export of animal products produced with those substances to the EU. However, such an approach may be difficult to implement in practice considering the costs and potential market difficulties it may create for Australian operators.

FTA

AMR is part of the currently negotiated EU-Australia Free Trade Agreement (FTA). The EU has stated that AMR is a key strategic issue in any future EU FTA.

For more information on the EU Vet Med Legislation, see the European Commission website at https://ec.europa.eu/food/animals/animal-health/vet-meds-med-feed/implementation_en

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Antimicrobial Resistance (AMR) and the EU

Key points / impacts on Australia

- The European position is to tightly control all antimicrobials (medically and non-medically important) to protect human health.
- The EU legislative changes on anti-microbial resistance (AMR) have implications for Australia's trade and market access and reduces Australia's ability to preserve the health and welfare of Australian animals.
- Australia and its animal industries need to retain the option to responsibly use antimicrobials that are essential to preserve the health and welfare of animals.
- Unilateral pursuit of AMR-related trade policies outside the international standard setting organisations has the potential to undermine collaborative global efforts, and the integrity and relevance of these organisations.
- Australia cannot lose access to ionophores (non-medically important antimicrobials), and this antimicrobial class should not be included in prescription requirements along with medically important antimicrobials.

EU Legislation

- Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products (the "**Vet Med Regulation**") became applicable in the EU as from 28 January 2022. In line with the EU Farm to Fork Strategy, the Vet Med Regulation aims to reduce overall EU sales of antimicrobials by 50% for farmed animals.
- As part of its implementation, the Vet Med Regulation required the European Commission to adopt delegated and implementing acts. For this purpose, the European Commission adopted:
    - Delegated Regulation (EU) 2021/1760 of 26 May 2021, establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans.
    - Implementing Regulation (EU) 2022/1255 of July 2022, 'designating antimicrobials or groups of antimicrobials to be reserved for the treatment of certain infections in humans' (the "Implementing Regulation on reserved antimicrobials"), which provides in its Annex, the **EU list of reserved antimicrobials**. The Regulation which was notified in its draft version to the WTO SPS Committee on 21 April 2022, has been applicable since 9 February 2023.
    - Delegated Regulation (EU) 2023/905 of 27 February 2023 on 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 (the '**Delegated Regulation'**).

Delegated Regulation (EU) 2023/905

- Under the Delegated Regulation, food-producing animals and products of animal origin intended for human consumption:
    - cannot enter the EU if they have been administered an antimicrobial medicinal product (Article 3 of the Delegated Regulation):
        - used for the purpose of promoting growth or improving yield or;
        - that contains an antimicrobial that is included in the EU list of reserved antimicrobials.
    - must meet the following cumulative conditions if they are to be exported to the EU:
        - originate from a **country which is on the EU list of approved countries** (Article 5 of the Delegated Regulation), which is to be drawn up by the Commission, and
        - be accompanied with an **official certificate and an attestation** (to be drawn up by the Commission) stating compliance with EU rules (Article 6 of the Delegated Regulation).
        - by implication, operators that do not meet **both** these two conditions will not be able to export to the EU.

Next steps

- Third countries have until November 2023 to complete the information template that was sent by the Commission (DG SANTE) to assess third countries' eligibility to be part of the list of approved third countries. The list will be established by the Commission through a **revision of the EU Official Control Regulation** (Regulation (EU) 2017/625) on the basis of the warranties provided by third countries in the template.

- The Commission will adopt a **new Regulation** (*Commission Implementing Regulation (EU) …/ … of XXX amending Annex III to Implementing Regulations (EU) 2020/2235 and Annex II to Implementing Regulation 2021/403 as regard model certificates for entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals*) amending the relevant models of official certificates, so that a **new attestation model** certifying compliance with the Vet Med legislation can be added to those certificates.
  =>A draft of the implementing Regulation was notified to the WTO SPS Committee meeting on 18 July 2023 (G/SPS/N/EU/656). Entry into force of the Implementing Regulation is expected by the end of 2023/beg 2024.

- **Delegated Regulation (EU) 2023/905** will enter into force 24 months after the date of application of the Implementing Regulation amending the certificates – i.e., by the end of 2025/beg 2026.

Specific Trade Concern at the WTO
Australia has raised its Specific Trade Concern (STC) against the EU Vet Med legislation eleven times within the WTO SPS Committee (first raised July 2018) (see STC 446 and Cables on SPS Committee meetings, notably our July SPS Committee meeting Cable in the WTO file in the G-Drive) and intends continuing doing so at next SPS Committee meetings.

The ionophore issue
Australia is currently discussing with s. 33(b) to see if ionophores should be de facto excluded from the scope of the EU Vet Med legislation s. 33(b) which are excluded from the scope of the Vet Med legislation. For Australia, a no-risk approach would imply relabelling ionophores in Australia to allow the export of animal products produced with those substances to the EU. However, such an approach may be difficult to implement in practice considering the costs and potential market difficulties it may create for Australian operators.

FTA
AMR was part of the negotiated EU-Australia Free Trade Agreement (FTA). The EU has stated that AMR is a key strategic issue in any future EU FTA.

For more information on the EU Vet Med Legislation, see the European Commission website at https://ec.europa.eu/food/animals/animal-health/vet-meds-med-feed/implementation_en

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: ExportStandards
Sent: Wednesday, 29 November 2023 9:03 AM
To: s. 22(1)(a)(ii)
Cc: Somerville, Anna
Subject: FW: Re AUSTRALIA: 2023, Declaration of compliance with Article 118(1) [SEC=OFFICIAL]

Hi EU vetmeds interested staff,

Email for your files.

Kind regards,

Anne R

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Wednesday, November 29, 2023 1:16 AM
To: SANTE-VETERINARY-MEDICINES@ec.europa.eu
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; Europe.tmad <europe.tmad@aff.gov.au>; ExportStandards <ExportStandards@aff.gov.au>; s. 47F(1) @ec.europa.eu>; Dawr Brussels <dawr.brussels@dfat.gov.au>
Subject: Re AUSTRALIA: 2023, Declaration of compliance with Article 118(1) [SEC=OFFICIAL]

OFFICIAL

Dear SANTE Vet Meds Team

I am getting in touch regarding Australia's response to the information requested in regard to (EU) 2023/905. A final response is currently going through our internal clearance process and we expect to have it to you in coming weeks.

I apologise we have not met the six month deadline and respectfully request you consider our submission when received.

We will endeavour to have it to you as soon as possible.

Kind regards

s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | www.eu.mission.gov.au
ph: s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/@s. 22(1)(a)(ii)

© Kim Hill, Among Women (2011)

We acknowledge the Traditional Custodians of Country throughout Australia, and their continuing connection to land, waters and community. We pay our respects to all First Nations peoples, their cultures and to their Elders, past, present and emerging.

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Tuesday, 5 December 2023 11:40 AM
To: s. 22(1)(a)(ii) E-Cert Administrator
Cc: s. 22(1)(a)(ii) Europe.tmad; s. 22(1)(a)(ii) (DFAT); s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: EU Reply certificate changes for edible animal product certificates mid2024 G/SPS/N/EU/656 [SEC=OFFICIAL]
Attachments: Letter EU reply to comments from Australia on notification EU656.pdf; Australia comments on G.SPS.N.EU.656.pdf

Dear s. 22(1)(a)(ii) and teams,

The EU have replied to our SPS 656 comments about their proposed changes to certificates. We proposed a delay to the certificate changes and a change to the wording of the attestations to avoid implying compliance prior to the commencement of the requirement.

- The certificate changes will go ahead as planned (~ mid 2024) but the new attestations will need to be crossed out until the conditions are implemented (I estimate mid 2026).

I am sorry that this implies two certificate changes for both eCert and any remaining paper certificates 1st to add the attestations (crossed out) and then 2nd to remove the cross-outs.

- The EU will not change the wording of the attestation (which could be read as requiring life-time freedom from use of antimicrobials for growth promotion). They consider that there is a sufficient period from when 2019/6 came into force in the EU (28 Feb 2022) until the attestations will be required (estimated mid-2026). I suggest we take this to mean that they do not consider that the attestation implies life-time freedom and that we can issue the certificates in 2026 if we have the controls in place by then.

We will know exact dates of implementation when the EU publish the proposed certificate change regulation (expected in January next year).

The EU has committed to having any future changes to certificates the TRACES-NT system well ahead to allow us to set up our eCerts correctly – they may need a reminder of this.
eCert cover meat, dairy and fish.
I am not sure how many paper certificates are still used for edible products – they need to be ready for use 6 months after the EU publish the new regulation.
Such as honey, composites, collagen, gelatine, fats and greaves.

We may also need a calendar reminder for removing the cross-outs in mid-2026 when the requirements will come into force.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

From: SPS Contact Point - Australia <SPS.Contact@aff.gov.au>
Sent: Tuesday, December 5, 2023 9:24 AM

To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; SPS Contact Point - Australia <SPS.Contact@aff.gov.au>
Subject: FW: Reply of the European Union to the comments from Australia on the measure notified to the WTO in notice G/SPS/N/EU/656 [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)

Please find below the EU's response to the comments from Australian on the measure notified to the WTO in notice G/SPS/N/EU/656.

Our apologies for not passing this across to you earlier, it was somehow missed in all the emails.

Kind Regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)
Graduate

WTO and Free Trade Agreements Section
International Organisations and Negotiations Branch
Trade and International Division

Department of Agriculture, Fisheries and Forestry

Email: s. 22(1)(a)(ii) @aff.gov.au

Phone: s. 22(1)(a)(ii)

Mobile: s. 22(1)(a)(ii)

From: Sps@ec.europa.eu <Sps@ec.europa.eu>
Sent: Tuesday, November 21, 2023 9:28 PM
To: SPS Contact Point - Australia <SPS.Contact@aff.gov.au>
Cc: s. 47F(1) @ec.europa.eu>; delegation-australia@eeas.europa.eu; 'austemb.brussels@dfat.gov.au' <austemb.brussels@dfat.gov.au>; dawr.brussels@dfat.gov.au; s. 47F(1) s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) s. 47F(1) @ec.europa.eu>; Sps@ec.europa.eu; s. 47F(1) s. 47F(1)@ec.europa.eu>
Subject: Reply of the European Union to the comments from Australia on the measure notified to the WTO in notice G/SPS/N/EU/656

Dear colleagues,

Please find attached the reply of the European Union to the comments from Australia on the measure notified to the WTO in notice G/SPS/N/EU/656.

Kind regards,

s. 47F(1)
EU SPS team

European Union Notification Authority & Enquiry Point
European Commission Directorate General for Health and Food Safety
Directorate D Unit A.4 Multilateral International Relations
Phone s. 47F(1)
E-mail: sps@ec.europa.eu
See http://ec.europa.eu/comm/food/international/organisations/wto_en.htm

Legal notice

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH & FOOD SAFETY

One Health
Multilateral International Relations

Brussels,
SANTE A4 VS/tt(2023)9942830

To:	s. 22(1)(a)(ii) Department of Agriculture and Water Resources	**E-mail:**	sps.contact@agriculture.gov.au
From:	s. 47F(1) EU SPS Notification Authority	**E-mail:**	sps@ec.europa.eu
Copy to:	**EU Delegation in Canberra**	**E-mail:**	delegation-australia@eeas.europa.eu
	Mission of Australia to the EU	**E-mail:**	austemb.brussels@dfat.gov.au dawr.brussels@dfat.gov.au
Subject:	**Reply of the EU to the comments of Australia on the legal draft notified in notice G/SPS/N/EU/656**		

Dear Sir/Madam,

Please find attached the reply of the European Union to the comments of Australia on the draft regulatory text notified to the WTO in notification G/SPS/N/EU/656.

Sincerely yours,

s. 47F(1)
EU SPS Notification Authority

REPLY OF THE EUROPEAN UNION TO THE COMMENTS SUBMITTED BY AUSTRALIA CONCERNING THE NOTICE G/SPS/N/EU/656 NOTIFIED TO THE SECRETARIAT OF THE WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

The European Union (EU) would like to thank Australia for the comments submitted in relation to notification G/SPS/N/EU/656.

The EU has carefully studied the comments received and is pleased to provide its reply as follows.

1. **Timing of certificate amendments described in SPS Notice G.SPS.N.EU.656**

The draft Commission Implementing Regulation, which is the subject of this notification, will apply from six months after the date of its entry into force, with the latter occurring on the twentieth day following its publication (the exact date to be confirmed). This is the standard period applicable when there are any amendments to Implementing Regulation (EU) 2020/2235[1] or Implementing Regulation (EU) 2021/403[2].

According to Article 8 of Commission Delegated Regulation (EU) 2023/905[3], the conditions for the entry into the Union of consignments of animals or products, as set out in this Regulation, will apply as of 24 months *after* the date of application of the Implementing Regulation amending the model certificates.

Consequently, the *effective* implementation of Article 118 of Regulation (EU) 2019/6[4] on veterinary medicinal products will occur 30 months after the date of entry into force of this Implementing Regulation.

Concerning the certificates, there will be a transitional period of nine months from the date of entry into force of the Implementing Regulation. This transitional period includes an initial six-month period, along with an additional three-month extension during which border control posts in the EU Member States will continue to accept old certificate models, provided that they were issued within the first six months of the Implementing Regulation's entry into force. During this transitional period, the use of both old and new certificates will be allowed. Furthermore, the newly added attestations on the amended certificates will need to be crossed out until the date of application of the Implementing Regulation.

---

[1] Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates (*OJ L 442, 30.12.2020, p. 1*)

[2] Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates (*OJ L 113, 31.3.2021, p. 1*)

[3] 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 (OJ L 116, 4.5.2023, p. 1)

[4] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (*OJ L 4, 7.1.2019, p. 43)*

2. Wording of the proposed attestation G/SPS/N/EU/656

Article 107(2) of Regulation (EU) 2019/6 establishes that antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth or increasing yield. Article 118 of said Regulation concerns animals and products of animal origin imported into the Union and it specifies that Article 107(2) will apply to operators in third countries and that such operators shall not use antimicrobials reserved for treatment of certain infections in humans for the treatment of animals which are intended for export to the EU for human consumption (or products therefrom are intended for human consumption).

As stated in point 1 above, the *full* enforcement of Article 118 will only take place 30 months after the date of application of the Implementing Regulation. Bearing in mind that Regulation (EU) 2019/6 has already applied from 28 February 2022 the EU considers that the timeframe before full enforcement will be sufficient to allow third countries and operators to readily adapt to this regulatory framework and that competent authorities will be in a position to reliably attest to operator compliance.

The EU would like to thank Australia again for providing comments on this regulatory proposal and hopes that the responses conveyed address the concerns of Australia.

Australian Government

Comments from the Australian Government to the European Union on Draft Commission Implementing Regulation (EU) …/... amending Annex III to Implementing Regulation (EU) 2020/2235 and Annex II to Implementing Regulation (EU) 2021/403 as regards model certificates for the entry into the Union of consignments of certain products of animal origin and certain categories of animals (G/SPS/N/EU/656).

1. General comments

Australia thanks the European Union (EU) for the opportunity to comment on the draft Implementing Regulation that amends the model certificates for the export to the Union of food-producing animals and products derived therefrom intended for human consumption to include the relevant attestations of compliance with the provisions set by Regulation (EU) 2019/6.

Australia would appreciate consideration by the Commission of the following specific comments.

2. Timing of certificate amendments described in SPS Notice G.SPS.N.EU.656

The proposed regulation made available in SPS Notice G.SPS.N.EU.656 states in Article 2 that the transitional period applies to certificates issued no later than 6 months from the date of entry into force of the regulation. After this period all certificates issued must include the proposed new attestation.

However, in the annexe, the relevant footnote for each certificate explains that the attestation is not applicable for a further 24 months. "*Applicable to consignments entering the Union as from… [30 months after the date of entry into force of this Regulation]*".

This will result in there being a period of 24 months between when the attestations must be included in the certificates and when those attestations apply.

Australia requests that the Commission clarify whether the attestation should be deleted or crossed out during that 24-month period when the attestation is not applicable.

To avoid confusion and multiple changes to certification procedures, Australia requests that the Commission extend the transition period for the issuing of certificates to align it more closely with the date of applicability of the attestation.

3. Wording of the proposed attestation G/SPS/N/EU/656

The proposed attestation includes the words *"and in particular, that the animals from which the meat is derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 ...."*

These words imply compliance with the regulations **prior to their date of publication or applicability**. This is of particular concern for longer lived animals such as dairy or beef cattle.

Australia requests that the Commission explain the legal basis for this apparent retrospective application of these legal requirements.

The Commission has assured third countries that they will be given sufficient time to comply with these new regulations. However, the proposed attestation implies compliance with these requirements for animals that may have been born prior to the commencement of this requirement.

We recommend that the attestation or its footnote be amended to either recognise the date of commencement of the required controls on treatment of animals or to link the requirement to the date of applicability of the regulations. The current footnote only gives the date of applicability for consignments entering the Union rather than for the time of treatment of animals.

We propose wording similar to that used for the residues guarantee:

The guarantees covering live animals and products thereof provided by the declaration of compliance submitted in accordance with Article 5 of Delegated Regulation (EU) 2023/905, are fulfilled and the concerned animals and products are included in the list of approved countries adopted by the Commission in accordance with Article 5 of Delegated Regulation (EU) 2023/905;

Conclusion

Australia welcomes the Commission's consideration of the concerns and points raised in this submission.

s. 22(1)(a)(ii)

From: SANTE VETERINARY MEDICINES <sante-veterinary-medicines@ec.europa.eu>
Sent: Thursday, 14 December 2023 1:32 AM
To: Maclachlan, Dugald
Cc: (Department of Agriculture and Water Resources); s. 22(1)(a)(ii) (DFAT); s. 22(1)(a)(ii) ; Somerville, Anna; s. 22(1)(a)(ii)
Subject: [Re] AUSTRALIA RE2: 2023, Declaration of compliance with Article 118(1) - Ares(2023)8554062
Attachments: EC reply to Australia.pdf

[Some people who received this message don't often get email from sante-veterinary-medicines@ec.europa.eu. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Sir, Madam,

Please find attached a reply to your letter, signed by Dr s. 47F(1) .

Best regards,
SANTE VETERINARY MEDICINES
European Commission
Health and Food Safety Directorate General Veterinary Medicines

s. 33(b)

s. 33(b),s. 47F(1),s. 22(1)(a)(ii)

s. 33(b),s. 47F(1),s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Thursday, 14 December 2023 2:57 PM
To: SANTE VETERINARY MEDICINES; Maclachlan, Dugald
Cc: (Department of Agriculture and Water Resources); s. 22(1)(a)(ii) (DFAT); s. 22(1)(a)(ii) ; Somerville, Anna; s. 22(1)(a)(ii)
Subject: RE: [Re] AUSTRALIA RE2: 2023, Declaration of compliance with Article 118(1) - Ares(2023)8554062 [SEC=OFFICIAL]
Attachments: 2023 12 14 s. 22(1)(a)(ii) to s. 47F(1) - Seek Extension AU compliance EU AMR.pdf

Dear Sir, Madam,

Thank you for your letter. Please find a reply and request for extension, signed by Dr s. 22(1)(a)(ii)

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) (she / her)
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
+61 (s. 22(1)(a)(ii)
Export Standards Branch| Exports and Veterinary Services Division

-----Original Message-----
From: SANTE VETERINARY MEDICINES <sante-veterinary-medicines@ec.europa.eu>
Sent: Thursday, December 14, 2023 1:32 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: (Department of Agriculture and Water Resources) <dawr.brussels@dfat.gov.au>; s. 22(1)(a)(ii) (DFAT) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; Somerville, Anna <Anna.Somerville@aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @dfat.gov.au>
Subject: [Re] AUSTRALIA RE2: 2023, Declaration of compliance with Article 118(1) - Ares(2023)8554062

Dear Sir, Madam,

Please find attached a reply to your letter, signed by Dr s. 47F(1)

Best regards,
SANTE VETERINARY MEDICINES
European Commission
Health and Food Safety Directorate General Veterinary Medicines

Australian Government
Department of Agriculture, Fisheries and Forestry

Ref: D23/824532

s. 47F(1)
Head of Unit
Veterinary Medicines
Medical Products and Innovation
Directorate General for Health and Food Safety
European Commission

Dear s. 47F(1)

Thank you for your letter of 13 December 2023 (SANTE.D.4/AVO/mm(2023)12571210) requesting additional information to be added to the Australian guarantees of compliance with Article 3 of (EU) 2023/905 within a period of ten working days following receipt of the letter.

We regret that we had apparently misapplied the instructions in second half of Statement 1: "*If you have ticked (a) (authorised for use) please carefully read each of the statements below and tick only those which apply*" which we interpreted as meaning that none of the statements that followed in that table need be completed.

On behalf of the Department of Agriculture, Fisheries and Forestry, I am writing to request an extension to this period. The period of ten working days expires on 5 January 2024. This period coincides with the shutdown period for the festive season and New Year. Additionally, Australia is heading into its annual summer season and many staff are scheduled to take annual leave in January. Noting these factors, the department would like to request an extension to the response time until Friday 16 February 2024.

We can provide the information required for Statements 2, 3 and 4, as Australia does have effective controls over "off-label" use, imports of animal products and exports of animal products to the EU. However, as noted above, due to the summer season shutdown, we request additional time to prepare and provide these details.

I look forward to receiving your earliest response to this request. Should you have any questions, please contact the department through Ms s. 22(1)(a)(ii) Counsellor (Agriculture) of the Australian Embassy, Brussels, at s. 22(1)(a)(ii) @dfat.gov.au or dawr.brussels@dfat.gov.au or s. 22(1)(a)(ii) Alternatively, I may be contacted on s. 22(1)(a)(ii) or by e-mail: s. 22(1)(a)(ii) @aff.gov.au .

Yours sincerely

s. 22(1)(a)(ii)

Director, Residues and Microbiology Policy
Export Standards Branch
Exports and Veterinary Services Division

14 December 2023

T +61 2 6272 3933
F +61 2 6272 5161
Agriculture House
70 Northbourne Ave
Canberra ACT 2600
GPO Box 858
Canberra ACT 2601
agriculture.gov.au
ABN 34 190 894 983

s. 22(1)(a)(ii)

Subject: EU Antimicrobial restrictions - Discuss growth/ yield use patterns [SEC=OFFICIAL]
Location: ACT CQ2 11.008 (VC Unit Type 2)

Start: Thu 1/02/2024 2:00 PM
End: Thu 1/02/2024 3:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: s. 22(1)(a)(ii)
Required Attendees: s. 22(1)(a)(ii) s. 22(1)(a)(ii); s. 47F(1)@dairyaustralia.com.au; s. 47F(1) @j2e.com.au); s. 47F(1) s. 47F(1) ; ceo@cattleaustralia.com.au; s. 47F(1) s. 47F(1) @bigpond.com; s. 47F(1)
Optional Attendees: s. 22(1)(a)(ii)
Resources: ACT CQ2 11.008 (VC Unit Type 2)

Dear friends,

This is a meeting to discuss the EU requirement that antimicrobials not be used on animals for growth promotion and increased yield if their products are to be exported to the EU.
(EU regulations 2019/6 (prohibition of use) and 2023/905 (application to exporting countries))

We had a few people unable to attend Wed morning – so have moved the meeting to 2pm Thursday 1 February 2024.
Please let me know if this time des not suit or if Teams is not suitable for you.

Microsoft Teams meeting

Join on your computer, mobile app or room device
Click here to join the meeting

Meeting ID: 430 355 596 811
Passcode: PYhB5C
Download Teams | Join on the web

Join with a video conferencing device
597361658@t.plcm.vc
Video Conference ID: 138 583 601 6
Alternate VTC instructions

Or call in (audio only)
+61 2 7208 4605,,528094969# Australia, Sydney
Phone Conference ID: 528 094 969#
Find a local number | Reset PIN

Learn More | Meeting options

Fact Sheet: European Union antimicrobial use restrictions and exports

- The EU will prohibit the import of edible animal products unless Australia has controls to prevent the use of antimicrobials for growth promotion or yield increase. This will take effect from June 2026 onwards.
- This will affect Australian exports of beef, dairy and sheep-meat to the EU unless we take action to comply.
- There is no prohibition of any medical uses of antimicrobials to cure or prevent diseases of livestock in countries outside the EU.

What has happened?

The EU has further restricted the use of antimicrobials in animals by EU farmers [Regulation (EU) 2019/6 (Articles 37 and 107)]. For the first time, some of these restrictions will apply to Australian exports after June 2026.

In the EU, animals must not be treated with any antimicrobial reserved for human use. EU farmers may not use antimicrobials to promote growth or increase yield.

Additionally, EU farmers may not use antimicrobials for prevention of disease except under exceptional circumstances and for limited numbers of animals, unless it is in-feed use for parasite control. This restriction does not apply to countries exporting to the EU like Australia.

What impact does this have on exporting countries like Australia?

Regulation 2019/6 applies restrictions on animals and edible animal products imported into the EU (Article 118) for the first time. These will apply to consignments arriving in the EU after 30 June 2026. Exporting countries such as Australia, need ONLY comply with the following restrictions for animals and products exported to the EU for human consumption:

- Producers must not use any antimicrobials that are reserved for human use by the EU
    - (currently none are registered in Australia for food animals)
- Antimicrobial medicinal products (including ionophores) shall not be used in animals for the purpose of promoting growth nor to increase yield

The restrictions on antimicrobial use for prevention of disease have not been applied to producers outside of the EU. Therefore, there are no restrictions on uses of antimicrobials for any medical purposes (therapeutic uses) that apply to Australian production.

What commodities and products will this affect?

The EU is applying these rules to most edible products from farmed animals (not wild game animals) except composite products (which have a high percentage of plant ingredients). It also applies to products made in a third country using Australian ingredients. This may affect exports of eggs to third countries that wish to send processed foods containing eggs to the EU.

Australia has market access to the EU for edible products from cattle (beef and dairy), sheep, goats, horses, camels and deer. Eggs and egg products could potentially be exported to the EU, if establishment listings and avian influenza surveillance were in place. Australia does not have access to send meat products from poultry or farmed pigs to the EU, so these are unaffected.

There are currently antimicrobial products with a permitted use for growth promotion or increased yield registered in Australia for Sheep, Cattle and Laying Poultry in Australia. The APVMA database PUBCRIS does not identify any growth promotion or increased yield uses of antimicrobials for goats, horses, camel or deer.

Please refer to attached product descriptions for further details of the products.

Are the ionophore antimicrobials exempt from these restrictions?

No. Some sources have claimed that the ionophore antibiotics are exempt from the EU requirements, because they are classified as feed additives. Examples of ionophores include lasalocid, monensin, narasin and salinomycin.

The confusion has arisen because Article 2 in (EU)2019/6 gives an exemption for products that are permitted as a feed additive under Regulation (EC) 1831/2003, Article 5 (3)(g).

However, they are only permitted under (EC) 1831/2003 when used as feed additives and **intended** to kill or inhibit protozoa (also known as coccidiostats or histomonostats).

DAFF have confirmed with the EU that the use of these products for growth promotion or yield increase is prohibited under EU regulation 2019/6.

What must Australia do to maintain access to export to the EU?

Australia needs to be listed by the EU as having sufficient controls to ensure that edible animal products exported to the EU do not come from animals treated with antimicrobials for growth promotion or increased yield. Then, once the regulations are in force, Australia must also declare compliance with these rules in all export certificates for edible products exported to the EU from farmed animals.

The EU require either that:

- Either, 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 to ensure that products from treated animals are not exported to the EU

DAFF recommendations on how Australia can comply by the implementation date

DAFF has received strong feedback from animal industries that a segregated system would be complex and costly to implement.

The alternative is to remove label instructions for growth promotion and yield increase from a small number of antimicrobial products so that these uses are not authorised and the EU requirements are met.

Therefore, we propose that DAFF request the APVMA to amend the labels of affected antimicrobial products to remove label directions for growth promotion or increased yield for beef cattle, dairy cattle and sheep by 30 June 2024 with the labels to be phased out from the market over 2 years (so that uses are not authorised as of June 2026 - the earliest implementation date).

If the egg industry requires access for eggs to the EU (other than as a small component of composite goods), then growth promotion uses of flavophospholipol would also need to be removed from labels.

Antimicrobial product labels can keep all therapeutic uses such as to control coccidiosis or bloat because the EU restrictions on prevention of disease within the EU **do not** apply to Australia.

Once label changes are completed, then DAFF can advise the EU that there are no authorised uses of these products for growth promotion or yield increase, and therefore a segregated system is not required.

Advice sought from the livestock production industries

1. Confirmation of earlier advice that a segregated production system is not practical for exports to the EU of edible products from beef cattle, dairy cattle and sheep.
2. Confirmation on whether label instructions allowing "reproductive efficiency", "increased milk production", "feed efficiency" or "improved feed conversion" should be kept as uses that have value for each specific species. Retaining such claims where they have value to industry would be on the basis that these uses should not be classified as growth promotion or yield increase and are scientifically justified.

   There is a risk that the EU may disagree and find that "feed efficiency" and "improved feed conversion" are NOT permitted uses at a later date. The EU may impose trade restrictions or refuse to list Australia as being suitable to export edible animal products.

Beef – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For beef cattle there are growth promotion label use claims with five actives.

Flavophospholipol (also known as bambermycin) Is NOT an ionophore

Known as Flaveco, Flavo, Nutriflav, Gainpro 5 of 6 products affected, 3 registrants – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Flavophospholipol	Improvement of productivity	Increasing feed conversion efficacy	None
Calves, Cattle	Stimulating growth rate		
	Growth promotion		

Products registered in the EU - none found for this active in this species

IONOPHORE PRODUCTS

Lasalocid sodium, 3 of 5 products, 1 registrant (Zoetis)

Also known as Bovatec, Avatec . Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in growing cattle	Improved feed conversion efficiency in growing cattle	Control of clinical signs of coccidiosis and the reduction of faecal shedding (Eimeria) in growing cattle
			Aid in reduction of bloat scores on pasture

Products registered in the EU - none found for cattle – one for use as coccidiostat in game birds, poultry

Monensin 30 of 31 products, 7 registrants,

Also known as Rumensin, Moneco, Doxaban, Monendox, Kexxtone. In-feed or ruminal capsules (3)

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gain	Improved feed conversion efficiency feedlot cattle, heifers	Aid in the control of bloat feedlot cattle
		Improved reproductive performance	Aid in the prevention of coccidiosis

Products registered in the EU – Capsule for ketosis dairy cattle, in-feed for poultry as a coccidiostat

Narasin

Known as Monteban, Naravin, AF0252. 3 of 4 products have cattle uses, 1 registrant (Elanco) – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Narasin		Improved feed efficiency (Cattle / lot fed cattle) - Not for cows producing milk	None for cattle

Products registered in the EU - none for cattle – two for use as coccidiostat in chickens

Salinomycin

Also known as Salinomix, Sadox, Salindox, Coxistac. 14 of 15 products have a growth promotion claim for feedlot cattle and pigs in addition to coccidiosis in chickens.

Active	Label use to remove	Label use to discuss	Medical label uses
Salinomycin	Increasing the rate of weight gain	Improving feed efficiency	None for cattle
Feedlot beef cattle	Stimulating growth rate		

Products registered in the EU - none for cattle – one for use as coccidiostat in chickens

Dairy – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For dairy cattle there are growth promotion or yield increase label claims for four actives.

Flavophospholipol (also known as bambermycin) Is NOT an ionophore

Known as Flaveco, Flavo, Nutriflav, Gainpro 5 of 6 products affected, 3 registrants – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Flavophospholipol	Improvement of productivity	Increasing feed conversion efficacy	None
Calves, Cattle	Stimulating growth rate		
	Growth promotion		

Products registered in the EU - none found

IONOPHORE PRODUCTS

Lasalocid sodium, 3 of the 5 products, 1 registrant (Zoetis)

Also known as Bovatec and Avatec . Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in growing cattle	Improved feed conversion efficiency in growing cattle	Control of clinical signs of coccidiosis and the reduction of faecal shedding (Eimeria) in growing cattle
		Improvement of milk production	Control of ketosis which can aid control mastitis
			Aid in reduction of bloat scores on pasture

Products registered in the EU - none found for cattle – one for use as coccidiostat in game birds, poultry

Monensin 30 of 31 products, 7 registrants

Also known as Rumensin, Moneco, Doxaban, Monendox, Kexxtone. In-feed or ruminal capsules (3)

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gain heifers	Improved feed conversion efficiency heifers	Aid in the control of bloat
		Improved reproductive performance heifers	Aid to reduce severity of sub-clinical ketosis
		Increased milk production	Aid in the prevention of coccidiosis

Products registered in the EU - Capsule for ketosis dairy cattle, in-feed for poultry as a coccidiostat

Narasin

Known as Monteban, Naravin, AF0252. 3 of 4 products have cattle uses, 1 registrant (Elanco) – feed additives. Possibly used in Dairy heifers

Active	Label use to remove	Label use to discuss	Medical label uses
Narasin		Improved feed efficiency (cattle or lot fed cattle) *	None for cattle
		* *Not for cows producing milk*	

Products registered in the EU - none for cattle – two for use as coccidiostat in chickens

Sheep – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For sheep that affected actives are lasalocid and monensin.

Lasalocid sodium

Also known as Bovatec and Avatec . 3 of the 5 products, 1 registrant (Zoetis). Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in sheep	Improved feed conversion efficiency in sheep	To aid in the reduction of faecal shedding of coccidia Eimeria spp. in sheep maintained in confinement

Products registered in the EU - none found with approved uses on sheep.

Monensin

Also known as Rumensin, Moneco, Doxaban, Monendox. 27 of 28 products, 7 registrants, in-feed for sheep

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gains	Improved feed conversion efficiency	Some products include - Prevention of coccidiosis in sheep

Products registered in the EU - none found with approved uses on sheep.

s. 22(1)(a)(ii)

From: s. 47F(1) @international.gc.ca
Sent: Tuesday, 30 January 2024 10:41 PM
To: s. 22(1)(a)(ii)
Cc: s. 22(1)(a)(ii) (DFAT)
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

Hello s. 22(1)(a)(ii)

Thanks again for the message, and for connecting me with s. 22(1)(a)(ii) I hope we will be able to meet in person soon.

Regarding your question on our communication with the EU, we did receive a reply from DG SANTE. My apologies for not sharing this earlier with you.

Essentially, DG SANTE's response is that "Commission Delegated Regulation (EU) 2023/905 does not prevent third countries from using antimicrobials for the purpose of growth promotion/yield increase". However, "in the event of coccidiostats being administered for the purpose of promoting growth or increasing yield", "this particular use does fall within the scope of statement 5 of section 2 of the declaration template". We interpret that as use of coccidiostats for growth promotion or yield increase would not meet the EU's requirement, although they are not classified as an antimicrobial in the EU.

Following that rationale, I think it is safe to assume that ionophores used for growth promotion or yield increase would not meet the EU requirements under 2023/905, regardless of its classification.

From a regulatory perspective, this nuance should be clarified in the EU regulations. But I don't know if and how they will manage that.

I hope this helps.

Best,
s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: January 30, 2024 10:43 AM
To: s. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

OFFICIAL

Hi Hong

Another email from me this morning!

Did you ever receive a reply from the Commission on this?

Also, s. 22(1)(a) replacement, s. 22(1)(a)(ii), has commenced here at the Mission. I look forward to introducing you in person, but in the interim, you at least have his contact details now.

Best, s. 22(1)(a)(

From: s. 47F(1) @international.gc.ca>
Sent: Thursday, August 31, 2023 11:41 AM
To: s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

Dear s. 22(1)(a)(ii)

Thank you so much for the detailed technical explanation! It is very informative and helpful!

With so many pieces of regulations published by the EU on any given subject, we sometimes find discrepancies among those regulations. Perhaps this is one of those incidences?

Your points are well taken. I agree it is good to seek clarification from the Commission for certainty. It would seem that uses of ionophores, not intended to kill or inhibit protozoa, would be prohibited by the EU. If this is confirmed, then the question becomes how third countries provide guarantee and certify for this prohibition.

We did discuss internally on our concerns, including the coccidiostats. We had asked for a technical discussion with Commission experts, but was declined. Instead they invited us to write them with questions. This is what we ended up doing. We are still waiting for a response from the Commission. Depending on how they respond to our questions, we can include a specific question on ionophores in our follow up.

I will keep you and Jo posted on what we receive from the Commission when we do.

Kind regards,
s. 47F(1)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: August 31, 2023 10:06 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) BREU -AC s. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

Dear s. 22(: and s. 47F(1)

We are very concerned about s. 33(b)

However, we are also concerned about the ionophores and want to seek clarification from the Commission about this.
We are not confident that the ionophores are exempt from the prohibition of any use for growth promotion or yield increase. (Thanks s. 22(1)(a)(ii) for the following).

Apparently some of our dairy stakeholders have been convinced that the EU classify the ionophores a feed additive, not as an antibiotic or anti-microbial. However, both (EU) 2019/6 and (EC) 1831/2003 have fairly consistent definitions of antimicrobial that include anti-protozoals

- Regulation 2019/6 Article 4 ‘antimicrobial’ means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals;
- Regulation 1831/2003 Article 2 ‘antimicrobials’ means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

It is correct that Regulation 2019/6 – indicates that feed additives are excluded

- Article 2 (7) This Regulation shall not apply to (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

However, Regulation 1831/2003 prohibits the use of any antimicrobials unless they are intended to kill or inhibit protozoa. Yes 1831/2003 does not apply to exporting countries bu tit does not appear And as you note from the EU website “Antibiotics, other than coccidiostats or histomonostats, are not feed additives under European legislation”

- Article 5(4) - Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.
- Article 2 Definitions (2) k - ‘coccidiostats’ and ‘histomonostats’ means substances **intended** to kill or inhibit protozoa

Ionophores are antibiotics (originally derived from bacterial / fungal species). Yes 1831/2003 does not apply to exporting countries but neither does it appears to give a valid exemption for ionophores when they are not used to kill or inhibit protozoa.

The feed conversion or growth promotion effects are attributed to ionophore effects on bacteria (not just protozoa).

When questioned in our response to G.SPS.N.EU.605, the EC replied that *“Coccidiostats and histomonostats, including ionophores, **when exclusively used as feed additives intended to kill or inhibit protozoa**, do not fall under the scope of the Regulation on veterinary medicinal products, but fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)).”*

Hence, we understand that a coccidiostat such as an ionophore being used for another purpose - ie. growth promotion, yield increase or possibly feed conversion efficiency - is not excluded from 2019/6. Therefore, there are products in both Australia (and possibly Canada) that contain active ingredients such as monensin, lasalocid, narasin and salinomycin may have uses that the EU regulations prohibit.

From an internal EU point of view the exclusion of ‘coccidiostats’ and ‘histomonostats’ is significant because they are the only group of antimicrobials exempt from the prohibition of use for prophylaxis and the limits on use for metaphylaxis that apply to EU farmers but not to us. Perhaps this is why they have not given precise advice.

We are keen to get clear EU guidance on this – and also on the status of the use pattern “feed conversion efficiency”.

The worst outcome for me is that we go ahead on the assumption that ionophores are exempt and then get the EU disagree and refuse to list Australia as having access or worse still do not react until the regulations come into force and then remove our access and cause trade disruptions.

Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
+s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, August 31, 2023 1:11 AM
To: s. 47F(1) @international.gc.ca
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

Many thanks.

Cheers
s. 22(1

From: s. 47F(1) @international.gc.ca>
Sent: Wednesday, 30 August 2023 4:55 PM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

Dear s. 22(1)

Yes, we did consider the label claims for coccidiostats. This is actually what triggered our concern in the first place.

However, as coccidiostats are considered feed additives, not VMPs in the EU, and are excluded from the VMP regulation (Regulation (EU) 2019/6), we think it is fairly clear that coccidiostats are not prohibited under Regulation (EU) 2019/6, regardless of the label claim.

There is also a statement on the Commission website concerning feed additives (Legislation on feed additives (europa.eu)), that provides further clarity:

"Antibiotics, other than coccidiostats or histomonostats, are not feed additives under European legislation."

Hope this helps.

s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: August 30, 2023 4:37 PM
To: s. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: RE: [EXTERNAL] Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear Hong

Thanks for your response. s. 33(b) My colleagues from Canberra can advise on that one.

We are grappling with the label claims for coccidiostats and whether labels that include growth or feed efficiency claims (in addition to the protozoa claim) would meet the EU's rules to be considered feed additives.

Is this factoring in to Canada's thinking?

Cheers
s. 22(1

From: s. 47F(1) @international.gc.ca>
Sent: Wednesday, 30 August 2023 3:32 PM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)@aff.gov.au; s. 22(1)(a)(ii) @aff.gov.au
Subject: [EXTERNAL] RE: Vet meds question [SEC=OFFICIAL]

CAUTION: This email originated from outside the organisation. Do not click links or open attachments unless you recognise the sender.

Dear s. 22(1)(a)(ii)

Thank you very much for your email! I am doing well. Hope you have had a good summer too.

In Canada (Health Canada and CFIA), we have a similar concern regarding how coccidiostats are treated by the EU. From reading EU regulations on Feed Additives (Regulation (EC) No 1831/2003) and VMPs (Regulation (EU) 2019/6), it would seem that coccidiostats are not within the scope of VMPs, and therefore, are not implicated by Regulation (EU) 2019/6.

Regulation (EU) 2019/6
Article 2
……
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 ([1]);
(d) veterinary medicinal products intended for research and development;
……

s. 33(b)

Kind regards,

s. 47F(1)

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: August 30, 2023 1:53 PM
To: s. 47F(1) @international.gc.ca>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)

s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: Vet meds question [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

How are you going? How was your summer?

We are thinking thru the Vet meds issue and ionophores. I have a question as to how Canada is interpreting the rules.

Our understanding is that ionophores are classified as feed additives when **exclusively used as feed additives intended to kill or inhibit protozoa** (ie. there is no claim for growth promotion or increased yield).

Are these products used in Canadian dairy for more purposes than intending to kill or inhibit protozoa? Do you think this practice can continue and meet the Vet med rules?

Do you have any plans to make label changes to this set of products in order to comply with the vet meds rules?

Welcome your advice.

Thanks
s. 22(1

s. 22(1)(a)(ii)
Minister-Counsellor (Agriculture)
Australian Embassy to Belgium and Luxembourg and
Mission to the European Union and NATO

Avenue des Arts 56, Brussels 1000, Belgium | www.eu.mission.gov.au
ph: +s. 22(1)(a)(ii) email: s. 22(1)(a)(ii) @dfat.gov.au

Facebook: www.facebook.com/AustraliainBrussels
Twitter: @AustraliaEU | https://twitter.com/@s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 9 February 2024 3:41 PM
To: s. 47F(1)
Cc: s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: EU antimicrobial regulations - next steps [SEC=OFFICIAL]
Attachments: 2023 12 06 FINAL Fact Sheet EU AMR rules impact on exports.docx; 1. Beef - Affected Antimicrobial Products.docx; 2. Dairy - Affected Antimicrobial Products.docx; 3. Sheep - Affected Antimicrobial Products.docx; 2024 02 07 List of Commodities EU AMR rules .docx

Dear s. 47F(1) and s. 47F(1),

Thank you for ALFA's participation in our meeting on Thursday 1 February 2024 about the EU antimicrobial usage regulations regarding growth promotion and increased yield uses.

- You confirmed that segregated EU supply chains are not a suitable option for any of your commodities.
- You confirmed that you would prefer to remove growth promotion and increased yield uses – as long as the therapeutic uses (including bloat prevention) are retained.
    - The EU regulations do not require any limitations on the therapeutic claims in exporting countries – so these can be retained.
- We noted that the EU wording prohibits exports of products from animals "*treated for the purpose of promoting growth or to increase yield*". This does not make it exactly clear if the uses for "*feed conversion efficiency*", "*improvement of milk production*" or "*improvement of reproductive performance*" are prohibited. If we choose to retain these uses, there is a risk that the EU may dispute these uses and thus delay or refuse our market access. We are seeking your advice on which of these you are comfortable to retain these claims on labels.
- The final piece of EU legislation is not yet published – so the date of full implementation is not exactly known – should be on or after July 2026.
- This gives a suitable time for amendment of product labels and the phase out of current labels.

DAFF was asked to recheck the feed efficiency wording – s. 47F(1) was correct – I did not find any labels with a feed conversion **efficacy** claim so have corrected the "affected antimicrobial products lists" to the wording "efficiency" – I have used brackets and "/" marks to show where there is some variation in the wording of labels.

- I have attached a copy of the product lists for beef, dairy and sheep so that you can compare these.
- I have also attached a list of the affected commodities (eg meat, milk, albumins) and their EU CN codes (equivalent to HS codes to about 4 digits) as requested by Dairy Australia.

To progress this work to maintain our EU access for your commodities and inform our recommendations, I would appreciate a written response from you regarding:

Do you support the removal of growth promotion and increased yield claims from the labels of antimicrobial products (labels of Australian products as approved by the APVMA)?
Specifically, do you support the removal of claims such as "Improved liveweight gains", "Improved weight gains", "Increasing the rate of weight gain", "Enhancement of productivity", "Stimulating growth rate" and "Growth promotion" in the column headed "Label use to remove" of the tables in the attached lists of products.
YES/NO

Reproductive claims - Do you support the retention of claims regarding reproductive performance for cattle such as "Improved reproductive performance of heifers", in in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

Milk production claims - Do you support the retention of claims regarding milk production for dairy cattle such as “Increased milk production” or “Improvement of milk production”, in the column headed “Label use to discuss” of the tables in the attached lists of products.
YES/NO

Feed conversion efficiency claims - Do you support the retention of claims regarding feed efficiency for cattle and sheep such as “Increasing feed conversion efficiency”, “Improved feed conversion efficiency”, in the column headed “Label use to discuss” of the tables in the attached lists of products.
YES/NO

If we could have a reply as soon as possible and no later than COB Monday 26 February 2024.

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)
Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry

From: s. 22(1)(a)(ii)
Sent: Thursday, January 18, 2024 3:46 PM
To: s. 47F(1) @feedlots.com.au; s. 47F(1) @feedlots.com.au
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: EU antimicrobial regulations - fact sheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1) and s. 47F(1)

I am following up about the issue of the EU regulations limiting the use of antimicrobial compounds in exporting countries.

There is a meeting on this topic tomorrow, Friday 19 January 2023 however this meeting is focussed on the EU list of antimicrobials that are “reserved for human use”. Australia needs to be able demonstrate that these will not be used on food animals, or that their products will be excluded from the EU. None of these substances are currently approved for animal use in Australia, however restrictions on “off-label” prescription are not uniform across the states and territories so we will seek their advice on how “off-label” use can be ruled out.

We will not have sufficient time to discuss the “growth promotion” or “increased yield “ use patterns at tomorrow’s meeting. I have set up a placeholder meeting for 10:30 am 31 January to discuss those issues with Dairy Australia, Sheep Producers, Cattle Australia and the Australian Lot Feeders Association. Let me know if you are available for that meeting or would like to propose a different time or a separate meeting.

We will need a clear written response from each producer group stating whether you support either removal of particular use patterns, or a segregated EU supply chain by mid-February 2024, so that we can determine the actions needed to maintain access to the EU market. We appreciate that we have received feedback from you on this issue – but are seeking to confirm this advice with you.

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii)
Sent: Monday, December 11, 2023 5:42 PM
To: s. 47F(1) @feedlots.com.au; s. 47F(1) @feedlots.com.au
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: EU antimicrobial regulations - fact sheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1) and s. 47F(1)

I work in the meat market access section of DAFF dealing with the EU and have been working with s. 22(1)(a)(ii) on how best to maintain access to the EU market once the new EU antimicrobial regulations take effect for exports. Thank you for your previous input about this issue.

Regarding the EU antimicrobial regulations, we have prepared a fact sheet on the regulations and a list of potentially affected actives for each stakeholder group.
This includes our recommendations on how to respond to these regulations.

We would like your opinions on which label use patterns should be preserved – as flagged in the attached documents.
We will also be communicating with other stakeholder groups, including the AMA.

I would be very happy to discuss this with you by telephone on s. 22(1)(a)(ii) or to organise a virtual meeting on Teams this week or in the New Year .

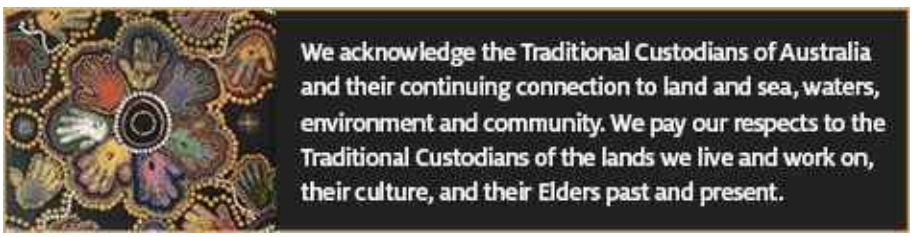
Cheers,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**

Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry
Ngunnawal and Ngambri country
70 Northbourne Ave, Canberra ACT
GPO Box 858 Canberra ACT 2601 Australia



s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 9 February 2024 3:40 PM
To: CEO@cattleaustralia.com.au; Trade@cattleaustralia.com.au; s. 47F(1)@bigpond.com
Cc: s. 47F(1)@gmail.com; s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: RE: EU antimicrobial regulations impacts on exports - fact sheet and active lists [SEC=OFFICIAL]
Attachments: 2023 12 06 FINAL Fact Sheet EU AMR rules impact on exports.docx; 1. Beef - Affected Antimicrobial Products.docx; 2. Dairy - Affected Antimicrobial Products.docx; 3. Sheep - Affected Antimicrobial Products.docx; 2024 02 07 List of Commodities EU AMR rules .docx

Dear s. 47F(1)

Thank you for your participation in our meeting on Thursday 1 February 2024 about the EU antimicrobial usage regulations regarding growth promotion and increased yield uses.

- You confirmed that segregated EU supply chains are not a suitable option for any of your commodities.
- You confirmed that you would prefer to remove growth promotion and increased yield uses – as long as the therapeutic uses (including bloat prevention) are retained.
    - The EU regulations do not require any limitations on the therapeutic claims in exporting countries – so these can be retained.
- We noted that the EU wording prohibits exports of products from animals "*treated for the purpose of promoting growth or to increase yield*". This does not make it exactly clear if the uses for "*feed conversion efficiency*", "*improvement of milk production*" or "*improvement of reproductive performance*" are prohibited. If we choose to retain these uses, there is a risk that the EU may dispute these uses and thus delay or refuse our market access. We are seeking your advice on which of these you are comfortable to retain these claims on labels.
- The final piece of EU legislation is not yet published – so the date of full implementation is not exactly known – should be on or after July 2026.
- This gives a suitable time for amendment of product labels and the phase out of current labels.

DAFF was asked to recheck the feed efficiency wording – Johann was correct – I did not find any labels with a feed conversion **efficacy** claim so have corrected the "affected antimicrobial products lists" to the wording "efficiency" – I have used brackets and "/" marks to show where there is some variation in the wording of labels.

- I have attached a copy of the product lists for beef, dairy and sheep so that you can compare these.
- I have also attached a list of the affected commodities (eg meat, milk, albumins) and their EU CN codes (equivalent to HS codes to about 4 digits) as requested by Dairy Australia.

To progress this work to maintain our EU access for your commodities and inform our recommendations, I would appreciate a written response from you regarding:

Do you support the removal of growth promotion and increased yield claims from the labels of antimicrobial products (labels of Australian products as approved by the APVMA)?
Specifically, do you support the removal of claims such as "Improved liveweight gains", "Improved weight gains", "Increasing the rate of weight gain", "Enhancement of productivity", "Stimulating growth rate" and "Growth promotion" in the column headed "Label use to remove" of the tables in the attached lists of products.
YES/NO

Reproductive claims - Do you support the retention of claims regarding reproductive performance for cattle such as "Improved reproductive performance of heifers", in in the column headed "Label use to discuss" of the tables in the attached lists of products.

YES/NO

Milk production claims - Do you support the retention of claims regarding milk production for dairy cattle such as "Increased milk production" or "Improvement of milk production", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

Feed conversion efficiency claims - Do you support the retention of claims regarding feed efficiency for cattle and sheep such as "Increasing feed conversion efficiency", "Improved feed conversion efficiency", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

If we could have a reply as soon as possible and no later than COB Monday 26 February 2024.

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)
Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry

From: s. 22(1)(a)(ii)
Sent: Thursday, January 18, 2024 3:44 PM
To: CEO@cattleaustralia.com.au; Trade@cattleaustralia.com.au; s. 47F(1)@bigpond.com
Cc: s. 47F(1)@gmail.com; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: EU antimicrobial regulations impacts on exports - fact sheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1)

I am following up about the issue of the EU regulations limiting the use of antimicrobial compounds in exporting countries.

There is a meeting on this topic tomorrow, Friday 19 January 2023 however this meeting is focussed on the EU list of antimicrobials that are "reserved for human use". Australia needs to be able demonstrate that these will not be used on food animals, or that their products will be excluded from the EU. None of these substances are currently approved for animal use in Australia, however restrictions on "off-label" prescription are not uniform across the states and territories so we will seek their advice on how "off-label" use can be ruled out.

We will not have sufficient time to discuss the "growth promotion" or "increased yield " use patterns at tomorrow's meeting. I have set up a placeholder meeting for 10:30 am 31 January to discuss those issues with Dairy Australia, Sheep Producers, Cattle Australia and the Australian Lot Feeders Association. Let me know if you are available for that meeting or would like to propose a different time or a separate meeting.

We will need a clear written response from each producer group stating whether you support either removal of particular use patterns, or a segregated EU supply chain by mid-February 2024, so that we can determine the actions needed to maintain access to the EU market.

Kind regards,

s. 22(1)(a)(ii)

Dr Robyn Schipp (she / her)
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
+61 (0) 2 6272 5058

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii)
Sent: Monday, December 11, 2023 5:41 PM
To: CEO@cattleaustralia.com.au; Trade@cattleaustralia.com.au; s. 47F(1)@bigpond.com
Cc: s. 47F(1)@gmail.com; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @aff.gov.au>
Subject: EU antimicrobial regulations impacts on exports - fact sheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1)

I work in the meat market access section of DAFF dealing with the EU and have been working with Jeevan on how best to maintain access to the EU market once the new EU antimicrobial regulations take effect for exports (best estimate June 2026 but we need to prepare soon). Thank you for your previous input about this issue, noting that Bob has been following developments in the EU for some years. This was discussed at Safemeat in March 2023 , but we appreciate that it will be a new topic for some.

Regarding the EU antimicrobial regulations, we have prepared a fact sheet on the regulations and a list of potentially affected actives for each stakeholder group.
This includes our recommendations on how to respond to these regulations.

We would like your opinions on which label use patterns should be preserved – as flagged in the attached documents.
We will also be communicating with other stakeholder groups, including the AMA.

I would be very happy to discuss this with you by telephone on s. 22(1)(a)(ii) or to organise a virtual meeting on Teams this week or in the New Year .

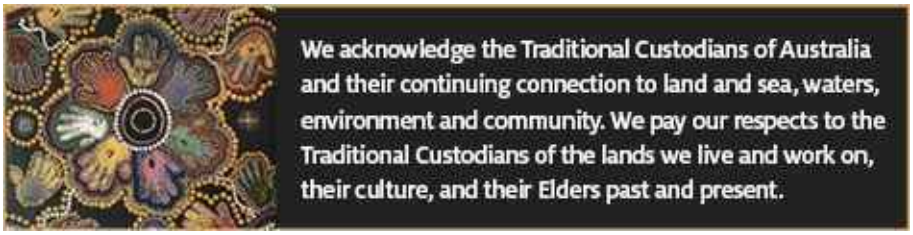
Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**

Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry
Ngunnawal and Ngambri country
70 Northbourne Ave, Canberra ACT
GPO Box 858 Canberra ACT 2601 Australia



s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 9 February 2024 3:40 PM
To: s. 47F(1)
Cc: s. 47F(1) ; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) s. 47F(1)
Subject: RE: EU antimicrobial regulations - factsheet and active lists (growth and yield) [SEC=OFFICIAL]
Attachments: 2023 12 06 FINAL Fact Sheet EU AMR rules impact on exports.docx; 1. Beef - Affected Antimicrobial Products.docx; 2. Dairy - Affected Antimicrobial Products.docx; 3. Sheep - Affected Antimicrobial Products.docx; 2024 02 07 List of Commodities EU AMR rules .docx

Dear s. 47F(1) and team,

Thank you for your participation in our meeting on Thursday 1 February 2024 about the EU antimicrobial usage regulations regarding growth promotion and increased yield uses.

- You confirmed that segregated EU supply chains are not a suitable option for any of your commodities.
- You confirmed that you would prefer to remove growth promotion and increased yield uses – as long as the therapeutic uses (including bloat prevention) are retained.
    - The EU regulations do not require any limitations on the therapeutic claims in exporting countries – so these can be retained.
- We noted that the EU wording prohibits exports of products from animals "*treated for the purpose of promoting growth or to increase yield*". This does not make it exactly clear if the uses for "*feed conversion efficiency*", "*improvement of milk production*" or "*improvement of reproductive performance*" are prohibited. If we choose to retain these uses, there is a risk that the EU may dispute these uses and thus delay or refuse our market access. We are seeking your advice on which of these you are comfortable to retain these claims on labels.
- The final piece of EU legislation is not yet published – so the date of full implementation is not exactly known – should be on or after July 2026.
- This gives a suitable time for amendment of product labels and the phase out of current labels.

DAFF was asked to recheck the feed efficiency wording – Johann was correct – I did not find any labels with a feed conversion **efficacy** claim so have corrected the "affected antimicrobial products lists" to the wording "efficiency" – I have used brackets and "/" marks to show where there is some variation in the wording of labels.

- I have attached a copy of the product lists for beef, dairy and sheep so that you can compare these.
- I have also attached a list of the affected commodities (eg meat, milk, albumins) and their EU CN codes (equivalent to HS codes to about 4 digits) as requested by Dairy Australia.

To progress this work to maintain our EU access for your commodities and inform our recommendations, I would appreciate a written response from you regarding:

Do you support the removal of growth promotion and increased yield claims from the labels of antimicrobial products (labels of Australian products as approved by the APVMA)?
Specifically, do you support the removal of claims such as "Improved liveweight gains", "Improved weight gains", "Increasing the rate of weight gain", "Enhancement of productivity", "Stimulating growth rate" and "Growth promotion" in the column headed "Label use to remove" of the tables in the attached lists of products.
YES/NO

Reproductive claims - Do you support the retention of claims regarding reproductive performance for cattle such as "Improved reproductive performance of heifers", in in the column headed "Label use to discuss" of the tables in the attached lists of products.

YES/NO

Milk production claims - Do you support the retention of claims regarding milk production for dairy cattle such as "Increased milk production" or "Improvement of milk production", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

Feed conversion efficiency claims - Do you support the retention of claims regarding feed efficiency for cattle and sheep such as "Increasing feed conversion efficiency", "Improved feed conversion efficiency", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

If we could have a reply as soon as possible and no later than COB Monday 26 February 2024.

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)
Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry

From: s. 22(1)(a)(ii)
Sent: Thursday, January 18, 2024 3:23 PM
To: s. 47F(1) @dairyaustralia.com.au>
Cc: s. 47F(1) @dairyaustralia.com.au>; s. 47F(1) s. 47F(1) @dairyaustralia.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) @j2e.com.au>
Subject: RE: EU antimicrobial regulations - factsheet and active lists (growth and yield) [SEC=OFFICIAL]

Dear s. 47F(1)

Thank you for your replies about this issue of the EU regulations limiting the use of antimicrobial compounds in exporting countries.

You will note that you are invited to a meeting tomorrow, Friday 19 January 2023 however this meeting is focussed on the EU list of antimicrobials that are "reserved for human use". Australia needs to be able demonstrate that these will not be used on food animals, or that their products will be excluded from the EU. None of these substances are currently approved for animal use in Australia, however restrictions on "off-label" prescription are not uniform across the states and territories so we will seek their advice on how "off-label" use can be ruled out.

We will not have sufficient time to discuss the "growth promotion" or "increased yield " use patterns at tomorrow's meeting. I have set up a placeholder meeting for 10:30 am 31 January to discuss those issues with Dairy Australia, Sheep Producers, Cattle Australia and the Australian Lot Feeders Association. Let me know if you are available for that meeting or would like to propose a different time or a separate meeting.

We will need a clear written response from each producer group stating whether you support either removal of particular use patterns, or a segregated EU supply chain by mid-February 2024, so that we can determine the actions needed to maintain access to the EU market.

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii)
Sent: Tuesday, December 12, 2023 3:50 PM
To: s. 47F(1) @dairyaustralia.com.au>
Cc: s. 47F(1) @dairyaustralia.com.au>; s. 47F(1) s. 47F(1) @dairyaustralia.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) @j2e.com.au>
Subject: RE: EU antimicrobial regulations - factsheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1)

I am sorry that I will be away next week, however s. 22(1)(a)(ii) and s. 22(1)(a)(ii) may be available. Tuesday looks like a better day for them.

I am available most of this week and will be back in the office from 2 January 2024.
We had a discussion today with Animal Medicines Australia.

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 47F(1) @dairyaustralia.com.au>
Sent: Monday, December 11, 2023 2:31 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 47F(1) @dairyaustralia.com.au>; s. 47F(1) s. 47F(1) @dairyaustralia.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>; s. 47F(1) @j2e.com.au>
Subject: RE: EU antimicrobial regulations - factsheet and active lists [SEC=OFFICIAL]

> You don't often get email from s. 47F(1)@dairyaustralia.com.au. Learn why this is important

Hi s. 22(1)(a)(ii)

Thanks for your email and for providing the fact sheet. It would be good to talk through in further detail and I'd be keen to hear how other stakeholder groups have responded to the proposed way forward.

Would you have time for a Teams call Monday or Tuesday afternoon next week?

Cheers
s. 47F(1)

s. 47F(1) - Sustainable Markets, Workforce and Competitiveness Manager

M: s. 47F(1) W: dairyaustralia.com.au

From: Schipp, Robyn <Robyn.Schipp@aff.gov.au>
Sent: Friday, December 8, 2023 5:20 PM
To: s. 47F(1) @dairyaustralia.com.au>
Cc: s. 47F(1) @dairyaustralia.com.au>; s. 47F(1) @dairyaustralia.com.au>; s. 47F(1) @dairyaustralia.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: EU antimicrobial regulations - factsheet and active lists [SEC=OFFICIAL]

Dear s. 47F(1) and team,

I work in the meat market access section of DAFF dealing with the EU and have been working with s. 22(1)(a)(ii) on how best to maintain access to the EU market once the new EU antimicrobial regulations take effect for exports. Amber and s. 22(1)(a)(ii) work in the Food and Organics section – including dairy, so we are working together on this issue.
Regarding the EU antimicrobial regulations, we have prepared a fact sheet on the regulations and a list of potentially affected actives.
This includes our recommendations on how to respond to these regulations.

We would like your opinions on which label use patterns should be preserved – as flagged in the attached documents.
We will also be communicating with AMA, and other stakeholder groups.

I would be very happy to discuss this with you by telephone on s. 22(1)(a)(ii) or to organise a virtual meeting on Teams in the next week or in the New Year .

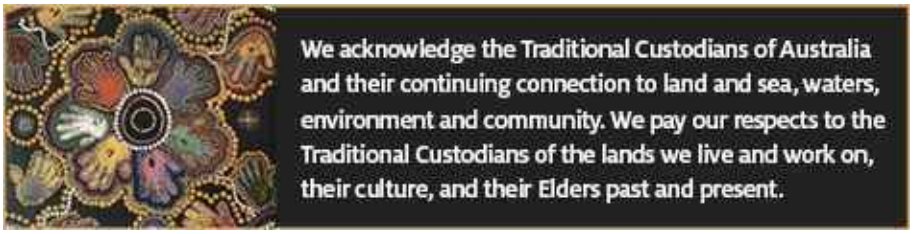
Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**

Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry
Ngunnawal and Ngambri country
70 Northbourne Ave, Canberra ACT
GPO Box 858 Canberra ACT 2601 Australia



s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Friday, 9 February 2024 3:39 PM
To: ceo@sheepproducers.com.au
Cc: s. 47F(1) s. 22(1)(a)(ii) s. 22(1)(a)(ii)
Subject: RE: EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]
Attachments: 2023 12 06 FINAL Fact Sheet EU AMR rules impact on exports.docx; 1. Beef - Affected Antimicrobial Products.docx; 2. Dairy - Affected Antimicrobial Products.docx; 3. Sheep - Affected Antimicrobial Products.docx; 2024 02 07 List of Commodities EU AMR rules .docx

Dear s. 47F(1)

Thank you for your participation in our meeting on Thursday 1 February 2024 about the EU antimicrobial usage regulations regarding growth promotion and increased yield uses.

- You confirmed that segregated EU supply chains are not a suitable option for any of your commodities.
- You confirmed that you would prefer to remove growth promotion and increased yield uses – as long as the therapeutic uses (including bloat prevention) are retained.
    - The EU regulations do not require any limitations on the therapeutic claims in exporting countries – so these can be retained.
- We noted that the EU wording prohibits exports of products from animals "*treated for the purpose of promoting growth or to increase yield*". This does not make it exactly clear if the uses for "*feed conversion efficiency*", "*improvement of milk production*" or "*improvement of reproductive performance*" are prohibited. If we choose to retain these uses, there is a risk that the EU may dispute these uses and thus delay or refuse our market access. We are seeking your advice on which of these you are comfortable to retain these claims on labels.
- The final piece of EU legislation is not yet published – so the date of full implementation is not exactly known – should be on or after July 2026.
- This gives a suitable time for amendment of product labels and the phase out of current labels.

DAFF was asked to recheck the feed efficiency wording – Johann was correct – I did not find any labels with a feed conversion **efficacy** claim so have corrected the "affected antimicrobial products lists" to the wording "efficiency" – I have used brackets and "/" marks to show where there is some variation in the wording of labels.

- I have re-attached a copy of the Fact Sheet
- I have attached a copy of the product lists for beef, dairy and sheep so that you can compare these.
- I have also attached a list of the affected commodities (eg meat, milk, albumins) and their EU CN codes (equivalent to HS codes to about 4 digits) as requested by Dairy Australia.

To progress this work to maintain our EU access for your commodities and inform our recommendations, I would appreciate a written response from you regarding:

Do you support the removal of growth promotion and increased yield claims from the labels of antimicrobial products (labels of Australian products as approved by the APVMA)?
Specifically, do you support the removal of claims such as "Improved liveweight gains", "Improved weight gains", "Increasing the rate of weight gain", "Enhancement of productivity", "Stimulating growth rate" and "Growth promotion" in the column headed "Label use to remove" of the tables in the attached lists of products.
YES/NO

Reproductive claims - Do you support the retention of claims regarding reproductive performance for cattle such as "Improved reproductive performance of heifers", in in the column headed "Label use to discuss" of the tables in the attached lists of products.

YES/NO

Milk production claims - Do you support the retention of claims regarding milk production for dairy cattle such as "Increased milk production" or "Improvement of milk production", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

Feed conversion efficiency claims - Do you support the retention of claims regarding feed efficiency for cattle and sheep such as "Increasing feed conversion efficiency", "Improved feed conversion efficiency", in the column headed "Label use to discuss" of the tables in the attached lists of products.
YES/NO

If we could have a reply as soon as possible and no later than COB Monday 26 February 2024.

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)
Export Standards Branch| Exports and Veterinary Services Division
Department of Agriculture, Fisheries and Forestry

From: s. 22(1)(a)(ii)
Sent: Thursday, January 18, 2024 3:37 PM
To: ceo@sheepproducers.com.au
Cc: s. 47F(1) <advisor@sheepproducers.com.au>; s. 47F(1) <Policy@sheepproducers.com.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Dear s. 47F(1) and s. 47F(1)

Thank you for your replies about this issue of the EU regulations limiting the use of antimicrobial compounds in exporting countries and your advice (as attached) that the "removal of a growth promotion / performance enhancement claim from labels for monensin and lasalocid used as anticoccidials for sheep would be the lesser of "two evils". A segregated market approach (EU/non-EU) would not be practically feasible."

You will note that s. 47F(1) has been invited to a meeting tomorrow, Friday 19 January 2023 on the EU regulation, however this meeting is focussed on the EU list of antimicrobials that are "reserved for human use". Australia needs to be able demonstrate that these will not be used on food animals, or that their products will be excluded from the EU. None of these substances are currently approved for animal use in Australia, however restrictions on "off-label" prescription are not uniform across the states and territories so we will seek their advice on how "off-label" use can be ruled out.

We will not have sufficient time to discuss the "growth promotion" or "increased yield " use patterns at tomorrow's meeting. If you would like to discuss this issue with other producer groups, I have set up a placeholder meeting for 10:30 am 31 January to discuss those issues with Dairy Australia, Sheep Producers, Cattle Australia and the Australian Lot Feeders Association. Let me know if you wish to attend that meeting or would like to propose a different time or a separate meeting.

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **(she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii)
Sent: Friday, December 8, 2023 5:34 PM
To: s. 47F(1)@sheepproducers.com.au; policyadvisor@sheepproducers.com.au
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Dear s. 47F(1) and s. 47F(1)

I work in the meat market access section of DAFF dealing with the EU and have been working with s. 22(1)(a)(ii) on how best to maintain access to the EU market once the new EU antimicrobial regulations take effect for exports. Thank you for your previous input about this issue.

Regarding the EU antimicrobial regulations, we have prepared a fact sheet on the regulations and a list of potentially affected actives for each stakeholder group.
This includes our recommendations on how to respond to these regulations.

We would like your opinions on which label use patterns should be preserved – as flagged in the attached documents.
We will also be communicating with other stakeholder groups, including the AMA.

I would be very happy to discuss this with you by telephone on s. 22(1)(a)(ii) or to organise a virtual meeting on Teams in the next week or in the New Year .

Kind regards,

s. 22(1)(a)(ii)

Dr s. 22(1)(a)(ii) **she / her)**
Assistant Director | Meat Market Access (Europe, Eurasia and UK)
s. 22(1)(a)(ii)

Export Standards Branch| Exports and Veterinary Services Division

---

From: s. 22(1)(a)(ii)
Sent: Tuesday, October 10, 2023 1:17 PM
To: Dr s. 47F(1) <policyadvisor@sheepproducers.com.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Hi s. 47F(1)

Please find some thoughts below

1. *Could you please update on chemical manufacturers' appetite to minimise the cost of deleting the label claims that allow existing stock to expire, and phase in a label that doesn't include the reference*

I suggest that this is a discussion primarily between APVMA and the chemical manufacturers.

2. *Could you please clarify the EU's definition of "production" in the context of the EU regulation?*
   'Production' is not a term that is specifically defined in either 2019/6 or 1831/2003. I expect that the dictionary definition applies. In the absence of any context, I am not sure of the intent of this question?
3. *Has DAFF collected information on a cost comparison of a label change vs. creation of a segregated market?*
   *No, we have been consulting with you and other impacted industries on these options for your feedback on costs and practicalities for your industries. With this in mind, I note that the two affected ionophores (Lasalocid and Monensin) that have current growth promotion / yield increase label claims **for sheep** also have label claims for control or prevention of coccidiosis in sheep (these latter claims consistent with the EU feed additive regulation 1831/2003). In this context, please can I clarify the concerns of the sheep industry.*
4. *Has DAFF clarified whether an extension on the timeline is possible?*
   We are considering requesting an extension.

Cheers, Jeevan

From: Dr s. 47F(1) <policyadvisor@sheepproducers.com.au>
Sent: Thursday, October 5, 2023 9:39 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)

I hope you're well.

Our Policy Council have asked some further questions and requested some clarification on elements of the EU 2019/6 Regulation implementation.

I had a few questions to ask:

1. Could you please update on chemical manufacturers' appetite to minimise the cost of deleting the label claims that allow existing stock to expire, and phase in a label that doesn't include the reference
2. Could you please clarify the EU's definition of "production" in the context of the EU regulation?
3. Has DAFF collected information on a cost comparison of a label change vs. creation of a segregated market?
4. Has DAFF clarified whether an extension on the timeline is possible?

Cheers,
s. 47F(1)

Dr s. 47F(1)
Senior Policy Advisor

t s. 47F(1)
e policyadvisor@sheepproducers.com.au
m PO Box 4225 Manuka ACT 2603

Ngunnawal Country
Level 2 Burns Centre
28 National Circuit Forrest ACT 2603

www.sheepproducers.com.au/

From: s. 22(1)(a)(ii) a@aff.gov.au>
Sent: Wednesday, August 30, 2023 3:13 PM
To: Dr s. 47F(1) <policyadvisor@sheepproducers.com.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Hi s. 47F(1)

Yes, we have been engaging with s. 47F(1) and s. 47F(1) from Animal Medicines Australia.

Cheers, s. 22(1)(a)(ii)

From: Dr s. 47F(1) <policyadvisor@sheepproducers.com.au>
Sent: Wednesday, August 30, 2023 2:47 PM
To: s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Hi s. 22(1)(a)(ii)

Thanks for your email. We are still discussing the potential knock-on effect of such label changes in our sector. This conversation is ongoing.

However, I was wondering if you have been connected with s. 47F(1) from Animal Medicines Australia?

The organisation's membership comprises several large pharmaceutical manufacturers who will be impacted by a label change to the currently registered veterinary medicines.

Please let me know if you've been in contact, otherwise I can connect with her.

Cheers,
s. 47F(1)

Dr s. 47F(1)
Senior Policy Advisor

t s. 47F(1)
e policyadvisor@sheepproducers.com.au
m PO Box 4225 Manuka ACT 2603

Ngunnawal Country
Level 2 Burns Centre
28 National Circuit Forrest ACT 2603
www.sheepproducers.com.au/

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, August 28, 2023 5:05 PM
To: Dr s. 47F(1) <policyadvisor@sheepproducers.com.au>
Cc: s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Subject: RE: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials [SEC=OFFICIAL]

Hi s. 47F(1)

Thanks for the introduction. I am working closely with s. 22(1)(a)(ii) on this issue. We are in the export standards branch.

While we are planning to request an extension on the deadline to provide our guarantees (Nov 2023) in our next correspondence there is no certainty of the EU's response, thus we still need to plan against the current timelines.

Noting that the two affected ionophores (Lasalocid and Monensin) that have current growth promotion / yield increase label claims **for sheep** also have label claims for control or prevention of coccidiosis in sheep (these latter claims consistent with the EU feed additive regulation 1831/2003).

In this context, please could you elaborate on the affected use/s of most concern to the sheep industry. If the uses in red below were removed how would this affect you.

Many thanks, s. 22(1)(a)(ii)

Lasalocid sodium (Bovatec and Avatec), 3 of the 5 products (60761, 54144, 52693) – feed additives
Lot fed sheep improved liveweight gains and feed conversion efficiency
"Control of clinical signs of coccidiosis and reduction of faecal shedding " in confined sheep.

Monensin (Rumensin) some in-feed products (such as 47359)
Sheep:
For the prevention of ovine coccidiosis.
For improved weight gain and feed efficiency.

Dr s. 22(1)(a)(ii) *(he/him)* s. 22(1)(a)(ii)

Assistant Director Residues and Microbiology Policy | Phone s. 22(1)(a)(ii)
Department of Agriculture, Fisheries and Forestry
Export Standards Branch | Exports and Veterinary Services Division
Agriculture House, 70 Northborne Avenue, Canberra ACT 2601 Australia
GPO Box 858 Canberra ACT 2601 Australia

From: s. 47F(1) policyadvisor@sheepproducers.com.au>
Sent: Monday, August 28, 2023 11:23 AM
To: s. 22(1)(a)(ii) @aff.gov.au>
Subject: Re. EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials

Hi s. 22(1)(a)(ii)

I wanted to introduce myself. I work as a Senior Policy Advisor for Sheep Producers Australia.
We have been in discussions with Animal Medicines Australia and other stakeholders regarding the EU regulation implementation on growth promotant claims listed on ionophores registered for use in Australia.

I was wondering what the capacity for extension on the EU's timeline is?

Happy to discuss this matter further!

Cheers,
s. 47F(1)

Dr s. 47F(1)
Senior Policy Advisor

t s. 47F(1)
e policyadvisor@sheepproducers.com.au
m PO Box 4225 Manuka ACT 2603

Ngunnawal Country
Level 2 Burns Centre
28 National Circuit Forrest ACT 2603
www.sheepproducers.com.au/

Sheep Producers Australia acknowledge the Traditional Owners of the land in all states and territories on which we work. We pay our respects to Aboriginal and Torres Strait Islander Elders past, present and emerging, and honour their history, cultures, and traditions of storytelling.

------ IMPORTANT - This email and any attachments have been issued by the Commonwealth of Australia (Commonwealth). The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Commonwealth. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Commonwealth is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------

Fact Sheet: European Union antimicrobial use restrictions and exports

- The EU will prohibit the import of edible animal products unless Australia has controls to prevent the use of antimicrobials for growth promotion or yield increase. This will take effect from June 2026 onwards.
- This will affect Australian exports of beef, dairy and sheep-meat to the EU unless we take action to comply.
- There is no prohibition of any medical uses of antimicrobials to cure or prevent diseases of livestock in countries outside the EU.

What has happened?

The EU has further restricted the use of antimicrobials in animals by EU farmers [Regulation (EU) 2019/6 (Articles 37 and 107)]. For the first time, some of these restrictions will apply to Australian exports after June 2026.

In the EU, animals must not be treated with any antimicrobial reserved for human use. EU farmers may not use antimicrobials to promote growth or increase yield.

Additionally, EU farmers may not use antimicrobials for prevention of disease except under exceptional circumstances and for limited numbers of animals, unless it is in-feed use for parasite control. This restriction does not apply to countries exporting to the EU like Australia.

What impact does this have on exporting countries like Australia?

Regulation 2019/6 applies restrictions on animals and edible animal products imported into the EU (Article 118) for the first time. These will apply to consignments arriving in the EU after 30 June 2026. Exporting countries such as Australia, need ONLY comply with the following restrictions for animals and products exported to the EU for human consumption:

- Producers must not use any antimicrobials that are reserved for human use by the EU
    - (currently none are registered in Australia for food animals)
- Antimicrobial medicinal products (including ionophores) shall not be used in animals for the purpose of promoting growth nor to increase yield

The restrictions on antimicrobial use for prevention of disease have not been applied to producers outside of the EU. Therefore, there are no restrictions on uses of antimicrobials for any medical purposes (therapeutic uses) that apply to Australian production.

What commodities and products will this affect?

The EU is applying these rules to most edible products from farmed animals (not wild game animals) except composite products (which have a high percentage of plant ingredients). It also applies to products made in a third country using Australian ingredients. This may affect exports of eggs to third countries that wish to send processed foods containing eggs to the EU.

Australia has market access to the EU for edible products from cattle (beef and dairy), sheep, goats, horses, camels and deer. Eggs and egg products could potentially be exported to the EU, if establishment listings and avian influenza surveillance were in place. Australia does not have access to send meat products from poultry or farmed pigs to the EU, so these are unaffected.

There are currently antimicrobial products with a permitted use for growth promotion or increased yield registered in Australia for Sheep, Cattle and Laying Poultry in Australia. The APVMA database PUBCRIS does not identify any growth promotion or increased yield uses of antimicrobials for goats, horses, camel or deer.

Please refer to attached product descriptions for further details of the products.

Are the ionophore antimicrobials exempt from these restrictions?

No. Some sources have claimed that the ionophore antibiotics are exempt from the EU requirements, because they are classified as feed additives. Examples of ionophores include lasalocid, monensin, narasin and salinomycin.

The confusion has arisen because Article 2 in (EU)2019/6 gives an exemption for products that are permitted as a feed additive under Regulation (EC) 1831/2003, Article 5 (3)(g).

However, they are only permitted under (EC) 1831/2003 when used as feed additives and **intended** to kill or inhibit protozoa (also known as coccidiostats or histomonostats).

DAFF have confirmed with the EU that the use of these products for growth promotion or yield increase is prohibited under EU regulation 2019/6.

What must Australia do to maintain access to export to the EU?

Australia needs to be listed by the EU as having sufficient controls to ensure that edible animal products exported to the EU do not come from animals treated with antimicrobials for growth promotion or increased yield. Then, once the regulations are in force, Australia must also declare compliance with these rules in all export certificates for edible products exported to the EU from farmed animals.

The EU require either that:

- Either, 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 to ensure that products from treated animals are not exported to the EU

DAFF recommendations on how Australia can comply by the implementation date

DAFF has received strong feedback from animal industries that a segregated system would be complex and costly to implement.

The alternative is to remove label instructions for growth promotion and yield increase from a small number of antimicrobial products so that these uses are not authorised and the EU requirements are met.

Therefore, we propose that DAFF request the APVMA to amend the labels of affected antimicrobial products to remove label directions for growth promotion or increased yield for beef cattle, dairy cattle and sheep by 30 June 2024 with the labels to be phased out from the market over 2 years (so that uses are not authorised as of June 2026 - the earliest implementation date).

If the egg industry requires access for eggs to the EU (other than as a small component of composite goods), then growth promotion uses of flavophospholipol would also need to be removed from labels.

Antimicrobial product labels can keep all therapeutic uses such as to control coccidiosis or bloat because the EU restrictions on prevention of disease within the EU **do not** apply to Australia.

Once label changes are completed, then DAFF can advise the EU that there are no authorised uses of these products for growth promotion or yield increase, and therefore a segregated system is not required.

Advice sought from the livestock production industries

1. Confirmation of earlier advice that a segregated production system is not practical for exports to the EU of edible products from beef cattle, dairy cattle and sheep.
2. Confirmation on whether label instructions allowing "reproductive efficiency", "increased milk production", "feed efficiency" or "improved feed conversion" should be kept as uses that have value for each specific species. Retaining such claims where they have value to industry would be on the basis that these uses should not be classified as growth promotion or yield increase and are scientifically justified.

   There is a risk that the EU may disagree and find that "feed efficiency" and "improved feed conversion" are NOT permitted uses at a later date. The EU may impose trade restrictions or refuse to list Australia as being suitable to export edible animal products.

Beef – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For beef cattle there are growth promotion label use claims with five actives.

Flavophospholipol (also known as bambermycin) Is NOT an ionophore

Known as Flaveco, Flavo, Nutriflav, Gainpro 5 of 6 products affected, 3 registrants – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Flavophospholipol	Improvement of productivity	Increasing feed conversion efficiency	None
Calves, Cattle	Stimulating growth rate	Improved feed conversion efficiency	
	Growth promotion		

Products registered in the EU - none found for this active in this species

IONOPHORE PRODUCTS

Lasalocid sodium, 3 of 5 products, 1 registrant (Zoetis)

Also known as Bovatec, Avatec . Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in growing cattle	Improved feed conversion efficiency in growing cattle and lot fed beef cattle	Control of clinical signs of coccidiosis and the reduction of faecal shedding (Eimeria) in growing cattle
			Aid in reduction of bloat scores on pasture

Products registered in the EU - none found for cattle – one for use as coccidiostat in game birds, poultry

Monensin 30 of 31 products, 7 registrants,

Also known as Rumensin, Moneco, Doxaban, Monendox, Kexxtone. In-feed or ruminal capsules (3)

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gain	Improved feed / feed conversion efficiency feedlot cattle, heifers	Aid in the control of bloat feedlot cattle
	Increased weight gain beef cattle	Improved reproductive performance of heifers	Aid in the prevention of coccidiosis

Products registered in the EU – Capsule for ketosis dairy cattle, in-feed for poultry as a coccidiostat

Narasin

Known as Monteban, Naravin, AF0252. 3 of 4 products have cattle uses, 1 registrant (Elanco) – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Narasin		Improved feed efficiency (Cattle / lot fed cattle) * *Not for cows producing milk*	None for cattle

Products registered in the EU - none for cattle – two for use as coccidiostat in chickens

Salinomycin

Also known as Salinomix, Sadox, Salindox, Coxistac. 14 of 15 products have a growth promotion claim for feedlot cattle and pigs in addition to coccidiosis in chickens.

Active	Label use to remove	Label use to discuss	Medical label uses
Salinomycin	Enhancement of productivity	Improving feed efficiency	None for cattle
	Increasing the rate of weight gain		
Feedlot beef cattle	Stimulating growth rate		

Products registered in the EU - none for cattle – one for use as coccidiostat in chickens

Dairy – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For dairy cattle there are growth promotion or yield increase label claims for four actives.

Flavophospholipol (also known as bambermycin) Is NOT an ionophore

Known as Flaveco, Flavo, Nutriflav, Gainpro 5 of 6 products affected, 3 registrants – feed additives

Active	Label use to remove	Label use to discuss	Medical label uses
Flavophospholipol	Improvement of productivity	Increasing feed conversion efficiency	None
Calves, Cattle	Stimulating growth rate	Improved feed conversion efficiency	
	Growth promotion		

Products registered in the EU - none found

IONOPHORE PRODUCTS

Lasalocid sodium, 3 of the 5 products, 1 registrant (Zoetis)

Also known as Bovatec and Avatec . Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in growing cattle	Improved feed conversion efficiency in growing cattle	Control of clinical signs of coccidiosis and the reduction of faecal shedding (Eimeria) in growing cattle
		Improvement of milk production	Control of ketosis which can aid control mastitis
			Aid in reduction of bloat scores on pasture

Products registered in the EU - none found for cattle – one for use as coccidiostat in game birds, poultry

Monensin 30 of 31 products, 7 registrants

Also known as Rumensin, Moneco, Doxaban, Monendox, Kexxtone. In-feed or ruminal capsules (3)

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gain heifers	Improved feed conversion efficiency heifers	Aid in the control/reduction of bloat
		Improved reproductive performance heifers	Aid to reduce severity of (treat / prevent) sub-clinical ketosis
		Increased milk production	Aid in the prevention of coccidiosis

Products registered in the EU - Capsule for ketosis dairy cattle, in-feed for poultry as a coccidiostat

Narasin

Known as Monteban, Naravin, AF0252. 3 of 4 products have cattle uses, 1 registrant (Elanco) – feed additives. Possibly used in Dairy heifers

Active	Label use to remove	Label use to discuss	Medical label uses
Narasin		Improved feed efficiency (cattle / lot fed cattle) *	None for cattle
		* *Not for cows producing milk*	

Products registered in the EU - none for cattle – two for use as coccidiostat in chickens

List of Commodities subject to European Union antimicrobial use restrictions and exports

The European Commission Delegated Regulation (EU) 2023/905[1] prohibits the use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union. This applies the rules in 2019/6

(EU) 2023/905 applies to certain live food-producing animals and also to products of animal origin intended for human consumption. Article 1 states which commodities are included and excluded.

Commodities included:

- meat, and edible offal
- fish
- dairy, eggs, honey
- guts and bladders
- meat preparations (such as sausages, meat extracts and juices)
- edible fats and
- caseins, albumins and peptones.

Article 1 of (EU) 2023/905 states that these are as listed in Part Two, Chapters 2 to 5, 15 and 16, of the Annex I to Regulation (EEC) No 2658/87[2], and also those for which Harmonised System subheadings have been laid down under headings 3501, 3502 and 3504. See Table 1 for a summary.

Commodities excluded from these requirements are:

- Gelatine and raw materials for the production of gelatine
- Collagen and raw materials for the production of collagen
- Certain highly refined products*
- Wild animals and their products
- Insects, frogs, snails and reptiles, and their products
- Composite products
- Inedibles - animals or products of animal origin not intended for human consumption, unless that has not been decided before entry into the EU
- Transit - animals or products of animal origin for transit through the EU
- Samples - products of animal origin intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market.

*The highly refined substances are as listed in Annexe III of regulation (EC) 853/2004. These are chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass, amino acids that are authorised as food additives, food flavouring and fat derivatives.

Composite products are defined in point (21) of Article 2 of Delegated Regulation (EU) 2022/2292 as “food containing both products of plant origin and processed products of animal origin”.

[1] http://data.europa.eu/eli/reg_del/2023/905/oj
[2] June 2023 version of (EEC) 2658/87 http://data.europa.eu/eli/reg/1987/2658/2023-06-17

Table 1 – Summary of description of included commodities from Regulation (EEC) No 2658/87[3]

Code	Description
CHAPTER 2 MEAT AND EDIBLE MEAT OFFAL	
0201	Meat of bovine animals, fresh or chilled
0202	Meat of bovine animals, frozen
0203	Meat of swine, fresh, chilled or frozen (Note: Wild pig products are exempt)
0204	Meat of sheep or goats, fresh, chilled or frozen
0205	Meat of horses, asses, mules or hinnies, fresh, chilled or frozen
0206	Edible offal of bovine animals, swine, sheep, goats, horses, asses, mules or hinnies, fresh, chilled or frozen:
0207	Meat and edible offal, of poultry (Australia already has nil access poultry)
0208	Other meat and edible meat offal, fresh, chilled or frozen – ones relevant to AU are 0208 60 00 – Of camels and other camelids (Camelidae) – unless wild 0208 90 30 – Of game, other than of rabbits or hares – unless wild 0208 90 60 – Of reindeer – unless wild 0208 90 98 – Other – covers kangaroo which is exempt as wild
0209	Pig fat, poultry fat exempt if wild boar – farmed pig and poultry not sent
0210	Meat and edible meat offal, salted, in brine, dried or smoked; edible flours and meals of meat or meat offal
CHAPTER 03 FISH AND CRUSTACEANS, MOLLUSCS AND OTHER AQUATIC INVERTEBRATES	
CHAPTER 04 DAIRY PRODUCE; BIRDS' EGGS; NATURAL HONEY; EDIBLE PRODUCTS OF ANIMAL ORIGIN, NOT ELSEWHERE SPECIFIED OR INCLUDED *includes dairy permeates, milk products characterised by a high content of lactose	
0401	Milk and cream, not concentrated nor containing added sugar or other sweetener
0402	Milk and cream, concentrated or containing added sugar or other sweetening matter
0403	Yogurt; buttermilk, curdled milk and cream, kephir and other fermented or acidified milk and cream, whether or not concentrated or containing added sugar or other sweetening matter or flavoured or containing added fruit, nuts or cocoa:
0404	Whey, whether or not concentrated or containing added sugar or other sweetening matter; products consisting of natural milk constituents, whether or not containing added sugar or other sweetener, not elsewhere specified
0405	Butter and other fats and oils derived from milk; dairy spreads:
0406	Cheese and curd
0407	Birds' eggs, in shell, fresh, preserved or cooked (N/A no establishments listed)
0408	Birds' eggs, not in shell, and egg yolks, fresh, dried, cooked, moulded, frozen or otherwise preserved (N/A no establishments listed)
0409	Natural honey
0410	Insects and other edible products of animal origin, not elsewhere specified or included – Note that insects are exempt
CHAPTER 5 PRODUCTS OF ANIMAL ORIGIN, NOT ELSEWHERE SPECIFIED OR INCLUDED	
0504	Guts, bladders and stomachs of animals (other than fish), whole and pieces thereof, fresh, chilled, frozen, salted, in brine, dried or smoked
Chapter 15 ANIMAL, VEGETABLE OR MICROBIAL FATS	
Chapter 16 PREPARATIONS OF MEAT, OF FISH, OF CRUSTACEANS, MOLLUSCS OR OTHER AQUATIC INVERTEBRATES, OR OF INSECTS	

[3] June 2023 version of (EEC) 2658/87 http://data.europa.eu/eli/reg/1987/2658/2023-06-17

Food preparations fall in this chapter provided that they contain more than 20 % by weight of sausage, meat, meat offal, blood, insects, fish or crustaceans, molluscs or other aquatic invertebrates, or any combination thereof.	
1601	Sausages and similar products, of meat, meat offal, blood or insects; food preparations based on these product
1602	Other prepared or preserved meat, meat offal, blood or insects
1603	Extracts and juices of meat, fish or crustaceans, molluscs
1604	Prepared and preserved fish
1605	Prepared and preserved crustaceans, molluscs and other aquatic invertebrates
CHAPTER 35 - ALBUMINOIDAL SUBSTANCES; MODIFIED STARCHES; GLUES; ENZYMES	
3501	Casein, caseinates and other casein derivatives; casein glues:
3502	Albumins (including concentrates of two or more whey proteins, containing by weight more than 80 % whey proteins, calculated on the dry matter), albuminates and other albumin derivatives:
	3502 11 and 3502 19 - Egg albumins
	3502 20 - Milk albumin, including concentrates of two or more whey proteins
	3502 90 - Other Albumins, (other than egg albumin and milk albumin)
3504	Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included; hide powder, whether or not chromed:
Note that 3503 Gelatine is not included in the list of affected codes and nor is 3507 Rennet	

Sheep – Potential impacts of EU Antimicrobial regulations

Label claims on Australian registered products

For sheep that affected actives are lasalocid and monensin.

Lasalocid sodium

Also known as Bovatec and Avatec . 3 of the 5 products, 1 registrant (Zoetis). Feed additives, not to be used as a single dose treatment

Active	Label use to remove	Label use to discuss	Medical label uses
Lasalocid	Improved liveweight gains in sheep	Improved feed conversion efficiency in sheep	To aid in the reduction of faecal shedding of coccidia Eimeria spp. in sheep maintained in confinement

Products registered in the EU - none found with approved uses on sheep.

Monensin

Also known as Rumensin, Moneco, Doxaban, Monendox. 27 of 28 products, 7 registrants, in-feed for sheep

Active	Label use to remove	Label use to discuss	Medical label uses
Monensin	Improved weight gains	Improved feed (conversion) efficiency	Some products include - Prevention of coccidiosis in sheep

Products registered in the EU - none found with approved uses on sheep.