

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Eighth Session

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (CXC 61-2005)

(AT STEP 7)

Comments at Step 6 (Replies to CL 2021/32-AMR)

*Comments of Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, European Union (EU),
Ghana, Jamaica, Japan, Morocco, Norway, Republic of Korea, Uruguay, United States of America (USA),
International Dairy Federation (IDF/FIL), and International Feed Industry Federation (IFIF)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/32-AMR issued in April 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 **Annex I** and are presented in table format.
4. All comments submitted in reply to this CL will be included in an Annex to the report of the Working Group on the revision to the COP that met in June 2021.

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

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Australia thanks the Code of Practice (COP) EWG Chair and Co-Chairs for their comprehensive and dedicated work on this document, which has been achieved through robust scientific and risk-based compromise and consensus processes.</p> <p>Australia advises that stakeholder feedback is indicating that the document is understandable and clear from their perspective.</p> <p>Australia notes that the COP has received considerable updating as a risk management piece in line with the Codex mandate, including but not limited to:</p> <ol style="list-style-type: none"> The insertion of key concepts, such as the One Health/multidisciplinary approach, antimicrobial stewardship and other principles, risk-based approach, the exclusion of medically important antimicrobials for growth promotion, and enhanced risk management and harmonisation aspects. The recognition of, and how the COP will be supported by, the other two Codex AMR texts – Guidelines for integrated monitoring and surveillance of foodborne AMR (being drafted) and Guidelines for Risk Analysis of Foodborne AMR (CXG 77-2011). The introduction and linkage to key international texts, including the OIE Code Chapters on AMR. The expansion of the scope to ‘along the food chain’ and its alignment with the CXG 77-2011’s scope. The focus being mainly antibacterials, although it has relevance to antiparasitics, antivirals and antifungals (where applicable). The increased clarification on what is considered therapeutic use (for treatment, control and prevention of disease). Disease prevention is critically important for animal welfare and health. There are times in a production cycle where some animals are highly likely to become stressed and a bacterial infection is triggered (e.g. weaning time for pigs or introduction of cattle into feedlots). It is vital that veterinarians have the ability to prevent animal diseases where possible to support animal welfare and be consistent with best practice principles for the responsible and judicious use of antimicrobials. the practical feasibility of the text for all Codex members. <p>Australia supports the Step 6 version of the COP without further amendments given the considerable level of refinement and discussion over the last 4 years. This version should be moved forward for adoption by the end of 2021 to support timely implementation and AMR mitigation given this is a priority global health challenge. Based on the advanced refinement of the COP, Australia strongly encourages a focused effort on the draft Guidelines for integrated monitoring and surveillance of foodborne AMR to ensure this also meets the Codex Secretariat’s deadline for adoption at the end of 2021.</p>	<p>Australia</p>
<p>Brazil would also like to congratulate the chair and co-chairs of the Electronic Working Group (EWG/COP4) for the work done and to support the conclusions and recommendations of the Report presented in Appendix I of CL2021/32/OCS-AMR.</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 have to be considered.</p> <p>Concluding, Brazil strongly supports the adoption of the current draft of the Code of Practice at Step 6, finalizing this task at TFAMR8.</p>	<p>Brazil</p>
<p>Canada appreciates the opportunity to provide comments on the text at Step 6 and is looking forward to the advancement of this document in the Codex step process.</p>	<p>Canada</p>
<p>Chile está de acuerdo y apoya el texto aprobado en tramite 5 en la última reunión de TFAMR 7 y creemos que no es necesario volver a discutirlo en el próximo TFAMR 8, pues creemos que la nueva revisión del CoP brinda recomendaciones y directrices que son amplias y abordables por todos los países en la lucha contra la resistencia a los antimicrobianos, tal como fue aconsejado por el CCEXEC 79.</p>	<p>Chile</p>
<p>Although there are some disputes on some points, under the concept of one world one health, we believed that the COP will reach consensus and continue to be promoted.</p>	<p>China</p>
<p>Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos transmitida por los alimentos (CXG 61-2005) a trámite 8.</p> <p>El Anteproyecto de revisión del Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos transmitida por los alimentos (CXG 61-2005) esta armonizado en general con las regulaciones nacionales de nuestro país dentro del ámbito de competencia de la cadena alimentaria.</p>	<p>Costa Rica</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Comentarios de Cuba en relación con la solicitud de observaciones en el trámite 6 sobre la revisión del Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos transmitida por los alimentos (CXC 61-2005)</p> <p>Respecto a las definiciones de: Uso terapéutico</p> <p>Se debe considerar que el termino terapéutico se refiere a la parte de la medicina que se ocupa de los medios empleados para en el tratamiento de enfermedades y de la forma de aplicarlos, también lo relativo a tratamiento que se emplea para la curación de una enfermedad. Lo que no se ajusta a la prevención/profilaxis es destinada a un individuo o un grupo de plantas/cultivos o animales que no están enfermos. Por tanto, consideramos no debía de incluirse en lo referente a uso terapéutico.</p> <p>Las recomendaciones para el uso de antimicrobianos con el propósito de prevención/profilaxis queda claro en el principio 14, en lo referente al principio 13 pudiera excluirse el termino terapéutico y la redacción de la siguiente forma no pierde el sentido: Los agentes antimicrobianos de importancia médica pudieran utilizarse con finalidad de tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades.</p> <p>Una de las preocupaciones de la comunidad científica es que,el uso indiscriminado de antibióticos se quisiera justificar con el fin de profilaxis, se conoce que en ocasiones se pretende compensar las condiciones no higiénicas en las granjas con el uso de antibióticos y esta sería una causa importante de selección de bacterias resistentes a los antimicrobianos.</p> <p>En el Principio 10: La elección del agente antimicrobiano a utilizar se debería realizar teniendo en cuenta las directrices profesionales pertinentes, cuando existan, los resultados de los análisis de sensibilidad a los antimicrobianos de aislados de las zonas de producción, cuando proceda, y realizar ajustes en la selección de agentes antimicrobianos a partir de resultados clínicos o cuando los riesgos de RAM transmitida por los alimentos sean evidentes.consideramos que algunos términos como los resaltados en negro dan un sentido de ambigüedad y sugestivita.</p> <p>Recomendamos la siguiente redacción: La elección del agente antimicrobiano a utilizar se debería realizar teniendo en cuenta las directrices profesionales pertinentes, en correspondencia con los resultados de los análisis de sensibilidad a los antimicrobianos de aislados de las zonas de producción si se disponen y cuando no se cuenta con estos datos considerar la información nacional o regional disponible sobre susceptibilidad a los antimicrobiana del agente etiológico en particular y realizar ajustes en el tratamiento a partir de evolución clínica.</p> <p>En el Principio 12: El uso responsable y prudente de los agentes antimicrobianos no incluye el uso para estimular el crecimiento de agentes antimicrobianos que se consideren de importancia médica. Los agentes antimicrobianos que no se consideren de importancia médica no deberían utilizarse para estimular el crecimiento, a menos que se hayan evaluado los riesgos potenciales para la salud humana mediante procedimientos coherentes con las Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos.</p> <p>Se sugiere la siguiente redacción:El uso de antimicrobianos para para estimular el crecimiento o engorde animal no se recomienda, el empleo responsable y prudente de los agentes antimicrobianos no incluye el uso de los clasificados de importancia médica para este fin y de ser necesario el uso de algún antimicrobiano se deben evaluar los riesgos potenciales para la salud humana mediante procedimientos coherentes con las Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos.</p> <p>En el Principio 13: Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con finalidad terapéutica (tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades).</p> <p>En la redacción de este principio debe quedar claro que los agentes antimicrobianos de importancia médicadeberían emplearse con estos fines cuando no exista otra alternativa en relación con los antibióticos disponibles. Se sugiere: Principio 13: Los agentes antimicrobianos de importancia médica pudieran utilizarse con finalidad de tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades, siempre que se cumplan con lo recomendado para cada caso en esta guía.</p>	<p>Cuba</p>
<p>Ecuador agradece al Comité del Codex por el esfuerzo para el desarrollo del CODIGO DE PRÁCTICAS PARA REDUCIR AL MÍNIMO Y CONTENER LA RESISTENCIA A LOS ANTIMICROBIANOS TRANSMITIDA POR LOS ALIMENTOS, el país señala que no tiene observaciones; ya que los criterios técnicos descritos están bien estructurados.</p>	<p>Ecuador</p>
<p>Mixed Competence, European Union Vote</p>	<p>European Union</p>
<p>Ghana supports the overall content of the COP.</p>	<p>Ghana</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Japan supports the proposed draft revised Code of Practice as agreed at the TFAMR7 and presented in CL 2021/32/OCS-AMR after the discussions at the EWG/COP4, with one 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 organisation.</p>	Japan
<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 can lead to increased resistance, and cross- and co-resistance can contribute to increased resistance to medically important antimicrobial agents. • 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 responsible and prudent use of all antimicrobial agents should be promoted. Medically important antimicrobial agents should not be allowed for prophylactic use. 	Norway
<p>Uruguay agradece el trabajo desarrollado por Estados Unidos de América en su rol de presidente del Grupo de trabajo electrónico y de las copresidencias de Chile, China, Kenia y el Reino Unido, para lograr esta nueva versión del documento.</p> <p>Uruguay apoya el nuevo documento con las recomendaciones surgidas de la compilación de respuestas del grupo de trabajo electrónico y del análisis y la discusión de los copresidentes del grupo.</p> <p>Uruguay agradece el trabajo desarrollado por Estados Unidos de América en su rol de presidente del Grupo de trabajo electrónico y de las copresidencias de Chile, China, Kenia y el Reino Unido, para lograr esta nueva versión del documento.</p> <p>Uruguay apoya el nuevo documento con las recomendaciones surgidas de la compilación de respuestas del grupo de trabajo electrónico y del análisis y la discusión de los copresidentes del grupo.</p>	Uruguay
<p>The United States supports the Code of Practice as agreed at TFAMR7 and endorses the recommendations of the EWG/COP4.</p> <p>The current draft of the COP at Step 6 fulfills the mandate of the TFAMR as described in the original project document 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 World Health Organization (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>	USA

GENERAL COMMENTS	MEMBER/OBSERVER
<p>The IDF supports the COP as adopted at TFAMR7 and supports the conclusions and recommendations of the EWG/COP4.</p> <p>The current draft of the COP at Step 6 fulfills the mandate of the TFAMR as described in the original project document. The COP contains many significant advancements in AMR risk management founded on best available scientific information, is risk-based and is practical and feasible for implementation. The COP also aligns with OIE standards and appropriately references other Codex and WHO texts.</p> <p>The IDF looks forward to the successful adoption of the COP at TFAMR 8.</p>	<p>IDF/FIL</p>
<p>The revised CoP provides Member States and stakeholders with a modernized document that can help guide countries and stakeholders to apply risk analysis and interventions that are proportionate to their public health risks from antimicrobial resistance and curb the emergence of antimicrobial resistance to medically important drugs. There are many new definitions, principles, and elaborated concepts included in the revision that will be beneficial to countries and stakeholders. It is important for the TFAMR and EWG for the CoP to only focus on those items within bracketed text. The agreed upon provisions as adopted at Step 5 by CAC43 include significant improvements over the previous version.</p>	<p>IFIF</p>

SPECIFIC COMMENTS

Section/paragraph and Rationale	Member/Observer
INTRODUCTION	
<p>3. In keeping with the Codex mandate this Code of Practice addresses antimicrobial use along the food chain. It is recognized that the use of antimicrobial agents along the food chain may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health approach to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.</p>	<p>Jamaica Change bacteria to microorganism</p>
<p>4. El presente Código de prácticas forma parte integrante del análisis de riesgos centrado en las opciones de la gestión de riesgos y debería leerse juntamente con el resto de los textos del Codex, entre ellos, las <i>Directrices para el seguimiento y la vigilancia integrados de la resistencia a los antimicrobianos transmitida por los alimentos</i> y las <i>Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos</i> (CXG 77-2011). Además, el <i>Código de prácticas de higiene para las frutas y hortalizas frescas</i> (CXC 53-2003), el <i>Código de prácticas sobre buena alimentación animal</i> (CXC 54-2004) y las <i>Directrices para el diseño y la implementación de programas nacionales reglamentarios de aseguramiento de inocuidad alimentaria relacionados con el uso de medicamentos veterinarios en los animales destinados a la producción de alimentos</i> (CXG 71-2009) resultan especialmente pertinentes para el uso de agroquímicos en plantas/cultivos, piensos y medicamentos veterinarios, respectivamente.</p>	<p>Colombia Cambiar el término “juntamente” por “en conjunto”</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. • 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 (CXG77-2011) 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 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. 	<p>USA</p>

Section/paragraph and Rationale	Member/Observer
<ul style="list-style-type: none"> 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><u>Introduction</u> – The One Health Approach is a key concept that the TFAMR brought into the COP which did not exist in the previous version of the text.</p>	<p>IDF/FIL</p>
<p>SCOPE</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. 	<p>USA</p>
<p><u>Scope</u> – The TFAMR clearly recognized the existing Codex and internationally recognized guidelines related to antimicrobial agents and AMR clearly stating those which are within and those which are outside the scope of the document.</p>	<p>IDF/FIL</p>
<p>DEFINITIONS (including specific comments on “therapeutic use”)</p>	
<p>Brazil agrees to retain the definition on therapeutic use in Section 3 and supports suggested refinement to the current definition by the EWGs co-chairs, inserting “food-producing animals or plants/crops”, as presented in Appendix II of CL2021/32/OCS-AMR.</p>	<p>Brazil</p>
<p>Canada maintains its position to recommend deleting this definition. The components of the “therapeutic use” definition, i.e., “treatment of disease”, “prevention of disease/prophylaxis”, and “control of disease/metaphylaxis”, are already well defined within the document. Thus, including an overarching term of “therapeutic use” in the list of definitions does not add value to the document and has the potential of being taken out of context or be misconstrued.</p> <p>Canada would bring to the attention of the Task Force that the term “therapeutic use” is only used once in the whole document (other than in its own definition), in the definition of “medically important antimicrobials “ (Antimicrobial agents important for therapeutic use in humans”) 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 occur anywhere else in the document, would not be appropriate in Canada’s view.</p> <p>Further, the definition of “therapeutic use” is no longer aligned with the OIE definition of “veterinary medical use” which provides separate explanation around the use of antimicrobials for treatment, control and prevention under a generally defined term “veterinary medical use”. This is in contrast to the current proposed definition of “therapeutic use” in this Codex document, which does not provide the same level of detail for treatment, control and prevention. In doing so, this definition provides open-ended guidance around the administration of antimicrobial agents which could lead to their inappropriate use.</p>	<p>Canada</p>
<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>Chile apoya el texto sugerido por el GTe para la definición de uso terapéutico, pues hace una clara distinción entre lo que es el uso terapéutico y el uso no terapéutico o de estimulación del crecimiento. Además, la definición propuesta, es lo suficientemente amplia para incluir tanto el uso en animales como en vegetales, que es además uno de los objetivos de realizar esta revisión, ampliando el alcance código de prácticas.</p>	<p>Chile</p>
<p>China suggests adjust the order of the four definitions (therapeutic use, prophylaxis, metaphylaxis, treatment). It’s better to place these four definitions together.</p>	<p>China</p>

Section/paragraph and Rationale	Member/Observer
<p>Prevención de enfermedades/profilaxis: La administración o aplicación de agentes antimicrobianos a un individuo o a un grupo de plantas/cultivos o animales en riesgo de adquirir una infección concreta o que se hallan en una situación específica en la que es probable que se produzca una enfermedad infecciosa si no se administra o aplica un agente antimicrobiano.</p>	<p>Colombia Se propone eliminar esta definición.</p>
<p>Se propone organizar la definición, de la siguiente forma: Uso terapéutico: La administración o aplicación de agentes antimicrobianos para el tratamiento y, el control /metafilaxis de enfermedades, en animales / plantas /cultivos destinados a la producción de alimentos.</p>	<p>Colombia</p>
<p>Agregar al final de la definición “en animales y plantas/cultivos” Justificación: Brindará mayor claridad que se considere la definición en el alcance en dos áreas de producción de animales y plantas/cultivos.</p>	<p>Costa Rica</p>
<p>The definition for “therapeutic use”: 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>European Union</p>
<p>Position: Ghana supports the amended definition for the term “Therapeutic use”. Rationale: Therapy/therapeutic use where used in the COP document is in relation to animals and plants/crops. A definition that is in harmony with other related documents on AMR particularly the OIE standards is essential to ensure coherence among internationally recognized texts on the subject. Qualifying the definition in Section 3 as relating to food producing animals, plants/crop helps to further clarify the use to the reader</p>	<p>Ghana</p>
<p>Include a definition for Microorganisms</p>	<p>Jamaica</p>
<p>Japan supports maintaining the proposed definition of 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. 	<p>Japan</p>

Section/paragraph and Rationale	Member/Observer
<p>Le Maroc est en faveur de la définition proposée: [Usage thérapeutique: Administration ou application d’agents antimicrobiens pour le traitement, la maîtrise/métaphylaxie ou la prévention/prophylaxie des maladies.]</p>	<p>Morocco</p>
<p>We do not support the inclusion of a definition for “therapeutic use”, the rationale being:</p> <ul style="list-style-type: none"> • First and foremost, treatment, control/metaphylaxis and prevention/prophylaxis of disease are all defined in separate definitions. We are of the opinion that by combining these actions into one definition, we lose the common understanding and clarity each one of the definitions give. This could lead to different interpretation in different countries and could therefore make us unable to reach the goal of a common practice. The purpose of having more precise definitions for each action, whether it would be for example “treatment” or “prevention”, would be to highlight that different assessments must be taken into account in each individual situation, before the decision to use antimicrobials is made (management). • Secondly, it is our view, that the suggested definition does not add any clarity or value to the document, rather the opposite. 	<p>Norway</p>
<p><u>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.</u></p> <p>Creemos que esta definición es lo suficientemente clara y que no requiere perfeccionarse. 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.</p> <p>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>Uruguay</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. • The United States supports inclusion of a definition for “therapeutic use.” 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 for treatment, control, and preventive uses. The definition will advance stewardship by distinguishing uses to address disease from those for production purposes. The United States believes that including preventive uses is consistent with current scientific understanding of therapeutic use in humans. (See (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127564/). The article refers to preventive uses as “treatment” regimens.) Particular uses (prevention, control, treatment) are not injudicious in themselves; any of these uses could be judicious or injudicious. While the United States believes therapeutic use does include preventive uses in humans, we can accept the new text to include the definition to be limited to food-producing animals and plants/crops in the spirit of compromise. 	<p>USA</p>
<p><u>Definitions</u> – To facilitate understanding of risk management measures related to the responsible and prudent use of antimicrobial agents, the TFAMR established and agreed on definitions for treatment of disease, control of disease/metaphylaxis, and prevention of disease/prophylaxis.</p>	<p>IDF/FIL</p>

Section/paragraph and Rationale	Member/Observer
<p>IFIF is supportive of the use of the term therapeutic in brackets. Many food chain stakeholders utilize this term and would benefit from the definition that is inclusive of prevention, control, and treatment uses for medically important antimicrobials.</p> <p>IFIF observes that the existence of diverse national legislation on antimicrobials should not preclude the EWG, TFAMR or Codex Members from completing the revised text. The inclusion of prevention, control, and treatment for medically important antimicrobials within the scope of therapeutic are reasonable because those terms reflect the underlying practice. Member States use a wide range of terminology to define permissible uses of medically important antimicrobials and the criteria applied to their use. It is not uncommon that a Member State will use the terms therapy or treatment to be inclusive of control or prevention uses as described in this document.</p>	<p>IFIF</p>
<p>4. GENERAL PRINCIPLES TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE</p>	
<p>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:</p> <ul style="list-style-type: none"> • Principles on AMR Risk Management (generally) • Principle on preventing infections and reducing the need for antimicrobials • Principles on the responsible and prudent use of antimicrobials (generally) • Principles on the use of antimicrobials in specific circumstances • Principle on surveillance of antimicrobial resistance and use <p>The United States would like to highlight that the Principles on the use of antimicrobials in specific circumstances represent an advancement in risk management concepts and harmonization.</p>	<p>USA</p>
<p>Principle 3: The font-size of this principle is different with other principle. Please keep the format consensus.</p>	<p>China</p>
<p>Principio 4: Se debería utilizar la <i>Lista de la OMS de antimicrobianos de importancia crítica para la medicina humana</i>, la <i>Lista de la OIE de antimicrobianos de importancia veterinaria</i>, o las listas nacionales, cuando se disponga de ellas, para establecer prioridades en la evaluación del riesgo y la gestión del riesgo con el objeto de reducir al mínimo y contener la resistencia a los antimicrobianos. Estas listas se deberían revisar y actualizar periódicamente, cuando así lo requieran los descubrimientos científicos, a medida que vayan surgiendo nuevos datos científicos sobre patrones de resistencia.</p>	<p>Colombia Cambiar el término “descubrimientos” por “avances”</p>
<p>Principle 12: 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>European Union</p>
<p>Principle 13: Australia supports the proposed amendments and decisions relating to the therapeutic use definition, Principle 6 (which has become Principle 13), therapeutic terminology, and paragraph 54 made by the EWG Co-Chairs in this revised version of the COP.</p>	<p>Australia</p>
<p>Principle 13: Brazil agrees to retain Principle 13 (former Principle 6), as presented in Appendix II of CL2021/32/OCS-AMR.</p>	<p>Brazil</p>
<p>Principle 13: Canada continues to recommend deletion of this principle as it is not aligned with the other principles and contradicts guidance around the prudent use of antimicrobials.</p> <p>More specifically, Principles 7 to 11 under “Principles on the responsible and prudent use of antimicrobials (generally)” as well s Principle 14 and 15 cover the contents of Principle 13 in a manner which provides the needed qualifying conditions for use (i.e., only authorized products should be used, medically important antimicrobials should be used under guidance of a veterinarian, the veterinarian should make the best clinical judgement using available evidence for treatment purposes, and the principles to be followed when using these products for control or for prevention purposes).</p> <p>Further, Principle 13 is included under the heading “Principles on the use of antimicrobials in specific circumstances”, however, the rationale for this principle is similar to the definition of “Therapeutic use” which provides a broad overview on the use of medically important antimicrobials, rather than specific circumstances for its use. Canada is of the opinion that this principle is open-ended which could be misconstrued and be taken out of context and hence should not be included as a principle.</p>	<p>Canada</p>

Section/paragraph and Rationale	Member/Observer
<p>Principio 13: Principio 13 (ex 6): Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con finalidad terapéutica (tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades.</p> <p>Chile apoya la retención del principio 13 (ex 6), pues brinda una recomendación esencial para la lucha contra la resistencia a los antimicrobianos y la mantención de la efectividad de los antimicrobianos denominados de importancia medica por la OMS para el tratamiento de enfermedades en humanos.</p>	Chile
<p>Principle 13: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of diseasedisease) in food-producing animals and plants/crops</p> <p>Rationale: To make consistent to the definition of therapeutic use. China suggests to emphasize the special therapeutic use in food-producing animals and/or plants/crops.</p>	China
<p>Principio 13: Costa Rica apoya la eliminación del principio 13, numerado en el documento anterior, como Principio 6.</p> <p>Justificación: En el principio 14 se ha detallado y aclarado bajo un uso prudente y responsable de los AMR con un uso terapéutico en animales. Por tanto, mantener, el principio 13 podría generar confusión a los lectores generales del Código de Practicas</p> <p>Adicionalmente, repetir principios puede diluir el valor de otros principios, sobre todo en este documento en que existen gran variedad de principios.</p>	Costa Rica
<p>Principle 13: 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>To address these concerns, the EUMS propose principle 13 to read as follows to clearly spell out under which conditions medically important antimicrobials may be used for treatment, control and prevention of disease:</p> <p><i>“Medically important antimicrobial agents should be used for treatment only when no other antimicrobial agent can be envisaged, following appropriate professional oversight, dose, and duration. Furthermore, medically important antimicrobial agents should be used for prevention/prophylaxis and control/metaphylaxis only exceptionally, and under the conditions laid down in principles 14 and 15, respectively.”</i></p>	European Union
<p>Principle 13: We have strong concerns about the current wording in principle 13. Combining treatment, control/metaphylaxis and prevention/prophylaxis of disease into this principle, would promote the use of medically important antimicrobial agents for control and prevention of disease, rather than ensuring prudent use of medically important antimicrobial agents. This could compromise the efforts to limit the spread of AMR. We anticipate further discussions on this principle.</p>	Norway
<p>Principle 13: Japan supports maintaining the proposed Principle 13 about therapeutic use.</p> <p>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>	Japan
<p>Principio 13: Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con finalidad terapéutica (tratamiento/control/metafilaxis <u>tratamiento, control/metafilaxis</u> o prevención/profilaxis de enfermedades.</p> <p>Uruguay está de acuerdo en mantener el principio 6 en su redacción actual.</p>	Uruguay
<p>Principle 15: When used for the control of disease/metaphylaxis <u>control/metaphylaxis of 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>“Control of disease/metaphylaxis” should be changed to “control/metaphylaxis of disease” for consistency with Principle 13.</p>	Japan
<p>General Principles – The TFAMR identified a set of Principles to address AMR Risk Management which includes:</p> <ul style="list-style-type: none"> • The One Health Approach; • Integration with OIE and IPPC standards; • Integration with GL77 and consideration of unintended consequences; • Guidance on the use of WHO List of Critically Important Antimicrobials for Human Medicine, the OIE List of Antimicrobial Agents of Veterinary Importance, and national lists, where available; and • Guidance on progressive implementation of risk management measures with prioritization of public health impact 	IDF/FIL

Section/paragraph and Rationale	Member/Observer
5. RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS	
<p>13. The <i>OIE Terrestrial and Aquatic Animal Health Codes</i> and the <i>OIE List of Antimicrobial Agents of Veterinary Importance</i> contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture.</p> <p>Ghana supports the retention of principle 13, previously principle 6.</p> <p>Rationale: The principle is in alignment with the standards of the OIE. The additional advice, restrictions and limitations provided in other principles of Section 4 particularly principles 14 and 15, further clarifies the circumstances of use of medically important antimicrobial agents in the prevention and control of disease thus providing additional control over therapeutic use of medically important antimicrobials in food producing animals and plants/crops.</p>	Ghana
<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"> ○ Competent Authorities ○ Manufacturers and Marketing Authorization Holders ○ Wholesale and Retail Distributors ○ Veterinarians and Plant/Crop Health Professionals ○ 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. • 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 therapeutic uses. 	USA
5.1 Responsibilities of the competent authorities	
Establishment of a summary of characteristics for each antimicrobial product	
<p>Canada would recommend reordering the bulleted list. Canada would propose that:</p> <ul style="list-style-type: none"> • the bullet on “indications for use” be the 3rd bullet (i.e., below the bullet on “product description”); • the bullets on “application interval” and “duration of treatment” be combined as one bullet “duration of treatment or application interval” (move to below the bullet on “dosage forms/strengths/application rate”); and, • the bullet on “withdrawal periods” to be changed to “withdrawal periods or pre-harvest intervals”. <p>The rationale is that on the summary of product characteristics or similar documents, this is the logical and typical ordering of the information. The suggestion to include “pre-harvest intervals” is to align with our comments on Paragraph 64 (below).</p>	Canada brand/chemical/ drug name

Section/paragraph and Rationale	Member/Observer
<ul style="list-style-type: none"> product description <u>indications for use</u> <p>The bullet on “indications for use” be the 3rd bullet (i.e., below the bullet on “product description”);</p>	Canada
<ul style="list-style-type: none"> dosage forms/strengths/application rates <u>duration of treatment or application intervals</u> <p>The bullets on “application interval” and “duration of treatment” be combined as one bullet “duration of treatment or application interval” (move to below the bullet on “dosage forms/strengths/application rate”);</p>	Canada
<p>withdrawal periods<u>periods or pre-harvest intervals</u></p>	Canada
<p><u>application intervals</u></p>	Canada
<p><u>duration of treatment</u></p>	Canada
<p><u>indications for use</u></p>	Canada
Training on foodborne antimicrobial resistance and the responsible use of antimicrobial agents	
<p>32. Training should be supported, to the extent possible, by the competent authorities on topics related to minimizing antimicrobial resistance and encouraging the responsible use of antimicrobial agents. Training may take the form of <u>education</u>, communication and outreach and should be relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain as appropriate. Training and communication may broadly address other public health-related activities.</p> <p>Canada suggests adding “education” to the list since training can be through education.</p> <p><u>Rationale</u>- for additional clarity</p>	Canada
<p>32. En la medida de lo posible, las autoridades competentes deberían apoyar la capacitación en temas relacionados con la reducción al mínimo de la resistencia a los antimicrobianos y la fomentación del uso responsable de los agentes antimicrobianos. La capacitación puede adoptar la forma de comunicación y divulgación y debería-ser de interés para los veterinarios y los profesionales de la sanidad de plantas/cultivos, los fabricantes y los titulares de autorizaciones de comercialización, los distribuidores al por mayor y al por menor, los productores de animales destinados a la alimentación y de plantas/cultivos, y otros participantes a lo largo de la cadena alimentaria, según corresponda. La capacitación y la comunicación pueden abordar en general otras actividades de salud pública conexas.</p>	<p>Colombia</p> <p>Cambiar el término “la fomentación” por “el fomento”</p>
Knowledge gaps and research	
<p>Knowledge gaps and research<u>Encouragement of public and private research</u></p> <p>In 5.1, as all the other subtitles are verbal nouns, China suggest replace the subtitle “Knowledge gaps and research” with “Encouragement of public and private research”</p>	China
<p>Cambiar el término “Lagunas” por “Vacíos”</p>	Colombia
<p>34. To further elucidate the risk from foodborne AMR, the relevant authorities could encourage public and private research in the following areas and not limited to:</p> <p>Change “could encourage” to “should collaborate with”</p>	Jamaica
<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><u>Rationale</u> –optimize the dosing regimen instead of therapeutic regimen as the research could define what the dosing regimen should be or could be to answer any knowledge gaps there may be.</p>	Canada
5.2 Responsibilities of manufacturers and marketing authorization holders	
Advertising	
<p>To distinguish the advertising in the 5.1 and 5.2, China suggest replace the subtitle “advertising” here with “appropriate advertising of antimicrobial agents”.</p>	China

Section/paragraph and Rationale	Member/Observer
Training	
There are two "training" subtitles in 5.2 and in 5.4, but they have different content. China suggests to distinguish these two subtitles to make text more accurate.	China
43. It is the responsibility of the marketing authorization holders to support training on topics related to foodborne antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate. After responsible insert the words "and prudent"	Jamaica
5.4 Responsibilities of Veterinarians and Plant/Crop Health Professionals	
Nota a pie de página (4): Se propone eliminar la frase: por ejemplo, un profesional de la sanidad de los animales acuáticos. Puede generar confusión, ya que el profesional idóneo es el médico veterinario.	Colombia
Footnote (4): Under some circumstances, this <u>This</u> may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional. This footnote should be moved to the "veterinarians" in paragraph 2 where the "veterinarians" first appear in the document. Otherwise, Korea suggests adding "or other suitably trained persons authorized in accordance with national legislation" after "veterinarians" or "veterinarians and plant/crop health professionals" in each paragraph 2,17, 32, 49, 52, 55, 54, 59 and 59bis, etc as necessary. Furthermore, Korea suggests deleting "Under some circumstance," in the footnote. It is unclear and can limit the role of a suitably trained person authorized in accordance with national legislation.	Republic of Korea
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. When a group of food-producing animals, which may have has been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease. Rationale: Veterinary practice is a better term here rather than therapeutic practice which is hardly used in such context. The term therapeutic is not relevant here as the appropriate use of an antimicrobial should be based on clinical knowledge and judgment. The updated text improves the clarity and flow of the sentence.	Canada
54 <ul style="list-style-type: none">the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the commencement of the administration. 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 therapy-administration based on susceptibility testing. Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant samples; Rationale: Adjustment of administration is a better option rather than using therapy here and will add clarity and avoid any confusion.	Canada
<ul style="list-style-type: none">evidence-based therapeutic guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available; Rationale: The term therapeutic is not adding any value to this statement as evidence based guidelines is clear enough.	Canada
<ul style="list-style-type: none">the importance of the antimicrobial agents to human and veterinary medicine. Replace: "and veterinary medicine" with ",veterinary and plant medicine"	Jamaica

Section/paragraph and Rationale	Member/Observer
<p>▲ If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a [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.] 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> <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>Canada</p>
<p>• 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> <p><u>Propuesta de redacción:</u> El veterinario o el profesional de la sanidad de plantas/cultivos debería considerar un régimen [terapéutico] suficiente como para permitir un tratamiento eficaz, y que limite la resistencia antimicrobiana.</p>	<p>Colombia</p>
<p>• 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] <u>régimen</u> 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> <p>Uruguay está de acuerdo en mantener la redacción del párrafo 54, removiendo el corchete al término terapéutico.</p>	<p>Uruguay</p>
<p>Off-label use</p>	
<p>55. For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with the national legislation including the use of approved or appropriate withdrawal periods. It is the veterinarian’s responsibility to define the conditions of use including the therapeutic <u>dosing</u> regimen, the route of administration, and the duration of the administration and the withdrawal period.</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.</p>	<p>Canada</p>
<p>5.5 Responsibilities of food animal and plant/crop producers</p>	
<p>64.</p> <ul style="list-style-type: none"> to isolate sick animals and dispose of dead or dying animals or plants/crops promptly under conditions approved by competent authorities; <p>Reword bullet - To isolate sick and dying animals, dispose of dead animals, diseased plants/crops promptly under approved condition by competent authorities.</p>	<p>Jamaica</p>
<ul style="list-style-type: none"> withdrawal periods<u>periods or pre-harvest intervals</u>; <p>Canada would like to add “pre-harvest intervals” to account for the time an antimicrobial is administered to plants/crops and harvesting. The new text for the bullet would read “withdrawal periods or pre-harvest intervals”.</p> <p>The rationale is to ensure the “pre-harvest intervals” are documented for plant/crop antimicrobial use (“withdrawal periods” are not applicable to plants/crops).</p>	<p>Canada</p>
<ul style="list-style-type: none"> To address on-farm biosecurity measures and take infection prevention and control measures as appropriate and as provided in the <i>OIE Terrestrial and Aquatic Animal Health Codes</i>; <p><u>Put another bullet below:</u></p> <p>* to address on-farm biosecurity measures and take infection prevention and control measures as appropriate and as provided in the International Plant Protection Convention (IPPC) and FAO</p>	<p>Jamaica</p>

Section/paragraph and Rationale	Member/Observer
<p><u>Responsible and prudent use of antimicrobial agents</u> – The TFAMR developed important risk management guidance for the participants along the food chain:</p> <ul style="list-style-type: none"> • Competent Authorities • Manufacturers and Marketing Authorization Holders • Wholesale and Retail Distributors • Veterinarians and Plant/Crop Health Professionals • Food animal and Plant/Crop Producers 	<p>IDF/FIL</p>
<p>6. Practices during production, processing, storage, transport, retail and distribution of food</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>USA</p>
<p><u>Practices during production, processing, storage, transport, retail and distribution of food</u> – The TFAMR added this new section to the COP. This new section references HACCP and Codex General Principles of Food Hygiene 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>	<p>IDF/FIL</p>
<p>7. Consumer practices and communication to consumers</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 	<p>USA.</p>
<p><u>Consumer practices and communication to consumers</u> – The TFAMR added this new section to the COP. Mindful that Codex guidelines are guidance to countries and not directly to consumers, the TFAMR developed this section to focus on how government, food industry, and other stakeholders should inform and educate consumer on the risks of foodborne illness, including infection with resistant microorganisms.</p>	<p>IDF/FIL</p>