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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Tuesday, December 1, 2020 10:29 PM
To: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>
Cc: s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>; europe.tmad@awe.gov.au
Subject: For Review: EU answers to AMR questions from third countries [SEC=OFFICIAL]

OFFICIAL

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

The EU has provided the following document to third countries ahead of the call to update on the AMR package next Wed 9 December.

Welcome your review of this document and if you have any comments or questions you would like us to raise at the meeting.

I will send you the invite so if you wish to dial in you can. If you are doing so please let me know and we can set up a whattsapp group between you, s. 22(1)(a)(ii) and I for while the call is on.

Kind regards

s. 22(1

Replies to third country questions – reply to mail of 25 September 2020

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

Reply:

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

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

Reply:

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

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

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

Reply:

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

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

Reply:

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

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

Reply:

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

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

Reply:

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

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

Reply:

Article 118 reflects the global recognition that the widespread use of antimicrobials for growth promotion is neither a prudent, nor a responsible use of antimicrobials. An extensive body of scientific literature has been developed over the last decades, showing that the use of antimicrobials for growth promotion can trigger antimicrobial resistance and that therefore

such use cannot be considered as responsible. This has led international organisations and many countries around the world to start ruling out or restricting such use. The use of antibiotics for growth promotion as feed additives is banned in the EU since 2006. Regulation (EU) 2019/6 expands this ban to antimicrobial medicinal products.

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

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

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

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

Reply:

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

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

Third Countries will also have the opportunity to provide input during the "feedback mechanism", as foreseen under the Commission's Better Regulation agenda, for a period of 4 weeks. Legal acts subject to the feedback mechanisms are published at regular intervals on the

'Have your say' webpage of the Commission's website[1] and open to citizens and stakeholders for feedback.

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

Reply:

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

11. Article 107(2) of EU regulation 2019/6 prescribes that "antimicrobials medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield". We understand that a certain antimicrobial class of polyether, also known as "ionophore", is used in the EU as a feed additive for "preventing coccidiosis" and that this is done with neither veterinary examination nor veterinary prescription, while the same ionophore is used elsewhere for the purpose of promoting growth. We ask the EU to clarify whether it includes ionophore among antimicrobial feed additives to be banned only in cases where its nominal purpose is growth promotion rather than preventing coccidiosis. If so, please provide a scientific rationale for banning a substance for reasons other than the chemical properties of such substance.

Reply:

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

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

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Wednesday, 9 December 2020 6:03 AM
To: s. 22(1)(a)(ii)
Subject: Fwd: Follow up to January 30th discussion on Regulation 2019/6 [SEC=OFFICIAL]

OFFICIAL

FYI

OFFICIAL

From: s. 22(1)(a)(ii) @dfat.gov.au>
Date: Tuesday, 8 December 2020 at 17:48:05
To: s. 47F(1) @state.gov>, "s. 47F(1) s. 47F(1) @ec.europa.eu>
Cc: s. 47F(1) @agrithai.be>, s. 47F(1) @minagri.gob.cl>, s. 47F(1) @mfat.govt.nz>, s. 47F(1) @mre.gov.py>, s. 47F(1) @magyp.gob.ar>, s. 47F(1) @agricultura.gov.br>, s. 47F(1) @international.gc.ca>, s. 47F(1) @agricultura.gov.br>, "hrv@mrecic.gov.ar" <hrv@mrecic.gov.ar>, s. 47F(1) @embassyofindonesia.eu>, s. 47F(1) @korea.kr>, s. 47F(1) @fda.hhs.gov>, s. 47F(1) s. 47F(1) @dfat.gov.au>, s. 47F(1) @skynet.be>, s. 47F(1) @itamaraty.gov.br>, s. 47F(1) s. 47F(1)@agricola-ue.org>, s. 47F(1) @fda.hhs.gov>, "pfn@mrecic.gov.ar" <pfn@mrecic.gov.ar>, s. 47F(1) @mrree.gub.uy>, s. 47F(1) @mrree.gub.uy" s. 47F(1) @mrree.gub.uy>, s. 47F(1) @comex.go.cr>, s. 47F(1) @fas.usda.gov>, s. 47F(1) s. 47F(1) @aphis.usda.gov>, s. 47F(1) @agricola-ue.org>, s. 47F(1) @indembassy.be>, s. 47F(1) @mofa.go.jp>, s. 47F(1) @international.gc.ca>, s. 47F(1)@mincit.gov.co" s. 47F(1)@mincit.gov.co>, s. 47F(1) @embachile.be>, s. 47F(1)@gob.ar" s. 47F(1)@gob.ar>, s. 47F(1) @embassyofindonesia.eu>, s. 47F(1)@sre.gib.mx" s. 47F(1)@sre.gib.mx>, "s. 47F(1) @mrecic.gov.ar>, s. 47F(1) @minagri.gob.cl" s. 47F(1) @minagri.gob.cl>, s. 47F(1) @agricultura.gov.br" s. 47F(1) @agricultura.gov.br>, s. 47F(1) @fda.hhs.gov>, s. 47F(1) @mincit.gov.co>, "adviser2.brussels@mea.gov.in" <adviser2.brussels@mea.gov.in>, s. 47F(1) @economia.gob.mx>, s. 47F(1) @state.gov>, s. 47F(1) @ec.europa.eu>, s. 47F(1) @ec.europa.eu>, s. 47F(1) s. 47F(1)@ec.europa.eu>, s. 47F(1) @ec.europa.eu>, s. 47F(1) s. 47F(1) @ec.europa.eu>, s. 47F(1) - s. 47F(1) @ec.europa.eu>, s. 47F(1) @ec.europa.eu>, s. 47F(1) @ec.europa.eu>, "SANTE-CONSULT-E@ec.europa.eu" <SANTE-CONSULT-E@ec.europa.eu>
Subject: RE: Follow up to January 30th discussion on Regulation 2019/6 [SEC=OFFICIAL]

OFFICIAL

Dear s. 47F(1)

Thank you for your email of 24 November 2020 to my US colleague s. 47F(1) and providing the written responses to questions from third countries.

We are looking forward to the briefing tomorrow on the Veterinary Medicines legislation. There are a number of themes we would welcome discussing with you in detail on the call.

These relate to:

1. What control measures and detailed rules you envisage putting in place to implement Article 118?
2. What is the scope of agrifood products that will be captured by this new rule?
3. When will the list and the draft delegated act for compliance be available for review/discussion with third countries?
4. What transition opportunity exists?

We also expect a number of third countries will have more questions, including some detailed technical questions, to be presented during and after Wednesday's briefing.

Thanks again for your consideration.

We look forward to speaking with you tomorrow.

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

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From: s. 47F(1) @state.gov>
Sent: Tuesday, 24 November 2020 3:47 PM
To: s. 47F(1) @ec.europa.eu
Cc: s. 47F(1)@agrithai.be; s. 47F(1) @minagri.gob.cl; s. 47F(1) @mfat.govt.nz; s. 47F(1)@mre.gov.py; s. 47F(1)@magyp.gob.ar; s. 47F(1) @agricultura.gov.br; s. 47F(1) @international.gc.ca; s. 47F(1) @agricultura.gov.br; hrv@mrecic.gov.ar; s. 22(1)(a)(ii) @dfat.gov.au>;

s. 47F(1) @embassyofindonesia.eu; s. 47F(1)@korea.kr; s. 47F(1) @fda.hhs.gov; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1)@skynet.be; s. 47F(1) @itamaraty.gov.br; s. 47F(1)@agricola-ue.org; s. 47F(1) @fda.hhs.gov; pfn@mrecic.gov.ar; s. 47F(1) @mrree.gub.uy; s. 47F(1)@mrree.gub.uy; s. 47F(1) @comex.go.cr; s. 47F(1)@fas.usda.gov; s. 47F(1) (Dept of USDA-APHIS) s. 47F(1) @aphis.usda.gov>; s. 47F(1)@agricola-ue.org; adviser2@indembassy.be; s. 47F(1) @mofa.go.jp; s. 47F(1) @international.gc.ca; s. 47F(1)@mincit.gov.co; s. 47F(1)@embachile.be; s. 47F(1)@gob.ar; s. 47F(1)@embassyofindonesia.eu; s. 47F(1)@sre.gib.mx; hrv@mrecic.gov.ar; s. 47F(1) @minagri.gob.cl; s. 47F(1) @agricultura.gov.br; s. 47F(1) @fda.hhs.gov>; s. 47F(1)@mincit.gov.co; adviser2.brussels@mea.gov.in; s. 47F(1) @economia.gob.mx; s. 47F(1) (USEU) s. 47F(1)@state.gov>; s. 47F(1) @ec.europa.eu; s. 47F(1)@ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu; SANTE-CONSULT-E@ec.europa.eu

Subject: Re: Follow up to January 30th discussion on Regulation 2019/6

Dear s. 47F(1)

On behalf of the interested livestock exporting countries, I'd like to thank you for responding to our questions. We all will study the Commission's responses in preparation for our meeting next month.

Again, thank you.

Warm regards,

s. 47F(1)

From: s. 47F(1) @ec.europa.eu> on behalf of s. 47F(1) @ec.europa.eu s. 47F(1) @ec.europa.eu>
Sent: Tuesday, November 24, 2020 3:41 PM
To: s. 47F(1) @state.gov>
Cc: s. 47F(1) @agrithai.be>; s. 47F(1) @minagri.gob.cl s. 47F(1) @minagri.gob.cl>; s. 47F(1) @mfat.govt.nz>; s. 47F(1) @mre.gov.py>; s. 47F(1) @magyp.gob.ar>; s. 47F(1) @agricultura.gov.br>; s. 47F(1) @international.gc.ca s. 47F(1) @international.gc.ca>; gs. 47F(1) @agricultura.gov.br>; hrv@mrecic.gov.ar <hrv@mrecic.gov.ar>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @embassyofindonesia.eu>; s. 47F(1)@korea.kr s. 47F(1)@korea.kr>; s. 47F(1) @fda.hhs.gov>; s. 47F(1) @dfat.gov.au s. 47F(1) @dfat.gov.au>; primebxl@skynet.be <primebxl@skynet.be>; s. 47F(1) @itamaraty.gov.br s. 47F(1) @itamaraty.gov.br>; s. 47F(1) @agricola-ue.org>; s. 47F(1) @fda.hhs.gov>; pfn@mrecic.gov.ar <pfn@mrecic.gov.ar>; s. 47F(1) @mrree.gub.uy>; s. 47F(1)@mrree.gub.uy s. 47F(1) @mrree.gub.uy>; s. 47F(1) @comex.go.cr>; s. 47F(1) @fas.usda.gov>; s. 47F(1) (Dept of USDA-APHIS) s. 47F(1) @aphis.usda.gov>; s. 47F(1) @agricola-ue.org>; adviser2@indembassy.be <adviser2@indembassy.be>; s. 47F(1) @mofa.go.jp>; s. 47F(1) @international.gc.ca>; s. 47F(1)@mincit.gov.co s. 47F(1)@mincit.gov.co>; s. 47F(1) @embachile.be>; s. 47F(1)@gob.ar s. 47F(1)@gob.ar>; s. 47F(1) @embassyofindonesia.eu>; s. 47F(1)@sre.gib.mx s. 47F(1)@sre.gib.mx>; hrv@mrecic.gov.ar <hrv@mrecic.gov.ar>; s. 47F(1) @minagri.gob.cl s. 47F(1) @minagri.gob.cl>; s. 47F(1) @agricultura.gov.br s. 47F(1) @agricultura.gov.br>; s. 47F(1) @fda.hhs.gov>; s. 47F(1) @mincit.gov.co>; adviser2.brussels@mea.gov.in

<adviser2.brussels@mea.gov.in>; s. 47F(1) @economia.gob.mx>; s. 47F(1)
s. 47F(1) @state.gov>; s. 47F(1) @ec.europa.eu>;
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s. 47F(1)@ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu
s. 47F(1) @ec.europa.eu>; SANTE-CONSULT-E@ec.europa.eu <SANTE-CONSULT-E@ec.europa.eu>
Subject: RE: Follow up to January 30th discussion on Regulation 2019/6

Dear Mr. s. 47F(1)

In response to your email below, I am pleased to send you in attachment the replies to the questions you raised. We are organising the next meeting with third countries on 9 December 2020, 09h30-11h30. An official invitation has been sent out yesterday. The purpose of this meeting will be to update third countries on the state of play in the implementation of Article 118 of Regulation 2019/6 and other related acts.

Kind regards,
s. 47F(1)

European Commission
DG Health and Food Safety
Directorate E – Food and feed safety, innovation

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From: s. 47F(1) @state.gov>
Sent: Friday, September 25, 2020 10:51 AM
To: s. 47F(1) @ec.europa.eu>
Cc: s. 47F(1)

Subject: RE: Follow up to January 30th discussion on Regulation 2019/6

Dear Ms. s. 47F(1)

While it may look different this year, it seems "rentree" is back in full swing in Brussels. We wanted to again follow up with you regarding the veterinary medicine legislation. The Commission mentioned on several occasions that it planned to host a meeting with third countries to discuss the status of the various pieces of the legislation, including the potential list of antimicrobials reserved for human use, as well as the application of Article 118. Back in April 2020, the third countries submitted a list of questions to which we have not received answers. Could you please provide an update on when we could expect answers to the questions, as well as when the update meeting will be held?

Thank you,

s. 47F(1)

s. 47F(1)
Agriculture Minister Counselor
US Mission to the EU
Tel: s. 47F(1)

From: s. 47F(1) @ec.europa.eu>
Sent: Wednesday, July 1, 2020 1:41 PM
To: s. 47F(1) @state.gov>
Cc: s. 47F(1)

Subject: RE: Follow up to January 30th discussion on Regulation 2019/6

Dear s. 47F(1) dear colleagues,

I would like to thank you for your continued interest in the implementation of the new Regulation (EU) 2019/6 on veterinary medicines. I understand you would like to know more about the most recent developments in the preparatory work for the EU tertiary legislation under Article 118 on animals or products of animal origin imported into the Union.

The Commission is moving forward in its reflections on the best approach for the application of Article 118. In this light, the questions sent to us by your colleague s. 47F(1) on 15 April were particularly relevant, as they highlight some of the specific elements of concern of third countries. I would like to assure you that it is extremely useful for the Commission to be aware of such issues, as it draws our attention to those elements as we shape the detailed rules to be laid down in the delegated act under Article 118.

I greatly appreciated our constructive exchanges during the meetings we organised previously on this topic with other third countries, in March last year and more recently in January this year. I am pleased to inform you that we intend to organise a meeting to update third country representatives during the fall. Invitations will be sent in due course.

Wishing you a pleasant summer in these difficult times and looking forward to continuing our fruitful collaboration,

Kind regards,
s. 47F(1)

From: s. 47F(1) @state.gov>
Sent: Tuesday, June 16, 2020 5:52 PM
To: s. 47F(1) @ec.europa.eu>
Cc: s. 47F(1)

Subject: Re: Follow up to January 30th discussion on Regulation 2019/6

Dear Ms. s. 47F(1)

Thank you for the response. We certainly appreciate the challenges currently faced with the ongoing COVID-19 crisis.

As the Commission continues to conceive the more detailed measures including scope and control mechanisms, we want to reiterate our desire to engage in the process, especially with the short time frame for implementation of the legislation. We look forward to your response to the questions we already have asked of you and your office. Further, we reiterate our desire for a virtual discussion of such responses.

Thank you again,

s. 47F(1)
Minister Counselor for Agricultural Affairs
US Mission to the European Union
Brussels, Belgium

From: s. 47F(1)
@ec.europa.eu>
Sent: Monday, April 27, 2020 12:27 PM
To: s. 47F(1) @state.gov>
Cc: s. 47F(1)

>
Subject: RE: Follow up to January 30th discussion on Regulation 2019/6

Dear Ms s. 47F(1)

Thank you for your email and let me extend our warmest wishes in hoping you are also doing well during these trying times.

In response to your pertinent questions, please let me inform you that we are still conceiving the detailed measure, including regarding the precise scope and control mechanisms.
The work on the IA/DA setting out various details is ongoing and we got a bit delayed due to the COVID-19 situation but will get back to you once our thinking is more advanced.

In regards to your specific question on the Article 107(2) of EU regulation 2019/6 and the antimicrobial class of polyether (a.k.a. "ionophore"), please note that Coccidiostats and histomonostats used as feed additives do not fall under the scope of the Regulation on veterinary medicinal products but fall under the Regulation

(EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)). In this setting, ionophores would not be included in the list of antimicrobials to be reserved to human use, nor would their use be forbidden as regards animals or products of animal origin to be imported in the EU from Third Countries.

We do appreciate your support in our collaborative effort with third countries and look forward to getting back to you once times will be settled down.

Stay safe,

s. 47F(1)

s. 47F(1)
Director

European Commission
DG Health and Food Safety
Directorate E – Food and feed safety, innovation

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From: s. 47F(1) @state.gov>
Sent: Wednesday, April 15, 2020 9:36 AM
To: s. 47F(1) r@ec.europa.eu>
Cc: s. 47F(1)

s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1)
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s. 47F(1)

s. 47F(1)

Subject: Follow up to January 30th discussion on Regulation 2019/6

Dear Ms. s. 47F(1),

Hello. We hope you are doing well during these trying times. We wanted to reach out to you regarding the Veterinary Medicinal Products regulations. We appreciated the third country meeting held in January 2020 related to the EMA's scientific advice on the criteria. It was useful to discuss with the Commission and EMA this advice and the next steps.

In the January meeting, you mentioned that there would be a future third country meeting on Article 118. We know that there is no timeframe on when that meeting would be a possibility given the crisis everyone is facing. With that in mind, we wanted to ask if the Commission would be willing to do a conference call with third countries to provide an update of the Commission's work on this portfolio and address some questions related to Article 118. We know that you are faced with tight timeframes on this regulation, and while there are challenges during these times, we imagine that the work will still move forward.

If you are willing to do a conference call, we have attached a list of some questions we hope to have addressed so that you have them in advance. If a call is not possible, we would request written responses if possible.

We appreciate your collaboration with third countries on this topic and look forward to your response.

Thank you and stay safe,

s. 47F(1)

s. 47F(1)
Agricultural Attaché
Foreign Agricultural Service, USDA
U.S. Mission to the European Union
Brussels, Belgium
Tel: s. 47F(1)
Cell: s. 47F(1)
Email: s. 47F(1) @usda.gov

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, December 11, 2020 10:56 PM
To: sante-consult-d3@ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>; s. 47F(1) @ec.europa.eu; s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu; s. 47F(1) g@ec.europa.eu; s. 47F(1) @ec.europa.eu; s. 47F(1)@ec.europa.eu; sante-consult-e5@ec.europa.eu
Subject: RE: Presentations of the meeting on latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (9.10.2020) [SEC=OFFICIAL]

OFFICIAL

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

Thank you for the briefing to third countries on Wednesday 9 December regarding the AMR package and Art 118 and for providing the presentations given on the day.

I appreciate there is considerable work for the Commission to do to deliver this package.

I recognise there are still a number of issues that are yet to be decided but below are the questions which Australian industry is raising with the Department and which we will need to provide responses to as soon as the information is available.

I welcome your response to as many of these as can be answered now and ongoing advice when further matters are settled.

1/ Will composite food products be included in the scope of food products captured by these rules? If yes, what is the rationale for cooked product to be included given cooking removes the AMR risk?

2/ Will the rules for prophylactic (preventive use) and metaphylactic (treating all animals in a group when only part of them show signs of illness) use of antibiotics apply to Third Countries? If prophylactic and/or metaphylactic use is not allowed, how is animal welfare addressed during this process?

3/ Has the OIE been consulted directly during this process? Is there a plan to consult the OIE directly prior to finalising the criteria and list to ensure alignment with OIE recommendations and intentions?

4/ There was a great deal of interest and level of concern about how third countries will demonstrate compliance and the transition time to be offered, recognising animal production cycles need multi-year planning. Would it be possible to provide a draft note on the implementation options and a transition time for how the new requirements will apply to third countries for discussion and feedback? That would go some way to providing assurance that the

administrative burden will be minimised and that trading partners will have the required time to meet the new rules.

5/ With the assessment of antibiotics for inclusion into the reserved list for human use, will a third country's national antibacterial importance ratings (covering the country's context on resistance priorities for human and animal health) be recognised and taken into account?

6/ For the purposes of importing animals and animal products into the EU as opposed to the reserved list of antimicrobials for human use, would coccidostats and histomonstats also be excluded from the ban on use of antimicrobials for promoting growth and increasing yield?

7/ If coccidostats and histomonstats are delivered in a different method other than feed additives (e.g. rumen boluses), will these still fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b))?

Thank you again for the briefing and we look forward to working with you on this file going forward.

I look forward to your advice.

With 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

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

From: sante-consult-d3@ec.europa.eu <sante-consult-d3@ec.europa.eu>
Sent: Friday, 11 December 2020 10:58 AM
To: s. 47F(1)
s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii)
@dfat.gov.au>; s. 47F(1)

s. 47F(1)

Cc: s. 47F(1)

Subject: Presentations of the meeting on latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (9.10.2020)

Dear Participants,

Please find attached the presentations given during the virtual meeting on “Latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products” which took place on 9 December.

Thank you again for your interest in this meeting.

With kind regards,

SANTE Unit D3 – Bilateral international relations

European Commission
Directorate-General for Health and Food safety
Directorate for Sustainable food, international relations
Unit D3 – Bilateral international relations

European Commission

Regulation on veterinary medicinal products

State of Play on implementation of Article 118

Meeting with third countries
9 December 2020

s. 47F(1)
Unit E5 Animal nutrition, veterinary medicines
Directorate E Food and feed safety, innovation
Directorate-General for Health and Food Safety

Provisions linked to Article 118

Article 118

Animals or products of animal origin imported into the Union

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

2. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Article by providing the necessary detailed rules on the application of paragraph 1 of this Article.

Article 107

Use of antimicrobial medicinal products

2. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield.

Article 37

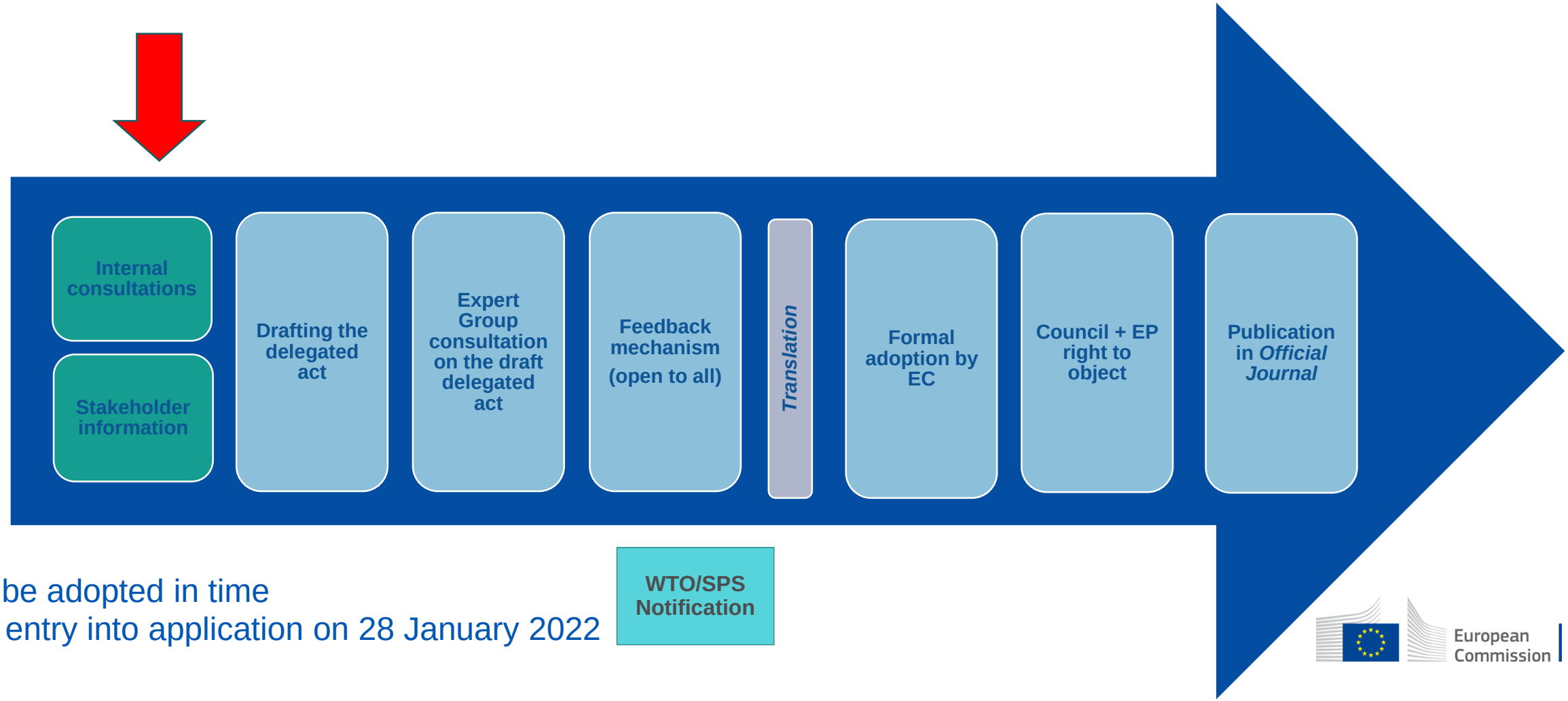
Decisions refusing marketing authorisations

5. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

4. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials.

Legislative process for delegated acts

DA on imports (Article 118(2))



To be adopted in time
for entry into application on 28 January 2022

WTO/SPS Notification

European Commission

Scope

- Animals
- Products of animal origin – mirror scope in hygiene legislation:
  - Regulation 853/2004, Annex I, point 8.1:
    - Food of animal origin, including honey and blood;
    - Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;
    - Other animals destined to be prepared with a view to being supplied live to the final consumer.

Controls

- Intend to have system similar to the one for imports under the Official Controls Regulation (2017/625)
- List of third countries, certificates
- Exact mechanism still under discussion

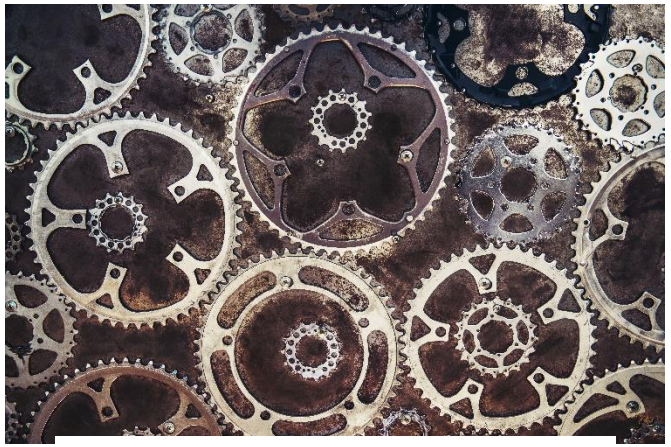
Regulation on veterinary medicinal products

State of Play on implementation of provisions linked to Article 118

Meeting with third countries
9 December 2020

Dr s. 47F(1)
Head of Unit E5 Animal nutrition, veterinary medicines
Directorate E Food and feed safety, innovation
Directorate-General for Health and Food Safety

Main achievements of the VMP Regulation



Modern, innovative and fit for purpose legal framework on veterinary medicines

Provides incentives to stimulate innovation

Strengthens EU action to fight antimicrobial resistance

In force but applicable as from 28 January 2022

7.1.2019 EN Official Journal of the European Union L 4/43

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

(Text with EEA relevance)

European Commission

Concrete Measures to fight AMR applicable to EU operators

- ban on preventive use of antibiotics in groups of animals
- ban on preventive use of antimicrobials via medicated feed
- restrictions on metaphylactic use
- ban on the use of certain antimicrobials designated as reserved to **human use**
- reinforced ban on the use of antimicrobials for promoting growth (**in addition to the 2006 EU ban of using antibiotics as growth promoters in feed**)
- compulsory data collection on sales & use of antimicrobials
- other measures: prudent & responsible use

Concrete Measures to fight AMR relevant to Third Country operators exporting to the EU

- **Ban** on the use of antimicrobials **for promoting growth and increasing yield**
- **Ban** on the use of certain antimicrobials designated as reserved to **human use**

Provisions linked to Article 118

Article 118

Animals or products of animal origin imported into the Union

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

2. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Article by providing the necessary detailed rules on the application of paragraph 1 of this Article.

Growth promotion/ yield increase

Article 107

Use of antimicrobial medicinal products

2. Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield.

AM reserved for human use

Article 37

Decisions refusing marketing authorisations

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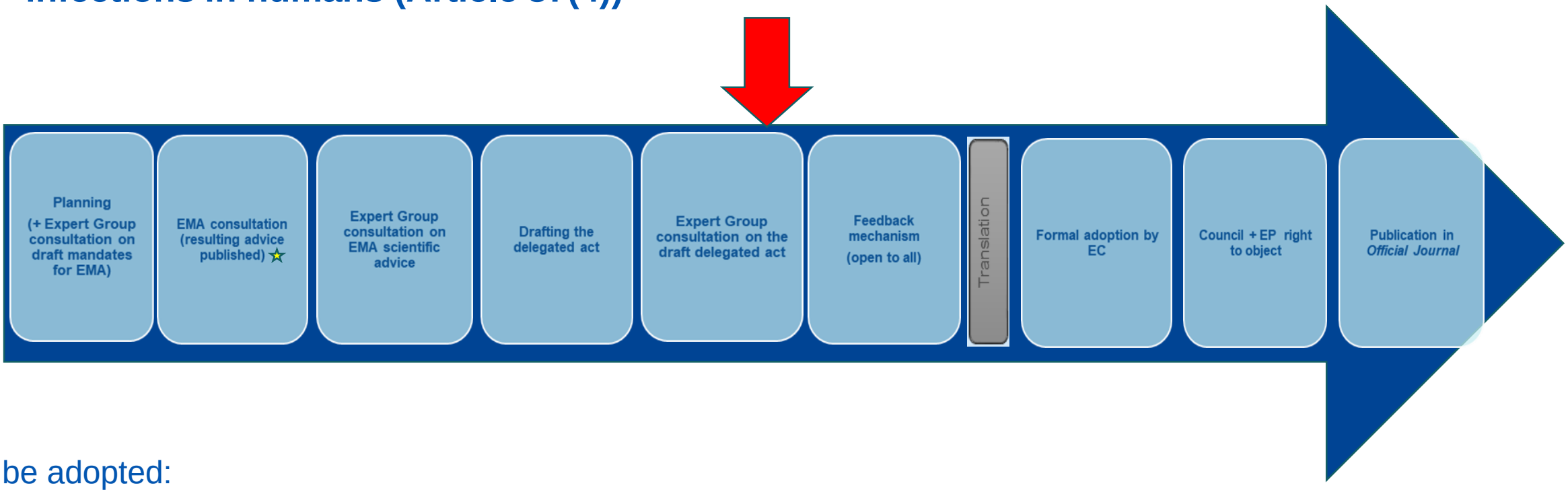
4. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials.

Legislative process for delegated acts

Delegated act on criteria for designation of antimicrobials to be reserved for treatment of certain infections in humans (Article 37(4))

WTO/SPS Notification



To be adopted:

4 months prior to the date of application of the Regulation: 28 September 2021

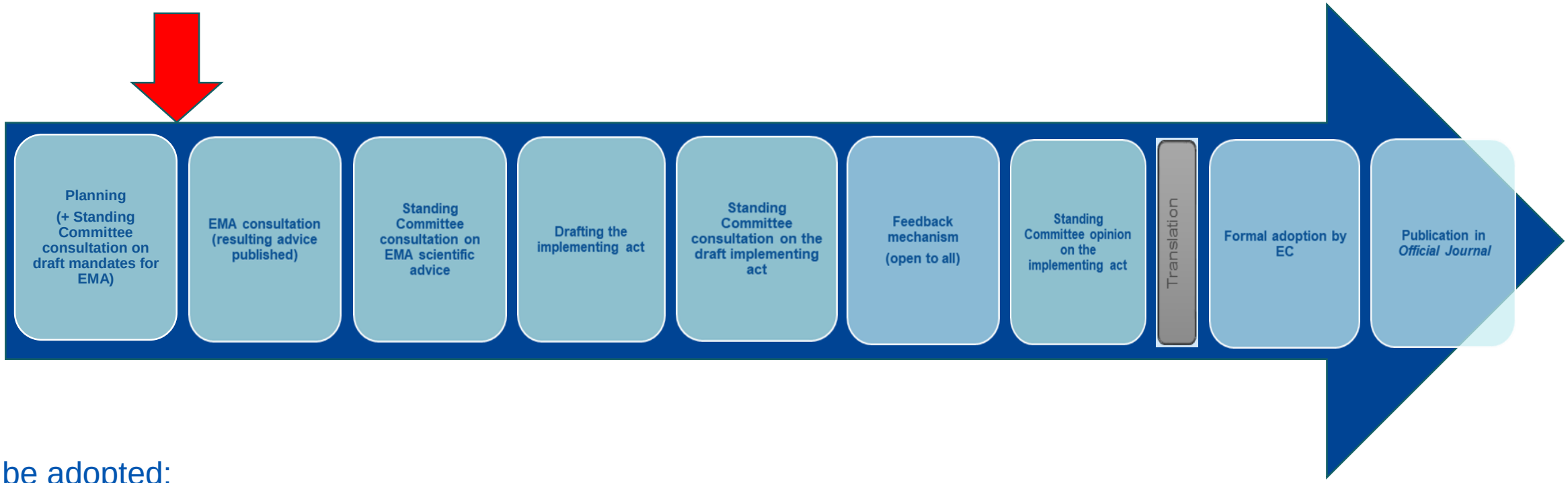
★ EMA advice: https://ec.europa.eu/food/sites/food/files/animals/docs/ah_vet-med_imp-reg-2019-06_ema-advice_del_art-37-4.pdf

European Commission

Legislative process for implementing acts

Implementing act on list of antimicrobials reserved for treatment of certain infections in humans (Art 37(5))

WTO/SPS Notification



To be adopted:

by the date of application of the Regulation (EU) 2019/6: 28 January 2022

European Commission

Minister-Counsellor (Agriculture) Jo Grainger of the Australian Embassy in Brussels contacted European Commission representatives in December 2020 with queries regarding the proposed regulation. The Commission advised the following:

- The Commission is still reflecting on the precise scope of the regulation.
    - Composite food products (including cooked product) are likely to be captured by the proposed regulation. The Commission's position is that cooking does not affect the bacteria harbouring the resistance genes in the production environment of food-producing animals.
- The rules for prophylactic (preventive use) and metaphylactic (treating all animals in a group when only part of them show signs of illness) use of antimicrobials do not apply to Third Countries (including Australia).
- Adjustments to animal production cycles often need multi-year planning to minimise administrative burden when new Third Country requirements are applied. The Commission is not in a position to share its internal discussions at this stage regarding the timeline for implementation. Further details will be shared as they become available.
- Regarding recognition of Third Countries' antibacterial importance ratings, the proposed criteria for designating antimicrobials reserved for treatment of certain human infections took into account other worldwide criteria, including those from international organisations (e.g., WHO and OIE) and certain Third Countries.
    - The OIE participated in a scientific workshop held by the Commission and European Medicines Agency in June 2019 and provided preliminary advice on these criteria.
    - The Commission may also use the feedback mechanism, as foreseen under the Commission's Better Regulation agenda[1], to collect input from stakeholders and citizens on draft legal acts. Once ready, the draft delegated act on the criteria may be published on the 'Have your say' webpage of the Commission's website[2] and open to citizens and stakeholders for feedback over a period of 4 weeks.
- Animals intended for export to the EU that have been treated with coccidiostats or histomonostats authorised as veterinary medicinal products, with the indication of promoting growth or increasing yield, or products derived from such animals, would be covered by the ban in Article 118 of Regulation (EU) 2019/6.
    - This means that coccidiostats or histomonostats used as feed additives will be allowed (i.e. not included in the scope of the ban under Regulation (EU) 2019/6).
    - Different methods of oral administration (e.g. rumen boluses) of coccidiostats or histomonostats will be allowed provided they are used as feed additives and not to promote growth or increase yield.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0215&from=EN
[2] https://ec.europa.eu/info/law/better-regulation/have-your-say

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

From: s. 47F(1) @ec.europa.eu>
Sent: Friday, February 5, 2021 11:47 PM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @awe.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>; s. 47F(1) @ec.europa.eu>; s. 47F(1) s. 47F(1) @ec.europa.eu>; sante-consult-e5@ec.europa.eu; s. 47F(1) s. 47F(1) @ec.europa.eu>
Subject: Re:: Presentations of the meeting on latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (9.10.2020) [SEC=OFFICIAL]

Dear s. 22(1)(

I refer to your message below.

Please find the replies to the AUS pending questions.

With kind regards
s. 47F(1)

s. 47F(1)
Head of Unit
DDG2. D3 – Bilateral International Relations

European Commission

Directorate-General for Health & Food Safety
Directorate D – Food Sustainability, International Relations
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http://ec.europa.eu/food/food/index_en.htm

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, December 11, 2020 12:56 PM
To: SANTE CONSULT-D3 <sante-consult-d3@ec.europa.eu>; s. 47F(1) (SANTE) s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @awe.gov.au>; Vs. 47F(1) s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) (SANTE) s. 47F(1) @ec.europa.eu>; s. 47F(1) s. 47F(1)@ec.europa.eu>; s. 47F(1) @ec.europa.eu>; SANTE CONSULT-E5 <sante-consult-e5@ec.europa.eu>
Subject: RE: Presentations of the meeting on latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (9.10.2020) [SEC=OFFICIAL]

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I appreciate there is considerable work for the Commission to do to deliver this package.

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7/ If coccidostats and histomonstats are delivered in a different method other than feed additives (e.g. rumen boluses), will these still fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b))?

Thank you again for the briefing and we look forward to working with you on this file going forward.

I look forward to your advice.

With 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

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From: sante-consult-d3@ec.europa.eu <sante-consult-d3@ec.europa.eu>
Sent: Friday, 11 December 2020 10:58 AM
To: s. 47F(1) @yahoo.fr; s. 47F(1) @yahoo.fr; czm@mrecic.gov.ar; eii@mrecic.gov.ar; s. 47F(1)@magyp.gob.ar; s. 47F(1)@agricola-ue.org; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @baha.org.bz; s. 47F(1) @baha.org.bz; s. 47F(1)@baha.org.bz; s. 47F(1) @baha.org.bz; s. 47F(1) @baha.org.bz; s. 47F(1)@health.gov.bz; s. 47F(1) @agricultura.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @itamaraty.gov.br; s. 47F(1) @itamaraty.gov.br; s. 47F(1) @international.gc.ca; s. 47F(1) @minagri.gob.cl; s. 47F(1)@minCIT.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1) @ica.gov.co; s. 47F(1) @comex.go.cr; info@costaricaembassy.be; mission.equateur@skynet.be; s. 47F(1) @agrocalidad.gob.ec; bruxelles@ecs.gov.eg; brusselsecs@gmail.com; s. 47F(1) @yahoo.com; trade3.brussels@mea.gov.in; adviser2.brussels@mea.gov.in; s. 47F(1) @mofa.go.jp; s. 47F(1) @mofa.go.jp; ljskorea@korea.kr; s. 47F(1)@miti.gov.my; s. 47F(1)@sre.gob.mx; s. 47F(1) @agricultura.gob.mx; s. 47F(1) @madrm.gov.md; s. 47F(1) @ansa.gov.md; s. 47F(1) @madrm.gov.md; s. 47F(1) @madrm.gov.md; s. 47F(1) @ubh.gov.me; s. 47F(1) @ubh.gov.me;

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Cc: s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) - s. 47F(1)@ec.europa.eu>; s. 47F(1) @ec.europa.eu>; s. 47F(1) s. 47F(1) @ec.europa.eu>; sante-consult-e5@ec.europa.eu
Subject: Presentations of the meeting on latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (9.10.2020)

Dear Participants,

Please find attached the presentations given during the virtual meeting on “Latest developments on implementation of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products” which took place on 9 December.

Thank you again for your interest in this meeting.

With kind regards,

SANTE Unit D3 – Bilateral international relations

European Commission
Directorate-General for Health and Food safety
Directorate for Sustainable food, international relations
Unit D3 – Bilateral international relations

Replies to questions from Australia December 2020

Question 1
Will composite food products be included in the scope of food products captured by these rules? If yes, what is the rationale for cooked product to be included given cooking removes the AMR risk?

Reply
The Commission is still reflecting on the precise scope of the delegated act to be adopted under Article 118.

The issue of AMR in food does not address the risks associated with its consumption. AMR is a public health issue and the use of antibiotics in animal production, especially as growth factors, creates a risk of resistance development. Once the resistance is around, cooking food does not affect the bacteria harbouring the resistance genes that are found on the farm, the environment, farmers etc.

Question 2
Will the rules for prophylactic (preventive use) and metaphylactic (treating all animals in a group when only part of them show signs of illness) use of antibiotics apply to Third Countries? If prophylactic and/or metaphylactic use is not allowed, how is animal welfare addressed during this process?

Reply
The rules for prophylactic and metaphylactic use of antimicrobials do not apply to Third Countries.

In the case of the EU, Regulation (EU) 2019/6 provides that antimicrobials may be administered for prophylaxis to a restricted number of animals in exceptional cases, when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe. If the antimicrobial is an antibiotic it may be administered to an individual animal only, subject to the same conditions. The objective is to prevent infection occurrence in the first place, through means such as vaccination, good hygiene and animal husbandry practices, appropriate biosecurity measures, so that there is no need for the use of antimicrobials.

The Regulation also provides that antimicrobials may be used for metaphylaxis, but only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available. Hence, a prudent use of antimicrobials is applied.

Question 3
Has the OIE been consulted directly during this process? Is there a plan to consult the OIE directly prior to finalising the criteria and list to ensure alignment with OIE recommendations and intentions?

Reply
The Commission has established a very good collaboration with OIE over the years and notably follows with great interest the work progress of its Permanent Working Group on AMR. Upon invitation by the Commission and the European Medicines Agency, OIE colleagues participated in the scientific workshop, which took place in June 2019 in order to provide feedback on the preliminary advice prepared by the EMA expert working group in charge of reflecting on the criteria to be established under Article 37(4). In addition, the Commission may use the feedback mechanism, as foreseen under the Commission's Better Regulation agenda[1], to collect input from stakeholders and citizens on draft

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0215&from=EN

legal acts. Once ready, the draft delegated act on the criteria may be published on the 'Have your say' webpage of the Commission's website[2] and open to citizens and stakeholders for feedback over a period of 4 weeks. The feedback received is then analysed and taken into consideration, as appropriate, by the Commission prior to finalising the draft delegated act and submitting it for adoption by the College.

Question 4

There was a great deal of interest and level of concern about how third countries will demonstrate compliance and the transition time to be offered, recognising animal production cycles need multi-year planning. Would it be possible to provide a draft note on the implementation options and a transition time for how the new requirements will apply to third countries for discussion and feedback? That would go some way to providing assurance that the administrative burden will be minimised and that trading partners will have the required time to meet the new rules.

Reply

The Commission is not in a position to share its internal discussions at this point in the process. As promised in past occasions, we will share further details with third countries in due course as they become available.

Question 5

With the assessment of antibiotics for inclusion into the reserved list for human use, will a third country's national antibacterial importance ratings (covering the country's context on resistance priorities for human and animal health) be recognised and taken into account?

Reply

The Commission has tasked the European Medicines Agency to provide scientific advice on:

1) The criteria necessary to designate antimicrobials to be reserved for treatment of certain infections in humans;
2) The list of such antimicrobials itself.

The criteria proposed by the European Medicines Agency to the Commission were presented to Third Countries during the meeting organised by the Commission in January 2020. They were established taking into account other criteria existing worldwide, including those of international organisations such as WHO and OIE and those used by certain Third Countries.

Question 6

For the purpose of importing animals and animal products into the EU as opposed to the reserved list of antimicrobials for human use, would coccidostats and histomonstats also be excluded from the ban on use of antimicrobials for promoting growth and increasing yield?

Reply

Coccidiostats and histomonostats used as feed additives do not fall under the scope of the Regulation on veterinary medicinal products, but fall under Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b)). Animals intended for export to the EU that have been treated with coccidiostats or histomonostats authorised as veterinary medicinal products, with the indication of promoting growth or increasing yield, or products derived from such animals, would be covered by the ban in Article 118 of Regulation (EU) 2019/6.

Question 7

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

If coccidostats and histomonstats are delivered in a different method other than feed additives (e.g. rumen boluses), will these still fall under the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (Art. 1, 2. (b))?

Reply

When coccidostats and histomonstats are used as feed additives, different methods of oral administration are possible, including the use of a rumen bolus (even if no feed additives are authorised for ruminants in the EU). The method of administration is not linked to the classification of the product.

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

From: s. 22(1)(a)(ii) @agriculture.gov.au> **On Behalf Of** Schipp, Mark
Sent: Thursday, April 22, 2021 11:20 AM
To: sps@ec.europa.eu
Cc: paul.kelly@health.gov.au
Subject: Australian Government response to delegated regulation [SEC=OFFICIAL]

Good morning

Please find attached correspondence from Dr Mark Schipp, Chief Veterinary Officer.

Kind regards

s. 22(1)(a)(ii)
Australian Chief Plant Protection Office/Australian Chief Veterinary Office
Executive Assistant to Dr Gabrielle Vivian-Smith | Australian Chief Plant Protection Officer
Executive Assistant to Dr Mark Schipp | Australian Chief Veterinary Officer

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

Department of Agriculture, Water and the Environment
GPO Box 858, Canberra ACT 2601 Australia

The department acknowledges the traditional owners of country throughout Australia and their continuing connection to land, sea and community. We pay our respects to traditional owners, their cultures and elders past and present.

Australian Government
Department of Agriculture, Water and the Environment

CHIEF VETERINARY OFFICER

s. 47F(1)
Director
Food and Feed Safety, Innovation
Directorate General for Health and Food Safety
Rue Breydel 4
Brussels, 1040

Via email: sps@ec.europa.eu

Dear Director s. 47F(1)

I refer to DG SANTE's public consultation on the draft delegated regulation supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans.

Australia's action to combat Antimicrobial Resistance (AMR)

In 2015, the Australian Government released Australia's First *National Antimicrobial Resistance Strategy 2015–2019*. It was closely aligned with the *World Health Organization's (WHO) Global Action Plan on Antimicrobial Resistance* and provided a national framework for a coordinated cross-sectoral response to the very real dangers posed by AMR.

Australia made significant progress in its response under the first strategy, including the creation of a One Health AMR online hub, which acts as a central repository for trusted information and resources related to antibiotic use and antimicrobial resistance generally; the establishment of the Antimicrobial Use and Resistance in Australia (AURA) Surveillance System; the completion of specific proof-of-concept antimicrobial resistance surveillance projects in the animal sector; and significant investment in research and development through National Health and Medical Research Council grants, the Medical Research Future Fund and the Cooperative Research Centres Program.

Last year, the Australian Government released its latest strategy – *Australia's National Antimicrobial Resistance Strategy – 2020 and Beyond* (2020 Strategy). The 2020 Strategy presents a 20-year vision and seeks to further embed the One Health approach through a coordinated and sustained cross-sectoral response to AMR.

The 2020 Strategy builds on the original 2015 strategy, broadening its ambit to encompass food, the environment and other classes of antimicrobials such as antifungals and antivirals. It will be underpinned by a series of national and sector-specific action plans which will outline the short- to medium-term goals that are needed to achieve the vision.

The 2020 Strategy represents the collective, expert views of stakeholders – from across governments and the animal and human health, environment, agricultural and food sectors –

on how best to combat AMR. It also maintains its alignment with the *WHO Global Action Plan on Antimicrobial Resistance* and a commitment to continue to support global and regional efforts to manage the threat of AMR.

I believe Australia's position and practice on managing AMR is world leading and aligned with the international momentum on this important issue. Australia would welcome further opportunity to outline its AMR strategy and implementation with the European Commission.

Australia's feedback on the draft delegated regulation

Australia is committed to fighting AMR and supports the European Commission (EC) taking action on this important issue, which is critical for human and animal health.

However, Australia's model differs from EC's approach and will deliver the same outcome. The proposed EC's approach may negatively impact Australia's ability to manage our animal welfare and the delivery of our 2020 Strategy to fight AMR, if this is applied to Australia as a third country trading partner.

Australia requests the EC consider an approach that recognises, under a mutual recognition model, trading partner's AMR settings, which deliver comparable outcomes and does not impose the exact requirements of the EU's domestic settings on trading partners as per Article 118 of (EU) 2019/6.

Specific comments are set out below:

Clause (5): The EC proposes that banning the use of certain antimicrobials in veterinary medicine is a risk management measure. Australia requests the EC to recognise that equivalent approaches are available to deliver similar outcomes suitable to national circumstances.

Australia applies strict controls to register antimicrobials. Antimicrobials are approved for use in food-producing animals using positive mechanisms. This includes guidance (e.g. AMR risk assessment guidance for product registration), codes (e.g. product labelling), and legal instruments (e.g. *Agricultural and Veterinary Chemicals Code Act 1994*) amongst others, which give effective control and regulatory powers similar to delegated and implementing regulations. As an outcome, fluoroquinolones have never been permitted for use in food-producing animals.

Clauses (6) – (8): The EC discusses the basis for using the criteria (i.e. high importance for human health, risk of transmission of resistance and non-essential need for animal health) to reserve an antimicrobial for treatment of certain infections in humans and whether its absence would result in significant morbidity or mortality or have a major impact on animal welfare and public health, as well as, whether antimicrobial alternatives are available.

Australia requests the EC to recognise that countries will have differing availabilities of antimicrobials based on commercial market drivers (including size of, and demand within, the animal population) and national AMR priorities. For example in Australia, macrolides such as erythromycin and the penicillins such as ampicillin, which are listed as **critically important** on the WHO *Critically Important Antimicrobials for Human Medicine* list, are considered **low** importance in our national Antibacterial Importance Ratings. The difference in the importance rating reflects the relatively low reliance on these antibacterial agents in Australia, because resistance is widespread in many human pathogens causing infection in Australia or that some of the pathogens of interest to WHO are less important in Australia.

The proposed EC restriction through the application of these criteria could present harm to animals in those countries, including Australia, where there may be no registered antimicrobial alternative(s) available. For Australia, this has the potential to violate Australian welfare legislation for those animals being prepared for the European Union market.

Clauses (10) – (11): The EC proposes to apply the criteria to antimicrobials that are yet to be authorised and to existing antimicrobials. Australia is concerned this draft legislation will impact Australia's right to independently determine antimicrobial access based on our national antibacterial importance ratings to address national circumstances in an already limited market. The imposition of this legislation will potentially lead to further loss of access of antimicrobials due to commercial market drivers and decision-making by veterinary product manufacturers. Again, we are concerned about subsequent animal welfare issues.

Draft Annex

Part B 1 (a) and 1 (b): The EC proposes that "…transmission of such resistance from animal sources to humans is significant/would likely be significant….". Australia requests the definition of 'significance' in this context.

Part B 1 (a), 1 (b) and 2: The EC proposes that "…or induction of/potential for inducing cross-resistance or co-selection of resistance to other antimicrobials…" or similar. Australia would appreciate clarity about the EU's tolerance level in relation to cross-resistance or co-selection of resistance. Would this be zero risk or another tolerance level?

Thank you again for the opportunity to provide a formal submission.

I look forward to your advice.

Yours sincerely

Dr Mark Schipp

21 April 2021

cc Professor Paul Kelly, Australian Government Chief Medical Officer

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

From: Schipp, Mark <Mark.Schipp@agriculture.gov.au>
Sent: Friday, July 23, 2021 7:04 PM
To: s. 22(1)(a)(ii) @agriculture.gov.au>; s. 22(1)(a)(ii) @agriculture.gov.au>; s. 22(1)(a)(ii)
s. 22(1)(a)(ii) @agriculture.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Fwd: RE - Australian Government response to the draft delegated regulation establishing the criteria for the designation of antimicrobials to be reserved for treatment of certain inf... - Ares(2021)4730680 [SEC=UNOFFICIAL]

Mark Schipp
Australian Chief Veterinary Officer

From: SANTE CONSULT-E5 <sante-consult-e5@ec.europa.eu>
Sent: Friday, July 23, 2021 6:51:01 PM
To: s. 22(1)(a)(ii) @agriculture.gov.au>
Cc: (Mission of Australia to the EU = Mission d'Australie auprès de l'UE) <austemb.brussels@dfat.gov.au>; KELLY Paul (Australian Government Department of Health) <paul.kelly@health.gov.au>
Subject: RE - Australian Government response to the draft delegated regulation establishing the criteria for the designation of antimicrobials to be reserved for treatment of certain inf... - Ares(2021)4730680 [SEC=UNOFFICIAL]

Please find attached the ares document (2021) 4730680 signed by s. 47F(1)

Best regards,
Sante-consult-e5

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director

Brussels
SANTE/E.5/AL/mcd Ares (2021) 5110067

Dear Dr Schipp,

I would like to thank you for Australia's comments on the draft delegated regulation establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans.

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

The Commission wishes to underline that the scope of this draft Delegated Regulation is to establish criteria to designate antimicrobials that should be reserved for the treatment of certain infections in humans. It is not about detailed rules on how the provisions of Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products will apply to imports from third countries into the EU, which will be the object of another Delegated Regulation.

As regards your concerns about the EU approach chosen to fight antimicrobial resistance (AMR), Regulation (EU) 2019/6 on veterinary medicinal products is a cornerstone of the European One Health Action Plan to fight antimicrobial resistance, adopted in 2017. Before that, the European Commission adopted Guidelines for the prudent use of antimicrobials in veterinary medicine in 2015, in line with the previous Action Plan against the rising threats from AMR, adopted in 2011. More and more EU Member States have a One Health National Action Plan against AMR and sizeable progress has been achieved in Europe in reducing sales of antimicrobials used in animals, including antimicrobials considered important to human health. However, more needs to be done, which is why the EU took a wide range of concrete measures under Regulation (EU) 2019/6, among which is the provision to reserve certain antimicrobials for treatment of certain infections in humans.

Dr Mark Schipp
Chief Veterinary Officer
Australian Government
Department of Agriculture, Water and the Environment
GPO Box 858
Canberra ACT 2601
Australia
email : s. 22(1)(a)(ii)@agriculture.gov.au

As regards different national AMR priorities across the world and issues relating to the availability of medicines and concerns about animal welfare, the Commission wishes to clarify that it is not asking third countries not to treat animals that are in need of treatment to preserve their health and welfare. However in the event that such a treatment would be necessary with an antimicrobial designated in the EU as reserved for use in human medicine, the animal(s) considered, or animal products derived from those animals, should not be exported to the EU. These animals and products may instead be used for domestic production purposes, if in line with national legislation.

As regards the definition of 'significance', the draft Delegated Regulation does not specify a corresponding numerical value that would allow to indisputably determine whether the criterion is fulfilled or not. Such numerical values would vary depending on a range of parameters considered, such as, for example, the antimicrobial considered, the micro-organism and disease considered or the animal species concerned, making it unrealistic to draw up an exhaustive list.

In line with Article 37(6) of Regulation (EU) 2019/6, the Commission will take into account the scientific advice of the European Medicines Agency (EMA), the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) in preparing the list of antimicrobials to be reserved for the treatment of certain infections in humans. The scientific experts in these agencies will jointly carry out a case-by-case basis evaluation to determine which antimicrobials fulfil the criteria set in the draft Delegated Regulation. The scientific advice will be used as the basis to draft the Implementing Regulation establishing the list of those antimicrobials to be reserved for use in human medicine. This scientific assessment will be published by the EMA in a scientific advice report, which will be available to the general public to ensure transparency.

As regards the 'induction/potential for inducing cross-resistance or co-selection of resistance', the Commission confirms that if there is induction/potential for inducing cross-resistance or co-selection of resistance and that, if this transmission for animals to humans is significant/likely to be significant and linked to the use in animals, then the second criterion of risk of transmission of resistance will be considered as met.

I would like to thank you once again for providing comments on this legislative proposal and hope that the responses conveyed clarify the concerns raised.

Yours sincerely,

[e-signed]

s. 47F(1)

c.c.: s. 47F(1)
(SANTE), s. 47F(1) (EU Delegation to Australia)
Professor Paul Kelly, Australian Government Chief Medical Officer (paul.kelly@health.gov.au)
Australian Mission to the European Union (austemb.brussels@dfat.gov.au)

Minister-Counsellor (Agriculture) s. 22(1)(a)(ii) of the Australian Embassy in Brussels contacted European Commission representatives in December 2020 with queries regarding the proposed regulation[1]. The Commission advised the following:

- The Commission is still reflecting on the precise scope of the regulation.
    - Composite food products (including cooked product) are likely to be captured by the proposed regulation. The Commission's position is that cooking does not affect the bacteria harbouring the resistance genes in the production environment of food-producing animals.
- The rules for prophylactic (preventive use) and metaphylactic (treating all animals in a group when only part of them show signs of illness) use of antimicrobials do not apply to Third Countries (including Australia).
- Adjustments to animal production cycles often need multi-year planning to minimise administrative burden when new Third Country requirements are applied. The Commission is not in a position to share its internal discussions at this stage regarding the timeline for implementation. Further details will be shared as they become available.
- Regarding recognition of Third Countries' antibacterial importance ratings, the proposed criteria for designating antimicrobials reserved for treatment of certain human infections took into account other worldwide criteria, including those from international organisations (e.g., WHO and OIE) and certain Third Countries.
    - The OIE participated in a scientific workshop held by the Commission and European Medicines Agency in June 2019 and provided preliminary advice on these criteria.
    - The Commission may also use the feedback mechanism, as foreseen under the Commission's Better Regulation agenda[2], to collect input from stakeholders and citizens on draft legal acts. Once ready, the draft delegated act on the criteria may be published on the 'Have your say' webpage of the Commission's website[3] and open to citizens and stakeholders for feedback over a period of 4 weeks.
- Animals intended for export to the EU that have been treated with coccidiostats or histomonostats authorised as veterinary medicinal products, with the indication of promoting growth or increasing yield, or products derived from such animals, would be covered by the ban in Article 118 of Regulation (EU) 2019/6.
    - This means that coccidiostats or histomonostats used as feed additives will be allowed (i.e. not included in the scope of the ban under Regulation (EU) 2019/6).
    - Different methods of oral administration (e.g. rumen boluses) of coccidiostats or histomonostats will be allowed provided they are used as feed additives and not to promote growth or increase yield.

[1] https://europa.eu/!rJ63kT
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0215&from=EN
[3] https://ec.europa.eu/info/law/better-regulation/have-your-say

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

From: s. 47F(1) @mofa.go.jp>
Sent: Wednesday, 18 May 2022 10:04 PM
To: s. 47F(1) @international.gc.ca; Agriculture@Brussels.mfa.gov.il
Cc: info@embassyafghanistan.be; mission.eu@mfa.gov.al; s. 47F(1)@agricola-ue.org; s. 47F(1)@agricola-ue.org; s. 47F(1)@magyp.gob.ar; s. 22(1)(a)(ii) (DFAT); s. 22(1)(a) s. 22(1)(a)(ii) Ls. 47F(1) @agricultura.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @international.gc.ca; s. 47F(1) @international.gc.ca; s. 47F(1) @minagri.gob.cl; s. 47F(1) @minagri.gob.cl; s. 47F(1) @mofcom.gov.cn; s. 47F(1)@mincit.gov.co; info@costaricaembassy.be; brusselsecs@gmail.com; bruxelles@ecs.gov.eg; s. 47F(1) @mfa.gov.ge; info@hondurasembassy.be; trade3.brussels@mea.gov.in; adviser2.brussels@mea.gov.in; secretariat@iranembassy.be; s. 47F(1)@israeltrade.gov.il; s. 47F(1) ; s. 47F(1)@korea.kr; ambassadebruxelles@libaneurope.be; brussels@embmongolie.be; s. 47F(1)@embmongolie.be; s. 47F(1) @mfat.govt.nz; oman@omanembassy.be; commercialsecretary@embassyofpakistan.be; secretary.parkbrussels@yahoo.co.uk; parepbrussels@mofa.gov.pk; s. 47F(1)@mre.gov.py; s. 47F(1)@mre.gov.py; s. 47F(1) @embaperu.be; s. 47F(1) @dirco.gov.za; s. 47F(1) @eda.admin.ch; syria.mission@skynet.be; s. 47F(1)@gmail.com; s. 47F(1)@agrithai.be; s. 47F(1)@fco.gov.uk; s. 47F(1) l@fcdo.gov.uk; s. 47F(1) @mfa.gov.ua; s. 47F(1) @mrree.gub.uy; s. 47F(1) @fas.usda.gov; s. 47F(1) @fas.usda.gov; s. 47F(1) @aphis.usda.gov; s. 47F(1)@usda.gov; s. 47F(1)@usda.gov; s. 47F(1) @usda.gov; s. 47F(1)@fas.usda.gov; s. 47F(1)@uzbekistan.be; eumission@uzbekistan.be; s. 47F(1) @skynet.be; s. 47F(1) @agricultura.gob.mx; secretariat.brussels@mfa.af; s. 47F(1)@skynet.be; embassy@southafrica.be; s. 47F(1) @international.gc.ca; s. 47F(1)@dalrrd.gov.za; s. 47F(1)@mofa.go.kr; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1) @embaperu.be
Subject: [EXTERNAL] RE: list of antimicrobials reserved for human use
Attachments: Feedback from_ Anonymous(JP).pdf

Dear All

FYI

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欧州連合日本政府代表部
一等書記官　武部　真也
s. 47F(1) (Mr.)
First Secretary
Mission of Japan to the European Union
Rue Van Maerlant 1
1040 Brussels, Belgium

Tel:s. 47F(1) 6
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****

From: s. 47F(1)
Sent: Thursday, May 5, 2022 12:27 PM
To: s. 47F(1) @international.gc.ca; Agriculture@Brussels.mfa.gov.il
Cc: info@embassyafghanistan.be; mission.eu@mfa.gov.al; s. 47F(1)@agricola-ue.org; s. 47F(1)@agricola-ue.org; s. 47F(1)@magyp.gob.ar; s. 22(1)(a)(ii) @dfat.gov.au; s. 22(1)(a)(ii) @dfat.gov.au; s. 22(1)(a)(ii)@dfat.gov.au; s. 47F(1) @agricultura.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @international.gc.ca; s. 47F(1) @international.gc.ca; s. 47F(1) @minagri.gob.cl; s. 47F(1) @minagri.gob.cl; s. 47F(1) @mofcom.gov.cn; s. 47F(1)@mincit.gov.co; info@costaricaembassy.be; brusselsecs@gmail.com; bruxelles@ecs.gov.eg; s. 47F(1) @mfa.gov.ge; info@hondurasembassy.be; trade3.brussels@mea.gov.in; adviser2.brussels@mea.gov.in; secretariat@iranembassy.be; s. 47F(1)@israeltrade.gov.il; s. 47F(1) s. 47F(1) @mofa.go.jp>; s. 47F(1)@korea.kr; ambassadebruxelles@libaneurope.be; brussels@embmongolie.be; s. 47F(1)@embmongolie.be; s. 47F(1) @mfat.govt.nz; oman@omanembassy.be; commercialsecretary@embassyofpakistan.be; secretary.parkbrussels@yahoo.co.uk; parepbrussels@mofa.gov.pk; s. 47F(1)@mre.gov.py; s. 47F(1)@mre.gov.py; s. 47F(1) @embaperu.be; s. 47F(1) @dirco.gov.za; s. 47F(1) @eda.admin.ch; syria.mission@skynet.be; s. 47F(1)@gmail.com; s. 47F(1)@agrithai.be; s. 47F(1)@fco.gov.uk; s. 47F(1) @fcdo.gov.uk; s. 47F(1) @mfa.gov.ua; s. 47F(1) @mrree.gub.uy; s. 47F(1) @fas.usda.gov; s. 47F(1) @fas.usda.gov; s. 47F(1) @aphis.usda.gov; s. 47F(1)@usda.gov; s. 47F(1)@usda.gov; s. 47F(1) usda.gov; s. 47F(1)@fas.usda.gov; s. 47F(1)@uzbekistan.be; eumission@uzbekistan.be; s. 47F(1) @skynet.be; s. 47F(1) @agricultura.gob.mx; secretariat.brussels@mfa.af; s. 47F(1)@skynet.be; embassy@southafrica.be; s. 47F(1) @international.gc.ca; s. 47F(1) @dalrrd.gov.za; s. 47F(1)@mofa.go.kr; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1) @embaperu.be
Subject: RE: list of antimicrobials reserved for human use

Thank you s. 47F(1),

Japan is planning to send comments on this consultation as following points are important for Japan.

-Fosfomycin

s. 33(b)

-Transitional period

The transitional period is 6 months, s. 33(b)

-In introducing the measure, the method of proving antimicrobial non-use should be clarified.

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欧州連合日本政府代表部
一等書記官　武部　真也
s. 47F(1)
First Secretary
Mission of Japan to the European Union
Rue Van Maerlant 1
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Tel:s. 47F(1)
Email: s. 47F(1) @mofa.go.jp
****

From: s. 47F(1) @international.gc.ca>
Sent: Tuesday, April 19, 2022 9:55 PM
To: Agriculture@Brussels.mfa.gov.il
Cc: info@embassyafghanistan.be; mission.eu@mfa.gov.al; s. 47F(1)@agricola-ue.org; s. 47F(1)@agricola-ue.org; s. 47F(1)@magyp.gob.ar; s. 22(1)(a)(ii) @dfat.gov.au; s. 22(1)(a)(ii) @dfat.gov.au; s. 22(1)(a)(ii)@dfat.gov.au; s. 47F(1) @agricultura.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @international.gc.ca; s. 47F(1) @international.gc.ca; s. 47F(1) @minagri.gob.cl; s. 47F(1) @minagri.gob.cl; s. 47F(1) @mofcom.gov.cn; s. 47F(1)@mincit.gov.co; info@costaricaembassy.be; brusselsecs@gmail.com; bruxelles@ecs.gov.eg; s. 47F(1) @mfa.gov.ge; info@hondurasembassy.be; trade3.brussels@mea.gov.in; adviser2.brussels@mea.gov.in; secretariat@iranembassy.be; s. 47F(1)@israeltrade.gov.il; s. 47F(1) s. 47F(1) @mofa.go.jp>; s. 47F(1) @mofa.go.jp>; s. 47F(1)@korea.kr; ambassadebruxelles@libaneurope.be; brussels@embmongolie.be; s. 47F(1)@embmongolie.be; s. 47F(1) @mfat.govt.nz; oman@omanembassy.be; commercialsecretary@embassyofpakistan.be; secretary.parkbrussels@yahoo.co.uk; parepbrussels@mofa.gov.pk; s. 47F(1)@mre.gov.py; s. 47F(1)@mre.gov.py; s. 47F(1) @embaperu.be; s. 47F(1) @dirco.gov.za; s. 47F(1) @eda.admin.ch; syria.mission@skynet.be; s. 47F(1)@gmail.com; s. 47F(1)@agrithai.be; s. 47F(1)@fco.gov.uk; s. 47F(1) @fcdo.gov.uk; s. 47F(1) @mfa.gov.ua; s. 47F(1) @mrree.gub.uy; s. 47F(1) @fas.usda.gov; s. 47F(1) @fas.usda.gov; s. 47F(1) @aphis.usda.gov; s. 47F(1)@usda.gov; s. 47F(1)@usda.gov; s. 47F(1) @usda.gov; s. 47F(1)@fas.usda.gov; s. 47F(1)@uzbekistan.be; eumission@uzbekistan.be; s. 47F(1) @skynet.be; s. 47F(1) @agricultura.gob.mx; secretariat.brussels@mfa.af; s. 47F(1)@skynet.be; embassy@southafrica.be; s. 47F(1) @international.gc.ca; s. 47F(1) @dalrrd.gov.za; s. 47F(1)@mofa.go.kr; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1)@mincit.gov.co; s. 47F(1) @embaperu.be
Subject: RE: list of antimicrobials reserved for human use

If you haven't already seen, the EU has opened public consultation on list of reserved antimicrobials

Have your say

Dear Sir or Madam,

One initiative has been published or updated on the European Commission's 'Have your say' portal:

Feedback opportunities.

Title	Topic	Deadline	Action
Draft Act			
Drug resistance – list of antimicrobial medicines reserved for treating humans	Food safety	17/05/2022	Published for feedback

To consult all the existing initiatives please visit the portal:

https://ec.europa.eu/info/law/better-regulation/have-your-say_en

This is an automatic notification message. Please do not reply to it.

With kind regards,

European Commission
Secretariat-General

You can change your subscription preferences online:

https://ec.europa.eu/info/law/better-regulation/account_en

s. 47F(1) DVM (she/her)
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Law

Feedback from: Anonymous

Feedback reference
F3259989

Submitted on
17 May 2022

User type
Public authority

Organisation
Ministry of Agriculture, Forestry and Fisheries of s. 33(b)

Organisation size
Large (250 or more)

Scope
National

Level of governance
Authority

Country of origin
s. 33(b)

Initiative
Drug resistance – list of antimicrobial medicines reserved for treating humans *(/info/law/better-regulation/have-your-say/initiatives/11653-Drug-resistance-list-of-antimicrobial-medicines-reserved-for-treating-humans_en)*

s. 33(b) is fully aware of the importance of AMR measures, and understands the EU's efforts, however, we would like to submit the following comments so that EU will be able to implement more practical and effective AMR measures.
1. Provide a sufficient transition period
Application of this rule will be effective 6 months after the date of entry into force of the regulation. When this rule is applied to the exporting countries, sufficient transition period should be set, taking into account of the breeding period of livestock and marine products. Otherwise, it will have a damaging effect on exports of these products to EU. For example, the breeding period for red sea bream and other marine products that are exported to the EU from s. 33(b) is 1.5 to 2.0 years, and the breeding period for beef cattle is about 2.5 years. Furthermore, there should be a period set aside, say about 6 months, for business operators to prepare for the new rule. Therefore, we request that the transition period of three year for the imported products.
Also, regarding the application date that is set at 6 months after the date of entry into force of the Regulation, we would like to clarify that the antimicrobials specified in this rule can be used during this 6 months period.

2. Clarify the method of certifying the non-use of antimicrobials.
In order to establish a control system for the use of antimicrobials in the exporting country, the draft rules on the import procedure of animals and animal-derived products imported into the EU based on Article 118 of the Veterinary Medicinal Products Regulation (EU) 2019/6 should be published at an earliest opportunity. It is essential to make it public and clarify how to prove the non-use of prohibited antimicrobials.
Furthermore, we would like to receive a confirmation that non-use means that the concerned antimicrobials have not been used to individual animals during the period from birth to shipment.

3. Interpretation and Application of the Commission Delegated Regulation (EU) 2021/1760
According to the Commission Delegated Regulation(EU) 2021/1760 which supplements the Article 37 (4) of the Regulation (EU) 2019/6, there are three criteria which must be met for designating the antimicrobials prohibited from use in animals. They are: Criterion A: "High Importance to Human Health", Criterion B: "Risk of Transmission of Resistance", Criterion C: "Non-Essential Need for Animal Health".
Among the antimicrobials banned from use in animals, the evaluation sheet of the European Medicines Agency (EMA) states that Fosfomycyn meets the designated criteria, and states in the report as follows:
"Fosfomycin resistance in isolates of animal origin is rarely reported in Europe, while data from the Asia region indicate low to moderate resistance rates in E. coli isolated from companion animal and food-producing animals."
"Transmission of resistance to Fosfomycin from animals to humans is not likely to be significant at present in the EU; however, there is a potential pathway for transmission of mobile Fosfomycyn resistance genes through commensal E. coli."

In these statements, livestock, pet animals, and aquatic animals are evaluated together, but since the risk factors for transmitting drug-resistant microbials to humans differ depending on each animal species, the risk assessment should be performed for each animal species separately.
In addition, it is stated in the report that " Fosfomycyn is used for the treatment of pseudotuberculosis in marine fish in s. 33(b) However, in s. 33(b) it is also used for the treatment of red sea bream Edwardsiellosis, because there is no alternative drug for the disease, it is considered essential as a veterinary medicine. This aspect has not been considered in the report.
Furthermore, we would like to point out the fact that the Fosfomycin is not included in HPCIA(Highest Priority Critically Important Antimicrobials) in the WHO CIA list. We strongly request further assessment based on science.

Report an issue with this feedback *(/info/law/better-regulation/have-your-say/initiatives/11653-Drug-resistance-list-of-antimicrobial-medicines-reserved-for-treating-humans/F3259989/report_en)*

All feedback

Australian Government

Comments from the Australian Government to the European Commission on the proposed *Commission Implementing Regulation designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (Text with EEA relevance)* (G/SPS/N/EU 557)

The Australian Government welcomes the opportunity to provide comments on the European Union (EU) World Trade Organization notification (G/SPS/N/EU/557) of 21 April 2022.

1. General comments

Australia seeks assurance that any future revisions of the reserved list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans will continue to follow a science-based, consultative and inclusive process. If, in the future, the Commission seeks to add further antimicrobials to the reserved list, then we seek assurances that any prohibition of use will not be retrospectively applied to animals that may have been treated prior to the date of that addition.

2. Specific comments

Australia notes that the proposed regulation follows the European Medicines Agency (EMA) scientific advice, which took into consideration both human health importance and animal health needs. We seek assurance that any future revisions of the list will follow a similar science-based, consultative process.

However, Australia would argue that imposing restrictions on third party countries exporting to the European Union is not appropriate where those third-party countries have undertaken their own risk assessments and no risk has been identified to consumers. Australia notes that it does not permit any use of colistin or fluoroquinolone antimicrobials on food producing animals in Australia, yet Australia has not proposed any similar restriction on exports of animal products from the EU where such antimicrobials are used.

Article 118 in 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, provides that operators in third countries shall not use any reserved antimicrobials on animals, when those animals or products derived from those animals are exported to the European Union and that the European Commission shall adopt delegated acts to provide the necessary detailed rules on this prohibition. Australia seeks an adequate opportunity to comment on any such proposed delegated acts and considers that it should not be necessary for the Commission to impose any additional certification, residues monitoring or record keeping requirements for exports of animals or animal products on those third countries where there are already adequate controls prohibiting the use of those reserved antimicrobials on food producing animals.

Conclusion

Australia welcomes the EU's consideration of the concerns and points raised in this submission. We look forward to future collaboration with the EU on the content and the implementation of any further regulations proposed regarding the use of reserved antimicrobials in third countries, including ensuring WTO consistency.

EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Directorate D – Food sustainability, international relations
D2- Multilateral International Relations

Brussels,
SANTE D2 VS/tt (2022) 5142715

To:	s. 22(1)(a)(ii) Trade, Market Access and International Division	**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
Subject:	**Reply of the EU to the comments of Australia on the legal draft notified in notice G/SPS/N/EU/557**		

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/557.

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/557 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 it has made on the legislation notified to the WTO in notification G/SPS/N/EU/557.

The EU has carefully examined the comments provided and is pleased to submit its reply as follows.

The EU wishes to explain that after the adoption of the draft implementing regulation, the list of antimicrobials included in its annex should be kept under continual review in the light of new scientific evidence or emerging information. This will be explicitly stated in recital (10) of the draft implementing regulation. The process for any modification of the implementing regulation (including of its annex) would be the same as the one followed for the establishment of the implementing regulation. This process would include a scientific assessment led by the European Medicines Agency (EMA), a public consultation and notification for comments to the Secretariat of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

The EU would like to recall that the application of Article 118(1) of Regulation (EU) 2019/6 requires the adoption of a number of measures. The Commission is currently working on the development of a delegated act that will set out the requirements to be met by exports to the EU of animals and products of animal origin to comply with Article 118. In this process, due account will be taken of the need for the operators concerned to take necessary steps to comply with the EU requirements. Moreover, in compliance with the EU's international obligations, the draft delegated act will be notified to WTO SPS Committee. Therefore, Australia will have the opportunity to comment on the draft delegated act before this is adopted by the Commission.

The EU would like to thank Australia again for providing comments on this legislative proposal and hopes that the responses conveyed clarify the raised concerns.

EU Notification Authority and Enquiry Point of the WTO Agreement on SPS measures.
Rue Froissart 101, B-1049 Brussels (Belgium) Tel:+32 (0)2 29 59922, Fax: +32 (0)2 29 98090. Email: sps@ec.europa.eu

This Delegated Regulation provides for details on the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin that are exported from third countries into the Union, which is set out in Article 118(1) of the Regulation (EU) 2019/6.

QUESTIONS THAT MIGHT BE WORTH RAISING/ISSUES OF CONCERN/COMMENTS

1. The use of antimicrobials for the purpose of promoting growth or to increase yield is prohibited. This includes antimicrobials contained in veterinary medicinal products.

   (Para 2) If this includes those antimicrobials that are used only in animals (for example Salinomycin – an Ionophore used to improve growth and increase yields in pigs), this will have trade impacts for Australia. In addition to ionophores, there are three antimicrobial agents registered with growth promotant claims (avilamycin, flavophospholipol and olaquindox), which are **not medically important** to human health.

   a. This might not be a huge problem in the pig industry as we don't export very much pork, but it will likely affect other animal/animal product exports (feedlot beef, poultry products, dairy products etc.) that use antimicrobials contained in vet med products to improve yields/promote growth. And these stricter requirements may encourage other countries to follow suit.

   b. There could be the potential (albeit slight) for the EU to impose a blanket ban on Australia's meat exports (even if they are abiding with the EU regs), if one of our meat industries (e.g. pork) does not meet the EU requirement, irrespective of whether we export that product to EU-member countries or not.

   c. Proof-of-concept AMR surveys in Australian pig, chicken meat and layer chicken industries have shown good results about the current prevalence of resistance against specified antimicrobials in one or more indicator organisms.

2. The prohibition should also apply when antimicrobial medicinal products are administered via medicated feed

   a. It is not clear whether the following still applies, as it would depend on the distinction between medicated feed vs feed additives:
      Based on EU advice on 5 February 2021, animals intended for export to the EU that have been treated with coccidiostats or histomonostats authorised as veterinary medicinal products, with the indication of promoting growth or increasing yield, or products derived from such animals, would be covered by the ban.
      i. This means that coccidiostats or histomonostats used as feed additives will be allowed (i.e. not included in the scope of the ban under Regulation (EU) 2019/6).
      ii. Different methods of oral administration (e.g. rumen boluses) of coccidiostats or histomonostats will be allowed provided they are used as feed additives and not to promote growth or increase yield.

   b. (Para 5) What about antimicrobial medicinal products that are administered in-water medication (which are more efficient, targeted and minimise overuse), or non-feed administration, such as intramuscular? Are these included in the ban?

3. For reasons of effectiveness and reduction of administrative burden, the existing Union framework on official controls is to be used to verify compliance of animals or products of animal origin entering the Union from third countries with Regulation (EU) 2019/6. To this effect

Regulation (EU) 2017/625 has been amended.
The conditions for entry into the Union of consignments of animals or products concerned will be known to third country operators as from the date of publication of this Regulation.

Lack of transparency, opportunity to comment:

a. (Para 6) It would be good to know what this "framework" comprises, and what additional resources and requirements third countries would need to implement to satisfy this framework.

b. (Para 15) It would also be good to know "the conditions for entry" into the EU of animal product consignments *before* the date of publication of this Regulation.

Lack of detail on "specific requirements" to be provided by third countries in relation to the compliance certificates:

c. (Para 13; Arts 4, 6) Consignments should also be accompanied by an official certificate confirming compliance.

d. (Para 14) The Commission should adopt specific requirements on the official certificates.

4. In accordance with the *principle of proportionality*, targeting the use of antimicrobial medicinal products in food-producing animals or products of animal origin intended for human consumption will contribute effectively to address the international dimension of the development of antimicrobial resistance while minimising the impacts on trade.

a. (Para 8) There is high uncertainty regarding how the burden of AMR in humans is apportioned across each of the One Health sectors (including food animal production). Therefore, it is unclear how the "*principle of proportionality*" can be used to realistically (and accurately) justify the extent/proportion of AMR in humans contributable by food animal production.

b. It is unclear how the imposition of EU regulations on third countries, which go above and beyond internationally agreed standards set by international scientific panels, will "*minimise the impacts on trade*". Such bans on third countries act as non-tariff barriers, thereby increasing production and compliance costs of exporting countries, and increasing the costs of animal and food animal imports to the EU, and ultimately EU consumers.

5. Third countries are to be included in a list that is to be drawn up by the Commission, on the basis of available evidence and guarantees that the concerned animals or products originating in them comply with the Union's prohibition. And the Commission shall delete reference to a third country from the list if conditions for inclusion on the list cease to be met.

a. (Para 12), Art 5 Para 1) It would be good to know if third countries that currently export to the EU are automatically included on the list; and the nature/extent of the "evidence and guarantees" that is required, particularly as countries have wide and varying M&E systems.

b. If a country is removed from the list, is there a minimum period before it can be returned to the list, and whether any additional evidence and guarantees will be required?

c. If a country does not use a particular prohibited antimicrobial, how does it provide evidence and guarantees, and how often is this required (e.g. for every export consignment, or only once)?

BACKGOUND

- The application of the prohibition requires the setting up of an effective enforcement system, which currently does not exist under Regulation (EU) 2019/6.
- Regulation (EU) 2017/625 was amended in 2021 to include the verification of compliance with the prohibition in Article 118(1) of the Reg EU 2019/6 by establishing detailed rules its application, including the setting of conditions to be respected by exporters.
- Third countries were consulted by means of a notification to the WTO within the framework of the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures.

THE DETAILS

- The use of antimicrobial medicinal products to promote growth or to increase yield is neither prudent nor responsible.
- Therefore the use of antimicrobials for the purpose of promoting growth or to increase yield is prohibited.
- This includes antimicrobials contained in veterinary medicinal products and human medicinal products.
- Reg (EU) 2019/6 also provides for the procedure for certain antimicrobials to be reserved for the treatment of infections in humans—and are not to be used in antimicrobial products administered to animals.
- Criterial for the designation of antimicrobials reserved for the treatment of infections in humans are laid down in Commission Delegated Reg (EU) 2021/1760, and the list of antimicrobials reserved for treatment of certain infections in humans is set out in Commission Implementing Reg (EU) 2022/1255.
- Operators in third countries are not to use antimicrobial medicinal products to promote growth or to increase yield, and are not to use the designated antimicrobials or groups of antimicrobials reserved for treatment of infections in humans.
- This prohibition should also apply when such antimicrobial medicinal products are administered via medicated feed.
- A robust system of controls is essential to ensure compliance with the requirements laid down in Reg (EU) 2019/6.
- No specific system of controls on imports of animal or products of animal origin exists under the Union framework on veterinary medicinal products.
- Setting up such a system would have necessitated significant amounts of resources and time, and duplication at the level of the competent authorities and also on the operators concerned.
- For reasons of effectiveness and reduction of administrative burden, the existing Union framework on official controls is to be used to verify compliance of animals or products of animal origin entering the Union from third countries with Regulation (EU) 2019/6.
    - To this effect, Regulation (EU) 2017/625 has been amended. Therefore, the verification of compliance with the requirements set out in Article 118(1) of Regulation (EU) 2019/6 is to be done in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

- Consignments of animals and products of animal origin entering the Union that are subject to the prohibition on the use of antimicrobial medicinal products to promote growth, improve yield or use reserved antimicrobials should be clearly set out.
- In accordance with the principle of proportionality, taking such action will contribute effectively to address the international dimension of the development of antimicrobial resistance while minimising the impacts on trade.
- To ensure legal certainty, the animals and products of animal origin concerned should be identified by means of references to the Combined Nomenclature codes set out in Council Regulation (EEC) No 2658/875.
- Products in transit and products intended for the purpose of samples for product analysis and quality testing are exempt.
- Consignments should only be allowed where third countries can ensure compliance with the prohibition on the use of antimicrobial medicinal products.
- Third countries that meet those requirements are to be included in a list that is to be drawn up by the Commission.
- Third countries are to be included on that list on the basis of available evidence and guarantees that the concerned animals or products originating in them comply with the Union's prohibition.
- Consignments should also be accompanied by an official certificate confirming compliance.
- The Commission should adopt specific requirements on the official certificates.
- The conditions for entry into the Union of consignments of animals or products concerned will be known to third country operators as from the date of publication of this Regulation.
- To allow sufficient time to comply with Union requirements, the conditions for entry set out in this Reg should be deferred.

REGULATIONS

- **Regulation (EU) 2019/6** – One of the main objectives of the Regulation is to mitigate the risk of development of antimicrobial resistance, including by strengthening the prudent use of antimicrobial medicinal products. Among others, the Regulation prohibits the use of antimicrobial medicinal products for growth promotion and yield increase, and it forbids the use in animals of medicinal products containing antimicrobials that are reserved for treatment of infections in humans.
- **Regulation (EU) 2021/1760 -** The criteria for the designation of antimicrobials reserved for treatment of certain infections in humans are laid down in Commission Delegated Regulation (EU) 2021/1760.
- **Regulation (EU) 2022/1255 -** The designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans is contained in Commission Implementing Regulation (EU) 2022/1255.
- **Article 118(2) of the Regulation (EU) 2019/6 -** requires third country operators exporting animals or products of animal origin to the Union to respect the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on the use of antimicrobials that have been reserved for the treatment of certain infections in humans.
- **Regulation (EU) 2021/1756** of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs.
- **Council Regulation (EEC) No 2658/87** of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff.
- **Regulation (EU) 2017/625** of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
- **Regulation (EC) No 853/2004** of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
- **Regulation (EU) 2019/4** of the European Parliament and of the Council of 11 December 2018 - on the manufacture, placing on the market and use of medicated feed.
- **Regulation (EC) No 470/2009** of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Wednesday, 25 January 2023 2:37 AM
To: s. 22(1)(a)(ii) (DFAT)
Cc: s. 22(1)(a)(ii)

Subject: RE: EU SPS/n/eu/605 - Antimicrobials [SEC=OFFICIAL]
Attachments: Extract of the Presentation from DG Sante.pdf; Q&A - AMR - Draft Commission Delegated Regulation.docx; 1. Australia comments on G.SPS.N.EU.605 v3 - LM comments.docx

Follow Up Flag: Follow up
Flag Status: Flagged

OFFICIAL

Hi All,

Please find below a readout of the (virtual) meeting that was held on Thursday 12 January between the Commission (DG Sante) and third countries on the Draft Commission Delegated Regulation supplementing Regulation (EU) 2019/6 as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union (hereafter, the 'Draft Delegated Regulation').

Various questions were raised during the meeting by third country representatives. We also raised some questions to reflect on the Australian draft SPS response for EU 605 (see attached document with comments in track changes). I've also attached the list of questions we raised during the meeting and the answers from DG SANTE (see attached Q&A document). Overall, the answers given by DG SANTE showed that the Commission is not willing to put more flexibility to its approach.

Introducing the meeting, s. 47F(1) (DG SANTE – Head of Unit – Medical devices), indicated that:

- Antimicrobial resistance (AMR) is the second cause of death in the world and is a *"real global threat to public and animal health". "This is why we are acting at the EU level".*
- EU Regulation 2019/6 on veterinary medicinal products ("the Vet Med Regulation" - **VMP**) which has been applicable since February 2022 is *'in line with the One Health approach' ' the only efficient approach to tackle AMR'.*
- The EU is acting in full transparency in accordance with its WTO obligations. *"All relevant drafts were notified to the WTO"* and the EU *"replied to all observations received".*
- The Draft Delegated Regulation applies Article 118 of EU Regulation 2019/6 of the Vet Med Regulation on animals or products of animal origin imported into the EU.
- *"AMR does not stop at borders". "This is why the Vet Med Regulation applies to goods exported to the EU". "it is not a trade barrier".* The Vet Med Regulation even *"imposes stricter rules on EU operators than on third country operators".*
- The Draft Regulation establishes *"a balance"* between the necessity to fight AMR, while minimizing the impacts on trade.
- *"Cooperation is key on this issue". "We will continue to engage with our trade partners to contain AMR".*

s. 47F(1) (DG SANTE – Head of Unit Veterinary Medicines) then conducted a presentation analysing the Draft Regulation article by article.

- As a preliminary remark, s. 47F(1) indicated that third countries will have until 6 February 2023 to comment on the Draft Delegated Regulation.
- She then recalled the purpose of the Draft Delegated Regulation which is to ban the export to the EU of animal or products of animal origin which have been administered with the antimicrobial medicinal products

(hereafter '**AMP**') referred in its Article 3 (i.e., AMP used for the purpose of promoting growth or to increase yield; and AMP containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255) (Article 1). She also indicated that Implementing Regulation (EU) No 2022/1255, which sets the list of antimicrobials reserved for human, will be applicable as from 9 February 2023.

- On **EU official controls** (Para 6): s. 47F(1) mentioned that EU Regulation 2017/625 setting up the EU legal framework on official controls on animals and products of animal origin exported to the EU (hereafter the 'Official Control Regulation ' - **OCR**) was amended to reflect the changes brought by Article 118 of the Vet Med Regulation. The Official Control Regulation will therefore provide for an **EU single framework** for official controls for animal & animal products, which according to s. 47F(1) *"is an important step to facilitate exports to the EU"*. Verification of compliance with the requirements set in Article 118 of the Vet Med Regulation (and the Draft Delegated Regulation) will therefore be done in accordance with the OCR.

- On the **scope** of the EU Draft Delegated Regulation (Article 1) : s. 47F(1) indicated that the Draft Delegated Regulation only applies to live-food producing animals and product of animal origin:
  - that are intended for human consumption
  - whose tariff codes are provided in the Draft Regulation. Answering a question from the US, Eva specified that *"any commodities whose tariff code is not in the Regulation will not be covered within its scope".*

  Certain commodities are expressly excluded from the scope of the Draft Regulation (e.g. **composite products**, wild animals, products in transit through the EU, etc.).
  DG SANTE confirmed that feed additives are not covered by the Draft Regulation. As such, coccidiostats or histomonostats marketed as feed additives would be allowed under the Draft Delegated Regulation.

- On the **conditions for entry into the EU** (Article 4): s. 47F(1) recalled that the exported commodities must:
  - Originate from a country listed in the list of approved third countries;
  - An official Certificate must accompany the consignment.

- On the establishment of the **list of approved third countries** (Article 5):
  Answering a question from Brazil, s. 47F(1) indicated that the inclusion of third countries in this list will depend on the warranties they will be able to provide. For this purpose, **third countries will have to provide written statements certifying that warranties will be put in place to comply with the new requirements and that there are systems/controls in place to ensure this**. Examples of such warranties include the following:
  - AMR that are listed in EU Regulation No 2022/1255 are not used in the exporting country;
  - The exporting country already have those controls in place, etc.

  Argentina asked '*why the EU needs to establish a new list (in relation to the Vet Med Regulation) when there are already lists of countries authorised to export animal products to the EU?*' Eva specified that this is a new list which is linked to the new requirements set in the Vet Med Regulation. She also indicated that in case of non-compliance issues, the conditions will not be met and that third countries will be removed from the list. **The Official Control Regulation will be amended to include this new list** once it is established on the basis of the guarantees provided by third countries.

- On **certification of compliance** (Article 6), s. 47F(1) specified that **an attestation requirement will be added to existing EU official certificates** (e.g., certificate on export of fresh meat). The attestation will have to certify that the products exported to the EU comply with the Vet Med Regulation and other applicable requirements. Private attestations (e.g. companies' declarations) won't be considered by the Commission as a certification option, *"as in this case, this will not be an official certification"*. **The legal acts laying down the relevant models of official certificates** (e.g. Commission Implementing Regulation EU 2020/2235) **will be amended so that the attestation model can be added to those certificates**.

- **Entry into force** of the Draft Delegated Regulation (Article 8): the new requirements set in the Draft Delegated Regulation will **apply 2 years after the entry into force of the Implementing acts** (e.g. Implementing Regulations amending the OCR to provide for the list of authorised third country - and the existing official certificates to include the attestation model). Eva indicated that it will take several months for those Regulations to be adopted.

- After 6 February, the Commission will consider if the Draft Delegated Regulation is to be amended on the basis of the comments received.
- The Draft text will then go to the Council of the EU and the European Parliament which will have two months to object to the text (delay which can be extended to 2 months) before the text is published (i.e. **not before mid-April/May 2023**)
- Only then, the Commission will start the process re. the elaboration of the implementing acts (which will go through the standing committee)**.**

s. 47F(1) concluded on this point by saying that *"in the end you will have much more than 2 years to implement the new rules".*

Concluding the meeting, s. 47F(1) indicated that "*we recognise that we are not the simplest Regulator" "but are at your disposal"* to provide clarification on the new requirements.

I'll send you the Power Point that was presented by s. 47F(1) , as soon as it is available on the Commission website. In the meantime, I have attached the two last slides of the presentation (pics), which provide a summary of the new EU legal framework on the matter.

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

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Wednesday, 18 January 2023 5:09 AM
To: s. 22(1)(a)(ii) @dfat.gov.au>
Cc: 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. 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. 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>
Subject: RE: EU SPS/n/eu/605 - Antimicrobials [SEC=OFFICIAL]

Hi s. 22(1)

Attached is an updated draft SPS response for EU 605 (Antimicrobials). Many thanks to Jay and others for input so far.

Appreciate if you would contribute any feedback from your meeting with the EU on this issue on 12 Jan.

If anyone else has any further comment – appreciate if you would send that through.

The deadline for submitting this SPS response to the EU is 6 Feb 2023. Noting clearance time and coord etc I am aiming to finalise this by early next week if possible.

Many thanks, s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, 9 January 2023 11:54 AM
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>; 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. 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) @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: EU SPS/n/eu/605 - Antimicrobials [SEC=OFFICIAL]
Importance: High

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

I've also attached the notes and feedback I put together which went to s. 22(1)(a)(ii) and s. 22(1)(a)(ii) in December.
I think s. 22(1)(a)(ii) might still be on leave, so have cc'd s. 22(1)(a)(ii) into this email.

In response to your comments to me in attachment 3 (EU.605.v2):

Re: Point 2: Administration in water etc. is discussed in 2019/6, Article 106 (6). Ok thanks

Re: Point 3: Framework of 2017/625 is already in place, so I am unclear on this point. Article 5 (2) of the proposed legislation seems to specify? Can we be more specific on this concern.

My understanding is that the regulation has been amended, but the framework and conditions of entry are yet to be defined/published. It would be good to know what these "conditions of entry" will be before they are formally published and implemented.

Hope this clarifies.

Cheers s. 22(1)(

From: s. 22(1)(a)(ii) @aff.gov.au>
Sent: Monday, 9 January 2023 10:35 AM
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>; 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. 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) @dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii)@aff.gov.au>
Subject: EU SPS/n/eu/605 - Antimicrobials [SEC=OFFICIAL]

Hi s. 22(1)(a)

s. 22(1)(a)(ii) shared your earlier comments on this SPS notification with me. We have prepared a draft SPS response (attached).

I understand that you and others on this email have relevant experience and history on this issue so appreciate your input on this text.

I gather that s. 22(will meet with the EU concerning this issue on the 12th so expect that comments would also assist with those discussions.

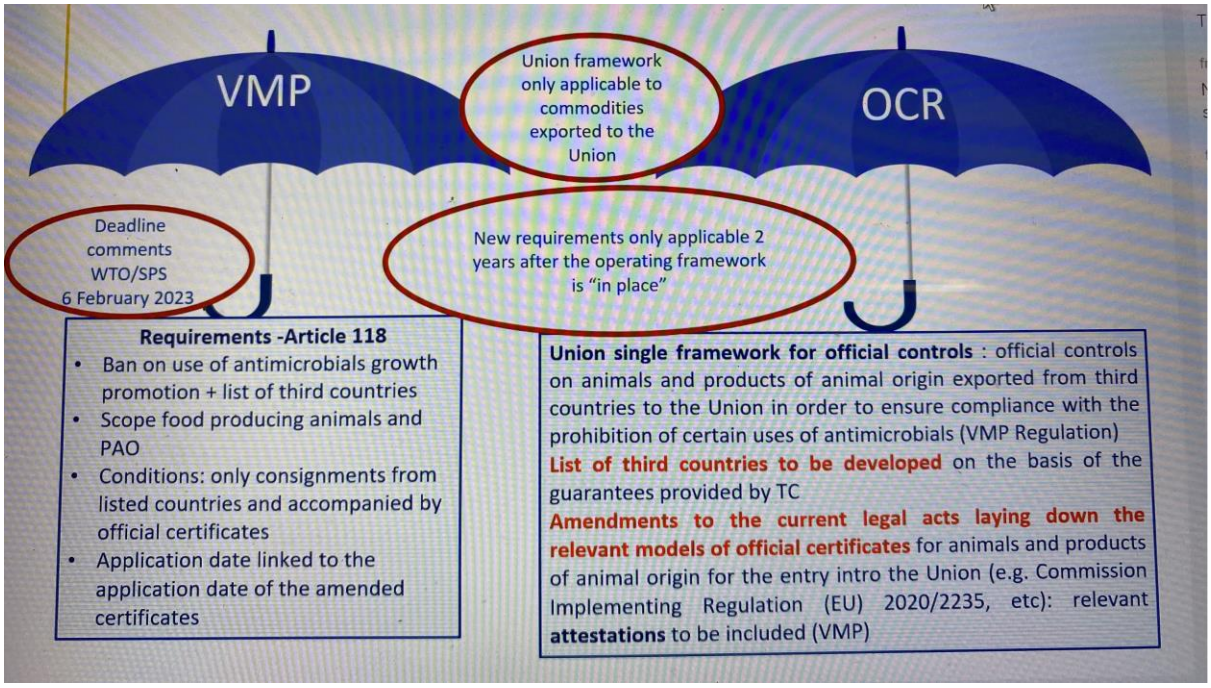
Cheers, s. 22(1)(a)(ii)

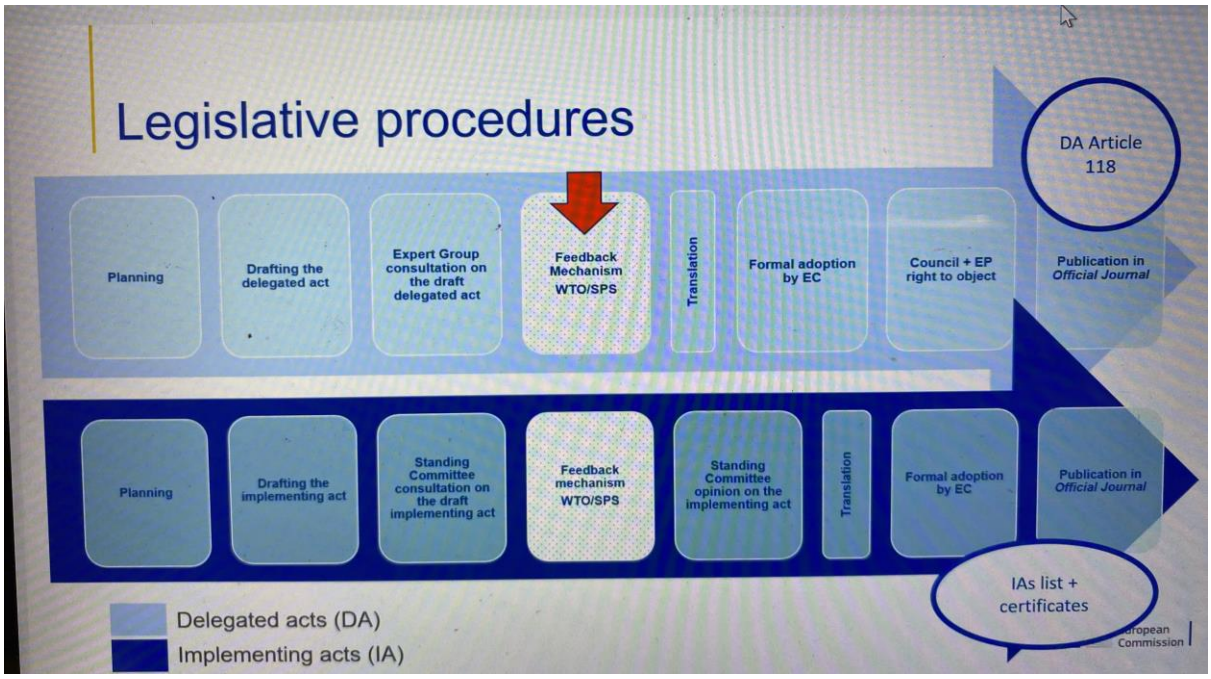
+s. 22(1)(a)(ii)

Extract of the Presentation from DG Sante for the meeting with third countries on the Draft Commission Delegated Regulation Supplementing Regulation (EU) 2019/6 as regards the application of Article 18

Dr. s. 47F(1) **Head of Unit Veterinary Medicines**

12 January 2023





Draft Commission Delegated Regulation Supplementing Regulation (EU) 2019/6 as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union (G/SPS/N/EU/605)

Key Questions raised by Australia during the (virtual) meeting of 12 January Between the Commission (DG SANTE) and third countries

I. Scope of the Draft Regulation

1) Question:

The prohibition of use of antimicrobial medicinal products provided in the Draft Regulation applies to the products referred in Article 3 (i.e., antimicrobial medicinal products used for the purpose of promoting growth or to increase yield; and antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255), including when they are administered as medical feed (para 5 and Article 2.2). However, feed additives are not part of the scope of the Draft Regulation and thus, are not covered by the prohibition. This means that coccidiostats or histomonostats authorised as veterinary medicinal products, with the indication of promoting growth or increasing yield would be covered by the ban. However, coccidiostats or histomonostats marketed as feed additives would be allowed. Could you please confirm if our understanding is correct?

- Response from DG SANTE: Your understanding is correct, as **feed additives are not covered by the Draft Regulation**.

II. Compliance issues

2) Question:

Could you please clarify what will be the requirements (notably referred in Article 6) to show compliance with the Draft Regulation?

- Response from DG SANTE: **An attestation requirement will be added to existing EU official certificates** (e.g., certificate on export of fresh meat). The attestation will have to certify that the products exported to the EU comply with the Vet Med Regulation and other applicable rules. Private attestations (e.g., companies' declarations) won't be considered by the Commission as a certification option, *"as in this case, this will not be an official certification"*. **The legal acts laying down the relevant models of official certificates** (e.g., Commission

Implementing Regulation EU 2020/2235) **will be amended so that the attestation model can be added to those certificates**.

3) Question:

Could you please indicate what would be the practical options to avoid unnecessary costs linked to consignment-based certification for operators and third country authorities who have undertaken their own risk assessments and no reasonable AMR risk has been identified to consumers?

- Response from DG SANTE: s. 47F(1) answered that the Commission is establishing EU requirements for imports and that there are no alternatives to consignment-based certification (even for countries who carry their own risk assessments). *"We are not importing on the basis of the risk assessments"* carried out in third countries.

4) Question:

Could you please specify if the Draft Regulation will impose new requirements for residue testing of products of animal origin exported from third countries to the EU?

- Response from DG SANTE: No, the Draft Regulation **will not impose new requirements for residue testing**.

III. Implementation period

5) Question

The Draft Regulation will apply as from 24 months after the date of application of an implementing act (Article 8). Could you please indicate if longer transition time will be considered for animal products which originate from animals whose production cycle is more than two years (e.g., dairy cows 4-5 years)?

- Response from DG SANTE: s. 47F(1) answered that it will take several months for the implemented acts to be adopted, which **will add up to the 24-transition time** provided in Article 8. *"This will leave third countries sufficient time to implement the new rules".*

Australian Government

Comments from the Australian Government to the European Union on Draft Commission Delegated Regulation supplementing Regulation (EU) 2019/6 as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union (G/SPS/N/EU/605).

1. General comments

Australia thanks the European Union (EU) for the opportunity to comment on the draft Regulation that develops the requirements to be met by animals and products of animal origin, intended for human consumption, exported from third countries to the Union in connection with the ban on the use of antimicrobials for growth promotion and yield increase and the ban on the use of certain antimicrobials reserved for treatment of infections in humans (Commission Implementing Regulation (EU) 2022/1255) set out in Regulation (EU) 2019/6.

Australia has also taken action to mitigate antimicrobial resistance (AMR) risks and protect human and animal health. However, Australia remains concerned about the EU's approach with regard (1) a broad prohibition on the use of any antimicrobial medicinal product used for the purpose of promoting growth or to increase yield may encompass products that do not invoke significant AMR risks to health that this legislative package intends to mitigate and (2) the transparency of the process for future selection of compounds to be added to the reserved list.

Australia also makes several further observations regarding the text.

2. Specific comments

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

- Australia seeks further clarification on certain products used as coccidiostats and histomonostats [e.g. lasalocid] with regard these rules and definitions. Regulation (EC) 1831/2003 of the European Parliament and of the Council of 22 September 2003 on

additives for use in animal nutrition indicated that provided such products are marketed as feed additives and did not include growth/yield claims these would be allowed.

> *Article 5 conditions for authorisation - 3. The feed additive shall. [..]*
> *(f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or*
> *(g) have a coccidiostatic or histomonostatic effect.*

This demonstrates an acknowledgement that long term usage of these compounds does not result in any relevant AMR risk. The EU rules are therefore unnecessarily capturing products that do not result in relevant AMR risk and are unnecessarily interfering with national regulatory approaches (i.e. label claims).

- Australia also maintains that imposing restrictions on third party countries exporting to the European Union is not appropriate where those third-party countries have undertaken their own risk assessments and no reasonable AMR risk has been identified to consumers. Australia further notes that it does not permit any use of colistin or fluoroquinolone antimicrobials on food producing animals in Australia, yet Australia has not proposed any similar restriction on Australian imports of animal products from the EU where such antimicrobials are used. We continue to request assurance that any future revisions of the reserved list will follow a science-based and consultative process.
- Australia seeks written confirmation on Article 1 point 3 *This regulation does not apply to the following*: (g) *animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the union.* Please confirm the advice given at the 12 January 2023 meeting that destination in this context means the intention to place on the market for human consumption.
- Australia seeks clarification on the entry into force. Article 8 states that the conditions of entry will apply as from 24 months after the date of application of an implementing Act. Australia maintains that implementation over 24 months is short considering typical animal production cycles (e.g. dairy cows 4-5 years) noting that the wording of the proposed regulation appears to imply animal freedom from treatment prior to the implementation of the regulation (rather than stopping further treatment from the implementation date).
- Australia notes that the EU will amend official certificates to include these new requirements. Australia and the EU currently use electronic certification for edible

meat, dairy and fish products. Australia requests assurance that the EU will provide the new EU model certificates in TRACES-NT sufficiently (e.g. 6-months) in advance to allow sufficient time to make the necessary changes to our corresponding electronic certification system.

Conclusion

Australia welcomes the EU's consideration of the concerns and points raised in this submission. We value our ongoing collaboration with the EU on the development of food safety standards.

THE MEAT INDUSTRY/GOVERNMENT FOOD SAFETY PARTNERSHIP	MEETING NO: **Advisory Group No. 17** DATE: **8 March 2023** LOCATION: **MS Teams** AGENDA ITEM: 4f

FOR INFORMATION
COMMITTEE-IN-CONFIDENCE

Update on EU Regulation (EU) 2019/6 implementation - prohibition of certain antimicrobials

RECOMMENDATION

1. That Advisory Group **NOTE** the update on EU Regulation (EU) 2019/6 implementation and prohibition of certain antimicrobials.

PURPOSE

To update Advisory Group of anticipated implications to Australian exports of the implementation of the EU ban on the use of antimicrobials for growth promotion and yield increase and the ban on the use of certain antimicrobials reserved for treatment of infections in humans.

SUMMARY

1. The implementation of this 2019 EU regulation that aims to mitigate antimicrobial resistance risks is progressing.

2. The reserved list in force from 9 February 2023 (Commission Implementing Regulation (EU) 2022/1255) is not anticipated to have any impact on Australian export industries as none of the actives are registered for use in livestock in Australia, as concluded by Department of Agriculture, Fisheries and Forestry (DAFF) internal and MLA investigations. Noting that this list is under 'continual review', we continue to advocate that any additions to the reserved list be science-based and consultative.

3. The ban on the use of antimicrobials for growth promotion and yield increase (to be implemented 24 months after a future implementing Act) is anticipated to impact use of flavophospholipol (bambermycin) and ionophore products where (1) the product has label claims for growth promotion or yield increase and (2) these are used in (or not distinguishable from) the EU export product supply chain.

ISSUES

4. The ban on the use of antimicrobials for growth promotion and yield increase captures Australian registered products, flavophospholipol (bambermycin) and some ionophores. Some other antimicrobials are captured but are not of current concern as we do not export that production class to the EU – these are farmed chicken (avilamycin) and farmed pig products (olaquindox).

5. Flavophospholipol labels include statements such as 'improvement of productivity by stimulating the growth rate…" and "for growth promotion" and are marketed as feed supplements. Consideration of potential mechanisms to effectively restrict the use of flavophospholipol products in the EU supply chain may be needed to preserve trade.

6. For the ionophores, EU advice has confirmed that these products may be marketed as feed additives provided that they do not include growth/yield claims.

Note: Regulation (EC) 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

> Article 5 conditions for authorisation - 3. The feed additive shall. [..]
>
> (f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or
>
> (g) have a coccidiostatic or histomonostatic effect.

7. Label claims on some ionophore products, such as "for improved liveweight gains" and "improvement in milk production" or similar (e.g. lasalocid, monensin, salinomycin labels) may become problematic, depending on the wording of necessary guarantees required by the EU. However, the use patterns of these products in practice is anticipated to be largely unaffected.

8. While the EU position infers an acknowledgment that there is no relevant antimicrobial resistance risk to be managed for the coccidiostats, representations on this issue have so far been unsuccessful.

9. Further detail on the new EU certification requirements, necessary guarantees to maintain EU market access and more detail on permitted label claims is anticipated later in 2023.

BACKGROUND

10. The EU recently notified via the WTO (EU SPS605) the text of a draft supplementing Regulation that develops the requirements to be met by animals and products of animal origin, intended for human consumption, exported from third countries to the Union in connection with the ban on the use of antimicrobials for growth promotion and yield increase and the ban on the use of certain antimicrobials reserved for treatment of infections in humans.

11. The following background text is taken from the explanatory memorandum of the draft regulation notified in SPS605.

> *Article 118(1) of the Regulation (EU) 2019/6 requires third country operators exporting animals or products of animal origin to the Union to respect the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on the use of antimicrobials that have been reserved for the treatment of certain infections in humans.*
>
> *Article 118(2) of the Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts providing detailed rules on the application of the above-referred prohibitions.*
>
> *The application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin that are exported from third countries into the Union requires the setting up of an effective enforcement system. As a system permitting controls of animals or products of animal origin imported into the Union does not exist under the Regulation (EU) 2019/6, resort has been made to the Union framework on official controls. Specifically, the Regulation (EU) 2017/625 was amended in 2021 to include the verification of compliance with the prohibition in Article 118(1) of the Regulation (EU) 2019/6 within the scope of the Union framework on official controls.*

12. With regard the implementation date (entry into force), when effective controls and guarantees need to be in place, the following is from the draft regulation notified in SPS605.

The conditions for entry into the Union of consignments of animals or products set out in this delegated act shall apply as from 24 months after the date of application of the implementing act referred to in Article 6(1).

[note that the implementing Act referred to is expected in the future]

CONSULTATION

13. APVMA was consulted in the development of this paper.

Prepared by: s. 22(1)(a)(ii) DAFF, s. 22(1)(a)(ii) @aff.gov.au

Cleared by: s. 22(1)(a)(ii) (for s. 22(1)(a)(ii)), DAFF, s. 22(1)(a)(ii) @aff.gov.au

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH & FOOD SAFETY

One Health
Multilateral International Relations

Brussels,
SANTE A4 VS/tt (2023)

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/605**		

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/605.

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/605 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 it has made on the legislation notified to the WTO in notification G/SPS/N/EU/605.

The EU has carefully examined the comments provided and is pleased to submit its reply as follows.

Regarding future revisions of the reserved list laid down in Commission Implementing Regulation (EU) 2022/1255[1], the EU would like to kindly refer you to the reply of the EU to the comments sent by Australia to the legal draft in notification G/SPS/N/EU/557[2].

The EU wishes to underline that the scope of the notified draft delegated Regulation is to establish detailed rules on the application of the provisions in Article 118(1) of Regulation (EU) 2019/6[3] on veterinary medicinal products. Article 118(1) refers to Article 107(2) of Regulation (EU) 2019/6, which requires that no antimicrobial medicinal product shall be used for the purpose of promoting growth or to increase yield. 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)).

As regards your comment on Article 1(3) of the notified draft delegated Regulation, it states that "*this regulation does not apply to the following […]: (g) animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the Union*". The wording '*the destination of the animals or products has not been decided*', in this context, refers to the placing on the market for human consumption. The absence of a definitive destination at the moment of entry into the Union implies that the concerned animals or products could be placed on the market for human consumption at a later stage and therefore, they should fall under the scope of the notified draft delegated Regulation.

As for the date of application referred to in Article 8 of the notified draft delegated Regulation, this will be set in the implementing Regulations referred to in Article 6(1) of the notified draft Regulation. In this process, due account is being given to the need for third countries' concerned operators and competent authorities to take the necessary steps to comply with the EU requirements. In this respect, the conditions for entry into the Union of consignments of animals or products shall only apply as from 24 months after the date of application of the implementing Regulation Referred to in Article 6 of the draft delegated Regulation. The EU would like to underline that, in compliance with the EU's international obligations, the above-mentioned draft Implementing Regulation will be notified to the Secretariat of the WTO, Committee on Sanitary and Phytosanitary Measures (the SPS Committee). Therefore, Australia will have the opportunity to comment on the draft implementing Regulation before they are adopted by the EU.

---

[1] Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191/58, 20.7.2022, p.58).

[2] Our reference Ares (2022)4957394- 07/07/2022.

[3] 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).

The EU will provide the amended model certificates in TRACES-NT in due course.

The EU would like to thank Australia again for providing comments on this legislative proposal and hopes that the responses conveyed clarify the raised concerns.

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Wednesday, 14 June 2023 12:39 AM
To: s. 22(1)(a)(ii)

Cc: s. 22(1)(a)(ii)
Subject: Vet Med / COM-TC Meeting of 8 June / Readout [SEC=OFFICIAL]
Attachments: DG SANTE Presentations - Extract - COM-TC meeting of 8 June.docx; Australia.pdf; Annex to letter - TC requirements article.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

OFFICIAL

Hi all,

Please find below a readout on the informative session that was held on 8 June between the Commission (DG SANTE) and third countries on the implementation of Commission Delegated Regulation (EU) 2023/905 on the prohibition of certain antimicrobials in animals/animal products exported to the EU, which was adopted on 27 February 2023 (hereafter, the 'Delegated Regulation').

EU speakers (DG SANTE):
s. 47F(1) Head of Unit - Deputy Director General for Health responsible for Directorates B, C and D - Medical Products and Innovation - Veterinary Medicines
s. 47F(1) , Head of Unit - Deputy Director General for Food Sustainability

There were 3 topics on DG SANTE's agenda for this session:

1. The **elaboration of the list of third countries** authorised to export animals/animal products to the EU (hereafter, the 'list of approved countries) (Article 5 of the Delegated Regulation). The Commission also discussed the warranties to be provided by third countries to be included in the list via the **information template** annexed to the letter sent by the Commission to third countries on 23 May 2023 (see attached documents).
2. **Certification of compliance** with the Delegated Regulation and EU Vet Med rules (in particular, Article 118 of the EU Vet Med Regulation (2019/6). (Article 6 of the Delegated Regulation).
3. **Entry into force and application** of the Delegated Regulation (Article 8 of the Delegated Regulation).

DG SANTE provided useful clarifications on how to implement the Delegated Regulation and complete the information template. More flexibility was showed (in comparison with DG SANTE's last third country meeting of 12 January 2023) notably regarding timeframe for compliance, as it was indicated that an additional transition period (than the 24 months provided in the Delegated Regulation) could be provided in the forthcoming implementing Regulation amending the relevant models of official certificates (see details below). DG SANTE also committed to meeting/discussing more with third countries on the topic and provide further clarifications if needed.

There were many comments & questions raised by third country delegates present on the call, which pointed out to:

- The **lack of clarify** of the Delegated Regulation, template and timeframe for compliance with the new rules. In particular third country delegates (e.g. Canada) asked for more details & guidance on the types of controls expected from third country authorities to ensure compliance.
- The **heavy burden** represented by the new requirements (e.g. the consignment-based certification requirements and the warranties to be put in place for third countries to be included in the list).
- Doubts were also expressed regarding the **WTO compatibility** of the new rules.

More specifically:

1. **On the list of approved countries and information template**

DG SANTE indicated that:

- The list of authorised third countries 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 information template. Third countries have six months (i.e., by November 2023) to complete and submit the template to DG SANTE. In order to be eligible to export animals/animal products to the EU, third countries must be listed in this list but also in all the other relevant EU lists. The objective according to DG SANTE is to show compliance with EU rules related to animal health, residue plants and antimicrobial resistance (AMR).
- Once the warranties received, the Commission will start elaborating the list, which will be subject to the Member States' opinion and then notified to the WTO SPS Committee.
- All questions and boxes provided in the template must be answered/completed. In case of inconsistencies or if the answers provided are considered as insufficient, the Commission will revert to third countries so that the missing/inconsistent information can be provided.
- **All the national authorities involved in the process must be identified** in the template.
- Third country delegates expressed difficulties with regard to the control and traceability requirements to be put in place to ensure compliance with the new rules, notably to ensure that:
    - The **segregation system** in place works effectively to ensure that antimicrobials used domestically for promoting growth or increasing yield have not been administered to the 'food-producing animal species' and products therefrom intended for export to the EU market (see statement 6 of the template).
    - Animals/animal products sourced from other third countries which are intended to be exported to the EU, comply with the EU rules (e.g. ingredients originating in Country A, further processed in Country B and exported to the EU). For this purpose the third country from which the products are sourced from (Country A in our example) must be listed in the EU list of approved third countries and provide the guarantees/warranties that the products comply with the EU Vet Med rules. However, if the ingredients originate from an EU Member State, those guarantees will not be needed. Jo and other delegates (e.g. Canadian Delegate) expressed doubts regarding the WTO compatibility of this double standard. In response, the EU indicated that *"we don't need to ask warranties from ourselves as we know what we have in place"*.
- At this stage, the Commission is only expected some commitments from third countries that the controls are put in place to ensure compliance with the EU Vet Med rules. However, as specified by John McEvoy, *"at one point in the future the Commission **audit** services will seek to verify whether or not the controls are in place meet the requirements".* Eva Zamora also specified that *"we will base our decisions on your statements. The day where colleagues are conducted audit they will check this".*
- DG SANTE tried to be reassuring indicating that *"we are not being prescriptive regarding the methods to be put in place to provide the warranties" "The fact that you have the legislation and controls in place is already a warranty".*

DG SANTE encouraged third countries to submit the completed information template before the deadline, so that the list of approved countries can be published as soon as possible.

2. **On the certification requirements**

- 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.
- DG SANTE showed examples of possible attestation models in its presentation (see attached document, pages 13-14). These are only preliminary versions which will be subject to further internal consultations.

3. On the entry into force and application of the new requirements

- As specified in Article 8 of the Delegated Regulation, the new EU rules will enter into force 24 months after the date of application of the Implementing Regulation amending the certificates.
- DG SANTE was unable to provide a precise date for adoption of the implementing Regulation but indicated that a draft could be discussed with EU Member States after summer and notified to the WTO SPS Committee afterwards.
- The US Delegate raised a question regarding the **risk of retroactive application** of the new rules, asking about the Commission's intentions to *"make sure that products produced before the adoption of the Delegated Regulation won't be impacted".*
- DG SANTE answered that a precise date for entry into force of the new rules will be provided in the Implementing Regulation – with a possible additional transition period to be included in this Regulation – although no certainty was provided on this point.
- DG SANTE reminded Delegates that *'as from the date of application of the Implementing Regulation the conditions will be applicable. If the commodities are not in compliance with the requirements – you will not be in position to export the product to the EU".*
- DG SANTE indicated that third countries will have time to adapt to the new rules *"you will have enough time to take preparatory measures".*

Although DG SANTE was enable to provide a precise date for entry into force of the new rules, we expect that the Implementing Regulation will be adopted around the end of this year/beginning of next year. This means that the new rules (the Delegated Regulation) should enter into force by the end of 2025/ beginning of 2026. This may be more if the Commission decides to add an additional transition time in the implementing Regulation, although we don't expect the Commission to grant much more than the two years already provided under the Delegated Regulation.

I have attached some extracts of DG SANTE's power point presentations. I'll send the full presentations once available on their website.

Happy to answer and question/comment you may have on the topic.

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

s. 22(1)(a)(ii)
WTO & Research Officer (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
s. 22(1)(a)(ii)@dfat.gov.au
s. 22(1)(a)(ii)

Meeting between the European Commission and Third Countries on next steps concerning the implementation of Commission Delegated Regulation (EU) 2023/905 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

June 8th, 2023 (Webex)

Ref. Ares(2023)3375369 - 15/05/2023

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

One Health
Medical products and Innovation
(Acting) Directors

Meeting between the European Commission and Third Countries on next steps concerning the implementation of Commission Delegated Regulation (EU) 2023/905 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

8 June 2023

10:00 to 13:00 (Brussels time)

Virtual meeting

AGENDA

1. Introduction

2. Information and exchange of views on next steps concerning the implementation of Commission Delegated Regulation (UE) 2023/905 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

   - List of approved third countries (Article 5)
   - Certification of compliance (Article 6)
   - Entry into force and application (Article 8)

3. AOB

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

Article 118: Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.
2. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Article by **providing the necessary detailed rules on the application of paragraph 1 of this Article**

Article 107: Use of antimicrobial medicinal products

2. Antimicrobial medicinal products **shall not be used in animals for the purpose of promoting growth nor to increase yield**

Article 37: Decisions refusing marketing authorisation

5. The Commission shall, by means of **implementing acts**, **designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

European Commission

Article 37: Decisions refusing marketing authorisation

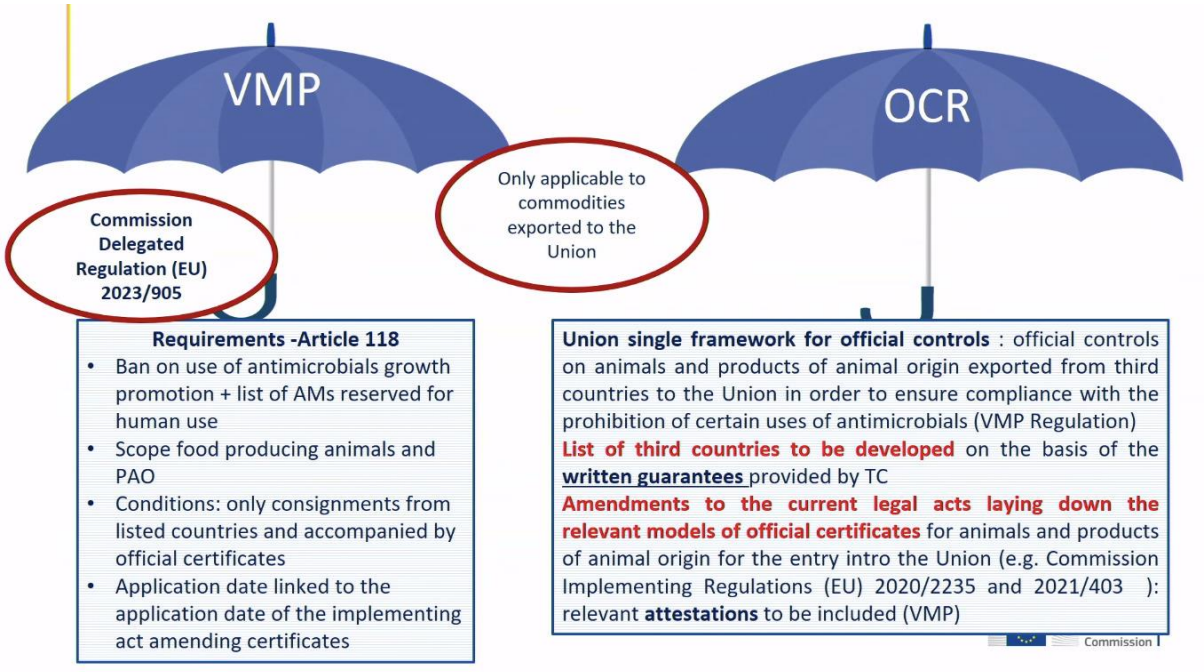
4. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Regulation by **establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans** in order to preserve the efficacy of those antimicrobials
5. The Commission shall, by means of **implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

Commission Delegated Regulation (EU) 2021/ 1760 (criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans)

Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

- **It shall apply from 9 February 2023**

European Commission



Commission Delegated Regulation (EU) 2023/905 of 27 February supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 1

Subject matter and scope

1. This Regulation lays down detailed **rules on the application of the prohibition of use, in animals or products of animal origin that are exported from third countries into the Union, of antimicrobial medicinal products for growth promotion and yield increase, and antimicrobials reserved for treatment of certain infections in humans.**

2. This Regulation applies to live **food-producing animals** for which Combined Nomenclature codes ('CN codes') have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87.

   This Regulation also applies to **products of animal origin intended for human consumption**, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16, of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings have been laid down under headings 3501, 3502 and 3504.

European Commission

3. This Regulation **does not apply** to the following:

(a) gelatine and raw materials for the production thereof referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council;

(b) collagen and raw materials for the production thereof referred to in Section XV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(c) highly refined products referred to in Section XVI, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(d) wild animals and products derived therefrom;

(e) insects, frogs, snails and reptiles, including products derived therefrom;

(f) composite products;

(g) animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the Union;

(h) animals or products of animal origin intended for human consumption only for transit through the Union without being placed on the market;

(i) products of animal origin intended for human consumption for the purpose of sampling for product analysis and quality testing without being placed on the market.

Commission Delegated Regulation (EU) 2023/905

Article 3

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

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

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

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255.

Commission Delegated Regulation (EU) 2023/905

Article 4

Conditions for the entry into the Union

1. Consignments of the animals or products referred to in Article 1(2) shall only enter the Union where the following conditions are met:

   (a) they originate from a **third country or region thereof included in the list of countries** referred to in Article 5, and

   (b) they are **accompanied by an official certificate** referred to in Article 6 attesting that the consignment complies with the requirements in Article 3.

2. By way of **derogation** from paragraph 1, point (a), consignments of the animals or products referred to in Article 1(2) may enter the Union from third countries that are not included in the list referred to in Article 5(1), where such third countries ensure that the consignments entering the Union originate from a Member State or from a third country included in the list.

Commission Delegated Regulation (EU) 2023/905

Article 5

List of approved third countries

1. The list referred to in Article 4(1), point (a), is **to be established by means of an implementing act adopted by the Commission in accordance with Article 127 of Regulation (EU) 2017/625**. If appropriate, that list may be combined with other lists developed under Article 127 of Regulation (EU) 2017/625.

2. The Commission shall decide on the inclusion of third countries in the list in accordance with the requirements laid down in Article 127(3), points (a) to (d), and points (f) and (g), of Regulation (EU) 2017/625, on the basis of **available evidence and guarantees** that the requirements laid down in Article 3 are complied with, including information received on the procedures in place to guarantee the traceability and origin of animals or products referred to Article 1(2).

3. In accordance with Article 127(4) of Regulation (EU) 2017/625, the Commission shall delete the reference to a third country or a region of a third country from the list if the conditions for inclusion in the list cease to be met.

Commission Delegated Regulation (EU) 2023/905

Article 6

Certification of compliance

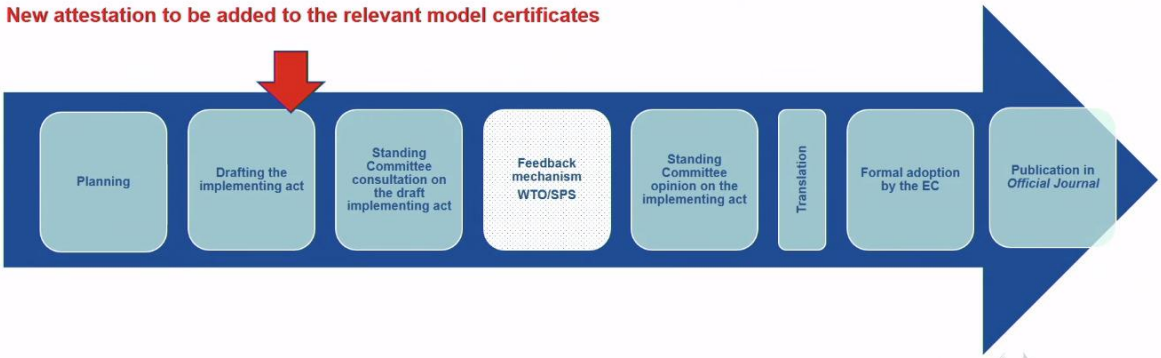
1. **Specific requirements on the official certificates** referred in point (b) of Article 4(1) **are to be laid down by the Commission**, by means of implementing acts, in accordance with the examination procedure referred to in Article 126(3) of Regulation (EU) 2017/625.
2. The official certificates may include details required in accordance with other Union legislation on public and animal health matters.

European Commission

Certification of compliance

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 entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals

New attestation to be added to the relevant model certificates



European Commission

Commission Delegated Regulation (EU) 2023/905

Article 7

Controls

Controls to verify compliance of consignments of the animals or products referred to in Article 1(2) with Article 3 shall be carried out in accordance with Regulation (EU) 2017/625.

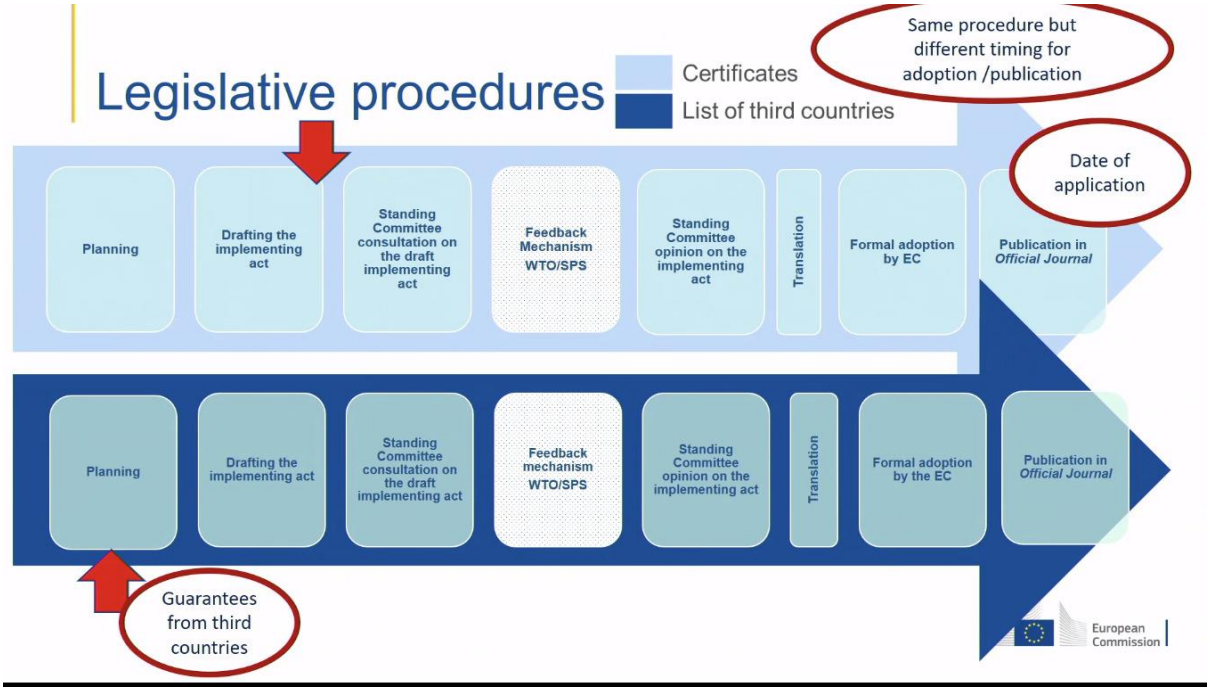
Article 8

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

The conditions for entry into the Union of consignments of animals or products set out in this delegated act shall apply as from 24 months after the date of application of the implementing act referred to in Article 6(1) [certificates]

European Commission



Where can you follow progress?

https://europa.eu/!rJ63kT

European Commission

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

Article 118: Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.
2. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Article by **providing the necessary detailed rules on the application of paragraph 1 of this Article**

Article 107: Use of antimicrobial medicinal products

2. Antimicrobial medicinal products **shall not be used in animals for the purpose of promoting growth nor to increase yield**

Article 37: Decisions refusing marketing authorisation

5. The Commission shall, by means of **implementing acts**, **designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

European Commission

Specifications as regards the listing of third countries and the amendments of the official export certificates

Brussels, 8 June 2023

Listing of Third Countries

- Letters sent to TCs listed in Annex -1 of Commission Implementing Regulation (EU) 2021/405 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council

- Template annexed to the letter **must be completed** in English and sent within **6 months after reception of the letter**

- To send by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu

TEMPLATE ANNEX

GENERAL INFORMATION + 3 SECTIONS

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]

Section 2: Competent authority statement/information – antimicrobials for growth promotion

Section 3: Competent authority statement/information – traceability of food-producing animals/products

All sections/boxes MUST be filled

European Commission

The competent authority response and supporting documents should be e-mailed to: SANTE-CONSULT-D4@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 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**
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
Statement 1: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 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 ☐	

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)

PUBLIC HEALTH SECTION

DRAFT TEXT

'(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

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

One Health
Medical products and Innovation
(Acting) Directors

Brussels
SANTE.DDG1.D.4/AVO/ci(2023)

Subject: Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Dear Sir, Dear Madam,

Animals and goods entering the Union must comply with certain requirements laid down in EU legislation.

Commission Delegated Regulation (EU) 2023/905[1] establishes that consignments of food-producing animals and certain products derived therefrom intended for human consumption, as defined in Article 1(2), shall enter the Union only from a third country which guarantees that those animals shall not have been administered any of the following:

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

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255[2].

[1] Commission Delegated Regulation (EU) 2023/905 of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in food-producing animals or products derived therefrom intended for human consumption of animal origin exported from third countries into the Union. OJ L 116, 4.5.2023, p. 1

[2] Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. OJ L 191, 20.7.2022, p. 58

Mr s. 22(1)(a)(ii)
Director Residues and Microbiology Policy
Exports Standards Branch
Exports and Veterinary Services Division
Department of Agriculture, Water and the Environment
18 Marcus Clarke Street
Canberra ACT 2601
Australia

Third countries that meet those requirements are to be included in a list that is to be drawn up by the Commission in accordance with Article 127 of Regulation (EU) 2017/625[3].

The Commission shall decide on the inclusion of a third country in the above-mentioned list only if that third country provides guarantees of compliance with the requirements established in Article 3 of Delegated Regulation (EU) 2023/905. These guarantees shall take the form of a written declaration issued by the relevant competent authorities in the third country.

In order to facilitate the provision of the guarantees, the **template** annexed to this letter must be completed and submitted by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu. **No hard copies are required**. When providing this information, please state in the subject line of your email first the name of your country and the subject matter (i.e. Country X: 2023, Declaration of compliance with Article 118(1). This information shall be provided to the Commission **within 6 months of receipt of this letter**. Failure to provide the required information within that period could result in your country not being included in the above-mentioned list.

If after submitting the written declaration there are any changes in circumstances which would preclude your country's listing, you are requested to inform the Commission services without undue delay.

Should you have any queries in relation to the above, please do not hesitate to contact SANTE-VETERINARY-MEDICINES@ec.europa.eu.

Yours faithfully,

(e-signed) (e-signed)

s. 47F(1) s. 47F(1)

Enclosure: TC requirements

c.c.: s. 47F(1)
(SANTE)

[3] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). OJ L 95, 7.4.2017, p. 1.

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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 5: Animal species and commodities intended for export to the EU <u>for human consumption</u> (please tick)

Bovine	Ovine/Caprine	Porcine	Equine	Aquaculture	Poultry	Milk	Eggs	Rabbit	Farmed Game	Honey	Casings
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
<u>**Statement 1**</u>: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	

[1] See Annex to Commission Implementing Regulation (EU) No 2022/1255

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

(b) **not authorised** for use in food producing animal species in my country ☐	
If you have ticked (a) **(authorised for use)** please specify which of those antimicrobial substances are authorised in your country and for which species of food-producing animals 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:	
<u>Statement 2</u> 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 reserved for human use [1] 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. ☐	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Statement 3 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 reserved for human use [1] have not been used in those animals/products imported into my country for that purpose. ☐	
Statement 4 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 reserved for human use [1] 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:	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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
<u>Statement 9</u> 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:	

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

From: s. 22(1)(a)(ii)
Sent: Thursday, 25 May 2023 5:33 PM
To: Somerville, Anna; s. 22(1)(a)(ii)
Subject: Fwd: Transmission letter addressed to Director Residues and Microbiology Policy, Exports Standards Branch, Exports and Veterinary Services Division of the Department of Agriculture, Water and the Environment Mr s. 22(1)(a)(ii)
Attachments: ARES3624130 - TL - MacLachlan - May 2023.pdf; Letter from DG SANTE - May 2023.pdf; Annex to letter - TC requirements article.pdf

Fyi

From: DELEGATION AUSTRALIA HOD <delegation-australia-hod@eeas.europa.eu>
Sent: Thursday, May 25, 2023 5:03 pm
To: DFAT - Protocol Branch <Protocol.Branch@dfat.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @aff.gov.au>
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) @dfat.gov.au>; s. 47F(1) (EEAS-CANBERRA) s. 47F(1) @eeas.europa.eu>; s. 47F(1) (EEAS-CANBERRA) s. 22(1)(a)(ii) @eeas.europa.eu>; s. 47F(1) @eeas.europa.eu>
Subject: Transmission letter addressed to Director Residues and Microbiology Policy, Exports Standards Branch, Exports and Veterinary Services Division of the Department of Agriculture, Water and the Environment Mr s. 22(1)(a)(ii) s. 22(1)(a)(ii)

Good afternoon,

On behalf of the EU Ambassador to Australia, Mr s. 47F(1) , please find enclosed a letter addressed to the Director Residues and Microbiology Policy, Exports Standards Branch, Exports and Veterinary Services Division of the Department of Agriculture, Water and the Environment, Mr Dugald MacLachlan.

Thank you for ensuring its good transmission.

Sincerely yours,

s. 47F(1)

s. 47F(1)

PA to the Ambassador, Mr s. 47F(1)
Delegation of the European Union to Australia

18 Arkana Street, Yarralumla
ACT 2600
Phone: s. 47F(1)
Mob: s. 47F(1)
Email: s. 47F(1) **@eeas.europa.eu**

EUinAustralia | @EUinAustralia
EUinAustralia | Web: https://eeas.europa.eu/delegations/australia_en

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

One Health
Medical products and Innovation
(Acting) Directors

Brussels
SANTE.DDG1.D.4/AVO/ci(2023)

Subject: Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Dear Sir, Dear Madam,

Animals and goods entering the Union must comply with certain requirements laid down in EU legislation.

Commission Delegated Regulation (EU) 2023/905[1] establishes that consignments of food-producing animals and certain products derived therefrom intended for human consumption, as defined in Article 1(2), shall enter the Union only from a third country which guarantees that those animals shall not have been administered any of the following:

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

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255[2].

[1] Commission Delegated Regulation (EU) 2023/905 of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in food-producing animals or products derived therefrom intended for human consumption of animal origin exported from third countries into the Union. OJ L 116, 4.5.2023, p. 1

[2] Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. OJ L 191, 20.7.2022, p. 58

Mr s. 22(1)(a)(ii)
Director Residues and Microbiology Policy
Exports Standards Branch
Exports and Veterinary Services Division
Department of Agriculture, Water and the Environment
18 Marcus Clarke Street
Canberra ACT 2601
Australia

Third countries that meet those requirements are to be included in a list that is to be drawn up by the Commission in accordance with Article 127 of Regulation (EU) 2017/625[3].

The Commission shall decide on the inclusion of a third country in the above-mentioned list only if that third country provides guarantees of compliance with the requirements established in Article 3 of Delegated Regulation (EU) 2023/905. These guarantees shall take the form of a written declaration issued by the relevant competent authorities in the third country.

In order to facilitate the provision of the guarantees, the **template** annexed to this letter must be completed and submitted by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu. **No hard copies are required**. When providing this information, please state in the subject line of your email first the name of your country and the subject matter (i.e. Country X: 2023, Declaration of compliance with Article 118(1). This information shall be provided to the Commission **within 6 months of receipt of this letter**. Failure to provide the required information within that period could result in your country not being included in the above-mentioned list.

If after submitting the written declaration there are any changes in circumstances which would preclude your country's listing, you are requested to inform the Commission services without undue delay.

Should you have any queries in relation to the above, please do not hesitate to contact SANTE-VETERINARY-MEDICINES@ec.europa.eu.

Yours faithfully,

(e-signed) (e-signed)

s. 47F(1) s. 47F(1)

Enclosure: TC requirements

c.c.: s. 47F(1)
(SANTE)

[3] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). OJ L 95, 7.4.2017, p. 1.

EUROPEAN UNION

DELEGATION OF THE EUROPEAN UNION TO AUSTRALIA

The Ambassador

Canberra25/05/2023
GV/asm/ARES(2023) 3624130

Mr s. 22(1)(a)(ii)
Director
Residues and Microbiology Policy, Exports Standards Branch, Exports and Veterinary Services Division
Department of Agriculture, Water and the Environment
Canberra
Australia

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

I have the honor to hereby convey a copy of a letter addressed to you by Mr s. 47F(1) s. 47F(1) and Ms s. 47F(1) Directors of One Health, Medical Products and Innovation, of the Directorate-General for Health and Food Safety of the European Commission.

Yours sincerely,

s. 47F(1)

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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 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
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
Statement 1: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	

[1] See Annex to Commission Implementing Regulation (EU) No 2022/1255

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

(b) **not authorised** for use in food producing animal species in my country ☐	
If you have ticked (a) **(authorised for use)** please specify which of those antimicrobial substances are authorised in your country and for which species of food-producing animals 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:	
<u>Statement 2</u> 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 reserved for human use [1] 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. ☐	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Statement 3 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 reserved for human use [1] have not been used in those animals/products imported into my country for that purpose. ☐	
Statement 4 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 reserved for human use [1] 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 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	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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
<u>Statement 9</u> 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:	

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Thursday, 1 June 2023 5:43 PM
To: s. 22(1)(a)(ii)

Cc: s. 22(1)(a)(ii)
Subject: Vet Med / TC Meeting / Readout [SEC=OFFICIAL]
Attachments: Australia.pdf; Annex to letter - TC requirements article.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

OFFICIAL

Hi All,

We had a short third country (TC) call yesterday (organised by the Canadian and US Missions) to align before the Commission/TC information session that will be held on 8 June on next steps concerning the implementation of Commission Delegated Regulation (EU) 2023/905 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 main topic of discussion was the communication received from the Commission (see attached) and in particular, the template (annexed to the letter) to collect information from third countries on usage of restricted antimicrobials. This template must be completed within 6 months (i.e. by November 2023) for the Commission to make its assessment regarding TCs' eligibility to be part of the forthcoming EU list of TCs authorised to export animal products to the EU.

TC delegates present on the call indicated that they were still waiting for feedback from capital on the above – but deplored:

- The **lack of clarity** of the Delegated Regulation and template on the concepts/criteria used – but also on the types of control and traceability systems required in TCs to be on the list. Delegates present on the call thought that the template may not be enough for the Commission to make a full assessment on TCs' eligibility.
- The absence of a mention of the **equivalence principle** in the Delegated Regulation or in the template.
- The **insufficient transition period** to implement the Delegated Regulation. It was stressed in this regard that the Delegated Regulation will only apply as from 24 months after the entry into force of the implementing acts (implementing acts providing for the list of authorised third countries and amending the existing official certificates to reflect on the new requirements).
- The fact that the Delegated Regulation is **more trade restrictive than necessary** and not in line with the **no one size fits all** approach.

Key questions raised during the meeting were as follows:

- How will TCs be required to demonstrate **compliance** with the Delegated Regulation, notably in terms of monitoring, controls and traceability of the products? (See for instance Statement 3 page 3 and statement 7 page 5 of the template on imported animal products intended for the EU market; statement 6 page 4 on originating animal products and statement 9, page 6 on traceability requirements).
- Which **TC authorities** will have to complete and certify the information provided in the template? For most TCs the competent authority will be the Veterinary authority.
- What are the **criteria** to be used to select the antimicrobials to be listed in the template? (see for instance statement 5, page 4 on the antimicrobials used as growth promotants). See also the questions raised by Japan in this regard in their below email.

Next steps:

- TC Delegates were encouraged to ask the Commission for any materials before the COM-TC 8 June meeting (which we already did) so we can prepare in advance; and share any materials received with the group.
- The US and Canadian Mission will share their statements and questions to the group ahead of the meeting. They will also organise another TC call after the Commission 8 June meeting.

We will keep you updated on those meetings.

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

From: s. 47F(1) @mofa.go.jp>
Sent: Tuesday, 30 May 2023 2:50 PM
To: s. 47F(1) @international.gc.ca; s. 47F(1) @magyp.gob.ar; s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>; s. 47F(1) @itamaraty.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @minagri.gob.cl; s. 47F(1) @minagri.gob.cl; s. 47F(1) @mincit.gov.co; s. 47F(1) @comex.go.cr; s. 47F(1) @mofa.go.jp>; s. 47F(1) @mre.gov.py; s. 47F(1) @state.gov; s. 47F(1) @mrree.gub.uy; s. 47F(1) @state.gov
Subject: [EXTERNAL] RE: Art 118 Touch Base

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

Thank you very much for taking an initiative on the meeting tomorrow. Indeed, it is a good idea to exchange our views among third countries before the SANTE's meeting on 8 June. Once the time of the tomorrow's meeting is set, please let us know.

If possible, tomorrow, Japan would like to hear your comments on the following points.

1) In the "Response" column of Statement 5 (Section 2) of the Questionnaire (attached), there is an item to list antimicrobials that are approved for use in food animals for growth promotion purposes in third countries (home countries), but what specific substances are you planning to write down? (We assume countries that can use antimicrobials for growth promotion and therapeutic purposes under the medicated feed system would select (a) in Statement 5 (Section 2).)

2) We would like to know, for our reference, on what criteria you consider the substances to be selected for the above question.

3) In Statements 3 (Section 1) and 7 (Section 2) of the Questionnaire for the Third Country List, it is stated that for food-producing animals or products derived from them from third countries other than your country, we are asked to assure that (1) antimicrobials for the purpose of growth promotion or yield enhancement must not be used, and (2) antimicrobials on the list of antimicrobials restricted for human use must not be used. However, it seems difficult to obtain

assurance from a third country and include it in the questionnaire when new regulations are about to be introduced. What about your observations? And, how do you plan to prove these two points, and what specific methods and systems do you have in place (Japan would especially like to know the methods for beef and farmed fish)?

Best regards

s. 47F(1)

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欧州連合日本政府代表部
参事官
植竹　哲也
Mission of Japan to the European Union
Counsellor
Dr. s. 47F(1) (Phd. in Economics)
s. 47F(1) @mofa.go.jp
Mobile: s. 47F(1)
Tel: s. 47F(1)
◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇◇

From: s. 47F(1) @international.gc.ca>
Sent: Friday, May 26, 2023 11:59 AM
To: s. 47F(1)@magyp.gob.ar; s. 22(1)(a)(ii) @dfat.gov.au; s. 22(1)(a)(ii) @dfat.gov.au; s. 47F(1) @itamaraty.gov.br; s. 47F(1) @agricultura.gov.br; s. 47F(1) @minagri.gob.cl; s. 47F(1) @minagri.gob.cl; s. 47F(1)@mincit.gov.co; s. 47F(1) @comex.go.cr; s. 47F(1) s. 47F(1) @mofa.go.jp>; s. 47F(1) @mofa.go.jp>; s. 47F(1) @mre.gov.py; s. 47F(1)@state.gov; s. 47F(1) @mrree.gub.uy; s. 47F(1)@state.gov
Subject: Art 118 Touch Base

Hello everyone,

You all would have received by now the invitation from DG SANTE to the information session on next steps with respect to implementing Art 118 on June 8, and a template to collect information from third countries on usage of restricted antimicrobials. As we enter this next phase of EU's regulation making process, which is on the details of how EU intends to implement the requirements targeted to third countries, we thought it is timely that we have a touch base with the group.

To this end we would like to propose a virtual meeting next week to check in with each other, coordinate our collective approach on engagement with the EU, potential questions we want to pose to the EU at the information session, and any other concerns or issues you would like to raise.

Apologies for the short notice. Time wise, we would suggest next Wednesday, May 31, 2023, at 10am, 11am or 1pm. Please use the Doodle link below to select the time that works best for you, by COB Monday. We will select the time slot when most people are available. Once that is determined, I will send out a Teams invite.
https://doodle.com/meeting/participate/id/egnlLXGd.

Please feel free to share with other colleagues at your Mission, if we missed anyone.

Thank you! Looking forward to talking with you all!

s. 47F(1)

s. 47F(1)

Counsellor Sanitary and Phytosanitary Affairs
Canadian Food Insepction Agency
Mission of Canada to the EU
Brussels, Belgium
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Mobile: s. 47F(1)
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Agricultural Attaché
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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

One Health
Medical products and Innovation
(Acting) Directors

Brussels
SANTE.DDG1.D.4/AVO/ci(2023)

Subject: Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Dear Sir, Dear Madam,

Animals and goods entering the Union must comply with certain requirements laid down in EU legislation.

Commission Delegated Regulation (EU) 2023/905[1] establishes that consignments of food-producing animals and certain products derived therefrom intended for human consumption, as defined in Article 1(2), shall enter the Union only from a third country which guarantees that those animals shall not have been administered any of the following:

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

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255[2].

[1] Commission Delegated Regulation (EU) 2023/905 of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in food-producing animals or products derived therefrom intended for human consumption of animal origin exported from third countries into the Union. OJ L 116, 4.5.2023, p. 1

[2] Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. OJ L 191, 20.7.2022, p. 58

Mr s. 22(1)(a)(ii)
Director Residues and Microbiology Policy
Exports Standards Branch
Exports and Veterinary Services Division
Department of Agriculture, Water and the Environment
18 Marcus Clarke Street
Canberra ACT 2601
Australia

Third countries that meet those requirements are to be included in a list that is to be drawn up by the Commission in accordance with Article 127 of Regulation (EU) 2017/625[3].

The Commission shall decide on the inclusion of a third country in the above-mentioned list only if that third country provides guarantees of compliance with the requirements established in Article 3 of Delegated Regulation (EU) 2023/905. These guarantees shall take the form of a written declaration issued by the relevant competent authorities in the third country.

In order to facilitate the provision of the guarantees, the **template** annexed to this letter must be completed and submitted by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu. **No hard copies are required**. When providing this information, please state in the subject line of your email first the name of your country and the subject matter (i.e. Country X: 2023, Declaration of compliance with Article 118(1). This information shall be provided to the Commission **within 6 months of receipt of this letter**. Failure to provide the required information within that period could result in your country not being included in the above-mentioned list.

If after submitting the written declaration there are any changes in circumstances which would preclude your country's listing, you are requested to inform the Commission services without undue delay.

Should you have any queries in relation to the above, please do not hesitate to contact SANTE-VETERINARY-MEDICINES@ec.europa.eu.

Yours faithfully,

(e-signed) (e-signed)

s. 47F(1) s. 47F(1)

Enclosure: TC requirements

c.c.: s. 47F(1)
(SANTE)

[3] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). OJ L 95, 7.4.2017, p. 1.

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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 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
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
Statement 1: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	

[1] See Annex to Commission Implementing Regulation (EU) No 2022/1255

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

(b) **not authorised** for use in food producing animal species in my country ☐	
If you have ticked (a) **(authorised for use)** please specify which of those antimicrobial substances are authorised in your country and for which species of food-producing animals 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:	
<u>Statement 2</u> 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 reserved for human use [1] 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. ☐	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

Statement 3 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 reserved for human use [1] have not been used in those animals/products imported into my country for that purpose. ☐	
Statement 4 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 reserved for human use [1] 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:	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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	

Information for listing third countries eligible to export food-producing animals and products intended for human consumption to the EU as regards the requirements established in Commission Delegated Regulation (EU) 2023/905

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
<u>Statement 9</u> 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:	

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

From: s. 22(1)(a)(ii) @dfat.gov.au>
Sent: Friday, 16 June 2023 8:16 PM
To: s. 22(1)(a)(ii)

Cc: s. 22(1)(a)(ii)
Subject: RE: Vet Med / COM-TC Meeting of 8 June / Readout [SEC=OFFICIAL]
Attachments: ah_vet-med_imp-reg-2019-06_det-rules_meeting-third-countries_20230806_.pdf; ah_vet-med_imp-reg-2019-06_det-rules_meeting-third-countries_20230 (1).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi All,

Please find attached the presentations that were showed by DG SANTE during the Commission/third countries meeting of 8 June.

Those are now available on the Commission's website at https://food.ec.europa.eu/animals/animal-health/vet-meds-med-feed/implementation/regulation-eu-20196-delegated-acts_en

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

From: s. 22(1)(a)(ii)
Sent: Tuesday, 13 June 2023 4:39 PM
To: 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) @agriculture.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>; s. 22(1)(a)(ii) s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @aff.gov.au>
Cc: s. 22(1)(a)(ii) @dfat.gov.au>; s. 22(1)(a)(ii) @dfat.gov.au>
Subject: Vet Med / COM-TC Meeting of 8 June / Readout [SEC=OFFICIAL]

OFFICIAL

Hi all,

Please find below a readout on the informative session that was held on 8 June between the Commission (DG SANTE) and third countries on the implementation of Commission Delegated Regulation (EU) 2023/905 on the prohibition of certain antimicrobials in animals/animal products exported to the EU, which was adopted on 27 February 2023 (hereafter, the 'Delegated Regulation').

EU speakers (DG SANTE):
s. 47F(1) Head of Unit - Deputy Director General for Health responsible for Directorates B, C and D - Medical Products and Innovation - Veterinary Medicines
s. 47F(1) , Head of Unit - Deputy Director General for Food Sustainability

There were 3 topics on DG SANTE's agenda for this session:

1. The **elaboration of the list of third countries** authorised to export animals/animal products to the EU (hereafter, the 'list of approved countries) (Article 5 of the Delegated Regulation). The Commission also discussed the warranties to be provided by third countries to be included in the list via the **information template** annexed to the letter sent by the Commission to third countries on 23 May 2023 (see attached documents).

2. **Certification of compliance** with the Delegated Regulation and EU Vet Med rules (in particular, Article 118 of the EU Vet Med Regulation (2019/6). (Article 6 of the Delegated Regulation).
3. **Entry into force and application** of the Delegated Regulation (Article 8 of the Delegated Regulation).

DG SANTE provided useful clarifications on how to implement the Delegated Regulation and complete the information template. More flexibility was showed (in comparison with DG SANTE's last third country meeting of 12 January 2023) notably regarding timeframe for compliance, as it was indicated that an additional transition period (than the 24 months provided in the Delegated Regulation) could be provided in the forthcoming implementing Regulation amending the relevant models of official certificates (see details below). DG SANTE also committed to meeting/discussing more with third countries on the topic and provide further clarifications if needed.

There were many comments & questions raised by third country delegates present on the call, which pointed out to:

- The **lack of clarify** of the Delegated Regulation, template and timeframe for compliance with the new rules. In particular third country delegates (e.g. Canada) asked for more details & guidance on the types of controls expected from third country authorities to ensure compliance.
- The **heavy burden** represented by the new requirements (e.g. the consignment-based certification requirements and the warranties to be put in place for third countries to be included in the list).
- Doubts were also expressed regarding the **WTO compatibility** of the new rules.

More specifically:

1. **<u>On the list of approved countries and information template</u>**

DG SANTE indicated that:

- The list of authorised third countries 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 information template. Third countries have six months (i.e., by <u>November 2023</u>) to complete and submit the template to DG SANTE. In order to be eligible to export animals/animal products to the EU, third countries must be listed in this list <u>but also</u> in all the other relevant EU lists. The objective according to DG SANTE is to show compliance with EU rules related to animal health, residue plants and antimicrobial resistance (AMR).
- Once the warranties received, the Commission will start elaborating the list, which will be subject to the Member States' opinion and then notified to the WTO SPS Committee.
- All questions and boxes provided in the template must be answered/completed. In case of inconsistencies or if the answers provided are considered as insufficient, the Commission will revert to third countries so that the missing/inconsistent information can be provided.
- **All the national authorities involved in the process must be identified** in the template.
- Third country delegates expressed difficulties with regard to the <u>control and traceability requirements</u> to be put in place to ensure compliance with the new rules, notably to ensure that:
    - The **segregation system** in place works effectively to ensure that antimicrobials used domestically for promoting growth or increasing yield have not been administered to the 'food-producing animal species' and products therefrom intended for export to the EU market (see statement 6 of the template).
    - Animals/animal products sourced from other third countries which are intended to be exported to the EU, comply with the EU rules (e.g. ingredients originating in Country A, further processed in Country B and exported to the EU). For this purpose the third country from which the products are sourced from (Country A in our example) must be listed in the EU list of approved third countries and provide the guarantees/warranties that the products comply with the EU Vet Med rules. However, if the ingredients originate from an EU Member State, those guarantees will not be needed. Jo and other delegates (e.g. Canadian Delegate) expressed doubts regarding the WTO compatibility of this double standard. In response, the EU indicated that *"we don't need to ask warranties from ourselves as we know what we have in place"*.
- At this stage, the Commission is only expected some commitments from third countries that the controls are put in place to ensure compliance with the EU Vet Med rules. However, as specified by s. 47F(1) *"at one point in the future the <u>Commission **audit** services</u> will seek to verify whether or not the controls are in*

place meet the requirements". s. 47F(1) also specified that *"we will base our decisions on your statements. The day where colleagues are conducted audit they will check this".*

- DG SANTE tried to be reassuring indicating that *"we are not being prescriptive regarding the methods to be put in place to provide the warranties" "The fact that you have the legislation and controls in place is already a warranty".*

DG SANTE encouraged third countries to submit the completed information template before the deadline, so that the list of approved countries can be published as soon as possible.

2. On the certification requirements

- 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.
- DG SANTE showed examples of possible attestation models in its presentation (see attached document, pages 13-14). These are only preliminary versions which will be subject to further internal consultations.

3. On the entry into force and application of the new requirements

- As specified in Article 8 of the Delegated Regulation, the new EU rules will enter into force 24 months after the date of application of the Implementing Regulation amending the certificates.
- DG SANTE was unable to provide a precise date for adoption of the implementing Regulation but indicated that a draft could be discussed with EU Member States after summer and notified to the WTO SPS Committee afterwards.
- The US Delegate raised a question regarding the **risk of retroactive application** of the new rules, asking about the Commission's intentions to *"make sure that products produced before the adoption of the Delegated Regulation won't be impacted".*
- DG SANTE answered that a precise date for entry into force of the new rules will be provided in the Implementing Regulation – with a possible additional transition period to be included in this Regulation – although no certainty was provided on this point.
- DG SANTE reminded Delegates that *'as from the date of application of the Implementing Regulation the conditions will be applicable. If the commodities are not in compliance with the requirements – you will not be in position to export the product to the EU".*
- DG SANTE indicated that third countries will have time to adapt to the new rules *"you will have enough time to take preparatory measures".*

Although DG SANTE was enable to provide a precise date for entry into force of the new rules, we expect that the Implementing Regulation will be adopted around the end of this year/beginning of next year. This means that the new rules (the Delegated Regulation) should enter into force by the end of 2025/ beginning of 2026. This may be more if the Commission decides to add an additional transition time in the implementing Regulation, although we don't expect the Commission to grant much more than the two years already provided under the Delegated Regulation.

I have attached some extracts of DG SANTE's power point presentations. I'll send the full presentations once available on their website.

Happy to answer and question/comment you may have on the topic.

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

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

WTO & Research Officer (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
s. 22(1)(a)(ii)@dfat.gov.au
T: s. 22(1)(a)(ii)
M: s. 22(1)(a)(ii)

Meeting with Third Countries on the implementation of Commission Delegated Regulation (EU) 2023/905 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

Brussels, 8 June 2023

Dr. s. 47F(1)
Head of Unit Veterinary Medicines,
Health and Food Safety Directorate-General

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

Article 118: Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.
2. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Article by **providing the necessary detailed rules on the application of paragraph 1 of this Article**

Article 107: Use of antimicrobial medicinal products

2. Antimicrobial medicinal products **shall not be used in animals for the purpose of promoting growth nor to increase yield**

Article 37: Decisions refusing marketing authorisation

5. The Commission shall, by means of **implementing acts**, **designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

Article 37: Decisions refusing marketing authorisation

4. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Regulation by **establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans** in order to preserve the efficacy of those antimicrobials

5. The Commission shall, by means of **implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

Commission Delegated Regulation (EU) 2021/ 1760 (criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans)

Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

- **It shall apply from 9 February 2023**

The VMP Regulation: **no provisions for official controls on imports of animals and animal products**

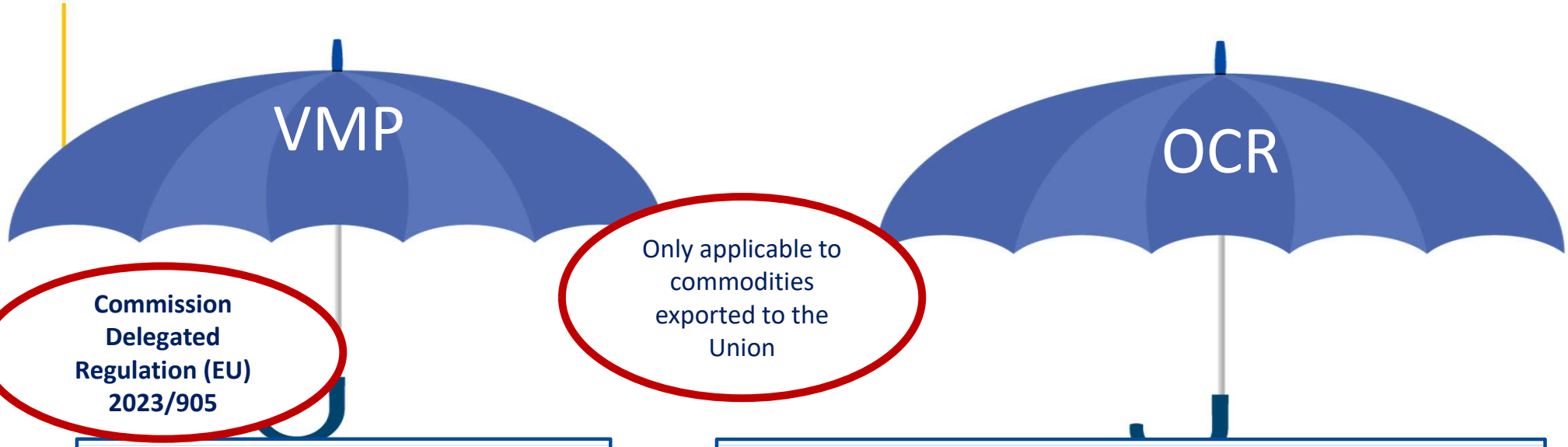
To provide a **Union single framework for official controls** to third countries Regulation (EU) 2017/625 was amended : Regulation **(EU) 2021/1756** of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards **official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation** (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs

Article 1

Subject matter and scope

4. This Regulation shall not apply to official controls for the verification of compliance with:

(c) Regulation (EU) 2019/6 of the European Parliament and of the Council (2); however, **this Regulation shall apply to official controls for the verification of compliance with Article 118(1) of that Regulation**



Requirements -Article 118

- Ban on use of antimicrobials growth promotion + list of AMs reserved for human use
- Scope food producing animals and PAO
- Conditions: only consignments from listed countries and accompanied by official certificates
- Application date linked to the application date of the implementing act amending certificates

Union single framework for official controls : official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials (VMP Regulation)

List of third countries to be developed on the basis of the **written guarantees** provided by TC

Amendments to the current legal acts laying down the relevant models of official certificates for animals and products of animal origin for the entry intro the Union (e.g. Commission Implementing Regulations (EU) 2020/2235 and 2021/403): relevant **attestations** to be included (VMP)

Commission

Commission Delegated Regulation (EU) 2023/905 of 27 February supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 1

Subject matter and scope

1. This Regulation lays down detailed **rules on the application of the prohibition of use, in animals or products of animal origin that are exported from third countries into the Union, of antimicrobial medicinal products for growth promotion and yield increase, and antimicrobials reserved for treatment of certain infections in humans.**

2. This Regulation applies to live **food-producing animals** for which Combined Nomenclature codes ('CN codes') have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87.

   This Regulation also applies to **products of animal origin intended for human consumption**, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16, of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings have been laid down under headings 3501, 3502 and 3504.

Commission Delegated Regulation (EU) 2023/905

3. This Regulation **does not apply** to the following:

(a) gelatine and raw materials for the production thereof referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council;

(b) collagen and raw materials for the production thereof referred to in Section XV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(c) highly refined products referred to in Section XVI, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(d) wild animals and products derived therefrom;

(e) insects, frogs, snails and reptiles, including products derived therefrom;

(f) composite products;

(g) animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the Union;

(h) animals or products of animal origin intended for human consumption only for transit through the Union without being placed on the market;

(i) 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.

Commission Delegated Regulation (EU) 2023/905

Article 3

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

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

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

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255.

Commission Delegated Regulation (EU) 2023/905

Article 4

Conditions for the entry into the Union

1. Consignments of the animals or products referred to in Article 1(2) shall only enter the Union where the following conditions are met:

   (a) they originate from a **third country or region thereof included in the list of countries** referred to in Article 5, and

   (b) they are **accompanied by an official certificate** referred to in Article 6 attesting that the consignment complies with the requirements in Article 3.

2. By way of **derogation** from paragraph 1, point (a), consignments of the animals or products referred to in Article 1(2) may enter the Union from third countries that are not included in the list referred to in Article 5(1), where such third countries ensure that the consignments entering the Union originate from a Member State or from a third country included in the list.

Commission Delegated Regulation (EU) 2023/905

Article 5

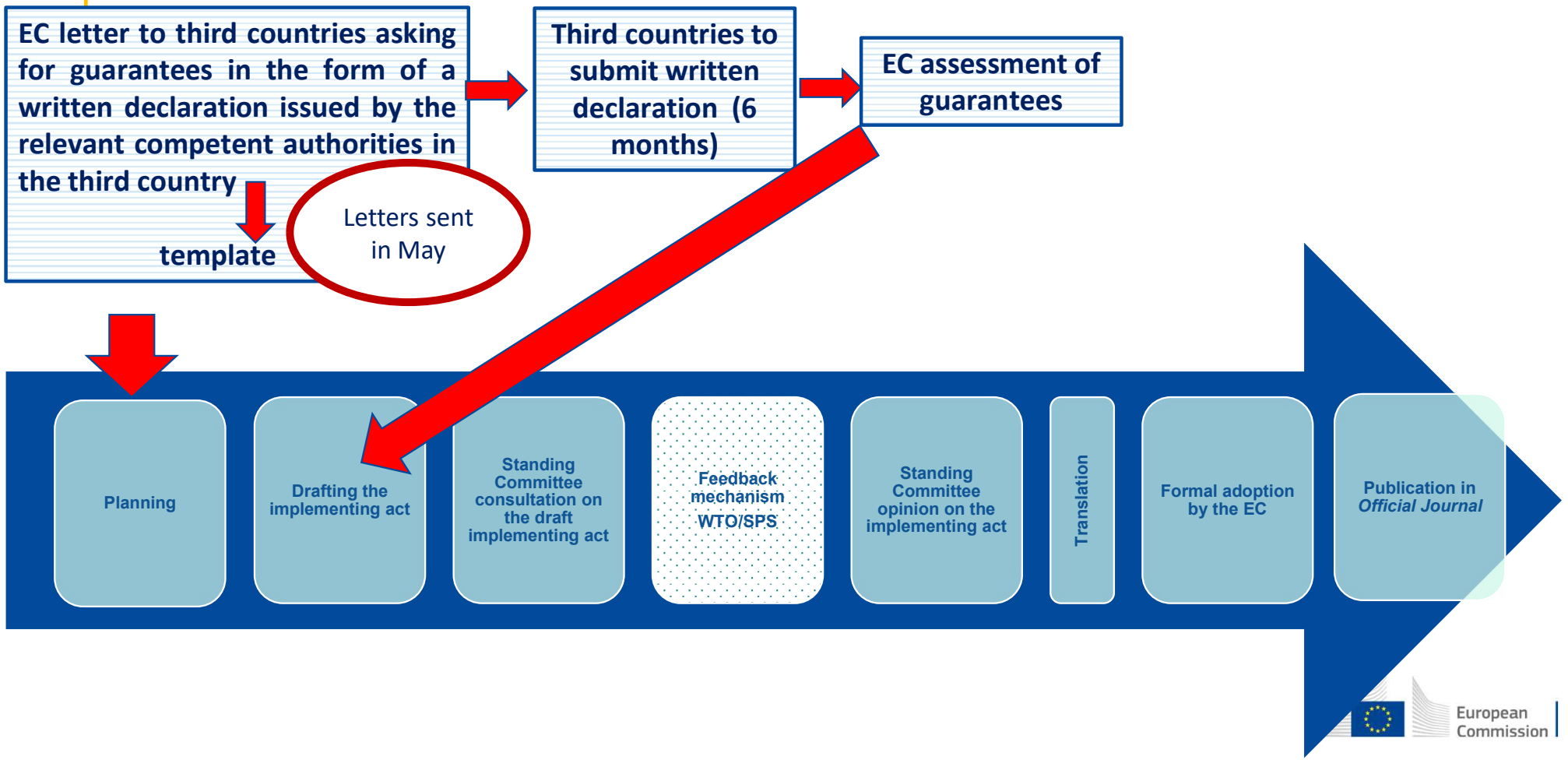
List of approved third countries

1. The list referred to in Article 4(1), point (a), is **to be established by means of an implementing act adopted by the Commission in accordance with Article 127 of Regulation (EU) 2017/625**. If appropriate, that list may be combined with other lists developed under Article 127 of Regulation (EU) 2017/625.

2. The Commission shall decide on the inclusion of third countries in the list in accordance with the requirements laid down in Article 127(3), points (a) to (d), and points (f) and (g), of Regulation (EU) 2017/625, on the basis of **available evidence and guarantees** that the requirements laid down in Article 3 are complied with, including information received on the procedures in place to guarantee the traceability and origin of animals or products referred to Article 1(2).

3. In accordance with Article 127(4) of Regulation (EU) 2017/625, the Commission shall delete the reference to a third country or a region of a third country from the list if the conditions for inclusion in the list cease to be met.

List of approved third countries



European Commission

Commission Delegated Regulation (EU) 2023/905

Article 6

Certification of compliance

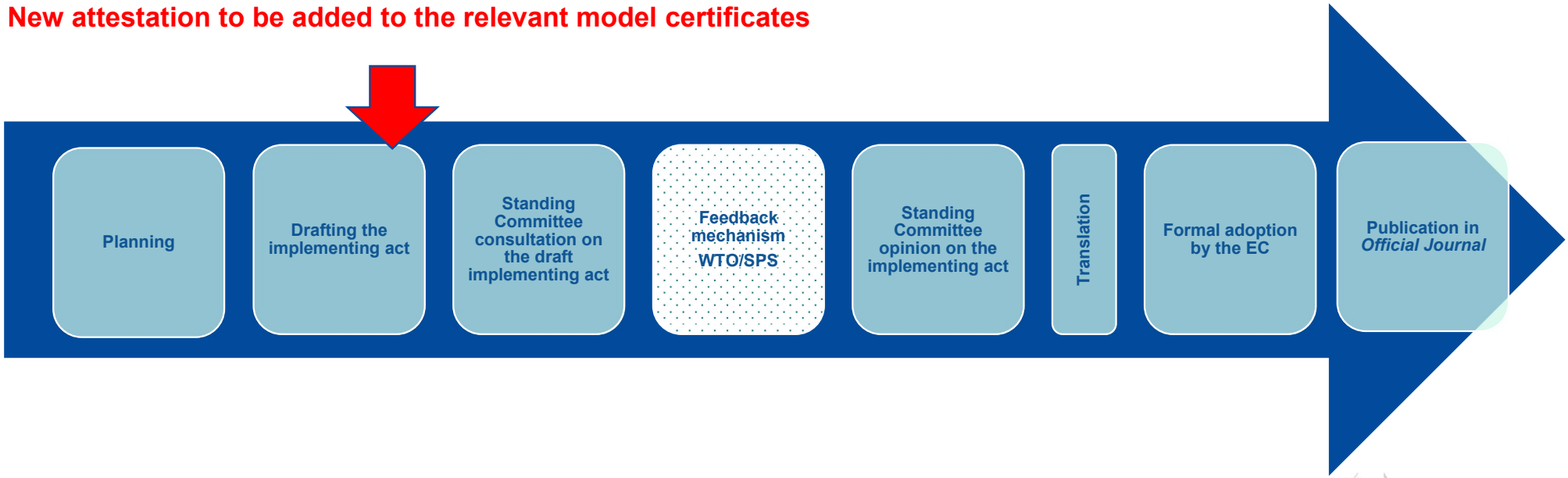
1. **Specific requirements on the official certificates** referred in point (b) of Article 4(1) **are to be laid down by the Commission**, by means of implementing acts, in accordance with the examination procedure referred to in Article 126(3) of Regulation (EU) 2017/625.

2. The official certificates may include details required in accordance with other Union legislation on public and animal health matters.

Certification of compliance

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 entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals

New attestation to be added to the relevant model certificates



European Commission

Commission Delegated Regulation (EU) 2023/905

Article 7

Controls

Controls to verify compliance of consignments of the animals or products referred to in Article 1(2) with Article 3 shall be carried out in accordance with Regulation (EU) 2017/625.

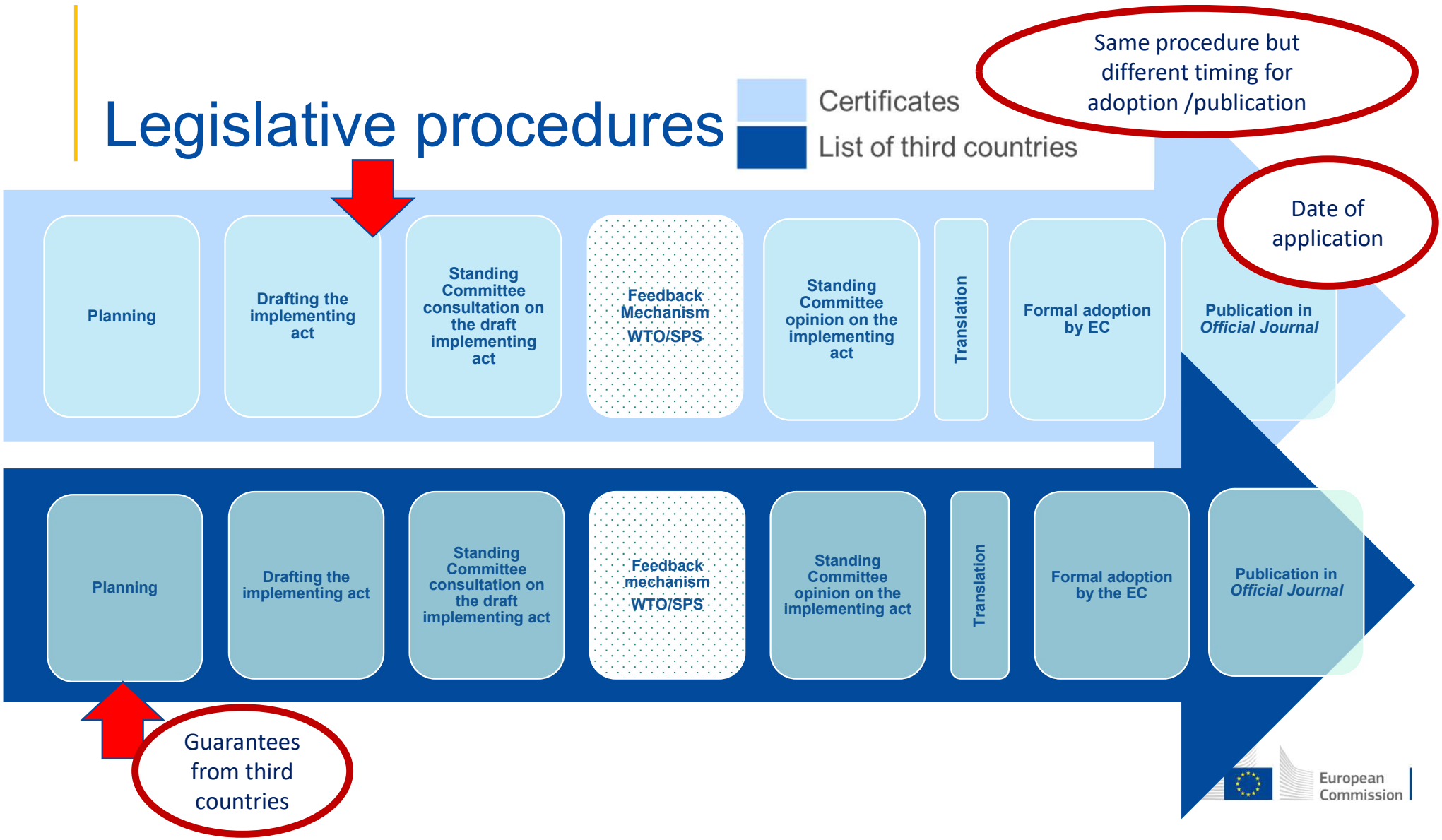
Article 8

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

The conditions for entry into the Union of consignments of animals or products set out in this delegated act shall apply as from 24 months after the date of application of the implementing act referred to in Article 6(1) [certificates]

Legislative procedures



Where can you follow progress?

https://europa.eu/!rJ63kT

Thank you

European Commission

Specifications as regards the listing of third countries and the amendments of the official export certificates

Brussels, 8 June 2023

Listing of third countries

- Letters sent to TCs listed in Annex -1 of Commission Implementing Regulation (EU) 2021/405 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council

- Template annexed to the letter **must be completed** in English and sent within **6 months after reception of the letter**

- To send by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu

TEMPLATE ANNEX

GENERAL INFORMATION + 3 SECTIONS

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]
Section 2: Competent authority statement/information – antimicrobials for growth promotion
Section 3: Competent authority statement/information – traceability of food-producing animals/products

All sections/boxes MUST be filled

European Commission

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 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**
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
Statement 1: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	

[1] See Annex to Commission Implementing Regulation (EU) No 2022/1255

If you have ticked (a) **(authorised for use)** please specify which of those antimicrobial substances are authorised in your country and for which species of food-producing animals 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:	
<u>Statement 2</u> 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 reserved for human use [1] 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. ☐	
<u>Statement 3</u> 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 reserved for human use [1] have not been used in those animals/products imported into my country for that purpose. ☐	
Statement 4 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 reserved for human use [1] 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:	