

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 5

CX/AMR 19/7/5-Add.1

Original Language Only

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**  
**Seventh Session**  
**PROPOSED DRAFT REVISION OF THE**  
**CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE**  
**(CXC 61-2005)**

**Comments at Step 3 (Replies to CL 2019/84-AMR)**

**Comments of Australia, Brazil, Canada, China, Ghana, Iran, Iraq, Japan, Morocco, Republic of Korea, Switzerland, Uruguay, USA, CCTA, Consumers International, Healthforanimals, International Association of Consumer Food Organizations and OIE**

## Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/84-AMR issued in October 2019. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.  
Explanatory notes on the appendix
2. The comments submitted through the OCS are, hereby attached as **Annex I** and are presented in table format.

**Comments on the proposed revision of the code of practice to minimize and contain antimicrobial resistance (CXP 61-2005)**

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Brazil would like to congratulate the EWG Chairs for their excellent work in providing a new draft after discussions during the EWG with clear guidance and proposals for our work at the PWG and the TFAMR sessions. In general Brazil agrees with the aspects that have been covered for each of the sections of the revised COP and is of the opinion that the document has improved during discussions along this last year. About the suggested "points for comment and discussion at TFAMR", Brazil is of the opinion that paragraphs 18, 19, 21, 29, 33, 50, 52 and 62 should not be adopted as proposed, but should be discussed and revised at the PWG/TFAMR. Brazilian specific comments to the proposed draft are provided below.</p>	<p><b>Brazil</b></p>
<p>Canada recognizes the significant amount of work undertaken by the co-chairs and the members of the EWG on the current draft of the document. We have provided a number of suggestions, mostly to enhance readability of the text and minimize duplication.</p> <ul style="list-style-type: none"> <li>• A number of definitions proposed in the text have been carried over from other Codex documents. Instead of re-including those definitions in the text, it is suggested to include a reference to the text, for example "The definitions of terms incorporated in the Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance (CX/GL 77- 2011) shall apply. See definitions of adverse health effect, antimicrobial agent, antimicrobial resistance, antimicrobial resistance determinant, co-resistance, cross-resistance, extra- or off-label use, food producing animals.</li> <li>• The term 'plant/crop health professional' is used throughout the text; however, this term isn't widely used term in many countries and can therefore lead to confusion despite the attempt to include a definition. There would be merit for the Task Force to consider the terminology that could be used.</li> <li>• Canada has reservations about the inclusion of the term 'therapeutic use/purpose', as there is a different understanding of what it means in human and animal health. We would suggest avoiding use of the term and instead including text explaining the intent.</li> </ul>	<p><b>Canada</b></p>
<p>We agree with proposed draft and we have no comment.</p>	<p><b>Iraq</b></p>
<p>Uruguay felicita la labor realizada por el Presidente y Vicepresidentes, y a su vez agradece la posibilidad de enviar comentarios.</p>	<p><b>Uruguay</b></p>
<p>Overall it is felt the draft Code of Practice can hopefully be completed in December 2019 as it addressed the bulk of outstanding issues satisfactorily</p>	<p><b>HealthForAnimals</b></p>
<p>This is the preliminary feedback from the OIE to be further developed during the working groups, and TFAMR7 plenary meeting. In general, we would like to see the OIE references, standards and guidelines clearly stated when mentioning issues related with animal health/veterinary medicine</p>	<p><b>OIE</b></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>1. Introduction</b>	
Paragraphs 1, 4 and 6	<p><b>Australia</b></p> <p><i>Paragraph 1:</i> Australia supports this proposed text subject to the amendments of the plants/crops definition in Section 3.</p> <p><i>Rationale:</i> The plants/crops definition in Section 3 has been improved for clarity of the end user.</p> <p>Paragraphs 4 and 6: Australia supports this proposed text.</p>
1. Antimicrobial resistance (AMR) poses an important, complex, and priority and global public health challenge. Throughout the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), plant/crop production of food of plant origin and food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR.	<p><b>Canada</b></p> <p>Suggests deletion of the last sentence in the paragraph as it appears duplicative. In addition, minor edits have been made to improve readability.</p>
1.	<p><b>China</b></p> <p>Agrees to use “the crop/plant production” in the text of this document.</p>
Paragraphs 1, 4 and 6	<p><b>Morocco</b></p> <p>Takes note of the proposed amendments to these paragraphs and supports the adoption of the revised text as recommended by the EWG.</p>
1. Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. <del>Throughout</del> Along the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), <u>plant/crop</u> production of food of plant origin and food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR.	<p><b>USA</b></p> <ul style="list-style-type: none"> <li>• "Along the food chain" means there are specific points where foodborne AMR risks need to be addressed. "Throughout the food chain" lacks the specificity needed for risk management and could be read to imply measures are needed everywhere.</li> <li>• Supports replacing “food of plant origin” with “plant/crop production”</li> </ul>
2.	<p><b>Canada</b></p> <p>Suggests deletion of this paragraph as this is already covered in the Scope section. If the paragraph is retained, we find “foodborne antimicrobial resistance in the food supply” – duplicative wording. It is suggested to delete “in the food supply.</p> <p>We are also concerned about whether it is the role of a COP to identify knowledge gaps. These gaps will change over time, rendering the advice of the COP obsolete over time. Canada is of the view that the COP should provide guidance or an approach to identify and address knowledge gaps, rather than the gaps themselves.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, <del>the role of</del> competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	<b>Iran</b> The role of should be deleted, because the sentence is declaring the antimicrobial agents and participants which can be the competent authorities.
2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, the role of competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food <u>animal and plant/crop</u> producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	<b>Japan</b> For clarification and alignment with the suggested subheading of 5.5, food animal and plant/crop producers is preferable.
<del>3 2bis. In keeping with the Codex mandate this</del> This Code of Practice addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in <del>exposure to</del> antimicrobial resistant bacteria or their determinants <del>being present</del> in the food production environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.	<b>Canada</b> The sentence 'In keeping with the Codex mandate...' is <b>not</b> needed since this is a Codex document. In addition, minor edits have been made to improve readability
<del>3 2bis. In keeping with the Codex mandate this</del> Code of Practice addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized <u>antimicrobial</u> products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.	<b>USA</b> Clarity
<del>4 3. This Code of Practice is provides risk management advice as</del> an integral part of risk analysis <del>focusing on risk management options</del> and should be read in conjunction with other <u>relevant</u> Codex texts including <del>the</del> , <u>but not limited to:</u> <ul style="list-style-type: none"> <li>• <i>Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance</i> and the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> (CXG 77-2011), <del>in addition,</del></li> <li>• the <i>Code of hygienic practice for fresh fruits and vegetables</i> (CXC 53-2003),</li> <li>• <del>and the</del> <i>Code of practice on good animal feeding</i> (CXC 54-2004),</li> </ul>	<b>Canada</b> Minor edits are suggested to improve readability

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Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li><del>and the Guidelines for the design and implementation of national regulatory food safety assurance program associated with the use of veterinary drugs in food producing animals (CXG 71-2009) are particularly relevant for use of agricultural chemicals on plants/crops, animal feed, and veterinary drugs, respectively.</del></li> </ul>	
<p>4.3. This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the <i>Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance</i> and the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> (CXG 77-2011). In addition, the <i>Code of hygienic practice for fresh fruits and vegetables</i> (CXC 53-2003), <del>and the Code of practice on good animal feeding</del> (CXC 54-2004), <del>and the Guidelines for the design and implementation of national regulatory food safety assurance program associated with the use of veterinary drugs in food producing animals</del> (CXG 71-2009) are particularly relevant for use of <b>agricultural chemicals</b> on plants/crops, animal feed, <u>and veterinary drugs</u>, respectively.</p>	<p><b>China</b></p> <ul style="list-style-type: none"> <li>It is suggested that all conjunct documents or reference be listed at the end of this document.</li> <li>The agricultural chemicals on plants/crops appearing in this paragraph should be defined in Chapter 3 Definitions.</li> </ul>
4.3.	<p><b>USA</b></p> <p>Supports the addition of CX/G 71-2009.</p>
<p>5.3bis. This Code of Practice provides risk management advice, including the responsible and prudent use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i>. <del>Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk and to introduce levels of protection appropriate for circumstances.</del></p>	<p><b>Canada</b></p>
<p>5.3bis. This Code of Practice provides risk management advice, including the responsible and prudent use of antimicrobial agents <del>and should that can be read applied proportionate to risks identified through the risk analysis process described in conjunction with</del> the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i>. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk and to introduce levels of protection appropriate for circumstances.</p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>The text should simply refer to the Guidelines for risk analysis of foodborne AMR.</p>
<p>6.4.</p> <ul style="list-style-type: none"> <li>[WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;]</li> </ul>	<p><b>Canada</b></p> <p>Supports the inclusion of the reference to the WHO list of critically important antimicrobials for human medicine, however, we would suggest that reference be made to the whole document, not just the annex, since it includes general principles on risk management that may be relevant.</p>
<p>6.4.</p> <ul style="list-style-type: none"> <li>[WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;]</li> </ul>	<p><b>USA</b></p> <p>Supports adoption of this text, as drafted at TFAMR06.</p>

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Section/paragraph	Member/Observer/ rationale
<p>6.4.</p> <ul style="list-style-type: none"> <li>[WHO list of critically important antimicrobials for human medicine, <del>specifically</del> especially the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;]</li> </ul>	<p><b>Consumers International</b></p> <p>We agree with the text in this para, and particularly support the second bullet, with the replacement of “specifically” by “especially” to make clear that the whole document contains information that is of use. We also support removing the square brackets from this bullet</p>
<p>6.4.</p> <ul style="list-style-type: none"> <li>[WHO list of critically important antimicrobials for human medicine, <del>specifically</del> especially the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;]</li> </ul>	<p><b>International Association of Consumer Food Organizations</b></p> <p>Replace "specifically" with "especially" so it is clear that the entire document contains guidance that should be taken into account, although the Annex is particularly relevant.</p>
<p>6.4.</p> <ul style="list-style-type: none"> <li>Relevant chapters of the OIE terrestrial and aquatic animal health codes and the OIE List of antimicrobial agents of veterinary importance; and</li> </ul>	<p><b>OIE</b></p>
<p>8.5bis: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR. <del>These are measures</del> that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.</p>	<p><b>Canada</b></p> <ul style="list-style-type: none"> <li>Minor edits are suggested to improve readability.</li> <li>Suggests to delete this sentence as this paragraph is describing the utility of this document.</li> </ul>
<p>8.5bis: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, <del>based on and</del> their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.</p>	<p><b>China</b></p> <p>Line 2-3, the phrase should be “in accordance with their capabilities and their national priorities”.</p>
<p>8.5bis: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.</p>	<p><b>USA</b></p> <p>The word, “inappropriately” should be deleted for clarity.</p>
<p>8.5bis:</p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>This language is acceptable. There are appropriate barriers to trade. For example if a country is not appropriately managing AMR then that would appropriately be a barrier to trade.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>2. Scope</b>	
Paragraph 9	<p><b>Australia</b></p> <p>Supports this proposed text subject to the amendments of the plants/crops definition in Section 3.</p> <p><b>Rationale:</b> The plants/crops definition in Section 3 has been improved for clarity of the end user.</p>
<p>9.7. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food <del>and feed</del> chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), <u>plant/crop production</u>, <del>[feed of plant origin]</del> and <del>feed</del> and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.</p>	<p><b>Brazil</b></p> <p>Suggests the deletion of “and feed” to avoid redundancy, since it is already part of the proposed definition for “food chain”.</p>
<p>9.7. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed <del>chain chains</del> to minimize and contain the development and spread of foodborne antimicrobial resistance, <del>including. This also includes</del> guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), <u>plant/crop production</u>, <del>[feed of plant origin]</del> and <del>feed</del> and references other best management practices, as appropriate. <del>Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.</del></p>	<p><b>Canada</b></p> <p>Minor edits are suggested to improve readability. The last sentence seems redundant with the first sentence, which reads that the code of practice will address the risk to human health.</p>
<p>9.7. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), <u>plant/crop production</u>, <del>[feed of plant origin]</del> and <del>feed</del> and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of <b>antimicrobial agents</b> in the food chain.</p>	<p><b>Iran</b></p> <p>It is recommended to state clearly that antimicrobial agents cover biocides and disinfectants or not</p>
9.7.	<p><b>Japan</b></p> <p>Agrees to delete “feed,” as antimicrobial agents are used to produce primary material to be processed to make feed.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Paragraphs 9, 11 and 12	<p><b>Morocco</b></p> <p>Takes note of the proposed amendments to these paragraphs and supports the adoption of the revised text as recommended by the EWG.</p>
9.7.	<p><b>USA</b></p> <ul style="list-style-type: none"> <li>• Supports the replacement of “food of plant origin” with “plant/crop production”.</li> <li>• Supports the deletion of “feed” because it is included in plant/crop production.</li> </ul>
10.8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents in the food chain, <u>who have a role to play in ensuring the responsible and prudent use of antimicrobial agents,</u> together with those involved in the handling, preparation, food processing, storage, transport, wholesale and retail distribution and consumption of food who have a role <u>to play in ensuring the responsible and prudent use of antimicrobial agents and/or who have a role</u> with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.	<p><b>Canada</b></p> <p>Minor edits are suggested to improve readability of the text.</p>
Paragraph 11	<p><b>Australia</b></p> <p>Supports the new phrase.</p> <p><u>Rationale:</u> The COP is to have a science-based and risk-based approach according to paragraph 21 (second dot point; REP19/AMR).</p>
11.8bis. Recognizing there are mechanisms of co-resistance or co-selection in <u>microorganisms</u> <u>to</u> a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, [however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, <u>where scientific evidence supports foodborne AMR risk to human health.</u> ]	<p><b>Canada</b></p> <ul style="list-style-type: none"> <li>• Suggests minor edits to improve clarity.</li> <li>• Supports the inclusion of the last sentence.</li> </ul>
11.8bis.	<p><b>China</b></p> <p>Agrees that this document focus on antibacterials. However, the agricultural chemicals/biocides such as pesticides (e.g salinomycin), fungicides (e.g kasugamycin) and herbicides (e.g tribenuron-methyl) should be taking into consideration.</p>
11.8bis.	<p><b>Ghana</b></p> <p><u>Position:</u> Supports the addition in Paragraph 11 as appropriate. “.....where scientific evidence supports foodborne AMR risk to human health”.</p> <p><u>Rationale:</u> There is evidence that there has been resistance from antiprotozoal, antiviral and antifungal agents.</p>
11.8bis.	<p><b>Japan</b></p> <p>Supports adding "where scientific evidence supports foodborne AMR risk to human health" to clarify the situation where such application is desirable.</p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
11 <del>8</del> bis. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, <del>[however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.]</del>	<b>Republic of Korea</b> For the purpose of this document, it would be better to focus on 'antibacterials'. Thus, Korea supports deleting "[however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.]".
11 <del>8</del> bis.	<b>Uruguay</b> Está de acuerdo en retirar los corchetes de la oracion, aceptando la modificacion propuesta en el documento.
11 <del>8</del> bis. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, Most of the recommendations in this Code of Practice will focus on antibacterials, [however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, <u>where scientific evidence supports foodborne AMR risk to human health.</u> ]	<b>USA</b> <ul style="list-style-type: none"> <li>Delete the introductory phrase. It is not necessary for the remainder of the sentence because the recommendations go well beyond the context of co-resistance or co-selection.</li> <li>Supports adoption of the bracketed phrase with the addition of underlined text.</li> </ul>
11 <del>8</del> bis.	<b>Consumers International</b> Support this para as drafted and can support the removing the square brackets since the bracketed language is acceptable qualifying language
11 <del>8</del> bis. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, <del>[however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.]</del>	<b>HealthForAnimals</b> The focus of the COP is on bacterial food-borne risk. Recommendations to combat resistance in parasites are different than it is to reduce resistance in bacteria.
11 <del>8</del> bis. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, [however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, <del>where scientific evidence supports foodborne AMR risk to human health.</del> ]	<b>International Association of Consumer Food Organizations</b> The underlined phrase should be deleted; it is unnecessary, and not in keeping with the Terms of Reference to broaden the scope of the Code. The sentence is already qualified enough, it says "may also be applicable."
12 <del>9</del> .	<b>Australia</b> The addition of 'non-food plants/crops' is supported subject to the amendments of the plants/crops definition in Section 3. <u>Rationale:</u> The plants/crops definition in Section 3 has been improved for clarity of the end user.
12 <del>9</del> .	<b>Canada</b> Delete the reference to footnote 3. Footnote 3 refers to recombinant-DNA microorganisms; however, the text refers to non-genetically modified organisms.
12 <del>9</del> .	<b>Japan</b> Supports adding "non-food plants/crops."

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>12 9.</u>	<b>Republic of Korea</b> Suggests replacing 'non-food plants/crops' with 'non-food(or feed) plants/crops'. Because 'feed' is included in the scope of this document, especially used in the definition of 'plants/crops'
<u>12 9.</u>	<b>USA</b> Biocides should be listed here based to align with the decision taken at TFAMR6 with respect to GLIS. The decision is captured in the REP19/AMR at para 94. We also note that the 2018 FAO Expert Consultation concluded that while biocides present theoretical concerns for co-selection, "...there is an absence of empirical data to indicate that the use of biocides drives this co-selection under the conditions present in the food production or processing environments." Support insertion of "non-food plants/crops".
<u>12 9.</u> As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops <sup>1</sup> and recombinant DNA microorganisms <sup>2</sup> ; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose <sup>3</sup> ; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics <sup>4</sup> . In addition, AMR from non-food animals, <u>non-food plants/crops</u> , or non-food routes are also outside the scope of this document, <u>unless they are part of the food production environment and may contribute to foodborne AMR.</u>	<b>International Association of Consumer Food Organizations</b> The food production environment may include non-food routes and animals that contribute to the development of foodborne AMR (e.g., pets living on farms or animals raised for non-food purposes (e.g., wool) or non-food plants/crops (e.g., used to fertilize or insulate food crops)).
3. Definitions	
<b>Definitions</b>	<b>Canada</b> Believes that it is not necessary to include the definition of terms that have already been defined in other Codex documents, for example 'Adverse health effect', 'Antimicrobial agent', 'Antimicrobial resistance' and 'Antimicrobial resistance determinant', which are already defined in the Codex Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance.
<b>Antibacterial</b>	<b>Canada</b> Believes that the term is self-explanatory and thus it is not necessary to include a definition.
<b>Antibacterial:</b> A substance that acts against bacteria <u>to kill or inhibit growth.</u>	<b>USA</b> Clarity

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>Adverse health effect:</b> An undesirable or unwanted outcome in humans. In this document, this refers to the human infections caused by AMR microorganisms and determinants in food or acquired from food of animal/crop origin as well as increased frequency of infections and treatment failures, loss of treatment options, and increased severity of infections manifested by prolonged duration of disease, increased hospitalization and mortality<sup>5</sup>.</p>	<p><b>Australia</b></p> <p>Adverse health effect: It is noted that this definition comes directly from CX/G 77-2011, and the principle of not altering definitions between relevant Codex texts was previously agreed. If this proposed amendment is supported by the Task Force, then see suggested amendment below.</p> <p><b>Rationale:</b> To remove obsolete text and improve the understanding of the sentence.</p>
<p><b>Adverse health effect:</b> An undesirable or unwanted outcome in humans. In this document, this refers to the human infections caused by AMR microorganisms and determinants in food or acquired from food of animal/crop origin as well as <b>["such as" or "including"]</b> increased frequency of infections and treatment failures, loss of treatment options, and increased severity of infections manifested by prolonged duration of disease, increased hospitalization and mortality<sup>5</sup>.</p>	<p><b>Japan</b></p> <ul style="list-style-type: none"> <li>Doesn't see the reason to delete "of animal/crop origin."</li> <li>Suggests replacing "as well as" with "such as" or "including," as the following pints are part of the problem of human infection.</li> </ul>
<p><b>Antimicrobial agent:</b> Any substance of natural, semi-synthetic, or synthetic origin that at <i>in vivo</i> concentrations kills or inhibits the growth of microorganisms by interacting with a specific target.</p>	<p><b>Iran</b></p> <ul style="list-style-type: none"> <li>It is not clear what In vivo concentrations means. Does it mean in vivo usage in animals used in food chain? What does it can be interpreted for plants/crops?</li> <li>It is suggested to mention that Antimicrobial agent encompass antimicrobial drugs such as antibiotics as well as biocides and disinfectants.</li> </ul>
<p><b>Competent Authority(ies):</b></p>	<p><b>Australia</b></p> <p>Supports the proposed text.</p>
<p><b>[Competent Authority(ies):</b> The government authority or official body authorized by the government organization/agency(ies) having jurisdiction that is responsible for the setting of regulatory requirements and/or for the organization of official controls including enforcement.]</p>	<p><b>Brazil</b></p> <p>Suggests a new text to provide clarity, consistent with the definition recently approved at CCFH Session for the General Principles of Food Hygiene (CXC 1-1969).</p>
<p><b>Competent Authority(ies):</b></p>	<p><b>Canada</b></p> <p>Does not support inclusion of this definition. The term "competent authorities" is used in numerous Codex documents and there has not been a need to include a definition of the term.</p>
<p><b>Competent Authority(ies):</b></p>	<p><b>Ghana</b></p> <p><b>Position:</b> Agrees with the proposed definition of competent authority.</p> <p><b>Rationale:</b> The definition is in line with the content of the document and its linkage with jurisdiction is appropriate.</p>
<p><b>[Autoridad(es) competente(s): la autoridad gubernamental u organismo oficial autorizado por el gobierno que es responsable de establecer los requisitos reglamentarios de inocuidad alimentaria y/o de la organización de los controles oficiales, incluida su aplicación. La(s) organización(es)/El(los) ente(s) gubernamental(es) oficial(es) que tengan competencia.]</b></p>	<p><b>Uruguay</b></p> <p>ugiere utilizar la definición acordada en el documento de PRINCIPIOS GENERALES DE HIGIENE DE LOS ALIMENTOS (CX/C 1-1969) y de su ANEXO SOBRE EL HACCP en el CCFH 51</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>Competent Authority(ies):</b>	<b>USA</b> Supports the new definition.
<b>Competent Authority(ies):</b>	<b>Consumers International</b> Support this definition as drafted and support removing the square brackets.
<b>Control of disease/metaphylaxis:</b> Administration of antimicrobial agents to a group of animals containing sick and healthy individuals (presumed to be <del>infected</del> exposed to an infectious agent), to minimize or resolve clinical signs and to prevent further spread of the disease.	<b>Canada</b> Suggests using the term “exposed” instead of “infected”, as healthy animals may or may not be infected.
<b>Co-resistance:</b> <b>Cross-resistance:</b> <b>Extra- or off-label use:</b>	<b>Canada</b> As indicated previously, these are defined in CX/G 77-2011
<b>Foodborne AMR:</b> AMR microorganisms or genetic determinants present in food and transmitted to humans that may adversely impact human health.	<b>Brazil</b> Suggests including this new definition to provide clarity to the document.
<b>Food chain:</b>	<b>Australia</b> Supports this proposed text.
<b>Food chain:</b>	<b>Canada</b> For consistency, it is suggested to use wording from CX/G77-2011: ‘Production to consumption continuum’, instead of ‘Food chain’
<b>Food chain:</b> Production to consumption continuum including, primary production (food-producing animals, plants/crops), <del>feed</del> , harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.	<b>Ghana</b> <u>Position:</u> Proposes the deletion of “feed” from the definition of food chain to read: <u>Rationale:</u> It is implied in the definition of plants/crop which is defined as “plant/crop cultivated or harvested as food or feed.”
<b>Food chain:</b> Production to consumption continuum including, primary production (food-producing animals, plants/crops), <del>feed</del> , harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.	<b>USA</b> Feed is one input into the production of animals so its being listed out separately does not make sense if a country does an evaluation and finds other inputs to be of more significant risk. Singling it out as more important than other risks in a definition, without an evaluation of foodborne AMR risk under local conditions could be misleading.
<b>Food-producing animals:</b>	<b>Canada</b> As indicated previously, these are defined in CX/G 77-2011
<b>[Food production environment:]</b>	<b>Australia</b> Supports the inclusion of this definition. <u>Rationale:</u> The text gives a tighter focus of the definition of an environment and provides sufficient clarity to the end user.
<b>[Food production environment:</b> The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to where scientific evidence supports foodborne AMR risk to human health.]	<b>Brazil</b> Suggests a new text to provide clarity.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Food production environment:]</b>	<b>Canada</b> Agrees with inclusion, but suggests that there is more clarity needed about what is meant by immediate vicinity.
<b>[Food production environment:</b> The immediate vicinity of food to be harvested, <u>produced</u> , processed, or <u>distributed</u> that has reasonable probability to contribute to foodborne AMR.]	<b>China</b> “Food production environment” should include all environments of food production, processing, storage, transport, retail and distribution.
<del><b>[Food production environment:</b> The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.]</del> <b>Food Production Environment:</b> The vicinity of food, feed, plants/crops, animals to be harvested or processed that could contribute to foodborne AMR.	<b>Ghana</b> <b>Position:</b> Proposes the adoption of the definition of “Food production environment” in Agenda 6. <b>Rationale:</b> For consistency in other standards “Proposed Draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance”.
<b>[Food production environment:]</b>	<b>Japan</b> Supports proposed definition. While the wordings of “vicinity” and “reasonable” may sound vague, it is inevitable to ensure flexibility. Once agreed, this has to be reflected in the GLIS.
<b>[Food production environment:</b> The immediate vicinity of food to be harvested or processed that has <u>reasonable significant</u> probability to contribute to foodborne AMR.]	<b>Morocco</b> Proposes amendment to the definition of Food production environment by replacing the term “reasonable” with the term “significant”. <b>Rationale:</b> The term “reasonable” in the definition is subjective. The use of the term “significant” will provide for a quantifiable indicator to the environment that could contribute to foodborne AMR.
<b>[Food production environment:]</b> The immediate vicinity of food <u>and feed</u> to be harvested or processed that has reasonable probability to contribute to foodborne AMR	<b>Republic of Korea</b> It is appropriate that ‘immediate’ and ‘reasonable’ are used to define “Food production environment” in this document. Especially, while the aquatic production environment is the whole sea area due to the nature of the fisheries, the only environment that are directly affected by antimicrobial resistance should be covered by this document Given the scope of this document, ‘and feed’ should be added after ‘food’.
<b>{Entorno-de producción de alimentos:}</b>	<b>Uruguay</b> Acuerda con la redacción propuesta.
<del><b>[Food production environment:</b> The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to <u>where scientific evidence supports</u> foodborne AMR <u>risk to human health</u>.]</del>	<b>USA</b> Text is edited to emphasize the need to ground the work in science and to be consistent with 8bis above.
<b>{Food production environment:}</b>	<b>Consumers International</b> Supports this definition as drafted and support removing the square brackets.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>Growth promotion:</b> Administration of antimicrobial agents <del>to only to</del> increase the rate of weight gain and/or the efficiency of feed utilization in animals. The term does not apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases.</p>	<p><b>International Association of Consumer Food Organizations</b> Uses of AM agents for growth promotion could be justified as having a second purpose (e.g., prophylactic). Medically important AM agents should not be used for growth promotion, period, as stated in Principle 5. The second sentence addresses the concept that agents properly used for treating, controlling, preventing disease which may also affect growth are permitted.</p>
<p><b>Medically important antimicrobials:</b></p>	<p><b>Australia</b> Supports this proposed text.</p>
<p><b>Medically important antimicrobials:</b> Antimicrobial agents important for therapeutic use in humans taking into account those described in the <i>WHO list of critically important antimicrobials</i> and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national/<u>regional</u> lists, where available. It does not include <del>ionophores or other</del> antimicrobial agents not important for human therapeutic use, <u>such as ionophores</u>.</p>	<p><b>Brazil</b> Suggests adding “regional” to be consistent with the rest of the document.</p>
<p><b>Medically important antimicrobials:</b> Antimicrobial agents important for therapeutic use in humans taking into account those described in the <i>WHO list of critically important antimicrobials</i> and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national lists, where available. <del>It does not include ionophores or other antimicrobial agents not important for human therapeutic use, such as ionophores.</del></p>	<p><b>Canada</b> Suggests deletion of this sentence as it goes beyond the definition. It is unclear why this specific class of antimicrobials is mentioned and not others.</p>
<p><b>Medically important antimicrobials:</b></p>	<p><b>Japan</b> Agrees to the addition of "such as ionophores" as a practical clarification.</p>
<p><b>Medically important antimicrobials:</b> Antimicrobial agents important for therapeutic use in humans taking into account those described in the WHO list of critically important antimicrobials and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established <u>in regional or</u> national lists, where available. It does not include <del>ionophores or other</del> antimicrobial agents not important for human therapeutic use, <del>such as ionophores</del>.</p>	<p><b>Morocco</b> Proposes amendment to the definition of medically important antimicrobials to include “regional” list to the definition. It is also proposed to maintain the former text concerning ionophores. The revised text of the definition as proposed is as follows. <u>Rationale:</u> There exists regional list of medically important antimicrobials in some regions. The OIE glossary of terms regarding antimicrobial classes for use in animals (ref Guidance for completing OIE template for the collection of data on AM agents in animals, OIE 2017) does not consider ionophores among AM classes. Therefore, ionophores should not be given as example of AM agents.</p>
<p><b>Antimicrobianos de importancia médica:</b> Agentes antimicrobianos importantes para su uso terapéutico en humanos, teniendo en cuenta aquellos que figuran en la <i>Lista de la OMS de antimicrobianos antimicrobianos de importancia crítica</i>, y clasificados con arreglo a criterios específicos como importantes, muy importantes y de importancia crítica para la medicina humana o según criterios equivalentes establecidos en listas nacionales, cuando existan. No incluye <del>ionóforos u otros</del> agentes antimicrobianos que no son importantes para usos terapéuticos en seres humanos, <u>como los ionóforos</u>.</p>	<p><b>CCTA</b></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>One Health Approach:</b> A collaborative, multisectoral, and trans-disciplinary approach - working at the local, regional, national, and global levels - with the goal of achieving optimal health outcomes recognizing the interconnection between humans, animals, <del>erops</del> plants/crops, and their shared environment.	<b>OIE</b>
<b>Plants/crops:</b> A plant <del>or crop</del> (or edible part thereof) that is cultivated or harvested as food or feed.	<b>Australia</b> <u>Rationale:</u> This improvement better reflects the merging of the 'plants/crops' and 'food of plant origin' definitions partially agreed and shown in AMR/06 CRD/20. Otherwise, clarity will be lost for the end user in the currently proposed text.
<b>Plants/crops:</b>	<b>Canada</b> Definitions should not include the words they are defining in the explanation.
<del>[Food of plant origin:]</del>	<b>Australia</b> Supports the deletion of this definition subject to the amendments shown for the plants/crops definition. <u>Rationale:</u> The plants/crops definition below has been improved for clarity of the end user.
[ <b>Food of plant origin:</b> All edible parts of plants/crops used as foods/ <u>feed</u> .]	<b>Canada</b> Agrees with inclusion.
[ <b>Food of plant origin:</b> ]	<b>Ghana</b> <u>Position:</u> Supports the definition of "food of plant origin" as presented. <u>Rationale:</u> The proposed definition is appropriate for the term.
<del>{Alimento de origen vegetal:}</del>	<b>Uruguay</b> Está de acuerdo con la definición, con la aclaración que en español, esta definición abarca tanto a la alimentación humana como la animal.
<del>[Food of plant origin:]</del>	<b>USA</b> Recommends deletion of this definition, if not used in the text.
[ <b>Plant/crop health professional / <del>plant pathologist:</del></b> ]	<b>Australia</b> Supports the draft definition
[ <b>Plant/crop health professional / <del>plant pathologist:</del></b> ]	<b>Canada</b> Does not support including this definition, as this category of profession may not exist in most countries
<b>Plant/crop health professional:</b> An individual professionally trained person with adequate and relevant <del>current</del> training, knowledge and experience in plant/crop health and protection practices.	<b>Ghana</b> <u>Position:</u> Supports the definition of plant/crop health professional and proposes the deletion of "current" to be replaced with "adequate and relevant" to read as follows: <u>Rationale:</u> The use of the words "adequate and relevant" to replace current is for clarity.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Plant/crop health professional / <del>plant pathologist</del> :]	<b>Japan</b> Supports this revision.
[Plant/crop health professional / <del>plant pathologist</del> :]	<b>Morocco</b> Takes note of the term for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases and proposes the use of the term “Plant Pathologist” as the professional to apply the key risk management measures described in the document in relation to administration or application of medically important antimicrobials. <u>Rationale:</u> Plant Pathology is defined as the study of the organisms and environmental conditions that cause disease in plants, the mechanisms by which this occurs, the interactions between these causal agents and the plant (effects on plant growth, yield and quality), and the methods of managing or controlling plant disease. A plant pathologist is a professional with skills to manage and control diseases in plants and capable of prescribing the appropriate drugs for use in treatment of plant diseases.
[Profesional de sanidad de las <del>plantas/cultivos/</del> plantas/cultivos: <del>patólogo de plantas</del> :]	<b>Uruguay</b> Está de acuerdo con la definición propuesta.
[Plant/crop health professional / <del>plant pathologist</del> :]	<b>USA</b> Support the text as revised, including deletion of “plant pathologist” as the term is overly specific and specialized and may not be globally applicable for professionals working in the area
[Therapeutic use:]	<b>Australia</b> Supports this proposed text.
[Therapeutic use:]	<b>Brazil</b> Supports the proposed definition.
[ <del>Therapeutic use</del> :]	<b>Canada</b> Suggest to delete this definition due to the different understanding of this term in veterinary and human medicine. Unless the term is changed to “Therapeutic use in animals”
[Therapeutic use: Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis <del>or and prevention/prophylaxis of disease.</del> <b>Therapeutic Use:</b> Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis.	<b>Ghana</b> <u>Position:</u> Proposes the deletion of ‘prophylaxis of disease’ in the definition of Therapeutic use to read as follows. We however recommended that metaphylaxis as used in definition of therapeutic use be defined for clarity. <u>Rationale:</u> Prevention of prophylaxis has been defined in the standard and therefore does not fall under therapeutic use.



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Therapeutic use:]	<b>Japan</b> Agrees this definition, in principle, recognizing the need of this to be applicable to plant/crop as well. However, it should be noted that the three components of therapeutic use are defined referring only to animal.
[Therapeutic use:]	<b>Morocco</b> Supports the definition of therapeutic use since it is consistent with the OIE definition.
[Therapeutic use:]	<b>Republic of Korea</b> Supports the definition because it is consistent with the definition of “Veterinary medical use of antimicrobial agents” used in OIE <i>terrestrial animal health code</i> , chapter 6.9.2.
<del>[Usó terapéutico:]</del>	<b>Uruguay</b> Está de acuerdo con la definición propuesta.
[Therapeutic use:]	<b>USA</b> Supports this definition, including replacing “and” with “or”.
<del>[Therapeutic use:]</del>	<b>Consumers International</b> This definition is not needed for this document, since it is inconsistent with the WHO definition of “therapeutic use” and since there are already agreed upon definitions for “Treatment of disease”, “Control of disease/metaphylaxis” and “Prevention of disease/prophylaxis” elsewhere in Section 3. Thus, we recommend deletion.
[Therapeutic use:]	<b>HealthForAnimals</b> This definition is now in line with the OIE and FDA which clearly state therapeutic includes treatment, control and prevention.
<del>[Therapeutic use:]</del>	<b>International Association of Consumer Food Organizations</b> It is best to delete this definition since it is not needed and is inconsistent with the WHO definition of therapeutic use. Most references to “therapeutic” in the document refer to use in humans and the others are unnecessary (simply refer to uses for treatment, management, and prevention of disease).
4. General principles to minimize and contain AMR	
Ordering of Principles	<b>Australia</b> Supports the proposed order.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
4. General principles to minimize and contain antimicrobial resistance	<b>Brazil</b> This section has improved after the last revision, but could still improve to be more consistent to “principles” and proportionate to the scope. Some of the principles still seem to be duplicated and/or redundant and could be more focused and concise. Brazil supports the proposal for discussion and revision of this section during PWG/TFAMR.
4. General principles to minimize and contain antimicrobial resistance	<b>Morocco</b> Takes note of the recommendations of the EWG and makes the following comments regarding the general principles.
4. Principios generales para reducir al mínimo y contener la resistencia a los antimicrobianos	<b>Uruguay</b> Comparte el orden dado a los principios.
<b>Principles on AMR Risk Management (generally)</b>	
<b>Principle 1:</b> A One Health Approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options. <u>It is everyone’s responsibility in the food supply chain to minimise and contain AMR.</u>	<b>Australia</b> <u>Rationale:</u> To improve clarity of the principle.
<b>Principle 4:</b> The <i>WHO list of critically important antimicrobials</i> , the <i>OIE list of antimicrobials of veterinary importance</i> , or national/ <u>regional</u> lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	<b>Brazil</b> Suggests adding “regional” to be consistent with the rest of the document.
<b>Principle 4:</b> The <i>WHO list of critically important antimicrobials</i> , <u>AWaRe antibiotic classification of the WHO</u> , the <i>OIE list of antimicrobials of veterinary importance</i> , or national lists, where-available and <u>new scientific data on resistance patters and AMU</u> , should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. <del>The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.</del>	<b>Canada</b> Suggests deletion of the last sentence, as the WHO and OIE are independent of this document.
<b>Principle 4:</b> <u>International guidance such as the WHO list of critically important antimicrobials</u> , the <i>OIE list of antimicrobials of veterinary importance</i> , or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	<b>USA</b> Edits clarify that these are not the only international documents that can be considered.
<b>Principle 4:</b> The <i>WHO list of critically important antimicrobials</i> , the <u>WHO guidelines on use of medically important antimicrobials in food-producing animals</u> , the <i>OIE list of antimicrobials of veterinary importance</i> , or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	<b>Consumers International</b> The WHO guidelines on use of medially important antimicrobials in food-producing animals should be added to the list, since it is highly relevant and useful guidance in this area.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>Principle 4:</b> The <i>WHO list of critically important antimicrobials</i>, the <u>WHO guidelines on use of medically important antimicrobials in food-producing animals</u>, the <i>OIE list of antimicrobials of veterinary importance</i>, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.</p>	<p><b>International Association of Consumer Food Organizations</b> The WHO guidelines on use of medically important antimicrobials in food-producing animals is highly relevant and useful international guidance and should be included.</p>
<p><b>Principle 9:</b></p>	<p><b>Australia</b> Supports the proposed text.</p>
<p><b>Principle 9:</b> Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk <u>to human health</u> and <u>is reviewed on a regular basis</u> as described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i>. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures. <u>When considering animal or plant health aspects risk managers should take into account relevant OIE and IPPC standards.</u></p>	<p><b>Canada</b> Principles 9 and 15 could be combined to say the same thing regarding priorities and considerations. In addition, IPPC should be spelled out.</p>
<p><b>Principle 9:</b></p>	<p><b>Ghana</b> <u>Position:</u> Accepts the addition. <u>Rationale:</u> OIE and IPPC are relevant authorities of issues on animal and plant health.</p>
<p><b>Principle 9:</b></p>	<p><b>Japan</b> Supports adding the third sentence.</p>
<p><b>Principle 9:</b></p>	<p><b>Morocco</b> Recommends adoption of principles 9, 10 and 14 as proposed by the EWG and concurs with the proposal to re arrange the principles and group them into the 5 categories {Principles on AMR Risk Management (generally) (1,9,4&amp;15); Principle on preventing infections and reducing the need for antimicrobials (2); Principles on the responsible and prudent use of antimicrobials (generally) (13,12,8,14,3); Principles on the use of antimicrobials in specific circumstances (5, 6,7,7bis &amp; 7ter); Principle on surveillance of antimicrobial resistance and use (10)}.</p>
<p><b>Principle 15:</b> <del>On</del> <u>To minimize the possible risks associated with foodborne AMR, priority in a continuous and progressive implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority</u> should be given to the most relevant elements from a public health perspective.</p>	<p><b>Canada</b> Minor edits are suggested to improve readability</p>
<p><b>Principle 15:</b> On a continuous and progressive implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective, <u>taking also into account animal health issues.</u></p>	<p><b>OIE</b></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>Principle on preventing infections and reducing the need for antimicrobials</b>	
<b>Principle 2:</b> Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and other alternative tools where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the <u>incidence of infections and hence reduce the</u> need for use of antimicrobial agents.	<b>Canada</b> Minor edits are suggested to improve readability
<b>Principles on the responsible and prudent use of antimicrobials (generally)</b>	
<b>Principles on the responsible and prudent use of antimicrobials</b> <del>(generally)</del>	<b>Canada</b>
[Principle 12:]	<b>Canada</b> Supports the inclusion of this principle
[Principle 12:]	<b>Ghana</b> <u>Position:</u> Supports Principle 12 without any comments. <u>Rationale:</u> The term "legislation" gives room to interpret this information driven by each country's legislation.
[Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.] <u>However, for plants/crops, it is possible to be administered, prescribed or applied according to guidelines for the safe use established under national legislation, if appropriate.</u>	<b>Republic of Korea</b> Suggests adding the last sentence. Because, for plants/crops, it may be practically difficult for plant/crop health professionals to administer, prescribe or apply all antimicrobials.
{Principio 12:}	<b>Uruguay</b> Está de acuerdo con las modificaciones planteadas a este parrafo.
[Principle 12:]	<b>Consumers International</b> Support this principle as drafted and support removal of the square brackets.
[Principle 12:]	<b>HealthForAnimals</b> Agrees.
<b>Principle 13:</b> The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial <u>cultures culture</u> and <u>integrated data from</u> resistance <u>surveillance</u> and <u>antimicrobial use monitoring and surveillance programs</u> should also be considered.	<b>Canada</b> Minor edits are suggested to improve readability, but see below comments for Principle 14
<b>Principle 14:</b>	<b>Australia</b> Supports the proposed text.
<b>Principle 14:</b> The <u>decision to use antimicrobial agents and the</u> choice of which antimicrobial agent to use should take into consideration relevant professional guidelines, where available, results of <u>antimicrobial</u> susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	<b>Canada</b> Proposes to delete principle 13 and amend principle 14 to include 'The decision to use...', in addition to some edits to improve readability

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<i>Principles on the use of antimicrobials in specific circumstances</i>	
<i>Principles on the use of antimicrobials in specific circumstances</i>	<b>Canada</b> Considers this heading unnecessary, as the principles below are also relevant to prevent infections.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for animal growth promotion of antimicrobial agents <del>that are considered medically important</del> <u>highest priority critically important or equivalent criteria within national lists. Antimicrobial agents that are not considered medically important, other than those referred to above, should not be used for animal growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis Foodborne Antimicrobial Resistance in te absence of risk analysis in accordance with GXG 77-2011.:</u>	<b>Australia</b> Rationale: The highest priority critically important criterion reflects <b>the OIE List recommendation covering urgent prohibition of fluoroquinolones, third and fourth generation cephalosporins, and colistin</b> . Amendments also reflect other OIE List recommendations. The insertion of 'animal' shows how it is only applicable to animal health. Australia prefers these amended sentences for clarity and brevity. The current proposed text leads to further misunderstandings. Australia proposes the statement about cross and co-resistance potential be deleted, as it is covered by the reference to risk analysis.
<b>[Principle 5:]</b>	<b>Brazil</b> Agrees to the new proposed text.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <del>that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.:</del>	<b>Canada</b> Supports the inclusion of this principle and suggests to move it after principle 15 as a general principle
<del><b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents</del> <u>Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.</u>	<b>Iran</b> The statement is not clear. Maybe it could be:  Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <del>that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.:</del>	<b>Japan</b> Supports this revision and suggests adding "as negligible" for clarification.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <del>that are considered medically important. Antimicrobial agents that are not considered medically important can only should not be used for growth promotion unless</del> <u>when the potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011:</u>	<b>Morocco</b> Proposes amendment to the text as follows:

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
{Principio 5:}	<b>Uruguay</b> Está de acuerdo con las modificaciones planteadas en este párrafo.
[Principle 5:]	<b>USA</b> Supports the text as revised.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <u>that are considered medically important or are able to cause cross- or co-resistance to antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.</u> :]	<b>Consumers International</b> Support the original language that was agreed upon at last year's TFAMR meeting. Not only should medically important antimicrobials not be used for growth promotion, but neither should antimicrobial agents that are not medically important but that are able to select for resistance, via cross-resistance or co-selection, to medically important antibiotics. For example, colistin is last line antimicrobial for use in human medicine. A study last year demonstrated that the non-medically-important antimicrobial bacitracin also selects for resistance to colistin, noting that "imprudent and extensive usage of bacitracin in food animals may serve as a non-colistin usage risk factor for the transmissible colistin resistance." (Xu et al., 2018). Thus, we can agree to this modified Principle 5 if the phrase "or are able to cause cross- or co-resistance to antimicrobial agents that are considered medically important" is added to this principle. Xu F, Zeng X, Hinenoya A and J Lin. 2018. MCR-1 confers cross-resistance to bacitracin, a widely used in-feed antibiotic. mSphere 3(5): e00411-18. At: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6126145/pdf/mSphere.00411-18.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6126145/pdf/mSphere.00411-18.pdf</a> Also support removal of the square brackets.
[Principle 5:]	<b>HealthForAnimals</b> The proposed language simplifies while maintaining the integrity of the principle. Principles should not be needlessly complex. This proposal fixes it. This removes potential ambiguity about selection conditions that should be considered within the context of a risk assessment. If not, it could justify a hazard-based decision and place countries at risk of their WTO obligations.;
[Principle 5:]	<b>International Association of Consumer Food Organizations</b> This principle is key, and this compromise wording reached at the last session is acceptable to IACFO.
<b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <u>that are considered medically important. Antimicrobial agents that are not considered medically important should <del>not be used</del> phased out for growth promotion unless potential risks to human and animal health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011 and OIE and chapter 6.11 of the OIE Terrestrial Animal Health Code and chapter 6.5 of the OIE Aquatic Animal Health Code.</u> :]	<b>OIE</b>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 6:</b> Medically important antimicrobial agents should only be <del>for therapeutic purposes (treatment, control/metaphylaxis therapeutically used in food-producing animals or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]</del>	<b>Australia</b> Rationale: 'Therapeutically used' rather than 'therapeutic purposes' is proposed, as it is a defined term in Section 3 (Definitions). Consequently, the struck out text becomes obsolete.
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); <del>or in certain circumstances for research and conservation.]</del>	<b>Brazil</b> Suggests deleting the last sentence, once it seems to be out of the scope of Codex and a principle should not deal with such specific exceptions.
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used for <del>therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]</del>	<b>Canada</b> Supports the inclusion of this principle, but suggests the deletion of the term 'therapeutic purposes'. It is unclear what research and conservation mean in the context of the food chain; hence, it is suggested to delete the last part of the sentence.
<b>{Principio_6:}</b>	<b>Uruguay</b> Está de acuerdo con este principio, pero sugiere aclarar el alcance del término "conservación"
<b>[Principle 6:]</b>	<b>USA</b> Supports this Principle.
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used for <del>therapeutic purposes (treatment or control/metaphylaxis prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]</del>	<b>Consumers International</b> In line with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals, we support the position that medically important antibiotics should only be used for treatment or control of disease and should not be allowed for prevention of disease, except under well defined, rare, circumstances. Thus, we think Principle 6 should be edited to remove the words "therapeutic purposes" and "or prevention/prophylaxis." In addition, we feel the final clause, "in certain circumstances for research and conservation" is not needed, and could be deleted
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used <u>in food production/processing when effective alternatives are not available</u> for <del>therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation</del> <u>where such uses will not contribute to antimicrobial resistance.]</u>	<b>International Association of Consumer Food Organizations</b> This principle as originally worded is basically a restatement of principle 5. Also, research and conservation uses should not be permitted if they may contribute to AMR.
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used for <del>therapeutic</del> <u>veterinary medical use</u> purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]	<b>OIE</b>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[Principle 7:</b> When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. <del>Medically important antimicrobials should be administered only when no other alternative treatment is available. Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del></p>	<p><b>Australia</b>  <b>Rationale:</b> The suggested text encourages the prescriber to consider alternative treatments or actions first before using antimicrobials. This supports the responsible and prudent use principle.</p>
<p><b>[Principle 7:</b> When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered <del>in well-defined circumstances</del>, based on epidemiological and clinical knowledge, <del>identification of a specific disease risk</del> and follow appropriate professional oversight, dose, and duration. <del>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del></p>	<p><b>Brazil</b>  Suggests revisions to provide clarity.</p>
<p><b>[Principle 7:]</b></p>	<p><b>Canada</b>  Supports the inclusion of this principle</p>
<p><b>Principle 7:</b> <i>When used for control of animal disease/prophylaxis and for the crop/plant protection, medically important antimicrobials should only on the basis of epidemiological and professional knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose and duration.</i></p>	<p><b>China</b>  Principle 7, Combine 3 paragraphs into the following sentence.</p>
<p><b>Principle 7:</b> <i>When used for prevention/prophylaxis of a specific disease risk or control of disease/metaphylaxis, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration.</i></p>	<p><b>Morocco</b>  Recommends the merger of these two principles: The proposed text reads:</p>
<p><b>{Principio 7:}</b></p>	<p><b>Uruguay</b>  Está de acuerdo con este principio y sus modificaciones.</p>
<p><b>[Principle 7:</b> When used for prevention/prophylaxis of <del>a specific disease risk</del>, medically important antimicrobials should only be administered <del>in well-defined circumstances</del><del>with professional judgement</del>, based on epidemiological and clinical knowledge, <del>identification of a specific disease risk</del>, and follow appropriate professional oversight, dose, and duration. <del>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del></p>	<p><b>USA</b>  Edited to be in line with 7bis. We suggest removing the phrase “in well-defined circumstances” and replacing it with “with professional judgement”. Appropriate preventive uses require the professional judgment of a licensed veterinarian, but such situations that warrant preventive use may not necessarily be well-defined, because by definition, evidence of disease or infection does not exist within the animal or animals in the group.</p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[Principle 7:</b> When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances <u>for a limited time period</u>, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. <u>Those antimicrobials most important for human and animal health, should not be administered in food or water for prevention/prophylaxis in the absence of clinical signs in the animals.</u> <del>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del></p>	<p><b>Consumers International</b></p> <p>Agree with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals that medically important antibiotics should not be allowed for prevention of disease, except under well defined, rare, circumstances. Using these medically important antimicrobials for a limited time period is important especially when using them for disease prevention purposes. In addition, as noted in the OIE List of Antimicrobial Agents of Veterinary Importance, “Among the list of veterinary critically important antimicrobials, some are considered to be critically important both for human and animal health; this is currently the case for Fluoroquinolones and for the third and fourth generation of Cephalosporins. Colistin has been moved in 2016 to the WHO category of Highest Priority Critically Important Antimicrobials.</p> <p>Therefore these two classes and Colistin should be used according to the following recommendations: Not to be used as preventative treatment applied by feed or water in the absence of clinical signs in the animal(s) to be treated.” (Pg. 4 in OIE. 2019. OIE List of Antimicrobial Agents of Veterinary Importance. July 2019. At: <a href="https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf">https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_OIE_List_antimicrobials_July2019.pdf</a>)</p> <p>Consequently, the sentence “Those antimicrobials most important for human and animal health should not be administered in food or water for prevention/prophylaxis in the absence of clinical signs in the animals” should be added to this Principle along with the addition of the phrase “for a limited time period.”</p> <p>Finally, we support removal of the square brackets.</p>
<p><b>[Principle 7:</b> When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. <u>“Well-defined circumstances” means circumstances where there is convincing evidence (1) of effectiveness, (2) of consistency with accepted practice, (3) that the use is linked to a specific etiologic agent and a specific disease to be prevented, (4) that the use is appropriately targeted to those at risk of developing a specific disease, and (5) that there are no reasonable alternatives for intervention.</u> This use should not be routine and should not be a substitute for good hygiene and/or good husbandry and production practices. <del>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del></p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>“Well-defined circumstances” should be clarified. See edits below.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 7:</b> When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight (veterinarian or other animal health professional properly trained), dose, and duration. <del>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</del>	<b>OIE</b>
<b>[Principle 7bis:]</b>	<b>Australia</b> Supports the proposed text.
<b>[Principle 7bis:]</b>	<b>Canada</b> Supports the inclusion of this principle
<b>[Principle 7bis:]</b>	<b>Morocco</b> Recommends the merger of these two principles:
<b>{Principio 7bis:}</b>	<b>Uruguay</b> Está de acuerdo con este principio.
<b>[Principle 7bis:</b> When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]	<b>USA</b> The statement is modified to provide flexibility for application globally and to allow for professionals to exert clinical judgement under local conditions. When trying to prevent a disease, it is not possible to “diagnose” a disease, because the disease has not yet occurred, but the professional would be exerting clinical judgement regarding disease risk.
<b>[Principle 7bis:]</b>	<b>Consumers International</b> Support this new principle as written since we think it is a good idea to put metaphylaxis and prophylaxis in separate principles. We support removal of the square brackets.
<b>[Principle 7bis:</b> When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used administered in well-defined circumstances, based on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease, and follow appropriate professional oversight, dose, and duration. Well-defined circumstances” means circumstances where there is convincing evidence (1) of effectiveness, (2) of consistency with accepted practice, (3) that the use is linked to a specific etiologic agent and a specific disease to be controlled, (4) that the use is appropriately targeted to those at risk of developing a specific disease, and (5) that there are no reasonable alternatives for intervention. This use should not be routine and should not be a substitute for good hygiene and/or good husbandry and production practices.]	<b>International Association of Consumer Food Organizations</b> Again, need greater clarity and specificity. Add definition of "well-defined circumstances" above, modified as appropriate for metaphylaxis.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>[Principle 7bis: When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight (veterinarian or other animal health professional properly trained), dose, and duration.]</u>	<b>OIE</b>
<u>[Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease when no other alternative treatment is available, and follow appropriate professional oversight, dose, and duration.]</u>	<b>Australia</b> Rationale: The suggested text encourages the plant/crop health professional to consider alternative treatments or actions first before using antimicrobials. The proposed text supports the responsible and prudent use principle.
<u>[Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.]</u>	<b>Canada</b> Supports the inclusion of this principle but suggests different wording should be used to make it more relevant to the plant/crop production sector
<u>[Principle 7ter:]</u>	<b>Morocco</b> Further recommends the deletion of 7ter. Rationale: The two (7 and 7bis) address specific circumstances related to therapy and are applied within the same circumstances. 7ter is recommended for deletion since currently there is insufficient data on use of Medically Important Antimicrobials in plants. ISPM diagnostic protocols and phytosanitary treatment do not show AMR as an issue. There is as yet no list of critically important Antimicrobials in plants
<u>[Principle 7ter:]</u>	<b>Uruguay</b> Sugiere suprimir este principio.
<u>[Principle 7ter:]</u>	<b>USA</b> The statement is redundant and should be deleted as 7 and 7bis are not written specifically for animals and apply for crops too.
<u>[Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.]</u>	<b>Consumers International</b> Support the addition of this principle since it involves use of antimicrobials in plant/crop protection. The suggested additional language should be added to make it closer in structure to Principles 7 and 7bis, since the need for epidemiological and clinical knowledge is just as true for use in plant bacterial diseases as animal diseases. We support removal of the square brackets.
<u>[Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents for plant/crop protection should only be used according to the extent necessary for a specific disease-label guidelines and follow appropriate professional oversight, dose, and duration in the context of integrated pest management strategies.]</u>	<b>International Association of Consumer Food Organizations</b> Delete existing language in Principle 7ter since it repeats what has already been said. Instead reflect advice from recent WHO/FAO expert consultation.
<u>[Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight (by a veterinarian or other animal health professional properly trained), dose, and duration.]</u>	<b>OIE</b>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>Principle on surveillance of antimicrobial resistance and use</b>	
<b>Principle 10:</b> Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. <del>Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and resistance genes between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i>.</del>	<b>Canada</b> The last sentence seems out of place and its intent has already been captured in the Introduction.
<b>Principle 10</b>	<b>Morocco</b> Recommends adoption of principles 9, 10 and 14 as proposed by the EWG.
<b>Principio 10:</b> El seguimiento y vigilancia del uso de agentes antimicrobianos, así como la incidencia o prevalencia, y, en determinadas pautas, los microorganismos resistentes y los determinantes de resistencia a los antimicrobianos en los alimentos transmitida por los alimentos se encuentran entre los factores críticos a tener <u>en</u> cuenta a la hora de desarrollar medidas de gestión del riesgo y de evaluar la eficacia de las medidas de gestión del riesgo aplicadas. El uso de agentes antimicrobianos en seres humanos, animales destinados a la producción de alimentos y plantas/cultivos y la transmisión de patógenos y de genes de resistencia entre los seres humanos, los animales destinados a la producción de alimentos, <u>las plantas/cultivos</u> y el ambiente son factores adicionales a tener en cuenta en el análisis de riesgos de RAM transmitida por los alimentos que se describe en las <i>Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos</i> .	<b>CCTA</b>
<b>5. Responsible and prudent use of antimicrobial agents</b>	
Paragraphs 13 to 14	<b>Australia</b> Supports the proposed text.
Paragraphs 13 to 14	<b>Canada</b> These paragraphs do not flow well as introductory paragraphs for this section. For example para 14 mentions data requirements, which could be incorporated into section 5.1. Para 14 indicates that internationally harmonized guidelines can be used for data requirements, yet para 15 places a responsibility on competent authorities to develop guidelines on data requirements. We question the need to include that level of specificity in para 15.
<u>13 40.</u>	<b>Canada</b> Suggests ensuring consistency within the document. This COP uses food animals (terrestrial and aquatic) in Paras 9, 16 and 63, while this para refers to food-producing animals and aquaculture.

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
<u>13 40.</u>	<b>China</b> The International Plant Protection Convention (IPPC), besides OIE reference, should be included in this document.
<u>13 40.</u>	<b>Ghana</b> <u>Position:</u> Accepts the new addition in paragraph 13 without any amendment. <u>Rationale:</u> This context is appropriate.
<u>13 40.</u>	<b>Japan</b> Supports adding "and the OIE list of antimicrobial agents of veterinary importance."
<u>13 40.</u>	<b>Uruguay</b> Está de acuerdo con la inclusión de la lista de la OIE de agentes antimicrobianos de importancia veterinaria.
<u>13 40.</u>	<b>USA</b> Supports as revised.
<u>14 44.</u> <u>14 44.</u>	<b>Brazil</b> Agrees to the new proposed text.
<u>14 44.</u>	<b>Ghana</b> <u>Position:</u> Accepts the new addition in paragraph 14 without any amendment. <u>Rationale:</u> This context is appropriate.
<u>14 44.</u> For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see relevant national guidelines or <u>internationally harmonized guidelines</u> . <u>The International Cooperation on Harmonization of Technical Requirements for Requirement for Veterinary Medicinal Products (VICH) may provide a useful reference. such as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines.</u>	<b>Japan</b> Suggests mentioning VICH, as a useful source of information rather than complete deletion.
<u>1444.</u>	<b>Uruguay</b> Está de acuerdo con mantener la referencia a las directrices nacionales pertinentes o a las directrices nacionales pertinentes o a las directrices internacionales armonizadas internacionalmente sin nombrar específicamente a ninguna.
<u>14 44.</u>	<b>HealthForAnimals</b> Prefers to keep VICH reference in but if it makes text more acceptable than can accept deletion.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
14 44.	<p><b>OIE</b></p> <p>Keep the reference to the VICH guidelines, as not only there is a reference to them on the OIE standards, but their importance is also highlighted by the fact that 16 countries and three regional organisations (ASEAN, CAMEVET and WAEMO/VEMOA) are members of the related outreach forum.</p>
<b>5.1 Responsibilities of the competent authorities</b>	
Paragraphs 15 to 18	<p><b>Australia</b></p> <p>Supports the proposed text.</p>
<p>15 42. The competent authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization <del>and in providing of antimicrobial agents. They should also provide</del> appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation, and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. <u>It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national and/or sub-national legislation.</u></p>	<p><b>Canada</b></p> <p>Suggests dividing up this very long sentence, for example as proposed in tracked changes</p>
15 42.	<p><b>Ghana</b></p> <p>Paragraphs 15, 16 and 17</p> <p><u>Position:</u> Supports the new additions made to paragraph 15 without any comments.</p> <p><u>Rationale:</u> This context is appropriate.</p>
15 42.	<p><b>USA</b></p> <p>Supports as revised.</p>
<p>16 43.</p> <p>16 bis. <u>National action plans may include recommendations to veterinarians and plant/crop health professionals entities/associations to develop species or sector-specific guidelines.</u></p>	<p><b>Brazil</b></p> <p>This sentence, that is similar to the last sentence of paragraph 50, should be moved to this section of the document, once the development of NAPs is a responsibility of the competent authority.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>16 43. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to minimize for the prevention and containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.</del>	<b>Canada</b> Principle 1 already mentions the One Health approach,; it seems duplicative to include it in this paragraph. Further, the last sentence is a repetition of wording in Principle 2.
16 43.	<b>Ghana</b> Paragraphs 15, 16 and 17 <u>Position:</u> Supports the new additions made to paragraph 16 without any comments. <u>Rationale:</u> This context is appropriate.
16 43.	<b>USA</b> Supports as revised.
<del>16 43. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to prevent, minimize for the prevention and containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.</del>	<b>International Association of Consumer Food Organizations</b>
[17 43bis:]	<b>Canada</b> Supports the inclusion of this paragraph.
[17 43bis: A fin de promover el uso responsable y prudente de los agentes antimicrobianos, es importante fomentar la utilización, el desarrollo, y la disponibilidad y el uso de instrumentos de diagnóstico validados, rápidos y fiables, cuando se disponga de ellos, para ayudar a los veterinarios y a los profesionales de sanidad de las plantas/cultivos a seleccionar los antimicrobianos más apropiados que deben administrarse o aplicarse. <del>prescribirse para el tratamiento.</del>	<b>Uruguay</b> Propone mantener el término "utilización" y eliminar "l desarrollo y la disponibilidad" del párrafo.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[17 <del>13bis</del> . In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the <del>use</del> development, <del>and</del> availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in selecting the most appropriate antimicrobial to be administered/applied <del>prescribed for treatment.</del> ]	<b>USA</b> Concurs with the deletion. For global applicability, “prescriptions” are not always how drugs are dispensed, though they are still administered under professional oversight.
[17 <del>13bis</del> .]	<b>Consumers International</b> Support this new para as written since use of validated, rapid, reliable diagnostic tools is very important in determining which antimicrobials to use for specific plant and animal disease and, consequently, support removal of the square brackets.
18. If dose ranges or different durations of treatment are indicated, the competent authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of resistance, when this information is available.	<b>Brazil</b> Suggests replacing the proposed text by the original text in CXC 61-2005. Brazil does not agree in a need of a risk analysis process to determine labelling. Labelling is determined during the marketing authorization process in accordance to national legislation and can be revised based on new information, specially from pharmacovigilance programs, but does not usually go through a risk analysis process.
[18 <del>14alt</del> .]	<b>Ghana</b> Paragraphs 15, 16 and 17 <u>Position</u> : We support the new additions made to paragraph 18 without any comments. <u>Rationale</u> : This context is appropriate.
[18 <del>14alt</del> .]	<b>Uruguay</b> Está de acuerdo con la redacción del párrafo.
[18 <del>14alt</del> .]	<b>USA</b> Supports replacing 14 with 14alt (now 18) which includes reference to professional judgement when the competent authorities develop guidance for approved labelling. Foodborne AMR risk and the need to maintain efficacy and safety were lost from the original paragraph, so inserted these as well as language for crop professionals.
[18 <del>14alt</del> . Tras el análisis de riesgos, las autoridades <del>competentes de reglamentación</del> deberían determinar el etiquetado adecuado, <u>incluidas las condiciones para reducir al mínimo el desarrollo de la RAM transmitida por los alimentos, al tiempo que se <del>mantiene</del> mantienen la eficacia y la inocuidad, siempre que esta información esté disponible.</u> Además, el criterio profesional <del>a la hora de su prescripción por parte del veterinario o del profesional de sanidad de las plantas/cultivos, sobre quien recae la responsabilidad de la supervisión, debería ser un factor a tenerse en cuenta cuando las autoridades de reglamentación competentes elaboren dicha orientación para el etiquetado de los productos aprobados.</del> ]	<b>CCTA</b>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
44.	<b>Consumers International</b> Support the deletion of this para, since the main points of the para have been inserted into para 18.
<b>Quality control of antimicrobial agents</b>	
Paragraph 19	<b>Australia</b> Supports the proposed text.
19 45. Competent authorities should ensure that quality controls are carried out in accordance with <u>national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.</u>	<b>Brazil</b> Suggests deleting the last sentence, once the examples may lead to misinterpretation focusing only in some parts of good manufacturing practices.
19 45. Competent authorities should ensure that quality controls are carried out in accordance with <u>national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.</u>	<b>Canada</b> Minor edit suggested to improve readability
19 45. Competent authorities should ensure that quality controls are carried out in accordance with <u>national, regional or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.</u>	<b>Morocco</b> Addition of the word “ regional” in the first sentence after national.
19 45.	<b>USA</b> Supports as revised.
19 45.	<b>Consumers International</b> Support the added language in this para as it gives examples of the important provisions of good manufacturing practices should be followed, and so support the entire paragraph.
19 45. Competent authorities should ensure that quality controls are carried out in accordance with <u>national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.</u>	<b>HealthForAnimals</b> Deletion because GMP does not apply to mixing in feed, water or other ingredients. It is impossible to apply pharma GMP rules on farm/in mills etc. There are different GMP rules for different industries. Furthermore, QC controls on every batch also do not apply at these stages.
<b>Assessment of efficacy</b>	
Paragraph 20	<b>Australia</b> Supports the proposed text.
20 46.	<b>Canada</b> It is unclear if the last sentence is referring to using pharmacovigilance data in assessing efficacy or having a good pharmacovigilance program in order to watch out for signals that might influence efficacy.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
20 46.	<b>USA</b> Supports as revised.
20 46. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, <del>it the assessment</del> should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing,) <del>and</del> pharmacokinetic (PK) data, and <del>as well as</del> pharmacodynamic (PD) data. <del>The Data collected from pharmacovigilance (monitoring of a product) can be considered as part of the assessment of efficacy. It may also include assessment may also include evaluation of through proper veterinary care, health program evaluation and good pharmacovigilance practices.</del>	<b>HealthForAnimals</b> Delete and replace text. Good pharmacovigilance practice is not substance/product specific but usually company specific.
Assessment of the potential antimicrobial agents to select for resistant microorganisms	
Paragraph 21	<b>Australia</b> Supports the proposed text.
Assessment of the potential antimicrobial agents to select for resistant microorganisms foodborne AMR	<b>Brazil</b> Suggests correcting the subtitle to be consistent with the paragraph.
21 47. The competent authorities should assess the potential of <del>medically important</del> antimicrobial agents to select for <del>resistant microorganisms</del> foodborne AMR taking into account <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> , the <i>WHO list of critically important antimicrobials</i> , the <i>OIE list of antimicrobials agents of veterinary importance</i> , or national/ <u>regional</u> lists, where available.	<b>Brazil</b> Suggests adding "regional" to be consistent with the rest of the document.
21 47. The competent authorities should assess the potential of <del>medically important</del> antimicrobial agents <u>used along the food chain</u> to select for <del>resistant microorganisms</del> <u>foodborne AMR</u> taking into account <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> , the <i>WHO list of critically important antimicrobials</i> , the <i>OIE list of antimicrobials agents of veterinary importance</i> , or national lists, where available.	<b>Canada</b> Suggests deleting the term 'foodborne' as consideration might be needed to assess potential of antimicrobial agents to select for AMR in animal or plant pathogens as referenced in Para 26
21 47.	<b>Ghana</b> <u>Position:</u> Agrees to the additions made in paragraph 21. <u>Rationale:</u> This is in line with international norms.
21 47. The competent authorities should assess the potential of <del>medically important</del> antimicrobial agents to select for <del>resistant microorganisms</del> <u>foodborne AMR</u> taking into account <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> , the <i>WHO list of critically important antimicrobials</i> , the <i>OIE list of antimicrobials agents of veterinary importance</i> , or national <u>regional</u> lists, where available.	<b>Morocco</b> Addition of the word "/regional" in last sentence after national.
21 47.	<b>USA</b> Supports as revised.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
21 47.	<p><b>Consumers International</b></p> <p>Agree with the edits to this para since we believe competent authorities should assess the potential for ANY antimicrobial agent, not just medically important antimicrobials, to select for foodborne AMR. In addition, it might be useful to define “foodborne AMR”.</p>
<b>Assessment of environmental impact</b>	
<p>22 19. In accordance with their national guidelines, competent authorities should consider environmental fate and behaviour data of antimicrobial agents (e.g. degradation of the active constituents, mobility, likely transport and final destination in the environment) to help estimate the environmental concentrations in different environmental substrates—soils, sediment, water and manure—as appropriate, based on the proposed use pattern and properties of the chemical. Examples of sources that could contribute to the food production environment include pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, <del>foodborne AMR risk characterization from of environmental sources that contribute to the food production environment, such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. The environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. When a foodborne AMR risk is determined through the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> the need for monitoring and proportionate risk management measures <del>can</del> should be considered.</del></p>	<p><b>Australia</b></p> <p>Supports the merger of the previous paragraph 18 with this one. Australia also seeks to merge the alternative and proposed text below.</p> <p><u>Rationale:</u> The merging of the alternative and proposed text provides the principles that need to be considered in an evaluation, avoids overlooking any waste pathways that may lead to a foodborne AMR risk, and strengthens the guidance.</p>
<p>22 49. In accordance with their national guidelines, <del>C</del>competent authorities should consider foodborne AMR risk <del>characterization</del> assessment from <del>from of environmental</del> sources that <del>contribute to the food production environment, such as pollution from pharmaceutical manufacturing, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> When a foodborne AMR risk is determined through the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> the need for monitoring and proportionate risk management measures <del>can</del> should be considered.</p>	<p><b>Canada</b></p> <p>It is unclear why ‘risk characterization’ is used here. While risk characterization is the end result of a risk assessment, it is preferable to use the more generic language of ‘results of risk assessment’. Minor edits are proposed to improve readability</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>22 49. In accordance with their national guidelines, <del>C</del>competent authorities should consider foodborne AMR risk characterization <del>from</del> of environmental sources that contribute to the food production environment, <del>such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, <del>and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> When a foodborne AMR risk is determined through <u>procedures consistent with</u> the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> the need for monitoring and proportionate risk management measures <del>can</del> <u>should</u> be considered.</p>	<p><b>USA</b></p> <p>Concurs with deletion of para 18 as it is outside the scope of Codex as written. The intent is included in the rewrite of para 19 as it says follow national guidelines then 19 has more specifics of what to do. An edit is offered for consistency.</p>
<p><del>22 49.</del></p>	<p><b>Consumers International</b></p> <p>Support the reference to pollution from pharmaceutical manufacture in this para since it is an environmental source of antimicrobials and this pollution could affect irrigation water, apart from reuse of waste water. Thus, we support this para as drafted and edited.</p>
<p>22 49. In accordance with their national guidelines, <del>C</del>competent authorities should consider foodborne AMR risk characterization <del>from</del> of environmental sources that contribute to the food production environment, <del>such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, <del>and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> When a foodborne AMR risk is determined through the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> the need for monitoring and proportionate risk management measures <del>can</del> <u>should</u> be considered.</p>	<p><b>HealthForAnimals</b></p> <p>Delete text. Pharmaceutical manufacture pollution is absolutely not the norm and including in this list in such an unqualified manner implies it is. That is not correct. The other environmental sources listed are considered standard practice, but they are also unqualified and vary widely from country to country. Second sentence: "When a .." is good</p>
<p>22 49. In accordance with their national guidelines, <del>C</del>competent authorities should consider <u>the role of the environment on</u> foodborne AMR <u>and conduct a risk characterization from</u> of environmental sources that contribute to the food production environment, <del>such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, <del>and other waste-based fertilizers and/or municipal wastes for soil fertilization.</del> When a foodborne AMR risk is determined through the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> the need for monitoring and proportionate risk management measures <del>can</del> <u>should</u> be considered.</p>	<p><b>International Association of Consumer Food Organizations</b></p>
Establishment of a summary of product characteristics for each antimicrobial agent	
<p>Paragraph 23</p>	<p><b>Australia</b></p> <p>Supports the proposed text.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
23. 20. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial agent <del>veterinary medicinal product</del> . The information in these documents <del>the summary of product characteristics</del> can be utilized in labelling and as a package insert. <u>Such information may include:</u>	<b>Ghana</b> <u>Position:</u> Proposes the deletion of “veterinary medicinal product” in paragraph 23 <u>Rationale:</u> To ensure alignment with the heading of this paragraph.
23. 20.	<b>Morocco</b> Addition of “withdrawal period” to the bullets.
<del>23.20.</del>	<b>Uruguay</b> Está de acuerdo con el párrafo y la información incluida.
23. 20.	<b>USA</b> Supports as revised.
<ul style="list-style-type: none"> <li><u>withdrawal period;</u></li> </ul>	<b>Brazil</b> Suggests adding a bullet on “withdrawal period” due to its importance.
<ul style="list-style-type: none"> <li><del>interacciones</del> <u>Interacciones con otros medicamentos y usos en poblaciones específicas para cada medicamento veterinario antimicrobiano autorizado, cuando se disponga de esta información.</u></li> </ul>	<b>CCTA</b>
<ul style="list-style-type: none"> <li><u>drug interactions and</u></li> <li><u>uses in specific populations for each authorized antimicrobial veterinary medicinal product, when available.</u></li> </ul>	<b>HealthForAnimals</b> Clarity. This should be two separate bullets: one for uses and one for interactions. Listing the together is confusing.
Surveillance and monitoring programs	
Paragraphs 24 to 26	<b>Australia</b> Supports the proposed text.
24 21. Competent authorities should establish systems for <del>the surveillance and the monitoring and surveillance</del> of antimicrobial resistance and antimicrobial use following the <i>Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance as developed by Codex</i> , taking into consideration relevant sections of <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> ; <i>WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach</i> ; and <i>OIE terrestrial animal health code Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes</i> and <i>Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals</i> , <del>the OIE aquatic animal health code Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance.</del>	<b>Canada</b> Minor edit to be aligned with GLIS.
24 21.	<b>USA</b> Supports as revised.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>25 <del>22bis</del>. Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of <u>suspected</u> adverse reactions to veterinary antimicrobial <u>agents</u> <u>drugs</u>, including lack of the expected efficacy <u>that could be</u> related to antimicrobial resistance. The information collected through the pharmacovigilance program <u>can contribute to a should form part of the</u> comprehensive strategy to minimize antimicrobial resistance <u>in food</u>.</p> <p>25 <del>22bis</del>. <i>Competent authorities should have in place a pharmacovigilance program. for the monitoring and reporting of suspected adverse reactions to veterinary antimicrobial agents drugs, including lack of the expected efficacy that could be related to antimicrobial resistance. The information collected through the pharmacovigilance program can contribute to a should form part of the comprehensive strategy to minimize antimicrobial resistance in food.</i></p>	<p><b>Morocco</b></p> <p>Editing the paragraph to read (see <i>Italics text</i>.)</p> <p><u>Rationale</u>: Pharmacovigilance is well defined in the definition section and does not require to be repeated in the text.</p>
<p>25 <del>22bis</del>. Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of <u>suspected</u> adverse reactions to veterinary antimicrobial <u>agents</u> <u>drugs</u>, including lack of the expected efficacy <u>that could be</u> related to antimicrobial resistance. The information collected through the pharmacovigilance program <u>can contribute to a should form part of the</u> comprehensive strategy to minimize antimicrobial resistance <u>in food</u>.</p>	<p><b>USA</b></p> <p>"Foodborne" added to keep within Codex scope. Otherwise, support as revised.</p>
26 <del>22ter</del> .	<p><b>USA</b></p> <p>Supports as revised.</p>
Distribution of antimicrobial agents	
Paragraphs 27 to 29	<p><b>Australia</b></p> <p>Supports the proposed text.</p>
<p>27 <del>23</del>. Competent authorities, <del>to the extent possible</del>, should make sure <u>approved</u> antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation, <del>including that and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</del></p>	<p><b>Brazil</b></p> <p>Suggests deleting "approved" antimicrobial agents once it should apply to all. Additionally, Brazil reiterates the need to delete the end of the sentence, once there are different realities between member countries on how the distribution of antimicrobials occurs. It is important that the distribution systems are in accordance with national legislation but there should not be any different distribution system suggested for the medically important antimicrobials.</p> <p>Brazil agrees that the use of antimicrobials should be under supervision/oversight of veterinarians, plant/crop health professionals, but these professionals in some countries will only prescribe the antimicrobials, but will not have the responsibility to receive them from the distribution systems.</p>
<p>27 <del>23</del>. Competent authorities, <del>to the extent possible</del>, should make sure <u>approved</u> antimicrobial agents are distributed through appropriate distribution systems in accordance with national <u>and sub-national</u> legislation, <u>including that</u> and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained <u>persons authorized in accordance with national legislation</u> <u>persons</u>.</p>	<p><b>Canada</b></p> <p>Suggests including a reference to sub-national government entities. Not all professionals may be necessarily authorized in accordance with national legislation.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
27 23. Competent authorities, <del>to the extent possible,</del> should <u>ensure make sure</u> approved antimicrobial agents <u>including MIA</u> are distributed through appropriate distribution systems <del>in accordance with national legislation, including that and medically important antimicrobials are distributed to through</del> appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.	<b>Morocco</b> Edit the paragraph to read: “ <i>Competent authorities should ensure approved antimicrobial agents including MIA are distributed through appropriate distribution systems through appropriately credentialed/ registered veterinarians, plant/crop health professionals or other suitably trained persons authorized in accordance with national legislation</i> ”.
27 23.	<b>USA</b> Question why the term “approved” is needed here, otherwise support as revised.
<del>28 23bis. Competent authorities, to the extent possible, should prevent illegal medicines and unapproved formulations from entering distribution systems are responsible for market controls and measures being implemented and enforced intended to limit the effects of illegal, counterfeit and unapproved products.</del>	<b>Brazil</b> Suggests a new text to provide clarity.
<del>28 23bis.</del>	<b>Consumers International</b> Agree with this new para as drafted and edited, since illegal medicines and unapproved formulations are a problem in many countries, so it’s good that this document mentions that.
<del>29 24.</del>	<b>Brazil</b> Suggests deleting this paragraph because it is redundant and already reflected in paragraph 27.
29 24.	<b>USA</b> Supports as revised.
Control of advertising	
30 25. Competent authorities should <del>assure ensure</del> that advertising <u>and promotion of</u> antimicrobial agents is done in accordance with national legislation <del>or policies or policies.</del>	<b>Australia</b> <u>Rationale:</u> To maintain flexibility in control of relevant guidance for member countries after the point of sale of antimicrobial agents. Paragraphs 31 to 32 – Australia supports the proposed text.
30 25. Competent authorities should <del>assure ensure</del> that advertising <u>and promotion of</u> antimicrobial agents is done in accordance with national legislation <del>or policies</del> <u>and in a manner consistent with specific regulatory recommendations for the product.</u> <del>31. 26 Advertising and promotion of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.</del>	<b>Canada</b> Suggests that paragraphs 30 and 31 could be combined to streamline the document.
30 25.	<b>USA</b> Supports as revised.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
30 <del>25</del> .	<b>Consumers International</b> Support the added language in para 30 since we agree that “promotion” should be included in addition to advertising.
30 <del>25</del> .	<b>HealthForAnimals</b> It is suggested to include a single section for advertising, training, research, and record keeping. Simplification improves readability. Maintain sections 30-31 and strike 41-42. 30-31 can be improved with minor edits. Strike 41 and 42 because they would need substantial editing to say the same thing as 30 and 31. Also, 30-31 give greater consideration to lower income countries that lack a formal veterinary service because manufacturer communication is a viable way to communicate directions for responsible use.
<del>31-26</del> .	<b>Brazil</b> Suggests deleting this paragraph because it is redundant and already reflected in paragraph 30.
<del>31-26</del> .	<b>USA</b> Delete. Redundant with para 30.
31 <del>26</del> . Advertising <u>and promotion</u> of antimicrobial agents should be done in a manner consistent with <u>prudent use guidelines and any other</u> <del>prudent use guidelines and any other</del> specific regulatory recommendations for the product.	<b>Consumers International</b> Disagree with the deletion of the phrase “prudent use guidelines and any other” since that language also occurs from para 35 of the earlier 2005 version of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005).
31 <del>26</del> . Advertising <u>and promotion</u> of antimicrobial agents should be done in a manner consistent with <u>prudent use guidelines and any other</u> specific regulatory recommendations for the product <u>and should only be allowed to persons permitted to prescribe or supply antimicrobials, not to the producer.</u>	<b>International Association of Consumer Food Organizations</b> This edit is taken from language in the current Code of Practice and should be retained since advertising to producers can lead to unauthorized and/or imprudent use of antimicrobials. We note that a 1984 legal opinion provided by the FAO/WHO legal counsel was cited in a 2006 Discussion Paper on Advertising. Codex Committee on Food Labelling. See <a href="http://www.fao.org/tempref/codex/Meetings/CCFL/ccfl34/fl34_10e.pdf">http://www.fao.org/tempref/codex/Meetings/CCFL/ccfl34/fl34_10e.pdf</a> CX/FL 06/34/10 citing the FAO/WHO legal opinion published at CX/FL 85/7
<del>27</del> .	<b>USA</b> Concurs with deletion given edits to para 30 as these paragraphs contained several redundancies and should be condensed. Furthermore, the introduction of “or policies” created confusion as regulations may be considered to have the force of law, whereas policies may not have the same standing with respect to enforcement.



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	In addition, these guidelines should provide adequate flexibility for competent authorities to take into consideration "free commercial speech" issues, as appropriate to their national legislation.
<b>Training on issues related to antimicrobial resistance and the responsible use of users of antimicrobial agents</b>	
Paragraph 32	<b>Australia</b> Supports the proposed text.
32 28.	<b>Brazil</b> This paragraph is very broad, confusing and the bullets should be revised and reordered to avoid wrong interpretation and prioritization by member countries. Bullets 6, 8 and 11 need clarification: 6) understanding relevant risk analysis of veterinary antimicrobial agent products and how to use that information; 8) good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period; 11) understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options.
<del>32 28. Training should be supported, to the extent possible, by the competent authorities on issues-topics related to minimizing antimicrobial resistance and encouraging the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be involve the competent authorities, all the relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain. Training and communication may broadly address other public health constituencies.</del>	<b>Canada</b> Minor edits are suggested to improve readability
<del>32 28. Training should be supported, to the extent possible, by the competent authorities on issues related to antimicrobial resistance and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be involve the competent authorities, all the relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants including consumers along the food chain. Training and communication may broadly address other public health constituencies.</del>	<b>Japan</b> Suggests adding the word "consumers" as it should not be forgotten that the risk of food-born AMR to human health can be effectively avoided by proper handling.
<del>32 28. Training should be supported, to the extent possible, by the competent authorities on issues related to antimicrobial resistance and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be involve the competent authorities, all the relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain. Training and communication may broadly address other public health constituencies.</del>	<b>Switzerland</b> The term "supported" can be understood to imply funding should originate from CA. A more general term such as "encouraged" or "promoted" would be preferable as other stakeholders also have an important role in training.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>32 <del>28</del>. Training should be supported, to the extent possible, by the competent authorities on issues related to antimicrobial resistance and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should <del>be involve the competent authorities, all the relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain, as appropriate.</del> Training and communication may broadly address <b>other public health constituencies</b>.</p>	<p><b>USA</b> It is unclear who “other public health constituencies” are that should be trained.</p>
<p>32 <del>28</del>.</p>	<p><b>Consumers International</b> Support the suggested changes in this para as they more clearly state who and what should be involved in training on issues related to antimicrobial resistance and responsible use of antimicrobial agents. We also support the language in all 11 bullets, since they are all useful areas for training of users of antimicrobial agents.</p>
<p>32 <del>28</del>.</p>	<p><b>International Association of Consumer Food Organizations</b> By broadening who can support such training beyond competent authorities to international and independent authorities, and including the phrase "to the extent possible", this should alleviate the concerns of some delegations that some items may not be conducted by competent authorities, without deleting this important and useful bulleted information.</p>
<p><u>Relevant information may include but not limited to:</u></p>	<p><b>Morocco</b> Amend the first sentence of sub paragraph 2.</p>
<p><u>Relevant information covered by such training may include:</u></p>	<p><b>International Association of Consumer Food Organizations</b></p>
<p><u>Relevant information may include:</u></p> <ul style="list-style-type: none"> <li>information on disease prevention and management strategies to reduce the need to use antimicrobial agents;</li> </ul>	<p><b>USA</b> Competent authorities are not the ones that do all of this training in all countries. Veterinarians for example are trained in universities to write prescriptions. The bulleted list does not apply to all stakeholders and is unclear regarding the list of organizations and venues. It is not practical or feasible for the competent authority to be responsible for training all these groups. As now drafted, the bullets capture such a broad swath of training that it seems unclear who needs which information. For example, although a knowledge of molecular analysis of AMR may be beneficial for some users of antimicrobial agents, this training is highly specialized and beyond the scope and general knowledge level for the CoP to Minimize Foodborne AMR document. Regarding bullet 3, “the need to” needs to remain for proper sentence structure and consistency with the other bullets. It is slightly revised to reflect current practice. We suggest the bullets should be replaced with the broad statement at the beginning as modified and limited to the original bullets in CAC/RCP 61-2005.</p>

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>information on disease prevention and management strategies to reduce the need to use antimicrobial agents;</li> </ul>	<p><b>Consumers International</b> Support this bullet as written.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>relevant information to enable the veterinarians and plant/crop health professionals to use or prescribe antimicrobial agents responsibly and prudently;</li> </ul>	<p><b>Consumers International</b> Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>the need to observe</del> <u>observing</u> responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice <del>the need to adhere to responsible and prudent use principles and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice;</del></li> </ul>	<p><b>USA</b></p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>La necesidad de respetar</del> <u>El respeto de</u> las recomendaciones de uso prudente y responsable y de utilizar el uso de agentes antimicrobianos en los entornos de producción, conforme a lo dispuesto en las autorizaciones de comercialización y al asesoramiento profesional.</li> </ul>	<p><b>CCTA</b> "... utilizar el uso..." es una expresión redundante, debería revisarse</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>the need to observe</del> <u>observing</u> responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice;</li> </ul>	<p><b>Consumers International</b> Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>the need to observe</del> <u>observing</u> <del>the need to adhere to</del> responsible and prudent use <u>principles</u> and recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice;</li> </ul>	<p><b>International Association of Consumer Food Organizations</b> Better to say "the need to adhere to" instead of "observing" since it is stronger</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>utilizing the WHO list of critically important antimicrobials; the OIE <del>List</del> <u>list</u> of antimicrobials of veterinary importance, and national lists where they exist;</li> </ul>	<p><b>Canada</b></p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>utilizing the <del>WHO list</del> <u>WHO list</u> of critically important antimicrobials; the OIE List of antimicrobials of veterinary importance, and national lists where they exist;</li> </ul>	<p><b>Iran</b> Or national/ regional lists (if available)</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>utilizing the WHO list of critically important antimicrobials; the OIE List of antimicrobials of veterinary importance, and national lists where they exist;</del></li> </ul>	<p><b>USA</b></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>La utilización de la <del>lista</del> <del>Lista</del> de la OMS de antimicrobianos de importancia crítica; la Lista de la OIE de antimicrobianos de importancia veterinaria y las listas nacionales cuando existan.</li> </ul>	CCTA
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>utilizing the WHO list of critically important antimicrobials; the OIE List of antimicrobials of veterinary importance, and national lists where they exist;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>utilizing the WHO list of critically important antimicrobials; the OIE List of <del>antimicrobials</del> <u>antimicrobial agents</u> of veterinary importance, and national lists where they exist;</li> </ul>	OIE
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobials;</del></li> </ul>	USA
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobials;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>understanding relevant risk analysis of <del>veterinary antimicrobial agent</del> <del>agents products</del> and how to use that information;</li> </ul>	<p><b>Canada</b></p> <p>Minor edits are suggested to improve readability</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>understanding relevant risk analysis of <del>veterinary antimicrobial agent</del> <u>agent</u> products and how to use that information;</li> </ul>	<p><b>Morocco</b></p> <p>Amend to read: "<i>understanding relevant risk analysis of antimicrobial agents products and how to use that information</i>";</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>understanding of relevant risk analysis of <del>veterinary antimicrobial agent</del> <del>agents products</del> and how to use that information;</li> </ul>	Switzerland
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>understanding relevant risk analysis of veterinary antimicrobial agent products and how to use that information;</del></li> </ul>	USA
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>understanding relevant risk analysis of <del>veterinary antimicrobial agent</del> <u>agent</u> products and how to use that information;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written and edited since we believe this useful area of training should cover all antimicrobial agents, not just veterinary antimicrobial agent, since it also applies to use of such agents in plants/crops.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>national action plans, if available, and international strategies to fight and control antimicrobial resistance;</del></li> </ul>	USA

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>national action plans, if available, and international strategies to fight and control antimicrobial resistance;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period;</del></li> </ul>	<p><b>USA</b></p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><del>training in new methodologies for molecular analysis of resistance; understanding methods and results of susceptibility testing of antimicrobials and molecular analysis;</del></li> </ul>	<p><b>USA</b></p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>training in new methodologies for molecular analysis of resistance; understanding methods and results of susceptibility testing of antimicrobials and molecular analysis;</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a particularly useful area for training of users of antimicrobial agents, given the advances made in whole genome sequencing and other molecular techniques.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>the ability of antimicrobial agents to select for resistant microorganisms or resistance determinants that may contribute to animal, plant/crop, or human health problems; and</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a particularly useful area for training of users of antimicrobial agents since it covers resistance for antibiotics that can cause health problems for animals, plants and humans.</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li><u>understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options.</u> <ul style="list-style-type: none"> <li><u>understanding of alternative products and approaches to minimize antimicrobial use.</u></li> <li><u>how to participate in the collection and reporting of data relevant to AMR and AMU surveillance.</u></li> </ul> </li> </ul>	<p><b>Canada</b></p> <p>Suggests adding these points as they are relevant for training purposes and participation in various stewardship and surveillance activities</p>
<p>Relevant information may include:</p> <ul style="list-style-type: none"> <li>understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options.</li> </ul>	<p><b>Consumers International</b></p> <p>Support this bullet as written. It is a useful area for training of users of antimicrobial agents.</p>
<b>Knowledge gaps and research</b>	
<p>Paragraphs 33 to 34</p>	<p><b>Australia</b></p> <p>Supports the proposed text.</p>
<p>33 29.</p>	<p><b>Brazil</b></p> <p>This paragraph is very broad, confusing and the bullets should be revised and reordered to avoid wrong interpretation and prioritization by member countries.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
33 29. The relevant authorities <del>should</del> <u>can</u> encourage public and private research <u>in the following areas but not limited to</u> :	<b>Morocco</b> The first sentence is amended to read as follows.
33 29. <u>To further elucidate the risk from foodborne AMR, the relevant authorities</u> <del>should</del> <u>can</u> encourage public and private research to:	<b>USA</b> This research section appears to go well beyond Codex scope, so text is added to try to ground it within Codex and TFAMR scope: <b>FOODBORNE AMR RIKS</b> . For example, just because resistance determinants are found in the environment that does not mean they contribute to foodborne AMR illness in humans. Bullets 6&7: Editorial changes are made to better describe the purpose of behaviour change interventions
33 29.	<b>International Association of Consumer Food Organizations</b> If the suggested edit in the previous paragraph was taken, to broaden who can do trainings to include international authorities and independent authorities as well as competent authorities, then "relevant" authorities presumably includes international and independent authorities as well as competent authorities. If not, then "relevant" should be clarified or changed to "competent."
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: • develop practical models for applying the concept of risk analysis <u>(such as development of risk-based priority setting tools)</u> to assess the public health concern precipitated by the development <u>and any change in trends</u> of resistance;	<b>Canada</b> Minor edits are suggested to improve readability
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: • develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of <del>resistance</del> <u>foodborne AMR</u> ;	<b>USA</b>
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: • further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of <del>resistance</del> <u>foodborne AMR development and spread</u> ;	<b>USA</b>
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: • <u>develop and encourage good animal production and plant/crop production best management practices and alternative methods to prevent and treat infectious diseases that would reduce the need to use antimicrobial agents</u>	<b>International Association of Consumer Food Organizations</b> This bullet should not be deleted as it is very important and germane.
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: • <u>assess the primary drivers leading to use of <del>medically important</del> antimicrobials at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior and reduce the need to use of <del>medically important</del> antimicrobial agents in food production</u> ;	<b>Canada</b>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>assess the <u>primary drivers leading to use of medically important antimicrobials at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior and reduce</u> related to the inappropriate use of <u>medically important antimicrobial agents in food production</u>;</li> </ul>	USA
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>develop safe and effective alternatives to <u>using</u> antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines;</li> </ul>	Canada Minor edits are suggested to improve readability: cost-effective is a more widely used term than cost-positive
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>determine the <del>potential risk of foodborne AMR</del> transfer to fresh produce and other plants/crops of resistant microorganisms and <u>resistance</u> determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers;</li> </ul>	USA
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms <u>in the context of foodborne AMR risk</u>;</li> </ul>	USA
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>determine the potential transfer to animals <u>and plants/crops of</u> resistant microorganisms and <u>resistance</u> determinants due to <b>agricultural chemical use</b>.</li> </ul>	Canada Suggests adding an example to illustrate what it is meant by this term.
The relevant authorities <del>should</del> <u>can</u> encourage public and private research to: <ul style="list-style-type: none"> <li>determine the potential transfer to animals <u>and plants/crops of</u> resistant microorganisms and <u>resistance</u> determinants due to agricultural chemical use <u>in the context of foodborne AMR risk</u>.</li> </ul>	USA
34 <del>30</del> .	Canada Suggests moving this as the first sentence of paragraph 33.
33 <del>29</del> & 34 <del>30</del> . 34bis <i>The relevant authorities <u>can</u> encourage public and private research to <u>fill knowledge gaps by conducting relevant research related to foodborne AMR risk in the following fields:...</u></i>	Morocco Merge this paragraph with 33 to be the first sentence. To be read as:
Collection and destruction of unused or out-of-date antimicrobial agents	
<del>3534</del> .	Uruguay Está de acuerdo con los cambios sugeridos en el documento.
35 <del>34</del> . The <u>competent</u> authorities should develop <del>and progress</del> <u>implement</u> effective procedures for the safe collection and destruction of unused, <u>counterfeit, illegally marketed, or out-of-date</u> antimicrobial agents, <u>including proper disposal of containers and packaging materials</u> .	Japan Disagrees to add the word "implement." It is not practical to expect for competent authority to actually collect and destruct unused drugs.

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
35 <del>34</del> . The competent authorities should develop and <del>progress</del> <u>implement</u> effective procedures for the safe collection and <del>destruction-disposal</del> of unused, counterfeit, illegally marketed, or out-of-date antimicrobial agents, <u>including proper disposal of containers and packaging materials</u> .	<b>USA</b> The term, "disposal" is more appropriate than "destruction".
<b>5.2 Responsibilities of manufacturers and marketing authorization holders</b>	
<b>Marketing authorization of antimicrobial agents</b>	
Paragraph 36	<b>Australia</b> Supports the proposed text.
Paragraph 36	<b>Iran</b> What about the imported antimicrobials?
Paragraph 36	<b>USA</b> Support as drafted.
36. It is the responsibility of the antimicrobial agent marketing authorization holders: <ul style="list-style-type: none"> <li>to utilize manufacturing standards/practices and comply with national regulations in order to minimize <u>environmental contamination of the food production environment with effluent containing active antimicrobial agents</u>.</li> </ul>	<b>Canada</b> In this scenario it is reasonable to consider the environment at large.
<b>Marketing and export of antimicrobial agents</b>	
Paragraphs 37 to 40	<b>Australia</b> Supports the proposed text.
37 <del>33</del> .	<b>OIE</b> Clarification requested: will this point be included, or not?
[38 <del>33bis</del> . Only antimicrobial agents meeting the quality <u>and safety</u> standards of the importing country should be exported <del>from a country in which the products were produced</del> .]	<b>Morocco</b> Add 'and safety' after quality.
<b>[38 <del>33bis</del>:]</b>	<b>HealthForAnimals</b> Delete. The responsibility for this lies with the receiving country
[39 <del>33ter</del> . The information necessary to evaluate the <u>amount quantity (sales or volume)</u> of antimicrobial agents marketed should be provided to the national competent authority <u>and, when feasible, information on estimated estimates of types of use (e.g. treatment, control, prevention), route of administration and target animal species]</u>	<b>Canada</b> Supports the introduction of these paragraphs, and suggests some edits to improve readability. This document includes concepts referring to animal species and bacterial species and we should be explicit to which we are referring.
[39 <del>33ter</del> . The information necessary to evaluate the <u>amount quantity by weight (sales or volume)</u> of antimicrobial agents <u>marketed</u> should be provided to the national competent authority <u>and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species]</u>	<b>Japan</b> "Quantity by weight (sales or use) of antimicrobial agents should be provided ..... " would make sense.



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[39 <del>33</del> ter. The information necessary to <del>evaluate</del> <u>monitor</u> the amount quantity (sales or volume) of antimicrobial agents marketed should be provided to the national competent authority <del>and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species]</del>	<b>USA</b> The term, "monitor" is more appropriate than "evaluate", and is in line with GLIS terminology.
[39 <del>33</del> ter. The information necessary to <del>evaluate</del> <u>monitor</u> the amount quantity (sales or volume) of antimicrobial agents marketed should be provided to the national competent authority <del>and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species]</del>	<b>HealthForAnimals</b> Replace "evaluate" with "monitor" - Evaluate would imply that there is a standard in which the quantity will be measured, which is not the case. There are many factors that affect the quantity of antimicrobials marketed including the size of the animal population. species, potencies of antibiotics, availability of vaccines or feed additives, food culture, the types of diseases, and level of development. Use data only captures one variable that has a relationship with potential resistance propagation or development and should be considered within this context. Delete sales because – sales info should not be required, only volume is needed. Deletion - This level of detail is unnecessary.
40 <del>34</del> . Package size and the concentration and composition of antimicrobial formulations should be adapted, as far as possible, to the approved indications of use in order to avoid improper dosing, overuse, and leftovers.	<b>OIE</b> This point could potentially be under "marketing authorization of antimicrobial agents", instead of "marketing and export of antimicrobial agents"
Advertising	
41 <del>35</del> . It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 <del>25-27</del> on the Responsibilities of the Competent Authorities, Control of Advertising <del>and to not advertise medically important antimicrobials to producers.</del>	<b>Australia</b> Rationale: Text is duplicated in paragraph 42. Paragraph 42 – Australia supports the proposed text.
41 <del>35</del> . It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 <del>25-27</del> on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to <u>encourage use of these products by</u> producers.	<b>Canada</b> Minor edits are suggested to improve readability
41 <del>35</del> . It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 <del>25-27</del> on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers <u>unless the need for prescription or professional supervision in use is clearly indicated.</u>	<b>Japan</b> This requirement may not be feasible to strictly implement. Advertisement can be used to disseminate correct information to producers.
41 <del>35</del> . It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 <del>25-27</del> on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers.	<b>Republic of Korea</b> Firstly, "Medically important antimicrobials" list should be clearly clarified. And secondly, some countries do not give Veterinarian prescription system on all antimicrobials. Also, it could infringe on consumers(breeders) right to know. These phrases might be understood as an excessive regulation, need to determine by each country.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
42 <del>36</del> . <i>Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged not be used.</i>	
41 <del>35</del> . It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 <del>25-27</del> on the Responsibilities of the Competent Authorities and Control of Advertising and to not advertise medically important antimicrobials to producers.	<b>USA</b>
41 <del>35</del> .	<p><b>Consumers International</b></p> <p>Support this para as written in the latest draft, since we do not think that advertising for antimicrobial agents, especially medically important antimicrobials, should be targeted to producers. We do not support deletion of this para as outside the scope of Codex since this para was lifted virtually verbatim from para 41 of CXC 61-2005.</p> <p>Also disagree with the rationale that marketing and advertising are covered by OIE and, thus, such language doesn't need to be in the COP. We believe that the COP should be maintained as the primary document for addressing the risk of antimicrobial resistance in food and that advice not be dispersed among documents of several international bodies including OIE, Codex, and possibly others.</p> <p>CI believes that fragmenting and dispersing the advice will impede establishing unified principles and approaches to minimizing antimicrobial resistance, potentially create difficulties in understanding the advice, and will make it doubly difficult for countries that are developing National Action Plans to structure their policies with a One Health approach, in a manner consistent with international norms.</p>
42 <del>36</del> . Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged not be used.	<p><b>USA</b></p> <p>Para 42 is problematic for a global document. Advertising can have a specific legal definition in national regulations of drugs and is often considered a subset of promotional activities. For example, in some countries, advertising is permissible, as long as the promotional activities and materials are not false or misleading, and do not recommend uses that are unapproved or lack supporting evidence.</p>
42 <del>36</del> .	<p><b>Consumers International</b></p> <p>Support this para as drafted since we do not think that promotional campaigns for antimicrobial agents should involve economic or material benefits for prescribers or suppliers of antimicrobials. We also agree that such advertising should be restricted to those that prescribe or supply antimicrobial agents.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Also disagree with the rationale that marketing and advertising are covered by OIE and, thus, such language doesn't need to be in the COP. We believe that the COP should be maintained as the primary document for addressing the risk of antimicrobial resistance in food and that advice not be dispersed among documents of several international bodies including OIE, Codex, and possibly others.</p> <p>CI believes that fragmenting and dispersing the advice will impede establishing unified principles and approaches to minimizing antimicrobial resistance, potentially create difficulties in understanding the advice, and will make it doubly difficult for countries that are developing National Action Plans to structure their policies with a One Health approach, in a manner consistent with international norms.</p>
<b>Training</b>	
Paragraph 43	<p><b>Australia</b> Supports the proposed text.</p>
43 <del>37</del> . It is the responsibility of the marketing authorization holders to <del>support</del> participate in the <del>promote and contribute to</del> training on issues related to antimicrobial resistance and the <del>responsible users</del> of antimicrobial agents as <del>defined</del> described in paragraph 32 <del>28</del> .	<p><b>Switzerland</b> The term "supported" can be understood to imply funding should originate from marketing authorization holders. A more general term such as "encouraged" or "promoted" would be preferable as other stakeholders also have an important role in training.</p>
43 <del>37</del> .	<p><b>International Association of Consumer Food Organizations</b> This language is in the current Code of Practice and should be retained.</p>
<b>Research</b>	
Paragraphs 44 to 45	<p><b>Australia</b> Supports the proposed text.</p>
44 <del>38</del> .	<p><b>Canada</b> Suggests to clarify how these activities are relevant for research purposes</p>
44 <del>38</del> .	<p><b>USA</b> Supports as revised.</p>
45 <del>39</del> . Research on the development of new antimicrobials, safe and effective alternatives to the use of antimicrobials, rapid diagnostics and vaccines <del>are</del> <u>is encouraged</u> <del>should be performed</del> .	<p><b>Canada</b> Minor edit suggested to improve readability</p>
45 <del>39</del> . Se <del>debería</del> <u>debería</u> llevar a cabo <del>fomenta</del> fomentar la investigación sobre el desarrollo de nuevos antimicrobianos, de alternativas inocuas y eficaces al uso de antimicrobianos, de diagnósticos rápidos y vacunas.	<p><b>Uruguay</b> Sugiere incluir "Se debería" al principio del parrafo.</p>
45 <del>39</del> . Se <del>debería</del> llevar a cabo <u>fomenta</u> la investigación sobre el desarrollo de nuevos antimicrobianos, de alternativas inocuas y eficaces al uso de antimicrobianos, de diagnósticos rápidos y vacunas.	<p><b>CCTA</b> Se debería fomentar ?</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>5.3 Responsibilities of wholesale and retail distributors</b>	
Paragraph 46 to 48	<b>Australia</b> Supports the proposed text.
46 40. Wholesalers and retailers distributing medically important antimicrobial agents should only do so <del>on</del> in accordance with national legislation, for example, pursuant to the prescription <del>of</del> by a veterinarian or <del>order from a plant/crop health professional</del> or other suitably trained person <del>authorized in accordance with national legislation</del> . All <u>distributed</u> products should be appropriately labelled.	<b>Canada</b> Suggests that references to plant/crop health professionals throughout the draft are removed, as it is unclear if these professionals exist in most countries. There needs to be clarity on the role of these individuals in the dispensing and application of antimicrobial agents.
46 40. Wholesalers and retailers distributing medically important antimicrobial agents should only do so on the <b>prescription order or recommendation</b> of a veterinarian or <del>order from a plant/crop health professional</del> or other suitably trained person authorized in accordance with national legislation. All <u>distributed</u> products should be appropriately labelled.	<b>USA</b> The term, "prescription" may not be globally applicable in all circumstances for veterinary medicine. For crop health, plant health specialists conduct disease modelling and recommend when crops should be treated, then plant health professionals will obtain the drug from distributors to treat the drug. So, the word, "recommendation" is most appropriate for crops. So using the term "prescription" or "recommendation" early in the sentence should cover global situations better.
47 44.	<b>Japan</b> Please add "target species" as an example.
47 44.	<b>Morocco</b> Add 'manufacturer name and address' to the bullets.
• name of <del>responsible</del> <del>receiving</del> prescribing veterinarian or plant/crop health professional or other suitably trained and authorized person	<b>Brazil</b> Suggests replacing "receiving" by "responsible" in the second bullet once there are different realities between member countries on how the prescription and distribution of antimicrobials occurs.
• name of <del>receiving</del> <del>prescribing</del> veterinarian <del>veterinarian</del> or <del>plant/crop health professional</del> or other suitably trained and authorized person	<b>Canada</b> Suggests that references to plant/crop health professionals throughout the draft are removed, as proposed in the general comments.
• name of <del>responsible</del> <del>receiving</del> prescribing veterinarian or plant/crop health professional or other suitably trained and authorized person	<b>USA</b> "Responsible" is a more appropriate qualifier than "receiving".
48 42. Distributors should support training, as appropriate, on <del>issues</del> topics related to minimizing antimicrobial resistance and encouraging the responsible use of antimicrobial agents using <u>information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described defined</u> in paragraph 32.	<b>Canada</b> Minor edit suggested to improve readability

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
48 42. Distributors should <del>support</del> encourage and contribute to training, as appropriate, on issues related to antimicrobial resistance and the responsible use of antimicrobial agents using <u>information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described defined in paragraph 32.</u>	<b>Switzerland</b> The term "supported" can be understood to imply funding should originate from distributors. A more general term such as "encouraged" or "promoted" would be preferable as other stakeholders also have an important role in training.
<del>48 42. Distributors should support training, as appropriate, on issues related to antimicrobial resistance and the responsible use of antimicrobial agents using information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described defined in paragraph 32.</del>	<b>USA</b> Focus and responsibility should be placed on the drug sponsor and not necessarily the distributor. For example, in many countries, the competent authority regulates the sponsors and not the distributors directly. It is the responsibility of the sponsors to make sure their product is distributed, promoted and marketed in accordance with national regulations.
48 42.	<b>Consumers International</b> Strongly agree with this para as written in the latest draft. We think it is a good idea that the distributors should support training, as appropriate, on issues related to antimicrobial resistance and responsible use of antimicrobial agents. This language does not say that distributors should do the training, only that they should support the training, as appropriate. Given the potential health and environmental problems associated with the misuse of antimicrobial agents, one would think that responsible distributors would want to support such training.
<b>5.4 Responsibilities of Veterinarians<sup>6</sup> and Plant/Crop Health Professionals</b>	
Paragraphs 49 to 50	<b>Australia</b> Supports the proposed text. <u>Footnote:</u> Australia supports the proposed text.
49 43. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and <u>work toward</u> developing <u>alternative</u> strategies to prevent, <u>control</u> , or treat infectious disease. These may include, but are not limited to, <u>enhanced</u> biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination <u>or integrated pest management practices</u> where applicable/available.	<b>Canada</b> Minor edit suggested to improve readability
49 43. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and <u>work toward</u> developing <u>alternative</u> strategies to prevent, <u>control</u> , or treat infectious disease. These may include, but are not limited to, biosecurity, improved production practices, <u>proper animal nutrition</u> , and safe and effective alternatives to antimicrobial agents, including vaccination <u>or integrated pest management practices</u> where applicable/available.	<b>USA</b> Nutrition is important for animal health so was added. Otherwise, support as revised.
50 45. Professional <u>or other</u> organizations should be <u>encouraged</u> to develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents. <del>National action plans may include recommendations to develop species or sector-specific guidelines.</del>	<b>Brazil</b> As suggested under section 5.1, Brazil is of the opinion that this sentence should be moved to section 5.1 of the document, once the development of NAPs is a responsibility of the competent authority.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
50 45. Professional <del>or other</del> organizations should <u>be encouraged to</u> develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents. National action plans may include recommendations to develop species or sector-specific guidelines.	<b>Japan</b> Disagrees to add "or other" unless the nature of intended organizations is appropriate. Considering that this section (5.4) is about the responsibilities of veterinarians and plant/crop professionals, professional organizations should be enough as the target. The same comment applies to para 60.
51 47. Antimicrobial agents should only be <del>used</del> <u>prescribed or administered</u> <u>only</u> when necessary, <del>as</del> only as long as necessary, and in an appropriate manner:	<b>Canada</b> Minor edit suggested to improve readability
51 47. Antimicrobial agents should only be <u>used</u> <del>used</del> <u>prescribed or administered</u> when necessary, <del>as</del> only as long as <u>required</u> necessary, and in an appropriate manner:	<b>Morocco</b> Amend the first sentence to read:
51 47.	<b>USA</b> The first 2 bullets appear to go beyond Codex's mandate into the on-farm mandate of OIE. The third bullet covers conditions of use enough for purposes of this document. Edits are provided in bullet one to be consistent with OIE language in 6.10.6
51 47.	<b>Consumers International</b> Agree with this para as drafted and edited.
<ul style="list-style-type: none"> <li>A prescription, <del>or</del> order for application, <u>or similar document</u> for medically important antimicrobial agents should indicate the dose, the dosage intervals, <u>route and</u> the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population to be treated, <u>in accordance with national legislation</u>. <u>Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;</u></li> </ul>	<b>Australia</b> <u>Rationale:</u> To improve the information flow for the end reader.
<ul style="list-style-type: none"> <li>A prescription, <del>or</del> order for application, <u>or similar document</u> for medically important antimicrobial agents should indicate the dose, the dosage intervals, <u>route and</u> the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial <del>agent</del> <u>agents</u> to be <del>delivered</del> <u>provided</u>, depending on the dosage and the <del>characteristics</del> <u>number</u> of the individual or population <del>animals</del> to be treated, <del>in accordance with national legislation;</del></li> </ul>	<b>USA</b>
<ul style="list-style-type: none"> <li>The quantity of the antimicrobial provided to the end-user should, <del>if feasible,</del> be limited only for the administration concerned. Prescriptions <u>or orders</u> should <del>also</del> indicate the owner and the identification of the <u>specific location of</u> food-producing animals or plants/crops to which the antimicrobials are to be administered;</li> </ul>	<b>Canada</b> Suggests to delete this qualifier "if feasible". We are of the view that the quantity of antimicrobial provided should not be greater than the administration concerned. Elsewhere Minor edit suggested to improve readability
<ul style="list-style-type: none"> <li>The quantity of the antimicrobial provided to the end-user should, <del>if feasible,</del> be limited only for the administration concerned <u>unless otherwise advised by the prescriber</u>. <u>Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;</u></li> </ul>	<b>Morocco</b> Amend the first sentence by deleting 'if feasible' and adding 'unless otherwise advised by the prescriber' at the end of the sentence to read: "The quantity of the antimicrobial provided to the end-user should, if feasible, be limited only for the administration concerned unless otherwise advised by the prescriber.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>The quantity of the antimicrobial provided to the end-user should, <u>if feasible</u>, be limited only for the administration concerned. <del>Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;</del></li> </ul>	<b>USA</b> Delete. Redundant with previous bullet.
<ul style="list-style-type: none"> <li>The quantity of the antimicrobial provided to the end-user should, <u>if feasible</u>, be limited only for the administration concerned. Prescriptions <u>or orders</u> should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;</li> </ul>	<b>Consumers International</b> We particularly support the bullet as written in the latest draft and do not think that it should be deleted. We disagree with the argument that this bullet appears to be outside the scope of Codex's mandate and into the mandate of OIE. We note that previous paras in this document, such as the section on responsibilities of wholesale and retail distributors, does discuss the quantity of antimicrobials supplied. Thus, we think the language in this bullet is appropriate should be included in this document.
<ul style="list-style-type: none"> <li>All medically important-antimicrobial agents should be prescribed or applied and used according to label directions and/or the <u>direction advice</u> of a veterinarian or plant/crop health professional, and <u>to</u> the conditions stipulated in the national legislation.</li> </ul>	<b>Canada</b> Minor edit suggested to improve readability
Paragraphs 52 to 54	<b>Australia</b> Supports the proposed text.
52 <del>48</del> . For food-producing animals, the appropriate use of <del>medically important</del> antimicrobial agents in practice is a clinical decision that should be based on the experience <del>and local expertise</del> of the prescribing veterinarian, and <u>epidemiological and clinical knowledge</u> <del>the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <del>they</del> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease <del>and for reasons of animal welfare</del> .	<b>Brazil</b> Suggests deleting the end of the sentence, once the main reason would be preventing development and spread of clinical disease and animal welfare issues would be a consequence.
52 <del>48</del> . For food-producing animals, the appropriate use of <del>medically important</del> antimicrobial agents in practice is a clinical decision that should be based on the experience <del>and local expertise</del> of the prescribing veterinarian, and <u>epidemiological and clinical knowledge</u> <del>the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <del>they</del> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	<b>Canada</b> <ul style="list-style-type: none"> <li>Suggests retaining the original wording, as a diagnosis is not based on susceptibility testing; both are independent tools for the veterinarian.</li> <li>Suggests linking "epidemiological and clinical knowledge" to the prescribing veterinarian, e.g., based on the experience, epidemiological and clinical knowledge of the prescribing veterinarian.</li> </ul>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
52 48. For food-producing animals, the appropriate use of <del>medically important</del> antimicrobial agents in <u>therapeutic</u> practice is a clinical decision that should be based on the experience <del>and local expertise</del> of the prescribing veterinarian; and <u>epidemiological and clinical knowledge</u> <del>the accurate diagnosis, based on adequate diagnostic procedures.</del> <del>There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <u>they</u> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	<b>Japan</b> Proposes adding “therapeutic” for clarification. Some non-medically important antimicrobial agents are used outside of clinical decision by veterinarians.
52 48. For food-producing animals, the appropriate use of <del>medically important</del> <del>important</del> antimicrobial agents in practice is a clinical decision that should be based on the experience <del>and local expertise</del> of the prescribing veterinarian; and <u>epidemiological and clinical knowledge</u> <del>the accurate diagnosis, based on adequate diagnostic procedures.</del> <del>There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <u>they</u> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal <del>welfare</del> <u>health</u> .	<b>USA</b> Added medically important to be consistent with crop paragraph below and as antimicrobials are addressing disease, the term “health” is more appropriate.
52 48. For food-producing animals, the appropriate use of <del>medically important</del> antimicrobial agents in practice is a clinical decision that should be based on the experience <del>and local expertise</del> of the prescribing veterinarian; <u>the conditions of the marketing authorization, and epidemiological and clinical knowledge</u> <del>the accurate diagnosis, based on adequate diagnostic procedures.</del> <del>There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <u>they</u> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	<b>International Association of Consumer Food Organizations</b>
52 48. For food-producing animals, the appropriate use of <del>medically important</del> antimicrobial agents in practice is a clinical decision that should be based on the experience <del>and</del> <u>epidemiological and clinical knowledge</u> <del>and local expertise</del> of the prescribing veterinarian <u>or other appropriately trained animal health professional,</u> <del>and epidemiological and clinical knowledge</del> <del>the accurate diagnosis, based on adequate diagnostic procedures.</del> <del>There will be occasions</del> When a group of food-producing animals, <del>which</del> may have been exposed to pathogens, <u>they</u> may need to be treated without recourse to an <del>accurate</del> laboratory confirmed diagnosis <u>based on</u> <del>and</del> antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	<b>OIE</b>
53 49. (...) <u>Alternatives to using medically important antimicrobials should be considered when available and their safety and effectiveness has been determined. Medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.</u>	<b>Canada</b> Minor edit suggested to improve readability
53 49.	<b>Uruguay</b> Está de acuerdo con este nuevo párrafo.



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
53 49.	<b>USA</b> Supports as revised.
53 49. Para la producción de plantas/cultivos, el uso adecuado de agentes antimicrobianos de <u>importancia médica para el manejo de enfermedades y plagas debería basarse en los principios del manejo integrado de plagas (MIP), la consulta con un profesional de la sanidad de las plantas/cultivos, el conocimiento histórico y epidemiológico de la situación de la enfermedad y la plaga, así como el seguimiento de la situación actual de la enfermedad y la plaga. Solamente se deberían utilizar productos autorizados siguiendo las instrucciones de la <del>etiquetas</del> etiqueta. Se deberían considerar alternativas a los antimicrobianos de importancia médica cuando estén disponibles y se haya determinado su inocuidad y eficacia. Los agentes antimicrobianos de importancia médica únicamente se deberían utilizar en la medida en que sea necesario para una enfermedad específica y se debería contar con una supervisión profesional, una dosificación y una duración adecuadas.</u>	<b>CCTA</b>
53 49. For plant/crop production, the appropriate use of medically important antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to medically important antimicrobials should be considered when available and their safety and effectiveness has been determined. Medically important antimicrobial agents should only be used <del>to the extent necessary for as a specific disease and follow appropriate professional oversight</del> last resort, <del>dose after other control methods have failed, and duration after accurate diagnosis and antimicrobial susceptibility testing indicating effectiveness, and use should be minimized.</del>	<b>Consumers International</b> Support this para on use of antimicrobials as part of an IPM program, with the suggested change. Unlike use of antimicrobials in animals--where the drug is given to the animals mixed in feed, water, or as an injection—the use of antimicrobials in plants entail spraying the crops with the antimicrobial, which means that there is a far wider dispersion of antimicrobials in crop production, compared to animal production. Consequently, the use of antimicrobials, particularly medically important antimicrobials, should not be used in crop production, unless they are the last resort, with the restrictions noted in our suggested added text.
53 49.	<b>International Association of Consumer Food Organizations</b> Some of this language should appear in principle 7 ter. Retain alt 2.
54 50. Determination of the choice of an antimicrobial agent should <del>be consider the expected efficacy of the administration and the need to minimize the adverse health effect from the development of antimicrobial resistance</del> based on:	<b>Canada</b> Suggests merging the two lists below, as there is some overlap between them. The heading for Para. 54 would become:
54 50. Determination of the choice of an antimicrobial agent <u>and regimen</u> should be based on:	<b>USA</b> Insertion to include a key concept.
<ul style="list-style-type: none"> <li>• The expected efficacy of the administration based on: <ul style="list-style-type: none"> <li>○ the spectrum of the antimicrobial activity towards the pathogens involved <u>when the pathogen has been identified</u>;</li> </ul> </li> </ul>	<b>USA</b> It is not always known what pathogen may be causing an illness and veterinary clinical judgement may dictate the need to begin empirical therapy before an etiological agent can be identified in a very ill animal.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>• The expected efficacy of the administration based on:               <ul style="list-style-type: none"> <li>○ the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved (...);</li> </ul> </li> </ul>	<b>Canada</b> While the information is useful, it seems quite detailed compared to the other points. A similar amount of detail could also be added to other points in this list, so it is unclear why this point deserves more attention
<ul style="list-style-type: none"> <li>• The expected efficacy of the administration based on:               <ul style="list-style-type: none"> <li>○ <del>results of initial administration;</del></li> </ul> </li> </ul>	<b>Canada</b> This is covered by the third bullet point
<ul style="list-style-type: none"> <li>• The expected efficacy of the administration based on:               <ul style="list-style-type: none"> <li>○ <del>• Los regímenes de dosificación optimizados;</del></li> </ul> </li> </ul>	<b>CCTA</b>
<ul style="list-style-type: none"> <li>• If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a <del>dosage</del> <u>therapeutic</u> regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in <del>foodborne</del> <u>pathogenic</u> and/or commensal microorganisms.</li> </ul>	<b>Canada</b> Believes that 'pathogenic' is more appropriate than 'foodborne', as commensals can also be foodborne. It could be changed to 'pathogenic and/or commensal foodborne microorganisms'
Off-label use	
55 <del>54</del> .	<b>Australia</b> Supports the proposed text.
55 <del>54</del> .	<b>Uruguay</b> Está de acuerdo con las modificaciones realizadas en el párrafo.
55 <del>54</del> .	<b>USA</b> Supports as revised.
55 <del>54</del> . For food-producing animals, the off-label use of a veterinary antimicrobial agent <u>should generally be avoided but</u> may be permitted in appropriate circumstances and should comply with the national legislation including the <u>appropriate and/or use of approved or appropriate withdrawal periods to be used</u> . It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period.	<b>International Association of Consumer Food Organizations</b>
<del>54bis:</del>	<b>Australia</b> Supports deletion based on the provided rationale.
<del>54bis:</del>	<b>International Association of Consumer Food Organizations</b> This deleted bullet should be retained.
56 <del>52</del> .	<b>Australia</b> Supports the proposed text.
56 <del>52</del> . Human health risk related to foodborne <u>and direct animal contact</u> antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents <u>in food-producing animals</u> .	<b>Canada</b> Suggests that this paragraph is moved to top of section. Some edits added for clarity.

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
56 <del>52</del> .	<b>USA</b> Supports as revised.
56 <del>52</del> . Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents <u>in food-producing animals. Medically important antimicrobial agents should only be used off-label in exceptional circumstances, and when warranted by susceptibility testing results.</u>	<b>International Association of Consumer Food Organizations</b>
57 <del>53</del> . <u>Medically important antimicrobials</u> should not be used off-label for plants/crops <u>without appropriate regulatory approval without appropriate regulatory approval.</u>	<b>Australia</b> Australia prefers the previously proposed text. <u>Rationale:</u> This reflects the main focus about human health in the COP.
57 <del>53</del> .	<b>Consumers International</b> Strongly agree with this para as written, e.g., that no antimicrobials should be used off-label for plants/crops.
<b>Record keeping and recording</b>	
Paragraphs 58 to 59	<b>Australia</b> Supports the proposed text.
58 <del>54</del> .	<b>Morocco</b> Restore the word 'administration' in the first sentence.
<ul style="list-style-type: none"> <li>record the antimicrobial used, the dosage <del>regimen</del> and the duration;</li> <li>investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available).</li> </ul>	<b>Canada</b> Last sentence should be a separate point, unless what is meant is to record the outcome of investigation of adverse reactions
59bis. <u>Record keeping should be designed to facilitate sharing of data with competent authorities administering integrated surveillance programs.</u>	<b>Canada</b> This is an editorial addition, to encourage data sharing.
<b>Training</b>	
60 <del>56</del> .	<b>Australia</b> Supports the proposed text.
60 <del>56</del> . Professional or other organizations should <del>participate in</del> support the development and/or delivery of training on <del>issues</del> topics related to minimizing antimicrobial resistance and <u>encouraging the responsible users</u> of antimicrobial agents as <del>defined</del> described in paragraph 3228.	<b>Canada</b> Minor edit suggested to improve readability
60 <del>56</del> .	<b>USA</b> Supports as revised.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
61 <del>57</del> . Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks. <del>They should call on the</del> with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. All participants involved in <del>the</del> primary production of food have an important role to play in preventing disease and <del>to reduce</del> reducing the need to use antimicrobials <del>ensuring the responsible and prudent use of antimicrobial</del> ensuring the responsible and prudent use of antimicrobial agents to minimize risk of foodborne AMR.	<b>Australia</b> Rationale: This ensures everyone uses antimicrobials in a responsible way.
61 <del>57</del> . Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks. <del>They should call on the</del> with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national/ <del>local</del> legislation. All participants involved in primary production of food have an important role to play in preventing disease and <del>to reduce</del> reducing the need to use antimicrobials <del>ensuring the responsible and prudent use of antimicrobial</del> ensuring the responsible and prudent use of antimicrobial agents to minimize risk of foodborne AMR.	<b>Canada</b> Minor edit suggested to improve readability
61 <del>57</del> .	<b>USA</b> Supports as revised.
Paragraphs 62 to 63	<b>Australia</b> Supports the proposed text
62 <del>58</del> . Producers of food animals and plants/crops have the following responsibilities <del>to</del> :	<b>Canada</b>
<ul style="list-style-type: none"> <li><del>to</del> use only nationally authorized antimicrobial agents and only when necessary, under the supervision of a veterinarian or plant/crop health professional when required, and not as a replacement for good management and farm hygiene practices, or other disease prevention methods;</li> </ul>	<b>Canada</b> Minor edit suggested to improve readability
<ul style="list-style-type: none"> <li><del>to</del> implement a health plan in cooperation with the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation that outlines measures to prevent disease;</li> </ul>	<b>Canada</b>
<ul style="list-style-type: none"> <li><del>to</del> use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site;</li> </ul>	<b>Canada</b>
<ul style="list-style-type: none"> <li>to isolate sick animals and dispose of dead or dying animals or plants/crops promptly <del>in a manner to minimize foodborne AMR</del> under conditions approved by relevant authorities;</li> </ul>	<b>Brazil</b> Suggests deleting “in a manner to minimize foodborne AMR” in the 4th bullet, once it is the rationale for the whole Code of Practice. The proposed text could lead to confusion on who is responsible to ensure it is “in a manner to minimize foodborne AMR”. Producers only have to comply with national legislation on these issues.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>to isolate sick animals and dispose of dead or dying animals or plants/crops promptly in a manner to minimize transmission of foodborne AMR under conditions approved by relevant authorities;</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to comply with the storage conditions of requirements for antimicrobial agents according to the approved product labelling;</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to comply with the recommended withdrawal periods or pre-harvest intervals to ensure that residue levels in or on the food do not present a foodborne AMR risk for the consumer;</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to address infection prevention and control measures regarding contacts between people, veterinarians, plant/crop health professional, breeders, owners, children, pets, wildlife and the food-producing animals or plants/crops treated;</li> </ul>	<b>International Association of Consumer Food Organizations</b> This bullet should be retained.
<ul style="list-style-type: none"> <li>to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product labels and national legislation;</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to inform the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or failures of suspected lack of efficacy of antimicrobial applications;</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.</li> </ul>	Canada
<ul style="list-style-type: none"> <li>to maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.</li> </ul>	USA
<ul style="list-style-type: none"> <li>to maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.</li> </ul>	<b>USA</b> This bullet should be moved to veterinarian responsibilities because in many cases the veterinarian would have these records rather than the producer.
<ul style="list-style-type: none"> <li>to keep adequate comprehensive records of all antimicrobial agents used, including, for example, the following:</li> </ul>	Canada
<ul style="list-style-type: none"> <li>To keep adequate records of all antimicrobial agents used, including, for example, the following:               <ul style="list-style-type: none"> <li>name of the prescribing-administering veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation.</li> </ul> </li> </ul>	<b>USA</b> "Administering" is more appropriate for animal and plant health professionals than "prescribing".
<ul style="list-style-type: none"> <li>To ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate food;</li> </ul>	Canada

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>To <del>address</del> <u>apply</u> on-farm biosecurity measures and take basic infection prevention and control measures as appropriate and as provided in the <i>OIE terrestrial and aquatic animal health codes</i>;</li> </ul>	<b>Canada</b> Could include national or industry codes of practice (FAO or other)
<ul style="list-style-type: none"> <li>To <del>participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate;</del></li> </ul>	<b>Canada</b>
<ul style="list-style-type: none"> <li>To <del>participate in training on issues related to antimicrobial resistance-AMR and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate;</del></li> </ul>	<b>USA</b>
<ul style="list-style-type: none"> <li>To <del>assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.</del></li> </ul>	<b>Canada</b> Minor edit suggested to improve readability
<ul style="list-style-type: none"> <li>To assist the relevant authorities in surveillance programs related to <del>antimicrobial use-AMU and antimicrobial resistance-AMR</del>, as appropriate.</li> </ul>	<b>USA</b>
<p>63 <del>59</del>. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. <del>and decrease exposure to antimicrobial agents.</del> Efforts should aim to improve <u>and maintain good</u> health, thereby reducing the need for <u>using antibiotics antimicrobial agents</u>. This can be achieved by, <u>for example</u>, improving hygiene, biosecurity, <del>and</del> health management on farms, improving animal and plant/crop genetics, <u>appropriate nutrition</u> and implementing <del>national or international</del> good animal production (terrestrial and aquatic), and plant/crop production practices.</p>	<b>Canada</b> Minor edit suggested to improve readability
<p>63 <del>59</del>. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. <del>and decrease exposure to antimicrobial agents.</del> Efforts should aim to improve health, thereby reducing the need for <u>antibiotics antimicrobial agents</u>. This can be achieved by, <u>for example</u>, improving hygiene, <u>animal nutrition</u>, biosecurity, <del>and</del> health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices.</p>	<b>USA</b> Animal nutrition is important for animal health as well.
<p>63 <del>59</del>. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during <u>production and decrease exposure to antimicrobial agents</u>. <del>and decrease exposure to antimicrobial agents.</del> Efforts should aim to improve health, thereby reducing the need for <u>antibiotics antimicrobial agents</u>. This can be achieved by, <u>for example</u>, improving hygiene, biosecurity, <del>and</del> health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices.</p>	<b>Consumers International</b> Support this para as written, except that we support the reinsertion of the words “and decrease exposure to antimicrobial agents” to the first sentence of the first paragraph since it is important to decrease exposure to antimicrobials so as to decrease the risk of antimicrobial resistance.
<p>Disease prevention through the use of vaccines, <del>integrated pest management</del>, and other measures that have been clinically proven to be safe and efficacious <u>for supporting animal health, such as adequate and appropriate nutrition and feed additives, such as probiotics (beneficial bacteria found in various foods), probiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may should/can</u> be considered and applied <del>wherever</del> when appropriate and available (...)</p>	<b>Canada</b> Minor edit suggested to improve readability

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Disease prevention through the use of vaccines,(...)	<b>Consumers International</b> Support this para as drafted and edited.
Prevention and reduction of the incidence and severity of plant pests and diseases (...)	<b>Consumers International</b> Support this para as drafted and edited.
Prevention and reduction of the incidence and severity of plant pests and diseases should be implemented by applying best agricultural practices, such as crop rotation, accurate and timely diagnosis and monitoring of diseases, use of disease resistant crop varieties, exclusionary practices that prevent introduction of pathogens into a crop/plant/crop, careful site selection and pest impact reduction strategies using host resistance, induced resistance, integrated pest management strategies and biological controls when appropriate and available.	<b>OIE</b>
6. Practices during production, processing, storage, transport, retail and distribution of food	
Paragraphs 64 to 67	<b>Australia</b> Supports the proposed text.
[64 <del>60bis</del> (a). Concerted efforts of all stakeholders within the entire along the food chain are required necessary to minimize and contain foodborne illness infections, including illness infections related to foodborne AMR. While this Code such efforts include focuses on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays an important role using appropriate interventions in preventing foodborne AMR infection and illness.]	<b>Canada</b>
[64 <del>60bis</del> (a).]	<b>USA</b> Support as revised.
[65 <del>60bis</del> (b). The food processing industry and food retailers should follow refer to consider the Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007).]	<b>Canada</b>
[65 <del>60bis</del> (b).]	<b>USA</b> Support as revised.
[66 <del>60bis</del> (c).]	<b>USA</b> Support as revised.
Paragraphs 64-67.	<b>Canada</b> Supports the inclusion of paragraphs 64-67. Minor edits are suggested to improve readability. Whether illness results or not is related to the human host immune system. We believe that actors along the food chain are responsible to minimize human exposure to foodborne bacteria (resistant or not), rather than foodborne illness, even if that is the outcome.
[67 <del>60ter</del> . Food business operators should provide training on good hygienic practices, including those for minimizing cross-contamination. The WHO Five Keys to Safer Food contains useful information for food handlers to minimize the transmission of foodborne illness infections, including AMR resistant infections.]	<b>Canada</b>

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
[67 <del>60</del> ter.]	<b>USA</b> Support as revised.
<b>7. Consumer practices and communication to consumers</b>	
Paragraphs 68 to 69	<b>Australia</b> Supports the proposed text.
68 <del>61</del> . Government, food industry and other <del>stakeholders interested parties</del> along the food chain should inform and educate consumers on the risks of foodborne illness, including infections with resistant microorganisms and ways to minimize the risk of infection.	<b>Canada</b>
68 <del>61</del> .	<b>USA</b> Support as revised.
68 <del>61</del> . Los gobiernos, la industria alimentaria y otras partes interesadas de la cadena alimentaria deberían informar y concientizar a los consumidores sobre los riesgos de enfermedades transmitidas por los alimentos, entre otras, sobre infecciones por microorganismos resistentes, y las formas de minimizar el riesgo de infección.	<b>CCTA</b> "concienciar" en vez de "concientizar", tal y como se utiliza también al final de dicho número 68
Some aspects to consider when communicating to consumers are: <ul style="list-style-type: none"> <li>Identifying all the <del>stakeholders interested parties</del> and having a common message;</li> </ul>	<b>Canada</b> Minor edit suggested to align with CX/G77-2011
Some aspects to consider when communicating to consumers are: <ul style="list-style-type: none"> <li>Identifying all the <u>relevant</u> stakeholders and having a common message;</li> </ul>	<b>OIE</b> Identifying ALL the stakeholders and having a common message, comes across as a potentially impossible task.
69 <del>62</del> .	<b>USA</b> Support as revised.