

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 4

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

#### Fifth 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 2017/83-AMR)

*Comments of Australia, Brazil, Canada, Colombia, China, Costa Rica, Ecuador, Egypt, Indonesia, Japan, Kenya, Russian Federation, Singapore, United States of America, CI<sup>1</sup>, FAO, FEFAC, Health for Animal, ICGMA, IACFO, IFIF, IMS, IPC and OIE*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/83-AMR issued in September 2017. 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.

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<sup>1</sup> CI (Consumers International); FAO (Food and Agriculture Organization of the United Nations); FEFAC (European Feed Manufacturers' Federation), ICGMA (International Council of Grocery Manufacturers Associations), IACFO (International Association of Consumer Food Organizations), IFIF (International Feed Industry Federation), IMS (International Meat Secretariat), IPC (International Poultry Council) and OIE (World Organization for Animal Health)

**Comments on the Proposed Draft Revision of The Code Of Practice To Minimize And Contain Antimicrobial Resistance (Cac/Rcp 61-2005)**

**GENERAL COMMENT**

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Issue to be considered/developed: Farm biosecurity Good Farming Practice Good Veterinary Practice</p>	<p><b>Albania</b></p>
<p>The current and proposed draft revision of the CAC/RCP 61 document has substantial overlap (from Paragraph 9 onwards) with the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code (Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine) and the Aquatic Animal Health Code (Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals). Indeed, the proposed draft revision references these chapters in its text.</p> <p>In addition, the existing CAC/RCP 61 document provides much guidance on activities to be undertaken by regulatory authorities, which are available elsewhere (viz. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), OIE, and Food and Agriculture Organization of the United Nations (FAO)). For example, Paragraphs 25 to 27 deal with distribution of veterinary medicines, this is a matter that is directly assessed through the OIE Performance of Veterinary Services, against OIE standards.</p> <p>Upon consideration of the Codex mandate, CAC/RCP 61 document appears to be beyond its scope.</p> <p>Given the era of tripartite collaboration on, and the existence of standards (e.g. OIE) in relation to, AMR, the standalone approach for such information has been superseded and leads to duplication of international standards. Such duplication is confusing to the end user and it is unclear what the value is provided by having multiple documents addressing the same content.</p> <p>It is highly recommended that:</p> <ul style="list-style-type: none"> <li>• CAC/RCP 61 be revoked and the revision be discontinued, because of the significant overlap with other international guidelines</li> <li>• a simple hyperlink to relevant tripartite webpages be provided on the Codex website for certain animal health aspects</li> <li>• if gaps are identified along the food supply chain, which are not covered by the relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes, then a fit-for-purpose document could be developed or other Codex publications updated. For example, the Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL 77-2011), which is about risk analysis and management, be reviewed as a result</li> <li>• the definition of 'medically important antibiotics' be clarified as a matter of priority between international standard setting bodies</li> </ul> <p>Gaps which could be addressed include, but are not limited to the following:</p> <ul style="list-style-type: none"> <li>• the use of antimicrobials in agriculture not related to livestock production (e.g. control of fungal and bacterial pathogens on crops and plants)</li> <li>• containment of environmental contamination with antimicrobials (e.g. agricultural run-off, contamination from pharmaceutical industries, waste management from intensive livestock facilities, and human waste discharge into sewers which re-enters the food chain through irrigation)</li> <li>• contribution of the food chain to human antimicrobial resistance, as it is unknown if food is making any or much contribution to the current antimicrobial resistance issues.</li> </ul> <p>This document does not distinguish between the specific reasons for use of antibiotics in animals. Different patterns of use (particularly between animals that do, or do not, enter the food chain, and use for prophylactic versus therapeutic reasons) pose very different risks to human health.</p> <p>Rationale: A Code of Practice needs to reflect these differences in patterns of use, country regulation and the associated health risks.</p>	<p><b>Australia</b></p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>This Code of Practice is also heavily focussed on agriculture and veterinary chemicals, and fails to acknowledge other key contributors to the antimicrobial resistance issue – in particular, the use of antibiotics in human medicine.</p> <p><b>Rationale:</b> Recent research has shown that over-use and incorrect use of antibiotics in human medicine has a critical impact on antimicrobial resistance and the prevalence of antimicrobial resistance infections. In addition, the transmission of antimicrobial resistance infections has also been shown to occur in both directions – from human to animal, as well as from animal to human. Antibiotics are vital medicines for both humans and animals, and antimicrobial resistance poses a significant threat to both human health, and animal health and welfare.</p> <p>With respect to the inclusion of agricultural chemicals in the document, there needs to be more focus on animals.</p> <p><b>Rationale:</b> Research on the risk of antimicrobial resistance from agricultural chemicals is warranted.</p> <p>If general consensus is to retain the CAC/RCP 61 document, then Australia also has specific comments section by section.</p> <p>Insert section on 'Responsibilities of animal feed manufacturers' with reference to OIE Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine.</p> <p><b>Rationale:</b> It is noted that 'Responsibilities of animal feed manufacturers' (of Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine) is not part of this CAC/RCP 61 document and should be included for consistency with the OIE standard.</p>	
<p>Brazil congratulates the EWG coordinators for their work and would like to express that Brazil is in favor of the approach of revising the current text aligned to the Terms of Reference of the Ad Hoc Codex Intergovernmental Task Force on Antimicrobial Resistance approved by the 39th CAC, specially reflecting provisions to the entire food chain, and also being consistent to the work done during the Physical Working Group in December 2016 in London and the agreed PROJECT DOCUMENT /1 - Proposal for new work on the revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005).</p> <p>As agreed, the purpose of the proposed new work is to revise the Code of Practice to Minimize and Contain Antimicrobial Resistance by broadening its scope, and developing risk-based guidance on the management of foodborne antimicrobial resistance that addresses the entire food chain, in line with the mandate of Codex. The revision should address the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of AMR micro-organisms or determinants. It should provide guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in agriculture and aquaculture.</p> <p>So it has been clearly agreed that the work is not only focused and not limited to the use of antimicrobials along the food chain, but on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance. It is also important to highlight that it was also agreed that this work should consider work undertaken in this area by FAO, WHO and OIE, aiming to minimize duplication, avoid contradiction, and ensure coherence.</p> <p>Considering the excellent work done and the human and financial resources spent by Codex members during the Physical Working Group, Brazil proposes changes in the structure of the new text to better reflect the purpose, scope, main aspects to be covered and criteria agreed in PROJECT DOCUMENT 1.</p> <p>Brazil suggests that the structure of the revised Code could have the following topics:</p> <ol style="list-style-type: none"> <li>1 – Introduction, 2 – Scope 3 – Definitions, 4 – General principles, 5 – Responsible use of antimicrobial agents in animals</li> <li>6 – Responsible use of antimicrobial agents in agriculture</li> <li>7 – Practices during production, processing, storage, transport, retail and distribution of food, 8 – Consumer Practices</li> </ol> <p>It is important that the Introduction and Scope are coherent to what was agreed in PROJECT DOCUMENT /1.</p> <p>The definitions have to be further developed and will depend on the content of the final document, taking note of the definitions in CAC/GL 77-2011 and elsewhere in existing Codex, FAO, WHO and OIE texts.</p> <p>The general principles should be revised, to be consistent to “principles” and proportionate to the agreed scope of the document. It seems that many of the suggested principles are proposed risk management measures and therefore should be included in the respective sections that address the issues.</p>	Brazil

GENERAL COMMENTS	MEMBER/OBSERVER
<p>While developing the other proposed items (Responsible use of antimicrobial agents in animals, Responsible use of antimicrobial agents in agriculture, Practices during production, processing, storage, transport, retail and distribution of food, Consumer Practices) it is important to take into account work undertaken in this area by FAO, WHO and OIE, aiming to minimize duplication, avoid contradiction, and ensure coherence. Nevertheless, it is important to identify gaps to be covered to achieve the main objective of this document, which is to provide guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance.</p> <p>Brazil would also like to submit its specific comments on the proposed draft, for the paragraphs as listed below.</p>	
<p>Canada appreciates the opportunity to provide comments on (i) the Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) (CX/AMR 17/5/5) and (ii) Proposed Draft Guidelines on Integrated Monitoring and Surveillance of Antimicrobial Resistance (CX/AMR 17/5/6). Canada particularly thanks the two Electronic Working Groups, in developing the documents for the Fifth Session of TFAMR.</p> <p>I. Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005)</p> <p>1. <b>Level of detail in the current draft of Code of Practice.</b> Canada noted two different opinions on the level of detail, either too high level or too prescriptive. Given that many contents (e.g., Strikethrough Paragraphs 10, 11, 13-16, 18, 22-35) were deleted with reference to OIE's Terrestrial/Aquatic Animal Codes, Canada considers this change makes the document too high level and not very useful as a stand-alone document. Canada suggests that the key points or elements should remain in this document, and some areas could be summarized or re-written in a way to reflect Codex mandate (rather than the mandate of the originating organizations). References could still be made to specific guidelines in other areas (e.g., OIE). Overall, we believe the new Code of Practice needs to be more of a stand-alone document.</p> <p>2. <b>Scope.</b> Canada recommends that the main focus of the document should be on medically-important antimicrobial agents while acknowledging other agents with antimicrobial properties being used in the food chain such as biocides or disinfectants could contribute to antimicrobial resistance.</p> <p>3. <b>Definitions.</b> Canada notes different or even contradictory definitions among the Codex, WHO and OIE guideline documents on the treatment, prevention, control, and/or therapeutic use of antimicrobial agents. Canada suggests to reinforce the use of specific simple terms, appropriate to the host species (for example, control is a concept not really applicable in humans, yet is a common use practice in animals – hence to attempt to harmonize this across humans and animals could be challenging). Careful consideration should be taken as to which definitions are truly useful to harmonize across host species.</p> <p>4. <b>Off-label (Extra-label) use of antimicrobial agents.</b> (i) Currently, this is covered under Responsibilities of Veterinarians and Plant Health Professionals. Canada suggests that this issue is also covered under the Responsibilities of Regulatory Authorities to provide a guideline on their role in establishing restrictions or conditions of the off-label use of medically important antimicrobial agents (in particular, of critically important agents) in food animals. (ii) Off-label use for antimicrobials for growth promotion should be particularly addressed. A description in Para 51 "Off-label use of [medically important] antimicrobial growth promoters should not be permitted" is considered incorrect and is suggested to be revised as "Off-label use of medically important antimicrobial agents for growth promotion purpose should not be permitted." Furthermore, Para 51 as currently written, mixes up several key points. It is suggested to re-write this paragraph for clarity.</p> <p>5. <b>Antimicrobial categorization.</b> Currently, the WHO has its list of Critically Important Antimicrobials while several countries including Canada have their national lists of antimicrobials based on the importance in human medicine. How should a country make a choice between using WHO or its own national list while making relevant decisions? In Canada, the national categorization has been used for setting priorities for risk analysis while taking into consideration WHO's CIA Lists. In Principle 4, several lists are mentioned. It is suggested to include reference to the recognition of national lists in this context. Canada recognizes that national lists may have been developed for different purposes and using different criteria than the WHO CIA list; hence general recommendations regarding choices and uses of these lists may warrant further discussion.</p> <p>6. <b>Co-resistance.</b> Co-resistance is a fundamental mechanism contributing to the emergence and spread of antimicrobial resistance. This document does not mention co-resistance. However, GL 77-2011 guidelines do capture co-resistance. It is suggested to modify Principle #5 and include "or co-resistance" after "cross-resistance". We also suggest adding "co-resistance" to Definitions (i.e., "Co-Resistance: The ability of a microorganism to multiply or persist in the presence of different classes of antimicrobial agents due to possession of various resistance mechanisms." from GL 77).</p>	Canada

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<p>Colombia, desea compartir algunos comentarios generales respecto al el documento:</p> <ul style="list-style-type: none"> <li>• El uso de antimicrobianos en el marco de las actividades del sector agrícola, solo se mencionó en algunos apartes del documento, a pesar de que se trata de un tema importante que probablemente requerirá de asesoramiento científico por parte de la FAO/OMS para que el grupo de acción pueda establecer medidas de gestión del riesgo.</li> <li>• Se sugiere retener el documento en el trámite 3, dado que es necesario contar con el resultado del asesoramiento científico acorde al documento CX/CAC 17/40/12 Apéndice 3. Términos de Referencia para la Provisión de Asesoramiento Científico sobre la Resistencia a los Antimicrobianos.</li> <li>• En diversos apartes del documento se menciona el enfoque de "Una Salud", mientras que en otros se utiliza el término "Salud Única", se sugiere estandarizar el término para todo el documento. Adicionalmente se sugiere aclarar cuál es el alcance del Codex en el marco del enfoque de "Una Salud".</li> <li>• En términos generales se observan problemas de traducción al español en el el documento.</li> <li>• Se sugiere evaluar la pertinencia del término "seguimiento", el cual se utiliza en diferentes apartados del documento, ya que se considera que el término "monitoreo" es más apropiado.</li> <li>• Se sugiere revisar en el contexto del documento la pertinencia de utilizar la palabra "bacterias" y en que apartes es necesario referirse a los "microorganismos", ya que el espectro del segundo es más amplio.</li> </ul>	<p><b>Colombia</b></p>
<p><b>1. General comments on the overall framework of the CAC RCP text</b></p> <p><b>1.1 RCP Scope Extensions but Content Not Matched:</b> Although the scope of RCP document has been extended to control the antimicrobial resistance associated with the food chain of animals, crops and aquaculture. However, the control of antimicrobial resistance related to agriculture and environment has not been reflected in all chapters and specific contents, and there is no respective responsibilities of authorities and relevant stakeholders. It is recommended that experts in the field of agriculture and environment should be invited to join the Electronic Working Group to participate in the revision of the CAC RCP.</p> <p><b>1.2 There are more coincidences between RCP and OIE documents:</b> RCP documents refer to the contents of OIE Terrestrial Animal Health Code chapter 6.9 and aquatic animal health code chapter 6.2 for many times, and there are many coincidences. It is suggested to properly summarize the overlapping parts and refine the key points to form the RCP's distinctive language.</p> <p><b>1.3 Some texts in the RCP text are inconsistent:</b> There was a literal inconsistency in the RCP document. For example, most Antimicrobial agents are used in the article, but a few are used with antimicrobials, or with antimicrobial drugs, or with antibiotics, and the scope of the text defines antimicrobial agents as more appropriate. Therefore, the experts recommended to the CAC Secretary-General to check the text throughout to ensure consistency of the text.</p> <p><b>2. Comments on some key controversial points</b></p> <p><b>2.1 About alternatives of antimicrobial agents:</b> Antimicrobial agents are irreplaceable. Alternatives are no substitute for antimicrobial agents in terms of their safety (antimicrobial resistance, residue) or effectiveness or quality control. And some alternatives, such as probiotics, herbs and their extracts, have higher risk for drug residue and antimicrobial resistance.</p> <p><b>2.2 About the category of antimicrobial agents:</b> The WHO and OIE has developed the list of the importance of antimicrobial agents in human medicine and in veterinary medicine, respectively. China MOA has almost established Chinese list of veterinary antimicrobial agents. The RCP should follow OIE list to prudent regulate the registration of the medical important antimicrobials in food-producing animals.</p> <p><b>2.3 About prophylaxis/metaphylaxis/treatment:</b> For animal bacterial infections, early treatment should be promoted, that is, prevention and prophylactic use of antimicrobials.</p>	<p><b>China</b></p>
<p>1) FAO and WHO should provide scientific advice in order to appropriately address AMR in crop protection area in the revision of the Code of Practice. There is little information on the link between the use of antimicrobials on crops and foodborne AMR, which necessitates scientific advice from FAO and WHO. FAO and WHO called for data on foodborne AMR in livestock area and crop protection area to be submitted by 31 December 2017.</p>	<p><b>Japan</b></p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>2) Japan notes that there are inconsistent use of the terms. Firstly, “antimicrobials”, “antimicrobial agents” and “antimicrobial drugs” are used interchangeably in many places. In order to avoid confusion, Japan proposes to define one of these terms and include other terms as synonyms in the definition. Secondly, with respect to the proposed definitions “antimicrobial agent”, “antibiotic” and “antibacterial”, Japan considers it appropriate to use antimicrobial agent only where these three terms are used interchangeably. As a consequence, the definition of “antibiotic” can be deleted (see specific comments below).</p> <p>3) Japan recalls that the purpose of the work of the TF is “to revise the Code of Practice by broadening its scope, and developing risk-based guidance on the management of foodborne antimicrobial resistance” (see point 1 of the appendix 1 to CX/CAC 17/40/12 Add.2). However, Japan considers the proposed draft revision not fully risk-based, in particular, several principles in the section “General Principles to Minimise and Contain Antimicrobial Resistance” (See specific comments below)</p> <p>4) Japan notes that the OIE Codes are not correctly referenced. An example of correct reference is given in specific comments.</p>	
<p>Kenya appreciates the work of the EWG chaired by the US and Co-chaired by Kenya, China and the United Kingdom in proposed Draft Revision of the COP to minimize and contain Antimicrobial Resistance for comments by member countries.</p> <p>We also note the key areas of consensus as well as areas lacking consensus. We fully support the the approach to the format of the document as presented in the appendix 1 (table of contents and the list of acronyms used in the documents).</p> <p>Kenya proposes the refined definitions of treatment/metaphylaxis/control/prophylaxis/prevention adequately as appropriate to assist in their application within the document.</p> <p>We also propose the withdrawal of the term Medically Important Antimicrobials(MIAs) in the document since it is amorphous and therefore might open a wider room of abuse. This affects the principle 12 of application as well.</p> <p>We also note the no. of principles presented the document, some of which a quite lengthy.</p>	<b>Kenya</b>
<p>Singapore appreciates the effort of the working group to update this document and agree with overall approach to expand the scope to address the entire food chain and to reference existing documents to avoid duplication.</p>	<b>Singapore</b>
<p>1. Thailand is of the opinion that the scope of this document in para 7 should revised to reduce some of the redundancy, especially in a context of Minimize Antimicrobial Resistance. In addition, the format and sequence of terms “agriculture (crops), animal husbandry, and aquaculture” should be considered and clearly defined in this draft document and proposed draft Guidelines on integrated monitoring and surveillance of antimicrobial resistance.</p> <p>2. Thailand would like the TFAMR to defined only definitions which are used in proposed draft revision of CAC/RCP61-2005. For the consistency, we would like to request the TFAMR to harmonize the meaning of the identical definitions that appear in both draft documents. Moreover, some definitions especially Medically important antimicrobials, Therapeutic use and Growth promotion should be considered in conjunction with the WHO guidelines on use of medically important antimicrobials in food-producing animals (new released: November 7, 2017)</p> <p>3. Thailand is of the opinion that there are too many general principles in this document. We suggested that the common and proximity principles could be grouped together. In order to clearly understand, some broad principles should added sub-principles. A clear set of principles will give us immediate focus and clarity on the Codex work on AMR in the future.</p> <p>4. Thailand would like to stress once again that it is necessary to include the sections on the control of Active Pharmaceutical Ingredients (APIs), the alternatives to antimicrobials especially autogenous vaccine as well as the responsibilities of feed manufacturers in the documents. Moreover, the detail of “Responsibilities of Importers” and “Food Producers and Distributors” should also be added in the document.</p> <p>5. The draft Guidelines should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies. For example, the OIE Aquatic Animal Health code should be added in relevant section as it is a very important document of Aquatic Animal production. The phytosanitary measures or treatments from the International Plant Protection Convention (IPPC) should also be added (if available) to ensure that the application of phytosanitary measures does not contribute to increased antimicrobial resistance.</p>	<b>Thailand</b>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>6. Thailand in general supports the section of “Advocacy and Communication”. Nevertheless, we are opinion that this section should only focus on “Communication”, rather than “Advocacy”. It is because of communication is a part of risk based approach (risk assessment, risk management, and risk communication). Considering that regulatory authorities are responsible for developing the communication strategy with multi-stakeholder to minimize and control of antimicrobial resistance along the food chain. With this in mind, the effective communication will lead to advocacy and social mobilizations. Therefore, we suggest that “Advocacy” may be not appropriate to include in this section.</p>	
<ul style="list-style-type: none"> <li>• The United States appreciates the opportunity to comment on the proposed draft revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and takes note of the significant work by the EWG to develop a comprehensive document that took into consideration the many comments submitted.</li> <li>• The United States supports the proposal of the EWG to revise the format of the Code of Practice (COP) to be consistent with Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011) and improve coherence between the texts.</li> <li>• The United States supports the proposals of the EWG to streamline the COP by revising and deleting sections of text that are redundant with the OIE Terrestrial Animal Health Code Chapter 6.9 and Aquatic Animal Health Code Chapter 6.2.</li> <li>• The United States supports the proposal to maintain in square brackets text that refers to the use of antimicrobials on plants/crops pending the outcome of scientific advice to the TFAMR.</li> </ul>	<b>USA</b>
<p>As a general comment, we would like to welcome the introduction of a reference to adequate nutrition as part of preventative tools to enhance the ability of animals to cope with pathogens. However, we believe this significant step would benefit from a clarification of what is meant by the concept of animal nutrition, i.e. not just meeting the nutritional requirements of animals but also helping the animals to maintain a proper health status during certain sensitive physiological stages (such as weaning) or even to enhance the ability of animals to cope with pathogens via action on the gastro estinal tract. We do appreciate that this there may still be scope for discussions whether the responsibility to further develop elements related to adequate nutrition within the present Code or should be referred to OIE as the leader on animal health management on the farm. In our opinion, the “One Health Strategy” requires a coordinated approach between the two sectors and cross-references may be used as long as they contribute to meet the common objective of reducing AMR.</p> <p>Additional comments have been introduced in the form of edits in the attached file.</p>	<b>FEFAC</b>
<p>HealthforAnimals takes seriously the issue of antimicrobial resistance (AMR) and the importance of One Health. It has recently unveiled a global Commitment on AMR supported by 200+ companies and endorsed by two leading veterinary groups representing 700,000 veterinarians. Codex Alimentarius can further contribute to the work on AMR, but it is also necessary to understand and take stock of the work of Codex and tripartite organizations (FAO, WHO, and OIE).</p> <p>HealthforAnimals believes the Code of Practice adopted in 2005 (CAC/RCP 61-2005) is widely redundant with chapter 6.9 of the OIE Terrestrial Code, which has been revised on a consistent basis by OIE since 2005.</p> <p>HealthforAnimals considers that responsible use of antibiotics at the farm level falls very clearly within the scope of OIE. We strongly recommend that the direction taken should be in alignment with the OIE chapter 6.9 of the Terrestrial Code and possibly other relevant texts of OIE. Additionally, the Code of Practice and Surveillance of AMR documents outline principles and policies that are risk management recommendations without reference to risk analysis or risk assessment.</p> <p>We recommend that the principles and polices outlined in the documents be based on risk analysis as per Codex principles.</p> <p>Guiding principles for the Task Force on Antimicrobial Resistance:</p> <ul style="list-style-type: none"> <li>• Scope of the Task Force on AMR should stay within the mandate of Codex and not duplicate work of WHO, FAO, AGISAR and OIE. We would challenge the Codex TFAMR to consider drawing more from the OIE’s Terrestrial Code to support this work. Most notable, the responsibilities for veterinarians and responsibilities for producers are documented in the OIE code (chapter 6).</li> <li>• Adoption of policies should be science-based and have supporting risk assessment. Risk assessment must precede risk management and remain consistent with Codex procedures.</li> </ul>	<b>HealthforAnimals</b>

GENERAL COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• Antimicrobial resistant risk management strategies should only focus on medically important antibiotics. There are many animal health products that prevent bacterial disease in animals that are not medically important to people, therefore efforts to discourage the use of these animal health products do not meet the goal of the Task Force on AMR.</li> <li>• The ability to use a medically important antibiotic under the supervision of an animal health provider to treat, control, or prevent a disease should be maintained as policy. This judicious use guidance will ensure the therapeutic use of antibiotics to protect animal health, food safety, and animal welfare.</li> <li>• Decisions about access to medicines are best made by the competent regulatory authority in countries (ex. FDA, EMA). Broad legislative initiatives should be avoided and instead follow a careful, risk assessed approach by regulatory agencies to address stewardship of antibiotics in animal health.</li> </ul>	
<p>Thank you for giving the International Feed Industry Federation (IFIF) the opportunity to comment on the Proposed Revised Code of Practice to Minimize and Contain Antimicrobial Resistance CAC/RCP 61, at Step 3, and please find our general comments below and our specific comments marked in the document. IFIF acknowledges and welcomes the fact that 'adequate' nutrition has been specifically mentioned in principle 2 describing preventative measures. However, the term 'adequate' would require further definition to better reflect the need of a well balanced diet to support animal health status. IFIF proposes to specifically add 'adequate nutrition' when it is appropriate in the code to support the implementation of principle 2.</p> <p>The text has still some inconsistency in the use of 'antimicrobials' and IFIF suggest to use systematically the terminology: 'antimicrobial agents'.</p> <p>IFIF notes as well the need for further discussion on whether to reference the OIE chapter or develop a new section, and this is an important aspect and IFIF welcomes the opportunity to discuss more in detail during the physical meeting in Korea. While the emphasis of supporting adequate nutrition strategies is relevant for the Code, it may not be the most appropriate place to address more details requirements as the Code focuses on human health, while adequate nutrition focuses on animal health. As mentioned in our first comments, it is important that in a One Health approach, this Code which is aiming at protecting human health, should refer to, and is read in conjunction with, on farm preventative measures OIE or other consensus-based international organizations would have established or would establish in the framework of the global action plan on AMR to contribute to animal health.</p>	<p><b>International Feed Industry Federation</b></p>
<p>The International Meat Secretariat (IMS) appreciates the opportunity to offer our comments regarding the Step 3 Proposed Draft Revision of the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (AMR). Ensuring animal health and well-being ranks as a top priority for the membership of IMS. Antimicrobial drugs serve as a valuable tool used to protect animal health. Prevention, control, and treatment of animal diseases are necessary actions for any successful animal health management program.</p> <p>IMS understands the need to revise the Codex Code of Practice to Minimize and Contain AMR in order to achieve greater clarity and consistency with the more recent Codex documents, such as the Guidelines for Risk Analysis of Foodborne AMR (CAC/GL 77-2011). Additionally, IMS agrees that the Code of Practice document could be streamlined by removing redundant sections of text and providing references to the appropriate Codex and OIE documents.</p> <p>We believe that the work of the Codex task force on AMR should be focused on minimizing the potential adverse impacts to public health resulting from foodborne AMR. The efforts of the Codex Alimentarius (Codex), the World Organization for Animal Health (OIE), the World Health Organization (WHO), and the Food and Agriculture Organization of the United Nations (FAO) to work to better identify and manage the problem of AMR, using a One Health approach, should remain coordinated and supportive.</p> <p>IMS requests that the Codex AMR Task Force consider the following general recommendations while working to revise and update the Codex Code of Practice to Minimize and Contain AMR:</p> <ul style="list-style-type: none"> <li>• Maintain a science-based approach to controlling AMR that identifies and reviews all relevant data regarding the risks for developing foodborne AMR.</li> <li>• Explore improved management control measures and stewardship practices for the use of antimicrobial drugs rather than simply eliminating the use of these products.</li> <li>• Examine any challenges and/or consequences to animal health resulting from efforts to significantly reduce or eliminate the use of antimicrobial drugs.</li> </ul>	<p><b>International Meat Secretariat</b></p>



GENERAL COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>Guard that the scope of the Codex Code of Practice to Minimize and Contain AMR remains foodborne AMR, which is consistent with the Codex mandate for ensuring food safety.</li> <li>Uphold transparency within all aspects of the process to review and revise the Code of Practice document and solicit widespread participation of all Codex member governments in the process.</li> <li>Use commonly accepted definitions in the Code of Practice that will foster and support a One Health approach to AMR.</li> <li>Avoid the use of politically-charged language (such as “advocacy”) and adhere to a more science-based tone in the language of the Code of Practice document. IMS has also submitted specific edits to Step 3 for CL 2017/83/OCS-AMR</li> </ul>	
<p>We thank the EWG and particularly the chair and co-chairs, the United States, China, Kenya, and the United Kingdom, for their work to broaden the scope of the Code and to lay out areas of potential consensus and areas where further consideration is needed.</p> <p>While we appreciate the effort to streamline and simplify the Code by referring to other texts, and support the cross-referencing of relevant texts, we urge TFAMR to take primary responsibility for and control of elaborating the text of the Code, and to consider clarity, coherence, and ease of use to be more important than avoiding duplication. In our view, too much important text has been deleted and the current draft too often refers the reader to OIE texts. Moreover, key concepts (e.g., ensuring that all antimicrobials used in food-producing animals be prescribed by veterinarians or other suitably trained persons) no longer appear in the Code.</p> <p>IACFO notes that chapter 6.9 of the OIE Terrestrial Animal Health Code was last revised in 2014 and that chapter 6.2 of the OIE Aquatic Health Code was adopted in 2011 and has not been revised since. These chapters thus do not take into account “new developments,” as requested by the Physical Working Group on Antimicrobial Resistance [cite 1], and should not replace portions of the Code.</p> <p>Sources cited:            (1) Codex Alimentarius Commission, Fortieth Session Agenda Item 12, CX/CAC 17/40/12 Add.2, Report of the Physical Working Group on Antimicrobial Resistance (AMR), July 2017.</p> <p>We support efforts to strengthen the text—for example re: the importance of reducing the need to use antimicrobials, by using measures such as improved biosecurity, husbandry, non-antimicrobial disease prevention activities, etc.—and identify additional ways that the text can be further strengthened in our specific comments.</p> <p>IACFO suggests dropping the term “therapeutic use” from the text and instead clearly characterizing uses separately as either for treatment, control (metaphylaxis), prevention (prophylaxis), or growth promotion. The current proposed definition of the term “therapeutic use” to include the first three of these is inconsistent with the approach taken by the World Health Organization, which clearly distinguishes between antimicrobials used in animals for growth promotion, prophylactic, and therapeutic/treatment purposes [cite 2]:</p> <p><b>“Disease Treatment/Therapy/Therapeutic Use:</b> Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness. (Codex texts on foodborne antimicrobial resistance, 2015.)</p> <p><b>Disease Prevention/Prophylactic Use:</b> Prevention/Prophylactic Use refers to use of an antimicrobial(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This treatment includes:</p> <ul style="list-style-type: none"> <li>control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and</li> <li>prevention of an infectious disease that has not yet been clinically diagnosed. (Codex texts on foodborne antimicrobial resistance, 2015.)</li> </ul> <p>Growth Promotion/Growth Promoter: Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does not apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained. (Codex texts on foodborne antimicrobial resistance, 2015.)”</p> <p>Clearly, there is no consensus on the meaning of the term “therapeutic,” so we suggest instead that the four potential uses simply be itemized as appropriate.</p>	<p><b>International Association of Consumer Food Organizations</b></p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>More fundamentally, the proposed category of “therapeutic use” to include all but growth promotion obscures important distinctions between treatment, control, and prevention that are relevant to minimizing and containing antimicrobial resistance. While each of these uses may be justified under certain specific circumstances (for example, prophylactic use prior to surgery), such uses should be differentiated so that approaches to each can be individualized. In our specific comments we suggest wording to more clearly define those circumstances.</p> <p>Source cited:  (2) World Health Organization, 2016, Critically important antimicrobials for human medicine – 5th rev., p. 39, ISBN 978-92-4-151222-0.  <a href="http://www.who.int/foodsafety/publications/antimicrobials-fifth/en/">www.who.int/foodsafety/publications/antimicrobials-fifth/en/</a>.</p> <p>With regard to whether the Code should use “antimicrobial” resistance or “antibiotic” resistance, we suggest that the more encompassing term “antimicrobial” generally be used, unless it would not be appropriate in a particular context.</p> <p>We propose including the WHO’s recommendation that certain classes of antimicrobials important to human medicine that currently have no veterinary equivalent not be used in animals, plants, or aquaculture. These include carbapenems, lipopeptides, and oxazolidinones, as well as any new class of bial developed for human therapy.[cite 3]</p> <p>Source cited:  (3) Critically Important Antimicrobials for Human Medicine, 3rd Rev., 2011, p. 3.  <a href="http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf">http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf</a>.</p> <p>We recommend that further consideration be given to ensuring that appropriate conflict of interest safeguards are in place when deciding to establish, establishing, implementing, and monitoring a policy or programme to minimize and contain antimicrobial resistance, consistent with the conclusions of a recent World Health Organization consultation.[cite 4]</p> <p>Sources cited:  (4) World Health Organization, “Addressing and Managing Conflicts of Interest in the Planning and Delivery of Nutrition Programmes at Country Level,” Geneva, 2016.</p> <p>In keeping with the proposed scope laid out in the Report of the Physical Working Group on Antimicrobial Resistance (TFAMR PWG) to address “the entire food chain,” and with the One Health approach, we agree with the recommendation that TFAMR should consider not only animals but also crops, the environment, manure, biocides, waste, packaging, production systems and practices, food processing, retail handling, and consumption. In addition, we think that apiculture (bees), food storage, and the use of antimicrobials as food additives and/or food contact substances should be included. We believe that the scope should include all uses of antimicrobial agents in all sectors throughout the food chain, and all ways that food can be contaminated with organisms resistant to antimicrobials, or with antimicrobial resistance determinants.</p> <p>Currently, many sections of the Code do not address the entire food chain. That includes the sections on quality control of antimicrobial agents, assessment of efficacy, assessment of environmental impact, and, of particular importance, assessment of the potential of antimicrobial agents to select for resistant organisms. While the Code now addresses (at least to some extent) crops and aquaculture in addition to animals, there is no mention in the Code itself of apiculture, biocides, or antimicrobials used as processing aids or as secondary or direct food additives (e.g., natamycin), and very little attention is devoted to food processing. Simply stating that the food processing industry should take necessary action in accordance with the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) is insufficient.</p> <p>Biocides are used at various points along the food chain, including as disinfectants and food preservatives, in animal husbandry (as feed preservatives and for specific applications such as teat dips), and for decontamination of carcasses. A European assessment of the antibiotic resistance effects of biocides noted that “any application that encompasses the widespread regular use of biocides at sub-lethal concentrations maintains a continuous selective pressure and thus increases the risk of selecting resistant bacteria. This may occur in a number of uses including ... food production...” [cite 5]</p> <p>This concept should be incorporated in the Code.</p> <p>Source cited:(5) European Commission Directorate-General for Health &amp; Consumers, Scientific Committee on Emerging and Newly Identified Health Risks, “Assessment of the Antibiotic Resistance Effects of Biocides,” 2009.  <a href="http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf">http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf</a>.</p>	

## SPECIFIC COMMENTS

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
1. Introduction	
Table of Contents	
[Introduction]	
[Scope]	
[Definitions]	
[General Principles to Minimize and Contain Antimicrobial Resistance]	
[Responsibilities of the Regulatory Authorities]	
[Responsibilities of Manufacturers]	
[Responsibilities of Wholesale and Retail Distributors]	
[Responsibilities of Veterinarians and Plant Health Professionals]	
	<p><b>Albania</b> Issue to be considered/developed: Farm biosecurity; Good farming practice; Good veterinary practice <i>Category: TECHNICAL</i></p>
	<p><b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i></p>
[Responsibilities of Producers]	
[Responsibilities of Consumers]	
[Advocacy and Communication]	
Introduction	
	<p><b>China</b> It is unnecessary to highlight marketing authorization in the introduction part. It is suggested to consolidate the para 4 and 5. It is suggested that some of the statements of aims and objectives part be moved after the sixth paragraph to highlight the objectives of the RCP. The RCP aims to ensure the one health, namely the ecological health of human beings, animals, plants and the environment. The effective reduction and control of antimicrobial resistance should be under the protection of the health of animal and the effective supply of food from animal and plant source.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[1. Antimicrobial resistance poses a complex, global public health challenge. Within the food production to consumption continuum, there is a need to address the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies for good practices in agriculture (crops), aquaculture and animal husbandry including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.]</b></p>	
<p>[1. Antimicrobial resistance poses a complex, global public health challenge. Within the food production to consumption continuum, there is a need to address the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies for good practices in agriculture (crops), aquaculture and animal husbandry including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.]</p>	<p><b>Australia</b> Paragraph 1 Comment: It is important to include fuller text on One Health. Suggest words along the lines of “Risks may transfer in both directions between humans and (other) animals”. Rationale: The ‘One Health’ approach needs to be defined or explained in the introduction, as it is used later in the document e.g. Principle 1. Paragraph 1 Comment: Include text that acknowledges all sources of AMR microorganisms in food for a One Health approach. Rationale: Environmental and human sources of contamination should also be mentioned even if not addressed by this Code of Practice. <i>Category: SUBSTANTIVE</i></p>
<p>[1. Antimicrobial resistance poses a complex, global public health challenge. Within the food production to consumption continuum, there is a need to address the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies <u>along the food chain to minimize the possible risks associated with foodborne AMR, including guidance for good practices in agriculture (crops), aquaculture and animal husbandry including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.}] There are shared responsibilities of all involved through the food production to consumption continuum, including competent authorities, veterinary pharmaceutical industry, veterinarians, animal feed manufacturers, distributors of veterinary drugs, food animal producers, food industry, distributors of food and end consumers to help to mitigate possible risks of foodborne AMR.</u> <u>The continued availability of veterinary antimicrobial drugs, which are essential for animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobials in food-producing animals.</u></p>	<p><b>Brazil</b> <i>Category: SUBSTANTIVE</i></p>
<p>[1. Antimicrobial resistance poses a complex, global public health challenge. Within the food <del>production to consumption continuum</del><u>chain</u>, there is a need to address the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies for good practices in agriculture (crops), aquaculture and animal husbandry including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.]</p>	<p><b>Egypt</b> replace <i>Category: TECHNICAL</i></p>

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<p>[1. Antimicrobial resistance poses a complex, global public health challenge. Within the food production to consumption continuum, there is a need to address the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies for good practices in <del>agriculture (crops)</del><u>agriculture (crops)</u>, aquaculture and animal husbandry including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.]</p>	<p><b>USA</b></p> <p>The United States supports the adoption of the revised and deleted text in the Introduction with the following exceptions.</p> <p>Paragraph 1: Maintain “agriculture (crops)” in square brackets.</p> <p>Paragraph 2: Maintain “agricultural chemicals on crops and” in square brackets.</p> <p>Paragraph 4: Maintain “and plant health professionals” in square brackets.</p> <p><b>Rationale:</b> Text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. To develop appropriate guidance on the use of antimicrobials on plants and crops significant gaps in data and information must be addressed.</p> <p>Among the areas where data gaps exist are:</p> <ul style="list-style-type: none"> <li>• Information on the antimicrobial classes and application methods used on crops,</li> <li>• Types of crops and agricultural settings where antimicrobials may be used,</li> <li>• Information of the selection and dissemination of resistant bacteria associated with antimicrobial use on crops,</li> <li>• Evidence of the transfer of resistance determinants between bacteria associated with crops,</li> <li>• Evidence of a causal link for human foodborne illness due to consumption of food contaminated with antimicrobial resistant bacterial pathogens originating from plants/crop as a result of treatment of that plant/crop with an antimicrobial.</li> </ul> <p>Adequate information on the antimicrobials, target bacteria, food commodities, use patterns, and other parameters is critical to the development of effective and efficient risk management guidance. This information is currently lacking for antimicrobial use on crops.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>[1. Antimicrobial resistance <u>is a major public health problem and</u> poses a complex, global public health challenge. Within the <u>entire</u> food production to consumption continuum, there is a need to <del>address-minimize and contain</del> the selection and dissemination of resistant microorganisms and resistance determinants. The development of strategies for good practices <u>throughout the entire food chain, including in</u> agriculture (crops), aquaculture and animal husbandry <u>(whether for mammals, birds, fish, or insects), food processing, packaging, storage, distribution, and through to consumption and</u> including the responsible and prudent use of antimicrobials in all sectors following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.]</p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>Broaden to include all uses and all sectors throughout the entire food chain, and strengthen wording to emphasize that AMR is a major public health problem.</p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>Australia</b> Paragraph 2 Comment: A different approach for the document is suggested – part of the risk analysis process focusing on ‘risk management’. The proposed document should include mention about traceback mechanisms when an incident with a foodborne pathogen with AMR arises. Rationale: This would help referencing to the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011, which contains a comprehensive section on ‘Foodborne AMR Risk Management’. Comment: With respect to the inclusion of agricultural chemicals in the document, there needs to be more focus on animals. Rationale: Research on the risk of antimicrobial resistance from agricultural chemicals is warranted. Category: <i>SUBSTANTIVE</i></p>
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> <i>Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011 and General Principles of Food Hygiene (CAC/RCP 1-1969). In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>Brazil</b> Category: <i>SUBSTANTIVE</i></p>

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<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and <del>relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.</del> <u>taken into account as appropriate</u></p>	<p><b>USA</b> Rationale: Codex texts should be read in conjunction with other internationally-recognized texts developed through transparent processes of review and consensus by Member Countries, such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e. Codex, OIE, and International Plant Protection Convention (IPPC)]. <i>Category: TECHNICAL</i></p>
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL <del>77-2011</del> <u>77-2014</u> and <u>relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes</u>. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>USA</b> The United States recommends moving “and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes” to the first sentence. <i>Category: TECHNICAL</i></p>
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of <del>agricultural chemicals</del> <u>antimicrobial agents</u> on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>

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<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and 53-2003), the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), <u>the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programs Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009)</u>, the Code of Practice for Fish and Fishery Products (CAC/RCP 53-2003), the General Principles of Food Hygiene (CAC/RCP 1-1969), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively relevant. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i></p>
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes and the List of Antimicrobials of Veterinary Importance should also be referenced.]</p>	<p><b>OIE</b> Veterinary public health is part of the OIE Terrestrial Animal health Code (section 6) Code. To clarify that its about human health it would be preferable to distinguish between “human “health and “animal “ health where appropriate. Category: <i>TECHNICAL</i></p>
<p>[2. 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>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i> and Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011. In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) are particularly relevant for use of agricultural chemicals on crops and animal feed, respectively. WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017) and Critically Important Antimicrobials for Human Medicine (2016) and <del>relevant chapters</del> <u>Chapter 6.10 Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals of the OIE Terrestrial Animal Health Code (2017), and Chapter 6.5 Risk Analysis for antimicrobial resistance arising from the use of antimicrobial agents in aquatic animals of the OIE Aquatic Animal Health Codes Code (2017)</u> and the <u>OIE List of Antimicrobials of Veterinary Importance should also be referenced</u> Importance.]</p>	<p><b>OIE</b> Category: <i>TECHNICAL</i></p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[3. Where available, national and local guidelines to minimize and contain antimicrobial resistance should be taken into consideration. Best practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.]</b>	
<del>[3. Where available, national and local guidelines to minimize and contain antimicrobial resistance should be taken into consideration. Best practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.]</del>	<b>Brazil</b> <i>Category: EDITORIAL</i>
<del>[3. Cuando se disponga de ellas, deberían tenerse en consideración las directrices para reducir al mínimo y contener la resistencia a los antimicrobianos. También deberían tenerse en cuenta las mejores prácticas y las directrices sobre el uso responsable y prudente de los antimicrobianos elaboradas por organizaciones gubernamentales y profesionales.]</del>	<b>Colombia</b> Ya que hace referencia precisamente al documento que se está elaborando <i>Category: TECHNICAL</i>
<b>4. [4.] This document provides additional guidance for [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993. It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial [agents]drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups[relevant stakeholders] involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of food-producing animals.</b>	
<del>1. [4.] This document provides additional guidance for [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993. It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial [agents]drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups[relevant stakeholders] involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of food-producing animals.</del>	<b>Brazil</b> <i>Category: EDITORIAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>4- [4.] This document provides <del>additional</del> guidance <del>for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-<del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-<del>producing animals</del>, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents] drugs in veterinary medicine</del> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del>[relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry</del>[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] <del>of food-producing animals.</del></p>	<p><b>Canada</b> - Para 4. Suggest further defining “manufacturers” by adding the deleted “pharmaceutical” to have “pharmaceutical manufacturers “. “manufacturers” alone is too broad. Moreover, producers of antimicrobial products are regarded as pharmaceutical makers. <i>Category: EDITORIAL</i></p>
<p>4- [4.] Este documento brinda orientación <del>adicional</del> para [sobre las medidas pertinentes a lo largo de la cadena alimentaria para reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, entre otras, orientaciones sobre] el uso responsable y prudente de los antimicrobianos en [la cadena alimentaria]-<del>los animales productores de alimentos, y debería leerse juntamente con el Código Internacional Recomendado de Prácticas CAC/RCP 38-1993.</del> Su objetivo[, en el marco del enfoque “Una Salud”,] es reducir al mínimo los posibles efectos adversos en la salud pública [y animal] del uso de agentes antimicrobianos en <del>los animales productores de alimentos</del> [la cadena alimentaria], en particular el desarrollo de resistencia de los antimicrobianos. También es importante para asegurar el uso inocuo y efectivo de los <del>medicamentos veterinarios</del> [agentes] antimicrobianos <del>en la medicina veterinaria</del> conservando su eficacia. Este documento define las respectivas responsabilidades de las autoridades y <del>los grupos</del> [partes interesadas pertinentes] que intervienen en la autorización, producción, control, distribución y uso de los antimicrobianos <del>veterinarios</del>, en concreto las autoridades de reglamentación nacionales, <del>la industria farmacéutica la industria farmacéutica veterinaria</del> [los productores], los veterinarios [y profesionales de sanidad vegetal], los distribuidores [minoristas y mayoristas,] y [los] productores [y los consumidores]<del>de animales de los que se obtienen alimentos.</del></p>	<p><b>Colombia</b> Se sugiere no eliminar la industria farmacéutica como parte de los actores responsables y referirse en en general las comercializadores de insumos agrícolas, además se considera un actor importante dentro de la problemática de resistencia antimicrobiana en la cadena agro-alimentaria. <i>Category: TECHNICAL</i></p>

SPECIFIC COMMENTS	
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<p>4. [4.] Este documento brinda orientación <del>adicional para</del> [sobre las medidas pertinentes a lo largo de la cadena alimentaria para reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, entre otras, orientaciones sobre] el uso responsable y prudente de los antimicrobianos en [la cadena alimentaria] <del>los animales productores de alimentos, y debería leerse juntamente con el Código Internacional Recomendado de Prácticas CAC/RCP 38-1993.</del> Su objetivo[, en el marco del enfoque “Una Salud”,] es reducir al mínimo los posibles efectos adversos en la salud pública [y animal] del uso de agentes antimicrobianos en <del>los animales productores de alimentos</del> [la cadena alimentaria], en particular el desarrollo de resistencia de los antimicrobianos. También es importante para asegurar el uso inocuo y efectivo de los <del>medicamentos veterinarios</del> [agentes] antimicrobianos <del>en la medicina veterinaria</del> conservando su eficacia. Este documento define las respectivas responsabilidades de las autoridades y <del>los grupos</del> [partes interesadas pertinentes] que intervienen en la autorización, producción, control, distribución y uso de los antimicrobianos <del>veterinarios</del>, en concreto las autoridades de reglamentación nacionales, <del>la industria farmacéutica veterinaria</del> [los productores], los veterinarios [y profesionales de sanidad vegetal], los distribuidores [minoristas y mayoristas,] y [los] productores[ y los consumidores]<del>de animales de los que se obtienen alimentos.</del></p>	<p><b>Colombia</b> Se sugiere eliminar, ya que e encuentra repetido dentro de la oración. <i>Category: TECHNICAL</i></p>
<p>4. [4.] Este documento brinda orientación <del>adicional para</del> [sobre las medidas pertinentes a lo largo de la cadena alimentaria para reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, entre otras, orientaciones sobre] el uso responsable y prudente de los antimicrobianos en [la cadena alimentaria] <del>los animales productores de alimentos, y debería leerse juntamente con el Código Internacional Recomendado de Prácticas CAC/RCP 38-1993.</del> Su objetivo[, en el marco del enfoque “Una Salud”,] es reducir al mínimo los posibles efectos adversos en la salud pública [y animal] <del>pública</del> del uso de agentes antimicrobianos en <del>los animales productores de alimentos</del> [la cadena alimentaria], en particular el desarrollo de resistencia de los antimicrobianos. También es importante para asegurar el uso inocuo y efectivo de los <del>medicamentos veterinarios</del> [agentes] antimicrobianos <del>en la medicina veterinaria</del> conservando su eficacia. Este documento define las respectivas responsabilidades de las autoridades y <del>los grupos</del> [partes interesadas pertinentes] que intervienen en la autorización, producción, control, distribución y uso de los antimicrobianos <del>veterinarios</del>, en concreto las autoridades de reglamentación nacionales, <del>la industria farmacéutica veterinaria</del> [los productores], los veterinarios [y profesionales de sanidad vegetal], los distribuidores [minoristas y mayoristas,] y [los] productores[ y los consumidores]<del>de animales de los que se obtienen alimentos.</del></p>	<p><b>Colombia</b> Colombia sugiere eliminar [y animal] en concordancia con el objetivo del Codex que es “proteger la salud de los consumidores y asegurar prácticas equitativas en el comercio de los alimentos” por tanto, reducir los efectos adversos en la salud animal no forma parte de su competencia. Aunque se reconoce la importancia del tema. <i>Category: TECHNICAL</i></p>

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<p>4. [4.] Este documento brinda orientación <del>adicional para</del> [sobre las medidas pertinentes a lo largo de la cadena alimentaria para reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, entre otras, orientaciones sobre] el uso responsable y prudente de los antimicrobianos en [la cadena alimentaria] <del>los animales productores de alimentos, y debería leerse juntamente con el Código Internacional Recomendado de Prácticas CAC/RCP 38-1993.</del> Su objetivo[, en el marco del enfoque “Una Salud”,] es reducir al mínimo los posibles efectos adversos en la salud pública [y animal] del uso de agentes antimicrobianos en <del>los animales productores de alimentos</del> [la cadena alimentaria], en particular el desarrollo de resistencia de los antimicrobianos. También es importante para asegurar el uso inocuo y efectivo de los <del>medicamentos veterinarios</del> [agentes] antimicrobianos <del>en la medicina veterinaria</del> conservando su eficacia. Este documento define las respectivas responsabilidades de las autoridades <u>y los grupos [partes interesadas pertinentes] que intervienen en la autorización, producción, control, distribución y uso de los antimicrobianos a lo largo de la cadena alimentaria, en concreto las autoridades de reglamentación nacionales, la industria farmacéutica veterinaria [los productores], los grupos [partes interesadas pertinentes] que intervienen en la autorización, producción, control, distribución y uso</u> <del>los veterinarios [y profesionales de sanidad vegetal], los antimicrobianos distribuidores [minoristas y mayoristas.] veterinarios, en concreto las autoridades de reglamentación nacionales, la industria farmacéutica veterinaria [los productores], los veterinarios [y profesionales de sanidad vegetal], los distribuidores [minoristas y mayoristas,] y [los] productores[ y los consumidores] de animales de los que se obtienen alimentos.</del></p>	<p><b>Ecuador</b>  <i>Category: TECHNICAL</i></p>
<p>4. [4.] This document provides <del>additional guidance for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain] <del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain] <del>producing animals</del>, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents] drugs in veterinary medicine</del> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del> [relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials agents</del> such as the national regulatory authorities, <del>the veterinary pharmaceutical industry</del> [manufacturers], <del>other industrial users, including feed and possibly food producers, veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of food-producing animals.</del></p>	<p><b>International Feed Industry Federation</b>  <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>4- [4.] This document provides <del>additional guidance for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-<del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to <del>prevent or</del> minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-<del>producing animals,</del> in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents]drugs in veterinary medicine</del> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del>[relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials</del> such as the national regulatory authorities, <del>the veterinary pharmaceutical industry</del>[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, <del>processors, distributors, and handlers, and consumers</del>] of <del>food-producing animals.</del></p>	<p><b>International Association of Consumer Food Organizations</b> We support the changes proposed, with two additions: <i>Category: SUBSTANTIVE</i></p>
<p>4- [4.] This document provides <del>additional guidance for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-<del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to minimize the potential adverse impact on <del>public human</del> [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-<del>producing animals,</del> in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents]drugs in veterinary medicine</del> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del>[relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials</del> such as the national regulatory authorities, <del>the veterinary pharmaceutical industry</del>[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of <del>food-producing animals.</del></p>	<p><b>OIE</b> <i>Category: TECHNICAL</i></p>
<p>4- [4.] This document provides <del>additional guidance for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-<del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-<del>producing animals,</del> in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents]drugs in veterinary medicine</del> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del>[relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials</del> such as the national regulatory authorities, <del>the veterinary pharmaceutical industry</del>[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of <del>food-producing animals.</del></p>	<p><b>ICGMA</b> Recommend maintaining any mention of plant, plants, crop, crops or plant health professional(s) in brackets pending the outcome of scientific advice to the Taskforce. While we recognize that plants/crops are included within the scope of the Taskforce's work, we do not believe sufficient data exists currently on AMR in plants to allow for development of science-based practices consistent with Codex's high bar for scientific evidence and risk-based standards. Should sufficient data become available through the scientific advice process, we would support revisiting the aspects of the Code currently proposed for inclusion that deal with plants/crops. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
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<p>4. [4.] This document provides <del>additional</del> guidance <del>for</del> [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-<del>producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.</del> It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and <del>animal</del>-<u>animal and plant</u>] health resulting from the use of antimicrobial agents in [the] food [chain]-<del>producing animals</del>, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of <del>veterinary antimicrobial [agents]</del><u>drugs in veterinary medicine</u> by maintaining their efficacy. This document defines the respective responsibilities of authorities and <del>groups</del>[relevant stakeholders] involved in the authorization, production, control, distribution and use of <del>veterinary antimicrobials</del> such as the national regulatory authorities, <del>the veterinary pharmaceutical industry</del>[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] <del>of food-producing animals.</del></p>	<p><b>FAO</b> As the document is being expanded it is also important to minimize the impact on plant health, as a major food source. <i>Category: TECHNICAL</i></p>
<p><b>2. [5.] The marketing authorization procedure has a significant role in establishing the basis for [the responsible and] prudent use of veterinary antimicrobial drugs [agents] in food-producing animals through clear label indications, directions and warning statements.</b></p>	
<p><del>2. [5.] The marketing authorization procedure has a significant role in establishing the basis for [the responsible and] prudent use of veterinary antimicrobial drugs [agents] in food-producing animals through clear label indications, directions and warning statements.</del></p>	<p><b>Brazil</b> <i>Category: EDITORIAL</i></p>
<p><del>2. [5.] El procedimiento de autorización comercial desempeña un papel importante en el establecimiento de las bases para el uso prudente de medicamentos veterinarios [agentes] antimicrobianos en los animales productores de alimentos por medio de indicaciones de etiquetado, instrucciones de uso y advertencias claras.</del></p>	<p><b>Colombia</b> Porque no está en contexto o reubicarlo en el párrafo 4 donde se habla sobre el uso inocuo y efectivo. <i>Category: TECHNICAL</i></p>
<p><del>2. [5.] El procedimiento de autorización comercial desempeña un papel importante en el establecimiento de las bases para el uso prudente de <u>medicamentos veterinarios</u> [agentes] antimicrobianos <u>en los animales productores de alimentos</u> por medio de indicaciones de etiquetado, instrucciones de uso y advertencias <u>claras</u> sobre tiempos de retiro, vía de aplicación, eliminación de frascos vacíos, entre otros.</del></p>	<p><b>Ecuador</b> <i>Category: TECHNICAL</i></p>
<p><del>2. [5.] El procedimiento de autorización comercial desempeña un papel importante en el establecimiento de las bases para el uso prudente de <u>medicamentos veterinarios</u> <u>medicamentos veterinarios</u> [agentes] antimicrobianos en los animales <u>productores de alimentos</u> <u>en los animales productores de alimentos</u> por medio de indicaciones de etiquetado, instrucciones de uso y advertencias claras.</del></p>	<p><b>Ecuador</b> <i>Category: EDITORIAL</i></p>
<p><b>3. A number of codes of practice relating to the use of veterinary antimicrobial drugs and the conditions thereof have been developed by different organisations. These codes were taken into consideration and some elements were included in the elaboration of this Code of Practice to Minimize and Contain Antimicrobial Resistance.</b></p>	
<p><del>3. A number of codes of practice relating to the use of veterinary antimicrobial drugs and the conditions thereof have been developed by different organisations. These codes were taken into consideration and some elements were included in the elaboration of this Code of Practice to Minimize and Contain Antimicrobial Resistance.</del></p>	<p><b>Brazil</b> <i>Category: EDITORIAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>4- [6.] In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] food-producing animals[chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, the use of authorized products and best practices in the production sector should be followed to minimize the risks associated with the selection and dissemination of resistant microorganisms and determinants.] antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.</p>	
<p>4- [6.] In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] food-producing animals[chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, the use of authorized products and best practices in the production sector should be followed to minimize the risks associated with the selection and dissemination of resistant microorganisms and determinants.] antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.</p>	<p><b>Brazil</b> Category: EDITORIAL</p>
<p>4- [6.] In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] food-producing animals[chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, the use of authorized products and best practices in the production sector should be followed to minimize the risks associated with the selection and dissemination of resistant microorganisms and determinants.] antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.</p>	<p><b>Costa Rica</b> risks associated with the selection and dissemination of resistant microorganisms and [antimicrobial resistance] determinants.] Category: EDITORIAL</p>
<p>4- [6.] Para ser fiel a la misión del Codex, el presente código [de prácticas] se concentra en el uso de antimicrobianos en los animales productores de alimentos [la cadena alimentaria]. Se sabe que [el uso de agentes antimicrobianos en la cadena alimentaria puede dar lugar a una exposición en el entorno. Como parte de la estrategia "Una Salud" para reducir al mínimo y contener la resistencia a los antimicrobianos, debería seguirse un uso de productos autorizados y de mejores prácticas en el sector productivo para reducir al mínimo los riesgos asociados a la selección-aparición y difusión propagación de microorganismos resistentes y de determinantes.] la resistencia a los antimicrobianos es también un problema ecológico, y que su gestión puede requerir que se trate el asunto de la persistencia de microorganismos resistentes en el medio ambiente. Aunque esta cuestión es más relevante para el CCRVDF con respecto a los animales productores de alimentos, los mismos principios se aplican a las mascotas, que también pueden hospedar microorganismos resistentes.</p>	<p><b>Colombia</b> Ya que son términos técnicamente más apropiados en el contexto del párrafo. Category: TECHNICAL</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>4- [6.] Para ser fiel a la misión del Codex, el presente código [de prácticas] se concentra en el uso de antimicrobianos en <u>los animales productores de alimentos [la cadena alimentaria], cuya mala utilización puede dar lugar a una exposición en el entorno. Como parte de la estrategia “Una Salud” para reducir al mínimo y contener la resistencia a los antimicrobianos, debería seguirse un uso de productos autorizados y de mejores prácticas en el sector productivo para reducir al mínimo los riesgos asociados a la selección y difusión de microorganismos resistentes y de determinantes de resistencia.]</u> <del>los animales productores de alimentos [la cadena alimentaria]. Se sabe que [el uso de agentes antimicrobianos en la cadena alimentaria puede dar lugar a una exposición en el entorno. Como parte de la estrategia “Una Salud” para reducir al mínimo y contener la resistencia a los antimicrobianos, debería seguirse un uso de productos autorizados y de mejores prácticas en el sector productivo para reducir al mínimo los riesgos asociados a la selección y difusión de microorganismos resistentes y de determinantes.] la resistencia a los antimicrobianos es también un problema ecológico, y que su gestión puede requerir que se trate el asunto de la persistencia de microorganismos resistentes en el medio ambiente. Aunque esta cuestión es más relevante para el CCRVDF con respecto a los animales productores de alimentos, los mismos principios se aplican a las mascotas, que también pueden hospedar microorganismos resistentes.</del></p>	<p><b>Ecuador</b> Category: <i>TECHNICAL</i></p>
<p>4- [6.] In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] <del>food-producing animals</del>[chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, the use of <del>authorized</del><u>authorized products of assured quality</u> and best practices in the production sector should be followed to minimize the risks associated with the selection and dissemination of resistant microorganisms and determinants.] <del>antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.</del></p>	<p><b>OIE</b> Category: <i>TECHNICAL</i></p>
<p>4- [6.] In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] <del>food-producing animals</del>[chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in <u>exposure antimicrobials and/or resistant microorganisms and resistance determinants</u> in the environment, <u>and that management of antimicrobial resistance may require addressing these environmental factors.</u> As part of a One Health strategy to minimize and contain antimicrobial resistance, the use of authorized products and best practices in the production sector should be followed to minimize the risks associated with the selection and dissemination of resistant microorganisms and determinants.] <del>antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing animals, the same principles apply to companion animals, which also harbor resistant microorganisms.</del></p>	<p><b>International Association of Consumer Food Organizations</b> The phrase “may result in exposure in the environment” is unclear. Exposure of whom, to what? Furthermore, some of the deleted text was useful. Category: <i>SUBSTANTIVE</i></p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Scope]	
[Scope]	<p><b>Australia</b>  Comment: Deleted Aims and Objectives be replaced with new sections on Scope and Principles and follow the CAC/GL 77-2011 format.  Rationale: For consistency in format with other Codex texts.  Category: <i>SUBSTANTIVE</i></p>
	<p><b>China</b>  Since the scope of RCP has been extended to food chain, the animal feed in para 7 should be replaced by food chain.  The last sentence in para7 should change to “limiting the selection and spread of resistant microorganisms”.</p>
<p><b>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</b></p>	
	<p><b>Australia</b>  Paragraph 7  Rewrite: This Code of Practice addresses the management of risk of AMR microorganisms or determinants to human and animal health associated with their presence in food and animal feed, and the transmission through food and animal feed to other organisms including humans of AMR microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the in food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in agriculture and aquaculture. Its objectives is are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All parties actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, food processing, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.  Rationale: Some amendments in Paragraph 7 and the current CAC/RCP 61 document text duplicate information in OIE’s Chapter 6.9 (Responsible and prudent use of antimicrobial agents in veterinary medicine).</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Comment: The scope should also include consideration of the risk to livestock from anthroozoonotic transfer of resistant organisms. A single infected human could contaminate an entire flock/herd and amplify the risk of antimicrobial resistance spread.</p> <p>Internationally, not all food processing plants have sanitized food and beverage processing plants/factories and some sanitisers have an antimicrobial action, which can contribute to resistance. Therefore, there is an opportunity within the Task Force and during its current revision to take on board the following: 'Microbial Risk Management (MRM) with Continuous Sanitized Bio-security for Food Processing and Beverage Industry Factories'.</p> <p>An identified gap should be included in the scope:</p> <ul style="list-style-type: none"> <li>i. the containment of environmental contamination with antimicrobials along the food supply chain (e.g. agricultural run-off, contamination from pharmaceutical industries, waste management from intensive livestock facilities, and human waste discharge into sewers which re-enters the food chain through irrigation)</li> </ul> <p>Rationale: The document does not seem to acknowledge that some antimicrobial resistance will arise from sources other than direct consumption of food producing animals and also needs to directly apply to the food supply chain.</p> <p>Comment: With respect to the inclusion of agricultural chemicals in the document, there needs to be more focus on animals. Research on the risk of antimicrobial resistance from agricultural chemicals is warranted.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. <del>Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents.</del> All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>Brazil</b></p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[7. Este código de prácticas aborda el riesgo para la salud humana asociado a la presencia de microorganismos o determinantes resistentes a los antimicrobianos en los alimentos y piensos, así como a su transmisión a través de los mismos. Proporciona orientaciones sobre medidas pertinentes [basadas en el riesgo] a lo largo de la cadena alimentaria destinadas a reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, incluyendo orientaciones sobre buenas prácticas agrícolas (cultivos) y cría de animales, así como orientaciones sobre la utilización responsable y prudente de agentes antimicrobianos en la agricultura (cultivos), la cría de animales y la acuicultura. Su objetivo es reducir al mínimo los posibles efectos adversos sobre la salud pública derivados del uso de agentes antimicrobianos. Todos los agentes implicados en la autorización, producción, venta y suministro, prescripción y uso de antimicrobianos en la cadena alimentaria, junto con aquellos implicados en el manejo, preparación, distribución y consumo de alimentos desempeñan un papel en la optimización del uso de los antimicrobianos y en la limitación de la propagación de los microorganismos resistentes y <del>determinantes</del> <u>sus determinantes de resistencia.</u>]</p>	<p><b>Colombia</b> Es el término apropiado en el contexto de la oración. <i>Category: TECHNICAL</i></p>
<p>[7. Este código de prácticas aborda el riesgo para la salud humana asociado a la presencia de microorganismos o determinantes <del>resistentes de resistencia</del> <u>de resistencia</u> a los antimicrobianos en los alimentos y piensos, así como a su transmisión a través de los mismos. Proporciona orientaciones sobre medidas pertinentes [basadas en el riesgo] a lo largo de la cadena alimentaria destinadas a reducir al mínimo la aparición y la propagación de la resistencia a los antimicrobianos transmitida por los alimentos, incluyendo orientaciones sobre buenas prácticas agrícolas (cultivos) y cría de animales, así como orientaciones sobre la utilización responsable y prudente de agentes antimicrobianos en la agricultura (cultivos), la cría de animales y la acuicultura. Su objetivo es reducir al mínimo los posibles efectos adversos sobre la salud pública derivados del uso de agentes antimicrobianos. Todos los agentes implicados en la autorización, producción, venta y suministro, prescripción y uso de antimicrobianos en la cadena alimentaria, junto con aquellos implicados en el manejo, preparación, distribución y consumo de alimentos desempeñan un papel en la optimización del uso de los antimicrobianos y en la limitación de la propagación de los microorganismos resistentes y determinantes.]</p>	<p><b>Ecuador</b> <i>Category: EDITORIAL</i></p>
	<p><b>Thailand</b> This paragraph should revised to reduce some of the redundancy. The writing style of term “agriculture (crops), animal husbandry, and aquaculture” should be harmonized with the proposed draft Guidelines on integrated monitoring and surveillance of antimicrobial resistance.</p>

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in <del>in agriculture (crops)-(crops)]</del> and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in <del>agriculture [agriculture (crops),]</del> animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>USA</b></p> <p>Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR.</p> <p>Category: <i>TECHNICAL</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and <del>animal feed, and</del> the transmission through food and <del>animal feed,</del> of antimicrobial resistant microorganisms or determinants. <u>For guidance related to animal feed, the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) and the OIE Terrestrial Animal Health Code, section 6.9.8 – Responsibilities of animal feed manufacturers are relevant.</u>It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>USA</b></p> <p>Rationale: The Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) and the OIE Terrestrial Animal Health Code, section 6.9.8 – Responsibilities of animal feed manufacturers provide appropriate guidance with respect to animal feed. Reference to these texts would avoid duplication with existing guidance.</p> <p>Category: <i>TECHNICAL</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>International Meat Secretariat</b></p> <p>Replace in two places in the paragraph with reference to Codex Code of Good Animal Feeding (CAC/RCP 54-2004) and OIE Terrestrial Animal Health Code Section 6.9.8</p> <p>Reference to these texts avoids duplication or confusion with existing guidance.</p> <p>Category: <i>EDITORIAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in <del>feed and animal feed</del><u>food</u>, and the transmission through <del>feed and animal feed</del><u>food</u>, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>International Feed Industry Federation</b>  <i>Category: SUBSTANTIVE</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence <u>and transmission in food and animal feed</u>, and <del>throughout the transmission through</del> <u>food and animal feed</u><del>feed chains</del>, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices <del>in agriculture (crops) and animal husbandry and</del> <u>in agriculture (crops), animal husbandry (including mammals, birds, insects, and fish), and aquaculture, and in food processing, distribution, and storage</u>. Its objectives are to <del>prevent or</del> <u>minimise the potential adverse impact on public health resulting from the use of antimicrobial agents</u><del>agents throughout the food chain</del>. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>International Association of Consumer Food Organizations</b>                      The current scope is too narrow and should be broadened to include the presence and transmission of antimicrobial resistant microorganisms or determinants throughout the food chain, and not be limited to food and feed. It should include resistant organisms and determinants in water, as well as in the production and processing environments.  <i>Category: SUBSTANTIVE</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in <del>agriculture (crops)</del> <u>plant production</u> and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in <del>agriculture (crops)</del> <u>plants, animal husbandry, terrestrial and aquaculture</u><del>aquatic animals</del>. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>OIE</b>  <i>Category: EDITORIAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices [practices in agriculture (crops) (crops)] and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>ICGMA</b></p> <p>Animal feed is dealt with in other Codex and OIE texts, it should not be included here. We would not oppose references to those texts, but oppose inclusion in this scope.</p> <p>Support adding brackets on crops in this section pending outcome of scientific advice.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>FEFAC</b></p> <p>To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases.</p> <p>Category: <i>TECHNICAL</i></p>
<p>[7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry <del>and (feeding, housing, hygiene)</del>. It provides also guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in preventative measures (animal feed, housing, etc.) together with those involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain <del>together with</del> <u>and</u> those involved in the handling, preparation, distribution and consumption of food have a role to play in <del>optimizing-reducing the use of</del> <u>need for</u> antimicrobials <del>and, when needed, optimizing their use</del> and limiting the spread of resistant microorganisms and determinants.]</p>	<p><b>FEFAC</b></p> <p>To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases.</p> <p>Category: <i>TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[8. 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 and recombinant DNA microorganisms<sup>2</sup>; nongenetically 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 AMR genes, such as probiotics<sup>4</sup>.]</b></p>	
<p>[8. 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 and recombinant DNA microorganisms<sup>1</sup>; <del>nongenetically</del> <u>genetically</u> modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>2</sup>; and certain food ingredients, which could potentially carry AMR genes, such as probiotics<sup>3</sup>.]</p>	<p><b>Canada</b> <i>Category: EDITORIAL</i></p>
<p>[8. 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 and recombinant DNA microorganisms<sup>1</sup>; nongenetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>2</sup>; and certain food ingredients, which could potentially carry AMR genes, such as probiotics<sup>3</sup>.]</p> <p><u>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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]</u></p>	<p><b>Egypt</b> <i>Category: TECHNICAL</i></p>
<p>[8. 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 and recombinant DNA microorganisms<sup>1</sup>; nongenetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>2</sup>; and certain food ingredients, which could potentially carry AMR genes, such as probiotics<sup>3</sup>.]</p>	<p><b>International Association of Consumer Food Organizations</b> We recommend that any areas excluded from the scope (e.g., those listed in paragraph 8) be examined by the appropriate Codex Committee or other relevant authority to determine whether antimicrobial resistance has been appropriately addressed. <i>Category: SUBSTANTIVE</i></p>

<sup>2</sup> [The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).]

<sup>3</sup> [The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* (CAC/GL 46-2003).]

<sup>4</sup> [The food safety assessment on the use of probiotics in foods is addressed in a Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Foods (FAO/WHO, 2002).]

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
1. Aims and Objectives	
	<p><b>USA</b></p> <p>The United States supports the EWG proposal to move key concepts in the section to the Introduction, Scope, and General Principles.</p> <p>Rationale: Moving the key concepts into other sections and modifying the format accordingly will improve coherence with the Risk Analysis for Foodborne Antimicrobial Resistance (CAC/GL 77-2011).</p> <p>Category: <i>TECHNICAL</i></p>
<del>5. It is imperative that all who are involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in food-producing animals act legally, responsibly and with the utmost care in order to limit the spread of resistant microorganisms among animals so as to protect the health of consumers.</del>	
<del>6. Antimicrobial drugs are powerful tools for the management of infectious diseases in animals and humans. This Code and existing guidelines for the responsible use of antimicrobial drugs in food-producing animals include recommendations intended to prevent or reduce the selection of antimicrobial resistant microorganisms in animals and humans in order to:</del>	
<ul style="list-style-type: none"> <li><del>• Protect consumer health by ensuring the safety of food of animal origin intended for human consumption.</del></li> <li><del>• Prevent or reduce as far as possible the direct and indirect transfer of resistant microorganisms or resistance determinants within animal populations and from food-producing animals to humans.</del></li> <li><del>• Prevent the contamination of animal derived food with antimicrobial residues which exceed the established MRL.</del></li> <li><del>• Comply with the ethical obligation and economic need to maintain animal health.</del></li> </ul>	
<del>7. This Code does not address environmental issues related to antimicrobial resistance from the use of veterinary antimicrobial drugs but it encourages all those involved to consider the ecological aspects when implementing the Code. Efforts should be made to ensure that environmental reservoirs of veterinary antimicrobial drugs, antimicrobial resistant organisms and resistance determinants are kept to a minimum. In particular:</del>	
<ul style="list-style-type: none"> <li><del>• Regulatory authorities should assess the impact of proposed veterinary antimicrobial drug use on the environment in accordance with national guidelines or recognized international guidelines<sup>5</sup></del></li> <li><del>• Research should be conducted on resistant microorganisms in the environment and the magnitude of resistance determinant transfer among microorganisms in the environment.</del></li> </ul>	
<del>8. The responsible use of veterinary antimicrobial drugs in food-producing animals:</del>	
<ul style="list-style-type: none"> <li><del>• is controlled by the veterinary profession or other parties with the required expertise.</del></li> <li><del>• is part of good veterinary and good animal husbandry practice and takes into consideration disease prevention practices such as the use of vaccination and improvements in husbandry conditions.</del></li> <li><del>• aims to limit the use of veterinary antimicrobial drugs according to their approved and intended uses, and takes into consideration on-farm sampling and testing of isolates from food-producing animals during their production, where appropriate, and makes adjustments to treatment when problems become evident.</del></li> <li><del>• should be based on the results of resistance surveillance and monitoring (microbial cultures and antimicrobial sensitivity testing), as well as clinical experience.</del></li> </ul>	

<sup>5</sup> VICH (2000). Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, Phase I. [http://vich.eudra.org/pdf/2000/GI06\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI06_st7.pdf)



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>• <del>does not include the use for growth promotion of veterinary antimicrobial drugs that belong to or are able to cause cross resistance to classes of antimicrobial agents used (or submitted for approval) in humans in the absence of a risk analysis. This risk analysis should:</del> <ul style="list-style-type: none"> <li>○ <del>be undertaken by the appropriate national regulatory authority;</del></li> <li>○ <del>be based on adequate scientific evidence; and.</del></li> <li>○ <del>focus on the potential to impact resistance to antimicrobials used in human medicine.</del></li> </ul> </li> <li>• <del>is aimed at all the relevant parties, such as:</del> <ul style="list-style-type: none"> <li>○ <del>regulatory and scientific authorities;</del></li> <li>○ <del>the veterinary pharmaceutical industry;</del></li> <li>○ <del>distributors and others handling veterinary antimicrobial drugs;</del></li> <li>○ <del>veterinarians, pharmacists and producers of food-producing animals.</del></li> </ul> </li> </ul>	
[Definitions]	
[Definitions]	<p><b>Australia</b></p> <p>This section should include definitions for 'Adverse Health Effect' using CAC/GL 77-2011 definition.</p> <p>Rationale: Adverse Health Effect is used in CAC/GL 77-2011 whereas the current CAC/RCP 61 document uses 'adverse health impact'. However, the terms appear to have the same meaning and intent in both documents.</p> <p>Category: <i>SUBSTANTIVE</i></p>
[Definitions]	<p><b>Brazil</b></p> <p>The definitions have to be further developed and will depend on the content of the final document, taking note of the definitions in CAC/GL 77-2011 and elsewhere in existing Codex, FAO, WHO and OIE texts.</p> <p>Category: <i>SUBSTANTIVE</i></p>
	<p><b>China</b></p> <p>Adjust the order of definition. Move the definition of "one health" to the first one.</p> <p>Add some definition, such as food chain, susceptibility breakpoint, risk management options, prudent and responsible use of antimicrobial agents.</p> <p>Remove the definitions of Antibiotic, antibiotic resistance, antibacterial, etc. that have little to do with this document and avoid confusion with the concept of antimicrobial agents.</p>
[Definitions]	<p><b>Egypt</b></p> <p>Category: <i>TECHNICAL</i></p>
<p><u>A food chain is a linear network of links in a food web starting from producer organisms (such as grass or trees which use radiation from the Sun to make their food) and ending at apex predator species (like grizzly bears or killer whales), detritivores (like earthworms or woodlice), or decomposer species (such as fungi or bacteria)</u></p>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p><b>Thailand</b></p> <p>1. We propose the deletion of following terms, which are clearly defined with the definitions “Antimicrobial agent” and “Antimicrobial Resistance (AMR)”</p> <p>2. The definitions of “Medically important antimicrobials”, “Therapeutic use” and “Growth promotion” should be considered in conjunction with the WHO guidelines on use of medically important antimicrobials in food-producing animals (new released: November 7, 2017) In addition, the term “Therapeutic use” refers to their use to treat clinically ill animals. Therefore, we are opinion that the word “control/metaphylaxis and prevention/prophylaxis” may be not appropriate to include in this definition.</p>
	<p><b>FAO</b></p> <p>Discussions on definitions need to be cross cutting so that they are harmonized across all codex texts. There is also a need to review these in the context of the users of the code so that it is clear for example what antimicrobial agents the code covers.</p> <p><i>Category: EDITORIAL</i></p>
	<p><b>International Association of Consumer Food Organizations</b></p> <p>The definitions should be placed in alphabetical order.</p> <p><i>Category: EDITORIAL</i></p>
<p>[Definitions]</p> <p><u><b>Antimicrobial Class - Antimicrobial agents with related molecular structures, often with a similar mode of action because of interaction with a similar target and thus subject to similar mechanism of resistance. Variations in the properties of antimicrobial agents within a class often arise as a result of the presence of different molecular substitutions, which confer various intrinsic activities or various patterns of pharmacokinetic and pharmacodynamic properties.</b></u></p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>Antimicrobial Class: Add a definition for this term, since it is used in the text. We suggest using the definition in GL 77.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>[Definitions]</p> <p><u><b>Suggest the addition of:</b></u></p> <p><u><b>“Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans as determined by risk assessment.”</b></u></p>	<p><b>ICGMA</b></p> <p>The Codex TFAMR should strive to use a common definition of medically important antimicrobial across its work product. Many stakeholders remain concerned that the World Health Organization (WHO) list is not based on risk assessment or consensus. The proposed addition in this text addresses that concern. It is important that Codex’s documents reflect its commitment to the application of risk assessment to inform its work. Some countries have national lists that use risk assessment and determined certain drugs to be important for treating bacterial infections in people. In such cases, the Codex standard should expressly indicate such lists can be utilized.</p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><u>Competent authority (OIE Glossary): means the Veterinary Authority or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code and in the OIE Aquatic Animal Health Code in the whole territory.</u></p>	<p><b>OIE</b> We suggest adding the term defined in the OIE Code for coherence. <i>Category: EDITORIAL</i></p>
<p><b>[Antimicrobial agent: 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. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, and antiprotozoal agents.]</b></p>	
<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. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, and antiprotozoal agents.]</p>	<p><b>Australia</b> Use the antimicrobial agent definition from CAC/GL 77-2011, which includes semi-synthetic and synthetic origins. Rationale: The definition is incomplete and an antibiotic is not only a naturally derived substance. The definition needs consistency across Codex texts. The definition of 'antibiotic' and definitions of critically important to human medicine that may not align in a 'One Health' approach or within each country. to enter a comment <i>Category: SUBSTANTIVE</i></p>
<p><b>[Agente antimicrobiano:</b> Toda sustancia de origen natural, semisintético o sintético, que, en concentración <i>in vivo</i>, <del>mata</del> <u>elimina</u> o inhibe el desarrollo de microorganismos al interactuar con un objetivo específico. El término antimicrobiano engloba a agentes antivirales, antibacterianos, antimicóticos y antiprotozoarios.]</p>	<p><b>Colombia</b> Es un término más apropiado. <i>Category: TECHNICAL</i></p>
<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. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, and antiprotozoal agents.]</p>	<p><b>Costa Rica</b> [Antimicrobial agent: 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. The term antimicrobial is a collective for [chemotherapeutic agents such as] antiviral, antibacterial, antifungal, [antiparasitic], and antiprotozoal agents.] <i>Category: EDITORIAL</i></p>
<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. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, and antiprotozoal agents.]</p>	<p><b>USA</b> The United States supports the development of multisectoral definitions in the COP that are in line with a One Health approach. Rationale: The use of common definitions across sectors in the COP will foster a One Health approach and facilitate the adoption of best practices throughout the food chain. It will also promote coherence in risk assessment, risk management, and risk communication. <i>Category: TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[Antimicrobial]</del> <b>[Antimicrobial/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. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, and antiprotozoal agents.]	<b>International Association of Consumer Food Organizations</b> Both terms are used in the document. <i>Category: EDITORIAL</i>
<b>[Antimicrobial Resistance (AMR): The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species.]</b>	
<b>[Antimicrobial Resistance Determinant: The genetic element(s) encoding for the ability of microorganisms to withstand the effects of an antimicrobial agent. They are located either chromosomally or extra-chromosomally and may be associated with mobile genetic elements such as plasmids, integrons or transposons, thereby enabling horizontal transmission from resistant to susceptible strains.]</b>	
<b>[Determinante de la resistencia a los antimicrobianos: El o los</b> <del>Lo(s)</del> <b>elemento(s) genéticos que codifican la capacidad de un microorganismo de resistir los efectos de un agente antimicrobiano. Están situados cromosómica o extracromosómicamente y pueden estar asociados a elementos genéticos móviles como los plásmidos, integrones y transposones, por lo que permiten la transmisión horizontal de cepas resistentes a cepas sensibles.]</b>	<b>Colombia</b> Por redacción y sintaxis <i>Category: TECHNICAL</i>
<b>[Antibiotic: A naturally derived substance that acts against microorganisms, specifically bacteria.]</b>	
<del>[Antibiotic: A naturally derived substance that acts against microorganisms, specifically bacteria.]</del>	<b>Japan</b> Rationale: Japan proposes to delete this definition since the term appears only in the definition of “antibiotic resistance” and paras 24, 57 and 59, which can be replaced with either “antimicrobial agent” (para 57) or “antibacterial” (definition of “antibiotic resistance” and paras 24 and 59) <i>Category: SUBSTANTIVE</i>
<del>[Antibiotic: A naturally derived substance that acts against microorganisms, specifically bacteria.]</del> <b>[Antibiotic: An agent or substance that is produced from microorganisms that can act against another living microorganism specifically bacteria.]</b>	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
<b>[Antibiótico: Sustancia obtenida de forma natural o sintética que actúa contra los microorganismos, concretamente contra las bacterias.]</b>	<b>Ecuador</b> <i>Category: EDITORIAL</i>
<del>[Antibiotic: A naturally derived substance that acts against microorganisms, specifically bacteria.]</del>	<b>FAO</b> This is a very general definition and more precision could be useful in terms of application of the code. For example the recent G7 meeting of veterinarians proposed the following. ‘naturally occurring, semi-synthetic or synthetic substances <sup>1</sup> that exhibit antibacterial activity to kill or inhibit the growth of bacteria, at concentrations attainable in vivo. Biocide substances, such as disinfectants or antiseptics, are excluded from this definition’ <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Antibiotic: A naturally derived substance that acts against microorganisms, specifically bacteria.]	<b>International Association of Consumer Food Organizations</b> Delete “naturally derived,” since the term is now used to include synthetic substances that act against bacteria, such as fluoroquinolones. <i>Category: SUBSTANTIVE</i>
<b>[Antibiotic resistance: The ability of a microorganism, specifically bacteria, to multiply or persist in the presence of an increased level of an antibiotic relative to the susceptible counterpart of the same species.]</b>	
[Antibiotic resistance: The ability of a microorganism, specifically bacteria, to multiply or persist in the presence of an increased level of an antibiotic relative to the susceptible counterpart of the same species.]	<b>International Feed Industry Federation</b> Species: Define intrinsic and acquired resistance and the impact on the environment spread (transfer). <i>Category: SUBSTANTIVE</i>
<b>[Antibacterial: A substance that acts against bacteria.]</b>	
[Antibacterial: A substance that <del>acts against bacteria</del> <u>exhibits bactericidal or bacteriostatic activity.</u> ]	<b>FAO</b> <i>Category: TECHNICAL</i>
[Antibacterial: A substance that acts against bacteria.]	<b>FAO</b> This is very broad and not very helpful. Acts against is imprecise/ Propose revision if indeed this definition even needed? <i>Category: TECHNICAL</i>
<b>[Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans.]</b>	
[Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans.]	<b>Australia</b> Comment: The scope of this term needs to be defined and increased specificity of the term is preferred. Does this only mean ‘critically important’ antimicrobials of the WHO list? Comment: The medically important antimicrobials definition should specifically state the exclusion of ionophores. Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to ‘critically important antimicrobials’. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. Rationale: Ionophores are not included in the WHO’s Critically Important Antimicrobials for Human Medicine list, and are currently not approved for use in human medicine for systemic use. <i>Category: SUBSTANTIVE</i>
[Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans.], <u>[for example, the World Health Organization list of critically important antimicrobials]</u>	<b>Singapore</b> To include a reference “e.g. the WHO list of critically important antimicrobials” <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Medically important antimicrobialsantimicrobial agents:</b> Antimicrobial agents important for therapeutic use in humanshumans or animals.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[Medically important antimicrobials:</b> Antimicrobial agents important for therapeutic use in humans.]	<b>FAO</b> The WHO CIA list definition is an Antimicrobial used in human medicine. Need to clarify if this definition has the same intention or is proposing a subset of medicines. <i>Category: SUBSTANTIVE</i>
<b>[Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.]</b>	
<b>[Therapeutic use:</b> Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.]	<b>Australia</b> Comment: the definition should be consistent with the OIE definitions developed by the OIE's Ad Hoc Group on AMR. Rationale: The current definition does not distinguish from the 'Prevention of disease' definition. The OIE's Ad Hoc Group on AMR has developed these definitions (see Annex 16, Scientific Commission on Animal Diseases February 2017 report). <i>Category: SUBSTANTIVE</i>
<b>[Therapeutic use:</b> Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.]	<b>Russian Federation</b> The term "therapeutic use" should remain as in the Code of Practice 2005 original edition denoting only treatment of a sick animal diagnosed with an infectious disease or control of infectious diseases outbreaks found within the group of animals, and should not include the meaning of "prevention/prophylaxis." <i>Category: SUBSTANTIVE</i>
<b>[Therapeutic use:</b> Administration of antimicrobial agents for the treatment, <u>or</u> control/metaphylaxis and prevention/prophylaxis of disease.]	<b>Consumers International</b> The proposed definition of "therapeutic use" is not consistent with the definition of the term by the World Health Organization (WHO) and the Food and Agricultural Organization (FAO) and in line with a One Health approach. In 2016, FAO published "The FAO Action Plan on Antimicrobial Resistance 2016-2020," which states that "This Action Plan supports the WHO-led Global Action Plan on Antimicrobial Resistance in highlighting the necessity of adopting a 'One Health' approach," and defines "therapeutic use" as not including use for prevention of disease: "therapeutic use, i.e., for the treatment of infected or sick animals rather than for disease prevention or growth promotion." Similarly, WHO clearly states that "therapeutic use" of antimicrobials does not include use for "disease prevention" purposes and calls for the ban on use of medically important antimicrobials for disease prevention purposes.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	Consequently, the proposed definition of “therapeutic use” in the draft revised COP, is not consistent with the definition clearly accepted by FAO and WHO and so, clearly, is neither a “multisectoral definition,” nor is it in line with a One Health approach. <i>Category: SUBSTANTIVE</i>
<del>[Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.]</del>	<b>International Association of Consumer Food Organizations</b> This definition should be deleted, since there is no consensus on the definition, it is not included in GL 77, and for the reasons stated in the general comments, supra. <i>Category: SUBSTANTIVE</i>
administration of antimicrobial agents for the treatment [or] control/metaphylaxis and prevention/prophylaxis of disease	<b>Consumers International</b> The proposed definition of “therapeutic use” is not consistent with the definition of the term by the World Health Organization (WHO) and the Food and Agricultural Organization (FAO) and in line with a One Health approach. In 2016, FAO published “The FAO Action Plan on Antimicrobial Resistance 2016-2020,” which states that “This Action Plan supports the WHO-led Global Action Plan on Antimicrobial Resistance in highlighting the necessity of adopting a ‘One Health’ approach,” <sup>6</sup> and defines “therapeutic use” as not including use for prevention of disease: “therapeutic use, i.e., for the treatment of infected or sick animals rather than for disease prevention or growth promotion.” <sup>7</sup> Similarly, WHO clearly states that “therapeutic use” of antimicrobials does not include use for “disease prevention” purposes and calls for the ban on use of medically important antimicrobials for disease prevention purposes. <sup>8</sup> Consequently, the proposed definition of “therapeutic use” in the draft revised COP, is not consistent with the definition clearly accepted by FAO and WHO and so, clearly, is neither a “multisectoral definition,” nor is it in line with a One Health approach.
<b>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness.]</b>	
<b>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness, with appropriate oversight, dose and duration.]</b>	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
<b>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness.]</b> <b>Critically important antimicrobials: Antimicrobial agents regarded as critically important for therapeutic use in humans by WHO</b>	<b>FEFAC</b> New definition for critically important antimicrobials used later in the Code <i>Category: TECHNICAL</i>

<sup>6</sup> Pg. iv in Food and Agriculture Organization (FAO). 2016. The FAO Action Plan on Antimicrobial Resistance 2016-2020. 17 pp. At: <http://www.fao.org/3/a-i5996e.pdf>

<sup>7</sup> Pg. 2 in *Id.*

<sup>8</sup> World Health Organization (WHO). 2017. WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals. 67 pp. At: <http://apps.who.int/iris/bitstream/10665/258970/1/9789241550130-eng.pdf?ua=1>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations in certain circumstances, where indicated by a therapeutic need to resolve clinical signs, infection or illness.]</del> <b>[Antimicrobial treatment of disease: Administration of antimicrobial agents to infected individuals or populations, where indicated by a therapeutic need to resolve clinical signs, infection or illness.]</b>	<b>International Association of Consumer Food Organizations</b> This document is concerned with antimicrobial use, and not the broader topic of disease treatment, so the definition should be narrowed/clarified. Also, responsible and prudent use of antimicrobials involves limiting their use, generally, to individuals who have been diagnosed with an infectious disease, or for whom there is an appropriate indication for treatment. More rarely, such as where an entire population is infected, a population may be treated. <i>Category: SUBSTANTIVE</i>
<del>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness for the cure or the amelioration of a disease.]</del> <b>[Treatment of disease: Administration of antimicrobial agents to infected individuals or populations for the cure or the amelioration of a disease.]</b>	<b>IPC</b> <i>Category: SUBSTANTIVE</i>
<b>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness.]</b>	
<del>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness, with appropriate oversight, dose and duration.]</del> <b>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness, with appropriate oversight, dose and duration.]</b>	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
<del>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness, aimed at reducing the spread of, or incidence of, a disease]</del> <b>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness, aimed at reducing the spread of, or incidence of, a disease]</b>	<b>IPC</b> <i>Category: SUBSTANTIVE</i>
<del>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness.]</del> <b>[Control of disease/metaphylaxis: Administration of antimicrobial agents to populations which contain healthy and infected individuals to minimize or resolve clinical signs, infection or illness.]</b>	<b>FAO</b> Definitions of metaphylaxis and prophylaxis are also being discussed in other fora. A recent example is the G7 CVO forum. G7 – CVOs Second Forum – AMR – 5 October 2017, definition <a href="http://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf">http://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf</a> Important to note that any definitions should serve the purpose of this document while still contribution to global harmonization ont he understanding of these terms. <i>Category: SUBSTANTIVE</i>
<b>[Prevention of disease/prophylaxis: Administration of antimicrobial agents to healthy individuals or a population at risk of a specific disease, prior to the onset, with appropriate oversight, dose, and duration.]</b>	
<del>[Prevention of disease/prophylaxis: Administration of antimicrobial agents to healthy individuals or a population at risk of a specific infectious disease, prior to the onset, with appropriate oversight, dose, and duration.]</del> <b>[Prevention of disease/prophylaxis: Administration of antimicrobial agents to healthy individuals or a population at risk of a specific infectious disease, prior to the onset, with appropriate oversight, dose, and duration.]</b>	<b>International Association of Consumer Food Organizations</b> There are many ways to prevent disease, and it is not appropriate to exclude those methods that do not use antimicrobials or contribute to antimicrobial resistance from the definition, given the objective of this Code. Doing so sends the unintended message that antimicrobials are an expected or preferred method for disease prevention.



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	In addition, since the term “prevention” is used in the document to refer to non-antimicrobial preventive measures (see paragraph 57), the definition should also encompass non-antimicrobial preventive measures. Additional factors describing prophylactic use of antimicrobials are included in Principle 7. <i>Category: SUBSTANTIVE</i>
<b>[Prevention of disease/prophylaxis:</b> Administration of antimicrobial agents to healthy individuals or a population at risk of a specific disease, prior to the onset, with appropriate oversight, dose, and duration.]reducing the likelihood of a disease where there is a high probability of the occurrence of a disease in a susceptible population	<b>IPC</b> <i>Category: SUBSTANTIVE</i>
<b>Growth promotion: Administration of antimicrobial agents to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.</b>	
<b>Estímulo del Promotores de crecimiento:</b> La administración de agentes antimicrobianos para aumentar el índice de engorde o la eficacia de la utilización del pienso en los animales por otros medios que no sean puramente nutricionales. El término NO se aplica al uso de antimicrobianos para el propósito específico de tratar, controlar o prevenir enfermedades infecciosas, incluso cuando se pueda obtener un efecto secundario de crecimiento.	<b>Colombia</b> Se sugiere utilizar el término “promotores de crecimiento” en vez de “estímulo de crecimiento”. Dado que es un tema crítico en cuanto a la RAM. <i>Category: TECHNICAL</i>
<b>Growth promotion:</b> Administration of antimicrobial agents to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>Growth promotion:</b> Administration of antimicrobial agents to increase shifting the rate of weight gain and/or the efficiency of feed utilization microflora in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials gastrointestinal tract for the specific purpose better balance of treating beneficial and harmful bacteria, controlling, or preventing infectious diseases, even when an incidental thus improving nutrient utilization to support healthy growth response may be obtained and improved performance. Nutritional efficiency, feed efficiency and average daily gain are indicators of response.	<b>IPC</b> <i>Category: SUBSTANTIVE</i>
<b>[Cross-Resistance: The ability of a microorganism to multiply or persist in the presence of other members of a particular class of antimicrobial agents or across different classes due to a shared mechanism of resistance.]</b>	
<b>[Marketing Authorization: Process of reviewing and assessing a dossier to support a medicinal product to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (MA) (equivalent: product license).]</b>	
<b>[Marketing Authorization:</b> Process of reviewing and assessing a dossier to support a medicinal product to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (MA) (equivalent: product license).]	<b>Australia</b> Comment: Suggest replacement of this definition with “The granting by a regulatory authority to an applicant of permission to market or use a medicinal product. It generally involves the review and assessment by the regulatory authority of a dossier supporting the authorisation of the product”. Rationale: This is an appropriate legal approach. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[One Health: 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 people, animals, plants, and their shared environment.]</b>	
<b>[One Health:</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 people, animals, plants, and their shared environment.]	<b>FAO</b> This definition of OH better encapsulates the issue than that proposed in the surveillance document and suggest that this could be the appropriate one to use across all texts <i>Category: TECHNICAL</i>
<b>[One Health:</b> <del>A</del> <u>An internationally recognised collaborative, multisectoral, and trans-disciplinary approach - working at the local, regional, national, and global levels -- levels, with the goal of achieving optimal health outcomes - interest safeguards - to designing and implementing programmes, policies, legislation, and research on antimicrobial resistance in which multiple sectors, recognizing the interconnection between people, animals, plants, and their shared environment, communicate and work together to achieve optimal public health outcomes.]</u>	<b>International Association of Consumer Food Organizations</b> We note that the definition of the One Health approach here differs from the definition in the Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance, and that both have important elements that should be harmonized. Furthermore, whenever collaborative approaches are suggested, it is important to ensure that appropriate conflict of interest safeguards are included. A recent WHO consultation concluded that Member States have a duty to ensure that undue influence, either actual or perceived, for interests other than the public good is not exerted on individuals or institutions responsible for public decision-making, in order not to affect integrity and public trust.[cite 6] Source cited: (6) World Health Organization, "Addressing and Managing Conflicts of Interest in the Planning and Delivery of Nutrition Programmes at Country Level," Geneva, 2016. <i>Category: SUBSTANTIVE</i>
<b>[General Principles to Minimize and Contain Antimicrobial Resistance]</b>	
	<b>Brazil</b> The general principles should be revised, to be consistent to "principles" and proportionate to the agreed scope of the document. It seems that many of the suggested principles are proposed risk management measures and therefore should be included in the respective sections that address the issues. <i>Category: SUBSTANTIVE</i>
	<b>China</b> Adjust the order of principle 1-16. Principles 7, 13, 14 are relate to the clinical use of the drug and can be integrated. Principle 9, 10, 16 are associated with risk assessment and can be arranged together. Principles 6, 12 are about medically important antimicrobials and can be put together. In principle 2, there are no effective and safe alternatives. The RCP should emphasize that the application of alternatives also needs to be in line with risk assessment principles.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>In Principle 4, the RCP should consider the national conditions of each country. It is advisable to prudently regulate the registration and clinical use of the Medical important antimicrobials in the WHO and OIE list in food-producing animals.</p> <p>Add "in the food producing animal" after the first sentence of principle 6.</p> <p>Introduce the 5 Right principle to Principle 7, ie right drug, right time, right dose, right interval, right duration.</p> <p>There is a conflict between principle 8 and the text of the "off label use". Therefore, the principle 8 can be deleted.</p>
<b>[Principle 1: A One Health approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing AMR risk management options.]</b>	
<b>[Principle 1: A One Health approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing AMR risk management options.]</b>	<p><b>Australia</b></p> <p>Comment: Where reference is made to an approach being applied as 'applicable', this should be avoided.</p> <p>Rationale: There is a need to determine the magnitude of risk and decisions made about whether something is applicable and the management of risk based on that decision.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principle 1: A One Health approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing AMR risk management options.]</b></p> <p><u>[Principle xx: To minimize the possible risks to human health associated to foodborne AMR requires the implementation of risk-based measures along the entire food chain, from primary producers to end consumers, and identifying the respective responsibilities of all involved.]</u></p>	<p><b>Brazil</b></p> <p>Addition of this new principle is to be consistent with the aspects to be covered according to the agreed Project Document 1</p> <p>Category: <i>SUBSTANTIVE</i></p>
<b>[Principle 1: A One Health approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing <u>foodborne</u> AMR risk management options.]</b>	<p><b>Brazil</b></p> <p>Category: <i>SUBSTANTIVE</i></p>
<b>[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents<sup>9</sup> should be considered to reduce the need for use of antimicrobial agents.]</b>	
<b>[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents<sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]</b>	<p><b>Australia</b></p> <p>delete Principle 2</p> <p>Rationale: Deletion of Principles 2 is requested based on fit for purpose of this document.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<b>[Principle 2: <del>Biosecurity</del> <u>Infection prevention measures, such as biosecurity, adequate nutrition, vaccination, improved and other measures to improve production practices,</u> and alternatives to antimicrobial agents<sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]</b>	<p><b>Brazil</b></p> <p>Category: <i>SUBSTANTIVE</i></p>

<sup>9</sup> [Could include ethnoveterinary approaches, e.g. herbal medicine.]

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<p><b>Canada</b></p> <p>-In Principal 2, a footnote as “5” is included to describe an example of “herbal medicine” while there are numerous types of “alternatives to antimicrobials”. Given the complexity regarding quality, effectiveness and safety of herbal medicine, it is recommended to delete this footnote.</p> <p><i>Category: SUBSTANTIVE</i></p>
[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<p><b>USA</b></p> <p>The United States recommends inserting “feed additives and” into the footnote.</p> <p>The footnote should read as follows, “Could include feed additives and ethnoveterinary approaches, e.g., herbal medicine.”</p> <p>Rationale: Certain feed additives could be considered as alternatives to antibiotics.</p> <p><i>Category: TECHNICAL</i></p>
[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to <u>medically important</u> antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of <u>medically important</u> antimicrobial agents.]	<p><b>USA</b></p> <p>Rationale: An important objective of the TFAMR is to reduce the adverse impact on public health by protecting the efficacy of medically important antimicrobials. The edit’s distinction helps focus the Principle on public health objectives.</p> <p><i>Category: TECHNICAL</i></p>
[Principle 2: Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<p><b>FAO</b></p> <p>While agreeing with this it does very much reflect animal production. Perhaps consideration could be given to terminology which would also encapsulate food crop production such as integrated pest management.</p> <p><i>Category: SUBSTANTIVE</i></p>
[Principle 2: <del>Biosecurity</del> Preventive measures, such as biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<p><b>FEFAC</b></p> <p>To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases.</p> <p>The concept of adequate nutrition deserves some clarification, i.e. it is not just about meeting animals nutritional requirements but also a feeding regime that helps animals coping with pathogens, i.e. being enhancing animals’ resistance to diseases.</p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 2:</b> Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to <u>medically important antimicrobial agents</u> <sup>5</sup> should be considered to reduce the need for use of <u>medically important antimicrobial agents</u> .]	<b>ICGMA</b> An important objective of the TFAMR is to reduce the adverse impact on public health by protecting the efficacy of medically important antimicrobials. There are many antimicrobials that are not medically important but important to veterinary medicine. The proposed distinction helps focus the taskforce on its public health objectives. <i>Category: SUBSTANTIVE</i>
<b>[Principle 2:</b> <del>Biosecurity</del> The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors. Measures to promote health and to prevent, control, and treat disease should be used whenever possible and appropriate to reduce or eliminate the need for and use of antimicrobials, especially medically important antimicrobials, including good hygiene practices, biosecurity, adequate nutrition, adequate space requirements, vaccination, integrated pest management, other improved production practices, and alternatives to antimicrobial agents <sup>5</sup> <del>should be considered to reduce the need for use of antimicrobial agents.</del> ]	<b>International Association of Consumer Food Organizations</b> We strongly support Principle 15 and recommend it be combined with Principle 2, or moved near the beginning of the Principles section, and recommend that Principle 2 be strengthened to advocate measures to promote health and to prevent, control, and treat disease to reduce or eliminate the need for and use of antimicrobials. <i>Category: SUBSTANTIVE</i>
<b>[Principle 2:</b> Biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<b>International Feed Industry Federation</b> We believe it is necessary to describe what adequate nutrition is. Animal nutrition should provide appropriate/ adequate feeding strategies to contribute to a prudent use of antibiotics in animal husbandry via securing feed safety, improving feed quality and enhancing the self defense of animals to resist to bacterial infections. Rather than including animal nutrition options as alternative to antibiotics. <i>Category: SUBSTANTIVE</i>
<b>[Principle 2:</b> <del>Biosecurity</del> Preventative measures such as biosecurity, adequate nutrition, vaccination, improved production practices, and alternatives to antimicrobial agents <sup>5</sup> should be considered to reduce the need for use of antimicrobial agents.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[Principle 3: Species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in reducing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans on antimicrobial resistance with development and dissemination shared among countries and organisations.]</b>	
<b>[Principle 3: National</b> <del>Species or sector-specific responsible and prudent antimicrobial use guidelines</del> <b>for responsible and prudent use specific to species and sectors</b> should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in reducing the risk of foodborne antimicrobial resistance. <del>Such</del> <b>Development of such</b> guidelines could be included as a part of national action plans on antimicrobial resistance with development and dissemination <del>resistance.</del> <b>When developed, such guidelines can be</b> shared among countries and organisations.]	<b>Japan</b> Rationale: Japan proposes to amend the first line for clarity. In addition, Japan proposes to modify the second sentence because development of the guidelines rather than guidelines per se can be a part of national action plan. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[Principle 3:</b> Species or sector-specific responsible and prudent antimicrobial use guidelines <u>and good practices</u> should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in reducing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans on antimicrobial resistance with development and dissemination shared among countries and organisations. <u>The guidelines should recommend ways to limit or eliminate uses of antimicrobials, particularly uses of medically important antimicrobials and classes of antimicrobials important to human medicine that have no veterinary equivalent.</u>]</p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>This includes WHO's recommendation [cite 3] that certain classes of antimicrobials important to human medicine that currently have no veterinary equivalent not be used in animals, plants, or aquaculture. These include carbapenems, lipopeptides, and oxazolidinones, as well as any new class of antimicrobial developed for human therapy.</p> <p>Source cited: (3) Critically Important Antimicrobials for Human Medicine, 3rd Rev., 2011, p. 3. <a href="http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf">http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf</a>. <i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 3:</b> Species or sector-specific responsible and prudent antimicrobial use guidelines should be <del>developed,</del> <u>developed based on international standards where available</u> implemented, and reviewed on a regular basis to maintain their effectiveness in reducing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans on antimicrobial resistance with development and dissemination shared among countries and organisations.]</p>	<p><b>OIE</b></p> <p><i>Category: TECHNICAL</i></p>
<p><b>[Principle 4: The WHO list of Critically Important Antimicrobials, the OIE List of Antimicrobials of Veterinary Importance, and national lists, where available, should be used to set priorities for risk assessment and risk management. The lists should be regularly updated.]</b></p>	
<p><b>[Principle 4:</b> The WHO list of Critically Important Antimicrobials, the OIE List of Antimicrobials of Veterinary Importance, and national lists, where available, should be used to set priorities for risk assessment and risk management. The lists should be regularly updated.]</p>	<p><b>Australia</b></p> <p>Principle 4</p> <p>Rewrite: The WHO List of Critically Important Antimicrobials, the OIE List of Antimicrobials of Veterinary Importance, and national lists, and relevant OIE standards on animal health aspects, where available, should be used to set priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly updated.</p> <p>Rationale: To include consideration of appropriate international standards and the purpose of risk assessment and risk management needs to be stated. There may also need to be a discussion about 'minimize' and whether that means to zero. Is there an acceptable level of protection (in the WHO understanding of that term)? National lists developed by regulatory agencies are used by drug sponsors for the drug approval process. OIE or WHO lists become relevant when a regulatory agency indicates that this is the list adopted by them. These latter lists may not be relevant or appropriate in the Australian context, and there should be scope to adopt a nationally-relevant list where appropriate.</p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[<b>Principle 4:</b> The WHO list of Critically Important Antimicrobials <del>Antimicrobials for Human Medicine</del>, the OIE List of Antimicrobials <u>Agents</u> of Veterinary Importance, and national lists, where available, should be used to set priorities for risk assessment and risk management. The lists should be regularly updated.]</p>	<p><b>Brazil</b>                      Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should:</b></p> <ul style="list-style-type: none"> <li>• be undertaken by the appropriate national regulatory authority;</li> <li>• be based on adequate scientific evidence; and</li> <li>• include a publically available summary.]</li> </ul>	
<p>[<b>Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should:</p>	<p><b>Australia</b>                      Principle 5                      Rewrite: For responsible and prudent use administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered, medically important or able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs that are considered medically important agents should not be used for growth promotion in food-producing animals in the absence of risk analysis. This risk analysis should:</p> <ul style="list-style-type: none"> <li>• be undertaken by the appropriate national regulatory authority;</li> <li>• be based on adequate scientific evidence; and</li> <li>• include a publically available summary used in the process.</li> </ul> <p>Comment: The scope of ‘medically important’ used in Principle 5 needs to be defined and increased specificity of the term is preferred rather than additional phrases such as “are able to cause cross resistance to other antimicrobial drugs or classes of antimicrobial drugs”, which makes the statement cumbersome and ambiguous. Is this meaning ‘critically important’ antimicrobials of the WHO list?</p> <p>Rationale: The language needs to be clear and concise. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to ‘critically important antimicrobials’. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. It should be reviewed in light of:</p> <ul style="list-style-type: none"> <li>• The development and revision of WHO lists of critically important antimicrobials</li> <li>• The development of OIE list of critically important antimicrobials</li> <li>• Development of antimicrobial stewardship principles</li> <li>• One Health concepts.</li> </ul> <p>Category: <i>SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis <del>analysis as described in CAC/GL 77-2011</del>. This risk analysis should:</p>	<p><b>Brazil</b> Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should:</p>	<p><b>Costa Rica</b> [Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. [Consideration must also be paid to practices in human health and plant health that do not constitute a responsible and prudent use of antimicrobials (e.g.: prescription of antibiotics for uncomplicated viral diseases in humans).] This risk analysis should be undertaken by the appropriate national regulatory authority; Category: <i>TECHNICAL</i></p>
<p><b>[Principio 5:</b> La administración responsable y prudente en animales destinados a la producción de alimentos no incluye el uso de los medicamentos antimicrobianos como promotores del crecimiento ya que se consideran de importancia médica o pueden causar resistencia cruzada a otros medicamentos antimicrobianos, o a clases de medicamentos antimicrobianos, que se consideran de importancia médica a falta de análisis de riesgos. Este análisis de riesgos debería:</p>	<p><b>Ecuador</b> Es necesario contar con una lista de antimicrobianos prohibidos como promotores de crecimiento a nivel regional. Category: <i>TECHNICAL</i></p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion <u>in the absence of risk analysis,</u> of antimicrobial drugs that are considered medically important or are able to cause cross resistance to <del>other antimicrobial drugs, or classes of antimicrobial drugs, drugs</del> that are considered medically important <del>in the absence of a risk analysis</del>. This risk analysis should:</p>	<p><b>Japan</b> Rationale: Japan proposes the above amendments in Principle 5 in order to make the sentence unambiguous. Similarly, the part “are able to cause cross resistance to other antimicrobial drugs” is not risk-based. Focus should be put on the cross resistance to medically important antimicrobial drugs. Category: <i>SUBSTANTIVE</i></p>
	<p><b>Thailand</b> The term “antimicrobial drug” would be changed to “antimicrobial agent” in line with the definition to ensure consistent use of this term throughout the document. In addition this term should be changed to “antimicrobial agent” throughout the document.</p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should:</p>	<p><b>Russian Federation</b> We believe it is necessary to supplement principle 5 with the statement, that “antibiotics used to treat people can in no case be used to stimulate the growth of animals.” Category: <i>SUBSTANTIVE</i></p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should: <del>important</del>; <del>be undertaken by the appropriate national regulatory authority</del>; <del>be based on adequate evidence</del>; and <del>include a publically available summary</del>.</p>	<p><b>Consumers International</b> Growth promotion uses of medically important antimicrobials do not constitute “judicious use,” and they exacerbate the problem of antimicrobial resistance and so should be banned in all countries of the world, as pointed out by the just published WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals. <i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use <del>for growth promotion of antimicrobial drugs that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important in the absence of a risk analysis. This risk analysis should:</del> <u>for growth promotion.</u>]</p>	<p><b>International Association of Consumer Food Organizations</b> Principle 5 should be strengthened to eliminate loopholes and clarify that responsible and prudent use of antimicrobials in food producing animals does not include growth promotion uses, period. <i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial <del>drugs</del> <u>agents</u> that are considered medically important or are able to cause cross resistance to other antimicrobial <del>drugs</del> <u>agents</u>, or classes of antimicrobial <del>drugs</del> <u>agents</u>, that are considered medically important in the absence of a risk analysis. This risk analysis should:</p>	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 5:</b> Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs <del>that are considered medically important or are able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial drugs, that are considered medically important</del> in the absence of a risk analysis. This risk analysis should:</p>	<p><b>OIE</b> We suggest using the wording as agreed in the Global Action Plan <i>Category: TECHNICAL</i></p>
<p>• <b>be undertaken by the appropriate national regulatory authority;</b></p>	
<p><del>be undertaken by the appropriate national regulatory authority;</del></p>	<p><b>Japan</b> Rationale: Japan proposes to delete “regulatory”, since the term “regulatory” is redundant. <i>Category: SUBSTANTIVE</i></p>
<p><del>be undertaken by the appropriate national regulatory authority;</del></p>	<p><b>Egypt</b> <i>Category: TECHNICAL</i></p>
<p><del>be undertaken by the appropriate national regulatory authority;</del></p>	<p><b>Consumers International</b> <i>Category: SUBSTANTIVE</i></p>
<p><del>be undertaken by the appropriate national regulatory authority;</del></p>	<p><b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li><b>be based on adequate scientific evidence; and</b></li> </ul>	
<del>be based on adequate scientific evidence; and</del> <u>in accordance with CAC/GL 77-2011</u>	<b>Japan</b> Rationale: Japan proposes to modify the 2nd bullet point since CAC/GL 77-2011 adequately cover them. Category: <i>SUBSTANTIVE</i>
<del>be based on adequate scientific evidence; and</del>	<b>Egypt</b> Category: <i>TECHNICAL</i>
<del>be based on adequate scientific evidence; and</del>	<b>Consumers International</b> see comment above Category: <i>SUBSTANTIVE</i>
<del>be based on adequate scientific evidence; and</del>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><b>include a publically available summary.]</b></li> </ul>	
<del>include a publically available summary.]</del>	<b>Japan</b> Rationale: Japan proposes to modify the 3rd bullet point since CAC/GL 77-2011 adequately cover them. Category: <i>SUBSTANTIVE</i>
<del>include a publically available summary.]</del>	<b>Consumers International</b> See comment above Category: <i>SUBSTANTIVE</i>
<del>include a publically available summary.]</del>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
comprendre une synthèse mise à la disposition du public.]	<b>Costa Rica</b> <ul style="list-style-type: none"> <li>[it should be conducted using the One Health approach]</li> </ul> Category: <i>SUBSTANTIVE</i>
<b>[Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation (e.g. skeletal marking in fish).]</b>	
<b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation <del>(e.g. skeletal marking in fish).</del>	<b>Australia</b> Principle 6 Rewrite: Medically important antimicrobial agents should may only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) if no other alternative treatment is available and, where infrastructure exists, under veterinary or professional oversight; or in certain circumstances for research and conservation (e.g. skeletal marking in fish).

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Rationale: The suggested text is consistent with prudent use. Therapeutic use is previously explained in the Definitions section and does not need to be duplicated in this section.</p> <p>Comment: The scope of ‘medically important antimicrobial agents’ used in Principle 6 needs to be defined and increased specificity of the term is preferred. Does this only mean ‘critically important’ antimicrobials of the WHO list?</p> <p>Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to ‘critically important antimicrobials’. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. It should be reviewed in light of:</p> <ul style="list-style-type: none"> <li>• The development and revision of WHO lists of critically important antimicrobials</li> <li>• The development of OIE list of critically important antimicrobials</li> <li>• Development of antimicrobial stewardship principles</li> <li>• One Health concepts.</li> </ul> <p>Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for <del>research and research</del>, conservation <u>and special cases which are ruled by regulatory authority</u> (e.g. skeletal marking in fish).]</p>	<p><b>Indonesia</b></p> <p>Indonesia proposed additional “special cases which are ruled by regulatory authority”</p> <p>Category: <i>TECHNICAL</i></p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation (e.g. skeletal marking in fish) <b>fish</b>; <b><u>unless a risk analysis conducted by the national authority determines that the uses other than therapeutic use have negligible adverse effects to humans.</u></b>]</p>	<p><b>Japan</b></p> <p>Rationale: Japan considers that the use of antimicrobial agents should be risk-based and hence proposes an addition to Principle 6.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation (e.g. skeletal marking in fish).]</p>	<p><b>Russian Federation</b></p> <p>It is necessary to exclude from the current wording of principle 6 the possibility of use on animals the antibiotics for human treatment as a preventative measure. Antibiotics for human treatment can be used on animals only for the sole purpose of sick animals’ treatment and in the cases of disease outbreak control /metaphylaxis.</p> <p>We also believe that it is appropriate to develop and place the above mentioned limitations and well-defined conditions related to the use of medically important antibiotics in the text of the document, as there are plenty of cases when veterinary antibiotics are used in vast quantities only as a preventive measure.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Along with the supplementing the text with the relevant section related to the use of antimicrobial agents we propose to supply the principle 6 with the link to this section.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation <u>e.g., skeletal marking in fish</u>(<del>e.g., skeletal marking in fish</del>).]</p>	<p><b>USA</b></p> <p>Rationale: The example provides a helpful clarification of a familiar use in aquaculture for conservation and management of fish species.</p> <p><i>Category: TECHNICAL</i></p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, <del>control/metaphylaxis or prevention/prophylaxis</del> control/metaphylaxis of disease); or in certain circumstances for research and conservation (<del>e.g., skeletal marking in fish</del>).]</p>	<p><b>Consumers International</b></p> <p>See rationale for changing definition of “therapeutic use” since this principle uses the term “therapeutic use” as well as listing what that means</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, or control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation</p>	<p><b>Consumers Union</b></p> <p>See rationale for changing definition of “therapeutic use” since this principle uses the term “therapeutic use” as well as listing what that means</p>
<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (<del>treatment in food production as a last resort, control/metaphylaxis or prevention/prophylaxis of disease</del>); or <u>to treat disease in certain circumstances for research animals to save life or prevent serious suffering when there are no other effective treatments, and conservation when there is veterinary oversight</u>(<del>e.g., skeletal marking in fish</del>).]</p>	<p><b>International Association of Consumer Food Organizations</b></p> <p>The term “therapeutic use” obscures important distinctions between treatment, control, and prevention, as noted in our general comments, and should be deleted.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 7: Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</b></p>	
<p><b>[Principle 7:</b> Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</p>	<p><b>Australia</b></p> <p>delete principle 7</p> <p>Rationale: Deletion of principle 7 is requested based on fit for purpose of this document.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p><b>[Principle 7:</b> <del>Antimicrobial agents</del> Certain categories of medically important antimicrobials, e.g. <u>highest priority critically important antimicrobials</u>, should only be used in <u>limited</u>, well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration, <u>unless risk analysis as described in CAC/GL 77-2011 supports a different recommendation</u>.]</p>	<p><b>Brazil</b></p> <p><i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>[Principle 7: Foodborne AMR risk management measures, monitoring and surveillance should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in CAC/GL77. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.] and priority should be given to the most relevant elements as from a public health perspective.] Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>Egypt</b> Category: <i>TECHNICAL</i>
<u>[Principle 7: Antimicrobial agents should only be used in well-defined circumstances for the prevention and treatment of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>Indonesia</b> Category: <i>TECHNICAL</i>
<u>[Principle 7: When used for prevention purposes, Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>Japan</b> Rationale: Japan proposes to modify Principle 7 for clarity. Category: <i>SUBSTANTIVE</i>
<u>[Principle 7: Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>USA</b> Rationale: As revised, the sentence provides greater specificity on the categories of antimicrobials and better describes the circumstances and conditions of use. Category: <i>TECHNICAL</i>
<u>[Principle 7: Antimicrobial agents should only be used in well-defined circumstances for the prevention and treatment of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>Consumers International</b> The word “prevention” is confusing given the definition of “disease prevention.” We suggest using the word “treatment” in its place. Category: <i>EDITORIAL</i>
<u>[Principle 7: Antimicrobial agents-Disease prevention use of antimicrobials should only be used employed only in well-defined circumstances for the prevention of a specific disease and follow using appropriate oversight, dose, and duration.]A</u>	<b>FAO</b> The way the sentence is structured could be read to mean that antimicrobial should only be used for the prevention of disease (and not for disease treatment or control). A revision is proposed Category: <i>TECHNICAL</i>
<u>[Principle 7: Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]</u>	<b>ICGMA</b> This constitutes a risk management recommendation without application of a risk assessment or analysis by a Codex risk assessment body. Risk management should not precede risk assessment. This is a core tenant of Codex and included in the Codex Procedural Manual Section 4. Further, it is inconsistent to the content in the COP’s section on Responsibilities of Veterinarians [and Plant Health Professionals] (see paragraph 45) and of the OIE’s Terrestrial Code Chapter 6. Category: <i>SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 7:</b> Antimicrobial agents should only be used in <u>time-limited and well-defined</u> circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration. <u>Such well-defined circumstances include convincing evidence (1) of effectiveness, (2) of consistency with accepted veterinary 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 animals at risk of developing a specific disease, and (5) that there are no reasonable alternatives for intervention.]</u>	<b>International Association of Consumer Food Organizations</b> Principle 7 needs to be strengthened and “well-defined circumstances” clarified. <i>Category: SUBSTANTIVE</i>
<b>[Principle 7:</b> Antimicrobial agents should <del>only be used in well-defined circumstances for the prevention of a specific disease under veterinary or professional oversight where infrastructure exists and follow those antimicrobial agents of critical importance for human medicine should be minimized following</del> appropriate oversight, dose, and duration.]	<b>IPC</b> <i>Category: SUBSTANTIVE</i>
<b>[Principle 7:</b> Antimicrobial agents should only be used in well-defined circumstances for the prevention of a specific <del>disease and follow appropriate oversight</del> disease, <del>dose</del> under veterinary supervision, <u>using an appropriate dose and for a limited duration.</u> ]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>[Principle 7:</b> Antimicrobial agents should only be used in <u>animals</u> in well-defined circumstances for the prevention of a specific disease and follow appropriate oversight, dose, and duration.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>[Principle 8: Only legally authorized antimicrobial agents should be used and all applicable label directions should be followed; except where specific legal exemptions apply.]</b>	
<b>[Principle 8::</b> Administration of antimicrobial agents should take into consideration <u>sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the administration when problems become evident.]</u> and applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.] <del>Only legally authorized antimicrobial agents should be used and all applicable label directions should be followed; except where specific legal exemptions apply.]</del>	<b>Egypt</b> <i>Category: TECHNICAL</i>
<b>[Principle 8:</b> Only legally authorized antimicrobial agents should be used and all applicable label directions should be followed; except where specific legal exemptions apply.]	<b>ICGMA</b> Same as rationale provided for Principle 7 <i>Category: SUBSTANTIVE</i>
<b>[Principle 8:</b> <u>[It is imperative that all who are involved in the authorisation, manufacture, sale and supply, prescription, and use of antimicrobials in the food chain act legally, responsibly, and with the utmost care in order to limit the spread of resistant microorganisms.</u> Only legally authorized antimicrobial agents should be used and all applicable label directions should be followed; except where specific legal exemptions apply.]	<b>International Association of Consumer Food Organizations</b> Our suggested addition to Principle 8 is wording from the original Code, which did not remain in the Proposed Draft Revision but should be restored. <i>Category: SUBSTANTIVE</i>
<b>[Principle 9: Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in CAC/GL77. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.]</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 9:</b> Foodborne AMR risk management measures <u>along the entire food chain, from primary producers to end consumers</u> , should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in <u>CAC/GL77</u> CAC/GL77 - 2011. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.]	<b>Brazil</b> Category: <i>SUBSTANTIVE</i>
<b>[Principe 9:</b> Les mesures de gestion des risques liés à la RAM devraient être appliquée proportionnellement au risque et soumises régulièrement à révision, tel que l'indiquent les CAC/GL77. Les gestionnaires des risques devraient prendre en compte d'éventuelles conséquences involontaires pour la santé humaine et animale des mesures recommandées de gestion des risques.]	<b>Costa Rica</b> .unintended consequences to human, [plants] and animal health of recommended risk management measures.] Category: <i>EDITORIAL</i>
<b>[Principle 9::</b> The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.] <del>Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in CAC/GL77. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.]</del>	<b>Egypt</b> Category: <i>TECHNICAL</i>
<b>[Principle 9:</b> Foodborne AMR risk management measures should be implemented in a way that is <del>proportionate to the risk and</del> reviewed on a regular basis as described in CAC/GL77. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.]	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<b>[Principle 9:</b> Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in CAC/GL77. Risk managers should consider potential unintended consequences to human and animal health <u>and welfare</u> of recommended risk management measures.]	<b>OIE</b> Category: <i>TECHNICAL</i>
<b>[Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider.]</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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider.]	<b>Australia</b> Principle 10 Comment: The scope of 'medically important antimicrobial drugs' used in Principle 10 needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list? Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. Category: <i>SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial <del>drugs</del> <u>agents</u> in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider.]</p>	<p><b>Brazil</b> Category: <i>SUBSTANTIVE</i></p>
<p><b>[Principio 10:</b> El seguimiento y vigilancia del uso de agentes antimicrobianos así como la incidencia o prevalencia, y, en determinadas <del>pautas</del> <u>tendencias</u>, los microorganismos y determinantes resistentes a los antimicrobianos transmitidos por los alimentos se encuentran entre los factores críticos a tener cuenta a la hora de evaluar y determinar la efectividad de las medidas aplicadas de gestión del riesgo. El uso de medicamentos antimicrobianos de importancia médica en humanos y animales y la transmisión de patógenos y de genes de resistencia entre humanos, animales y el entorno son otros factores que deben tenerse en consideración.]</p>	<p><b>Colombia</b> Se ajusta mejor al contexto de la oración Category: <i>TECHNICAL</i></p>
<p><b>[Principe 10:</b> Lors de l'évaluation et détermination de l'efficacité des mesures de gestion des risques ayant été mises en œuvre, il est essentiel de procéder à la surveillance et au suivi de l'emploi des agents antimicrobiens, ainsi que de l'incidence et prévalence de microorganismes résistants aux antimicrobiens d'origine alimentaire et déterminants de résistance. D'autres facteurs à prendre en compte sont l'emploi de médicaments antimicrobiens d'importance médicale chez les humains et les animaux, ainsi que la transmission de pathogènes et de gènes résistants entre les êtres humains, les animaux et l'environnement.</p>	<p><b>Costa Rica</b> .drugs in humans, [plants], and animals, and transmission of pathogens and resistance genes between humans, [plants], animals..... Category: <i>EDITORIAL</i></p>
	<p><b>Thailand</b> The term “antimicrobial drug” would be changed to “antimicrobial agent” in line with the definition to ensure consistent use of this term throughout the document. In addition this term should be changed to “antimicrobial agent” throughout the document.</p>
<p><b>[<del>Principle</del>-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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, <del>and [and the environment-environment]</del> are additional factors to consider.]</p>	<p><b>USA</b> Rationale: There is a significant data and information gap with respect to the transmission of resistance genes in the environment and the potential risks associated with foodborne antimicrobial resistance (AMR). Before designing appropriate monitoring and surveillance activities and evaluating and determining the effectiveness of risk management measures intended to address foodborne AMR, a sound scientific understanding of the contribution of resistance genes in the environment to the overall risk of foodborne illness is essential. Category: <i>TECHNICAL</i></p>



SPECIFIC COMMENTS	
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<p><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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider. <u>Medically important antimicrobials should not be used without a defined limited duration of use in food production.</u>]</p>	<p><b>Consumers International</b> Continuous use or very long use of antimicrobials will contribute to resistance more than short term use. Given the importance of medically important antimicrobials in human medicine, they should not be used for short terms that are clearly defined. <i>Category: EDITORIAL</i></p>
<p><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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, <del>and</del> <u>and the environment environment</u> are additional factors to consider.]</p>	<p><b>ICGMA</b> Suggest maintaining and the environment in brackets until the outcome of scientific advice. <i>Category: SUBSTANTIVE</i></p>
<p><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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial <del>drugs agents</del> in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider.]</p>	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>
<p><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 determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes <u>from bacteria</u> between humans, animals, and the environment are additional factors to consider.]</p>	<p><b>FAO</b> the resistance genes are from the bacteria, not the people, plants and animals. For communication purposes it is important that this is clear in the text. <i>Category: TECHNICAL</i></p>
<p><b>[Principle 11: 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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]</b></p>	
<p><b>[Principle 11:</b> 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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]</p>	<p><b>Australia</b> Principle 11 Comment: Principle 2 could be incorporated into Principle 11 as the last sentence – insert “Biosecurity, vaccination, and alternatives to antimicrobial agents should be considered to reduce the need for medically important antimicrobial agents”. Last sentence – “A stepwise approach may be utilized...”. Rationale: The principle is a matter that should be an AMR risk management element for countries as a whole. There is a grammatical error in the last sentence. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[Principle 11:</b> 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 situation/capacities, and within a reasonable period of time <del>time</del> and should not be used inappropriately to generate barriers to trade. A continuous and stepwise approach may utilized by some countries to properly implement all of the elements in this document.]	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
<b>[Principio 11:</b> El presente documento está concebido para ofrecer un marco para el desarrollo de medidas destinadas a mitigar el riesgo de RAM transmitida por los alimentos, que los países pueden aplicar como parte de su estrategia nacional sobre RAM, según su capacidad, en función de su situación/capacidad nacional, y en un plazo de tiempo razonable. Algunos países pueden utilizar un método por pasos para aplicar debidamente todos los elementos de este documento.]	<b>Colombia</b> Cambiar la redacción para que no suene como un objetivo sino como un principio. "Debe seguirse el presente documento como (...)". Como está redactado pareciera un objetivo más que un principio <i>Category: SUBSTANTIVE</i>
<b>[Principle 11:</b> 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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]	<b>Egypt</b> cut and past at the end of the scope <i>Category: TECHNICAL</i>
<del><b>[Principle 11:</b> 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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]</del> <b>Delete or move to introduction</b>	<b>ICGMA</b> This language should be included in the introduction and scope. It is a statement of purpose for the COP not a principle of practice in itself. <i>Category: SUBSTANTIVE</i>
<b>[Principle 11:</b> This document is designed to provide a framework, for the development of measures to prevent or 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 situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<b>[Principle 11:</b> 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 situation/capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement all of the elements in this document.]	<b>International Feed Industry Federation</b> <i>Category: EDITORIAL</i>
<b>[Principle 12: Medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.]</b>	
<b>[Principle 12:</b> Medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.]	<b>Australia</b> Principle 12 Comment: The scope of 'medically important antimicrobial drugs' used in Principle 12 needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list?

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies.</p> <p>Comment: The text states, "should be administered or applied only by a veterinarians, plant health professionals or other suitably trained person authorized...". The use by non-veterinarians is not agreed.</p> <p>Rationale: The text is incongruous, as it states that antibiotics should be prescribed by a veterinarian and then immediately allows for use by non-veterinarians.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p><del>[Principle 12: Antimicrobial agents for therapeutic purposes</del> Medically important antimicrobials should be administered or applied only by <u>used by, or under the supervision of,</u> veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.]</p>	<p><b>Japan</b></p> <p>Rationale: Japan proposes to amend Principle 12, because in livestock/aquaculture sector antimicrobial agents are actually used by farmers based on prescription or order for application by veterinarians or other suitably trained person authorized in accordance with national legislation.</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p>[Principle 12: Medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.]</p>	<p><b>Russian Federation</b></p> <p>As we believe there is a need to supplement principle 12 with the following line - "critically important antibiotics of highest priority (reserved antibiotics) may be used only for individual therapy antibacterial therapy of animals diagnosed with an infectious disease, particularly when all test results have shown no sensitivity to all other antibiotics".</p> <p>Category: <i>SUBSTANTIVE</i></p>
<p><del>[Principle Principle 12: Medically important antimicrobials should be administered or applied only by under the oversight veterinarians, plant plant health professionals professionals] or other suitably trained person authorized in accordance with national legislation.]</del></p>	<p><b>USA</b></p> <p>The United States supports maintaining "plant health professionals" in square brackets.</p> <p>Rationale: The addition of "under the oversight of" is recommended to account for situations in which the decision and selection of therapy involving a medically important antimicrobial is made by a veterinarian, but the actual administration is carried out by another qualified individual. Oversight is different than administration. For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR.</p> <p>Category: <i>TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[Principle 12: Medically important antimicrobials should be administered or applied only by under the oversight of veterinarians, plant [plant health professionals professionals] or other suitably trained person authorized in accordance with national legislation.]</del>	<b>ICGMA</b> It is duplicative to the content of the OIE's Terrestrial Code Chapter 6. FDA's Guidance 213 includes a determination that when adequate directions cannot be written in a manner that enables a layperson to use a drug safely and for the purposes for which it is intended, the drug is restricted to use under veterinary oversight. Oversight is not the same as administration. The potential requirement for a veterinarian or similarly qualified person to administer each medically important antimicrobial is impractical. However, the decision and selection of therapy involving a medically important antimicrobial is an act that should be within the remit of a veterinarian or similarly qualified person. We also propose to keep plant health professionals in brackets pending additional scientific advice. <i>Category: SUBSTANTIVE</i>
[Principle 12: Medically important antimicrobials-antimicrobial agents should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<del>[Principle 12: Medically-Veterinary and medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized-authorized in accordance with national legislation.]</del>	<b>OIE</b> This statement is also of importance to veterinary important antimicrobial agents. <i>Category: TECHNICAL</i>
<b>[Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the administration when problems become evident.]</b>	
[Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate-feasible, and make adjustments to the administration when problems become evident.]	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
<del>[Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the administration when problems become evident.]</del>	<b>USA</b> The United States recommends deleting this principle. Rationale: Principle 13 is duplicative of Principle 14. <i>Category: TECHNICAL</i>
[Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the administration when problems become evident.]	<b>International Meat Secretariat</b> Delete Principle 13: Sampling and susceptibility testing of isolates at the farm level may not be practical in all country settings and the goal of action for Principle 13 is well achieved by Principle 14. <i>Category: SUBSTANTIVE</i>
<b>[Principle 14: Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[ <b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]	<b>Brazil</b> Need for clarification, specially related to what would be “sound clinical judgement”. <i>Category: SUBSTANTIVE</i>
[ <b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring ( <del>bacterial</del> (e.g.: bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.)	<b>Brazil</b> Need for clarification, specially related to what would be “sound clinical judgement”. <i>Category: SUBSTANTIVE</i>
[ <b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant <u>clinical</u> experience.]	<b>Canada</b> <i>Category: EDITORIAL</i>
[ <b>Principio 14:</b> La administración de agentes antimicrobianos debería estar basada en sólidos criterios clínicos y, cuando sea viable, en los resultados de la vigilancia y seguimiento de la resistencia integrada (cultivos bacterianos y pruebas de susceptibilidad antimicrobiana) así como la experiencia pertinente.]	<b>Colombia</b> Se sugiere eliminar paréntesis y adicionar “entre otros”, para mejorar la redacción y el contexto de la oración. <i>Category: EDITORIAL</i>
<del>[<b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]</del>	<b>USA</b> The United States recommends deleting this Principle. Rationale: The RRR strategy may not be widely understood. Key concepts, such as reducing the need for antimicrobial use, are already contained in Principle 2 and elsewhere in the document in greater detail. <i>Category: TECHNICAL</i>
[ <b>Principle 14:</b> Administration of <u>medically important</u> antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]	<b>FEFAC</b> For the sake of consistency with Principle 5. <i>Category: SUBSTANTIVE</i>
[ <b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement <del>and and, where feasible</del> <u>feasible</u> , on the results of <u>antimicrobial susceptibility testing</u> , integrated resistance surveillance and monitoring ( <del>bacterial cultures and antimicrobial susceptibility testing</del> ) <u>results</u> , as well as relevant experience.]	<b>FAO</b> At the point f making a treatment it is suggested that AST testing on individual isolates is preferred and different than national/regional historic trends. But this can be supported by national data or in the absence of data specific to the situation national trends are useful. <i>Category: TECHNICAL</i>
[ <b>Principle 14:</b> Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]	<b>International Feed Industry Federation</b> To be consistent with Principle 5. <i>Category: EDITORIAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[ <b>Principle 14:</b> Administration of <u>medically important</u> antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]</b>	
[ <b>Principle 15:</b> The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<p><b>Australia</b></p> <p>Principle 15</p> <p>Comment: There are '5R principles' that should be promoted for good antimicrobial stewardship.</p> <p>Rationale: There is scope to include all the 5R principles for good antimicrobial stewardship (AMS) in the principles set out in this document. Some are covered, but all could be included:</p> <ul style="list-style-type: none"> <li>• RESPONSIBILITY</li> <li>• REVIEW: of current usage practices (what's being used, how much, why and when?), sources of information and continuing professional development</li> <li>• REDUCE</li> <li>• REFINE</li> <li>• REPLACE: Develop AMS objectives by identifying ways to Reduce, Refine and Replace current antimicrobial use.</li> </ul> <p>Additional General Principles for inclusion are:</p> <ol style="list-style-type: none"> <li>a. that Codex will be limited to setting standards and providing guidance on risk within the food chain</li> <li>b. research needs to be conducted to determine the point in the ecosystem where resistance first occurs or is selected</li> <li>c. the robustness of surveillance design, sample collection, analysis, documentation and interpretation of monitoring/surveillance data should be taken into account when risk management actions are being considered</li> <li>d. contribution of the food chain to human antimicrobial resistance, as it is unknown if food is making any or much contribution to the current antimicrobial resistance issues.</li> </ol> <p>Rationale:</p> <ol style="list-style-type: none"> <li>a. Avoids duplication of international standards on animal health and veterinary prescribing.</li> <li>b. This is an identified gap.</li> <li>c. This supports the concepts outlined in Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine and the Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals. <i>Category: SUBSTANTIVE</i></li> </ol>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<b>Brazil</b> Need for clarification. It seems that this principle needs further development. <i>Category: SUBSTANTIVE</i>
[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<b>Consumers International</b> Principle 15 is valuable. Contrary to the rationale that the “RRR strategy may not be widely understood,” in our view, the RRR strategy is widely understood. Further, while the first “R,” reduce, may be already contained in Principle 2, the other 2 Rs—replace and rethink—are not clearly discussed elsewhere in the document in greater detail. In addition, succinctly stating the RRR strategy is very useful.
Keep text as is and do not delete this Principle	<b>Consumers Union</b> Principle 15 is valuable. Contrary to the US rationale that the “RRR strategy may not be widely understood,” in our view, the RRR strategy is widely understood. Further, while the first “R,” reduce, may be already contained in Principle 2, the other 2 Rs—replace and rethink—are not clearly discussed elsewhere in the document in greater detail. In addition, succinctly stating the RRR strategy is very useful.
[Principle 15: The reduce, replace and rethink (RRR) <u>inappropriate use</u> strategy should be actively promoted within all sectors.]	<b>ICGMA</b> With changes in animal populations and disease conditions, the goal should be to reduce inappropriate use of medically important antimicrobials rather than total quantity used. Eliminating medicine does not eliminate disease. Considerations might include an increase in animal population, weather developments, or high disease incidence. All of these considerations will influence the quantity of antimicrobials that may be used, but quantity will have limited impact on AMR instances if the use is appropriate. <i>Category: SUBSTANTIVE</i>
[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<b>International Association of Consumer Food Organizations</b> We strongly support Principle 15 and recommend that it be moved near the beginning, and/or combined with Principle 2. <i>Category: SUBSTANTIVE</i>
[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<b>International Feed Industry Federation</b> This is the same wording as the reduction, refinement and replacement of laboratory animal trial, one should be careful of possible misunderstanding. It might also be important to describe the strategy somewhere in the document. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.]	<b>International Meat Secretariat</b> Delete Principle 15: The RRR strategy is not well-defined or easily achieved in all country settings. Additionally, several principle components of RRR are found in other areas of the document. <i>Category: SUBSTANTIVE</i>
<b>[Principle 16: On a continuous and stepwise 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 as from a public health perspective.]</b>	
[Principle 16: On a continuous and stepwise 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 as from a public health perspective.] <b><u>Responsible use of antimicrobial agents in animals</u></b> <b><u>Responsible use of antimicrobial agents in agriculture</u></b> <b><u>Practices during production, processing, storage, transport, retail and distribution of food</u></b> <b><u>Consumer Practices</u></b>	<b>Brazil</b> Considering the General comments Brazil suggests that the following topics should be the structure of the document, to be further developed: – Responsible use of antimicrobial agents in animals – Responsible use of antimicrobial agents in agriculture – Practices during production, processing, storage, transport, retail and distribution of food – Consumer Practices <i>Category: SUBSTANTIVE</i>
[Principle 16: On a continuous and stepwise 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 as from a public health perspective.]	<b>Canada</b> Principle 16. Needs some editorial changes to improve readability. Whether risk management measures need to be implemented continuously or in a stepwise manner may require a discussion. One measure might be enough. What 'most relevant' means remains to be further clarified. <i>Category: SUBSTANTIVE</i>
[Principle 16: On a continuous and stepwise 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 as from a public health perspective.] <b><u>[Principle 17: General microbial risk mitigation measures should be in place within the entire food chain]</u></b>	<b>Japan</b> Rationale: Japan reiterates its comment to the EWG since the general microbial risk mitigation is an essential and integral part of risk mitigation measures. <i>Category: SUBSTANTIVE</i>
<del>[Principle 16: On a continuous and stepwise 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 as from a public health perspective.]</del> <b><u>New Principle 17: Highest Priority Critically Important Antimicrobials should only be used for individual antimicrobial treatment (not in feed, water, or other flock-wide or herd-wide administration) and stepwise implementation of risk management measures along only for the food chain to minimize the possible risks associated with foodborne AMR, priority treatment of clinically diagnosed illness when susceptibility testing indicates no other antimicrobials will work and should not be given to the most relevant elements as from a public health perspective used for crop agriculture.]</u></b>	<b>Consumers International</b> This new Principle is consistent with the recently released WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals. <i>Category: SUBSTANTIVE</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[ <b>Principle 16:</b> On a continuous and stepwise 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 <del>elements as elements</del> from a public health perspective.]	<b>FAO</b> <i>Category: EDITORIAL</i>
[ <b>Principle 16:</b> On a continuous and stepwise 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 as from a <del>public human health perspective, while preserving animal health and welfare.</del> ]	<b>OIE</b> <i>Category: TECHNICAL</i>
Suggest adding a new Principle [Principle 17: Highest Priority Critically Important Antimicrobials should only be used for individual antimicrobial treatment (not in feed, water, or other flock-wide or herd-wide administration) and only for the treatment of clinically diagnosed illness when susceptibility testing indicates no other antimicrobials will work and should not be used for crop agriculture.]	<b>Consumers Interntional</b> This new Principle is consistent with the recently released WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals. <sup>10</sup>
Responsibilities of the Regulatory Authorities	
	<b>China</b> Proposed to increase government regulation on plant antimicrobials. In the surveillance programs section, it is recommended to ask relevant stakeholders to cooperate with government surveillance, and to recommend increasing pharmacovigilance program for the monitoring and reporting of adverse reactions to the surveillance program. In the training of users of antimicrobial agents section, it is advisable to require the government to take regular training and assessment of farmers, enterprises and veterinarians. In the development of research section, several studies were proposed to be added, including a) to strengthen risk resistance studies for antimicrobial resistance; b) to enhance new technical and strategic research to reduce and control drug resistance; c) to strengthen research on safe and effective alternatives.
	<b>Singapore</b> As these refer to veterinary drugs, Paragraphs 9-22, 25-30 could be placed together under one subheading relevant to the marketing authorisation and distribution of antimicrobial agents, and to avoid multiple referencing to the OIE chapter <i>Category: EDITORIAL</i>
Responsibilities of the <del>Regulatory</del> <u>Competent</u> Authorities	
	<b>OIE</b> <i>Category: TECHNICAL</i>

<sup>10</sup> *Id.*

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk-analysis, as described in Paragraph 8.</del></p>	
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk-analysis, as described in Paragraph 8.</del></p>	<p><b>Australia</b> Paragraph 9 Comment: The inclusion of all regulatory authorities responsible for oversight of antimicrobials used in the food chain is not preferred. Rationale: There is limited value to including regulatory authorities responsible for oversight of antimicrobials used in the food chain. Comment: There are also International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines, which also address 'Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance (VICH GL27)' and 'Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI VICH GL36(R) (Safety) May 2004 - Implemented in June 2013'. Rationale: There are other, available international text, which can be referenced and cover the topics in this section. For example, distribution of veterinary antimicrobial drugs in veterinary medicine is directly assessed through the OIE Performance of Veterinary Services, against OIE standards. <i>Category: SUBSTANTIVE</i></p>
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <u>food-producing animals or agriculture</u> <del>food-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the <del>veterinarian [and plant health professionals]</del> <u>responsible professionals</u> through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <u>food production</u> <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <u>food-producing animals or agriculture</u> <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance.</p>	<p><b>Brazil</b> <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del>	
	<p><b>Thailand</b>  <b>Line 10-13</b>  “...Other elements of the national strategy should include <b>alternatives to antimicrobial agents</b>, good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment.”  <b>Rationale:</b> The alternatives to antimicrobial agents should be added in this section.</p>
9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del> [the the food chain]chain, have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the the responsible and] prudent use of <del>veterinary antimicrobial drugs</del> [agents]-agents in <del>food-producing animals</del> [the the food chain]chain. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del> [agent]-agent applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del> [One Health]-One Health approach to promote [the the responsible and] prudent use of antimicrobials in <del>food-producing animals</del> [the the food chain]chain as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry <del>[and production] practices</del> and <del>production]practices</del> , vaccination [and <del>biosecurity</del> biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del>	<p><b>USA</b>  The United States supports the adoption of the revised and deleted text in this section with the following exceptions.  Paragraph 9: The United States supports maintaining “plant health professionals” and “plant” in square brackets.  Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR.  Category: TECHNICAL</p>
9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del> [the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del> [agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del> [agent] applications.	<p><b>FEFAC</b>  Category: TECHNICAL</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry (<u>nutrition, housing, hygiene</u>) [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del></p>	
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] ] <u>and other relevant food chain partners through legal requirements on product labelling and/or by other means</u>, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del></p>	<p><b>FEFAC</b> The role of authorities is not to label but to establish labelling rules and regulation for operators to implement. <i>Category: EDITORIAL</i></p>
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment.</p>	<p><b>ICGMA</b> Support maintaining brackets on plant health professionals and plant in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.	
9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del> [the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del> [agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del> [agent] applications. National <del>governments</del> <u>governments</u> , in cooperation with <del>animal</del> <u>animal</u> , [plant,] and public health <del>professionals</del> <u>professionals</u> , should adopt a <del>proactive</del> [One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del> [the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, <u>good plant production/agriculture practices including for example integrated pest management, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should</u> <del>may</del> contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del>	<b>FAO</b> Some edits for clarity and an addition of an example of good practices at the plant production side. <i>Category: EDITORIAL</i>
9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del> [the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del> [agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del> [agent] <del>applications</del> <u>applications in food, food production, and food processing</u> . National <u>governments</u> in cooperation with <u>animal [plant, environmental,]</u> and public health <u>professionals</u> should adopt a <del>proactive</del> [One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>food-producing animals</del> [the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del>	<b>International Association of Consumer Food Organizations</b> In accordance with a One Health approach, and in recognition of reservoirs of antimicrobial agents and antimicrobial resistant microorganisms in the environment, it is appropriate to include environmental professionals in the list of professionals. Furthermore, it would be useful to clarify that this paragraph concerns evaluations of antimicrobial agent applications in food, food production, and food processing. <i>Category: SUBSTANTIVE</i>
9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>food-producing animals</del> [the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del> [agents] in <del>food-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del> [agent] applications.	<b>International Feed Industry Federation</b> “the implementation of adequate nutrition strategy (such as precision feeding)” should be included to be in line with principle 2. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>feed-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del></p>	
<p>9. The national regulatory authorities, which are responsible for granting the marketing authorisation for antimicrobials <del>agents</del> for use in <del>feed-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>feed-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>feed-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies <u>the implementation of adequate nutrition strategy (such as precision feeding)</u> and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment. <del>Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.</del></p>	<p><b>International Feed Industry Federation</b>  Category: <i>SUBSTANTIVE</i></p>
<p>9. The national <del>regulatory competent</del> authorities, which are responsible for granting the marketing authorisation for antimicrobials for use in <del>feed-producing animals</del>[the food chain], have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian [and plant health professionals] through product labelling and/or by other means, in support of [the responsible and] prudent use of <del>veterinary antimicrobial drugs</del>[agents] in <del>feed-producing animals</del> [the food chain]. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of <del>veterinary antimicrobial drug</del>[agent] applications. National governments in cooperation with animal [plant,] and public health professionals should adopt a <del>proactive</del>[One Health] approach to promote [the responsible and] prudent use of antimicrobials in <del>feed-producing animals</del>[the food chain] as an element of a national strategy for the containment of antimicrobial resistance. Other elements of the national strategy should include good animal husbandry [and production] practices, vaccination [and biosecurity] policies and development of animal [and plant] health care at the farm level, all of which should contribute to reduce the prevalence of animal [and plant] disease requiring antimicrobial treatment.</p>	<p><b>OIE</b>  Category: <i>TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Use of veterinary antimicrobial drugs for growth promotion that belong to classes of antimicrobial agents used (or submitted for approval) in humans and animals should be terminated or phased out in the absence of risk analysis, as described in Paragraph 8.	
<b>10. It is the responsibility of the pharmaceutical company or sponsor<sup>14</sup> to submit the data requested by the regulatory authorities for granting marketing authorisation.</b>	
<b>11. The use of antimicrobial agents in food-producing animals requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met.</b>	
<ul style="list-style-type: none"> <li><del>The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs.</del></li> <li><del>The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.</del></li> </ul>	
11. El uso de agentes antimicrobianos en los animales productores de alimentos requiere una autorización de comercialización que será otorgada por las autoridades competentes solo si se cumplen los criterios de inocuidad, calidad y eficacia.	<b>Ecuador</b> incluir nuevamente <i>Category: TECHNICAL</i>
11. El uso de agentes antimicrobianos en los animales productores de alimentos requiere una autorización de comercialización que será otorgada por las autoridades competentes solo si se cumplen los criterios de inocuidad, calidad y eficacia. 11. El uso de agentes antimicrobianos en los animales productores de alimentos requiere una autorización de comercialización que será otorgada por las autoridades competentes solo si se cumplen los criterios de inocuidad, calidad y eficacia.	<b>Ecuador</b> incluir nuevamente <i>Category: EDITORIAL</i>
11. The use of antimicrobial agents in food-producing animals requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met. 11. The use of antimicrobial agents in food-producing animals, crop production, and as food additives requires a marketing authorisation, granted by the competent authorities when the criteria of safety, quality and efficacy are met.	<b>International Association of Consumer Food Organizations</b> This paragraph contains important information and should be retained and edited to reflect the broadened scope. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><del>The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs.</del></li> </ul>	
The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of antimicrobial agents in food-producing animals. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs. The examination of dossiers/applications should include an assessment of the risks to humans, as well as animals and the environment as appropriate, resulting from the use of antimicrobial agents in the food chain. The evaluation should focus on each individual antimicrobial agent but take into consideration the class of antimicrobials to which the particular active principle belongs.	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>

<sup>14</sup> As defined in the VICH Good Clinical Practice Guideline, [http://vich.eudra.org/pdf/2000/GI09\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI09_st7.pdf)

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li><del>The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.</del></li> </ul>	
<p><del>The safety evaluation should include consideration of the potential impact of the proposed use in food-producing animals on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals and their environment associated with the use of veterinary antimicrobial drugs.</del> <u>The safety evaluation should include consideration of the potential impact of the proposed food use on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in food-producing animals, plants, and their environment associated with the use of antimicrobial agents, and the potential impact on the maintained effectiveness of antimicrobials in human medicine.</u></p>	<p><b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i></p>
<p><b>42. [10.]. If dose ranges or different durations of treatment are indicated, the national 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></p>	
<p><del>42. [10.] Si se indican escalas de dosis o tratamientos de distinta duración, las autoridades nacionales deberían brindar asesoramiento, en la etiqueta del producto aprobado, sobre las condiciones que reducirán al mínimo el desarrollo de resistencia, cuando esta información esté disponible.</del></p>	<p><b>Ecuador</b> esta de acuerdo Category: <i>EDITORIAL</i></p>
<p>Add an additional sentence: "Medically important antimicrobials should not be used without a defined limited duration of use in food production."</p>	<p><b>Consumers International</b> Continuous use or very long use of antimicrobials will contribute to resistance more than short term use. Given the importance of medically important antimicrobials in human medicine, they should not be used for short terms that are clearly defined.</p>
<p><b>[11. For more information on antimicrobial drugs for food-producing animals see the OIE Aquatic Animal Health Code Chapter 6.2.4- Responsibilities of competent authorities and Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 1. Marketing authorization.]</b></p>	
<p>[11. For more information on antimicrobial drugs for food-producing animals see the OIE Aquatic Animal Health Code Chapter <b>6.2.(Principles for responsible and prudent use of antimicrobial agents in aquatic animals), Article 6.2.4- (Responsibilities of competent authorities)</b> and Terrestrial Animal Health Code Chapter 6.9.3- <del>(Responsible and prudent use of antimicrobial agents in veterinary medicine section medicine), Article 6.9.3.(Responsibilities of the Competent Authorities) point</del> 1. Marketing authorization.]</p>	<p><b>Japan</b> Rationale: Refer to general comments. Category: <i>EDITORIAL</i></p>
<p>[11. For more information on antimicrobial drugs for food-producing animals see the OIE Aquatic Animal Health Code Chapter 6.2.4- Responsibilities of competent authorities and Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 1. Marketing authorization.]</p>	<p><b>FAO</b> While understanding this reference is valid for animals we do wonder if removing all the subsequent text is appropriate given the now wider scope of the document. For antimicrobial used in plant production the regulatory authorities also have a role in approval and registration and how they are used. In this context we wonder if some of the deleted text should be revisited with this wider perspective so the key principles are retained:</p>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	e.g. use in accordance with national legislation, actions if you do not have an efficient authorization system....combating illegal trade, fraud etc - These issues go beyond antimicrobials used in veterinary medicine and in this context think it would be appropriate to retain some of these contexts in a codex text. <i>Category: SUBSTANTIVE</i>
[11. For more information on antimicrobial <del>drugs-agents</del> for food-producing animals see the OIE Aquatic Animal Health Code Chapter 6.2.4- Responsibilities of competent authorities and Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 1. Marketing authorization.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[11. For more information on <u>responsible and prudent use of antimicrobial drugs-agents</u> for food-producing animals see the OIE <u>Aquatic-Terrestrial Animal Health Code (2017) Chapter 6.29 Responsible and prudent use of antimicrobial agents in veterinary medicine Article 6.4-9.3 - Responsibilities of competent authorities-the Competent Authority Point 1. Marketing authorisation and Terrestrial-the OIE Aquatic Animal Health Code (2017) Chapter 6.9.3 - Responsible 2 Principles for responsible and prudent use of antimicrobial agents in veterinary medicine section 1. Marketing authorization</u> aquatic animals Article 6.2.4- Responsibilities of competent authorities.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b><del>13. The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3))</del></b>	
<del>13. The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3))</del>	<b>Canada</b> Deleted old Para 13. The Code of Practice should clearly state that antimicrobials should be dispensed pursuant to veterinary prescription.
<del>13. The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3))</del> <u>The relevant authorities should make sure that all the antimicrobial agents used in food production or processing are used in accordance with national legislation or used under conditions stipulated in the national legislation. In particular, the relevant authorities should ensure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3))</u>	<b>International Association of Consumer Food Organizations</b> This paragraph contains important information and should be retained and edited to reflect the broadened scope. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
13. The relevant authorities should make sure that all the antimicrobial agents used in food-producing animals are prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation. (See OIE Guidelines for Antimicrobial Resistance: Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Terrestrial Animal Health Code, Appendix 3.9.3)	<b>International Meat Secretariat</b> Delete Principle 13: Sampling and susceptibility testing of isolates at the farm level may not be practical in all country settings and the goal of action for Principle 13 is well achieved by Principle 14. <i>Category: SUBSTANTIVE</i>
<b>14. No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.</b>	
14. No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.	<b>Indonesia</b> Indonesia proposed further discussion for this para <i>Category: TECHNICAL</i>
14. No veterinary antimicrobial drug should be administered to animals unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance. <del>No veterinary antimicrobial drug or antimicrobial used on crops or elsewhere in the food chain should be used unless it has been evaluated and authorized for such use by the relevant authorities or the use is allowed through off-label guidance or legislation. Regulatory authorities should, where possible, expedite the market approval process of new veterinary antimicrobial drug formulations considered to have the potential to make an important contribution in the control of antimicrobial resistance.</del>	<b>International Association of Consumer Food Organizations</b> This paragraph contains important information and should be retained and edited to reflect the broadened scope. <i>Category: SUBSTANTIVE</i>
<b>15. Countries without the necessary resources to implement an efficient authorisation procedure for veterinary antimicrobial drugs and whose supply of veterinary antimicrobial drugs mostly depends on imports from foreign countries should:</b>	
15. Countries without the necessary resources to implement an efficient authorisation procedure for veterinary antimicrobial drugs and whose supply of veterinary antimicrobial drugs mostly depends on imports from foreign countries should: <del>Countries without the necessary resources to implement an efficient authorisation procedure for antimicrobial agents and whose supply of antimicrobial agents mostly depends on imports from foreign countries should:</del>	<b>International Association of Consumer Food Organizations</b> This paragraph contains important information and should be retained and edited to reflect the broadened scope. It should be especially useful for those countries who need this Code the most. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><del>ensure the efficacy of their administrative controls on the import of these veterinary antimicrobial drugs,</del></li> </ul>	
<del>ensure the efficacy of their administrative controls on the import of these veterinary antimicrobial drugs, ensure the efficacy of their administrative controls on the import of these antimicrobial agents.</del>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>seek information on authorizations valid in other countries, and</li> </ul> develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs.	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li><del>seek information on authorizations valid in other countries, and seek information on authorizations valid in other countries, and</del></li> </ul>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<del>seek information on authorizations valid in other countries, and seek information on authorizations valid in other countries, and</del>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><b>develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs.</b></li> </ul>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<del>develop the necessary technical cooperation with experienced authorities to check the quality of imported veterinary antimicrobial drugs as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of veterinary antimicrobial drugs. develop the necessary technical cooperation with experienced authorities to check the quality of imported antimicrobial agents as well as the validity of the recommended conditions of use. Alternatively, a national authority could delegate a competent institution to provide quality certification of antimicrobial agents.</del>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
<del>16. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of illegal and/or counterfeit bulk active pharmaceutical ingredients and products. Regulatory authorities of importing countries could request the pharmaceutical industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority.</del>	
<del>16. Todos los países deberían hacer el mayor esfuerzo posible para combatir activamente la producción, publicidad, comercio, distribución y uso de ingredientes activos y productos farmacéuticos a granel ilegales o falsificados. Las autoridades de reglamentación de los países importadores podrían solicitar a la industria farmacéutica certificados de calidad o de cumplimiento de las buenas prácticas de fabricación expedidos por la autoridad nacional de reglamentación del país exportador.</del>	<b>Ecuador</b> Cada país debe instaurar una lista de antimicrobianos prohibidos como promotores de crecimiento, y establecer una tabla de concentración para los antimicrobianos permitidos como promotores de crecimiento. Category: <i>TECHNICAL</i>
<del>16. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of illegal and/or counterfeit bulk active pharmaceutical ingredients and products. Regulatory authorities of importing countries could request the pharmaceutical industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution, and use of illegal and/or counterfeit bulk active antimicrobial ingredients and products. Regulatory authorities of importing countries could request the relevant industry to provide quality certificates or, where feasible, certificates of Good Manufacturing Practices prepared by the exporting country's national regulatory authority.</del>	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
QUALITY CONTROL OF ANTIMICROBIAL AGENTS	
<b>17.[12. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices., in particular:</b>	
<ul style="list-style-type: none"> <li><del>to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.</del></li> <li><del>to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water.</del></li> <li><del>to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity.</del></li> </ul>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
47-[12.] La autoridad de reglamentación deberá garantizar que los controles de la calidad se apliquen de conformidad con las directrices internacionales y en cumplimiento de las disposiciones sobre las buenas prácticas de elaboración, <del>en particular:</del>	<b>Colombia</b> No es necesario particularizar. <i>Category: TECHNICAL</i>
47-[12. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices, <u>to ensure for example, that the quality and concentration (stability) of antimicrobial drugs as marketed is maintained under recommended storage conditions up to the expiry date, to ensure stability on the recommended use form and that they are manufactured to the appropriate quality and purity.</u> , <del>in particular:</del>	<b>FAO</b> Here also with the new structure and reference only to an OIE text some important guidance for antimicrobial agents used may be lost. <i>Category: SUBSTANTIVE</i>
47-[12. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices. <del>in particular:</del>	<b>International Association of Consumer Food Organizations</b> The text provides no specific information, except to reference OIE for antimicrobial agents used as drugs in veterinary medicine. IACFO recommends that quality control for antimicrobial agents at all points along the food chain (e.g., not just drugs in veterinary medicine but also antimicrobials used as pesticides in crop production, as direct food additives, as preservatives added to food packaging, and as disinfectants in food processing) be addressed. If a lack of quality control for antimicrobial agents results in sub-lethal concentrations being used, this would accelerate the development of antimicrobial resistance.
<ul style="list-style-type: none"> <li><del>to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.</del></li> </ul>	
<del>to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions. to ensure that the quality and concentration (stability) of antimicrobial agents in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions.</del>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><del>to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water.</del></li> </ul>	
<del>to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water. to ensure the stability of antimicrobial agents when they are mixed with feed or drinking water (for animals) or wetting agents or other inactive ingredients (for other uses).</del>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><del>to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity.</del></li> </ul>	
<del>to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity. to ensure that all antimicrobial agents are manufactured to the appropriate quality and purity.</del>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
[13. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 2. Quality control of antimicrobial agents and VMP containing medically important antimicrobial agents.]	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[13. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 2. Quality control of antimicrobial agents and VMP containing medically important antimicrobial agents.]	<p><b>Australia</b> Paragraphs 13, 16, and 25 Comment: The scope of 'medically important antimicrobial agents' used in these paragraphs needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list? Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. <i>Category: SUBSTANTIVE</i></p>
[13. Para obtener más información sobre medicamentos antimicrobianos para animales destinados a la producción de alimentos, véase el artículo 6.9.3. Uso responsable y prudente de agentes antimicrobianos en medicina veterinaria, sección 2, del Código Sanitario para los Animales Terrestres de la OIE: Control de calidad de los agentes antimicrobianos y productos médicos veterinarios que contengan agentes antimicrobianos.]	<p><b>Ecuador</b> Se debe indicar que las empresas importadoras y/o fabricantes tienen la responsabilidad de entregar la información y elementos necesarios para el análisis de los productos por parte la Autoridad Nacional Competente. <i>Category: TECHNICAL</i></p>
[13. For more information on antimicrobial <del>agents</del> <del>drugs</del> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 2. Quality control of antimicrobial agents and VMP containing medically important antimicrobial agents <b>and OIE Aquatic Animal Health Code Chapter 6.2. Principles for responsible and prudent use of antimicrobial agents in aquatic animals.</b> ]	<p><b>Thailand</b> <b>Rationale:</b> This para should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies.</p>
[13. For more information on antimicrobial <del>drugs</del> <del>agents</del> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 2. Quality control of antimicrobial agents and VMP containing medically important antimicrobial agents.]	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>
[13. For more information on antimicrobial <del>drugs</del> <del>agents</del> for food-producing animals see the OIE Terrestrial Animal Health Code (2017) Chapter 6.9.3 – 9 Responsible and prudent use of antimicrobial agents in veterinary medicine section 2. Quality control of antimicrobial agents and VMP containing medically important antimicrobial agents Article 6.19.3 – Responsibilities of the competent authority Point 3 Assessment of therapeutic efficiency.]	<p><b>OIE</b> <i>Category: TECHNICAL</i></p>
ASSESSMENT OF EFFICACY	
[14. Assessment of efficacy is important to assure adequate response to the administration of antimicrobials.]	
[14. Assessment of efficacy is important to assure adequate response to the administration of <del>antimicrobials</del> antimicrobial agents.]	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>
[15. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 3. Assessment of therapeutic efficacy.]	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[15. Para obtener más información sobre medicamentos antimicrobianos para animales destinados a la producción de alimentos, véase el artículo 6.9.3. Uso responsable y prudente de agentes antimicrobianos en medicina veterinaria, sección 3, del Código Sanitario para los Animales Terrestres de la OIE: Evaluación de la eficacia terapéutica.]	<b>Ecuador</b> Se debe indicar que es responsabilidad de la empresa importadora y/o fabricante, entregar las evidencias de eficacia de antimicrobianos en las especies sobre las que se desea aplicar, y de ser viable un estudio de eficacia sobre población animal nativa del país de origen. <i>Category: TECHNICAL</i>
[15. For more information on antimicrobial <u>agents drugs</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 3. Assessment of therapeutic efficacy <u>and OIE Aquatic Animal Health Code Chapter 6.2. Principles for responsible and prudent use of antimicrobial agents in aquatic animals.</u> ]	<b>Thailand</b> <b>Rationale:</b> This para should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies.
[15. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinar y medicine section 3. Assessment of therapeutic efficacy.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<del>18. Preclinical data should be generated to establish an appropriate dosage regimen necessary to ensure the efficacy of the veterinary antimicrobial drug and limit the selection of microbial resistant microorganisms. Such preclinical trials should, where applicable, include pharmacokinetic and pharmacodynamic studies to guide the development of the most appropriate dosage regimen.</del>	
<del>19. Important pharmacodynamic information may include:</del>	
<ul style="list-style-type: none"> <li><del>• mode of action;</del></li> <li><del>• the spectrum of antimicrobial activity of the substance;</del></li> <li><del>• identification of bacterial species that are naturally resistant relevant to the use of the veterinary antimicrobial drugs;</del></li> <li><del>• antimicrobial minimum inhibitory and/or bactericidal concentrations;</del></li> <li><del>• determination of whether the antimicrobial exhibits time or concentration-dependent activity or co-dependency,</del></li> <li><del>• evaluation of activity at the site of infection.</del></li> </ul>	
<del>20. Important pharmacokinetic information may include:</del>	
<ul style="list-style-type: none"> <li><del>• bio-availability according to the route of administration;</del></li> <li><del>• concentration of the veterinary antimicrobial drug at the site of infection and its distribution in the treated animal;</del></li> <li><del>• metabolism which may lead to the inactivation of veterinary antimicrobial drugs;</del></li> <li><del>• excretion routes.</del></li> </ul>	
<del>21. The use of fixed combinations of veterinary antimicrobial drugs should be justified taking into account:</del>	
<ul style="list-style-type: none"> <li><del>• pharmacodynamic (additive or synergistic effects towards the target microorganism);</del></li> <li><del>• pharmacokinetics (maintenance of the concentrations of associated antimicrobials responsible for additive or synergistic effects at the site of infection throughout the treatment period).</del></li> </ul>	
<del>22. Clinical data should be generated to confirm the validity of the claimed indications and dosage regimens established during the preclinical phase.</del>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>23. Criteria to be considered include:</b></p> <ul style="list-style-type: none"> <li><del>parameters for qualitatively and quantitatively assessing efficacy;</del></li> <li><del>diversity of the clinical cases met when carrying out clinical trials;</del></li> <li><del>compliance of the protocols of clinical trials with good clinical practice, such as VICH guidelines<sup>42</sup>;</del></li> <li><del>eligibility of the studied clinical cases based on appropriate clinical and microbiological criteria.</del></li> </ul>	
ASSESSMENT OF THE POTENTIAL OF VETERINARY ANTIMICROBIAL DRUGS[AGENTS] TO SELECT FOR RESISTANT MICROORGANISMS	
	<p><b>International Association of Consumer Food Organizations</b></p> <p>Here it is especially critical that the text be expanded to address all uses of antimicrobials throughout the food chain, since this section addresses the core objective of the Code. The Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011 should be cited and deleted text retained and edited to expand its scope.</p> <p>Category: SUBSTANTIVE</p>
[16. The competent authority should assess the potential of medically important antimicrobial drugs to select for resistant microorganisms taking into account CAC/GL77.]	
[16. The competent authority should assess the potential of medically important antimicrobial drugs to select for resistant microorganisms taking into account CAC/GL77.]	<p><b>Australia</b></p> <p>Paragraphs 13, 16, and 25</p> <p>Comment: The scope of 'medically important antimicrobial agents' used in these paragraphs needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list?</p> <p>Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies.</p> <p>Category: SUBSTANTIVE</p>
[16. The <del>Before authorization of antimicrobial agents,</del> the competent authority should assess the potential of <del>medically important</del> <del>the</del> antimicrobial drugs <del>agents</del> to select for resistant microorganisms taking into account CAC/GL77.]	<p><b>Japan</b></p> <p>Rationale: Japan proposes to amend para 16 in order to to clarify that this section is mentioning risk assessment which should be performed before authorization by competent authorities.</p> <p>Category: SUBSTANTIVE</p>
[16. The competent authority should assess the potential of <del>medically important</del> antimicrobial drugs <del>agents</del> to select for <del>resistant</del> microorganisms <del>resistant to medically important antimicrobials agents</del> taking into account CAC/GL77.]	<p><b>FEFAC</b></p> <p>Coresistance should also be considered.</p> <p>Category: TECHNICAL</p>

<sup>42</sup> VICH Good Clinical Practice Guideline, [http://vich.eudra.org/pdf/2000/GI09\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI09_st7.pdf)

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[16. The competent authority should assess the potential of medically important antimicrobial <del>drugs</del> <u>agents</u> to select for resistant microorganisms taking into account CAC/GL77.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[17. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 4. Assessment of the potential of antimicrobial agents to select for resistance and Chapter 6.10 Risk Analysis for Antimicrobial Resistance Arising from the Use of Antimicrobial Agents in Animals.]</b>	
[17. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 4. Assessment of the potential of antimicrobial agents to select for resistance and Chapter 6.10 Risk Analysis for Antimicrobial Resistance Arising from the Use of Antimicrobial Agents in Animals.]	<b>FAO</b> As above the scope of the document seems to be narrowed to animal use only when for such a risk assessment and other aspects. In this case as there is a Codex text which covers this point suggest that that should be the only cross reference here. That mentions OIE but if a stronger cross reference is to be included to the OIE text it should be in that document. <i>Category: SUBSTANTIVE</i>
[17. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 4. Assessment of the potential of antimicrobial agents to select for resistance and Chapter 6.10 Risk Analysis for Antimicrobial Resistance Arising from the Use of Antimicrobial Agents in Animals.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[17. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code (2017) Chapter 6.9.3 - <del>9</del> Responsible and prudent use of antimicrobial agents in veterinary medicine <del>section</del> <u>Article 6.9.3 Responsibilities of the competent authority Point 4.</u> Assessment of the potential of antimicrobial agents to select for resistance and Chapter 6.10 Risk Analysis for Antimicrobial Resistance Arising from the Use of Antimicrobial Agents in Animals.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b><del>24. Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.</del></b>	
<del>24. Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.</del> <u>Where applicable, data from preclinical or clinical trials should be used to evaluate the potential for target microorganisms, foodborne and/or commensal microorganisms to develop or acquire resistance.</u>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<b><del>25. Appropriate information should be provided to support an adequate assessment of the safety of veterinary antimicrobial drugs being considered for authorisation in food-producing animals. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline<sup>13</sup> may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:</del></b>	
<ul style="list-style-type: none"> <li><del>• the route and level of human exposure to food-borne or other resistant microorganisms;</del></li> <li><del>• the degree of cross resistance within the class of antimicrobials and between classes of antimicrobials;</del></li> <li><del>• the pre-existing level of resistance, if available, in pathogens causing gastrointestinal infections in humans (baseline determination);</del></li> <li><del>• the concentration of active compound in the gut of the animal at the defined dosage level.</del></li> </ul>	

<sup>13</sup> Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin, [http://www.oie.int/eng/publicat/rt/2003a\\_r20314.htm](http://www.oie.int/eng/publicat/rt/2003a_r20314.htm)



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>25. <del>Appropriate information should be provided to support an adequate assessment of the safety of veterinary antimicrobial drugs being considered for authorisation in food-producing animals. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline<sup>8</sup> may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:</del> <u>Appropriate information should be provided to support an adequate assessment of the safety of antimicrobial agents being considered for authorisation in food production and processing. The regulatory authorities should develop criteria for conducting such assessments and interpreting their results. Existing guidelines for antimicrobial resistance risk assessment, such as the OIE Guideline and the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011, may be used for more comprehensive information. The type of information to be evaluated in these assessments may include, but is not limited to, the following:</u></p> <ul style="list-style-type: none"> <li><u>• the route and level of human exposure to foodborne or other resistant microorganisms;</u></li> <li><u>• the degree of cross resistance within the class of antimicrobials and between classes of antimicrobials;</u></li> <li><u>• the pre-existing level of resistance, if available, in pathogens causing gastrointestinal infections in humans (baseline determination);</u></li> <li><u>• in the case of veterinary antimicrobial drugs, the concentration of active compound in the gut of the animal at the defined dosage level.</u></li> </ul>	<p><b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i></p>
<b>ESTABLISHMENT OF ADIS (ACCEPTABLE DAILY INTAKE), MRLS (MAXIMUM RESIDUE LIMIT), AND WITHDRAWAL PERIODS FOR VETERINARY ANTIMICROBIAL DRUGS</b>	
<p><del>26. When setting ADIs and MRLs for veterinary antimicrobial drugs, the safety evaluation is carried out in accordance with international guidelines and should include the determination of microbiological effects (e.g., the potential biological effects on the human intestinal flora) as well as toxicological and pharmacological effects.</del></p>	
<p><del>27. An acceptable daily intake (ADI) and a maximum residue limit (MRL) for appropriate food stuffs (i.e., meat, milk, eggs, fish and honey) should be established for each antimicrobial agent. MRLs are necessary in order that officially recognised control laboratories can monitor that the veterinary antimicrobial drugs are being used as approved. Withdrawal periods should be established for each veterinary antimicrobial drug, which make it possible to produce food in compliance with the MRLs.</del></p>	
<p><del>28. Withdrawal periods have to be established for each veterinary antimicrobial drug by taking into account:</del></p> <ul style="list-style-type: none"> <li><del>• the MRLs established for the considered veterinary antimicrobial drug;</del></li> <li><del>• the pharmaceutical form;</del></li> <li><del>• the target animal species;</del></li> <li><del>• the dosage regimen and the duration of treatment;</del></li> <li><del>• the route of administration.</del></li> </ul>	
<b>[ASSESSMENT OF ENVIRONMENTAL IMPACT]</b>	
	<p><b>International Association of Consumer Food Organizations</b> This section needs to be expanded to better address all uses of antimicrobials throughout the food chain. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[18. Regulatory authorities should assess the impact of proposed <del>veterinary antimicrobial drug</del>[agent] use on the environment in accordance with national guidelines or recognized international guidelines.]</b>	
[18. Regulatory authorities should assess the impact of proposed <del>veterinary antimicrobial drug</del> [agent] use on the environment in accordance with national guidelines or recognized international guidelines.] <u>and should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)</u>	<b>Egypt</b> <i>Category: EDITORIAL</i>
<b>[19. For more information on antimicrobial drugs for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products guidelines<sup>14</sup>.]</b>	
[19. For more information on antimicrobial drugs for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products guidelines <sup>9</sup> .]	<b>Canada</b> Para 19. A footnote is included by citing A 2000 VICH guidance document (i.e., GL6). For completeness, it is recommended to also cite GL38: VICH (2004). Environmental Impact Assessment for Veterinary Medicinal Products, Phase II. <i>Category: SUBSTANTIVE</i>
[19. For more information on antimicrobial drugs for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products guidelines <sup>9</sup> .]	<b>Egypt</b> cut and past at the end of the: [ASSESSMENT OF ENVIRONMENTAL IMPACT] <i>Category: EDITORIAL</i>
[19. For more information on antimicrobial <del>drugs</del> -agents for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products guidelines <sup>9</sup> .]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)]</b>	
[20. Las autoridades de reglamentación deberían considerar los aspectos ambientales de la RAM (p.ej., la contaminación por la producción farmacéutica, el impacto de reutilizar aguas residuales para el riego y de emplear estiércol para fertilizar los suelos, la armonización de la supervisión y el establecimiento de niveles máximos admisibles, etc.)]	<b>Ecuador</b> Debe ser responsabilidad de la empresa fabricante y/o importadora contar y aplicar un procedimiento para la recolección y correcta eliminación de envases vacíos de antimicrobianos. <i>Category: TECHNICAL</i>
[20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)]	<b>Egypt</b> <i>Category: EDITORIAL</i>
[20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)]	<b>USA</b> Paragraph 20: The United States supports maintaining this paragraph in square brackets pending the receipt of scientific advice to the TFAMR.

<sup>14</sup> [VICH (2000). Guidelines on Environmental Impact Assessment for Veterinary Medicinal Products, Phase I. [http://vich.eudra.org/pdf/2000/GI06\\_st7.pdf](http://vich.eudra.org/pdf/2000/GI06_st7.pdf)]

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>Rationale: There is a significant data and information gap with respect to the transmission of resistance genes in the environment and the potential risks associated with foodborne AMR. Before designing appropriate monitoring and surveillance activities and evaluating and determining the effectiveness of risk management measures intended to address foodborne AMR, a sound scientific understanding of the contribution of resistance genes in the environment to the overall risk of human illness from foodborne sources is essential.</p> <p>Category: <i>TECHNICAL</i></p>
[20. <del>Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)</del>	<p><b>International Meat Secretariat</b></p> <p>Delete para 20: environmental impact is not within the scope of this document</p> <p>Category: <i>SUBSTANTIVE</i></p>
[20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using <del>manure</del> <u>fecal material containing antimicrobial residues</u> for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.)]	<p><b>OIE</b></p> <p>Category: <i>TECHNICAL</i></p>
ESTABLISHMENT OF A SUMMARY OF PRODUCT CHARACTERISTICS FOR EACH VETERINARY ANTIMICROBIAL DRUG FOR FOOD-PRODUCING ANIMALS	
ESTABLISHMENT OF A SUMMARY OF PRODUCT CHARACTERISTICS FOR EACH <del>VETERINARY-ANTIMICROBIAL DRUG USED IN FOR FOOD-PRODUCING ANIMALS</del> <u>FOOD-PRODUCTION</u>	<p><b>FAO</b></p> <p>Propose to keep the heading in line with the scope of the document</p> <p>Category: <i>TECHNICAL</i></p>
ESTABLISHMENT OF A SUMMARY OF PRODUCT CHARACTERISTICS FOR EACH VETERINARY ANTIMICROBIAL DRUG FOR FOOD-PRODUCING ANIMALS	<p><b>International Association of Consumer Food Organizations</b></p> <p>We recommend that this section either be revised to also include antimicrobials used in crop production, or that a parallel section on antimicrobials used in crop production be developed.</p> <p>Category: <i>SUBSTANTIVE</i></p>
ESTABLISHMENT OF A SUMMARY OF PRODUCT CHARACTERISTICS FOR EACH <del>VETERINARY-ANTIMICROBIAL DRUG AGENT</del> FOR FOOD-PRODUCING ANIMALS	<p><b>International Feed Industry Federation</b></p> <p>Category: <i>SUBSTANTIVE</i></p>
[21. Regulatory authorities should establish a Summary of Product Characteristics that can be utilized in labelling and as a package insert.]	
[22. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents.]	
[22. For more information on antimicrobial <del>agents drugs</del> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents <u>and OIE Aquatic Animal Health Code Chapter 6.2. Principles for responsible and prudent use of antimicrobial agents in aquatic animals.</u> ]	<p><b>Thailand</b></p> <p>Rationale: This para should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies. Moreover, the phytosanitary measures or treatments from the IPPC should also be added (if available) to ensure that the application of phytosanitary measures does not contribute to increased AMR.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[22. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[22. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code (2017) Chapter 6.9.3—9 Responsible and prudent use of antimicrobial agents in veterinary medicine <del>section</del> <u>Article 6.9.3 Responsibilities of the competent authority</u> Point 7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<p><b><del>29. The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial drugs. It constitutes, for each veterinary antimicrobial drug, the official reference of the content of its labelling and package insert. This summary contains the following items:</del></b></p> <ul style="list-style-type: none"> <li><del>• pharmacological properties;</del></li> <li><del>• target animal species;</del></li> <li><del>• indications;</del></li> <li><del>• target microorganisms;</del></li> <li><del>• dosage and administration route;</del></li> <li><del>• withdrawal periods;</del></li> <li><del>• incompatibilities;</del></li> <li><del>• shelf-life;</del></li> <li><del>• operator safety;</del></li> <li><del>• particular precautions before use;</del></li> <li><del>• instructions for the return or proper disposal of un-used or out-of-date products;</del></li> <li><del>• any information on conditions of use relevant to the potential for selection of resistance should be included, for the purpose of guidance on prudent use;</del></li> <li><del>• class and active ingredient of the veterinary antimicrobial drug.</del></li> </ul>	
29. El resumen de las características del producto contiene la información necesaria para el uso adecuado de medicamentos veterinarios antimicrobianos. Constituye, para cada uno de ellos, la referencia oficial del contenido de su etiqueta y del folleto incluido en el envase. Dicho resumen incluirá lo siguiente: <del>29. El resumen de las características del producto contiene la información necesaria para el uso adecuado de medicamentos veterinarios antimicrobianos. Constituye, para cada uno de ellos, la referencia oficial del contenido de su etiqueta y del folleto incluido en el envase. Dicho resumen incluirá lo siguiente:</del>	<b>Ecuador</b> <i>Category: TECHNICAL</i>
29. El resumen de las características del producto contiene la información necesaria para el uso adecuado de medicamentos veterinarios antimicrobianos. Constituye, para cada uno de ellos, la referencia oficial del contenido de su etiqueta y del folleto incluido en el envase. Dicho resumen incluirá lo siguiente:	<b>Ecuador</b> incluir nuevamente esta condición del etiquetado <i>Category: TECHNICAL</i>
<del>29. The summary of product characteristics contains the information necessary for the appropriate use of veterinary antimicrobial drugs. It constitutes, for each veterinary antimicrobial drug, the official reference of the content of its labelling and package insert. This summary contains the following items:</del>	<b>FAO</b> Propose that some of this text is retained with a wider perspective and that the reference to OIE is moved to the end of the section. <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>SURVEILLANCE PROGRAMMES</b>	
<p><b>GOOD HYGIENE CONSIDERATIONS</b>  <u>##]. The relevant authorities should implement programs for preventing cross-contamination and the unintentional introduction of AMR during slaughter and processing, and prohibiting the sale of food contaminated by AMR organisms posing a threat to human health. [Refer to appropriate Codex documents.]</u></p> <p><b>SURVEILLANCE PROGRAMMES</b></p>	<p><b>International Association of Consumer Food Organizations</b>  We recommend that a new section be added on GOOD HYGIENE CONSIDERATIONS.  <i>Category: SUBSTANTIVE</i></p>
<p><b>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx), taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.]</b></p>	
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.]</p>	<p><b>Australia</b>  Paragraphs 23, 24, 31, and 33  Comment: Australia disagrees that the regulatory authorities are responsible for establishing systems for the surveillance and monitoring of antimicrobial resistance and usage, training of users of antimicrobial agents, and research development. These paragraphs should be stated as suggested areas for action under General Principles. <i>Category: SUBSTANTIVE</i></p>
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.]</p>	<p><b>Canada</b>  Para 23. Suggest indicating that implementation or enhancement of surveillance programs should be a part of national action plans and the surveillance programs should be designed to meet pre-defined objectives.  <i>Category: SUBSTANTIVE</i></p>
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.]</p>	<p><b>Japan</b>  Rationale: Regulatory authorities should also follow OIE Aquatic Animal Health Code Chapter 6.3 and Chapter 6.4.  <i>Category: SUBSTANTIVE</i></p>
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.]</p> <p><b><u>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.</u></b></p>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[23. Regulatory authorities should establish systems for the <b>monitoring and surveillance and monitoring</b> of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals and <b>OIE Aquatic Animal Health Code Chapter 6.4. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals.</b></p>	<p><b>Thailand</b>  <b>Rationale:</b> The term “surveillance and monitoring” would be changed to “monitoring and surveillance” in line with the work to ensure consistent use of this term throughout the document. This para should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies.</p>
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; <del>WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); and OIE Terrestrial Animal Health Code Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.</del>]</p>	<p><b>FAO</b>  As all the appropriate cross references will be provided in the Codex text propose that that only the surveillance and risk analysis texts are referenced here. These text then cross reference the other documents in the appropriate context so they are not needed here.  <i>Category: TECHNICAL</i></p>
<p>[23. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the Codex <i>Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)</i>, taking into consideration relevant sections of Guidelines for Foodborne Antimicrobial Resistance CAC/GL 77-2011; WHO guidelines on Integrated surveillance of antimicrobial resistance in foodborne bacteria, Application of a One Health Approach (2017); <del>and the</del> OIE Terrestrial Animal Health Code (2017) Chapter 6.7 Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals and the OIE <u>Aquatic Animal Health Code (2017) 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 programs for aquatic animals.</u>]</p>	<p><b>OIE</b>  <i>Category: TECHNICAL</i></p>
<p><b>[24. The surveillance and monitoring of antibiotic resistant bacteria in different production sectors and in different products is necessary for understanding the development and dissemination of antibiotic resistance, providing relevant risk assessment data, and assessing the effectiveness of interventions. Surveillance programmes involve specific and continuous data collection, analysis and reporting that quantitatively monitor temporal trends in the occurrence and distribution of resistance to antibiotics; it also allows the identification of emerging or specific patterns.]</b></p>	
<p>[24. The surveillance and monitoring of antibiotic resistant bacteria in different production sectors and in different products is necessary for understanding the development and dissemination of antibiotic resistance, providing relevant risk assessment data, and assessing the effectiveness of interventions. Surveillance programmes involve specific and continuous data collection, analysis and reporting that quantitatively monitor temporal trends in the occurrence and distribution of resistance to antibiotics; it also allows the identification of emerging or specific patterns.]</p>	<p><b>Australia</b>  Paragraphs 23, 24, 31, and 33  Comment: Australia disagrees that the regulatory authorities are responsible for establishing systems for the surveillance and monitoring of antimicrobial resistance and usage, training of users of antimicrobial agents, and research development. These paragraphs should be stated as suggested areas for action under General Principles. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>[24. Il est essentiel d'assurer la surveillance et le suivi des bactéries résistantes aux antibiotiques dans différents secteurs et différents produits, afin de comprendre l'avancée et la propagation de la résistance aux antibiotiques, au moyen de données d'évaluation des risques pertinentes et de l'évaluation de l'efficacité des interventions. Les programmes de surveillance impliquent la collecte, l'analyse et la communication permanente de données spécifiques, visant à surveiller les tendances en matière d'occurrence et de distribution dans le temps de la résistance aux antibiotiques; ils permettent également d'identifier des profils émergents ou spécifiques.]</p>	<p><b>Costa Rica</b></p> <p>[24. The surveillance and monitoring of [antimicrobial resistance] antibiotic resistant bacteria in different production sectors and in different products is necessary for understanding the development and dissemination of antibiotic resistance, providing relevant risk assessment data, and assessing the effectiveness of interventions. Surveillance programmes involve specific and continuous data collection, analysis and reporting that quantitatively monitor temporal trends in the occurrence and distribution of resistance to antibiotics [antimicrobials]; it also allows the.....</p> <p><i>Category: EDITORIAL</i></p>
<p>[24. The <b>monitoring and</b> surveillance <b>and monitoring</b> of antibiotic resistant bacteria in different production sectors and in different products is necessary for understanding the development and dissemination of antibiotic resistance, providing relevant risk assessment data, and assessing the effectiveness of interventions. Surveillance programmes involve specific and continuous data collection, analysis and reporting that quantitatively monitor temporal trends in the occurrence and distribution of resistance to antibiotics; it also allows the identification of emerging or specific patterns.]</p>	<p><b>Thailand</b></p> <p><b>Rationale:</b> The term “surveillance and monitoring” would be changed to “monitoring and surveillance” in line with the work to ensure consistent use of this term throughout the document. This para should include the list of the documents relevant and related to work on antimicrobial resistance from the specialized international bodies.</p>
<p><del>30. The relevant authorities should develop a structured approach to the investigation and reporting of the incidence and prevalence of antimicrobial resistance. For the purposes of this Code, priority should be given to the evaluation of antimicrobial resistance in foodborne microorganisms. For reasons of efficiency, the methods used to establish such programmes (laboratory techniques, sampling, choice of veterinary antimicrobial drug(s) and microorganism(s)) should be harmonized as much as possible at the international level (e.g. OIE documents on “Harmonisation of National Antimicrobial Resistance Monitoring and Surveillance Programmes in Animals and Animal Derived Food” <a href="http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm">http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm</a> and “Standardisation and Harmonisation of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance” <a href="http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm">http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm</a>).</del></p>	
<p><del>31. Preferably, epidemiological surveillance of antimicrobial resistance should be accompanied by data on the amounts of veterinary antimicrobial drugs used by veterinarians and other authorized users in food-producing animals. These data could be collected using one or more of the following sources:</del></p> <ul style="list-style-type: none"> <li><del>• production data from manufacturers;</del></li> <li><del>• importers and exporters;</del></li> <li><del>• if possible, data on intended and actual usage from manufacturers, wholesale and retail distributors including food mills, and veterinary prescription records;</del></li> <li><del>• surveys of veterinarians, farmers and producers of food-producing animals.</del></li> </ul>	
<p><del>32. Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.</del></p>	
<p>32. Regulatory authorities should have in place a pharmacovigilance or other programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs agents, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance or other programme should form part of the comprehensive strategy to minimize microbial resistance.</p>	<p><b>USA</b></p> <p>Former Paragraphs 32 and 33 (proposed for deletion): The United States recommends retaining these paragraphs with the following modifications</p> <p><i>Category: TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
32. Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.	
<b>33. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation.</b>	
33. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation. <u>33. In cases where the assessment of data collected from pharmacovigilance and from other post- authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug agent should be reviewed, regulatory authorities shall endeavour to achieve this re-evaluation.</u>	<b>USA</b> Rationale: Pharmacovigilance and other similar programmes designed to monitor and report adverse reactions, including lack of expected efficacy related to microbial resistance, are an important component of AMR surveillance. <i>Category: TECHNICAL</i>
DISTRIBUTION OF VETERINARY ANTIMICROBIAL DRUGS[AGENTS] IN VETERINARY MEDICINE	
<del>DISTRIBUTION OF VETERINARY ANTIMICROBIAL DRUGS[AGENTS] IN VETERINARY MEDICINE</del> <u>MEDICINE FOR THERAPEUTIC USE</u>	<b>FEFAC</b> This section is dealing with antimicrobials used for therapeutic purpose and this should be reflected in the title <i>Category: SUBSTANTIVE</i>
<del>DISTRIBUTION OF VETERINARY ANTIMICROBIAL DRUGS[AGENTS] IN VETERINARY MEDICINE</del> <u>MEDICINE FOR THERAPEUTIC USE</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]</b>	
[25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]	<b>Australia</b> Paragraphs 13, 16, and 25 Comment: The scope of 'medically important antimicrobial agents' used in these paragraphs needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list? Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. <i>Category: SUBSTANTIVE</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]	<b>Japan</b> Rationale: Refer to the above comment to Principle 12. This deleted sentence doesn't reflect actual situation in the veterinary sector. <i>Category: SUBSTANTIVE</i>
<del>[25</del> 25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]	<b>USA</b> Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. <i>Category: TECHNICAL</i>
[25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
[25. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed veterinarians, plant health professionals, or other suitably trained person authorized in accordance with national legislation.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>[26. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 9. Supply and administration of the VMP containing antimicrobial agents.]</b>	
<del>[26</del> 26. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 9. Supply and administration of the VMP containing antimicrobial agents.]	<b>USA</b> <i>Category: EDITORIAL</i>
[26. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 9. Supply and administration of the VMP containing antimicrobial agents.]	<b>FAO</b> Propose to move to the end of the section as the scope is wider than animals <i>Category: EDITORIAL</i>
[26. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 9. Supply and administration of the VMP containing antimicrobial agents.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[26. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code (2017) Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section Article 6.9.3 Responsibilities of the Competent Authority Point 9. Supply and administration of the VMP containing antimicrobial agents.]	<b>OIE</b> <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>34. The relevant authorities should make sure that all veterinary antimicrobial drugs used in food-producing animals are, to the extent possible:</b></p> <ul style="list-style-type: none"> <li>• <del>prescribed by a veterinarian or other suitably trained person authorized in accordance with national legislation or used under conditions stipulated in the national legislation;</del></li> <li>• <del>supplied only through licensed/authorized distribution systems;</del></li> <li>• <del>administered to animals by a veterinarian or, under the supervision of a veterinarian or other suitably trained person authorized in accordance with national legislation; and that</del></li> <li>• <del>proper records are kept of their administration (see Paragraph 58, Responsibilities of Veterinarians: Recording section).</del></li> </ul>	
34. The relevant authorities should make sure that all veterinary antimicrobial drugs used in food-producing animals are, to the extent possible:	<p><b>FAO</b></p> <p>Suggest that some of this text be retained in a more general manner to reflect the wider scope of the document and that not all intended users will be referencing the OIE texts as they will not be relevant to them eg horticulturists.</p> <p>Category: <i>TECHNICAL</i></p>
<p><b>[27. Where distribution and use are regularly controlled by the competent authorities, targeted checks could be carried out, where appropriate, on prescribers with high levels or concerning patterns of prescriptions.]</b></p>	
[27. Where distribution and use are regularly controlled by the competent authorities, targeted checks could be carried out, where appropriate, on prescribers with high levels or concerning patterns of prescriptions.]	<p><b>Canada</b></p> <p>Para 27. Suggest that the word “controlled” in the description “Where distribution and use are regularly controlled by the competent authorities” be better phrased as “under surveillance”.</p> <p>Category: <i>EDITORIAL</i></p>
[27. Cuando la distribución y el uso estén controlados regularmente por las autoridades competentes, deberían llevarse a cabo controles selectivos, cuando proceda, a prescriptores con un alto nivel de prescripción o con pautas de prescripción preocupantes.]	<p><b>Colombia</b></p> <p>Dado que los controles son continuos.</p> <p>Category: <i>TECHNICAL</i></p>
[ <del>27. Where distribution and use are regularly controlled by the competent authorities, targeted checks could be carried out, where appropriate, on prescribers with high levels or concerning patterns of prescriptions.]</del>	<p><b>USA</b></p> <p>Paragraph 27: The United States recommends deletion of this paragraph.</p> <p>Rationale: The practice of veterinary medicine relies on a valid client patient relationship, clinical judgment, applied knowledge in a variety of circumstances involving particular diseases, differing animal populations, epidemiological factors and antimicrobial susceptibility results, when available. More data and information on the feasibility of designing and implementing a monitoring system, as that described in Paragraph 27, is needed before such a system could be implemented by Member Countries.</p> <p>Category: <i>TECHNICAL</i></p>
<p><b>CONTROL OF ADVERTISING</b></p>	
CONTROL OF ADVERTISING/ADVERTISING FOR THERAPEUTIC USE	<p><b>FEFAC</b></p> <p>This section is dealing with antimicrobials used for therapeutic purpose and this should be reflected in the title. Category: <i>TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
CONTROL OF <del>ADVERTISING</del> ADVERTISING FOR THERAPEUTIC USE	<b>International Feed Industry Federation</b> Category: <i>SUBSTANTIVE</i>
<del>CONTROL</del> <u>REGULATION</u> OF ADVERTISING	<b>IPC</b> Category: <i>SUBSTANTIVE</i>
<b>[28. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance national legislation.]</b>	
<del>[28. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance national legislation.]</del>	<b>USA</b> Category: <i>EDITORIAL</i>
[28. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance <u>with</u> national legislation.]	<b>International Feed Industry Federation</b> Category: <i>EDITORIAL</i>
<b>[29. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 10. Control of advertising.]</b>	
<del>[29. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 10. Control of advertising.]</del>	<b>USA</b> Category: <i>EDITORIAL</i>
[29. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 10. Control of advertising.]	<b>FAO</b> While not disagreeing with the cross reference would propose to discuss how often the cross reference is needed and whether it needs to appear every few paragraphs Category: <i>SUBSTANTIVE</i>
[29. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 10. Control of advertising.]	<b>International Feed Industry Federation</b> Category: <i>SUBSTANTIVE</i>
[29. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter <del>(2017) Chapter 6.9.3 - 9</del> Responsible and prudent use of antimicrobial agents in veterinary medicine <del>section</del> <u>Article 6.9.3 Responsibilities of the competent authority Point 10. Control of advertising.</u> ]	<b>OIE</b> Category: <i>TECHNICAL</i>
<b><del>35.</del>[30.] Advertising of <del>veterinary</del> antimicrobial <del>drugs</del>[agents] should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.</b>	
<del>35.</del> [30.] Advertising of <del>veterinary</del> antimicrobial <del>drugs</del> [agents] for <u>veterinary and plant professional</u> should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.	<b>Indonesia</b> Category: <i>TECHNICAL</i>
<del>35.</del> [30.] <u>30.</u> Advertising of <del>veterinary</del> antimicrobial <del>drugs</del> [agents] should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product.	<b>USA</b> Category: <i>EDITORIAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
35.[30.] Advertising of <del>veterinary antimicrobial drugs</del> [agents] should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendation for the product. <u>Advertising of medically important antimicrobial agents should only be allowed to persons permitted to prescribe or supply antimicrobials and should not be permitted to be advertised to the producer.</u>	<b>International Association of Consumer Food Organizations</b> Text should be added that advertising should not be permitted directly to farmers or producers, consistent with the text under responsibilities of manufacturers, in paragraph [39]. <i>Category: SUBSTANTIVE</i>
<b>All advertising of <del>veterinary antimicrobial drugs</del>[agents] should be controlled by the relevant authorities.</b>	
All advertising of <del>veterinary antimicrobial drugs</del> [agents] <u>for veterinary and plant professional</u> should be controlled by the <del>relevant regulatory</del> authorities.	<b>Indonesia</b> <i>Category: TECHNICAL</i>
<ul style="list-style-type: none"> <li>• <b>The authorities should ensure that advertising of <del>veterinary antimicrobial drugs</del>[agents]:</b> <ul style="list-style-type: none"> <li>○ <b>complies with the marketing authorisation granted, in particular with the content of the summary of product characteristics; and</b></li> <li>○ <b>complies with each country's national legislation.</b></li> </ul> </li> </ul>	
The authorities should ensure that advertising of <del>veterinary antimicrobial drugs</del> [agents] <u>[agents] for veterinary and plant professional</u> :	<b>Indonesia</b> <i>Category: TECHNICAL</i>
<b>TRAINING OF USERS OF <del>VETERINARY ANTIMICROBIAL DRUGS</del>[AGENTS]</b>	
TRAINING OF USERS OF <del>VETERINARY ANTIMICROBIAL DRUGS</del> [AGENTS] <u>[AGENTS] FOR THERAPEUTIC USE</u>	<b>FEFAC</b> This section is dealing with antimicrobials used for therapeutic purpose and this should be reflected in the title <i>Category: TECHNICAL</i>
TRAINING OF USERS OF <del>VETERINARY ANTIMICROBIAL DRUGS</del> [AGENTS] <u>[AGENTS] FOR THERAPEUTIC USE</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>36.[31.] Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, <del>the pharmaceutical industry</del>[marketing authorization holders], <del>veterinary</del> schools, research institutes, professional associations[, trade associations] and other approved users such as farmers and producers <del>of feed animals</del> and should focus on:</b>	
36.[31.] Training <del>should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health.</del> Training should involve all the relevant professional organisations, regulatory authorities, <del>the pharmaceutical industry</del> [marketing authorization holders], <del>veterinary</del> schools, research institutes, professional associations[, trade associations] and other approved users such as farmers and producers <del>of feed animals</del> and should focus on:	<b>Australia</b> Paragraphs 23, 24, 31, and 33 Comment: Australia disagrees that the regulatory authorities are responsible for establishing systems for the surveillance and monitoring of antimicrobial resistance and usage, training of users of antimicrobial agents, and research development. These paragraphs should be stated as suggested areas for action under General Principles. <i>Category: SUBSTANTIVE</i>
36.[31.] Training <del>should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health.</del> Training should involve all the relevant professional organisations, regulatory authorities, <del>the pharmaceutical industry</del> <b>marketing authorization holders</b> ], <del>veterinary</del> schools, research institutes, professional associations[, trade associations] and other approved users such as farmers and producers <del>of feed animals</del> and should focus on:	<b>Thailand</b> <b>Rationale:</b> The new term “marketing authorization holders” is unclear and not specific to Pharmaceutical Industry. Therefore, we would like to retain the specific term “Pharmaceutical Industry” to clearly understand.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
36.[31.] Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, the pharmaceutical industry[marketing authorization holders], veterinary schools, research institutes, professional associations[, trade associations] and other approved users such as farmers and producers of food animals and should focus on:	<b>FEFAC</b> What is the difference between professional organisation and professional associations? Need to involve all partners, including animal nutritionists. <i>Category: SUBSTANTIVE</i>
36.[31.] Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should be undertaken to assure the safety to the consumer of food and the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, the pharmaceutical industry[marketing authorization holders], veterinary schools, research institutes, professional associations[, trade associations] and other approved users such as <u>food processors</u> , farmers and producers of <del>food</del> animals and should focus on:	<b>International Association of Consumer Food Organizations</b> IACFO believes that the first deleted sentence on consumer safety should be retained and the paragraph further edited to address the entire food chain and the appropriate public health focus. <i>Category: SUBSTANTIVE</i>
36.[31.] Training should be undertaken to assure the safety to the consumer of animal derived food and therefore the protection of public health. Training should involve all the relevant professional organisations, regulatory authorities, the pharmaceutical industry[marketing authorization holders], veterinary schools, research institutes, professional associations[, trade associations] and other approved users such as farmers and producers <u>or nutritionists</u> of food animals and should focus on:	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><b>information on disease prevention and management strategies to reduce the need to use veterinary antimicrobial drugs[agents];</b></li> </ul>	
information on disease prevention and management strategies <u>including adequate nutrition</u> to reduce the need to use <del>veterinary</del> antimicrobial drugs[agents];	<b>FEFAC</b> To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases. <i>Category: TECHNICAL</i>
information on disease <del>prevention</del> prevention, <u>adequate nutrition</u> and management strategies to reduce the need to use <del>veterinary</del> antimicrobial drugs[agents];	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><b>relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian [and plant health professionals] to use veterinary antimicrobial drugs[agents] prudently;</b></li> </ul>	
relevant pharmacokinetic and pharmacodynamic information to enable the veterinarian [and plant health professionals] to use <del>veterinary</del> antimicrobial drugs[agents] prudently;	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li><b>the ability of <del>veterinary</del> antimicrobial drugs[agents] to select for resistant microorganisms in <del>food-producing animals</del> that may contribute to animal[, plant] or human health problems; and</b></li> </ul>	
the ability of <del>veterinary</del> antimicrobial drugs[agents] to select for resistant microorganisms in <del>food-producing animals</del> that may contribute to animal[, plant] or human health <u>or environmental</u> problems; and	<b>FAO</b> In keeping with a One Health approach propose consideration of inclusion of environment here also. <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
the ability of <del>veterinary</del> antimicrobial drugs[agents] to select for resistant microorganisms in <del>food-producing animals</del> that may contribute to animal[, plant] or human health problems; and	<b>ICGMA</b> Support maintaining brackets on plant in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>the need to observe responsible use recommendations and using <del>veterinary</del> antimicrobial drugs[agents] in <del>animal husbandry</del>[production settings] in agreement with the provisions of the marketing authorisations and <del>veterinary</del>[professional] advice.</li> </ul>	
the need to observe responsible use recommendations and using <del>veterinary</del> antimicrobial drugs[agents] in <del>animal husbandry</del> [production settings] in agreement with the provisions of the marketing authorisations and <del>veterinary</del> [professional] public health advice.	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<b>[32. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 11. Training on the usage of antimicrobial agents.]</b>	
[32. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 11. Training on the usage of antimicrobial agents.]	<b>FAO</b> See earlier comments to consider how often this cross reference needs to be included as its very frequent repetition starts to disrupt the flow of the document <i>Category: EDITORIAL</i>
[32. For more information on antimicrobial <del>drugs-agents</del> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.3 - Responsible and prudent use of antimicrobial agents in veterinary medicine section 11. Training on the usage of antimicrobial agents.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[32. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code (2017 Chapter 6.9.3–9 Responsible and prudent use of antimicrobial agents in veterinary medicine <del>section</del> Article 6.9.3 Responsibilities of the competent authority Point 11. Training on the usage of antimicrobial agents.)	<b>OIE</b> <i>Category: TECHNICAL</i>
DEVELOPMENT OF RESEARCH	
	International Association of Consumer Food Organizations IACFO supports the revised text. These are excellent additions. <i>Category: SUBSTANTIVE</i>
<b>37.[33.] The relevant authorities should encourage public and private research to:</b>	
37.[33.] The relevant authorities should encourage public and private research to:	<b>Australia</b> Paragraph 33 Comment: With respect to the inclusion of agricultural chemicals in the document, there needs to be more focus on animals. Rationale: Research on the risk of antimicrobial resistance from agricultural chemicals is warranted. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
37.[33.] The relevant authorities should encourage public and private research to:	<p><b>Australia</b> Paragraphs 23, 24, 31, and 33 Comment: Australia disagrees that the regulatory authorities are responsible for establishing systems for the surveillance and monitoring of antimicrobial resistance and usage, training of users of antimicrobial agents, and research development. These paragraphs should be stated as suggested areas for action under General Principles. <i>Category: SUBSTANTIVE</i></p>
37.[33.] La autoridad competente deberá incentivar la investigación pública y privada con el fin de:	<p><b>Ecuador</b> Se debe estimular y apoyar la investigación de nuevas propuestas de control contra microorganismos, como fitofármacos y bacteriófagos. Apoyar a las actividades de vigilancia, mediante la obtención de datos científicos sobre los microorganismos circulantes y sus posibles capacidades de resistencia, y su interrelación con aquellos microorganismos que ocasionan problemas de salud pública <i>Category: TECHNICAL</i></p>
37.[33.] The relevant authorities should encourage public and private research to:	<p><b>Russian Federation</b> We propose to include in paragraph 33 the following statement- “Development of new methods and modern diagnostic products, including products based on the methods of molecular genetic analysis (real-time PCR, NGS, biochips) for Antimicrobial Resistance Marker analysis and identification of infectious agents in the food chain. <i>Category: SUBSTANTIVE</i></p>
<ul style="list-style-type: none"> <li>• <b>improve the knowledge about the mechanisms of action of antimicrobials in order to optimise the dosage regimens and their efficacy;</b></li> </ul>	
improve the knowledge about the mechanisms of action of <del>antimicrobials</del> antimicrobial agents in order to optimise the dosage regimens and their efficacy;	<p><b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i></p>
<ul style="list-style-type: none"> <li>• <b>improve the knowledge about the mechanisms of selection, emergence and dissemination of resistance determinants;</b></li> <li>• <b>develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;</b></li> <li>• <b>further develop protocols to predict, during the authorisation process, the impact of the proposed use of the <del>veterinary</del> antimicrobial drugs[agents] on the rate and extent of resistance development; and</b></li> </ul>	
further develop protocols to predict, during the authorisation process, the impact of the proposed use of the <del>veterinary</del> antimicrobial drugs[agents] on the rate and extent of resistance development; and	<p><b>Indonesia</b> <i>Category: EDITORIAL</i></p>
further develop protocols to predict, during the authorisation process, the impact of the proposed use of the <del>veterinary</del> antimicrobial drugs[agents] in food production systems on the rate and extent of resistance development; and	<p><b>FAO</b> There is a need to clarify where the proposed use would happen <i>Category: TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>develop and encourage [good animal husbandry practices and] alternative methods to prevent [and treat] infectious diseases [that would reduce the need to use antimicrobials]</li> </ul>	
develop and encourage <u>the application of [good practices including good animal husbandry practices, good agriculture practices and] alternative methods to prevent [and treat] infectious diseases [that would reduce the need to use antimicrobials]</u>	<b>FAO</b> Suggest that some text be added to again broaden from the animal only <i>Category: TECHNICAL</i>
develop and encourage [good animal husbandry practices <u>including adequate nutrition strategies</u> and] alternative methods to prevent [and treat] infectious diseases [that would reduce the need to use antimicrobials]	<b>FEFAC</b> To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases. <i>Category: TECHNICAL</i>
develop and encourage <u>RRR Strategies such as:</u> [good animal husbandry practices and] alternative methods to prevent [and treat] infectious diseases [that would reduce the need to use antimicrobials]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[develop alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines.]</b>	
<del>develop</del> <u>develop safe and efficacious</u> alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines.]	<b>USA</b> The United States recommends inserting “safe and efficacious” in the sixth bullet. The bullet should read as, “develop safe and efficacious alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines.” Rationale: Alternatives to antimicrobials should demonstrate safety and effectiveness for their intended use. <i>Category: TECHNICAL</i>
[develop alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines.] <ul style="list-style-type: none"> <li>Encourage the implementation of <u>adequate nutrition strategies (such as precision feeding)</u></li> </ul>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[develop alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and <del>vaccines, including autogenous vaccines.]vaccines]</del>	<b>International Meat Secretariat</b> <i>Category: SUBSTANTIVE</i>
<del>develop alternatives to antimicrobials, [develop new antimicrobialsantibiotics, rapid diagnostics, and vaccines, including autogenous vaccines]vaccines and other alternatives to antimicrobials.]</del>	<b>OIE</b> <i>Category: TECHNICAL</i>
<ul style="list-style-type: none"> <li><b>[determine the potential transfer to fresh produce and other crops of resistant microorganisms and determinants from animal manures used as fertilizer.]</b></li> </ul>	
[determine the potential transfer to fresh produce and other crops of resistant microorganisms and determinants from animal manures used as fertilizer.]	<b>USA</b> The United States supports maintaining the seventh (final) bullet in square brackets. Rationale: This bullet should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. The request for scientific advice to the TFAMR may address the exposure pathway described in this bullet. <i>Category: TECHNICAL</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[determine the potential transfer to fresh produce and other crops of resistant microorganisms and determinants from animal manures used as fertilizer.]</del>	<b>International Meat Secretariat</b> Category: <i>SUBSTANTIVE</i>
<b>[34. Research should be conducted, as resources permit, on AMR microorganisms in the environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment.]</b>	
[34. Research should be conducted, as resources permit, on AMR microorganisms in the environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment.]	<b>USA</b> Paragraph 34: The United States recommends retaining this paragraph in square brackets. Rationale: Scientific advice requested to inform the TFAMR may help further refine this paragraph. Category: <i>TECHNICAL</i>
<del>[34. Research should be conducted, as resources permit, on AMR microorganisms in the environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment.]</del>	<b>International Meat Secretariat</b> Category: <i>SUBSTANTIVE</i>
[34. Research should be conducted, as resources permit, on AMR microorganisms in the environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment.]	<b>International Meat Secretariat</b> Delete para 34: not within the scope Category: <i>SUBSTANTIVE</i>
<b>COLLECTION AND DESTRUCTION OF <del>UNUSED</del> [OUT-OF-DATE] <del>VETERINARY</del> ANTIMICROBIAL <del>DRUGS</del>[AGENTS]</b>	
COLLECTION AND DESTRUCTION OF <del>UNUSED</del> <del>UNUSED</del> [OUT-OF-DATE] <del>VETERINARY</del> ANTIMICROBIAL <del>DRUGS</del> [AGENTS]	<b>FEFAC</b> “USED” should be maintained: it is not always advisable to deliver to a group of animals part of a consignment of e.g. medicated feed containing an antimicrobial) that was meant for another group of animals. Even worst when talking about different farms. Category: <i>SUBSTANTIVE</i>
COLLECTION AND DESTRUCTION OF <del>UNUSED</del> [OUT-OF-DATE] <del>VETERINARY</del> ANTIMICROBIAL <del>DRUGS</del> [AGENTS]	<b>International Feed Industry Federation</b> UNUSED Should be maintained: it is not always advisable to deliver to a group of animals part of a consignment of e.g. medicated feed containing an antimicrobial) that was meant for another group of animals. Category: <i>SUBSTANTIVE</i>
COLLECTION AND DESTRUCTION OF <del>UNUSED OR UNUSED</del> [OUT-OF-DATE] <del>VETERINARY</del> ANTIMICROBIAL <del>DRUGS</del> [AGENTS]	<b>International Feed Industry Federation</b> Category: <i>SUBSTANTIVE</i>
<b>38:[35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs[agents].</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
38.[35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date <del>veterinary antimicrobial drugs</del> [agents].	<b>Australia</b> Paragraph 35 Comment: Australia disagree with the use of the word, 'compulsory'. Suggest it be replaced with "Relevant authorities should strive to..." Rationale: Australia does not support the use of this word or any compulsory activities in general because of potential regulatory burden. <i>Category: SUBSTANTIVE</i>
38.[35]35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date <del>veterinary antimicrobial drugs</del> [agents].	<b>USA</b> Rationale: Effective procedures for safe collection and destruction of unused or out-of-date antimicrobial agents need not be compulsory. Voluntary procedures may also be effective and more feasible to implement <i>Category: TECHNICAL</i>
38.[35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date <del>veterinary antimicrobial drugs</del> [agents].	<b>FAO</b> To achieve this an understanding of the volume of antimicrobials produced and where they went to would be important and propose to consider that the pharmaceutical industry also has a role here. For example as a starting point Pharmaceutical manufacturers should record the volume of product sold <i>Category: TECHNICAL</i>
Responsibilities of the <del>Veterinary Pharmaceutical Industry</del> [Manufacturers]	
	China In para 36, the GMP, GLP, GCP standard should be implemented in accordance with national guidelines.
"Responsibilities of <u>the Veterinary Pharmaceutical Industry</u> [Manufacturers]"	Thailand
<del>Responsibilities of the Veterinary Pharmaceutical Industry</del> [Manufacturers] <u>Manufacturers</u>	<b>USA</b> The United States supports revision of the title of this section as "Responsibilities of Manufacturers" <i>Category: TECHNICAL</i>
<u>Pharmaceutical manufacturers are responsible for implementing good manufacturing practices and also have some responsibility in protecting the environment from antimicrobial discharges</u>	<b>FAO</b> In terms of responsibilities of the manufacturers, their role in implementing GMP and responsibility in protecting the environment from antimicrobial discharges should also be considered here. <i>Category: TECHNICAL</i>
<del>Responsibilities of the Veterinary Pharmaceutical Industry</del> [Manufacturers] <u>[Manufacturers of antimicrobial agents]</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
MARKETING AUTHORISATION OF <del>VETERINARY ANTIMICROBIAL DRUGS</del> [AGENTS] FOR <del>FOOD-PRODUCING ANIMALS</del>	
39.[36. It is the responsibility of the <del>veterinary pharmaceutical industry</del> antimicrobial agent marketing authorization holders:	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p><b>Australia</b> Paragraphs 36 to 41 Comment: Suggest the following OIE chapters replace current text on the responsibilities of the manufacturers by reference in whole: Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals Rationale: Avoids duplication of international standards. Category: <i>SUBSTANTIVE</i></p>
<ul style="list-style-type: none"> <li>to supply all of the information requested by the national regulatory authority in order to establish objectively the quality, safety and efficacy of <del>veterinary antimicrobial drugs</del>[agents]; and</li> </ul>	
to supply <del>all of all</del> the information requested by the national regulatory authority in order to establish objectively the quality, safety and efficacy of <del>veterinary antimicrobial drugs</del> [agents]; and	<p><b>International Feed Industry Federation</b> Category: <i>EDITORIAL</i></p>
<ul style="list-style-type: none"> <li>to ensure the quality of this information on the basis of the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices.</li> </ul>	
MARKETING AND EXPORT OF <del>VETERINARY ANTIMICROBIAL DRUGS</del> [AGENTS]	
40.[37.] Only officially licensed/authorized <del>veterinary antimicrobial drugs</del> [agents] should be marketed, and then only through approved distribution systems.	
40.[37.] Only officially licensed/authorized <del>veterinary antimicrobial drugs</del> [agents] should be marketed, and then only through approved distribution systems.	<p><b>Canada</b> Para 37. Suggest adding a new bullet to request reporting of antimicrobial agent sales data from the manufacturers and distributors. Category: <i>SUBSTANTIVE</i></p>
Solo deben exportarse los <del>medicamentos veterinarios</del> [agentes] antimicrobianos que cumplan con las normas de calidad e inocuidad del país en el que fueron producidos; <u>y los requisitos específicos del país o región al que se destinen.</u>	<p><b>Colombia</b> Para complementar el sentido de las directrices Category: <i>TECHNICAL</i></p>
<ul style="list-style-type: none"> <li>Only <del>veterinary antimicrobial drugs</del>[agents] meeting the quality standards of the importing country should be exported from a country in which the products were produced;</li> </ul>	
<ul style="list-style-type: none"> <li>The information necessary to evaluate the amount of <del>veterinary antimicrobial drugs</del>[agents] marketed should be provided to the national regulatory authority</li> </ul>	
The information necessary to evaluate the amount of <del>veterinary antimicrobial drugs</del> [agents] marketed should be provided to the national regulatory authority. <u>Volume and purposes of antimicrobial imported and exported should be recorded</u>	<p><b>FAO</b> It is suggested to consider including some text here on recording of volumes produced and where they go. This understanding is critical to addressing AMR and needs to be somehow captured in this text. Category: <i>TECHNICAL</i></p>
[38. Package size and the strength of antimicrobial formulations should be adapted as far as possible to the approved indications of use (avoidance of improper dosing, overuse and leftovers).]	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[38. Package size and the strength of antimicrobial <u>agent</u> formulations should be adapted as far as possible to the approved indications of use (avoidance of improper dosing, overuse and leftovers).]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[38. Se debería adaptar tanto como sea posible el tamaño del envase y la fuerza de las formulaciones antimicrobianas a las indicaciones de uso aprobadas (prevención de una dosificación inadecuada, sobredosis y producto sobrante.)]	<b>Colombia</b> Se sugiere adicionar un ítem que mencione el listado de medicamentos críticos. Es de suma importancia poder priorizar los medicamentos de importancia crítica. <i>Category: SUBSTANTIVE</i>
ADVERTISING	
<b>44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del>[marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]</b>	
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]	<b>Australia</b> If comments rejected from para 36-41 then, Paragraph 39 Comment: The scope of 'medically important antimicrobial agents' used in these paragraphs needs to be defined and increased specificity of the term is preferred. Does this only mean 'critically important' antimicrobials of the WHO list? Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to 'critically important antimicrobials'. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies.
44-[39.] <del>Es responsabilidad de la industria farmacéutica veterinaria</del> <u>Es responsabilidad de la industria farmacéutica veterinaria [los titulares de la autorización de comercialización] dar publicidad a medicamentos veterinarios [los agentes] antimicrobianos [de importancia médica] con arreglo a las disposiciones del párrafo 35[30] sobre las responsabilidades de las autoridades de reglamentación y el control de la publicidad, y no hacer publicidad directa e impropia de los antimicrobianos [de importancia médica] entre los productores de animales de los que se obtienen alimentos. [Únicamente se debería poder realizar publicidad destinada a las personas que tienen autorización para prescribir o suministrar medicamentos antimicrobianos. Se deberían prohibir las campañas promocionales que impliquen beneficios económicos o materiales para los prescriptores o proveedores de antimicrobianos, e inclusive aquellas campañas que tengan como objetivo desplazar en la conciencia del consumidor, el compuesto genérico para reemplazarlo con un nombre comercial..] medicamentos veterinarios [los agentes] antimicrobianos [de importancia médica] con arreglo a las disposiciones del párrafo 35[30] sobre las responsabilidades de las autoridades de reglamentación y el control de la publicidad, y no hacer publicidad directa e impropia de los antimicrobianos [de importancia médica] entre los productores de animales de los que se obtienen alimentos.</u>	<b>Ecuador</b> <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><del>[Únicamente se debería poder realizar publicidad destinada a las personas que tienen autorización para prescribir o suministrar medicamentos antimicrobianos. Se deberían prohibir las campañas promocionales que impliquen beneficios económicos o materiales para los prescriptores o proveedores de antimicrobianos.]</del></p>	
<p><del>“41.[39.] It is the responsibility of the <u>veterinary pharmaceutical industry</u>[marketing authorization holders] to advertise...</del></p>	<p><b>Thailand</b>                      Rationale: The new term “Manufacturers” and “marketing authorization holders” is unclear and not specific to Pharmaceutical Industry. Therefore, we would like to retain the specific term “Pharmaceutical Industry” to clearly understand.</p>
<p><del>41.[39.] 39. It is the responsibility of the <u>veterinary pharmaceutical industry</u>[marketing authorization holders] to advertise <u>veterinary</u> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <u>inappropriately</u> advertise [medically important] antimicrobials <u>directly</u> to the <u>feed animal</u> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of <u>medically important</u> antimicrobials should be prohibited.]</del></p>	<p><b>USA</b>                      Paragraph 39: The United States recommends maintaining the last two sentences in square brackets pending further consideration.                      Rationale: As written, the text could broadly be interpreted to affect the cost and access to antimicrobial agents even when administered or applied under responsible and judicious conditions of use. Addressing concerns about incentivizing inappropriate or injudicious use of medically important antimicrobial agents requires further consideration.                      The United States recommends the addition of “medically important” in the last sentence. The sentence should read, “Promotional campaigns involving economic or material benefits for prescribers or suppliers of medically important antimicrobials should be prohibited.”                      Rationale: Many countries have demonstrated that adequate directions for animal-use only antimicrobials can be effectively communicated to lay persons to ensure that a product is used safely and for its intended purpose. The public health concern of the TFAMR focuses on medically important uses, which some countries restrict marketing status to prescription only, or under the oversight of a veterinarian or similarly qualified individual. Therefore, it is important to add the above qualification to distinguish the different types of products.                      Category: <i>TECHNICAL</i></p>
<p><del>41.[39.] It is the responsibility of the <u>veterinary pharmaceutical industry</u>[marketing <u>marketing authorization holders</u>] <u>holders</u> to advertise <u>veterinary</u> [medically important] antimicrobial[s] <u>medically important antimicrobials</u> drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <u>inappropriately</u> advertise [medically important] <u>medically important</u> antimicrobials <u>directly</u> to the <u>feed animal</u> producer. [Advertising <u>Advertising</u> should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]</del></p>	<p><b>Consumers International</b>                      CI supports the bracketed language on advertising restrictions and thus thinks that language should not be placed in square brackets                      Category: <i>EDITORIAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of <u>medically important</u> antimicrobials should be prohibited.]	<b>ICGMA</b> Many countries have demonstrated that adequate directions for use of animal-use-only antimicrobials can be effectively communicated to lay persons to ensure that a product is used safely and for its intended purpose. The public health concern of the TFAMR focuses on medically important uses, which some countries restrict marketing status to prescription or under the oversight of a veterinarian or similarly qualified individual. Therefore, it is important to add the above qualification to distinguish the different types of products. <i>Category: SUBSTANTIVE</i>
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]	<b>International Association of Consumer Food Organizations</b> In our view, the paragraph should apply to all antimicrobial agents, and should not be limited to medically important antimicrobials. <i>Category: SUBSTANTIVE</i>
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] <del>antimicrobials</del> <u>antimicrobial agents</u> <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial <del>drugs</del> <u>agents</u> . Promotional campaigns involving economic or material benefits for prescribers or suppliers of <del>antimicrobials</del> <u>antimicrobial agents</u> should be prohibited.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]	<b>OIE</b> : this should also be the case for veterinary important antimicrobial agents <i>Category: TECHNICAL</i>
44-[39.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to advertise <del>veterinary</del> [medically important] antimicrobial[s] drugs in accordance with the provisions of Paragraph 35[30] on the Responsibilities of the <del>Regulatory</del> <u>Competent</u> Authorities, Control of Advertising and to not <del>inappropriately</del> advertise [medically important] antimicrobials <del>directly</del> to the <del>food animal</del> producer. [Advertising should only be allowed to persons permitted to prescribe or supply antimicrobial drugs. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be prohibited.]	<b>OIE</b> <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>TRAINING</b>	
<b>42.[40.] It is the responsibility of the <del>veterinary pharmaceutical industry</del>[marketing authorization holders] to participate in the training of users of <del>veterinary antimicrobial drugs</del>[agents] as defined in Paragraph <del>36</del>[31].</b>	
It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to participate in...	<b>Thailand</b> Rationale: The new term “Manufacturers” and “marketing authorization holders” is unclear and not specific to Pharmaceutical Industry. Therefore, we would like to retain the specific term “Pharmaceutical Industry” to clearly understand.
<b>RESEARCH</b>	
<b>43.[41.] It is the responsibility of the <del>veterinary pharmaceutical industry</del>[marketing authorization holders] to contribute to the development of research as defined in Paragraph <del>37</del>[33]. [Research on the development of alternatives to the use of antimicrobials, new antimicrobials, rapid diagnostics and vaccines would be useful.]</b>	
43.[41.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders]- <del>veterinary pharmaceutical industry</del> to contribute to the development of research as defined in Paragraph <del>37</del> [33]. [Research on the development of alternatives to the use of antimicrobials, new antimicrobials, rapid diagnostics and vaccines would be useful.]	<b>Indonesia</b> <i>Category: TECHNICAL</i>
43.[41.] It is the responsibility of the <del>veterinary pharmaceutical industry</del> [marketing authorization holders] to contribute to...”	<b>Thailand</b> Rationale: The new term “Manufacturers” and “marketing authorization holders” is unclear and not specific to Pharmaceutical Industry. Therefore, we would like to retain the specific term “Pharmaceutical Industry” to clearly understand.
<b>Responsibilities of Wholesale and Retail Distributors</b>	
	<b>China</b> Delete para 43, the section that coincides with the Terrestrial animal health code chapter 6.9.5. It is recommended to quote directly or briefly.
<b>Responsibilities of Wholesale and Retail <del>Distributors</del>Distributors of antimicrobial agents</b>	
<b>44.[42.] Retailers distributing <del>veterinary</del> [medically important] antimicrobial[s] drugs should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.</b>	
44.[42.] Retailers distributing <del>veterinary</del> [medically important] antimicrobial[s] drugs should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.	<b>Australia</b> Paragraphs 42-44 Comment: Suggest the following OIE chapters replacing current text on the responsibilities of distributors by reference in whole: Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals Rationale: Avoids duplication of international standards.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
44.[42.] Retailers distributing <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
44.[42.] Retailers distributing <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.	<b>International Association of Consumer Food Organizations</b> We recommend deleting the words “medically important” in square brackets each time it appears, since this weakens the code. <i>Category: SUBSTANTIVE</i>
44.[42.] Retailers distributing <del>veterinary</del> <del>veterinar</del> [medically] <del>[human and veterinary medically important]</del> antimicrobial[s] <del>drugs</del> should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>45.[43.] Distributors should encourage compliance with the national guidelines on the responsible use of <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> and should keep detailed records of all [medically important] antimicrobials supplied according to the national regulations including:</b>	
45.[43.] Distributors should encourage compliance with the national guidelines on the responsible use of <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> and should keep detailed records of all [medically important] antimicrobials supplied according to the national regulations including:	<b>Australia</b> If comment above rejected for para 42-44 then, Paragraphs 42 and 43 Comment: The scope of ‘medically important antimicrobial agents’ used in these paragraphs needs to be defined and increased specificity of the term is preferred. Does this only mean ‘critically important’ antimicrobials of the WHO list? Rationale: The language needs to be clear. For consistency, it is noted that CAC/GL 77-2011 Principle 3 refers to ‘critically important antimicrobials’. Reference to a specific list and classification would be helpful, as there are several amongst the international standard setting bodies. <i>Category: SUBSTANTIVE</i>
45.[43.] Distributors should encourage compliance with the national guidelines on the responsible use of <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> and should keep detailed records of all <del>[medically important]</del> antimicrobials supplied according to the national regulations including:	<b>International Association of Consumer Food Organizations</b> We recommend deleting the words “medically important” in square brackets each time it appears, since this weakens the code. <i>Category: SUBSTANTIVE</i>
45.[43.] Distributors should encourage compliance with the national guidelines on the responsible use of <del>veterinary</del> [medically important] <del>antimicrobial[s]</del> <del>antimicrobial</del> [agents] <del>drugs</del> and should keep detailed records of all [medically important] <del>antimicrobials</del> <del>antimicrobial agents</del> supplied according to the national regulations including:	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
45.[43.] Distributors should encourage compliance with the national guidelines on the responsible use of <del>veterinary</del> [medically] <del>[human and veterinary medically important]</del> antimicrobial[s] <del>drugs</del> and should keep detailed records of all [medically important] antimicrobials supplied according to the national regulations including:	<b>OIE</b> <i>Category: TECHNICAL</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>date of supply</li> </ul>	
<ul style="list-style-type: none"> <li>name of prescribing veterinarian [, plant health professional, or other suitably trained and authorized person]</li> </ul>	
name of prescribing veterinarian [, plant health professional, or other suitably trained and authorized person]	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>name of user</li> </ul>	
<ul style="list-style-type: none"> <li>name of medicinal product</li> </ul>	
<ul style="list-style-type: none"> <li>batch number</li> </ul>	
<ul style="list-style-type: none"> <li>quantity supplied</li> </ul>	
<b>46.[44.] Distributors should participate in the training of users of <del>veterinary</del> antimicrobial drugs[agents] as defined in Paragraph 36[30].</b>	
46.[44.] Distributors should participate in the training of users of <del>veterinary</del> antimicrobial drugs[agents] as defined in Paragraph 36[30][30] Additional information on the standards on the responsibilities of wholesale and retail distributors can be found on Article 6.9.5 of the OIE Terrestrial Animal Health Code (2017) and Article 6.2.6 of the OIE Aquatic Animal Health Code (2017).	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>Responsibilities of Veterinarians<sup>15</sup> [and Plant Health Professionals]</b>	
	<b>China</b> Delete the section that coincides with the Terrestrial animal health code chapter 6.9.6. It is recommended to quote directly or briefly. All the veterinarians and plant health professionals should be trained by regulatory authorities.
	<b>Thailand</b> The term “Plant Health Professionals” should consult with specialized international bodies e.g. FAO, IPPC.
<b>Responsibilities of Veterinarians<sup>10</sup> [and Plant Health Professionals]</b>	<b>USA</b> The United States supports maintaining “plant health professionals” in square brackets. Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. <i>Category: TECHNICAL</i>

<sup>15</sup> Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>Responsibilities of Veterinarians<sup>10</sup> <del>[and, Plant Health Professionals]</del> <u>Professionals, Food Manufacturers, Food Processors, and Other Professionals Authorized to Prescribe/Administer Antimicrobial Agents</u></b>	<b>International Association of Consumer Food Organizations</b> The title should include all those who administer or prescribe antimicrobial agents. <i>Category: SUBSTANTIVE</i>
<b>Responsibilities of Veterinarians<sup>10</sup> <del>[and Plant Health Professionals]</del> <u>Manufacturers</u></b>	<b>ICGMA</b> Support Manufacturers as this seems to more clearly convey the party being discussed in this section. <i>Category: EDITORIAL</i>
<b>Responsibilities of Veterinarians<sup>10</sup> [and Plant Health Professionals]</b>	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<b>Responsibilities of Veterinarians<sup>10</sup> [and Plant Health Professionals]</b>	<b>International Feed Industry Federation</b> In the below paragraph, there is too much focus on veterinarian and not on plant health professionals. In addition, the text is not consistent when referring to 'veterinarian'. In most statements the wording "veterinarian, [plant health professional] or other suitably trained person" is used, but not always. <i>Category: SUBSTANTIVE</i>
<b>47.[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del>[biosecurity, improved production practices, and alternatives to antimicrobials].</b>	
47.[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [biosecurity, improved production practices, and alternatives to antimicrobials].	<b>Australia</b> Paragraphs 45 to 54 Comment: Suggest the following OIE chapters replace current text on responsibilities of veterinarians by reference in whole: Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals Rationale: Avoids duplication of international standards. Comment: Labelling requirements for veterinarians are not addressed in the document and should be included using an excerpt from the Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine. Rationale: Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine covers this topic. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
47-[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [biosecurity, improved production practices, and alternatives to antimicrobials].	<p><b>Australia</b></p> <p>If comments above rejected for paras 45-54 then, Paragraph 45</p> <p>Comment: The text states “the veterinarian and plant health professionals are responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease”.</p> <p>Rationale: The text is incongruous with other paragraphs in this section, as they intend for antibiotics to be prescribed by a veterinarian, but then it immediately allows for use by non-veterinarians.</p> <p>Category: <i>SUBSTANTIVE</i></p>
47-[45.] Los veterinarios [y los responsables de sanidad vegetal] son responsables de identificar las enfermedades recurrentes <del>y desarrollar e implementar</del> estrategias alternativas para prevenir o tratar enfermedades infecciosas. Esto puede incluir <del>cambios en las condiciones de cría del ganado y programas de vacunación cuando existan vacunas disponibles</del> [bioseguridad, mejora de las prácticas de producción y alternativas a los antimicrobianos.]	<p><b>Colombia</b></p> <p>Se considera un término más apropiado</p> <p>Category: <i>TECHNICAL</i></p>
47-[45.] Los veterinarios [y los responsables de sanidad vegetal] son responsables de identificar las enfermedades recurrentes y desarrollar estrategias alternativas para prevenir o tratar enfermedades infecciosas. Esto puede incluir <del>cambios en las condiciones de cría del ganado y programas de vacunación cuando existan vacunas disponibles</del> [bioseguridad, mejora de las prácticas de producción y alternativas a los antimicrobianos.] <del>cambios en las condiciones de cría del ganado y programas de vacunación cuando existan vacunas disponibles</del> [bioseguridad, mejora de las prácticas de producción y alternativas a los antimicrobianos.]	<p><b>Ecuador</b></p> <p>incluir nuevamente</p> <p>Category: <i>TECHNICAL</i></p>
47-[45.] 45. The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [ <u>biosecurity</u> , improved production practices, and alternatives to antimicrobials] <del>antimicrobials</del> .	<p><b>USA</b></p> <p>Paragraph 45: The United States supports maintaining “plant health professionals” in square brackets.</p> <p>Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR.</p> <p>Category: <i>TECHNICAL</i></p>
47-[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [biosecurity, improved production <del>practices</del> <u>practices including adequate nutrition</u> , and alternatives to antimicrobials]- <u>In developing adequate nutrition strategies, Veterinarians should seek advice from animal nutritionists and the feed industry, in accordance with the Code of Practice on Good Animal Feeding.</u>	<p><b>FEFAC</b></p> <p>To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases.</p> <p>Category: <i>TECHNICAL</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
47.[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [biosecurity, improved production practices, and alternatives to antimicrobials].	<b>ICGMA</b> Support maintaining brackets on plant health professionals and plant in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
47.[45.] The veterinarian is[ and plant health professionals are] responsible for identifying recurrent disease problems and developing alternative strategies to prevent or treat infectious disease. These may include <del>changes in husbandry conditions and vaccination programs where vaccines are available</del> [biosecurity, improved production practices, <u>adequate nutrition and alternatives to antimicrobials</u> ]. <u>In developing adequate nutrition strategies, Veterinarians should seek advice from nutritionists and the feed industry, in accordance with the Code of Practice on Good Animal Feeding.</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[46. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.6 – Responsibilities of veterinarians.]</b>	
[46. For more information on antimicrobial drugs for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.6 – Responsibilities of veterinarians.] <u>And Code of responsible and prudent antimicrobial agent use.</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[46. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code Chapter 6.9.6 – Responsibilities of veterinarians.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
[46. For more information on antimicrobial <del>drugs</del> <u>agents</u> for food-producing animals see the OIE Terrestrial Animal Health Code (2017) Chapter 6.9 Responsible and prudent use of antimicrobial <u>agents in veterinary medicine Article 6.9.6 – Responsibilities of veterinarians</u> , veterinarians and the OIE Aquatic Animal Health Code (2017) Chapter 6.2 Principles for responsible and prudent use of antimicrobial agents in aquatic animals, Article 6.2.7 Responsibilities of veterinarians and other aquatic animal health professionals.]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>48. <del>Veterinary antimicrobial drugs should only be prescribed for animals under his/her care, which means that:</del></b>	
<ul style="list-style-type: none"> <li><del>• the veterinarian has been given responsibility for the health of the animal or herd/flock by the producer or the producer's agent;</del></li> <li><del>• that responsibility is real and not merely nominal;</del></li> <li><del>• that the animal(s) or herd/flock have been seen immediately before the prescription and supply, or</del></li> <li><del>• recently enough for the veterinarian to have personal knowledge of the condition of the animal(s) or current health status of the herd or flock to make a diagnosis and prescribe; and</del></li> <li><del>• the veterinarian should maintain clinical records of the animal(s) or the herd/flock.</del></li> </ul>	
<b>49.[47.] It is recommended that <del>veterinary professional organizations develop for their members species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs</del>[species or sector-specific responsible and prudent antimicrobial use guidelines].</b>	
49.[47.] Se recomienda a las organizaciones profesionales <del>veterinarias</del> elaborar para sus miembros <del>directrices de prácticas clínicas específicas para cada especie sobre el uso responsable de los medicamentos veterinarios antimicrobianos</del> [directrices para un uso responsable y prudente de antimicrobianos específicas por especie o sector.], <u>con el aval de las autoridades competentes.</u>	<b>Colombia</b> Con el fin de que las normas se adapten a las regulaciones emitidas por las autoridades de cada país. <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
49.[47.] It is recommended that <del>veterinary</del> <b>national</b> professional organizations develop for their members <del>species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs</del> [species or sector-specific responsible and prudent antimicrobial use guidelines].	<b>Japan</b> Rationale: Japan proposes to add “national” for clarifying the meaning of the sentence. <i>Category: SUBSTANTIVE</i>
49.[47.] It is recommended that <del>veterinary</del> professional organizations develop for their members <del>species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs</del> [species or sector-specific responsible and prudent antimicrobial use guidelines].	<b>USA</b> Paragraph 47: “Global Action Plan” needs a complete reference and/or to be added to definitions. Rationale: This is the first time this term appears in the text and should be referenced. <i>Category: TECHNICAL</i>
49.[47.] It is recommended that <del>veterinary</del> professional organizations develop for their members <del>species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs</del> [species or sector-specific <del>responsible and prudent antimicrobial use</del> <u>treatment guidelines</u> ].	<b>Consumers International</b> In order to be consistent with CAC/GL77 (Table 1, page 15), use “treatment guidelines” rather than “responsible and prudent antimicrobial use guidelines.” <i>Category: EDITORIAL</i>
49.[47.] It is recommended that <del>veterinary</del> professional organizations develop for their members <del>species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial drugs</del> [species or sector-specific responsible and prudent antimicrobial <u>agent</u> use guidelines].	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[Within the national action plans, which countries are developing under the Global Action Plan, there should be the recommendation to develop species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial agents. These guidelines would be created by the sector specific veterinary professional organizations.]</b>	
	<b>Thailand</b> We support the development of species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial agents.
[Within the national action plans, which countries are developing under the Global Action Plan, there should be the recommendation to develop species-specific <del>clinical practice guidelines on the responsible use of veterinary antimicrobial agents</del> <u>treatment guidelines</u> . These guidelines would be created by the sector specific veterinary professional organizations.]	<b>Consumers International</b> In order to be consistent with CAC/GL77 (Table 1, page 15), use “treatment guidelines” rather than “responsible and prudent antimicrobial use guidelines.” <i>Category: EDITORIAL</i>
[Within the national action plans, which countries are developing under the Global Action Plan, there should be the recommendation to develop species-specific clinical practice guidelines on the responsible use of veterinary antimicrobial agents. These guidelines would be created by the sector specific veterinary professional <del>organizations</del> <u>organisations and be based on OIE standards.</u> ]	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>50.[48.] <del>Veterinary a</del>[A]ntimicrobial <del>drugs</del>[agents] should only be used when necessary and in an appropriate manner:</b>	
50.[48.] <del>Veterinary a</del> [A]ntimicrobial <del>drugs</del> [agents] should only be used when <del>necessary</del> <u>no other alternative strategies are available</u> and in an appropriate manner:	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>A prescription [or order for application] for <del>veterinary</del>[medically important] antimicrobial[s] <del>drugs</del> must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period[, when appropriate,] and the amount of antimicrobial to be delivered depending on the dosage, <del>the number, and the weight of the animals</del>[and the characteristics of the individual or population] to be treated;</li> </ul>	
<p>A prescription [or order for application] for <del>veterinary</del>[medically important] antimicrobial[s] <u>used for therapeutic purposes</u> <del>drugs</del> <u>should</u> must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period[, when appropriate,] and the amount of antimicrobial to be delivered depending on the dosage, <del>the number, and the weight of the animals</del>[and the characteristics of the individual or population] to be treated;</p>	<p><b>Japan</b> Rationale: While strict control by prescription is required for antimicrobials used for therapeutic purposes, national regulatory control may be sufficient for others. “Must” needs to be replaced with “should” for consistent use of terms. <i>Category: SUBSTANTIVE</i></p>
<p>A prescription [or order for application] for <del>veterinary</del>[medically important] antimicrobial[s] <del>drugs</del> <u>agent</u> must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period[, when appropriate,] and the amount of antimicrobial to be delivered depending on the dosage, <del>the number, and the weight of the animals</del>[and the characteristics of the individual or population] to be treated;</p>	<p><b>USA</b> Paragraph 48: The word antimicrobial should be followed by the word “agent” in the first and third bullet. Rationale: The edit is consistent with the definition of the term. <i>Category: TECHNICAL</i></p>
<p>A prescription [or order for application] for <del>veterinary</del>[medically important] antimicrobial[s] <del>drugs</del> must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period[, when appropriate,] and the amount of antimicrobial to be delivered depending on the dosage, <del>the number, and the weight of the animals</del>[and the characteristics of the individual or population] to be treated;</p>	<p><b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i></p>
<p>A prescription [or order for application] for <del>veterinary</del>[medically [human or medically important] antimicrobial[s] <del>drugs</del> must precisely indicate the treatment regimen, the dose, the dosage intervals, the duration of the treatment, the withdrawal period[, when appropriate,] and the amount of antimicrobial to be delivered depending on the dosage, <del>the number, and the weight of the animals</del>[and the characteristics of the individual or population] to be treated;</p>	<p><b>OIE</b> <i>Category: TECHNICAL</i></p>
<ul style="list-style-type: none"> <li>[The delivered amount should be limited only for the treatment concerned. It should also indicate the animal keeper/owner and the identification of the animal(s) to be treated;]</li> </ul>	
<ul style="list-style-type: none"> <li>All <del>veterinary [medically important]</del> antimicrobial[s] <del>drugs</del> should be prescribed [or applied] and used according to [label directions and] the conditions stipulated in the national legislation.</li> </ul>	
<p>All <del>veterinary [medically important]</del> antimicrobial[s] <del>drugs</del> should be prescribed [or applied] and used according to [label directions and] the conditions stipulated in the national <del>legislation</del><u>legislation and species-specific clinical practice guidelines, when available.</u></p>	<p><b>Brazil</b> <i>Category: SUBSTANTIVE</i></p>
<p>All <del>veterinary [medically important]</del> antimicrobial[s] <u>used for therapeutic purposes</u> <del>drugs</del> should be prescribed [or applied] and used according to [label directions and] the conditions stipulated in the national legislation.</p>	<p><b>Japan</b> Rationale: While strict control by prescription is required for antimicrobials used for therapeutic purposes, national regulatory control may be sufficient for others. “Must” needs to be replaced with “should” for consistent use of terms. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
All <del>veterinary [medically important] antimicrobial[s] drugs/drugs agents</del> should be prescribed [or applied] and used according to [label directions and] the conditions stipulated in the national legislation.	<b>USA</b> <i>Category: TECHNICAL</i>
<b>51-[49.] [For food-producing animals, the]The appropriate use of <del>veterinary [medically important] antimicrobial[s] drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.</b>	
51-[49.] <del>For. For</del> food-producing animals, the]theThe appropriate use of <del>veterinary [medically important] antimicrobial[s] drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal <del>welfare</del> health.	<b>USA</b> Rationale: Animal health is more appropriate to the context of administering antimicrobials related to disease. <i>Category: TECHNICAL</i>
51-[49.] [For food-producing animals, the]The appropriate use of <del>veterinary [medically important] antimicrobial[s] drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare. <u>Medically important antibiotics should not be used routinely in food production when there is no diagnosis of disease.</u>	<b>Consumers International</b> The added sentence clarifies the intent of the previous sentence and is consistent with the recently released WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals. <i>Category: EDITORIAL</i>
51-[49.] [For food-producing animals, the]The appropriate use of <del>veterinary [medically important] antimicrobial[s] drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated <del>without recourse</del> without or prior to an accurate <u>obtaining a definitive</u> diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.	<b>FAO</b> <i>Category: EDITORIAL</i>
51-[49.] [For food-producing animals, the]The appropriate use of <del>veterinary [medically important] antimicrobial[s] drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
51-[49.] [For food-producing animals, the]The appropriate use of <del>veterinary [medically important] antimicrobial[s] agents</del> <u>drugs</u> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures.	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.	
51.[49.] [For food-producing animals, the]The appropriate use of <del>veterinary</del> [medically important] antimicrobial[s] <del>drugs</del> in practice is a clinical decision which should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic <del>procedures</del> procedures following the responsible use standards published on the OIE Terrestrial Animal Health Code (2017) Chapter 6.9 Responsible and prudent use of antimicrobial agents in veterinary medicine and OIE Aquatic Animal Health Code (2017) Chapter 6.2 Principles for responsible and prudent use of antimicrobial agents in aquatic animals. There will be occasions when a group of animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.	<b>OIE</b> Category: <i>TECHNICAL</i>
<b>52.[50.] Determination of the choice of a <del>veterinary</del> antimicrobial [agents] <del>drug</del> by:</b>	
52.[50.] Determination of the choice of a <del>veterinary</del> antimicrobial [agents] <del>agents</del> drug by:	<b>USA</b> Category: <i>TECHNICAL</i>
<ul style="list-style-type: none"> <li><b>The expected efficacy of the treatment based on:</b> <ul style="list-style-type: none"> <li><b>the <del>clinical</del> clinical experience of the veterinarian [, plant health professional or suitably trained and authorized person];</b></li> </ul> </li> </ul>	
the <del>clinical</del> clinical and/or experience of the veterinarian [, plant health professional or suitably trained and authorized person];	<b>Indonesia</b> Category: <i>TECHNICAL</i>
the <del>clinical</del> experience of the veterinarian [, plant health <del>professional</del> professional] or suitably trained and authorized person];	<b>USA</b> Paragraph 50: The United States supports maintaining “plant health professionals” in square brackets. Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR.
the <del>clinical</del> experience <u>and professional knowledge</u> of the veterinarian [, plant health professional or suitably trained and authorized person];	<b>FAO</b> Consider that it is important to recognize the knowledge that these professional bring to the decision making process Category: <i>TECHNICAL</i>
the <del>clinical</del> experience of the veterinarian [, plant health professional or suitably trained and authorized person];	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. Category: <i>SUBSTANTIVE</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>⊖ the spectrum of the antimicrobial activity towards the pathogens involved;</li> </ul>	
<ul style="list-style-type: none"> <li>⊖ the epidemiological history of the rearing[production] unit particularly in regards to the antimicrobial resistance profiles of the pathogens involved. Ideally[Whenever possible], the antimicrobial profiles should be established before the commencement of treatment. [If this is not possible, samples should nevertheless be taken before start of the treatment to allow, if necessary, for adjustment of therapy based on sensitivity testing.] Should a first antimicrobial treatment fail or should the disease recur, the use of a second veterinary antimicrobial drug[agent] should be based on the results of microbiological tests;</li> </ul>	
<ul style="list-style-type: none"> <li>⊖ the appropriate route of administration;</li> </ul>	
<ul style="list-style-type: none"> <li>⊖ results of initial treatment;</li> </ul>	
<ul style="list-style-type: none"> <li>⊖ [ previous published scientific information on the treatment of the specific disease;]</li> </ul>	
<ul style="list-style-type: none"> <li>⊖ <del>known pharmacokinetics/tissue distribution to ensure that the selected veterinary antimicrobial drug is active at the site of infection;</del></li> </ul>	
<ul style="list-style-type: none"> <li>⊖ <del>prognosis[the likely course of the disease].</del></li> </ul>	
<ul style="list-style-type: none"> <li>• The need to minimize the adverse health impact from the development of microbial resistance based on:                             <ul style="list-style-type: none"> <li>○ the choice of the activity spectrum of the veterinary antimicrobial drug[agent] [(narrow-spectrum antimicrobials should be a preferred choice whenever possible/appropriate)];</li> <li>○ the targeting of specific microorganism;</li> <li>○ known or predictable susceptibilities using antimicrobial susceptibility testing;</li> <li>○ optimized dosing regimens;</li> <li>○ the use of effective combinations of veterinary antimicrobial drugs[agents];</li> <li>○ the importance of the antimicrobial drugs to veterinary and human medicine; and,</li> <li>○ the route of administration.</li> </ul> </li> </ul>	
<p><del>53. If the label conditions allow for some flexibility, the veterinarian should consider a dosage regimen that is long enough to allow an effective recovery of the animal but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.</del></p>	
OFF-LABEL USE	
<p>54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of [medically important] antimicrobial growth promoters should not be permitted.</p>	
<p>54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. <u>The restriction of off-label use of certain antimicrobial agents or uses of antimicrobial agents is an important risk management tool for competent authorities.</u> Off-label use of [medically important] antimicrobial growth promoters should not be permitted.</p>	<p><b>Consumers International</b>                      The added sentence is consistent with Table 1 of CAC/GL-77 and clarifies that the decision to use a drug off-label is not solely in the hands of veterinarians.                      Category: <i>SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. <u>Off-label use of [medically important] antimicrobial growth promoters <del>antimicrobials</del> should not be permitted.</u>	<b>FAO</b> Edited to try to improve clarity <i>Category: EDITORIAL</i>
54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug <u>should be avoided as far as possible, but</u> may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. <u>Off-label use of [medically important] antimicrobial <del>antimicrobials</del> for growth promoters <u>and/or routine use for disease prevention</u> should not be permitted.</u>	<b>International Association of Consumer Food Organizations</b> IACFO supports the inclusion of "exceptional" and recommends that the text be further strengthened. <i>Category: SUBSTANTIVE</i>
54.[51.] [For food-producing animals, the]The off-label use of <del>a veterinary</del> <u>an antimicrobial drug agent</u> may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of [medically important] antimicrobial growth promoters should not be permitted.	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. <u>following the standards published on the OIE Terrestrial Animal Health Code (2017) Chapter 6.9 Responsible and prudent use of antimicrobial agents in veterinary medicine, article 6.9.6 Responsibilities of veterinarians, and the OIE Aquatic Animal Health Code (2017) Chapter 6.2 Principles for responsible and prudent use of antimicrobial agents in aquatic animals, article 6.2.7 Responsibilities of veterinarians and other aquatic animal health professionals.</u> Off-label use of [medically important] antimicrobial growth promoters should not be permitted.	<b>OIE</b> During the meeting, we would like to clarify the sentence: "Off-label use of [medically important] antimicrobial growth promoters should not be permitted." <i>Category: TECHNICAL</i>
<b>[Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents.]</b>	
[Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents.]	<b>FAO</b> May also need to consider other aspects here such as off label use in plants and Bees (perhaps already covered under vet AM) <i>Category: TECHNICAL</i>
[Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use <del>of veterinary</del> <u>of antimicrobial agents</u> <del>agents for food producing animals.</del> ]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>RECORDING</b>	
<b>55.[52.] [For food-producing animals, records]Records on veterinary antimicrobial drugs should be kept in conformity with national legislation. Veterinarians may refer to recording information as covered in the relevant national legislation.<sup>46</sup></b>	
55.[52.] [For food-producing animals, records]Records on <del>veterinary antimicrobial drugs</del> <u>agents</u> should be kept in conformity with national legislation. Veterinarians may refer to recording information as covered in the relevant national legislation. <sup>44</sup>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>In particular, for investigation of antimicrobial resistance, veterinarians should:</b>	
<ul style="list-style-type: none"> <li>record the antimicrobial susceptibility testing results;</li> <li>investigate adverse reactions to veterinary antimicrobial drugs, including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities [(through a pharmacovigilance system)].</li> </ul>	
investigate adverse reactions to <del>veterinary antimicrobial drugs</del> <u>agents</u> , including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities [(through a pharmacovigilance system)].	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>56.[53.] [For food-producing animals, veterinarians]Veterinarians should also periodically review farm records on the use of veterinary antimicrobial drugs to ensure compliance with their directions.</b>	
56.[53.] [For food-producing animals, veterinarians]Veterinarians should also periodically review farm records on the use of <del>veterinary antimicrobial drugs</del> <u>agents</u> to ensure compliance with their directions.	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
56.[53.] [For food-producing animals, veterinarians]Veterinarians should also periodically review <del>farm records on follow the use of veterinary antimicrobial drugs to ensure compliance with their directions.</del> <u>standards published on the OIE Terrestrial Animal Health Code (2017) Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals Article 6.8.3 Development and standardisation of monitoring systems of antimicrobial agents, and on the Aquatic Animal Health Code (2017) Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals Article 6.3.3 Development and standardisation of monitoring systems of antimicrobial agents.</u>	<b>OIE</b> <i>Category: TECHNICAL</i>
56.[53.] [For food-producing animals, veterinarians]Veterinarians should also periodically review farm records on the use of veterinary antimicrobial drugs to ensure compliance with their directions, <u>follow the standards published on sections “Development and standardization of monitoring systems of antimicrobial agents”, 6.8.3 on the OIE Terrestrial Animal Health Code (2017) and 6.3.3 on the Aquatic Animal Health Code (2017).</u>	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>TRAINING</b>	
<b>57.[54.] Veterinary p[P]rofessional organizations should participate in the training of users of veterinary antimicrobial drugs[agents] as defined in Paragraph 36[31].</b>	
<b>Responsibilities of Producers</b>	

<sup>46</sup> Veterinarians can also refer to the “Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993.”

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p><b>China</b></p> <p>Delete the section that coincides with the Terrestrial animal health code chapter 6.9.7. It is recommended to quote directly or briefly.</p> <p>Delete the probiotics in para 57, because some of the probiotics carry antimicrobial resistance gene and can transfer resistant gene to other bacterial.</p>
<p><b>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</b></p>	
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>Australia</b></p> <p>Paragraphs 55 and 56</p> <p>Comment: The text states in different places, “prescribed by a veterinarian or other suitably trained person authorized...”.</p> <p>Rationale: The text is incongruous, as it states that antibiotics should be prescribed by a veterinarian and then immediately allows for use by non-veterinarians.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>Australia</b></p> <p>If above comment on paras 55-56 rejected then,</p> <p>Paragraph 55</p> <p>Comment: suggest the last sentence should be moved to the Introduction.</p> <p>Rationale: The location and intent of this sentence is out of place and would provide a good, overarching sentence in the Introduction.</p> <p><i>Category: SUBSTANTIVE</i></p>
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>Australia</b></p> <p>Paragraphs 55 to 56</p> <p>Comment: Suggest the following OIE chapters replace the current text by reference in whole:</p> <p>Terrestrial Animal Health Code, Chapter 6.9, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine</p> <p>Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals</p> <p>Rationale: Avoids duplication of international standards. This text will also adequately cover the transmission of resistant bacteria to food processing workers.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. <del>They</del> <u>They may, as appropriate,</u> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>Brazil</b> Category: <i>SUBSTANTIVE</i></p>
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p> <p><b>[55 bis] For more information on the responsibilities of producers, see the OIE Terrestrial Animal Health Code Chapter 6.9.(Responsible and prudent use of antimicrobial agents in veterinary medicine) Article 6.9.6 – (Responsibilities of food animal producers).</b></p>	<p><b>Japan</b> Rationale: Japan proposes to add a reference to the OIE Code for consistency. Category: <i>SUBSTANTIVE</i></p>
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>Russian Federation</b> We propose to supply the paragraph 55 with regulations to ban the use of antimicrobials as growth supplements in the animal husbandry, aquaculture, etc. Category: <i>SUBSTANTIVE</i></p>
<p>58.<del>[55]</del>55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare <del>animal health</del> programmes on their farms. They <del>may, as appropriate,</del> <del>[should]</del> <u>should</u> call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del><del>[the the food chain]</del> <u>chain</u> have an important part to play in [preventing <del>preventing</del> disease and] ensuring the responsible [<del>and and</del> prudent] use of <del>veterinary antimicrobial drugs</del><del>[agents]</del> <u>agents</u>.</p>	<p><b>USA</b> Rationale: Animal health is more appropriate to the context of administering antimicrobials related to disease. The United States supports maintaining “plant health professionals” in square brackets. Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. Category: <i>TECHNICAL</i></p>
<p>58.[55.] Producers are responsible for preventing disease outbreaks and implementing <u>animal health and welfare</u> programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del>[the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary antimicrobial drugs</del>[agents].</p>	<p><b>ICGMA</b> Animal welfare is not the subject of this document and could confuse the meaning of what is being discussed in this paragraph. Category: <i>SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person authorized in accordance with national legislation. All people involved with <del>food-producing animals</del> [the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary</del> antimicrobial <del>drugs</del> [agents].	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
58.[55.] Producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health <del>professional</del> professionals] or other suitably trained <del>person</del> persons authorized in accordance with national legislation. All people involved with <del>food-producing animals</del> [the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary</del> antimicrobial <del>drugs</del> [agents].	<b>International Feed Industry Federation</b> <i>Category: EDITORIAL</i>
58.[55.] <del>Producers</del> Food animal and plant producers are responsible for preventing disease outbreaks and implementing health and welfare programmes on their farms. They <del>may, as appropriate,</del> [should] call on the assistance of <del>their</del> veterinarian[, plant health professional] or other suitably trained person <del>authorized</del> authorised in accordance with national legislation. All people involved with <del>food-producing animals</del> [the food chain] have an important part to play in [preventing disease and] ensuring the responsible [and prudent] use of <del>veterinary</del> antimicrobial <del>drugs</del> [agents].	<b>OIE</b> <i>Category: TECHNICAL</i>
<b>59.[56.] Producers of food-producing animals have the following responsibilities:</b>	
59.[56.] Producers of <del>food-producing animals</del> have the following responsibilities:	<b>Australia</b> Paragraph 56 Comment: Australia recommends no further expansion in the scope of producers covered by the document. Rationale: The proposed actions for producers listed are appropriate and sufficient for food producing industries in Australia. Comment: Further clarification is requested on the need to delete the sentence, “to isolate sick animals and dispose of dead or dying animals promptly under conditions approved by relevant authorities;” Comment: Combine the dot point starting with “to address hygienic conditions regarding contacts...” with the second last dot point, “to prevent the unnecessary contact with and transmission of...” into a dot point as follows: To adopt appropriate hygiene measures to prevent unnecessary contact with and transmission of resistant bacteria to all personnel, including farm and food processing workers; Rationale: Avoids duplication within the text. <i>Category: SUBSTANTIVE</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
59.[56.] Los productores de animales de los que se obtienen alimentos tienen las siguientes responsabilidades:	<b>Ecuador</b> Recurrir a un médico veterinario, un profesional de sanidad vegetal o de otra debidamente capacitada y autorizada de conformidad con las leyes nacionales, para que evalúe, diagnostique cualquier sospecha de enfermedad y sea quien prescriba los agentes antimicrobianos que deban usarse, de ser el caso. <i>Category: TECHNICAL</i>
59.[56.] Producers of food-producing animals have the following responsibilities:	<b>USA</b> The United States supports maintaining “plant health professionals” in square brackets. Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. <i>Category: TECHNICAL</i>
<ul style="list-style-type: none"> <li>to use <del>veterinary</del> antimicrobial drugs[agents] only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods such as vaccination;</li> </ul>	
to use <del>veterinary</del> antimicrobial drugs[agents] only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods such as <del>vaccination</del> <u>vaccination and integrated pest management practices</u> ;	<b>FAO</b> propose to include an example from the plant sector. <i>Category: TECHNICAL</i>
to use <del>veterinary</del> antimicrobial drugs[agents] only when necessary and not as a replacement for good management and farm hygiene, <u>adequate nutrition</u> , or other disease prevention methods such as vaccination;	<b>FEFAC</b> To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases. <i>Category: TECHNICAL</i>
to use <del>veterinary</del> antimicrobial drugs[agents] only when necessary and not as a replacement for good management and farm hygiene, <u>adequate nutrition</u> or other disease prevention methods such as <u>adequate animal nutrition or vaccination</u> ;	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>to implement a health plan in cooperation with the veterinarian [, plant health professional, or other suitably trained person authorized in accordance with national legislation] <del>in charge of the animals that outlines preventative measures (e.g. mastitis plan, worming and vaccination programmes, etc.);</del></li> </ul>	
to implement a health plan in cooperation with the veterinarian [, plant health professional, or other suitably trained person authorized in accordance with national legislation] <del>in charge of the animals that outlines preventative measures (e.g. mastitis plan, worming and vaccination programmes, etc.);</del>	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>to use <del>veterinary</del> antimicrobial drugs[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 health professional or other suitably trained person authorized in accordance with national legislation] familiar with the animals <del>and</del>[or] the production site;</li> </ul>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
to use <del>veterinary</del> <u>veterinary</u> antimicrobial <del>drugs</del> [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 health professional or other suitably trained person authorized in accordance with national legislation] familiar with the animals <del>and</del> [or] the production site;	<b>Indonesia</b> <i>Category: TECHNICAL</i>
to use <del>veterinary</del> <u>veterinary</u> antimicrobial <del>drugs</del> [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 health professional or other suitably trained person authorized in accordance with national legislation] familiar with the animals <del>and</del> [or] the production site;	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <del>to isolate sick animals and dispose of dead or dying animals promptly under conditions approved by relevant authorities;</del></li> <li>• <del>to comply with the storage conditions of</del> <u>veterinary antimicrobial drugs</u>[agents] according to the approved product labelling;</li> <li>• <del>to address hygienic conditions regarding contacts between people (veterinarians, [plant health professionals,] breeders, owners, children) and the animals</del>[populations] treated;</li> </ul>	
to address hygienic conditions regarding contacts between people (veterinarians, [plant health professionals,] breeders, owners, children) and the <del>animals</del> [populations] treated;	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <del>to comply with the recommended withdrawal periods to ensure that residue levels in animal derived</del>[the] food do not present a risk for the consumer;</li> <li>• <del>to not use out-of-date</del> <u>veterinary antimicrobial drugs</u>[agents] and to dispose of all unused <u>veterinary antimicrobial drugs</u>[agents] in accordance with the provisions on the product labels [and national legislation];</li> <li>• <del>to inform the veterinarian</del>[, plant health professional, or other suitably trained person authorized in accordance with national legislation] in charge of the [production] unit of recurrent disease problems;</li> </ul>	
to inform the veterinarian[, plant health professional, or other suitably trained person authorized in accordance with national legislation] in charge of the [production] unit of recurrent disease problems;	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <del>to maintain all clinical and laboratory records of microbiological and susceptibility tests if required by the national regulatory authority. These data should be made available to the veterinarian</del>[professional] in charge of <del>treating the animals</del>[treatment] in order to optimize the use of <u>veterinary antimicrobial drugs</u>[agents].</li> </ul>	
to maintain all clinical and laboratory records of microbiological and susceptibility tests <u>in consultation with the health professional</u> <del>if required by the national regulatory authority</del> . These data should be made available to the <del>veterinarian</del> [professional] <u>professional</u> in charge of <del>treating the animals</del> [treatment] <u>treatment</u> in order to optimize the use of <del>veterinary</del> antimicrobial <del>drugs</del> [agents].	<b>USA</b> The United States recommends inserting “in consultation with the health professional” in the tenth bullet. The bullet should read as, “to maintain all clinical and laboratory records of microbiological and susceptibility tests in consultation with the health professional.” Rationale: Because the health professional may be the one who actually submits the request for diagnostic testing, clinical and laboratory results may also reside within the records of the health professional. The recommended edit would address this situation. <i>Category: TECHNICAL</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> <li>• to keep adequate records of all <del>veterinary</del> antimicrobial drugs[agents] used, including the following: <ul style="list-style-type: none"> <li>○ name of the <del>veterinary</del> antimicrobial drug[agent]/active substance and batch number;</li> <li>○ name of supplier;</li> <li>○ date of administration;</li> <li>○ identification of the <del>animal or group of animals</del>[production unit] to which the <del>veterinary</del> antimicrobial drug[agent] was administered;</li> <li>○ <del>clinical conditions</del>[disease] treated;</li> <li>○ quantity and duration of the antimicrobial agent administered;</li> <li>○ withdrawal periods;</li> <li>○ result of laboratory tests;</li> <li>○ result of treatment;</li> <li>○ name of the prescribing veterinarian [, plant health professional] or other suitably trained person authorized in accordance with national legislation.</li> </ul> </li> </ul>	
name of the prescribing <del>medical doctor</del> , veterinarian [, plant health professional] or other suitably trained person authorized in accordance with national legislation.	<b>Indonesia</b> Category: <i>TECHNICAL</i>
name of the prescribing veterinarian [, plant health professional] or other suitably trained person authorized in accordance with national legislation.	<b>ICGMA</b> Support maintaining brackets on plant health professionals in this section pending outcome of scientific advice. Category: <i>SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• To ensure sound management of animal wastes and other materials to avoid [minimize] dissemination of antimicrobial agents and resistance determinants into the environment;</li> <li>• To prevent the unnecessary contact with and transmission of resistant bacteria to all personnel, including farm workers;</li> <li>• To assist the relevant authorities in surveillance programs related to antimicrobial resistance.</li> </ul>	
<p><b>[57. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and other measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.]</b></p>	
<p>[57. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and other measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.]</p>	<p><b>Australia</b> Paragraphs 57 to 58 Comment: Suggest be made General Principles. Rationale: These paragraphs have broad applicability to other stakeholders. Category: <i>SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[5757. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and other measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.]</del>	<b>USA</b> <i>Category: TECHNICAL</i>
[57. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of <del>vaccines and other measures</del> <u>vaccines, maintenance of a good health status through adequate nutrition strategies such as low protein diets or management of diet transition as well as the use of probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or flourish, competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens), clays, phytogenics, bacteriophages, etc.</u> should be considered and applied wherever appropriate and available.]	<b>FEFAC</b> To reflect the importance of adequate nutrition as key element to enhance resistance of animals to diseases. Adequate nutrition is not just with the use of specific ingredients exerting certain functions but also with feed formulation. <i>Category: SUBSTANTIVE</i>
[57. The responsible and prudent use of <del>antimicrobials</del> <u>antimicrobial agents</u> must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of <del>antibiotics</del> <u>antimicrobial agents</u> used. Efforts should aim to improve health, thereby reducing the need for <del>antibiotics</del> <u>antimicrobial agents</u> . This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing <u>adequate nutrition strategies and</u> national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and <del>other</del> <u>maintenance of a good health status through adequate nutrition, including</u> measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[58. Concerted efforts of all stakeholders within the entire food chain is required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants.</b>	
<del>[5858. Concerted efforts of all stakeholders within the entire food chain is required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants.</del>	<b>USA</b> <i>Category: EDITORIAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>Food processing industry, food retailers and consumers should take necessary action in accordance with the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).]</b>	
<b>[Responsibilities of Consumers]</b>	
<b>[Responsibilities of Consumers]</b>	<p><b>Brazil</b></p> <p>This item should address responsibilities of competent authorities and food industry to provide advice on appropriate cooking and handling instructions that can help to mitigate possible risks of foodborne AMR. It also should address the five WHO keys for safe food: keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperatures, use safe water and raw materials. <i>Category: SUBSTANTIVE</i></p>
	<p><b>China</b></p> <p>It is suggested to change para 59 to “Safely cook the fresh products such as beef, pork, lamp and poultry. When possible, use a food thermometer to ensure that foods are cooked to a safe internal temperature</p>
<b>[Responsabilidades de los consumidores]</b>	<p><b>Ecuador</b></p> <p>Eliminar, debido a que es de difícil aplicación.</p> <p>Usar un termómetro alimentario para asegurarse de que los alimentos se cocinan hasta alcanzar una temperatura interna segura; 145°F (63°C) para piezas enteras de carne de bovino, cerdo, cordero y ternera (dejando reposar la carne durante 3 minutos antes de cortarla y consumirla), 160°F (71°C) para carne molida y 165°F (74°C) para todas las carnes de aves de corral, entre ellas el pollo y el pavo molidos.</p> <p><i>Category: TECHNICAL</i></p>
<b>[59. Consumers have an important role to play to minimize and control antimicrobial resistance. By practicing safe food handling techniques, following health recommendations, and maintaining awareness of antimicrobial resistance information, consumers can minimize the risk of contracting and spreading infectious bacteria thereby further reducing the need for antibacterials. Consumer should:</b>	
[59. Consumers have an important role to play to minimize and control antimicrobial resistance. By practicing safe food handling techniques, following health recommendations, and maintaining awareness of antimicrobial resistance information, consumers can minimize the risk of contracting and spreading infectious bacteria thereby further reducing the need for antibacterials. Consumer should:	<p><b>Australia</b></p> <p>Paragraph 59</p> <p>Comment: This section should be renamed to ‘Education of Consumers’.</p> <p>Rationale: This section is not clear how consumers can have a role in the antimicrobial resistance response, noting their position at the end of the food supply chain. As apart from human and animal health professionals being regulated, consumers cannot be regulated. Any key decision about the use of antimicrobial agents have been made by this point. It is not appropriate for this document to present a position where consumers are encouraged to resist/oppose the use of products that have been subject to a scientific risk assessment and considered safe and appropriate for use within a jurisdiction. <i>Category: SUBSTANTIVE</i></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[59. Consumers have an important role to play to minimize and control <u>foodborne antimicrobial resistance</u> . By practicing safe food handling techniques, following health recommendations, and maintaining awareness of antimicrobial resistance information, consumers can minimize the risk of contracting and spreading infectious bacteria thereby further reducing the need for antibacterials. <u>Consumer should:</u>	<b>Brazil</b> <i>Category: SUBSTANTIVE</i>
[59. Consumers have an important role to play to minimize and control antimicrobial resistance. By practicing safe food handling techniques, following health recommendations, and maintaining awareness of antimicrobial resistance information, consumers can minimize the risk of contracting and spreading infectious bacteria thereby further reducing the need for antibacterials. Consumer should:	<b>Canada</b> Para 59. The first bullet “Take antibiotics only when needed” is considered out of the context and suggested to be deleted. Instead, consumers should be expected to maintain awareness of antimicrobial resistance information. The seventh bullet “Report suspected outbreaks of illness from food to local health department” is not considered appropriate for consumers. <i>Category: EDITORIAL</i>
[59. Consumers <u>and consumer organizations</u> have an important role to play to minimize and control antimicrobial resistance. By practicing safe food handling techniques, following health recommendations, and maintaining awareness of antimicrobial resistance information, consumers can minimize the risk of contracting and spreading infectious bacteria <u>and other microorganisms</u> , including those that are resistant to antimicrobials, thereby <u>preventing illness and</u> further reducing the need for <u>antibacterials/antimicrobials</u> . Consumer should:	<b>International Association of Consumer Food Organizations</b> While the primary responsibilities for minimizing and containing antimicrobial resistance lie with industry, as well as government, IACFO welcomes the addition of a section addressing consumers. The paragraph as drafted is aimed at minimizing “the risk of contracting and spreading infectious bacteria thereby further reducing the need for antibacterials.” In addition, food can be contaminated with antimicrobial resistant microorganisms and/or resistance determinants, and consumers can take measures to protect themselves from these resistant organisms and determinants by following appropriate hygienic measures. Finally, consumer organizations also play a role in educating consumers about safe food handling procedures and other actions they can take. <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <b>Take antibiotics only when needed;</b></li> </ul>	
<del>Take antibiotics only when needed;</del>	<b>Brazil</b> <i>Category: EDITORIAL</i>
Take antibiotics only when <del>needed</del> <u>prescribed by a health care professional</u> ;	<b>FAO</b> Suggest that it needs to be clear that it is not the consumer to decide when needed. <i>Category: TECHNICAL</i>
Take antibiotics only when <del>needed</del> <u>needed (e.g., never for a viral infection such as the flu or common cold), and finish the entire course of treatment. The more you take an antibiotic unnecessarily, the more likely bacteria can adapt and become resistant to it;</u>	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <b>Use a food thermometer to ensure that foods are cooked to a safe internal temperature: 145°F (63°C) for whole beef, pork, lamb, and veal (allowing the meat to rest for 3 minutes before carving or consuming), 160°F (71°C) for ground meats, and 165°F (74°C) for all poultry, including ground chicken and ground turkey;</b></li> </ul>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Use a food thermometer to ensure that foods are cooked to a safe internal temperature: 145°F (63°C) for whole beef, pork, lamb, and veal (allowing the meat to rest for 3 minutes before carving or consuming), 160°F (71°C) for ground meats, and 165°F (74°C) for all poultry, including ground chicken and ground turkey;	<b>Brazil</b> Category: <i>EDITORIAL</i>
Use a food thermometer to ensure that foods are cooked to a safe internal temperature: 145°F (63°C) for whole beef, pork, lamb, and veal (allowing the meat to rest for 3 minutes before carving or consuming), 160°F (71°C) for ground meats, and 165°F (74°C) for all poultry, including ground chicken and ground turkey;	<b>Russian Federation</b> We propose the following wording of subparagraph 2, paragraph 59: consumers must adhere to technological and temperature regimes for cooking various types of food products.” Category: <i>SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <b>Wash hands after touching raw meat, poultry, and seafood. Also wash work surfaces, cutting boards, utensils, and grill before and after cooking;</b></li> </ul>	
Wash hands after touching raw meat, poultry, and seafood. Also wash work surfaces, cutting boards, utensils, and grill before and after cooking;	<b>Brazil</b> Category: <i>EDITORIAL</i>
Lavarse las manos después de tocar carne cruda, carnes de aves de corral y alimentos de origen marino(mariscos). Lavar y desinfectar también las superficies de trabajo, las tablas de corte, los utensilios y la plancha antes y después de cocinar;	<b>Colombia</b> El lavado por sí mismo no es suficiente para garantizar. Category: <i>TECHNICAL</i>
<ul style="list-style-type: none"> <li>• <b>Keep food below 40°F and refrigerating foods within 2 hours of cooking (1 hour during the summer heat);</b></li> </ul>	
Keep food below 40°F and refrigerating foods within 2 hours of cooking (1 hour during the summer heat);	<b>Brazil</b> Category: <i>EDITORIAL</i>
Keep food below 40°F (4.4°C) and refrigerating refrigerate foods within 2 hours of cooking (1 hour during the summer heat);	<b>USA</b> Paragraph 59: The United States recommends inserting (4.4°C) following 40°F and changing “refrigerating” to “refrigerate” in the fourth bullet. The bullet should read as “Keep food below 40°F (4.4°C) and refrigerateing foods within 2 hours of cooking (1 hour during the summer heat); Rationale: Edits improve consistency and grammar. Category: <i>TECHNICAL</i>
Keep Store food below 40°F and refrigerating refrigerate foods within 2 hours of cooking (1 hour in hot climates or during the summer heat);	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
Keep food below 40°F (5°C) and refrigerating foods within 2 hours of cooking (1 hour during the summer heat);	<b>International Feed Industry Federation</b> Category: <i>EDITORIAL</i>
Keep food below 40°F and (4.5°C) and refrigerating foods within 2 hours of cooking (1 hour during the summer heat);	<b>OIE</b> Category: <i>TECHNICAL</i>
<ul style="list-style-type: none"> <li>• <b>Separate raw meat, poultry, seafood and eggs from fresh produce and ready-to-eat foods to avoid cross contamination. Use different cutting boards to prepare raw meat or poultry and any food that will be eaten without cooking;</b></li> </ul>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Separate raw meat, poultry, seafood and eggs from fresh produce and ready-to-eat foods to avoid cross contamination. Use different cutting <del>boards</del> <u>boards, dishware, and utensils</u> to prepare raw meat or <del>poultry</del> <u>poultry</u> , and <u>separate them from any food that will be eaten without cooking</u> ;	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<ul style="list-style-type: none"> <li>• <b>Wash hands after contact with feces, animals or animal environments;</b></li> <li>• <b>Report suspected outbreaks of illness from food to local health department; and</b></li> <li>• <b>Review Competent Authority's traveler's health recommendations when preparing to travel to a foreign country.</b></li> </ul>	
Review Competent Authority's traveler's health recommendations when preparing to travel to a foreign country. Consumer organizations should assist in educating consumers about safe food handling techniques, and should provide information to consumers about actions they can take in the marketplace to address the problem of antimicrobial resistance (e.g., choosing foods raised under appropriate antimicrobial stewardship policies in order to encourage advances in antimicrobial stewardship).	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
<b>[Advocacy and Communication]</b>	
	<b>China</b> It is suggested to delete examples of bacteria in paragraph 65, deleting shigella and vibrio cholera because they are not an important foodborne pathogen listed by the WHO.
<del>[Advocacy and Communication]</del> <b>Risk Communication</b>	<b>USA</b> The United States recommends the section be entitled Risk Communication. Rationale: Advocacy is not an activity well described or understood in the context of food safety standards. Risk communication, however, is one of the three pillars of risk analysis and fits within a Codex standard <i>Category: TECHNICAL</i>
<del>[Advocacy and</del> <b>[Risk Communication]</b>	<b>ICGMA</b> Advocacy is not a term that is well understood by Codex and could lead to misinterpretations of this section. This section is also directed at governments, which do not typically engage in advocacy. It seems that Risk Communication is a much more appropriate term. <i>Category: SUBSTANTIVE</i>
<b>[Advocacy and Communication]</b>	<b>International Association of Consumer Food Organizations</b> IACFO welcomes the addition of this section on advocacy and communication. <i>Category: SUBSTANTIVE</i>
<b>[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]	<b>Australia</b> Paragraph 60 Comment: Suggest the following edit, “The successful control of antimicrobial resistance along the food chain needs to be risk-based with a focus on the identified hazards and the involvement and cooperation of all parties along the food chain”. Rationale: Action needs to be evidence based. Category: <i>SUBSTANTIVE</i>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the <u>pharmaceutical industry, animal feed manufacturers</u> , veterinarians and plant health professionals, wholesale and retail distributors, <u>primary producers, and consumers who are involved in the authorisation</u> food industry, production, control, importation, exportation, distribution and use <u>distributors of antimicrobial agents</u> food and final consumers.]	<b>Brazil</b> Category: <i>SUBSTANTIVE</i>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and <del>and or</del> use of antimicrobial agents.]	<b>Canada</b> Category: <i>EDITORIAL</i>
[60. El éxito del control de la resistencia a los antimicrobianos a lo largo de la cadena alimentaria exige la implicación y la cooperación de todas las partes que intervienen en dicha cadena. Esto incluye a las autoridades y partes pertinentes, como productores, veterinarios y profesionales competentes de <del>sanidad vegetal</del> acuerdo a la normatividad de cada país, distribuidores mayoristas y minoristas, productores y consumidores, que están implicados en la autorización, producción, control, importación, exportación, distribución y uso de agentes antimicrobianos.]	<b>Colombia</b> Aclarando las competencias en esta materia. Category: <i>TECHNICAL</i>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, <u>health professional</u> , veterinarians and plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]	<b>Indonesia</b> Category: <i>TECHNICAL</i>
<del>[60]</del> [60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and <del>plant</del> plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]	<b>USA</b> Paragraph 60: The United States supports maintaining “plant health professionals” in square brackets. Rationale: For the reasons stated above, text that refers to the use of antimicrobials on plants and crops should be maintained in square brackets pending the outcome of scientific advice to the TFAMR. Category: <i>TECHNICAL</i>

<b>SPECIFIC COMMENTS</b>	
<b>Section/paragraph</b>	<b>Member/Observer/ rationale</b>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, producers, and consumers who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]] <u>It should also involve animal nutritionists and feed producers.</u>	<b>FEFAC</b> Successful control of AMR is a multistakeholders task, in which the feed sector plays a key role. <i>Category: SUBSTANTIVE</i>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, <del>producers, and consumers</del> <u>producers</u> who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents, <u>with appropriate conflict-of-interest safeguards, as well as consumers and consumer organizations.</u> ]	<b>International Association of Consumer Food Organizations</b> Consumers are not involved in the authorization, production, control, importation, exportation, distribution, or use of antimicrobial agents along the food chain. In keeping with the recent WHO consultation on addressing and managing conflicts of interest, it is important that appropriate conflict of interest safeguards be used to ensure that undue influence, either actual or perceived, for interests other than the public good is not exerted on individuals or institutions responsible for public decision-making, in order not to affect integrity and public trust. <i>Category: SUBSTANTIVE</i>
[60. The successful control of antimicrobial resistance along the food chain requires the involvement and cooperation of all parties along the food chain. These include the relevant authorities and stakeholders such as the manufacturers, veterinarians and plant health professionals, wholesale and retail distributors, <del>producers, and consumers</del> who are involved in the authorisation, production, control, importation, exportation, distribution and use of antimicrobial agents.]. <u>It also covers nutritionists and feed producers, agricultural product producers, and consumers]]</u>	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[61. Advocacy and communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]</b>	
<del>[61. Advocacy and Risk</del> communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]	<b>USA</b> The sentence should read, "Risk communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain." Rationale: As stated above. <i>Category: TECHNICAL</i>
[61. Advocacy and communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, <u>animal nutritionists and feed producers</u> , farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]	<b>FEFAC</b> Successful control of AMR is a multistakeholders task, in which the feed sector plays a key role. <i>Category: SUBSTANTIVE</i>



SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
[61. <del>Advocacy and Risk</del> communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]	<b>ICGMA</b> See above comments on advocacy. <i>Category: SUBSTANTIVE</i>
[61. Advocacy and communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, farmers, <u>food manufacturers, processors, and other</u> players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
[61. Advocacy and communication strategies should identify relevant target audiences, such as policy makers, health, veterinary and agricultural professionals, <u>nutritionists and feed producers</u> , farmers, players in the food industry, the media and the general public, who all have a responsibility in minimising antimicrobial resistance along the food chain.]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[62. Advocacy and communication efforts at the international and national levels should aim to raise awareness of the importance of antimicrobials in treating bacterial infections and the public health challenges of antimicrobial resistance, including within a food safety perspective. ]</b>	
[62. El esfuerzo en materia de incidencia y comunicación a escala nacional e internacional debería tener como objetivo sensibilizar sobre la importancia de los antimicrobianos para el tratamiento de las infecciones <del>bacterianas causadas por microorganismos</del> y los retos que plantea para la salud pública la resistencia a los antimicrobianos, incluso desde una perspectiva de la inocuidad de los alimentos. ]	<b>Colombia</b> Se aborda un espectro más amplio. <i>Category: TECHNICAL</i>
[ <del>62</del> 62. <del>Advocacy and Risk</del> communication efforts at the international and national levels should aim to raise awareness of the importance of antimicrobials in treating bacterial infections and the public health challenges of antimicrobial resistance, including within a food safety perspective. }	<b>USA</b> <i>Category: TECHNICAL</i>
[62. <del>Advocacy and Risk</del> communication efforts at the international and national levels should aim to raise awareness of the importance of antimicrobials in treating bacterial infections and the public health challenges of antimicrobial resistance, including within a food safety perspective. ]	<b>ICGMA</b> See above comments on advocacy. <i>Category: SUBSTANTIVE</i>
[62. Advocacy and communication efforts at the international and national levels should aim to raise awareness of the importance of <u>the responsible and prudent use of antimicrobials in treating bacterial infections and infections</u> , the public health challenges of antimicrobial resistance, <u>and actions stakeholders can take to address the problem</u> , including within a food safety perspective. ]	<b>International Association of Consumer Food Organizations</b> <i>Category: SUBSTANTIVE</i>
[62. Advocacy and communication efforts at the international and national levels should aim to raise awareness of the importance of <del>antimicrobials-antimicrobial agents</del> in treating bacterial infections and the public health challenges of antimicrobial resistance, including within a food safety perspective. ]	<b>International Feed Industry Federation</b> <i>Category: SUBSTANTIVE</i>
<b>[63. Advocacy campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include good animal husbandry or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<del>[63.63. Advocacy campaigns–Risk comunicaton</del> should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include good animal husbandry or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.}	<b>USA</b> Category: <i>TECHNICAL</i>
[63. Advocacy campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include good animal husbandry-husbandry, including <u>adequate nutrition</u> , or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]	<b>FEFAC</b> Category: <i>TECHNICAL</i>
<del>[63. Advocacy–Risk communication</del> campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include good animal husbandry or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]	<b>ICGMA</b> See above. Advocacy campaigns do not have the meaning conveyed here. Category: <i>SUBSTANTIVE</i>
[63. Advocacy campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include good animal husbandry or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices, and <u>responsible sourcing of food and food ingredients</u> . National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]	<b>International Association of Consumer Food Organizations</b> Category: <i>SUBSTANTIVE</i>
[63. Advocacy campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the agricultural sectors should include <u>adequate nutrition strategy</u> , good animal husbandry or agricultural practices and the prudent use of antimicrobials, antimicrobial agents. Those at the food and feed industries should reinforce prevention of contamination and <u>feed-food/feed</u> hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]	<b>International Feed Industry Federation</b> Category: <i>SUBSTANTIVE</i>
[63. Advocacy campaigns should be tailored to the specific stakeholder groups. Campaigns targeted at the <del>agricultural</del> <u>animal and plant</u> sectors should include good animal husbandry or agricultural practices and the prudent use of antimicrobials. Those at the food industries should reinforce prevention of contamination and food hygiene practices. National guidelines and education programmes should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.]	<b>OIE</b> Category: <i>EDITORIAL</i>
<b>[64. The engagement and consultation of stakeholders prior to enforcement or introduction of prudent use policies or measures are critical for successful implementation. Regulatory authorities should engage all relevant stakeholder groups.]</b>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<b>[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae (<i>E.coli</i> O157H7, <i>Salmonella</i>, <i>Shigella</i>, <i>Campylobacter</i> and <i>Vibrio cholera</i>).</b>	
[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae ( <i>E.coli</i> O157H7, <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> and <i>Vibrio cholera</i> ).	<b>Australia</b> Paragraph 65 Comment: is there a budget allocation for this activity? <i>Category: SUBSTANTIVE</i>
[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae ( <i>Enterobacteriaceae</i> <i>E.coli</i> O157H7, <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> and <i>Vibrio cholera</i> ).	<b>Brazil</b> Taxonomically Enterobacteriaceae is not a genera. The Enterobacteriaceae are a large family of Gram-negative bacteria. Examples of bacteria should also be removed because they include only pathogens and the monitoring of AMR predicts that it is performed on pathogens and indicator bacteria. <i>Category: SUBSTANTIVE</i>
[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae ( <i>E.coli</i> O157H7, <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> and <i>Vibrio cholera</i> ).	<b>Canada</b> Para 65. Several bacteria are specified. Generic <i>E. coli</i> , <i>Enterococcus</i> spp. and <i>Staphylococcus</i> spp. are also suggested to be specified as important examples. <i>Category: SUBSTANTIVE</i>
[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae ( <i>E.coli</i> O157H7, <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> and <i>Vibrio cholera</i> ).	<b>USA</b> Paragraph 65: The United States takes note that newsletters and other communication tools on antimicrobial resistance are currently available from the tripartite organizations (FAO, WHO, and OIE). The United States recommends revising this paragraph to provide guidance to Member Countries on the types of communications that might be beneficial at the national level. <i>Category: TECHNICAL</i>
<del>[65. Establishment of an Adhoc scientific AMR Newsletter with the objective of collection of recent advances in AMR specially in the field of the tripartite organizations (FAO, WHO and OIE), Codex universities and institutions; with relevance to the development and transmission of food-borne antimicrobial resistance in the food chain (with special emphasis on the genera of Enterobacteriaceae (<i>E.coli</i> O157H7, <i>Salmonella</i>, <i>Shigella</i>, <i>Campylobacter</i> and <i>Vibrio cholera</i>).</del>	<b>International Meat Secretariat</b> Delete para 65: Duplicative of publications already present from the OIE, WHO, and FAO and not in the scope of the document. What purpose would the newsletter serve? Who is responsible for the content of the newsletter? <i>Category: SUBSTANTIVE</i>
<b>Conclusions</b>	
<del><b>60. Veterinary antimicrobial drugs are very important tools for controlling a great number of infectious diseases in both animals and humans. It is vital that all countries put in place the appropriate systems to ensure that veterinary antimicrobial drugs are manufactured, marketed, distributed, prescribed and used responsibly, and that these systems are adequately audited.</b></del>	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
60. Veterinary antimicrobial drugs are very important tools for controlling a great number of infectious diseases in both animals and humans. It is vital that all countries put in place the appropriate systems to ensure that veterinary antimicrobial drugs are manufactured, marketed, distributed, prescribed and used responsibly, and that these systems are adequately audited.	<b>USA</b> Conclusions The United States supports the proposal of the EWG to move key concepts to other areas of the document and delete this section to promote coherence with the Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance (CAC/GL 77-2011).
<b>61. This document is designed to provide the framework that countries may implement in accordance with their capabilities but within a reasonable period of time. A stepwise approach may be appropriate for a number of countries to properly implement all of the elements in this document.</b>	
<b>62. The continued availability of veterinary antimicrobial drugs, which are essential for animal welfare and animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobials in food-producing animals.</b>	
<b>End Notes</b> <sup>1</sup> A. Franklin, J. Acar, F. Anthony, R. Gupta †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, D.G. White, H. C. Wegener & M.L. Costarrica. Antimicrobial resistance: harmonization of national antimicrobial resistance monitoring and surveillance programmes in animals and in animal-derived food. <i>Rev. sci. tech. Off. Int. Epiz.</i> , 20 (3), 859-870. <a href="http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm">http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm</a> <sup>2</sup> D.G. White, J. Acar, F. Anthony, A. Franklin, R. Gupta, †T. Nicholls, Y. Tamura, S. Thompson, E.J. Threlfall, D. Vose, M. van Vuuren, H. C. Wegener & M.L. Costarrica. Antimicrobial resistance: standardization and harmonization of laboratory methodologies for the detection and quantification of antimicrobial resistance. <i>Rev. sci. tech. Off. Int. Epiz.</i> , 2001, 20 (3), 849-858. <a href="http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm">http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm</a>	
<b>End Notes</b>	<b>USA</b> End Notes The United States supports the proposal of the EWG to delete this section to promote coherence with the Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance (CAC/GL 77-2011). <i>Category: TECHNICAL</i>
<b>List of Abbreviations [Acronyms] Used in this Code</b> ADI — Acceptable Daily Intake CAC — Codex Alimentarius Commission CAC/RCP — Codex Alimentarius Commission/Recommended Code of Practice CCRVDF Codex Committee on Residues of Veterinary Drugs in Foods FAO Food and Agriculture Organization of the United Nations MRL — Maximum Residue Limit OIE — Office International des épizooties/International Office of Epizooties VICH — International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products WHO — World Health Organization	
<b>List of Abbreviations [Acronyms] Used in this Code</b>	<b>USA</b> List of Abbreviations [Acronyms] Used in this Code The United States supports the proposal of the EWG to move this section to the beginning of the document and to revise it in line with the final text of the document to promote coherence with the Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance (CAC/GL 77-2011). <i>Category: TECHNICAL</i>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><b>Glossary of Definitions and Terms</b></p> <p><b><u>Veterinary Antimicrobial Drug</u></b>                      Veterinary antimicrobial drug(s) refers to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of microorganisms). Where antiseptic products have antibacterial activity, they should be considered as veterinary antimicrobial drugs, except where this is precluded by national legislation.</p> <p><b><u>Disease Treatment/Therapeutic Use</u></b>                      Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.</p> <p><b><u>Disease Prevention/Prophylactic Use</u></b>                      Prevention/Prophylactic Use refers to use of an antimicrobial(s) in healthy animals considered to be at risk of infection or prior to the onset of clinical infectious disease. This treatment includes:</p> <ul style="list-style-type: none"> <li>• control of the dissemination of a clinically diagnosed infectious disease identified within a group of animals, and</li> <li>• prevention of an infectious disease that has not yet been clinically diagnosed.</li> </ul> <p><b><u>Growth Promotion</u></b>                      Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained.</p>	
<p><b>Glossary of Definitions and Terms</b></p>	<p><b>USA</b></p> <p>Glossary of Definitions and Terms</p> <p>The United States supports the proposal of the EWG to move this section to the beginning of the document and to revise it in line with the terms in the document to promote coherence with the Guidelines for Risk Analysis for Foodborne Antimicrobial Resistance (CAC/GL 77-2011).</p> <p>Category: <i>TECHNICAL</i></p>