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Maxine Gibson
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Department of Agriculture
Canberra ACT 2601

By email only: codex.contact@agriculture.gov.au

Dear Ms Gibson,

Regarding

- Proposed draft revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005), and
- Proposed draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (CL 2019/83)

Thank you for the opportunity to comment on the proposed draft *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005)* and the proposed draft *Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (CL 2019/83),* which will be considered by the Task Force on Antimicrobial Resistance (TFAMR) in December this year.

Animal Medicines Australia is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. One of our core functions is to advocate, educate and promote the safe use of antibiotics in animals. As such, we have a strong interest in ensuring that these products can continue to be registered for use in Australia to for the benefit of animal health and welfare, agricultural productivity and public health.

AMA has reviewed both draft documents and wishes to provide the following comments to assist the Australian delegation in their preparation for the TFAMR07 meeting. Our comments will refer to the documents as the “Code of Practice” (CXC 61-2005) and the “Surveillance guidelines” (CL 2019/83).

Key concerns

1. A priority for the Australian delegation should be to protect the scientific integrity of Codex activities. It is an expectation of Codex member countries that Codex will demonstrate the highest level of scientific integrity in its guidelines and codes of practice. AMA notes that the Surveillance guidelines includes text and makes recommendations that are not supported by current scientific evidence, and that the Code of Practice does not accurately reflect the scientific evidence regarding the use of non-medically important antibiotics for growth promotion. The scientific integrity of these documents should be improved as a priority.

2. AMA also notes that there is text in the Surveillance guidelines that could be used by importing countries to impose new trade barriers and, potentially, breach the rules of regulations of the World Trade Organisation (WTO). Most notably, the language in Section 7 implies a hierarchy of surveillance achievements that do not necessarily reflect the quality or effectiveness of that surveillance. This hierarchy could be used as a trade barrier by importing countries by implying that different phases of surveillance equate to 'unsafe' commodities or production systems. The language should be modified to support a *continuous* process of improvements to whatever system is currently in place, rather than defined steps or phases.

Comments on the Code of Practice

3. **Principle 5 – use of antimicrobial agents for growth promotion**
   a. "*Not for antimicrobials considered medically important*"
      - The differences between OIE and WHO definitions of 'medically important', and their respective lists of antibiotics that are 'important to human medicine' and 'important to veterinary medicine' need to be acknowledged in this document.
      - This text also creates potential for key definitions to be used as trade barriers, especially in relation to definitions of 'preventive' versus 'therapeutic' use of antibiotics, and the identification of 'medically relevant' antibiotic classes.

   b. Non-medically important antimicrobials should not be used in the absence of risk assessment of potential human health risks
      - Suggest adding 'where possible' – many low and middle income countries will not have the resources to do such risk analyses and there are significant animal welfare, human health and food security implications if the use of non-medically important antimicrobials is denied in such circumstances.
      - Suggest that this principle should also allow for the use of *relevant* data and risk analyses in the absence of local risk analysis (for example, southeast Asian countries could more usefully refer to risk analyses from nearby countries with similar production systems, in preference to using a risk analysis from Europe).

   c. AMA supports the deletion of the statement about cross and co-resistance potential to medically important antibiotics.

Comments on the Surveillance guidelines

AMA notes that there are a number of controversial issues that are still to be resolved, especially in Sections 7, 8 and 9. AMA would support the Australian delegation taking a position to defer the finalisation of this document until all issues have been satisfactorily addressed.

4. **In general**
   a. The proposed guidelines are overly complex, which detracts from its usefulness as a *guide,* especially for countries that do not have any existing surveillance and are looking to Codex for guidance.

   b. The proposed guidelines suggest actions that could place countries at odds with their WTO legal requirements. In particular, the text describes specific steps or levels of surveillance that will not necessarily lead to safer food or better consumer protection, but which could be used to justify trade barriers (see comments 5a,5d, 6a and 6b).

   c. There is significant potential for the proposed guidelines to misdirect resources towards actions that are inconsistent with the prevailing conditions and risk profile of a country. For example, the text suggests surveillance data should be linked with risk analysis *after* the data has been collected (Section 7.2.3 B). Ideally, the risk analysis is done first to identify the pathogens and antimicrobials that should be included in the surveillance program. In countries with constrained resources, efforts should be focused on risk analysis of local production systems and antibiotic use to identify the pathogens and antimicrobials of most concern in that context. Expansion of surveillance to less critical pathogens and antimicrobials can follow if required and/or desired.

   d. The document includes text that does not reflect the current science and includes several non-science-based recommendations (see comments 5b & 5c).

   AMA encourages the Australian delegation to advocate for the central role of science and risk analysis in the Codex process and outcomes. Scientific integrity is essential to support widespread adoption of Codex guidelines and global harmonization of food safety requirements, and to protect against unintended negative consequences for trade.

5. **Section 7 – progressive approach for implementation of integrated monitoring and surveillance of foodborne AMR**
   a. The current language emphasizes the importance of 'progression' between levels of performance. This stepwise approach could be used by countries to justify non-tariff trade barriers. In particular, Figure 1 implicitly suggests a level of performance that could justify a trade barrier.
      - Suggest deleting Figure 1.

A 'continuous improvement' approach builds on current food safety systems and is more consistent with WTO policy and obligations. A lack of 'progression' also implies the production of unsafe food and/or an inadequate level of protection for consumers. Continuous improvement does not add a point of demarcation that could be used to justify a trade barrier, and it will still achieve the objective of influencing the design of monitoring and surveillance systems.

- Suggest replacing 'progressive' with 'continuous improvement' throughout the document.

b. PARAGRAPH 36: a public health 'implication' is a speculative conclusion that is not explicitly drawn from the data, whereas a public health 'outcome' is a specific consequence related to foodborne AMR. Codex members have an expectation that Codex will utilize the highest level of scientific integrity in its guidance.
    - Suggest changing 'implications' to 'outcomes'.

c. PARAGRAPH 43: 'international recommendations' should be replaced with 'international data'. Antimicrobial use and resistance in each country will vary to the point that an international recommendation based on the prevailing conditions in another country would be inappropriate, lack scientific rigor, and could misdirect scarce resources to microorganisms of low public health importance.

National data is always best to evaluate organisms of high importance to public health, medically important antimicrobials and commodities. In the absence of national data, it is more scientifically sound to apply data from an international source that is similar to the country's prevailing condition, rather than accepting international recommendations based on different prevailing conditions and in the absence of appropriate scientific rigor.

- Suggest replacing 'recommendations' with 'data'.

d. SECTION 7.2.1, sub-section C:
    - Suggest inserting reference to General Guidelines on Sampling (CAC/GL 50-2004) before paragraph 53.

Sub-section E: the authorization and availability of medically important antimicrobials varies significantly by country. Use of nationally or regionally developed lists, where available, that are based on local authorisations, availability and risk assessments (rather than global lists), will support countries to monitor and address issues that are more relevant to their prevailing condition.

- Suggest that the use of national/regional lists is prioritized whenever possible. In the absence of a national/regional list, the WHO List of Critically Important Antimicrobials for Human Health could be used.

e. SECTION 7.2.3: This section provides guidance on risk management which is outside the Terms of Reference.
    - Suggest deleting this sub-section.

6. Section 8 - design of a monitoring and surveillance program for AMR

a. PARAGRAPH 76: use of the word 'stage' implies a level of performance, which could enable a trade barrier.
   - Suggest deleting 'whatever the stage of implementation'.

b. PARAGRAPH 77: need to make it clear that countries with limited resources can expand their existing pathogen sampling programs (rather than create new ones). This would save time, money and possibly improve adoption of AMR monitoring.
   - Suggest add a new bullet point at the top: 'integrate sampling into existing pathogen monitoring systems'.

c. PARAGRAPH 82: guidance in relation to sampling should be in accordance with, and not duplicate, existing Codex documents.
   - Suggest inserting reference to General Guidelines on Sampling (CAC/GL 50-2004).

d. PARAGRAPH 85: this is redundant with existing Codex text and earlier text in this document. The elements discussed in this text do not vary in consequence from what is presented in CAC/GL 50-2004).
   - Suggest deleting current text and replace with 'In the development and selection of sampling plans, consideration should be given to the principles of the General Guidelines on Sampling (CAC/GL 50-2004)'.

e. PARAGRAPH 116: the first two sentences are speculative and do not add meaningful guidance for a country or context that could help improve their surveillance and monitoring programs.
   - Suggest deleting first two sentences.

7. Section 9 – collection of national antimicrobial sale and use data in animals and plants/crops

a. SECTION 9.2: the scientific method highlights the importance of data, including its absence. A clear discussion of the limitations of data collected, analysed and/or presented would add value for policy makers who utilize this data. It is beneficial for competent authorities to assess, to the extent practical, the limitations of the data they have collected and disclose this accordingly.
   - Suggest adding 'Disclosure of the data should include a discussion and details of the limitations of the data collected and presented on antimicrobial sales and use, and the methods and sources that were marshalled to deliver the data.'

b. PARAGRAPH 132, 3rd bullet point: 'weight of commodity/food' is an important denominator used in the food chain that is overlooked in the literature. It is important to highlight that the application of a denominator is to benefit the Codex member country and their national action plan, *not* for international comparisons.
   - Suggest add 'weight of commodity/food' as another denominator.
   - Suggest adding at end of sentence: 'Countries should prioritise the standardization of this data for the purposes of longitudinal trend analysis within their own country'.

c. SECTION 9.2.4 and SECTION 9.3: AMA supports the use of metrics that go beyond measuring gross volumes of antibiotics used. Comparisons of the volume of antibiotics used in animals with that used in human medicine are inappropriate. Measurements focused on volume also imply that a continual decline over time is desired, without consideration of the need for or quality of use. The metrics used should assist in identifying the proportion of antibiotics that were used responsibly, judiciously and in line with best practice guidelines, and enable irresponsible use to be identified and reduced. This will support the development of effective policy to promote high quality use to protect human and animal health, whilst minimizing the selection pressures for resistance.

8. Section 10 – other considerations

a. SECTION 10.2: The overall reporting burden across multiple agencies should be taken into account to avoid duplication of effort and associated inefficiencies. Growing demands from multiple global agencies for data, often using different metrics and in different formats, poses a significant administrative burden, especially in countries where resources are scarce. Reporting requirements and systems should be streamlined and harmonized where possible.

b. SECTION 10.4: this is commentary for the Task Force and not guidance for Codex member countries. Paragraph 152 also includes risk management, which is out of scope for this document.
   - Suggest delete Section 10.4.

I hope these comments are useful as the Australian delegation prepares the national position. If you have any questions, please do not hesitate to contact me.

Yours sincerely

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Science and Technical Manager