

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5

CX/AMR 21/8/5-Add.1

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ORIGINAL LANGUAGE ONLY

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
AD HOC INTERGOVERNMENTAL CODEX TASK FORCE ON ANTIMICROBIAL RESISTANCE**

**Eighth Session
(Virtual)**

4-9 and 13 October 2021

**Revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial resistance
(At Step 6)**

Comments from Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union (EU), Iraq, Japan, Malaysia, Morocco, Norway, Republic of Korea, Saudi Arabia, Switzerland, Thailand, Uruguay, United States of America (USA)

Background

1. This document compiles comments at Step 6 received through the Codex Online Commenting System (OCS) in response to CL 2021/65-AMR issued in July 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.
2. The comments submitted through the OCS are, hereby attached as an Annex and are presented in table format.

GENERAL COMMENTS

COMMENT	MEMBER/OBSERVER
<ol style="list-style-type: none"> 1. Australia appreciates the dedicated efforts of the Code of Practice (COP) EWG Chair and Co-Chairs to continue achieving scientific and risk-based compromise and consensus with this document. 2. We agree with the Codex Secretariat's observation that very good progress has been made to date and their priority objective of completing this document for the Codex Alimentarius Commission's meeting later this year. 3. The current draft reflects the Codex values of risk-analysis and science in decision-making, and the significant improvements and consensus, which have been made over numerous meetings. The current draft strengthens efforts to address AMR along the food chain and includes a One Health approach. 4. Based on the depth of discussion and refinement of the COP over the last 4 years, Australia and its stakeholders strongly encourage TFAMR8 to progress the document towards adoption by the end of 2021. This will support timely implementation and AMR mitigation to support this UN priority health issue. 	Australia
<p>Brazil recognizes the efforts of all members during the three previous sessions of the Task Force, the numerous electronic, physical and virtual working groups and webinars, in which the Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance has been extensively discussed and where a significant amount of consensus has been obtained. Brazil also acknowledges the significant advances in AMR risk management contained in this revised document, in line with the mandate of TFAMR.</p> <p>It is important to recall that members worked hard on revising this Code of Practice. All the efforts during the discussions and the significant advancements that this document presents are in line with the mandate of TFAMR and must be considered. The document is consistent with Codex texts relevant to AMR and other AMR texts from recognized international organizations, it is a stand-alone document while consistent with Risk Analysis Principles for Foodborne AMR (CXG 77-2011) and complementary with the Guidelines for integrated monitoring and surveillance of foodborne AMR. The recommendations provided are practical, feasible and scientifically supported to minimize and contain foodborne AMR. Brazil strongly supports the adoption of the current draft of the Code of Practice, as presented in Appendix I of CX/AMR 21/8/5 at Step 7, without reopening any text for discussion and, therefore, finalizing this task at TFAMR8.</p>	Brazil
<p>Chile recognize all the work done by the Chair and Co chairs, but also of the members of Codex Alimentarius throughout the TFAMR meetings in the past years in built an enhanced revision with useful recommendations in line with Codex mandate that can be worldwide applied to reduce the emergence of AMR in the food chain. We support to remove the brackets from the current text and not re-open text that has already been extensively discussed and adopt at step 5 with consensus in order to adopt at TFAMR at step 5/8.</p>	Chile
<p>As one of the co-chairs, China thanks the efforts and contributions of chair, co-chairs and all members. China suggests to consider all the national conditions and strengthen the coordination to promote the final consensus of the COP under the one health concept.</p>	China
<p>Colombia agradece el avance en el documento y no tiene observaciones.</p>	Colombia
<p>Our country thanks to the eWG for the excellent work done on this document.</p> <p>We consider it important to advance the CoP to step 5/8. This document has been widely discussed for years, and being in step 5 reflects that the Intergovernmental Force has proven an important degree of concession for its advance, precisely due to the need to have an available update of the Code of Practice for the competent authorities.</p>	Costa Rica

COMMENT	MEMBER/OBSERVER
<p>El documento tiene un progreso considerable con respecto al existente, y describe la necesidad de supervisión profesional para la prescripción de antimicrobianos, requiriendo la identificación de circunstancias excepcionales bien definidas, reiterando la necesidad de que los productos se utilicen de acuerdo con la etiqueta y subrayando la expectativa de basar las decisiones en criterios clínicos y epidemiológicos. Estos avances deben mantenerse. No se recomiendan ediciones adicionales.</p>	<p>Ecuador</p>
<p>Agree with code of practice.</p>	<p>Iraq</p>
<p>First, Japan highly appreciates the tremendous efforts made by the participants in the past meetings. Japan also thanks the Chair and Co-Chairs of and participants in the fourth EWG for their continuous efforts towards the finalization of the draft. With these remarks, Japan supports the proposed draft revised Code of Practice as agreed at the TFAMR7 and presented in CL 2021/65 OCS-AMR after the discussions at the Working Group held on June 14 and 17 with editorial suggestion.</p> <p>Japan recalls that the important mandate of the TFAMR in revising the Code of Practice is to broaden its scope to address the entire food chain, in line with the mandate of the Codex. Noting that the OIE is mandated to develop international standards in animal health, the revision should be in line with the OIE standards to avoid any confusion among the users, not only about the recommendations themselves, but also about the mandate of each organization.</p>	<p>Japan</p>
<p>Malaysia supports the proposed draft of the Code Of Practice To Minimize And Contain Foodborne Antimicrobial Resistance.</p>	<p>Malaysia</p>
<p>Combatting AMR requires a One Health approach in which all relevant sectors cooperate, especially health, agriculture, aquaculture and environment. We strongly believe that scaling up efforts through the already existing cooperation between the Tripartite plus organizations (FAO, WHO, OIE and UNEP), are important. It is important that Codex takes part in the common fight to combat AMR.</p> <p>Reiterating our concerns for the ambitions of the work and the need for further discussions at the last session of CAC, we would like to underline the following:</p> <ul style="list-style-type: none"> • The COP should apply to all antimicrobial agents because all antimicrobial agents contribute to increased resistance. Cross- and co-resistance can in addition contribute to increased resistance to medically important antimicrobial agents, which would undermine all efforts done so far to reduce AMR. • The use of all antimicrobial agents for growth promotion should be phased out in line with the recommendation given by the UN Secretary General in his report to the General Assembly and supported by the WHO/FAO/OIE Tripartite. • The document should promote responsible and prudent use of all antimicrobial agents. Medically important antimicrobial agents should not be allowed for prophylactic use. <p>In the few paragraphs (34, 52, 54, 55) where the term “therapeutic” is used, Norway suggests either to delete or replace it with the term “dosage”. This is the term used in the corresponding paragraphs of the current version of CXC 61-2005.</p>	<p>Norway</p>
<p>Considering the urgent need for action against further emergence and spread of antimicrobial resistance throughout the food chain, our priority is to move the text forward. We would thus welcome a spirit of compromise for the upcoming session.</p>	<p>Switzerland</p>
<p>Uruguay apoya la nueva versión borrador del documento con las recomendaciones surgidas de la compilación y análisis de las respuestas de los grupos de trabajo electrónico y virtual y sugerimos se apruebe en el trámite 7.</p>	<p>Uruguay</p>

COMMENT	MEMBER/OBSERVER
<p>The United States would like to congratulate the delegations working at the 7th Session of the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR7) in December 2019, through careful discussions, negotiation and compromise, to arrive at the draft text of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (COP) which was adopted at Step 5 by the 43rd Session of the Codex Alimentarius Commission (CAC43) in November 2020. The United States also expresses its appreciation to the Co-chairs and participants in the fourth Electronic Working Group (EWG/COP4) and the June 2021 virtual meeting of the Physical Working Group (PWG) on the revision of the COP which further reviewed the text.</p> <p><u>General Comments</u></p> <p>The United States supports the Code of Practice as agreed at TFAMR7 and endorses the recommendations of the EWG/COP4 and June 21 virtual PWG on the revision of the COP.</p> <p>The current draft of the COP fulfills the mandate of the TFAMR as described in the original project document for this work, as approved by the CAC, to:</p> <ul style="list-style-type: none"> • Revise the COP 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, to be scientifically supported and take into account new developments, including the establishment of Lists of Critically Important Antimicrobials, and the work of FAO, WHO and OIE in this area. • Address risk mitigation measures including all uses of antimicrobial agents along the food chain and provide updated information, in particular with regard to: the inclusion of references to the lists of Critically Important Antimicrobials; the use of antimicrobials as growth promoters; and the use of alternatives to antimicrobials. <p>The United States observes that the COP contains many significant advances in AMR risk management based on best available scientific information; is risk-based, practical and feasible for implementation by countries; aligns with World Organisation for Animal Health (OIE) standards and appropriately references other Codex and WHO texts; represents a significant amount of careful thinking, negotiation and compromises; and recognizes areas for the future where data and knowledge gaps can be filled to further advance AMR risk management.</p> <p>The United States encourages Members and Observers to support this text at the next session of TFAMR8 so that the Task Force can succeed in achieving its mandate to complete the updated COP, devote time to advance the work on the draft Guidelines for Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (GLIS), and accomplish the vision for a suite of AMR texts within the mandate of Codex Alimentarius.</p> <p>The United States would like to highlight the specific advances in the revised and updated COP that will protect public health and minimize and contain antimicrobial resistance as follows.</p> <p>1. <u>Introduction</u></p> <ul style="list-style-type: none"> • The Introduction to the Code of Practice contains several new and important concepts in AMR risk management, many of which expand, augment, and go beyond the current version of the COP which was developed in 2005 and focused on the animal sector. • First, in line with the terms of reference for the Task Force and expanding the current text, the COP introduces the concept of the “food chain” with respect to risk management of AMR. The Task Force developed a new definition and used it throughout the document. • The text in the Introduction describes the important roles and responsibilities of all participants in the food chain to manage risks associated with the use of antimicrobial agents. 	<p>USA</p>

COMMENT	MEMBER/OBSERVER
<ul style="list-style-type: none"> • The One Health Approach is another key concept the Task Force brought into the Code of Practice that was not included in the previous version of the text. • While maintaining focus on its mandate to deal with foodborne AMR risk, the Task Force developed risk management advice to the greatest extent possible that addresses the essential interconnection between human health, animals and plants/crops, and the environment, including through the development of Definitions, General Principles, and other sections in the document. • Within the animal sector, the Introduction clearly includes both terrestrial and aquatic production. • The Introduction also identifies a long, though not exhaustive, list of participants in the food chain. The specific responsibilities of these participants are covered in sections 5 and 6. • It also describes many activities along the food chain where risk management measures may be taken into account. For example, in addition to primary production, the revised COP covers processing, storage, transport, and wholesale and retail distribution of food. • The Introduction also references other key AMR texts in the Codex Alimentarius, including most notably the Guidelines for Risk Analysis of Foodborne AMR (CXG 77-2011) developed in the last Task Force. • As well, the Introduction provides a framework for integration of texts in Codex with other relevant international guidance, particularly the OIE standards which contain guidance on AMR such as the Terrestrial and Aquatic Animal Health Codes and the OIE List of Antimicrobial Agents of Veterinary Importance. • Also in this framework, key guidance such as the WHO List of Critically Important Antimicrobials for Human Medicine and integrated surveillance are referenced – as well as the essential role of national guidance on AMR where it is available. • And finally, the Introduction is where the Task Force critically discussed the issue of how the guidance in this document should be implemented by countries to ensure it is in accordance with their capabilities, based on their national priorities and capacities, and is accomplished within a reasonable period of time – and in a way that is proportionate to the risk and avoids unjustified barriers to trade. • Unlike a simple introduction of a topic, the Introduction of the COP not only represents the thoughtful work of many hours of discussion, negotiation, and compromise, it sets the stage for one of the most impactful public health documents ever developed in Codex. <p>2. <u>Scope</u></p> <ul style="list-style-type: none"> • The Scope is another very important section to the revised Code of Practice. • The Scope clearly states the guidance in this text is in line with the mandate of Codex, that is to say, foodborne AMR. • Having said that, food – or the food chain - remains a large scope. • This section re-emphasizes the concept of the food chain, with all its participants and sectors. • An important issue discussed by the Task Force was whether to address all antimicrobials or only antibacterials. • After many hours of discussion, negotiation, and compromise the Task Force affirmed that most of the recommendations in the Code of Practice focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where there is scientific evidence of foodborne AMR risk to human health. • In addition, the Task Force recognized existing Codex or internationally recognized guidelines related to some antimicrobial agents or AMR and clearly stated which ones are outside the scope of the document. 	

COMMENT	MEMBER/OBSERVER
<p>3. <u>Definitions</u></p> <ul style="list-style-type: none"> • In order to accomplish its mandate to expand the AMR risk management guidance along the entire food chain, the Task Force developed new definitions to address advances in AMR risk management since the last version of the COP (adopted in 2005) to apply the One Health Approach. • To facilitate understanding of risk management measures related to the responsible and prudent use of antimicrobial agents, the Task Force developed and agreed on definitions for treatment of disease, control of disease/metaphylaxis, and prevention of disease/prophylaxis. • To help further highlight those antimicrobials that may need appropriate risk management measures due to their importance for therapeutic use in humans, a definition of medically important antimicrobials was developed by the Task Force. “Medically important antimicrobials” is an important risk management concept that has been used by WHO and some national authorities. • The Task Force further developed and agreed on a definition of the One Health Approach for the purpose of the revised Code of Practice. • To support the advice for the plant/crop sector, new definitions for “plants/crops” were developed as well as “plant/crop health professional.” These definitions are essential for understanding the risk management advice, to expand the COP along the food chain, and to implement a One Health Approach. • And a new definition of pharmacovigilance was developed and agreed by the Task Force to address collection and analysis of data on how antimicrobial agents perform in the field after authorization. • A common One Health definition for “therapeutic use” will facilitate harmonization in terminology and continue global efforts toward a common understanding and approach to antimicrobial stewardship by distinguishing uses for assuring health from those for production purposes, such as growth promotion. <p>4. <u>General Principles</u></p> <ul style="list-style-type: none"> • Following the approach taken by the Task Force in the Guidelines for Risk Analysis of Foodborne AMR (CXG77-2011), General Principles were developed to highlight and underscore key high level concepts that are important to minimize and contain AMR and promote the responsible and prudent use of antimicrobials • These principles include: <ul style="list-style-type: none"> o <i>Principles on AMR Risk Management (generally)</i> <ul style="list-style-type: none"> ☐ <u>Principle 1</u>: A One Health Approach should be applied, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options. ☐ <u>Principle 2</u>: Considering that this document is to provide risk management guidance to address foodborne AMR risks to human health, for animal health and plant health aspects, relevant OIE and IPPC standards should be considered. ☐ <u>Principle 3</u>: 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 the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures. 	

COMMENT	MEMBER/OBSERVER
<p> <input type="checkbox"/> <i>Principle 14</i>: Medically important antimicrobials should only be administered or applied for prevention/prophylaxis where professional oversight has identified well-defined and exceptional circumstances, appropriate dose and duration, based on clinical and epidemiological knowledge, consistent with the label, and in line with national legislation. Countries could use additional risk management measures for medically important antimicrobials considered highest priority critically important as described in the WHO List of Critically Important Antimicrobials for Human Medicine, the OIE List of Antimicrobial Agents of Veterinary Importance, or national lists, where available, including restrictions proportionate to risk and supported by scientific evidence. </p> <p> <input type="checkbox"/> <i>Principle 15</i>: When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration. </p> <p> <input type="checkbox"/> <i>Principle on surveillance of antimicrobial resistance and use</i> </p> <p> <input type="checkbox"/> <i>Principle 16</i>: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and resistance genes between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance. </p> <p> 5. Responsible and prudent use of antimicrobial agents </p> <ul style="list-style-type: none"> • Section 5, the largest section of the COP, contains risk management guidance for different participants along the food chain, namely: <ul style="list-style-type: none"> o Competent Authorities o Manufacturers and Marketing Authorization Holders o Wholesale and Retail Distributors o Veterinarians and Plant/Crop Health Professionals o Food animal and Plant/Crop Producers • Building on Principle 9 (restricting use to legally authorized antimicrobial agents), guidance to competent authorities provides advice on systems for evaluating antimicrobial agents and granting a marketing authorization. • The Task Force developed the concept of the “food production environment” as a means to address the environmental component of the One Health Approach in line with the mandate of Codex and address specific potential sources of contamination in the food production environment. • The role of pharmacovigilance systems to collect data on adverse reactions, including lack of efficacy that could be related to foodborne antimicrobial resistance, is addressed and guidance is provided on how these systems can be used in conjunction with monitoring and surveillance programs. • The Task Force substantively expanded the section on training on foodborne antimicrobial resistance and the responsible use of antimicrobial agents by identifying a range of potential educational and communication topics and highlighting the roles of different participants along the food chain. 	

COMMENT	MEMBER/OBSERVER
<ul style="list-style-type: none"> • Acknowledging the significant challenge of expanding the Code of Practice along the entire food chain, the Task Force recognized the need to fill knowledge gaps and identified a number of areas where additional data and information are needed to minimize and contain AMR. • The Task Force also included a reference for the first time to substandard and counterfeit drugs, and illegally marketed antimicrobial agents. • The Task Force developed additional guidance for the section on advertising and promotion of antimicrobial agents. • In Section 5.4, specific advice was developed by the Task Force for both Veterinarians and Plant/Crop Health Professionals. This is especially important for the plant sector, where limited guidance may be available with respect to minimizing and containing AMR. • Inclusion of the term, therapeutic, is appropriate in paragraph 54 as it puts parameters around all uses for assuring health. <p>6. <u>Practices during production, processing, storage, transport, retail and distribution of food</u></p> <ul style="list-style-type: none"> • This is a new section in the Code of Practice and does not exist in the previous version. • Its inclusion is a natural consequence of addressing the entire food chain, from farm to fork. • Where the current version of the Code of Practice was focused on primary production in the animal sector, the Task Force expanded the revised version to provide guidance on practices during production, processing, storage, transport, and retail and wholesale distribution of food. • The section references Hazard Analysis and Critical Control Points (HACCP) and the Codex General Principles of Food Hygiene (CXC 1-1969) as risk management measures which can minimize the introduction, presence and growth of microorganisms, which apart from having the potential to cause spoilage and foodborne illnesses can also disseminate foodborne AMR. <p>7. <u>Consumer practices and communication to consumers</u></p> <ul style="list-style-type: none"> • This is a new section in the Code of Practice and does not exist in the previous version. • Its inclusion is a natural consequence of addressing the entire food chain, from farm to fork. • However, keeping in mind that Codex guidelines are essentially guidance to countries and not directly to consumers, the Task Force adapted this section to focus on how government, the food industry, and other stakeholders should inform and educate consumers on the risks of foodborne illness, including infection with resistant microorganisms. • Minimizing foodborne infections in the first place lowers the risk of acquiring a potentially resistant infection and also reduces the need to use antimicrobial agents. 	

SPECIFIC COMMENTS

COMMENTS	MEMBER/OBSERVER
3. Definitions	
[Therapeutic use (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis <u>or</u> prevention/prophylaxis of disease.]	
<p>Australia</p> <p>Australia iterates its support for this definition and its current description.</p> <p>Furthermore, Australia iterates the need to provide clarity to end-users about the COP (e.g. veterinary prescribers, farmers, and other industry stakeholders). Our stakeholders have previously indicated and re-iterated their understanding of the current text. Australia is greatly concerned that the other proposal summarised in the CX/AMR 21/8/5 does not support this clarity. Given our experience with stakeholder feedback, fresh proposals for changing terminology at this point will lead to further confusion and conflict amongst stakeholders about using antimicrobials. Also, our stakeholders have shown no confusion between the OIE term ('veterinary medical use') and the Codex one ('therapeutic use'), which they view is equivalent terminology.</p> <p>Australia notes a previous point made about 'treatment of disease' and 'therapeutic use' were used together in the COP (CXC 61-2005). Given the passage of time and the significant amount of discussion and review about AMR and antimicrobial usage globally and in Tripartite fora, Australia believes that terminology and perspectives have evolved and matured since then.</p> <p>Ultimately, the COP needs to be practical and feasible for implementation by global stakeholders at the operational level using clearly understood policy to effect positive change right now against the spread of AMR.</p>	
<p>Brazil</p> <p>Brazil is in favor to retain the definition on "therapeutic use" in Section 3, as presented in Appendix I of CX/AMR 21/8/5. The proposed definition is needed for clarity in the rest of the document and aligns with the OIE definition of "veterinary medical use". It is an important concept to be kept in the document, it is widely encountered in practice and is also needed to provide a clear distinction between the different uses of antimicrobials.</p>	
<p>Canada</p> <p>Canada maintains its position to recommend deleting this definition in this document. The components of the "therapeutic use" definition (i.e., "treatment of disease", "prevention of disease/prophylaxis", and "control of disease/metaphylaxis") are already separately defined within the document. We believe this general definition is not appropriate for a Code of Practice document to contain and minimize AMR. In the AMR context specifically, treatment, prevention and control have different risk/benefit profiles, exposure assessments and hence different risk characterization/estimations. Each of these scenarios are unique and require separate risk management considerations and hence an overarching definition of therapeutic use, which includes treatment, prevention and control, goes against the prudent and responsible use principles.</p> <p>While the definition of therapeutic use was added to align with the OIEs definition of "veterinary medical use", the OIE definition distinguishes between the use of antimicrobials for treatment, prevention and control and this level of detail is very relevant and needed in the context of AMR:</p> <p>Veterinary medical use of antimicrobial agents': means the administration of an antimicrobial agent to an individual or a group of animals to treat, control or prevent infectious disease:</p>	

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> • 'to treat': means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease; • 'to control': means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease; • 'to prevent': means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered. <p>The term “therapeutic use” was initially used in the draft OIE text during its development, but was replaced by “veterinary medical use” at the 2018 General Sessions, when the relevant OIE chapter was presented for adoption (OIE 86th General Session Report, 2018, p. 79-80). The current definition as adopted in the OIE code uses the term “veterinary medical use”, rather than combining treatment, prevention and control under an umbrella definition “therapeutic use”. Again, the current definition under the bracketed text in this version of the Code of practice document provides open-ended reference to the distinctly specific administration of antimicrobial agents which when referenced as an umbrella term could promote their inappropriate/non-prudent use.</p> <p>Canada would bring to the attention of the Task Force that the term “therapeutic use” is only used once in the entire document (other than in its own definition), in the definition of “medically important antimicrobials” (Antimicrobial agents important for therapeutic use in humans”) and that is specifically in the context of human use. Hence, the inclusion of this proposed definition of “therapeutic use” for non-human use, when the term does not even occur anywhere else in the document, would not be appropriate in Canada’s view. In situations where the word “therapeutic/therapy” has been referenced in this document alternative text has been provided again for consideration of the Task force.</p>	
<p>Chile</p> <p>We consider this definition appropriate and should be retain in the document as it is because it set a clear difference between the use of antimicrobials for therapeutic purpose, and in which occasions can be used for therapy in plant and animal health, and the use in animal growth promotion. It is important to count with this clear definition which differentiate the uses of antimicrobials in an international standard made by countries in consensus.</p>	
<p>China</p> <p>China supports to retain the definition of therapeutic use and support the inclusion of treatment, metaphylaxis and prophylaxis in the definition, so as to ensure animal health and food safety</p>	
<p>Costa Rica</p> <p><u>Position</u>: We supports to maintain the definition of terapheutic use.</p> <p><u>Rationale</u>: Our country is of the opinion that the definitions are of importance for the document, to give clarity and context for the readers.</p>	
<p>Cuba</p> <p>Luego de revisar la definición de la OIE que incluye el tratamiento, el control y la prevención de enfermedades. Estamos de acuerdo con la definición de «uso terapéutico» en el borrador.</p>	
<p>Ecuador</p> <p>Ecuador aprueba el párrafo tal cual y solicita que se elimine los corchetes.</p>	

COMMENTS	MEMBER/OBSERVER
<p>[Therapeutic use (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis or prevention/prophylaxis of diseaseddisease taking into account the good veterinary practices.]</p>	<p>Egypt</p>
<p>European Union</p> <p>The EUMS reiterate their view that the proposed definition for “therapeutic use” should be deleted because:</p> <ul style="list-style-type: none"> • The proposed definition would put preventive/prophylactic and control/metaphylactic use of antimicrobials on equal footing with the use of antimicrobials for treatment of diseases. Indeed, if defined in this way, it could promote the use of antimicrobials for prevention when, on the contrary, we should aim at limiting this practice which demonstrably is a major driver of AMR. • In the current version of CXC 61-2005 the terms “treatment” and “therapeutic use” are considered synonyms with the following common definition: “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.” • In the World Organisation for Animal Health (OIE) context, when the relevant revised OIE Terrestrial Code chapter 6.9. was adopted in 2018, using the term “therapeutic use” for covering treatment, control/metaphylaxis and prevention/prophylaxis of disease was rejected, precisely because “therapeutic use” and “treatment” are considered synonyms. To overcome this hurdle and to avoid misunderstandings, OIE introduced the term “veterinary medical use” to encompass treatment, control and prevention. Thus, having the proposed definition for therapeutic use in Codex would not be in line with the agreed OIE international standards. On the contrary, it would undermine the consensus that was reached within OIE a few years ago and create a serious inconsistency between the international standards of OIE and Codex. • There is no need for such definition. In the few paragraphs (34, 52, 54, 55) where the term “therapeutic” is used, it could be either deleted or replaced with the term “dosage” which is the term used in the corresponding paragraphs of the current version of CXC 61-2005. • In the last bullet point of paragraph 54, the use of the term “therapeutic” with its proposed definition would create a particular confusion when it says that “the veterinarian or plant/crop health professional should consider a therapeutic regimen that is long enough to allow an effective treatment”. 	
<p>Morocco</p> <p>Morocco supports retention of the definition of therapeutic use in section 3 of the document.</p> <p><u>Rational:</u></p> <ol style="list-style-type: none"> 1. The term provides a clear distinction between responsible and prudent uses of medically important antimicrobials – that is for addressing conditions of disease and assuring the health of animals – as opposed to uses for improving animal production – that is for weight gain and feed efficiency 2. The term aligns with the definition of “veterinary medical use” in OIE that includes treatment, control and prevention of disease. 3. The definition provides clarity in the rest of the document where the term or related terms are used. 	
<p>Norway</p> <p>We do not support the inclusion of a definition for “therapeutic use”, the rationale being:</p> <ul style="list-style-type: none"> • At the OIE General Assembly in 2018, the OIE Terrestrial Code chapter 6.9 "Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals" was adopted. A discussion ahead of the adoption of this chapter, led to the rejection of the proposed definition of “therapeutic use” for both treatment, control/metaphylaxis and prevention/prophylaxis of disease. The wording was not accepted because several countries considered the definitions “treatment” and “therapeutic use” to be synonyms. 	

COMMENTS	MEMBER/OBSERVER
<p>Therefore, the OIE General Assembly instead agreed on using the definitions “veterinary medical use” and “non-veterinary medical use” within chapter 6.9. When the TFAMR proposes to use the same definition, which the OIE General Assembly rejected in 2018, Codex contradicts the conclusions of the OIE General Assembly. This is not in accordance with the Project document /1 (CX/CAC 17/40/12 Add.2) for the revision of the COP. See para 5 in the Project document /1 (CX/CAC 17/40/12 Add.2) - “This work will take into account work undertaken in this area by FAO, WHO and OIE, aiming to minimize duplication, avoid contradiction, and ensure coherence.”</p> <ul style="list-style-type: none"> • In CXC 61/2005, page 14, there is already a definition for “Disease treatment/Therapeutic use”- 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. The proposed new wording in the definition for “therapeutic use” in the revised COP, is contrary to the wording in the current definition in CXC 61/2005. The inclusion of wording on control/metaphylaxis and prevention/prophylaxis is an extension of the scope of the original definition in CXC 61-2005. We are of the opinion that this extension is not within the remit of the Terms of Reference nor the Project document / 1 (CX/CAC 17/40/12 Add.2) for the work on the revision of the COP in the TFAMR. • The definition does not meet the requirements for when a definition is necessary or needed. According to normal Codex Procedures a definition is only needed when the wording is used a significant number of times throughout the document and the text itself is not enough comprehensible. In this case, the wording “Therapeutic use” is only used in the definition of “Medically important antimicrobials”. Normal procedure is to elaborate on the wording in the text to give sufficient clarity, rather than creating a new definition. • The definition is redundant, because there are already three separate definitions for "treatment of disease", "control of disease/metaphylaxis" and "prevention of disease/prophylaxis of disease" in the revised COP. The purpose of having three separate and more precise definitions, is that different assessments must be considered in each individual situation, before the decision to use antimicrobial agents are made. • The definition is in conflict with paragraph 9 in the Scope of the revised COP. Paragraph 9 states that there should be a responsible and prudent use of antimicrobial agents. The definition could promote the use of antimicrobial agents for prevention when, on the contrary, we should aim at limiting this practice which demonstrably is a major driver of AMR. By combining the three separate definitions into one definition, we lose the common understanding and clarity that each one gives. Furthermore, this opens for the possibility of different interpretations in different countries, and contradicts our common goal – to have the same practice no matter what part of the world you live in. 	
<p>Switzerland</p> <p>The term is in conflict with the term “veterinary medical use” in OIE which includes uses of antimicrobials for treatment, control and prevention of disease. Also, the terms “treatment” and “therapeutic use” are synonymous in the current COP (2005). Switzerland proposes the deletion of this definition and to retain the term "treatment of disease".</p>	
<p>Thailand</p> <p>Thailand supports definition of “Therapeutic use” in Section 3 because this term is frequently used throughout a document. Retaining the definition will establish a common understanding of the term used in this document and avoid repeating explanations. Moreover, this term also links to Principle 13-15 and provides clarity on those principles. Besides, it aligns with the definition of “veterinary medical use” in animals adopted by the OIE.</p> <p>In some circumstances, the use of antimicrobial agents in veterinary practices for disease prevention/prophylaxis is still considerably required. Thus, the current definition of “Therapeutic use” is appropriate.</p>	
<p>Uruguay</p> <p>Uruguay está de acuerdo en mantener la definición de Uso terapéutico incluida en la sección 3 del documento:</p>	

COMMENTS	MEMBER/OBSERVER
<p>"Uso terapéutico (animales o plantas/cultivos destinados a la producción de alimentos): La administración o aplicación de agentes antimicrobianos para el tratamiento, el control/metafilaxis o la prevención/profilaxis de enfermedades."</p> <p>Creemos que esta definición es lo suficientemente clara y que no requiere perfeccionarse.</p> <p>Está alineada con las definiciones contenidas en el artículo 6.9.2 del Código terrestre de la OIE, lo que facilita el entendimiento y la adopción de acciones por parte de los países. Por otra parte, la inclusión de las plantas y cultivos es coherente con el concepto de Una salud que se mantiene y resalta a lo largo de este código.</p>	
<p>USA</p> <p>The United States supports inclusion of the definition for “therapeutic use”, as currently written in the draft COP. It is aligned with the OIE definition for “veterinary medical use” which also includes treatment, control, and prevention, however we note the term “veterinary” only refers to animals. A common One Health definition for “therapeutic use” will facilitate harmonization in terminology globally in distinguishing use of antimicrobials for assuring health versus production purposes (such as growth promotion). Such a definition facilitates global efforts toward a common understanding and approach to antimicrobial stewardship by providing clarity for limiting use of medically important antimicrobials to only addressing animal plant/crop health. The United States can accept the new text referring to food-producing animals and plants/crops.</p>	
<p>4. General principles to minimize and contain foodborne antimicrobial resistance</p>	
<p>Principle 8: Medically important antimicrobials should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</p>	
<p>Medically important antimicrobials- <u>Antimicrobials agents</u> should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</p> <p><u>Principle 8</u> should read: <i>Antimicrobial agents should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</i></p>	<p>Norway</p> <p>We are of the opinion that this principle should include all antimicrobial agents because this a general principle. Furthermore, this would be consistent with Article 6.10.6 of the OIE Terrestrial Animal Health Code.</p>
<p>Principle 12: Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i>.</p>	
<p>European Union</p> <p>The EUMS continue to be of the view that the use of all antimicrobials for purposes of growth promotion or weight gain should be phased out, starting immediately from medically important antimicrobials.</p>	
<p>Republic of Korea</p> <p>It would be better to add the document number “(CXG77-2011)” after ‘Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance’ to make it clear.</p>	

COMMENTS	MEMBER/OBSERVER
[Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)]	
<p>Australia Australia agrees to the current text for Principle 13. Clarity is achieved for the end-users of this document and this is verified by our stakeholders. It is clear that all principles should be read as a group rather than as individual items.</p>	
<p>Brazil Brazil is in favor to retain Principle 13 in Section 4 without any changes, as presented in Appendix I of CX/AMR 21/8/5. Substantive discussion has occurred on the set of proposed principles and at TFAMR7 a significant degree of consensus has been achieved. All these efforts should not be wasted.</p>	
<p>[Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)]</p> <p>Principle 13a: Medically important antimicrobial agents should only be used for treatment, control/metaphylaxis or prevention/prophylaxis of disease and should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</p> <p>Principle 13b: Medically important antimicrobials should only be used for treatment, control/metaphylaxis or prevention/ prophylaxis of disease and per the guidance under “Principles on the responsible and prudent use of antimicrobials (generally)”</p>	<p>Canada Canada maintains its position to delete this Principle and objects to the wording of Principle 13 as currently drafted. The original proposal brought forward by Canada as captured in CX/AMR 21/8/5 was provided to facilitate consensus. <i>“Medically important antimicrobials should only be used for disease treatment or prevention/prophylaxis and/or control/metaphylaxis purposes and only under the conditions laid down in Principles 7-10, and 14 and 15.”</i> Upon further reflection, Canada has proposed modifications to this proposal, as well as an additional proposal, in an effort to find compromise to advance this document. The first proposal (Principle 13a) retains the core purpose of Principle 13 while incorporating text from Principle 8 to provide specific guidance on the responsible and prudent use of antimicrobials. References to specific principles were removed. A second proposal for Principle 13 (Principle 13b) is also provided. This alternative proposal retains the core elements of the first proposal but is shortened for simplicity.</p>
<p>Chile The current draft off the principle is appropriate and in line with the OIE code for terrestrial animals, but there is no need to have the information in parenthesis, we suggest deleting it, and maintain the definition for therapeutic purpose.</p>	
<p>China China supports to combine principle 8 and 13. Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) and should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.</p>	

COMMENTS	MEMBER/OBSERVER
<p><u>Principle 13</u>: “Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) and should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.”</p>	<p>Costa Rica</p> <p><u>Position</u>: We supports the amendment principle proposal presented during the eWG meeting.</p> <p><u>Rationale</u>: We see this principle proposal (to unite the principles 13 and 8) solves the concerns of the countries that consider that there should be greater control over the use. In addition, it adequately contextualizes the therapeutic use (giving it greater meaning and adding greater coherence with the rest of the principles and giving it a better projection in responsible use under supervision), and finally. Besides, we recognize already there are many principles to strengthen the document.</p>
<p>Cuba</p> <p>Quitar:[Principio 13: Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con finalidad terapéutica (tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades.)</p> <p>Sustituir por la propuesta de Canadá: [Principio 13: Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con fines de tratamiento o prevención/profilaxis y/o control/metafilaxis de enfermedades y exclusivamente de conformidad con las condiciones establecidas en los principios 7 a 10 y 14 y 15</p>	
<p>[Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease<u>disease taking into account the good veterinary practices</u>)]</p>	<p>Egypt</p>
<p>[Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis disease treatment or control/metaphylaxis and/or prevention/prophylaxis of disease)<u>purposes and only under the conditions laid down in principles 7-10, and 14 and 15.</u>]</p> <p>“Medically important antimicrobials should only be used for disease treatment or control/metaphylaxis and/or prevention/prophylaxis purposes and only under the conditions laid down in principles 7-10, and 14 and 15.”</p>	<p>European Union</p> <p>The EUMS continue to have concerns that in its current form principle 13 does not reflect the extent to which prudent use should be applied to antimicrobials in general and to medically important antimicrobials in particular. In fact, as currently written, and together with the proposed definition for “therapeutic use”, it would promote the use of medically important antimicrobials for control and prevention of disease and thus compromise efforts to limit the spread of AMR.</p> <p>As became apparent in the physical working group in June 2021, the EUMS are not alone with these concerns. Since then, the Global Leaders Group on Antimicrobial Resistance (GLG) stated that “further improvements to reduce their [antimicrobials] use and ensure responsible and sustainable use in food systems are both of the utmost importance and attainable. Although challenging in some situations, this must be prioritized by all countries, sectors and organizations.”</p>

COMMENTS	MEMBER/OBSERVER
	<p>In the view of the GLG all countries should i.a. “Limit antimicrobial prophylaxis and metaphylaxis in animals and plants to well-defined situations, with a goal of markedly reducing use and ensuring that all use is performed with regulatory oversight and under the direction of an authorized prescriber.”</p> <p>For the sake of compromise, the EUMS could support the wording proposed by Canada during the physical working group meeting in June, with a slight editorial alteration (inversion of metaphylaxis and prophylaxis, as a more logical and usual order):</p>
<p>Japan</p> <p>Japan supports maintaining the proposed definition of therapeutic use and Principle 13 about therapeutic use.</p> <ul style="list-style-type: none"> - Having such term is useful to briefly expresses the important concept of the use of antimicrobials to protect health, namely, to fight against infectious diseases, as opposed to routine use in production to improve growth/yield unrelated to infectious diseases. While the draft Code of Practice contains different recommendations for treatment, control and prevention, during the past discussions, it was agreed that all these three types of use are for the purpose of fighting against infection. In order to clearly demarcate them from production use and maintain the same understanding among all stakeholders, this summary term should be retained. - Proposed “therapeutic use” is equivalent to the existing OIE definition of ‘veterinary medical use,’ which was adopted by the OIE Member Countries after thorough discussion. This fact indicates that such term is useful. Like many other parts of the text, in order to cover the plant/crop sector as well, defining use for treatment, control and prevention as therapeutic use is appropriate. - Principle 13 is a very clear statement which is useful to convey an important message, rather than expecting each reader to derive the notion from Principle 12. 	
<p>* “Medically important antimicrobial agents should only be used for therapeutic purposes and should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.”</p>	<p>Morocco</p> <p>Morocco supports the proposal to merge principles 8 and 13 and further recommends the following amendments to delete the bracketed section of principle 13 (treatment, control/metaphylaxis or prevention/prophylaxis of disease) as follows*:</p> <p><u>Rational</u>: Principle 13 must be qualified in order to provide clarity as well as professional oversight on the specific circumstances that medically important antimicrobials should be used.</p>

COMMENTS	MEMBER/OBSERVER
<p>Norway</p> <p>We do not support retaining Principle 13, because we still have strong concerns about the current wording. Principle 13 does not reflect how responsible and prudent use should be applied to antimicrobial agents in general, and to medically important antimicrobial agents in particular. This principle, together with the proposed definition of “therapeutic use”, would promote the use of medically important antimicrobials for control/metaphylaxis and prevention of disease/prophylaxis. This will compromise the global efforts to limit the spread of AMR and will be in conflict with the very essence of the concept "responsible and prudent use". In addition, it contradicts the scope in the Project document / 1 (CX/CAC 17/40/12 Add.2) which states that the revised COP should give guidance on the responsible and prudent use of antimicrobial agents.</p> <p>Lastly, principles 14 and 15 already states the specific circumstances of when to administer or apply antimicrobial agents for control/metaphylaxis or prevention/prophylaxis. Thus, there is no need for saying this in a different way in principle 13.</p>	
<p>Saudi Arabia</p> <p>Saudi Arabia supports to excludes the use of medically important antimicrobial agents for the purposes of growth promotion. As WHO Recommended on the document “WHO guidelines on use of medically important antimicrobial in food-producing animals”, the use of all classes of medically important antimicrobials in food-producing animals for growth promotion should be completely restricted.</p>	
<p>[Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatmenttherapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)]</p>	<p>Switzerland</p>
<p>Thailand</p> <p>We support Principle 13 and its texts as presented which provide details on the use of medically important antimicrobials on therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease).</p>	
<p>Uruguay</p> <p>Uruguay está de acuerdo en mantener el principio 13 en su redacción actual.</p>	
<p>USA</p> <p>The United States supports inclusion of Principle 13 regarding parameters around how medically important antimicrobials are used. Inclusion of a principle that medically important antimicrobials should only be used for therapeutic purposes, that is, for assuring health, and not for production purposes, including growth promotion, is critical for furthering the aim of global stewardship. Making the fundamental distinction between the use of medically important antimicrobial agents for production purposes (such as growth promotion) from their use for therapeutic purposes is a cornerstone of AMR risk management that has been embraced by OIE and many national authorities. Principle 13, as written, is simple and concise and uses terminology in common use. It is important to make this fundamental distinction as the counterpoint to Principle 12 and before going on to more specific risk management guidance in Principles 14 and 15.</p>	

COMMENTS	MEMBER/OBSERVER
<p>Principle 15: When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.</p>	
<p>Principle 15: When used for the control <u>control/metaphylaxis</u> of disease/metaphylaxis <u>disease</u>, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.</p>	<p>Japan Japan suggests replacing “control of disease/metaphylaxis ,by “control/metaphylaxis of disease” for consistency with Principle13</p>
<p>Saudi Arabia WHO Recommended on the document “WHO guidelines on use of medically important antimicrobials in food-producing animals”: - Antimicrobial agents categorized as Critically important for human medicine should not be used for control in the presence of the disease. - The use of all classes of medically important antimicrobial in food-producing animals for control in the absence of diseases that have not yet been clinically diagnosed should be completely restricted.</p>	
<p>5. Responsible and prudent use of antimicrobial agents</p>	
<p>5.1 Responsibilities of the competent authorities</p>	
<p>15. Se solicita dividir el párrafo 15.</p>	<p>Ecuador</p>
<p>16. ... Una buena producción animal (terrestre y acuática), las mejores prácticas de administración para la producción de plantas/cultivos, las políticas de vacunación y de bioseguridad, así como el desarrollo de programas de sanidad animal y de plantas/cultivos en la explotación, contribuyen a reducir la prevalencia de enfermedades en animales y plantas/cultivos que requieran la administración de antimicrobianos y se pueden incorporar a las estrategias nacionales para complementar las actividades en materia de salud humana.</p>	<p>Ecuador Se solicita eliminar la oración</p>
<p>Establishment of a summary of characteristics for each antimicrobial product</p>	
<p>24. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial product. The information in these documents can be utilized in labelling and as a package insert. Such information may include:</p>	
<p>Australia Australia supports the proposed changes to the text. The changes improve the clarity for the end-user of this document.</p>	
<p>Brazil Brazil agrees on the proposed revisions for paragraphs 24 and 64 of Section 5, that received consensus during the Virtual Working Group, as presented in Appendix I of CX/AMR 21/8/5.</p>	

COMMENTS	MEMBER/OBSERVER
<p>Chile Chile supports the inclusions made by the virtual pWG in this paragraph.</p>	
<p>Uruguay Uruguay apoya la nueva redacción de estos párrafos consensuada en la reunión de trabajo virtual.</p>	
<p>24.</p> <ul style="list-style-type: none"> • ‘Storage conditions <u>and shelf life</u>’ 	<p>Morocco Morocco recommends amendment of para 24 last bullet by adding the words “and shelf Life” as follows: <u>Rational:</u></p> <ol style="list-style-type: none"> 1. International requirements for the establishment of a Summary of Product Characteristics for veterinary medicinal products (VMPs) requires an indication of shelf life where applicable, after reconstitution or after first time opening of immediate package” ; 2. Expired antimicrobial agents may lose some potency contributing to resistance when administered. The COP document addresses antimicrobial resistance and thus its inclusion is necessary.
<p>Knowledge gaps and research</p>	
<p>34.</p> <ul style="list-style-type: none"> • improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the <u>therapeutic dosing</u> regimens and their efficacy; 	<p>Canada Canada recommends using the terminology “dosing regimens” instead of “therapeutic regimens”, as the research could define what the dosing regimen should be or could be to answer any knowledge gaps that may exist. Dosing regimen could be for any of the situations (i.e. treatment/prevention or control). Hence the term therapeutic is not needed here.</p>
<p>34.</p> <ul style="list-style-type: none"> • improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the <u>therapeutic dosage</u> regimens and their efficacy; 	<p>Norway With reference to our general comments</p>
<p>5.4 Responsibilities of Veterinarians⁴ and Plant/Crop Health Professionals</p>	
<p>Footnote 4</p>	<p>Republic of Korea Regarding footnote 4, the Republic of Korea suggests the following.</p>

COMMENTS	MEMBER/OBSERVER
	<p>In some countries, including the Republic of Korea, aquatic animal health professionals are taking the role of veterinarians such as diagnosis and prescription. And, the expression “Under some circumstances” in footnote 4 is too ambiguous. For this reason, the Republic of Korea proposes to replace “Under some circumstances” with “Depending on national circumstances” for clarity and flexibility.</p>
49.	<p>Ecuador</p> <p>Revisar concepto de MIP - Como el Manejo integrado de plagas interviene en la prevención a la RAM</p> <p>Esto en vista que en Ecuador para el manejo de plagas en plantas no se usan antibióticos debido a que pueden producir problemas con los humanos y no se ha visto el uso de estos para el control de plagas sobretodo en la producción de alimentos, no así para términos experimentales que no son comercializados.</p>
52. For food-producing animals, the appropriate use of medically important antimicrobial agents in therapeutic-veterinary practice is a clinical decision that should be based on the experience of the prescribing veterinarian, and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures...	<p>Canada</p> <p>Canada believes “veterinary practice” is a better term in this paragraph than “therapeutic practice”, which is rarely used in this context.</p> <p>The term “therapeutic” is not relevant here as the appropriate use of medically important antimicrobial agents should be based on clinical knowledge and judgment.</p>
52. For food-producing animals, the appropriate use of medically important antimicrobial agents in therapeutic-dosage practice is a clinical decision that should be based on the experience of the prescribing veterinarian, and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures...	<p>Norway</p> <p>With reference to the General comments</p>
54.	<p>Australia</p> <p>Australia wishes to retain the current text of this paragraph and supports the removal of the square brackets. Clarity is achieved for the end-users of this document and this is verified by our stakeholders.</p>
54.	<p>Brazil</p> <p>Brazil suggests that the brackets for the term “therapeutic” in the last bullet of paragraph 54 are removed.</p>

COMMENTS	MEMBER/OBSERVER
<p>54.</p> <ul style="list-style-type: none"> ○ If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of <u>therapy administration</u> based on susceptibility testing; 	<p>Canada</p> <p>Canada suggests “adjustment of administration” is a better wording than “adjustment of therapy” here, which will help add clarity and avoid confusion. In this case administration of an antimicrobial could be for any of the scenarios (i.e., for treatment/prevention or control).</p>
<p>54.</p> <ul style="list-style-type: none"> ○ evidence-based <u>therapeutic</u> guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available; 	<p>Canada</p> <p>The term therapeutic is not adding any value to this statement as evidence based guidelines is clear enough.</p>
<p>54.</p> <ul style="list-style-type: none"> ○ evidence-based <u>therapeutic dosage</u> guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available; 	<p>Norway</p> <p>With reference to our general comments</p>
<p>54.</p> <ul style="list-style-type: none"> • If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a <u>{therapeutic dosing regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.}</u> regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms. 	<p>Canada</p> <p>Canada maintains its position to support either substituting the term “therapeutic” in the last bullet with “dosing” or alternatively deleting “therapeutic”. The beginning of the sentence reads “If the label conditions allow for flexibility...,” which means that the competent authority has granted the veterinarian/plant health professional their own discretion in the matter; implying that the competent authority has already conducted an assessment on whether the drugs should be used for certain purposes. The main message is that the drug should be used for only as long as necessary to achieve the right balance between resistance development and effectiveness of the treatment.</p>
<p>54.</p> <ul style="list-style-type: none"> • If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a<u>{therapeutic}</u> regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms. 	<p>Norway</p> <p>Norway is of the opinion that "therapeutic" should be deleted in the last bullet point. The rationale for this deletion is that "therapeutic" is redundant in this paragraph, nor does it add clarity.</p>
<p>54.</p> <ul style="list-style-type: none"> • If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a {therapeutic} regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms. 	<p>Saudi Arabia</p> <p>Saudi Arabia agreed with the term “Therapeutic” in square brackets.</p> <p>Uruguay</p> <p>Uruguay está de acuerdo en mantener la redacción actual del párrafo 54, removiendo el corchete al término terapéutico.</p>

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> Si las condiciones de la etiqueta permiten cierta flexibilidad, el veterinario o el profesional de la sanidad de plantas/cultivos debería considerar un régimen {terapéutico} lo suficientemente prolongado como para permitir un tratamiento eficaz, pero lo suficientemente breve como para limitar la selección de resistencia en los microorganismos comensales o transmitidos por los alimentos. 	<p>USA</p> <p>The United States supports inclusion of the term, “therapeutic” which is currently bracketed in paragraph 54 of the draft revised COP. Inclusion of the term is appropriate as it puts parameters around all uses for assuring health.</p>
Off-label use	
<p>55. It is the veterinarian’s responsibility to define the conditions of use including the therapeutic dosing regimen, the route of administration, and the duration of the administration and the withdrawal period.</p>	<p>Canada</p> <p>Suggest replacing the term “therapeutic regimen” with “dosing regimen” as for off-label use of a product, the veterinarian defines the conditions of use which includes the dosing regimen, etc. Depending on the professional judgment, the purpose could be for treatment/prevention or control.</p>
<p>55. It is the veterinarian’s responsibility to define the conditions of use including the therapeutic dosage regimen, the route of administration, and the duration of the administration and the withdrawal period.</p>	<p>Norway</p> <p>With reference to the general comments.</p>
5.5 Responsibilities of food animal and plant/crop producers	
<p>64. Producers of food animals and plants/crops have the following responsibilities:</p>	<p>Australia</p> <p>Australia supports the proposed changes to the text.</p> <p>The changes improve the clarity for the end-user of this document.</p>
	<p>Chile</p> <p>Chile supports the inclusions made by the virtual pWG in this paragraph.</p>
	<p>Uruguay</p> <p>Uruguay apoya la nueva redacción de estos párrafos consensuada en la reunión de trabajo virtual.</p>
6. Practices during production, processing, storage, transport, retail and distribution of food	
<p><u>Quitar:</u></p> <p>69. La industria de elaboración de alimentos y los minoristas de productos alimentarios deberían consultar los Principios y directrices para la aplicación de la gestión de riesgos microbiológicos.</p>	<p>Cuba</p>

COMMENTS	MEMBER/OBSERVER
<u>Proponer:</u> 69. La industria de producción de alimentos y los minoristas en la elaboración de productos alimentarios deberían cumplir con los principios y directrices para la aplicación de la gestión de riesgos microbiológicos.	