CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/AMR 18/6/5-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Sixth Session

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

Comments at Step 3 (Replies to CL 2018/74-AMR)

Comments of Australia, Brazil, Canada, China, Colombia, Guyana, Indonesia, Iran, Japan, Kenya, Malaysia, Norway, Thailand, United States of America (USA) , Consumer Goods Forum, Consumers International, European Feed Manufacturers' Federation (FEFAC), Health for Animal, International Union of Food Science and Technology (IUFOST), International Association of Consumer Food Organizations, International Feed Industry Federation and International Meat Secretariat

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/74-AMR issued in October 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

   Explanatory notes on the appendix

2. The comments submitted through the OCS are, hereby attached as **Annex I** and are presented in table format.

ANNEX I

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

GENERAL COMMENT

GENERAL COMMENTS ON THE CODE OF PRACTICE	MEMBER/OBSERVER
Canada appreciates that the revised version of Code of Practice encompasses all antimicrobial agents, and notes that in certain places, the document is specific to medically important antimicrobials. We suggest to harmonize the language within this document to the extent feasible. Canada also proposes that this document needs to reflect possible changes in the future to what might be considered a medically important antimicrobial or the situation where new antimicrobials come on the market. Canada suggests that there should be due consideration of effectiveness of antimicrobial alternatives when promoting their use (for example in paragraph 59 where "probiotics", "prebiotics", and "competitive exclusion products" are mentioned). 2. Canada suggests that there should be due consideration of effectiveness of antimicrobial alternatives when promoting their use (for example in paragraph 59 where "probiotics", "prebiotics", and "competitive exclusion products" are mentioned). Canada would like clarity on how and when the information arising from the FAO/WHO Expert Meeting on Foodborne Antimicrobial Resistance: Role of Environment, Crops and Biocides will be included in the Code of Practice revisions. Canada requests verification of whether non-WHO/FAO/OIE documents such as VICH guidelines can be referenced in a Codex document (VICH guidelines are described in Paragraph 11).	**Canada**
Thanks to cover the scope of RCP to the whole food chain, However, the responsibility of crops health professionals and control of environment need to be further developed. Thanks for the statement on the biocide and probiotics. China also suggest to pay attention to the effects and potential risks of biocides, probiotics on the emergence and development of drug resistance. Risk analysis of these factors should be carried out. The new guidelines need to be developed and updated. Thanks to concern the mature and other excreta from livestock and poultry on the antimicrobial resistance in food chain. However, the corresponding control measures and good practice should be developed to contain the relative antimicrobial resistance in environments. Thanks to concern the practice during food produce and processing. China also suggest to include "\wholesale" and "catering" into the food chain. The catering industry has a responsibility to provide safe and reliable food to prevent the presence and spread of drug-resistant microorganisms in food. Thanks to concern the Consumer's Responsibility. China also suggest to elaborated five responsibilities for consumer, including (1) responsibility of learning food safety knowledge and knowledge on how to minimize and contain antimicrobial resistance by active participation in training; (2) improving the meaning and skills of identifying food quality; (3) keeping rationality, and promoting correct dissemination of information to avoid adverse opinions; (4) maintain a sense of justice, supervision, feedback and reporting on violations of food safety laws and regulations; (5) actively cooperate with the government and relevant academic institutions to carry out food safety related investigations Thanks to add the responsibilities of professional organizations. China also suggest that the responsibilities of the government, academic institutions and other social organizations should work together for the training, education, risk communication and risk management. Suggests to define the Pharmacovigilance and encourage the Pharmacovigilance program.	**China**
Colombia suggests to keep the section of "Surveillance and monitoring programmes" and to reference the guides that are being developed. Colombia agrees to maintain the terms: antimicrobial agents / antimicrobials / antimicrobial resistance, instead of ¨antibacterials/antibiotics/antibiotic resistance¨, since they are broader terms which includes the concepts of antibacterial, antiviral, antifungal, and antiparasitic agents, and also due to the numerous and complex interactions involved when mixed infections occur and the phenomenon of co-selection. In the case of Colombia, for example, some drugs that associate gentamicin + toltrazuril (GENZURIL, Reg. Ica No 8145-MV) are registered. Colombia considers that paragraph 6 doesn´t need further revision because ¨antimicrobial agents / antimicrobials / antimicrobial resistance¨ are broader terms which includes the concepts of antibacterial, antiviral, antifungal, and antiparasitic agents, in concordance with paragraph 6.	**Colombia**

GENERAL COMMENTS ON THE CODE OF PRACTICE	MEMBER/OBSERVER
Guyana is in agreement with the contents of the proposed draft document without any amendment. We look forward to the finalization of this draft document.	**Guyana**
1. It is proposed to define one or several “Key Performance Indicators” for each strategy in order to make the governments to be committed to implement the strategies in their own countries. According to One Health Approach, the Key Performance Indicators should be defined in different categories, i.e. crop/plants, animal, food and feed. Iranian codex mirror committee consists of high level skilled specialists and experts in different fields is ready to participate in KPI development project. 2. It is preferred to allocate numbers to subtitles to organize the text and make it more understandable and clearer. For example , following items for numbering can be used for paragraph 5: 5. Responsible and prudent use of antimicrobial agents 5.1 Responsibilities of the regulatory authorities 5.1.1 Quality control of antimicrobial agents 5.1.2 Surveillance and monitoring programmes 5.1.3 Distribution of antimicrobial agents 5.1.4 Control of advertising 5.1.5 Training of users of antimicrobial agents 5.1.6 Knowledge gaps and research 5.2 Responsibilities of Manufacturers and Marketing Authorization Holders 5.3 Responsibilities of wholesale and retail distributors 5.4 Responsibilities of Veterinarians and Plant/Crop Advisors or Consultants 5.5 Responsibilities of food producers 3. Antimicrobials vs. antibacterials Since some resistance determinants are raised by antimicrobial agents other than antibacterials (esp. antiviral agents), Iranian codex mirror committee agrees to antimicrobial agents/antimicrobials/ antimicrobial resistance in whole document, so it seems that there is no need to antibacterial definition. If a definition is existed for antibacterials, the definitions for antiviral, antifungal and should be given.	**Iran**
In the revision of this Code of Practice, it should be recalled that the purpose of the work of the TF is “to revise the Code of Practice by broadening its scope, and developing risk-based guidance on the management of foodborne antimicrobial resistance” (see point 1 of the appendix 1 to CX/CAC 17/40/12 Add.2). Also, it should be recalled that “the food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.” (see “Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are taken into Account” of “CODEX ALIMENTARIUS COMMISSION PROCEDURAL MANUAL”)	**Japan**
Malaysia generally agrees with the current structure of the draft of COP (CXC61-2005)	**Malaysia**
No comments	**Syrian Arab Republic**
We would like to support the progress of this document. In 2017 GFSI established a technical working group focused on addressing the correct use of cleaning chemicals by food producers, with one aim being to reduce microbial residues and minimise any risk of antimicrobial resistance. The work undertaken by this group, not yet published, may be used to inform the content of the Code of Practice; it includes substantial information on the areas that are recommended for inclusion in the Code of Practice	**Consumer Goods Forum**

GENERAL COMMENTS ON THE CODE OF PRACTICE	MEMBER/OBSERVER
We feel that the document needs to be strengthened in a number of ways in order to minimize and contain foodborne antimicrobial resistance. To save antimicrobials' effectiveness, we must drastically reduce their use in both human medicine and especially in agriculture. Animal agriculture currently accounts for the most antibiotic use, with 70% of all medically important antibiotics in the United States and the European Union sold for food animal consumption. Use of antimicrobials in animal production in Brazil, Russia, India, China and South Africa (BRICS) is rising rapidly (Van Boeckel TP, Brower C, Gilbert M, et al. 2015. Global trends in antimicrobial use in food animals. Proceedings of the National Academy of Sciences, doi: 10.1073/pnas.1503141112. At: http://www.pnas.org/content/pnas/early/2015/03/18/1503141112.full.pdf). This also has a great influence on food importing countries, including Japan and South Korea. The vast bulk of antibiotics are given to otherwise healthy animals to promote growth or prevent disease in intensive livestock production systems. The document should make clear that medically important antimicrobials should never been used for growth-promotion purposed in food animals, consistent with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals (2017). Principle 5 in the current draft allows use of medically important antimicrobials for growth promotion purposes as long as there is a risk assessment. We strongly feel that Principle 5 should be revised to delete the risk assessment loophole. The document should also make clear that medically important antimicrobials should not be routinely used for disease prevention purposes, consistent with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals (2017). The May 2018 OIE List Of Antimicrobial Agents Of Veterinary Importance also includes a recommendation against the routine use of critically important antimicrobials for disease prevention. Principles 6 in the current draft allow routine use of medically important antimicrobials for disease prevention purposes. We think Principle 6 should be revised to delete mention of prevention/prophylaxis of disease. The definition of "therapeutic use" should be deleted since it is overly broad, not agreed upon, and is not needed since there are definitions, consistent with OIE, for treatment of disease, control of disease, and prevention of disease. The document should be broad enough to include newer food production technologies, in particular food/meat produced from animal cell cultures, since a number of countries, such as Japan, European Union, Israel and the United States are actively pursuing work in this area and such foods may be on national and international markets within the next couple of years. Production of food from animal cell cultures will invariably use antimicrobial agents during the cell culture process to prevent contamination from bacteria, viruses, fungi, and mycoplasma.	**Consumers International**
The definition of feed was withdrawn compared to previous versions, which is regretabke as feed is not the same as food and certain good practices that are relevant for food may not be for feed and vice-versa (example: incorporation of antimicrobial for growth promotion purpose is relevant for feed, not for food).	**FEFAC**
We still consider that the draft needs to be considerably strengthened to achieve its goal of effectively addressing Antimicrobial Resistance (AMR). • It does not describe and highlight the importance and urgency of AMR, as reflected in paragraph 11 of the report of the Fifth Session of the Task Force, as well as at the most recent session of the Codex Alimentarius Commission, where delegations commented that the new work should "highlight the priority importance of combatting AMR." (Merely describing the problem as "complex" and "global" does not capture the importance and urgency of the AMR problem to health and is inadequate.) • It should clearly and unambiguously recommend complete restriction of use of all classes of medically important antimicrobials in food-producing animals for growth promotion, consistent with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals (2017). The current draft has loopholes permitting such uses which should be eliminated. • It should not group together the concepts of treatment, control, and prevention uses of antimicrobials as "therapeutic" since there is no consensus for doing so (it is contrary to the definition of therapeutic used by the WHO, for example), is unnecessary since these terms are separately defined in the document, and grouping them together obscures important distinctions between these uses. Furthermore, the term "therapeutic" is frequently used in the document to refer to use of antimicrobials in humans, and control/metaphylaxsis would not generally apply to human use. • The document needs significant revision with regards to prevention, since almost any antimicrobial use could be considered a prevention use as currently drafted, and the definition does not include practices aimed at preventing disease which do not involve the use of antimicrobials.	**International Association of Consumer Food Organizations**

GENERAL COMMENTS ON THE CODE OF PRACTICE	MEMBER/OBSERVER
• The draft currently omits any reference to the WHO Guidelines on Medically Important Antimicrobials in Food Producing Animals (2017); these Guidelines are highly relevant and should be cited at several points in the document. • Since substances other than antibacterials (e.g., antifungal agents) used throughout the food chain can contribute to antimicrobial resistance, the revision should not be limited to guidance on antibacterial agents. This would be consistent with the Proposal for New Work on the revision of the Code developed by the Physical Working Group on Antimicrobial Resistance in 2016 (Appendix I of CX/CAC 17/40/12 Add. 2) and agreed by the Commission. We disagree with not including biocides. We are awaiting the full report of the expert meeting, but the summary noted that, while data are lacking, bacteria with increased tolerance to biocides have been recovered from food production environments, and there is theoretical and experimental evidence that certain microbiocidal agents may co-select for AMR . Prudent measures to minimize AMR while ensuring good hygiene are needed.	
Producers place the highest priority on the health and well-being of their animals. Antimicrobial drugs are an important and necessary tool used in protecting health and well-being. Prevention, control, and treatment of animal diseases are necessary components of successful herd health management programs. As stated in our previous comments to the Ad Hoc Intergovernmental Codex TFAMR, we believe that the "Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance" should be focused on mitigating the potential adverse outcomes to public health arising from antimicrobial resistance related to food. The work of the Codex TFAMR needs to adhere to the Codex food safety mandate and remain coordinated and supportive, but not duplicative of the work of other international organizations to combat antimicrobial resistance, such as the World Organization for Animal Health (OIE), the World Health Organization (WHO), and the Food and Agriculture Organization (FAO). A basic set of core competencies for the Codex TFAMR to consider during the process to develop a code of practice document include: • Improve management control measures for the use of antimicrobial agents rather than simply eliminating uses of these drugs. • Examine the challenges and consequences presented for animal health and food safety resulting from any efforts to significantly reduce or eliminate antimicrobial use in food-producing animals. • Maintain a science-based approach to controlling antimicrobial resistance that identifies and reviews all new scientific data regarding the risks for developing foodborne antimicrobial resistance. • Ensure transparency in all actions of the Codex TFAMR and encourage widespread participation between Codex member governments in the process to develop the document for "Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance". The revised draft document shows improvement over the previous document and contains examples of valuable contributions for minimizing and containing foodborne antimicrobial resistance. At the same time, we caution that the revised draft document should focus on risk rather than solely on hazard and be consistent with the guidelines for risk analysis of foodborne antimicrobial resistance found in the Codex document, "Risk Analysis of Foodborne Antimicrobial Resistance" CAC/GL-77-2011. The code of practice document should be science-based and provide guidance that can be applied proportionate to the identified risk. We request that any measures in the revised draft code of practice document that are not supported by sound scientific evidence be deleted from the document. Capacity development for countries may be essential to promote effective action to identify and control foodborne antimicrobial resistance. Informed by an accurate gaps analysis, capacity development can function to educate, assist and empower positive action. We encourage the support of capacity development programs to assist with informing on foodborne antimicrobial resistance under the Codex mandate as guided by the work of the Codex TFAMR. In conclusion, we support science-based decision-making as the work of the Codex TFAMR continues to develop the document for revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005).	**International Meat Secretariat**
IUFoST continues to support development and adoption of this Code.	**IUFOST**

GENERAL COMMENTS ON SPECIFIC ISSUES IN THE COP (CX/AMR 18/6/5, PARAGRAPH 16)	MEMBER/OBSERVER
(a) Definition of plants/crops	
Australia prefers the use of 'food of plant origin' rather than 'crops/plants' or 'plants/plant products'. Rationale: The use of crops/plants and plants/plant products does not adequately capture all stages of production in the food chain	**Australia**
We propose the definition of plant, crop and foods of plat origin as per the scope of this COP. Since crop covers both animals and plants, crop should not be used the same or as alternate to plants. This definition can be considered; " A crop is a plant or animal product that can be grown and harvested extensively for profit or subsistence. Crop may refer either to the harvested parts or to the harvest in a more refined state. Most crops are cultivated in agriculture or aquaculture".	**Kenya**
Whatever the word used, it should encompass feed uses of crops/plants.	**FEFAC**
There should be coherence in the terminology used within the various Codex documents dealing with foodborne antimicrobial resistance. We prefer the use of the term "crops" rather than the more generic term of "plants" to differentiate that crops are plants used as foodstuffs. The more general term, "plants" could also refer to ornamental, non-edible vegetation. Furthermore, the term "crops" is used in the CAC/GL-77-2011 Codex document dealing with the risk analysis of foodborne antimicrobial resistance and it would show consistency in terminology to use "crops" in the code of practice document.	**International Meat Secretariat**
(b) Plant/crop health professional	
Australia agrees with the proposed term 'plant/crop advisor or consultant'.	**Australia**
We propose the replacement of "plant/crop professional" with "plant pathologist". Considering Plant Pathology is defined as the study of the organisms and environmental conditions that cause disease in plants, the mechanisms by which this occurs, the interactions between these causal agents and the plant (effects on plant growth, yield and quality), and the methods of managing or controlling plant disease, therefore plant pathologist would be the professional to undertake plant pathology work.	**Kenya**
We do not think that "plant/crop advisor and consultants" is an improvement over "plant/crop health professional" and disagree with the use of the former term. As the document notes, when medically important antimicrobials are used in animals, it is under the supervision of qualified professionals, such as veterinarians or a professional similarly authorized by national legislation. The language used should make it clear that for plant/crop production, antimicrobial uses should under the direction of professionals authorized to use of direct the use of such agents. Thus, we prefer the term "plant/crop health professional."	**Consumers International**
The term "plant/crop advisor or consultant" is not an improvement over "plant/crop health professional," in our view. Regardless of the term used, the document should clarify that these are professionals authorized to use or direct the use of antimicrobial agents on plants/crops.	**International Association of Consumer Food Organizations**
(c) Antimicrobials vs. antibacterials	
Australia prefers the use of 'antimicrobials' through the document. Rationale: The Global Action Plan on Antimicrobial Resistance (AMR) uses the term, antimicrobials. It covers antibiotic resistance in most detail, but also refers to medicines that are used to treat viral, parasitic and fungal diseases. The Tripartite Plus' Draft Global Framework for Development and Stewardship to Combat AMR also indicates the scope will broaden beyond antibiotics to include other antimicrobials. Thus, it is important to use antimicrobials, and this will provide consistent messaging across global documents. If antimicrobials is the agreed term, then Australia proposes the deletion of the current definitions of antibiotic, antibiotic resistance and antibacterials. However, if not, then changes are outlined under Specific Comments.	**Australia**

GENERAL COMMENTS ON SPECIFIC ISSUES IN THE COP (CX/AMR 18/6/5, PARAGRAPH 16)	MEMBER/OBSERVER
We propose definition of antibacterial, antimicrobial and antibiotic. Paragraph 6 should be retained. The COP should not be limited to antibacterial but accommodate all antimicrobials. Since the principle of antibiotic resistance applies to others(viruses and protozoans) and it's the same we propose the retention of document as is.	**Kenya**
We believe that the broader term antimicrobials—which includes antibacterial, antiviral, antifungal, and antiparasitic agents--should be used rather than antibacterials. We note that both CXG 77 and CXC 61 refer to antimicrobial resistance, while WHO documents refer to antimicrobials. Even the Proposal for New Work on the revision on the CXC 61 (Appendix I of CX/CAC 17/40/12 Add. 2), and agreed to by the Commission refers to antimicrobials. A recent publication, "Worldwide emergence of resistance to antifungal drugs challenges human health and food security," notes that antifungal drugs used along the food chain can contribute to antimicrobial resistance. Thus, we agree that references to antibacterials/antibiotics/antibiotic resistance in CXC 61 should be changed, as appropriate, to antimicrobial agents/antimicrobials/antimicrobial resistance. In addition, we fell that paragraph 6 is sufficient as is.	**Consumers International**
It would be useful to introduce a difference between those measures that are specifically relevant for antibacterials and those that are also relevant for other antimicrobials, assuming that the AMR issue is primarily with antibacterials.	**FEFAC**
Since substances other than antibacterials (e.g., antifungal agents) used throughout the food chain can contribute to antimicrobial resistance, the revision should not be limited to guidance on antibacterial agents. This would be consistent with the Proposal for New Work on the revision of the Code developed by the Physical Working Group on Antimicrobial Resistance in 2016 (Appendix I of CX/CAC 17/40/12 Add. 2) and agreed by the Commission. We also note that throughout the document, sometimes "antimicrobial" is used and sometimes "antimicrobial agent." The document should be consistent or include both terms in the definitions, clarifying the difference (if any).	**International Association of Consumer Food Organizations**
(d) Medically important antimicrobials	
Australia prefers consistency with CAC/GL 77-2011, which reflects critically important antimicrobials for human medicine throughout this guideline. Rationale: The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts. This approach will also take into account national lists, as recognised by the WHO in REP18/AMR.	**Australia**
We agree to the definition provided in the appendix.	**Kenya**
FEFAC supports the link established between the notion of medically important antimicrobials and the WHO list of critically important antimicrobials, excluding ionophores and other antimicrobials not relevant for human health.	**FEFAC**
We support the inclusion of a definition for "therapeutic use" as "administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease." We would also note that the OIE's definition of "veterinary use" is synonymous with the term "therapeutic use" in Codex. Clearly defining prevention as a therapeutic use in the Codex document will help to facilitate a global understanding for the importance of exerting veterinary clinical judgement in determining whether or not a particular drug is appropriate for therapeutic use versus any non-targeted use for production purposes.	**International Meat Secretariat**
(f) General principles	
Australia considers these require careful consideration. Rationale: The order of general principles needs consideration along with the inclusion of other general principles and words as provided under Specific Comments.	**Australia**
In Principle 2, it should be made clear that alternatives to antimicrobials can include both substances, e.g., organic acids, immunomodulators, essential oils, vaccines, bacteriophages, etc. as well as practices, such as good hygienic practices, animal and plant/crop best management practices. For Principle 5, it should be made clear that medically important antimicrobials should never be used for growth promotion purposes.	**Consumers International**

GENERAL COMMENTS ON SPECIFIC ISSUES IN THE COP (CX/AMR 18/6/5, PARAGRAPH 16)	MEMBER/OBSERVER
Principle 6 should be modified to make clear that medically important antimicrobials should only be used for treatment or control/metaphylaxis of disease, and should not be used for disease prevention purposes. In addition, Principle 7 should be modified to make it clear that antimicrobial agents should not be used for routine disease prevention purposes and that any preventative use of antimicrobials should be limited to well-defined cases.	
The principles are essential to maintain in these guidelines as they enable to get a better overview of the different types of measures and concepts further displayed in the rest of the document.	**FEFAC**
It is critical to state in Principle 2 that alternatives to antibiotics should be safe, effective and have passed through the appropriate national regulatory pathways of approval for use. A report from the OIE's Second International Symposium on Alternatives to Antibiotics held in Paris, France in 2016 stated that, "Alternatives to antibiotics are broadly defined as any substance that can be substituted for therapeutic drugs that are increasingly becoming ineffective against pathogenic bacteria due to antimicrobial resistance. Although antibiotics remain an essential tool for treating animal diseases on the farm, the availability of effective medical interventions to prevent and control animal diseases is one of the most significant challenges facing veterinary medicine in the 21st century. The call from the global public health community to reduce the use of medically important antibiotics in animals warrants further research to better understand the drivers of antimicrobial resistance in farm animals and develop new tools that can provide antibiotic alternatives." We would propose to delete footnote 6 in Principle 2 as the list of alternatives to antibiotics is not exhaustive and some of the products in the footnote lack a clear regulatory pathway and are not within the scope of the Codex document. Principle 5 needs further revision for clarity. It is important for the implementation of the guidance involved with this principle to have established a clear definition of medically important antimicrobial drugs as well as to delineate that risk-based decision making is a component of any assessment for the judicious use of medically important antimicrobial drugs in food-producing animals. Consideration for veterinary judgement in the clinical use of medically important antimicrobial drugs in food-producing animals should be acknowledged. We recommend deletion of Principle 15 which refers to the reduce, rethink, and replace (RRR) strategy for the use of antimicrobial agents in animals and on plants/crops. The RRR strategy is not broadly understood and refers to a specialized antimicrobial stewardship term, most often associated with human hospital settings. Many elements of the RRR strategy are already contained within the revised draft document and there is no need to specifically call out the strategy in the current text. The need to balance animal health needs could be addressed using language similar to that found in CAC/GL-77-2011 Principle 8, "Evaluation of foodborne antimicrobial risk management options should include, whenever appropriate, animal health aspects relevant to food safety. Foodborne antimicrobial risk analysis, when considering such animal health aspects, should take into account the relevant OIE standards."	**International Meat Secretariat**
(g) Stepwise approach	
Australia supports the need for flexibility in the document. Rationale: AMR should not disrupt trade. Flexibility is required for low-to-middle-income countries.	**Australia**
We propose the replacement of stepwise with progressive approach. Stepwise approach classifies the countries based on resources and we feel that the COP should be guiding countries towards achievement and progressive enough and therefore that would not be used as Technical barriers to trade once stepwise approach is used.	**Kenya**
(h) Surveillance and monitoring programs	
This section does not need to reside in the Code of Practice and reference to the new Guidelines for integrated monitoring and surveillance (under development) should be made in the Introduction. A separate section could be made within the Code of Practice covering pharmacovigilance aspects. Rationale: Surveillance and monitoring programmes paragraphs have been superseded by the new, separate guidelines. These guidelines will not just apply to producers. If deletion of the surveillance and monitoring paragraphs is not agreed, then changes are outlined under Specific Comments.	**Australia**

GENERAL COMMENTS ON SPECIFIC ISSUES IN THE COP (CX/AMR 18/6/5, PARAGRAPH 16)	MEMBER/OBSERVER
We agree to the replacement of the section.	**Kenya**
(i) Alternatives to antimicrobials	
Australia recognises a broader definition of this term. Rationale: The rationale in CX/AMR 18/6/5 (page 6, English version) is understandable. There are other alternatives to antimicrobials worthy of consideration such as on-farm biosecurity, vaccination, rapid diagnostics, etc.	**Australia**
We support the need for clarification on the alternative substances to antimicrobials and alternative practices implied above.	**Kenya**
We support the idea that there could be a need to clarify alternative (substances) vs. alternative (practices) when describing the role of “alternative to antimicrobials” in the Code of Practice. We indeed consider that practices such as good animal husbandry, including good animal feeding, are effective measures to implement to fight AMR but cannot be regarded as alternatives to antimicrobials.	**FEFAC**
(j) Practices during production, processing, storage, transport, retail and distribution of food	
Australia prefers the retention of this section. Rationale: This section completes the information for all stages of the food chain. The conditions of food processing and beverage plants are of a particular focus for some countries. It is important to reflect this focus in the document.	**Australia**
The section of the draft document concerning “Practices during production, processing, storage transport, retail and distribution of food” was added after discussion in the last physical meeting of the Codex TFAMR. This new section, as currently written, does not provide guidance and instead, states conclusions. We recommend that the section be reviewed and reformulated to provide guidance surrounding the stated practices, which would make the document more meaningful to the readers.	**International Meat Secretariat**

SPECIFIC COMMENTS

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Introduction	
General comment	**Indonesia** Indonesia agrees with the introduction content but we propose several suggestion such as considering that AMR is high concern in the world, the introduction should describe the importance of AMR control in the food chain, including gap analysis the existing condition and future target. We also propose that the worse impact of AMR should be categorized through risk based. Since the scope of the code of practice will cover the entire of food chain from plant, crop and animal production, the introduction should provide the proof of the relationship between the application of antimicrobial in plant/crop and the severity of AMR in animal/human.
General comment	**USA** The United States appreciates the work of the EWG and the co-chairs, in particular with respect to the many comments received and reconciliation of many suggestions in the revised text. We believe the draft continues to improve and contains valuable contributions to minimize and contain antimicrobial resistance.
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. Within the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop production animal production (terrestrial and ~~aquatic)~~ aquatic), plant/crop production and food processing should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**Canada** This is for consistency of the document to emphasize the animal/veterinary part of AMR.
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. Within the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in ~~plant/crop~~ crop production animal production (terrestrial and aquatic) and food processing should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**China** The scope of this COP includes all the food chain. Crops may be better to match this scope. The crops should be the food or feed from plant source.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. Within the food chain, there is a need to address the risks associated ~~with development~~with, selection and dissemination of foodborne ~~resistant microorganisms and resistance determinants~~AMR. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in ~~plant/crop~~ crop production animal production (terrestrial and aquatic) and food processing should form a key part of multi-sectoral national action plans to address risks of foodborne ~~antimicrobial resistance~~AMR.	**USA** "Development" is redundant with "selection". "Selection and dissemination" is consistent with GL77. Foodborne AMR includes microorganisms and resistance determinants-would be simpler to use the term "foodborne AMR" throughout. The term "crop" is consistent with CXG 77 and is defined below. Foodborne AMR includes microorganisms and resistance determinants-would be simpler to use the term "foodborne AMR" throughout
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. ~~Within~~ Along the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop production animal production (terrestrial and aquatic) and food processing storage, transport, retail and distribution; and should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**Consumers International**
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. Within the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne anti-microbial resistant ~~microorganisms and resistance determinants.~~ pathogens. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop production animal production (terrestrial and aquatic) and food processing should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**Healthforanimals** There should be consistency throughout the document the focus is on microorganisms of human health significance.
§1. Antimicrobial resistance (AMR) poses ~~a~~ an important, complex, ~~global~~ global, and urgent public health challenge. ~~Within~~ Throughout the food chain, there is a need to ~~address~~ prevent, minimize, and contain the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop production animal production (terrestrial and aquatic) and food ~~processing~~ processing, packaging, storage, transport, retail and distribution should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**International Association of Consumer Food Organizations** The text in the document does not describe and highlight the importance and urgency of AMR, as reflected in paragraph 11 of the report of the Fifth Session of the Task Force, as well as at the most recent session of the Codex Alimentarius Commission, where delegations commented that the new work should "highlight the priority importance of combatting AMR." (Merely describing the problem as "complex" and "global" does not capture the importance and urgency of the AMR problem to health and is inadequate.)

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§1. Antimicrobial resistance (AMR) poses a complex, global public health challenge. Within the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop ~~production~~ and animal production (terrestrial and aquatic) and food processing should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance.	**International Feed Industry Federation**
§2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including the role of regulatory authorities, pharmaceutical industry, animal health professionals and ~~plant/crop advisors or consultants~~crop health professionals, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, retail and distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	**China** The crop health professionals should include the regulators, experts, advisor and consultants who has knowledge and experience in crop production and protection practices on crop health or plant food safety.
§2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including the role of regulatory authorities, the pharmaceutical industry, animal health professionals and plant/crop advisors or consultants, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, retail and wholesale distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	**USA** The word “wholesale” is added for consistency with the title of the section below.
§2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants ~~in~~ along the entire food chain, including the role of regulatory authorities, pharmaceutical industry, animal health professionals and plant/crop advisors or consultants, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, retail and distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	**Consumers International**
§2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, ~~including the role of regulatory authorities, pharmaceutical industry, animal health professionals and plant/crop advisors or consultants, and food producers and processors~~to reduce illness in humans from AMR microorganisms found in food. It provides guidance on measures and practices at primary production, and during processing, storage, transport, retail and distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	**Healthforanimals** General comment: Mandate. The document should specify the scope is specific to food and the intended audience is the people working in the food chain. Some of the texts appear to be directed at ‘all people’ instead of ‘people working in the professions and involved with the responsible for use of antimicrobials in the food chain’. Codex should be vigilant that the core purpose of the text is maintained. Otherwise there is a risk that the utility of the document becomes diluted. Specific comments (corrections): There should be consistency throughout the document the focus is on microorganisms of human health significance.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants ~~in~~ throughout the food chain, including the role of regulatory authorities, pharmaceutical industry, animal health professionals and plant/crop advisors or consultants, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, retail and distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.	**International Association of Consumer Food Organizations** The purpose of this work to revise the code is to broaden the scope to address "the entire food chain," as stated in CX/CAC 17/40/12 Add. 2 (Appendix 1). The term "throughout" conveys this better than the word "in." Alternatively, the text could read "in the entire food chain."
§2bis. In keeping with the Codex mandate this Code of Practice ~~focuses on~~ addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the risks associated with the occurrence/persistence in the environment of antimicrobials and their metabolites from ~~anthropogenic sources~~food production related activities, and to minimize ~~the risks associated with the~~ the selection and dissemination of resistant microorganisms and resistance determinants ~~in the environment~~which may contaminate food.	**USA** Rationale: Replaced “focuses on” with “addresses” to better reflect the nature of the guidance, for example many measures seek to reduce the need for antimicrobial use. Moved the phase “risks associated with” to recognize the fact that best practices will minimize the risks rather than prevent occurrence/persistence in the environment. Replaced “anthropogenic sources” with “food production related activities” to keep within the mandate of Codex. Replaced “in the environment” with “which may contaminate food” to keep within the mandate of Codex.
§2bis. In keeping with the Codex mandate this Code of Practice focuses on antimicrobial use ~~in~~ along the entire food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the environment of antimicrobials and their metabolites from anthropogenic sources, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the environment.	**Consumers International**
§2bis. In keeping with the Codex mandate this Code of Practice focuses on antimicrobial use in the food chain. It is recognized that ~~the use of~~ antimicrobial ~~agents in the food chain~~ resistant bacteria may ~~result in exposure in~~ be transferred through the environment~~.~~ .As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the environment of antimicrobials and their metabolites from anthropogenic sources, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the environment.	**Healthforanimals** Revision to avoid confusion with ongoing discussions of scope pertaining to information on the role of environment as well as antimicrobial products that affect pathogens other than bacteria.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§2bis. In keeping with the Codex mandate this Code of Practice focuses on antimicrobial use ~~in~~ throughout the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the environment of antimicrobials and their metabolites from anthropogenic sources, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the environment.	**International Association of Consumer Food Organizations**
§3. This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistanc*e and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003) and the *Code of practice on good animal feeding* (CXC 54-2004) are particularly relevant for use of agricultural chemicals on plants/crops and animal feed, respectively.	**Indonesia** Indonesia suggests the addition of terminology of "plant/crop" which is used in this code of practice
§3. This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistanc*e and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003) and the *Code of practice on good animal feeding* (CXC 54-2004) are particularly relevant for use of agricultural chemicals on plants/crops and animal feed, respectively.	**International Feed Industry Federation** Prudent and judicious are used. It would be useful to be consistent and use only one of the two term along the text
§3bis. This Code of Practice provides risk management advice, including the responsible and ~~judicious~~ prudent use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk to introduce levels of protection appropriate for circumstances.	**Canada** Change to maintain consistency throughout the document
§3bis. This Code of Practice provides risk management advice, including the responsible and ~~judicious~~ prudent use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk to introduce levels of protection appropriate for circumstances.	**Norway** Replace judicious with prudent because this is more common used wording

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§3bis. This Code of Practice provides risk management advice, including the responsible and ~~judicious~~ prudent use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk to introduce levels of protection appropriate for circumstances.	**USA**
§4. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. Setting priorities and identifying risk management measures should reference the following: - *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria,* - *the application of a One Health Approach* and *critically important antimicrobials for human medicine*, • ~~and -~~ relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobials of veterinary importance* • ~~should also be referenced -~~ the International Cooperation on Harmonisation of Technical Requirements for ~~setting priorities and identifying risk management measures.~~ Registration of Veterinary Medicinal Products (VICH)	**Australia** This amendment complements the reference to VICH in paragraph 11 of the Code of Practice and suggest that references be listed as dot points to avoid a long sentence structure.
§4. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach* and *critically important antimicrobials for human medicine* and relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobials of veterinary ~~importance~~importance and national lists when they exist* should also be ~~referenced for setting priorities and identifying risk management measures~~taken into account	**USA** The WHO guidance was developed by an expert group rather than through a transparent process of review and consensus by Member Countries, such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e. Codex, OIE, and International Plant Protection Convention (IPPC)]. Therefore, the language as written that WHO guidance should be referenced for setting priorities and identifying risk management measures is too strong . In addition, national lists should be taken into consideration when they exist as they are likely more applicable to local risks and conditions. Also it is not fully consistent with the guidance provided by CCEXEC" either in comments or during discussion. See paragraph 14 of CCEXEC 75 report.
§4. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. *WHO guidelines on use of medically important antimicrobials in foodproducing animals, WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach* and *critically important antimicrobials for human medicine* and relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobials of veterinary importance* should also be ~~referenced~~ used for setting priorities and identifying risk management measures.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§4. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach* and *critically important antimicrobials for human medicine* and relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobials of veterinary importance* and national lists where they exist. should also be ~~referenced for setting priorities and identifying risk management measures.~~ taken into account as appropriate.	**Healthforanimals** 6. Lists. The Code refers to lists of antimicrobials (WHO list of critically important antimicrobials, OIE list of antimicrobials of veterinary importance, national lists). Whichever list is used by national authorities, appropriate science-based risk analysis should be used to focus on potential AMR to humans.
§4. The *Principles and ~~guidelines~~ Guidelines for the ~~conduct~~ Conduct of ~~microbiological risk management~~Microbiological Risk Management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. ~~*WHO guidance*~~ *WHO's Guidelines on ~~integrated surveillance~~ Medically Important Antimicrobials in Food Producing Animals; Integrated Surveillance of ~~antimicrobial resistance~~ Antimicrobial Resistance in ~~foodborne bacteria, application~~ Foodborne Bacteria: Application of a One Health ~~Approach~~ Approach;* and ~~*critically important antimicrobials*~~ *Critically Important Antimicrobials for ~~human medicine~~Human Medicine;* and relevant chapters of the ~~*OIE terrestrial*~~ *OIE's Terrestrial Animal Health Code and ~~aquatic animal health codes~~Aquatic Animal Health Code;* and the OIE *List of ~~antimicrobials~~ Antimicrobials of ~~veterinary importance~~Veterinary Importance* should also be ~~referenced~~ used for setting priorities and identifying risk management measures.	**International Association of Consumer Food Organizations** The WHO's Guidelines on Medically Important Antimicrobials in Food Producing Animals is very relevant and should be mentioned. All documents should be capitalized so that the reader understands that these are the titles of reports.
§5. Where available, national and local guidelines and best management practices to prevent, minimize and contain foodborne antimicrobial resistance should be taken into consideration. ~~Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.~~	**Canada** Suggest merging the two sentences into one
§5. Where available, national and local guidelines to prevent, minimize and contain foodborne ~~antimicrobial resistance~~ AMR should be taken into consideration. Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.	**USA**
§5. Where available, national and local guidelines to prevent, minimize and contain ~~foodborne antimicrobial resistance~~ pathogens that may be resistant should be taken into consideration. Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.	**Healthforanimals**
§6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, ~~however~~ however, whenever feasible, some recommendations may also be applicable to antiviral, ~~antiparasitic,~~ antiprotozoal, and antifungal agents.	**Brazil** To be more flexible and since “antiparasitic” can be a very wide range of products, we suggest that the term “antiprotozoal” is more adequate, for the purpose of this CoP.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§6. ~~Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this~~ This Code of Practice will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents.	**Canada** The reason of “co-resistance” or “co-selection” mechanism for the purpose of this paragraph seems not technically sound.
§6. ~~Recognizing there are mechanisms~~ Antimicrobial agent include antibiotics, antibacterial, antiviral, antifungal, antiparasitic, and antiprotozoal agents. Most of ~~co-resistance or co-selection in a range of antimicrobial agents, most of~~ the recommendations in this Code of Practice will focus ~~on~~ on ~~antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents.~~antimicrobial agent and antimicrobial resistance.	**Norway** This paragraph is confusing as it indicates co-resistance or co-selection between e.g. antibiotics and antiparasitics. To our knowledge, there is no evidence for that, thus the sentence should be revised.
§6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials~~, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents~~.	**USA** Rationale: It makes sense to focus countries to addressing the most important priority where most antimicrobial agent use takes place: antibacterial agents. The characteristics and risks associated with potential resistance development of these other categories are very different than antibacterial products and should be excluded from the scope. With the exception of formalin and hydrogen peroxide water immersion products, there are currently no approved drug applications actively marketed for antifungal and antiviral purposes in food-producing animals. Also, the OIE and several national authorities have policies, guidance, standards, or recommendations on these topics and continue to develop them based on data that is relevant for those topics.
§6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents.	**FEFAC** The concept of antibacterials not being used further in the document, it is not easy to clarify which provisions apply to antibacterials and which to antimicrobials at large.
§6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, ~~most of~~ the recommendations in this Code of Practice will focus on antibacterials~~, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents~~.	**Healthforanimals** Focus on addressing the most important priority where most antimicrobial agent use takes place: antibacterial agents. The large majority of antiparasitics are not antimicrobials (e.g. dewormer, fly, flea, tick, mange, etc. control products) and it is important not to confuse antiparasitics with antimicrobials. In line with this, the definition of “Antimicrobial agent” should be changed accordingly (see below).
§6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents.	**International Feed Industry Federation** The concept of antibacterials is not being used in the document, it is not easy to clarify which provisions apply to antibacterials and which to antimicrobials at large.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
2. Scope	
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food of antimicrobial resistant microorganisms or resistance ~~determinants~~determinants along the food chain. It provides ~~risk-based~~ guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in ~~plant/crop production and~~ animal production (terrestrial and aquatic) and plant/crop production, and references to other best management practices as ~~appropriate. It also provides risk-based guidance~~ appropriate such as those on practices during production, processing, storage, transport, retail and distribution of ~~food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.~~ food.	**Canada** The second and third sentences provide the same/similar guidance on the measures or practices along the food chain. Suggest merging them (to avoid duplication)
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and animal feed and the transmission through food and animal feed of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents ~~in the food chain.~~ in agriculture and aquaculture.	**Norway** We are of the opinion that for clarity it should be written food and animal feed .
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and wholesale distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize ~~the potential~~ adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.	**USA** The word “wholesale” is added for consistency with the title of the section below. “Potential” fails to recognize the scientific assessment that guides management of ‘actual’ impact or harm. Risk managers are responsible for assessing the impacts- and determining how best to reduce risk, not to anticipate risk levels and introduce levels of protection not established at the outset of the assessment.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food and along the food chain of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to prevent and minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents ~~in~~ along the entire food chain.	**Consumers International**
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and feed and the transmission through food and feed of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.	**FEFAC** It is useful to keep the words food and feed as not all measures mentioned in this code are relevant to both feed and food
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.	**Healthforanimals** Science-based practical recommendations. The Code should provide advice on what can realistically be achieved, and support recommendations made based on risk-assessment. • Medical therapies are used against an existing threat to the health/welfare of the animal and/or consumer. It is important that hazard and exposure are considered when calculating risk. • It is not appropriate to include recommendations on the environment, where risk-assessments have not yet been performed and are therefore unable to inform risk management positions. • The Code should not include recommendations about advertising rules that are based on national legislation.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food and the food chain of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures ~~along~~ throughout the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to prevent and minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.	**International Association of Consumer Food Organizations**
§7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food[1] and the transmission through food of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop ~~production~~ and animal production (terrestrial and aquatic) and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.	**International Feed Industry Federation**
§8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents ~~along the food chain~~ along the food chain together with those involved in the handling, preparation, food processing, distribution and consumption of food who have a role to play in optimizing the use of antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.	**Norway**
§8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents along the food chain together with those involved in the handling, preparation, food processing, distribution and consumption of food who have a role to play ~~in optimizing the use of antimicrobial agents and/or who have a role with~~ in limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.	**USA** The scope of the document includes other aspects, for example measures to reduce the need for antimicrobials

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents along the food chain together with those involved in the handling, preparation, food processing, ~~distribution~~ storage, transport, wholesale and retail distribution, and consumption of food who have a role to play in optimizing the use of antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.	**Consumers International**
§8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents along the food chain together with those involved in the handling, preparation, food processing, distribution and consumption of food who have a role to play in ~~optimizing~~ enabling the ~~use~~ availability of ~~antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.~~ safe food.	**Healthforanimals** The mandate of Codex is for food safety and fair trade. As it previously read, it was a leading statement and suggested a mandate for AMR.
§8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents ~~along~~ throughout the food chain together with those involved in the handling, preparation, ~~food~~ processing, storage, transport, retail, distribution and consumption of food who have a role to play in optimizing the use of antimicrobial agents and/or who have a role with ~~limiting~~ preventing or minimizing the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.	**International Association of Consumer Food Organizations**
§9. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms[2]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[3]; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics[4]. In addition, AMR from non-food animals or non-food routes are also outside the scope of this document. Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines.	**Brazil** It is important to clearly exclude biocides of the scope of the document
§9. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms[2]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[3]; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as ~~probiotics~~probiotics[4]. In addition, AMR from non-food animals or non-food routes are also outside the scope of this document.	**China** Thank to statement of biocides and probiotics. However, China also suggest to emphasize the risk assessment of probiotics and update new guideline for the risk of probiotics and biocides. Because they may be an important factor in the transmission of antimicrobial-resistant genes.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§9. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms[2]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[3]; biocides and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics[4]. In addition, AMR from non-food animals or non-food routes are also outside the scope of this document.	**USA** Consistency with GLIS and based on the summary of the FAO/WHO expert meeting on foodborne antimicrobial resistance: Role of environment, crops and biocides, Rome, 11-15 June 2018, it appears data gaps exist with regard to biocides and impact on foodborne AMR risk.
3. Definitions	
General comment	**Indonesia** Indonesia supports the use of the common definition in this code of practice as long as in line with Codex, OIE and IPPC
Antibacterial	
~~**Antibacterial:** A substance that acts against bacteria.~~	**China** China prefer to use the word of antimicrobial to replace the antibacteria. Because some other anti-microbial drugs, such as antiparasitic drugs, also have an antibacterial effect.
Antibacterial: A ~~substance~~ antimicrobial agent that acts against bacteria.	**International Feed Industry Federation** This enables to limit the scope of the definition of what is important for this guideline, i.e. antimicrobial with a specific target.
Antibiotic	
Antibiotic: ~~A naturally derived~~ Any substance ~~from a biological source that acts against microorganisms~~of natural, ~~specifically~~ semi-synthetic, or synthetic origin that kills or inhibits the growth of bacteria.	**Australia** The definition is incomplete. By ending this definition with “specifically bacteria”, it is not clear if it refers to substances that only act against bacteria or includes those substances that may have some antibacterial action, but primarily target other microorganisms (e.g. ionophores against parasites). Also, an antibiotic is not only a naturally derived substance.
Antibiotic: Any substance of natural, semi-synthetic, or synthetic origin that~~A naturally derived substance from a biological source~~ that acts against microorganisms, specifically bacteria.	**Brazil** Evaluate if the definition of antibiotic is really needed in the document.
~~**Antibiotic:** A naturally derived substance from a biological source that acts against microorganisms, specifically bacteria.~~	**Consumer Goods Forum** Propose to delete this term as this term is not required for this document. This document also has term “antibacterial”. Due consideration need to be given on appropriate usage of terminology in document to avoid confusion.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Antibiotic: A substance, usually naturally derived ~~substance~~ from a biological ~~source~~ source, that acts against microorganisms, specifically bacteria.	**Consumers International**
Antibiotic: A substance that is typically naturally derived ~~substance~~ from a biological source that acts against microorganisms, specifically bacteria.	**International Association of Consumer Food Organizations** Without this edit, the definition would exclude sulfa drugs, synthetic antibiotics
Antibiotic: A naturally derived ~~substance~~ antimicrobial agent from a biological source that acts against microorganisms, specifically bacteria.	**International Feed Industry Federation**
Antibiotic resistance	
~~**Antibiotic resistance**~~**Antimicrobial resistence:** The ability of a microorganism, specifically bacteria, to multiply or persist in the presence of an increased level of an antibiotic relative to the susceptible counterpart of the same species.	**Colombia** Colombia suggests to eliminate this term, in accordance with the first observation, where it was suggested to be replaced by ¨antimicrobial resistance¨. The definition is appropriately included in the document.
~~**Antibiotic resistance:** The ability of a microorganism, specifically bacteria, to multiply or persist in the presence of an increased level of an antibiotic relative to the susceptible counterpart of the same species.~~	**USA** Recommend deletion of this definition if it no longer appears in the document.
~~**Antibiotic resistance:** The ability of a microorganism, specifically bacteria, to multiply or persist in the presence of an increased level of an antibiotic relative to the susceptible counterpart of the same species.~~	**Consumer Goods Forum** Propose to delete this term as this term is not required for this document. This document also has term “antibacterial”. Due consideration need to be given on appropriate usage of terminology in document to avoid confusion.
Antimicrobial agent	
Antimicrobial agent: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, antiparasitic, and antiprotozoal agents, but does not includes disinfectants and antiseptics.	**Colombia** It is suggested to complement this definition, to clarify its scope and in concordance with the definition of the European, Medicines Agency (EMA) and the World Health Organization (WHO).
Antimicrobial agent: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. ~~The term antimicrobial is a collective for antiviral, antibacterial, antifungal, antiparasitic, and antiprotozoal agents.~~	**Norway** For consistency with other Codex documents.
Antimicrobial agent: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, antiparasitic, and antiprotozoal agents.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Antimicrobial Class - Antimicrobial agents with related molecular structures, often with a similar mode of action because of interaction with a similar target and thus subject to similar mechanism of resistance. Variations in the properties of antimicrobial agents within a class often arise as a result of the presence of different molecular substitutions, which confer various intrinsic activities or various patterns of pharmacokinetic and pharmacodynamic properties	
Antimicrobial agent: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. The term antimicrobial is a collective for antiviral, antibacterial, ~~antifungal, antiparasitic,~~ antifungal and antiprotozoal agents.	**Healthforanimals** The word antimicrobial is used throughout the document. It is more appropriate to use the word antibacterial. It should be made as clear as possible to which areas the guidelines apply. This will allow focus on addressing the most important priority where most antimicrobial agent use takes place: antibacterial agents. The large majority of antiparasitics are not antimicrobials and it is important not to confuse antiparasitics with antimicrobials. In line with this, the definition of "Antimicrobial agent" should not include 'antiparasitics'.
Antimicrobial agent/Antimicrobial: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, antiparasitic, and antiprotozoal agents. **Antimicrobial class:** Antimicrobial agents with related molecular structures, often with a similar mode of action because of interaction with a similar target and thus subject to similar mechanism of resistance. Variations in the properties of antimicrobial agents within a class often arise as a result of the presence of different molecular substitutions, which confer various intrinsic activities or various patterns of pharmacokinetic and pharmacodynamic properties.	**International Association of Consumer Food Organizations** 1) Both "antimicrobial agent" and "antimicrobial" are used in the text 2) The term "antimicrobial class" is used in the text and should be defined; this definition is from GL 77-2011
Control of disease/metaphylaxis	
Control of disease/metaphylaxis: Administration of an antimicrobial ~~agents~~ agent to a group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.	**Australia** The language implies that more than one antimicrobial agent would be used initially, which would not reflect responsible and prudent use. It is preferred that the singular noun and associated article are used with 'antimicrobial agents'. This ensures consistency with the OIE's definitions.
~~**Control of disease/metaphylaxis**~~**AMR food safety issue**: Combination of the hazard(s) (AMR microorganisms and / or determinant(s)), the antimicrobial agent(s) to which resistance is expressed and the food commodity in which the hazard is identified.[Control of disease/metaphylaxis: Administration of antimicrobial agents to group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.	**USA** The term and description is from CXG 77 and helps describe what the actual food safety hazard is.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Control of ~~disease/metaphylaxis~~disease/metaphylaxis use of antimicrobial agents: Administration of antimicrobial agents to group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.	**International Association of Consumer Food Organizations** This wording change is needed since there are other ways to control disease other than by using antimicrobial agents
Co-resistance	
Co-resistance: The ability of a microorganism to multiply or persist in the presence of ~~different classes~~ more than one class of antimicrobial agents due to possession of ~~various~~ more than one resistance ~~mechanisms~~mechanism in the one host.	**Australia** Improves clarity and updates the definition.
Cross-resistance	
Cross-resistance: The ability of a microorganism to multiply or persist in the presence of ~~other members~~ one or more classes of ~~a particular class of~~ antimicrobial agents ~~or across different classes~~ due to a ~~shared~~ single mechanism of resistance.	**Australia** Improves clarity and updates the definition.
Extra- or off-label use	
Extra- or off-label use: The use of an antimicrobial agent that is ~~not in accordance~~ inconsistent with the directions for use on the approved product ~~labelling~~labelling or inconsistent with instructions included in an issued permit. Extra- or off-lable use may be allowed according to national legislation.	**Australia** Improves clarity and updates the definition. Off-label use may be permitted according to national legislation in some countries and it also provides flexibility with countries' systems.
~~**Extra- or off-label use:**~~**Crop advisor and consultant:** Crop health professionals with knowledge and experience in crop production and protection practices. [Extra- or off-label use: ~~-~~The use of an antimicrobial agent that is not in accordance with the approved product labelling.	**USA** Since the term is used in the document, it would be helpful to include a definition.
Food chain	
Food chain: Production to consumption continuum including, primary production (food-producing animals, plants/crops), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.	**International Feed Industry Federation** Feed (i.e. beyond just plant/crops for feed use) is missing here.
Food-producing animals	
Food-producing animals: Animals raised for the purpose of providing food to humans~~.~~. Most commonly this term refers to poultry, swine, cattle, sheep, fish and crustacean but it does not exclude other domestically managed animals.	**Norway** For consistency with other Codex documents.
Food-producing animals: ~~Animals~~ Animals, or parts thereof, such as animal cell cultures, produced or raised for the purpose of providing food to humans.	**Consumers International**
Food-producing animals: Animals raised for the purpose of providing food to humans. Includes amphibians, birds, fish, invertebrates, reptiles, and mammals.	**International Association of Consumer Food Organizations** For clarity.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Growth promotion	
Growth ~~promotion~~promotion/feed efficiency: Administration of antimicrobial agents to only increase the rate of weight gain and/or the efficiency of feed utilization in animals. The term does not apply to the use of antimicrobials for ~~the specific purpose of treating, controlling, or preventing infectious diseases.~~ the specific purpose of treating, controlling, or preventing infectious diseases.	**Healthforanimals** The words 'growth promotion' are not on labels. It is most often 'feed efficiency'. The clinical outcome is most often weight gain relative to feed intake or conversion. The administration of an antimicrobial at levels for feed efficiency outcome will not create growth beyond what the animal's genetic makeup will allow. Feed efficiency uses really allow the 'maintenance' of growth instead of the promotion of growth.
Medically important antimicrobials	
~~Medically~~ Critically important antimicrobials~~: :Antimicrobial agents~~ Critically important antimicrobial agents or equivalent for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.	**Australia** The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries.
Medically important antimicrobials: Antimicrobial agents ~~important~~ used or intended for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available~~. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.~~ .	**Canada** The change would cover the novel antimicrobials for their potential use in humans. It is also suggested to delete the second sentence
Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	**China** Medically important antimicrobials are antimicrobial agents important for therapeutic use in humans as described in the WHO list of critically important antimicrobials or national lists, where available. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.
~~Medically~~ Critically important ~~antimicrobials~~antimicrobials for humane medicine: Antimicrobial agents important for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.	**Colombia** The panel suggests to modify this term, since in the WHO AGISAR guidelines, the term is used Critically important antimicrobials for human medicine. Additionally it is suggested to suppress the reference that is made of ionophores (not used in human medicine) or other antimicrobial agents since this is over understood.
Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.	**Iran** It is advised to describe a list for medically important antimicrobials which may be applied in plants or probably administered by plant/crop advisors, as an alternative the WHO guidelines on medically important antimicrobials in food may be developed.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~**Medically important antimicrobials:** Antimicrobial agents important for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.~~	**Norway** Redundant as we suggest deleting this in the text of the COP
Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not ~~used~~ important for human therapeutic use.	**USA** The language has been modified to account for the possibility that current or future antimicrobial agents could be used in humans and not contribute to foodborne AMR risk.
Medically important antimicrobials: Antimicrobial agents important for therapeutic use in ~~humans~~ humans, or those that belong to the same antimicrobial class, as described in the *WHO list of critically important antimicrobials* or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.	**Consumers International**
Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans as described in the *WHO ~~list~~ List of ~~critically important antimicrobials~~Critically Important Antimicrobials* for Human Medicine or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.	**International Association of Consumer Food Organizations**
One Health Approach	
One Health Approach: A collaborative, multisectoral, and trans-disciplinary approach - working at the local, regional, national, and global levels - with the goal of achieving optimal health outcomes in both humans and animals recognizing the interconnection between humans, animals, crops, and their shared environment.~~A collaborative, multisectoral, and trans-disciplinary approach - working at the local, regional, national, and global levels - with the goal of achieving optimal health outcomes recognizing the interconnection between humans, animals, crops, and their shared environment.~~	**Norway**
Pharmacovigilance	
Pharmacovigilance: The collection of information on how products perform in the field after authorisation to ensure that they continue to be ~~further developed~~safe and effective. This information may include information on adverse human health effects; harm to animals; damage to plants, property or the environment; or lack of efficacy when the products are used according to label directions.	**Australia** New definition proposed, as the term has been used in the Code of Practice. Also, for consistency with the OIE Standards.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Pharmacovigilance: to be further developed.Pharmacovigilance is scientific research and activity to discover, evaluate, understand and prevent adverse reactions or any other possible drug-related problems. Pharmacovigillance involves not only adverse drug reactions, but also other drug-related issues, such as substandard drugs, drug treatment errors, reports of lack of effectiveness, medication without adequate scientific basis and unacceptable indications, case reports of acute and chronic poisoning, and evaluation of drug-related mortality. The abuse and misuse of drugs, the adverse interactions between drugs and chemical drugs, other drugs and food.	**China** Pharmacovigilance is scientific research and activity to discover, evaluate, understand and prevent adverse reactions or any other possible drug-related problems. Pharmacovigillance involves not only adverse drug reactions, but also other drug-related issues, such as substandard drugs, drug treatment errors, reports of lack of effectiveness, medication without adequate scientific basis and unacceptable indications, case reports of acute and chronic poisoning, and evaluation of drug-related mortality. The abuse and misuse of drugs, the adverse interactions between drugs and chemical drugs, other drugs and food.
Pharmacovigilance: the science and activities related to ~~be further developed~~the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems". In the context of this guideline the focus is on adverse antimicrobials effects and RAM related problems, including therapeutic failure.	**Colombia** This definition already exists in another document: ¨The importance of pharmacovigilance. Safety monitoring of medicinal products. Geneva: World Health Organization; 2002.¨ The panel suggest to use this definition and considers it appropriate.
Pharmacovigilance: The practice of monitoring the effects of medical drugs, which are licensed for use, in relation to ~~be further developed~~the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.	**USA** Adapted from WHO and U.S. FDA definition
Plants/crops	
~~Plants/~~**crops:** A cultivated plant that is grown as food or feed, especially a grain, fruit or vegetable, including all edible parts.	**China** Antibacterial: A substance that acts against bacteria.
Plants/crops: A cultivated plant that is grown as food or feed, especially a grain, fruit or vegetable, including all edible parts.	**Thailand** It is important to note that the use of antimicrobials in plants and crops could contribute to increased antimicrobial resistance. To our understanding, "crop" is a term referred only to plants that are food, whereas a term "plant" provides boarder concept covering food and non-food. In this relation, we propose that definitions of the terms "plant" and "crops" should be separately defined and harmonised among codex documents. This is to avoid misinterpretation when this guideline is applied. Moreover, the clear definition of these terms would be also useful for the global cooperating work on AMR with International Plant Protection Convention (IPPC) as an international phytosanitary organisation.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Plant/crop advisor and consultant	
~~Plant/crop advisor and consultant~~crop health professional: Plant/crop health professionals with knowledge and experience in crop production and protection practices.	**China** The crop health professional should be further developed. The crop health professionals should include the regulators, experts, advisor and consultants who has knowledge and experience in crop production and protection practices on crop health or plant food safety.
Plant/crop advisor and consultant: Plant/crop health professionals with knowledge and experience in crop production and protection ~~practices~~practices who are authorized to use or direct the use of antimicrobial agents on crops.	**International Association of Consumer Food Organizations** The term "plant/crop health professionals" seems more inclusive.
Prevention of disease/prophylaxis	
Prevention of disease/prophylaxis: Administration of an antimicrobial ~~agents~~ 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 antimicrobial agent is not administered.	**Australia** The language implies that more than one antimicrobial agent would be used initially, which would not reflect responsible and prudent use. It is preferred that the singular noun and associated article are used with 'antimicrobial agents'. This ensures consistency with the OIE's definitions.
Prevention of disease/prophylaxis: ~~Administration~~ Specific measures taken to promote health and prevent disease, including good hygienic practices, integrated pest management, vaccination, and good animal husbandry practices related to diet, exercise, and housing/environment. May also in limited and well-defined circumstances, including when demonstrated to be effective, consistent with accepted veterinary practice, and with appropriate oversight, dose, and duration, involve administration of antimicrobial agents 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 antimicrobial agent is not administered.	**International Association of Consumer Food Organizations** The definition as originally drafted is problematic since (1) it is too narrow in the sense that "prevention of disease/prophylaxis" need not involve use of antimicrobials; indeed the document discusses multiple strategies for prevention of disease including good hygienic practices, vaccination, good animal husbandry, etc. The unedited definition appears to be saying that the only way to prevent disease is by using antimicrobial agents, which is incorrect, and unacceptable (it contradicts the purpose of the Code); and (2) it is too broad, in the sense that under this definition, almost any animal could be given antibiotics for prophylaxsis.
Therapeutic use	
Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease. Treatment of disease: Administration of antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease. Control of disease/metaphylaxis: Administration of antimicrobial agents to group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.	**China** The three definitions of prevention, treatment, metaphylaxis disease shoud be together for comparison. Early treatment should be advocated for animal bacterial infectious diseases.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~**Therapeutic**~~ **Veterinary medichal use:** Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.	**Norway** In order to be consistent with corresponding wording used in OIE guidance, we are of the opinion that it is best to use Veterinary medical use as written in OIE Terrestrial code chapter 6.9.2.
Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.	**USA** We support inclusion of this definition. Therapeutic uses are for addressing disease and animal health. Treatment, control, and prevention are therapeutic uses because they aim to address disease, while growth promotion is not aimed at addressing disease and is a production use. Clearly defining prevention as a therapeutic use will help facilitate global understanding regarding the importance of exercising clinical judgement in determining whether a particular drug is appropriate for therapeutic uses, versus non-targeted use for production purposes. It will be helpful for Codex to articulate the distinction to promote good global stewardship where a lot of confusion around these terms remains.
Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.	**Consumer Goods Forum** Propose to delete this term as this is not clear and also overlapping and confusing. Also there is duplicity with the next definition regarding treatment of disease
~~**Therapeutic use:** Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.~~	**Consumers International**
~~**Therapeutic use:** Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.~~	**International Association of Consumer Food Organizations** This definition should be deleted since there is no consensus for it (it is contrary to the definition of therapeutic used by the WHO, for example), it is unnecessary since these terms are separately defined in the document, and grouping them together obscures important distinctions between these uses. Furthermore, the term “therapeutic” is frequently used in the document to refer to use of antimicrobials in humans, and control/metaphylaxsis would not generally apply to human use.
Treatment of disease	
Treatment of disease: Administration of an antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease.	**Australia** The language implies that more than one antimicrobial agent would be used initially, which would not reflect responsible and prudent use. It is preferred that the singular noun and associated article are used with ‘antimicrobial agents’. This ensures consistency with the OIE’s definitions.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Treatment of disease: Administration of antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease.	**Kenya** Kenya proposes the need to define environment in regard to the COP. The environment in regards to production, transport, processing, sales and distribution plays an integral part of antimicrobial resistance. Practices that impact on hygiene, contamination(land and water bodies) may cause resistance need to be captured.
Treatment of disease (or therapeutic use): Administration of antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease.	**Consumer Goods Forum** Amend the title as "Treatment of disease (or therapeutic use)" to bring in clarity
4. General principles to minimize and contain antimicrobial resistance	
General comment	**Australia** Additional General Principles for inclusion in this part of the document are: a. that Codex will be limited to setting standards and providing guidance on risk within the food chain b. the robustness of surveillance design, sample collection, analysis, documentation and interpretation of monitoring/surveillance data should be taken into account when risk management actions are being considered c. the contribution of the food chain to human antimicrobial resistance. Rationale: a. Avoids duplication of international standards on animal health and veterinary prescribing. b. This supports the concepts outlined in Terrestrial Animal Health Code, Chapter 6.10, Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine and the Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals. c. It is currently unknown about the scale of contribution made by food to the antimicrobial resistance observed.
General comment	**Brazil** This section should be revised, to be more consistent to “principles” and proportionate to the scope of the document. Some of the principles seem to be duplicated and could be more focused and concise. Also, for a better understanding, the order of some of the principles could be slightly changed.
General comment	**Canada** Principles 9, 10 and 11. These principles refer to risk analysis, and come in the middle of principles for administration of antimicrobials. It is suggested to move these principles after Principle 15.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
General comment	**China** The General principles should be more concise. If there is too much content, it may weaken their importance. Both principle 4-8 and principle 12-14 focus on the prudent use of medical important antimicrobials. China suggest to combine and concise these principles.
General comment	**Iran** A Principle could be added with the following subject: Tracing antimicrobial residues in food chain should be implemented as a part of risk management in each country.
General comment	**Thailand** Thailand would like to stress once again that there are too many general principles should be revised. We suggested that the common and proximity principles could be grouped together. In order to clearly understand, some broad principles should added sub-principles. A clear set of principles will give us immediate focus and clarity on the Codex work on AMR in nearly future. For example, grouping of some broad principles and sub-principles as follows; Principle 1 One Health approach (to include principle 1 of current draft) • A One Health Approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options. Principle 2 Basic implementation for good health and wellbeing of human, animals and plants (to include principle 2 of current draft) • Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents6 where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents. Principle 3 Prudent use of antimicrobials (to include principle 3-8 and 12-14 of current draft) • Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	• The WHO list of critically important antimicrobials, the OIE list of antimicrobials of veterinary importance, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns. • Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should: o be undertaken by the appropriate national regulatory authority; o be based on adequate scientific evidence; and o include a publicly available summary. • Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation. • Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration. • Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply. • Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation. • Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident. • Administration of antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Principle 4 Principle 5 National monitoring, surveillance of AMU and evaluation to strengthen the national program (to include principle 9, 10, 16 of current draft) • 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 human and animal health of recommended risk management measures. • 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 medically important antimicrobial agents in humans and food-producing animals, and transmission of pathogens and resistance genes between humans, food-producing animals, 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. • On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.
Principle 1	
Principle 1: A One Health Approach should be considered, wherever ~~possible and applicable~~possible, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options.	**Australia** Where reference is made to an approach being 'applicable', this should be avoided and deleted. It implies a need to determine the magnitude of risk and decisions made about whether something is applicable and the management of risk based on that decision. The amendment also encourages the One Health approach.
Principle 1: A One Health Approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options.	**Iran** In addition to WHO list of critically important antimicrobials, the OIE list of antimicrobials of veterinary importance, it is recommended to define a valid list for plants important antimicrobials

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 2	
Principle 2: Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents[6] ~~where appropriate, and~~ that have been proven to be efficacious and ~~safe,~~ safe where appropriate, should be considered to reduce the need for use of antimicrobial agents.	**USA** Suggest revising the footnote as edited because this is not an exhaustive list, some products may not have a clear regulatory pathway, some products are described above as outside the scope of the document. Adapted from: https://www.sciencedirect.com/science/article/pii/S1045105618300587
Principle 2: Substances or practices to treat, control or prevent disease without the use of antimicrobial agents should be considered to reduce the need for use of antimicrobial agents. This includes b~~Biosecurity~~iosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents[6] where appropriate, and that have been proven to be efficacious and safe~~, should be considered to reduce the need for use of antimicrobial agents~~.	**Consumers International**
Principle 2: Biosecurity, ~~appropriate~~ adequate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents[6] where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents.	**FEFAC** The word appropriate is changed to adequate to reflect the wording used in paragraph 59.
Principle 2: ~~Biosecurity~~Practices and measures to prevent, ~~appropriate nutrition~~control, ~~vaccination, animal~~ and ~~plant/crop best management practices~~treat disease without the use of antimicrobials should be considered, ~~and alternatives~~ in order to reduce the need for antimicrobial agents. Such practices and measures include good hygienic practices, biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents[6] where authorized and appropriate, and that have been proven to be efficacious and safe~~, should be considered to reduce the need for use of antimicrobial agents~~.	**International Association of Consumer Food Organizations** In addition, restore footnote and revise to say "Where authorized, could include ethnoveterinary and other approaches, such as herbal medicine, probiotics, competitive exclusion, bacteriophages, immunomodulators, organic acids and teat sealants
Footnote 6: ~~Could include ethnoveterinary and other approaches, e.g. herbal medicine, prebiotics, competitive exclusion bacteriophages, immunomodulators, organic acids and teat sealants~~. Alternative substances as appropriate, that have clear regulatory pathway for authorization if intended for use for the diagnosis, cure, mitigation, treatment or prevention of disease.	**USA**
Footnote 6: ~~Could include ethnoveterinary and other approaches, e.g. herbal medicine, prebiotics, competitive exclusion bacteriophages, immunomodulators, organic acids and teat sealants.~~ Where authorized, could include ethnoveterinary and other approaches, e.g., herbal medicine, competitive exclusion bacteriophages, immunomodulators, organic acids and teat sealants.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 3	
Principle 3: Science-based species - or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.	**Canada** For clarity
Principle 3: Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. These guidelines could reference established livestock species science-based quality assurance programs. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.	**USA** Established livestock species science-based quality assurance programs at the national level could address responsible and prudent antimicrobial use and therefore be a valuable approach.
Principle 3: Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be ~~developed~~developed based on risk-assessment, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.	**Healthforanimals** The longstanding commitment of many countries to apply risk-based approaches needs to be empathized. Risk assessment is widely accepted in existing OIE, Codex, FAO and WHO texts as well as in many other international organizations.
Principle 3: Science-based species or sector-specific best practices for responsible and prudent antimicrobial ~~use guidelines~~ use should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such ~~guidelines~~ best practices could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations. Priority should be given on ways to limit or eliminate medically important antimicrobials.	**International Association of Consumer Food Organizations**
Principle 4	
Principle 4: The *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	**Canada** This paragraph describes the WHO and OIE lists by recommending their updating partly based on resistance pattern data. However, the OIE list does not use the criteria on AMR, which should be a requirement for the lists if they are going to be considered for AMR risk management purposes. It is suggested that the principle clarifies the value that OIE list provides from a risk to human health perspective. Otherwise, suggest deletion of reference to the OIE list

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 4: The *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or **regional/**national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.	**Norway**
Principle 4: The *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on ~~resistance patterns~~new antimicrobial products, emergence of new diseases and any factors influencing the development of AMR in bacteria of human, animal and crop health concern.	**USA** Provides more information regarding what is meant by scientific data.
Principle 5	
Principle 5: ~~Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:~~ For responsible and prudent use administration in food-producing animals does not include the use for growth promotion of antimicrobial drugs that are considered, medically critically important or able to cause cross resistance to other antimicrobial drugs, or classes of antimicrobial agents for human medicine that are considered medically important should not be used for growth promotion in food-producing animals, in the absence of risk analysis. This risk analysis should:	**Australia** For consistency with the growth promotion principle outlined in the OIE list of antimicrobial agents of veterinary importance. Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
Principle 5: Responsible and prudent administration in food-producing animals ~~does not include~~ includes the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:	**Colombia** It is considered important to include the use of antimicrobial agents as growth promoters since in several countries antimicrobials are still used as growth promoters and prophylactics.
Principle 5: Responsible and prudent ~~administration in food-producing animals~~ use of antimicrobial agents does not include the use ~~for growth promotion~~ of antimicrobial agents ~~that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important,~~ for growth promotion in the absence of ~~a~~ risk analysis. This risk analysis should:	**Japan** Both Principle 5 and Principle 6 primarily aim at restricting the use of antimicrobials as growth promoter and should be simplified for easy understanding as well as avoiding duplication. We propose that Principle 5 should be in align with the text of the same intent in the recently adopted "OIE List of Antimicrobial Agents of Veterinary Importance." Respecting the language already adopted by a relevant International Organisation should be agreeable by Member States. Japan does not see added value of current Principle 6 once Principle 5 is established, except the last part of it, i.e. "in certain circumstances for research and conservation," which seems outside of the remit of the CODEX. Thus, we propose that Principle 6 be deleted.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial ~~agents that are considered medically important or are able to cause cross-resistance to other antimicrobial~~ agents~~, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:~~	**Norway**
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:	**Thailand** We are of the view that, no matter for animal or plant, the responsible and prudent use of antimicrobial should be used for prevention and treatment purposes, not for growth promotion purpose.
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:	**USA** This principle could be further revised for clarity. The definition of medically important antimicrobials is essential for understanding and implementation of this principle.
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:	**Consumer Goods Forum** Comment: Propose to delete the text "that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important". Rationale: need further clarification on this principle. Does this principle refer only to growth promotion or does it mean that all animal uses of medically important antimicrobial agents are subject to risk analysis? Responsible use may include use of a particular agent as a last resort to treat a very sick animal
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important~~, in the absence of a risk analysis. This risk analysis should:~~	**Consumers International**
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents ~~that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important,~~ in the absence of a risk analysis. This risk analysis should:	**Healthforanimals** It will be more globally acceptable to remove this section and leave “in the absence of risk analysis” clause. Too many countries have different definitions for antimicrobials.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important~~, in the absence of a risk analysis. This risk analysis should:~~ .	**International Association of Consumer Food Organizations** The Code must clearly and unambiguously recommend complete restriction of use of all classes of medically important antimicrobials in food-producing animals for growth promotion, consistent with the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals (2017). The loophole permitting such uses which should be eliminated.
Principle 5 • ~~be undertaken by the appropriate national regulatory authority;~~	**Norway**
Principle 5 • be ~~undertaken~~ guided by the appropriate national regulatory authority;	**USA** The overwhelming majority of veterinary pharmaceutical data in OECD countries and LMICs are developed by private entities consistent with national guidelines. Making an exception for this area in review provides no clear public health or governance benefit that cannot be achieved without oversight. Further, it would shift resources away from other areas of a food and drug safety agency with no clear and compelling benefit.
Principle 5 • ~~be undertaken by the appropriate national regulatory authority;~~	**Consumers International**
Principle 5 • be ~~undertaken~~ guided by the appropriate national regulatory authority;	**Healthforanimals** Use the word “guided” instead of “undertaken”. The majority of veterinary pharmaceutical data in OECD countries and LMICs are developed by private entities consistent with national guidelines. Making an exception for this area in review provides no clear public health or governance benefit that cannot be achieved without oversight. Further, it would shift resources away from other areas of a food and drug safety agency with no clear and compelling benefit.
Principle 5 • ~~be undertaken by the appropriate national regulatory authority;~~	**International Association of Consumer Food Organizations**
Principle 5 • be based on adequate scientific evidence~~; and~~ ;	**Australia**
Principle 5 • ~~be based on adequate scientific evidence; and~~	**Norway**
Principle 5 • ~~be based on adequate scientific evidence; and~~	**Consumers International**
Principle 5 • ~~be based on adequate scientific evidence; and~~	**International Association of Consumer Food Organizations**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 5 • ~~include a publicly available summary.~~	**Norway**
Principle 5 • ~~include a publicly available summary.~~	**Consumers International**
Principle 5 • ~~include a publicly available summary.~~	**International Association of Consumer Food Organizations**
Principle 6	
Principle 6: ~~Medically~~ Critically important antimicrobial agents for human medicine should only be used in food-producing animals for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); preferably under veterinary or professional oversight, and when no other alternative treatment is available; or in certain circumstances for research and conservation.	**Australia** The suggested text supports responsible use. Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); ~~or in certain circumstances for research and conservation.~~	**Brazil**
Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of ~~disease); or in certain circumstances for research~~ a specific disease risk and ~~conservation.~~ follow appropriate professional oversight, dose and duration). ~~**Principle 7:** Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.~~	**Canada** Principles 6 and 7. These two principles may be merged to avoid the duplication
Principle 6: Medically important antimicrobial agents or veterinary antimicrobials belonging to the same group of them in the mentioned list should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.	**Colombia** It is considered important to include this fragment, because the WHO list reports the antimicrobials of critical importance in human medicine. Also to extend the spectrum of this principle.
Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.	**Indonesia** Indonesia proposes to reverse order the principle 6 and 7 because we consider that the use of medically important antimicrobial agents explained in principle 7 should come first rather than the scope of application which explained in principle 6.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~**Principle 6:** Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.~~	**Japan**
Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes ~~(treatment, control/metaphylaxis or prevention/prophylaxis~~ (to treat/control/prevent of disease); or in certain circumstances for research and conservation.	**Malaysia** Principle 6 should be define or rephrase aligned with OIE document
Principle 6: **Antimicrobial** ~~Medically important antimicrobial~~ agents should only be used for therapeutic purposes ~~(treatment, control/metaphylaxis~~ or ~~prevention/prophylaxis of disease); or~~ in certain circumstances for research and conservation.	**Norway**
Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.	**Consumer Goods Forum** Comment: Propose to revise this principle, so as to keep this only for therapeutic purpose or in certain circumstances for research and conservation. This revision need to be in line with the revision proposed for the definition of therapeutic purpose in section 3.
Principle 6: Medically important antimicrobial agents should only be ~~used for therapeutic purposes (treatment~~used, ~~control/metaphylaxis~~ as a last resort, for the treatment or ~~prevention/prophylaxis~~ control/metaphylaxis of ~~disease)~~disease, and in Integrated Pest Management systems in food plants/crops; or in certain circumstances for research and conservation.	**Consumers International**
Principle 6: Medically important antimicrobial agents should only be used ~~for therapeutic purposes (treatment~~in food production as a last resort, ~~control/metaphylaxis or prevention/prophylaxis of disease); or~~ to treat disease in ~~certain circumstances for research~~ animals in order to save life or prevent serious suffering when there are no other effective treatments and ~~conservation~~when there is veterinary oversight, and on crops in the context of an Integrated Pest Management program when there are no other viable alternatives.	**International Association of Consumer Food Organizations**
Principle 7	
~~**Principle 7:** Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.~~	**Australia** Deletion of Principles 7 is requested, as it is duplicated in Principle 6 - modified with the proposed amendment.
Principle 7: Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration. **Principle 12:** Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation.	**Brazil** Principle 12 - Change of order to provide better understanding.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 13: ~~Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.~~ **Principle 14:** ~~Administration of antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.~~ **Principle 13+14:** Administration of antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy and take into consideration sampling and susceptibility testing of isolates from the production setting and, where feasible and appropriate, make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	Principle 13 - Change of order to provide better understanding. Principle 14 - Change of order to provide better understanding. Principles 13 and 14 - Change of order and junction of principles 13 and 14 to provide better understanding.
~~**Principle 7:** Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.~~	**Canada**
Principle 7: Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration. Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation.	**China** Control of disease/metaphylaxis: Administration of antimicrobial agents to group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.
Principle 7: Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration~~.~~ . Antimicrobials of critical importance in human medicine should not be used as prophylactic agents in the veterinary field.	**Colombia** It is considered important to include this text, because of the importance of this problem in some countries that continue to use antimicrobial agents as growth promoters and prophylactics.
Principle 7: Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.	**Indonesia** Indonesia suggests the term of "specific disease" should be referring to disease that be associated to animal only
Principle 7: ~~Medically important~~ antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.	**Norway**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 7: A~~Medically important~~ ntimicrobial agents for the prevention/prophylaxis of a specific disease risk should only be used in well-defined cases for the administration to an individual animal or restricted number of animals when the risk of infection is very high or consequences are likely to be severe and follow appropriate professional oversight, dose, and duration. ~~antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.~~	**Consumers International**
Principle 7: Medically important antimicrobial agents should only be used in time-limited and well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration. Such well-defined circumstances include convincing evidence (1) of effectiveness, (2) of consistency with accepted practice, (3) that the use is linked to a specific etiologic agent and a specific disease to be prevented, (4) that the use is appropriately targeted to those at risk of developing a specific disease, and (5) that there are no reasonable alternatives for intervention. This use should not be routine and should not be a substitute for good hygiene and/or good husbandry and production practices.	**International Association of Consumer Food Organizations**
Principle 8	
Principle 8: Legally authorized Antimicrobial agents should be used ~~as legally authorized~~ and ~~following all applicable~~ label ~~directions~~directions be followed; except where specific legal exemptions apply.	**Australia** The previously revised text changed the context of the sentence. The proposed amendments reflects that antimicrobial agents are to go through an authorisation process before they are used in animals.
Principle 8: Antimicrobial agents should only be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.	**Canada**
Principle 8: Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions ~~apply.~~ apply and the off-label use under the direction of health professionals	**China** considering off-label use in principle 8.
Principle 9	
Principle 9: Foodborne AMR risk management measures should be implemented along the entire food chain 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 human and animal health of recommended risk management measures.	**Brazil**
Principle 9: Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.	**Canada** Principles 9, 10 and 11. These principles refer to risk analysis, and come in the middle of principles for administration of antimicrobials. It is suggested to move these principles after Principle 15.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 9: Foodborne AMR risk management measures should be ~~implemented in a way that is proportionate to the risk and~~ reviewed on a regular basis as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.	**Consumers International**
Principle 9: Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. ~~Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.~~	**Healthforanimals** Risk assessment already considers the potential consequences to human and animal health. Including the 2nd sentence introduces speculation without providing practical advice or improving clarity. “Potential unintended consequences” is not appropriate for the sound scientific guidelines Codex is supposed to implement.
Principle 9: Foodborne AMR risk management measures should be ~~implemented in a way that is proportionate to the risk and~~ reviewed on a regular basis as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers should consider potential unintended consequences to human and animal health of recommended risk management measures.	**International Association of Consumer Food Organizations**
Principle 10	
Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and 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 ~~medically~~ critically important antimicrobial agents ~~in humans~~ for human medicine and food-producing animals, and transmission of pathogens and resistance genes between humans, food-producing animals, 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*.	**Australia** Principles 9, 10 and 11. These principles refer to risk analysis, and come in the middle of principles for administration of antimicrobials. It is suggested to move these principles after Principle 15. Critically important antimicrobials for human medicine to replace medically important antimicrobials. ‘Critically important antimicrobials’ are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and 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 ~~medically important~~ antimicrobial agents in ~~humans and~~ humans, food-producing ~~animals~~animals and plants/crops, and transmission of pathogens and resistance genes between humans, food-producing animals, 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*.	**Canada** This principle does not mention "plants/crops"

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and 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 medically important antimicrobial agents in humans and food-producing animals, and transmission of pathogens and resistance genes between humans, food-producing animals, 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*.	**Colombia** Colombia considered important to maintain since they are indispensable to characterize risk profiles.
Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and 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 medically important~~ of antimicrobial agents in humans and food-producing animals, and transmission of pathogens and resistance genes between humans, food-producing animals, 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*.	**Norway**
Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and 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 medically important antimicrobial agents in humans and food-producing animals, and transmission of pathogens and resistance ~~genes~~ determinants between humans, food-producing animals, 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*.	**Consumers International**
Principle 11	
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade. Biosecurity, vaccination, and other alternatives to antimicrobial agents should be considered to reduce the need for antimicrobial agents.	**Australia** The proposed text relates to a country's AMR strategy, which is outlined in Principle 11. If this amendment is accepted, then Principle 2 is not required.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 11: ~~This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.~~	**Brazil** This "principle" should be removed into the Introduction of the document. It does not seem like a principle.
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**Canada** Principles 9, 10 and 11. These principles refer to risk analysis, and come in the middle of principles for administration of antimicrobials. It is suggested to move these principles after Principle 15.
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**Iran** A stepwise approach should be described not only in each country, but regionally for both various antimicrobial agents and different types of food matrices
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. ~~A stepwise~~ An incremental approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**USA** Consistent with our comments that the term "stepwise" be replaced with "incremental" in the GLIS, we also note the term "incremental" is used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/
Principle 11: This document is designed to provide a framework, for the development of measures to prevent or mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. ~~A stepwise~~ An incremental approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**Healthforanimals** Stepwise approach. Do not adopt a stepwise approach. The stepwise approach de facto categorizes countries, and this type of categorization can be, and has been, misused - even leading to trade disputes. Instead the focus should be developing national programs to promote responsible use. Specifying in a Codex document such detailed and specific processes - mostly based on the experiences of developed countries - risks the sovereignty of countries to develop their specific plans. In some instances, the Code provides prescriptive solutions that are not relevant, applicable or possible in countries. When drafting, the TFAMR needs to maintain flexibility in implementation to allow for differences. The term "incremental" is used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/"
Principle 11: This document is designed to provide a framework, for the development of measures to prevent or mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A stepwise approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**International Association of Consumer Food Organizations**
Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A ~~stepwise~~ incremental approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	**International Feed Industry Federation** Change from Stepwise to 'incremental'. We think this adjustment lowers the trade barrier risk and has a precedent with AGISAR.
Principle 12	
Principle 12: Critically ~~Medically~~ important antimicrobials for human medicine or equivalent should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principe 12:	**Brazil** See comments under Principle 7.
Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation. Antimicrobials of critical importance in human medicine should not be used as prophylactic agents in the veterinary field.	**Colombia** It is considered important to include this text, because of the importance of this problem in some countries that continue to use antimicrobial agents as growth promoters and prophylactics.
Principle 12: ~~Medically important~~ antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation.	**Norway**
Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other authorized and / or suitably trained ~~persons authorized in accordance with national legislation~~persons.	**USA** Revised to take into account countries where such legislation may not exist
Principle 13	
Principle 13:	**Brazil** See comments under Principle 7
Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of target pathogens and foodborne bacterial isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**Canada** Principles 13 and 14. The two principles show different (opposite) considerations for selecting antimicrobial agents: susceptibility testing vs. clinical experience/outcomes. Suggest moving Principle 14 before Principle 13 based on their contents.
~~**Principle 13:** Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.~~	**China** Principle 13 and 14 are about the prudent use of antimicrobial agents. Move to chapter 5.
Principle 13: Administration of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**Colombia** Colombia considered important to unify 13 and 14 in a single principle. This unification is suggested since both principles are referring to the same topic. The prescription and administration of antimicrobial agents should be done in accordance with the Good Practices for the Use of Antimicrobials and the Guidelines for the prudent, judicious and responsible use of them.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 13: Administration of antimicrobial agents should take into consideration ~~sampling and~~ results of susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**Norway**
Principle 13: The decision to use~~Administration of~~ antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and may be used to make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**USA** Edited for clarity.
Principle 13: The decision to use~~Administration~~ of antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**Healthforanimals** Administration' suggests that it is providing the animal the medicine. Whereas, the bulk of this paragraph is really about the decision-making process for when to/not to use antimicrobial therapy.
Principle 13: ~~Administration of~~ The decision to use antimicrobial agents should take into consideration sampling and susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.	**International Feed Industry Federation** Change from 'Administration' to 'decision to use.' It would be an unreasonable burden to have vets in a feed mill for all abx. The key objective is better decision-making not the actual introduction to an animal.
Principle 14	
Principle 14	**Brazil** See comments under Principle 7.
Principle 14	**Canada** See comments under Principle 13.
Principle 14	**China** See comments under Principle 13.
Principle 14: Administration of antimicrobial agents should be based on sound clinical judgement, experience, and knowledge about treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.	**Norway**
Principle 14: The decision to use~~Administration of~~ antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.	**USA** Edited for clarity.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 14: ~~Administration of~~ The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.	**International Feed Industry Federation** Change from 'Administration' to 'decision to use.' It would be an unreasonable burden to have vets in a feed mill for all abx. The key objective is better decision-making not the actual introduction to an animal.
Principle 15	
Principle 15: The 5R principles (responsibility, reduce, refine, replace and review)~~The reduce, replace and rethink (RRR) strategy~~ on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.	**Australia** There are '5R principles' that should be promoted for good antimicrobial stewardship. These include: • RESPONSIBILITY: a successful antimicrobial stewardship plan requires a shared responsibility between the livestock producer and the prescribing veterinarian. • REDUCE: wherever possible, means of reducing the use of antimicrobial agents should be implemented. Biosecurity measures, hygiene, precision nutrition, vaccination and expert animal husbandry underpin animal health and welfare and minimises the incidence of infectious diseases. • REFINE: implies the right diagnosis and, if antimicrobial agents are required, then the right drug, at the right time, at the right dose, through the right route, and for the right length of time. • REPLACE: identify ways to Reduce, Refine and Replace current antimicrobial use. Any measures taken to replace antimicrobial agents are based on sufficient evidence of effectiveness and safety in order to avoid unintended adverse consequences. • REVIEW: it involves recording and regularly reviewing the effectiveness of antimicrobial stewardship practices. With current practices, consider what is being used, how much, why and when. The '5R principles' also provides an encompassing approach about appropriateness of antimicrobial use rather than only focusing on reduction of use.
Principle 15: ~~The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.~~	**Brazil** This "principle" should be deleted or better clarified.
Principle 15: The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.	**Canada** This principle needs to be referenced (i.e., a WHO, Codex, or FAO reference).
~~**Principle 15:** The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.~~	**Thailand** We view that "RRR strategy" is not internationally recognised principle. Therefore, we purpose to delete this principle.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Principle 15:~~ ~~The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.~~	**USA** Recommend deletion of this principle. The RRR strategy is not broadly understood. As we understand it, many elements of the RRR strategy are already contained with the document.
Principle 15: The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in ~~animals~~ animals, animal cell culture food products and on plants/crops should be actively promoted within all sectors.	**Consumers International**
Principle 15: The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents ~~in animals and on plants/crops~~ throughout the food chain should be actively promoted within all sectors.	**International Association of Consumer Food Organizations**
~~Principle 15:~~ ~~The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.~~	**International Feed Industry Federation** Delete principle 15: Out of scope of the TFAMR Terms of Reference and arguably inconsistent with the Codex mandate.
Principle 16	
Principle 16: On a continuous and ~~stepwise~~ incremental implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.	**Brazil**
~~**Principle 16:** On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.~~	**Canada** This principle is suggested to be deleted as it lacks clarity
Principle 16: On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective. **Principle 17**: Due consideration should be given to measures to prevent microbial contamination and spread in food during production, processing, storage, transport, retail and distribution.	**Japan** Noting that this COP covers entire food chain, considerations at stages after farm level should also be clearly stated as a principle.
Principle 16: On a continuous and ~~stepwise~~ incremental implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a ~~public~~ consumer health perspective.	**USA** Codex scope

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Principle 16: On a continuous and ~~stepwise~~ incremental implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective. Evaluation of pre-harvest AMR food safety issues should include, whenever appropriate, potential unintended animal health aspects relevant to food safety. Foodborne AMR risk analysis when considering such animal health aspects should take into account relevant OIE standards.[	**USA** Codex scope Language from Principle 8 in CAC/GL 77 is inserted to help address the need to balance for animal health needs. The language is modified to include unintended consequences to clarify that AMR food safety issues may have animal health implications risk managers may need to consider while evaluating public health outcomes/impacts of RMO's.
~~**Principle 16:** On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.~~	**Healthforanimals** This principle should be deleted because it is addressed in GL77, it is redundant, and it suggest risk management without the full weight of the surveillance inputs or risk analysis.
~~**Principle 16:** On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.~~	**International Feed Industry Federation** Delete principal 16: Out of scope of the TFAMR Terms of Reference and arguably inconsistent with the Codex mandate.
5. Responsible and prudent use of antimicrobial agents	
5. Responsible and prudent use of antimicrobial agents	**Iran** The following items can be added to the paragraph: 1. The regulatory authorities should have rigorous mechanisms for tracing antimicrobial residues in food chain. It may be achieved by developing regulations, establishing accredited labs and monitoring of their activities in line with minimizing antimicrobial resistance. 2. It is the responsibility of regulatory authorities to check the antimicrobial agents used in food chain before and issuing any permit. As part of the marketing authorization process and in order to assess the efficacy and quality of antimicrobial agents for minimizing foodborne antimicrobial resistance, the regulatory authorities should force the manufacturers of antimicrobial agents used in veterinary and plant/ crop production to establish quality control mechanisms and labs. The regulatory authorities should set up an assessment system for determining the efficacy of antimicrobial agents by establishing accredited labs and monitoring of their activities.
§10. The *OIE terrestrial and aquatic animal health codes* and the *WHO guidelines on use of medically important antimicrobials in food-producing animals* (http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia_guidelines/en/) contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§10. The *OIE terrestrial and aquatic animal health codes* and the WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture.	**International Association of Consumer Food Organizations**
§11. ~~For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines.~~	**Brazil** Brazil recognizes the importance of the work of International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products. However, we believe that only the multilateral organizations that have broad representativeness should be referenced in this document.
~~11. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines.~~	**Indonesia** Indonesia proposes to delete para 11 as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines is not a multilateral guideline.
Responsibilities of the regulatory authorities	
General comments	**China** The regulatory authorities have responsibilities to part 5 -prudent use of antimicrobial agents, part 6- the food processing and part and part 7- communication to consumers. Therefore, the responsibilities of the regulatory authorities should be a separate part.
§12. The regulatory authorities, including the authority responsible for granting the marketing authorization for ~~antimicrobials~~ antimicrobial agents for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain.	**Consumers International**
§12. The regulatory authorities, including ~~the authority~~ those responsible for ~~granting the marketing authorization for~~ evaluating and authorizing antimicrobials for use ~~along~~ throughout the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. Authorization is granted when safety, quality, and efficacy criteria are met.	**International Association of Consumer Food Organizations** This adds back important wording deleted from the current Code. Even though it may appear in other referenced documents, it is important and should appear in the revised Code.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§13. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy for the containment of antimicrobial resistance. ~~Good animal production (terrestrial and aquatic) and best management practices for plant/crop production~~Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, ~~vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level~~ contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.	**Canada** Suggest providing references to "Good animal production (terrestrial and aquatic) and best management practices for plant/crop production" Also suggest deleting "vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level", which is expected to be included in best practices programs.
§13. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy for the containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement AMR and infection control activities in human health.	**USA** Previous mention of management practices in food production in this sentence focus on infection control, so this adds consistency
§13. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy for the prevention and containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§13. It is the responsibility of regulatory authorities to both develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, and for ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents ~~along~~ throughout the food chain as an element of a national strategy for the containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.	**International Association of Consumer Food Organizations** This adds back important concepts deleted from the current Code, which should be retained even if they appear in other referenced documents.
§13. It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy for the containment of antimicrobial resistance. Good animal production and nutritional strategies (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.	**International Feed Industry Federation** It is essential to include risk analysis. This is part of Codex and critical to ensuring a stable, predictable regulatory environment. In case good animal production does not include nutrition, we would propose to put good animal nutrition and appropriate nutritional strategies
§14. ~~If dose ranges/application rates or different durations/re-application intervals of antimicrobial agent administration are indicated, the regulatory~~ Regulatory authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of foodborne ~~AMR based on a risk assessment,~~ AMR. Consideration should be given to minimize duration of use while still maintaining efficacy and safety, when this information is available.	**Canada** For clarity, suggest revising the paragraph as
§14. ~~If dose ranges/application rates or different durations/re-application intervals of antimicrobial agent administration are indicated, the~~ Depending on risk analysis regulatory authorities should ~~give guidance on the approved product labelling regarding the conditions that will minimize the development~~ determine appropriate labeling and marketing status of ~~foodborne AMR~~ antimicrobial agents based on ~~a risk assessment, while still maintaining efficacy and safety, when this information is available~~risk~~.~~. Further, the professional judgement in prescribing from the veterinarian, who holds the responsibility of oversight, should be a factor when regulatory authorities develop such guidance for approved product labelling	**USA** Revised for clarity and to take into account the professional judgment of the veterinarian.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§14. ~~If dose ranges/application rates or different durations/re-application intervals of antimicrobial agent administration are indicated~~Depending on risk analysis, ~~the~~ regulatory authorities should ~~give guidance on the approved product labelling regarding the conditions that will minimize the development~~ determine appropriate labeling and marketing status of ~~foodborne AMR~~ antimicrobial agents based on ~~a risk assessment, while still maintaining efficacy and safety, when this information is available~~risk.	**Healthforanimals** The previous statement was not clear in intent to provide the regulators with clear description of their responsibility. This version is better. Risk analysis must consider the totality of evidence and proportion of management measure appropriate for each product. The previous language was selective, leading, more trade restrictive than necessary to protect public health, and confusing.
§14. If dose ranges/application rates or different durations/re-application intervals of antimicrobial agent administration are indicated, the regulatory authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of foodborne AMR based on a risk assessment, while still maintaining efficacy and safety, when this information is available.	**International Feed Industry Federation** It is essential to include risk analysis. This is part of Codex and critical to ensuring a stable, predictable regulatory environment.
Quality control of antimicrobial agents	
§15. Regulatory authorities should ensure that quality controls for the active pharmaceutical ingredients being used as antimicrobial agents are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices.	**Canada** Suggest clarifying this sentence by replacing with the following proposal.
§15. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.	**International Association of Consumer Food Organizations**
Assessment of efficacy	
§16. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, it should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) and pharmacokinetic data. ~~It may also include assessment of through proper veterinary care, program evaluation and good pharmacovigilance practices.~~It may also include assessment of through proper veterinary care, program evaluation and good pharmacovigilance practices.	**Brazil** It is necessary to clarify the last sentence, specially regarded to “proper veterinary car” and “program evaluation”
§16. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, it should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) and pharmacokinetic data. It may also ~~include assessment of through proper veterinary care, program evaluation and~~ include good pharmacovigilance practices. Efficacy should be observed via pharmacovigilance program and labels updated accordingly as needed to reflect such a change.	**Canada** It is suggested to clarify “assessment of thorough proper veterinary care, program evaluation” or to possibly delete this part of the sentence as it is not generally applicable to efficacy assessment. The phrase “good pharmacovigilance practices” (the second part of the last sentence) is suggested by a description that “Efficacy should be observed via pharmacovigilance program and labels updated accordingly as needed to reflect such a change.”

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§16. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, it should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) and pharmacokinetic ~~data~~data and pharmacodynamic/ pharmacokinetic (PD /PK) relationship. It may also include assessment of through proper veterinary care, program evaluation and good pharmacovigilance practices.	**Colombia** It is suggested to include these terms to update and complement the idea of the text
§16. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. ~~As part of the~~ The marketing authorization process, ~~it~~ should include ~~the~~ assessment of efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) and pharmacokinetic data. ~~It may also include assessment of through proper veterinary care, program evaluation and good pharmacovigilance practices.~~	**USA** Recommend deletion as this sentence references aspects that would either be controlled as part of a clinical trial or would occur in the post market phase. They are therefore redundant with the first part of the sentence or covered by the paragraphs below on pharmacovigilance
§16. ~~Assessment of~~ Regulatory authorities should ensure that efficacy is ~~important~~ assessed and demonstrated as a condition of authorization to assure adequate response to the administration of antimicrobial agents. ~~As part of the marketing authorization process, it~~ Efficacy should ~~include the efficacy~~ be demonstrated with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) and pharmacokinetic data. It may also include assessment of ~~through~~ proper veterinary care, program evaluation and good pharmacovigilance practices.	**International Association of Consumer Food Organizations** It would be helpful to provide more information/cites throughout the food chain (e.g., as drugs for food animals, as pesticides for crops, as direct additives, as slimicides added to food packaging, as disinfectants used in food processing)
Assessment of the potential antimicrobial agents to select for resistant microorganisms	
Assessment of the potential of antimicrobial agents to select for resistant microorganisms	**Norway**
Assessment of the potential antimicrobial agents to select for resistant ~~microorganisms~~microorganisms of importance to foodborne AMR	**USA** Statement is qualified to stay within the mandate of Codex
Assessment of the potential antimicrobial agents to select for resistant ~~microorganisms~~microorganisms of importance to foodborne disease.	**Healthforanimals** The mandate of Codex is for food safety. Reviews/assessments should be limited to foodborne pathogens instead of all bacteria.
§17. The regulatory authority should assess the potential of ~~medically~~ critically important antimicrobial agents for human medicine to select for resistant microorganisms taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§17. The regulatory authority should assess the potential of medically important antimicrobial agents to select for resistant microorganisms taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important antimicrobials*, ~~the *OIE list of antimicrobials of veterinary importance*,~~ or national lists, where available.	**Canada** The description of "the OIE List of antimicrobials of veterinary importance" appears not relevant in the context. Suggest deleting the reference to the OIE list.
§17. The regulatory authority should assess the potential ~~of medically important~~ of antimicrobial agents to select for resistant microorganisms taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available.	**Norway**
§17. The regulatory authority should assess the potential of medically important antimicrobial agents to select for resistant microorganisms taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important ~~antimicrobials~~antimicrobials in food-producing animals*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available.	**Consumers International**
§17. The regulatory authority should assess the potential of medically important antimicrobial agents to select for resistant microorganisms taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available. The regulatory authorities should develop criteria for conducting such assessments and interpreting the results.	**International Association of Consumer Food Organizations**
Assessment of environmental impact	
§~~18. Regulatory authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines.~~	**USA** Para (19) appropriately addresses environmental aspects on foodborne AMR, which may be within Codex scope.
§~~18. Regulatory authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines.~~	**Healthforanimals** The environmental considerations of pharmaceutical manufacture are outside the mandate of Codex.
§19. Regulatory authorities should consider the environmental aspects on foodborne AMR e.g. application of antimicrobial agents (used as pesticides) on crops, pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure and/or municipal wastes for soil fertilization. When foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures can be considered.	**Canada** Suggest adding "application of antimicrobial agents (used as pesticides) on crops" as an example before "pollution from pharmaceutical manufacture" Last sentence, it is unclear to what monitoring is referring to in this sentence; though if it is left as monitoring perhaps the intent is very broad (i.e., monitoring of use, monitoring of AMR, or monitoring of interventions?)

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§19. Regulatory authorities should consider the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure and/or municipal wastes for soil fertilization. When foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures can be considered.	**China** Thanks to concern the mature and other excreta from livestock and poultry on the antimicrobial resistance in food chain. However, the corresponding control measures and good practice should be developed to contain the relative antimicrobial resistance in environments.
§19. Regulatory authorities should consider the environmental aspects ~~on~~ of foodborne related AMR ~~e.g. pollution from pharmaceutical manufacture,~~ risk impacts of reusing waste water for irrigation, and using manure ~~and/or municipal wastes~~ for soil fertilization~~. When foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures can be considered.~~	**Indonesia**
§19. Regulatory authorities should consider the environmental aspects on foodborne ~~AMR e.g~~AMR. ~~pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure and/or municipal wastes for soil fertilization.~~ When foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures can be considered.	**Healthforanimals** It is never a good idea to list examples in a Code. The three 'environmental' examples have little to nothing to do with foodborne disease.
§19. Regulatory authorities should consider the ~~environmental aspects~~ role of the environment on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using ~~manure~~ manure, other waste-based fertilizers, and/or municipal wastes for soil fertilization. ~~When foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the~~ The need for monitoring and ~~proportionate~~ risk management measures ~~can~~ should be considered, taking into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.	**International Association of Consumer Food Organizations**
Establishment of a summary of product characteristics for each antimicrobial agent	
§20. Regulatory authorities should establish a Summary of Product Characteristics or similar document. The information in ~~the summary of product characteristics~~ such a document can be utilized in labelling and as a package insert.	**Canada** Suggest changing the second sentence "The information in the summary of product characteristics" to "The information in such a document" to reflect both a Summary of Product Characteristics and similar document described in the first sentence.
§20. ~~Regulatory~~ Where applicable regulatory authorities should establish a Summary of Product Characteristics or similar document. The information in the summary of product characteristics can be utilized in labelling and as a package insert.	**USA** The concept of a Summary of Product Characteristics may not be applicable in all countries.
§~~20. Regulatory authorities should establish a Summary of Product Characteristics or similar document. The information in the summary of product characteristics can be utilized in labelling and as a package insert.~~	**Healthforanimals** This is a highly specific concept that does not apply to many countries and should not be in a globally relevant Codex text.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Surveillance and monitoring programs	
General comments	**China** The surveillance and monitor system can be integrated to the document CX-AMR18/6/5. This chapter should emphasize that the regulator authorities have responsibilities to publish antimicrobial resistance monitoring data in time and share the data; the monitoring department should feedback the data and provide warning to users in time to help them take relevant measures to minimize and contain antimicrobial resistance in time.
General comments	**Thailand** Due to the "draft Guidelines for the integrated monitoring and surveillance of foodborne antimicrobial resistance (GLIS)" referred, for reason of clarity, we propose that the critical components of GLIS should be included in this section.
~~**Surveillance and monitoring programmes**~~	**USA** If the Code of Practice is to be read in conjunction with the Guidelines on Integrated Surveillance (GLIS), this section could be considered for replacement by a reference to the GLIS.
§21. ~~Regulatory authorities~~ Authorities or agencies should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance*, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and the relevant AMR chapters within the *OIE terrestrial and acquatic animal health* ~~*code*~~*codes.* ~~Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance.~~	**Australia** The statement is broadened to include other authorities and agencies to provide flexibility for countries' systems. To ensure succinctness of the Code of Practice, the OIE Code chapters can be referenced as shown and to allow for changes in Code Chapter formatting. This paragraph could be used in the Introduction of the Code of Practice.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§21. ~~Regulatory~~ Competent authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance*, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and *OIE terrestrial animal health code* Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance.	**Canada** Suggest revising "Regulatory authorities" to "Competent authorities" (or “mandated authorities”) to broaden the authorities who are to establish the surveillance and monitoring system.
§21. Regulatory authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance*, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and *OIE terrestrial animal health code* Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance.	**Indonesia** Considering that Codex members are vary in their capabilities in conducting surveillance and monitoring programs, Indonesia suggests that the type and methodology of the programs should be based on each countries capabilities
§~~22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach.~~	**Australia** This section does not need to reside in the Code of Practice and reference to the new Guidelines for integrated monitoring and surveillance (under development) be made in the Introduction.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a ~~stepwise approach~~incremental mapproach.	**Brazil**
§22. The surveillance and monitoring of ~~antimicrobial resistant~~ relevant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach.	**Canada** Suggest replacing "antimicrobial resistant bacteria" by "relevant bacteria" in the first sentence since the bacteria are not necessarily resistant.
§22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a ~~stepwise approach~~stepwise approach.	**China** The stepwise approach here is precisely because of the uneven development of various countries that we need to emphasize the need to implement following a stepwise approach according to their own national conditions, and we cannot limit our national standards as trade barriers.
§22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following ~~a stepwise~~ an incremental approach.	**USA** Consistent with our comments that the term “stepwise” be replaced with “incremental” in the GLIS, we also note the term “incremental” is used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach. The results should be made publicly available.	**Consumers International**
§~~22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach.~~	**Healthforanimals** International guidance and a process for regularly updating guidance on surveillance of resistance in foodborne pathogens, their determinants, and antibiotic use already exist. Redundancy in this area may risk conflicting statements of guidance and confuse national authorities. Inappropriate application of surveillance could misdirect the focus of protecting consumers as well as lead to non-tariff trade barriers.
§22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; ~~and also~~ and allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach.	**International Feed Industry Federation**
§22bis. Regulatory authorities should have in place a pharmacovigilance program for the monitoring and reporting of adverse reactions to ~~veterinary~~ antimicrobial ~~drugs~~agents, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance program should form part of the comprehensive strategy to minimize microbial resistance.	**Canada** Suggest replacing "veterinary antimicrobial drugs" by "antimicrobial agents".
§22ter. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavor to achieve this re-evaluation.	**China** Suggest to define the Pharmacovigilance and encourage the Pharmacovigilance program.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Distribution of antimicrobial agents	
§23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and ~~medically~~ critically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are ~~distributed~~ marketed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, ~~plant/crop advisors~~ or ~~consultants, or~~ or other suitably trained persons authorized in accordance with national legislation.	**Canada** (a) Suggest replacing "distributed" by "marketed" because of "distribution systems" in the sentence (i.e., too many "distribute" type words in the sentence). (b) Suggest deleting "plant/crop advisors or consultants" because they are apparently not relevant in this context.
§23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation.	**Indonesia** Since the coverage of this code of practice including animal production (terrestrial and aquatic), Indonesia suggests that we should add aquatic health care professional
§23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed ~~to appropriately credentialed/registered~~ to veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation, or farmers with prescriptions or order for application issued by veterinarian or other suitably trained person.	**Japan** 1. Is this additional requirement for veterinarians necessary? Japan is of the view that it should be deleted so that consistent terminology is used within this text. 2. In livestock/aquaculture sector, antimicrobial agents are directly distributed to and used by farmers based on prescription or order for application by veterinarians or other suitably trained person authorized in accordance with national legislation.
§23. ~~Regulatory authorities, to the extent possible,~~ Distribution of antimicrobials for food producing animals and plants should ~~make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with~~ only be allowed by distributors authorised by the national ~~legislation~~ competent authority and ~~medically important antimicrobials are~~ be distributed to ~~appropriately~~ pharmacies, credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation~~.~~	**Norway**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§23. Regulatory authorities, to the extent possible, should make sure approved antimicrobial agents are distributed through appropriate distribution systems ~~in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation~~.	**USA** 1. Occasionally in the manufacture of medicines, intermediate products are traded across borders. 2. Reduce duplication since the beginning of the sentence references regulatory authorities and covers both medically and non-medically important antibiotics.
§23. Regulatory authorities, to the extent possible, should make sure approved antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation.	**Healthforanimals** The scope of this document should be limited to the Codex mandate. Occasionally in the manufacture of medicines, intermediate products are traded across borders. The manufacture of medicines is the remit of national authorities, VICH, and not Codex.
§23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation.	**International Feed Industry Federation** Many companies transport intermediates that could be impacted by this language if not fixed. Also, VICH addresses this point.
§24. Distribution should be regularly controlled by the regulatory authorities, and monitoring of national/regional sales of antimicrobial agents could be undertaken and information ~~could be~~ analyzed with appropriate context to identify areas of concern and potential follow up.	**Canada** Suggest adding "national/regional" before "sale" and deleting the second "could be".
§24. Distribution should be regularly ~~controlled~~ monitored by the regulatory authorities, and monitoring of sales of antimicrobial agents could be undertaken and information could be analyzed with appropriate context to identify areas of concern and potential follow up.	**USA** To “control” is redundant with paragraph 23. Monitor is more accurate
§24. Distribution should be regularly ~~controlled~~ monitored by the regulatory ~~authorities,~~ authorities and ~~monitoring of sales of antimicrobial agents could be undertaken and~~ information could be analyzed with appropriate context to identify areas of concern and potential follow up.	**Healthforanimals** To “control” is redundant with paragraph 23. Monitor is more accurate. The sales monitoring is redundant with the previous section and the integrated surveillance document.
Control of advertising	
~~**Control of advertising**~~	**Healthforanimals** Guidance on advertising for pharmaceuticals is outside the scope of Codex. This is also covered in OIE codes that are updated annually.
§25. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance with national ~~legislation~~legislation and in a manner consistent with prudent use guidelines.	**Brazil** Junction of paragraphs 25 and 26.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§25. ~~Regulatory~~ To help ensure that antimicrobials are used responsibly, regulatory authorities should assure that advertising of antimicrobial agents ~~is done in~~ be consistent with prudent use guidelines and accordance with national legislation.	**USA**
§~~25. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance with national legislation.~~	**Healthforanimals** Delete whole section control of adverting.
§26. ~~Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.~~	**Brazil**
§~~26. Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.~~	**USA** Further guidance on advertising can be found in the OIE Codes. The proposed deleted text is redundant in some places and may go outside the mandate of Codex in others.
§~~26. Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.~~	**Healthforanimals** Delete whole section control of adverting.
§26. Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product. Advertising of medically important antimicrobial agents should only be allowed to persons permitted to prescribe or supply antimicrobials and should not be permitted to be advertised to the producer.	**International Association of Consumer Food Organizations**
§27. All advertising of ~~medically~~ critically important antimicrobial agents for human medicine should be controlled by the ~~relevant authorities~~authorities or agencies.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts. The insertion of "or similar" allows for global variation in the processes of regulatory authority systems.
§27. All advertising of medically important antimicrobial agents should be controlled by the relevant ~~authorities~~authorities ensuring compliance to the national legislation and the marketing authorization granted, in particular with the content of the summary of product characteristic.	**Brazil** To provide better understanding.
§27. All advertising of ~~medically important~~ antimicrobial agents should be controlled by the relevant authorities.	**Norway**
§~~27. All advertising of medically important antimicrobial agents should be controlled by the relevant authorities.~~	**USA** Further guidance on advertising can be found in the OIE Codes. The proposed deleted text is redundant in some places and may go outside the mandate of Codex in others.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§~~27. All advertising of medically important antimicrobial agents should be controlled by the relevant authorities.~~	**Healthforanimals**
§27. • ~~The authorities should ensure that advertising of antimicrobial agents:~~	**Brazil**
§27. • ~~The authorities should ensure that advertising of antimicrobial agents:~~	**USA**
§27. • ~~The authorities should ensure that advertising of antimicrobial agents:~~	**Healthforanimals**
§27. • o complies with the marketing authorization granted, in particular with the content of the summary of product ~~characteristics~~characteristics or similar; and	**Australia**
§27. • o ~~complies with the marketing authorization granted, in particular with the content of the summary of product characteristics; and~~	**Brazil**
§27. • o ~~complies with the marketing authorization granted, in particular with the content of the summary of product characteristics; and~~	**USA**
§27. • o ~~complies with the marketing authorization granted, in particular with the content of the summary of product characteristics; and~~	**Healthforanimals**
§27. • o ~~complies with each country's national legislation.~~	**Brazil**
§27. • o ~~complies with each country's national legislation.~~	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§27. • o ~~complies with each country's national legislation.~~	**Healthforanimals**
Training of users of antimicrobial agents	
Training of users of antimicrobial agents	**Canada** The section title "Training of users of antimicrobial agents" needs clarification – as the bullets that fall under this section may not apply to "all users".
§28. Training should involve all the relevant professional organizations, regulatory authorities, pharmaceutical industry, schools, research institutes, professional associations, trade associations and other approved users such as farmers and ~~producers and~~ producers. It should be tailored according to the role played by participants in the food chain and may focus on:	**Canada** Suggest additional clarification in the introductory sentences here as follows: Deleting "and should focus on" and adding a new sentence as "It should be tailored according to the role played by participants in the food chain and may focus on"
§28. Training should involve all the relevant professional organizations, regulatory authorities, pharmaceutical industry, schools, research institutes, professional associations, trade associations and other approved users such as farmers and producers and should focus on:	**International Feed Industry Federation** Per pars. 13&14, it is important to keep risk analysis in the document and equip countries.
§28. • information on infectious disease prevention and management strategies to reduce the need to use antimicrobial agents;	**Canada**
§28. Bullet points • Information on conducting a risk analysis of veterinary products and how to use that information; • information on disease prevention and management strategies to reduce the need to use antimicrobial agents; • the efficacy of risk management options and potential consequences or benefits with each option, including animal health and welfare;	**Healthforanimals** New bullet 1: FAO and Codex programming and side events continue to reveal a low or incomplete understanding of risk analysis. New bullet 3: Many risk management options come at a cost to antibiotic use elsewhere or animal health or welfare implications or food safety and security costs. It is important for countries to understand that risk management has costs. Countries should be informed of these costs before selecting options.
§28. • relevant information to enable the veterinarian and plant/crop ~~advisors or consultants~~ producers to use or prescribe antimicrobial agents responsibly and prudently;	**Canada**
§28. • relevant information to enable the veterinarian and plant/crop ~~advisors or consultants~~ health professionals and other relevant professionals to use or prescribe antimicrobial agents responsibly and prudently;	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§28. • relevant information to enable the veterinarian and plant/crop advisors or consultants and any other relevant authorized professionals to use or prescribe antimicrobial agents responsibly and prudently;	**International Association of Consumer Food Organizations**
§28. • ~~training in new methodologies for molecular analysis of resistance;~~	**Brazil** This item is to specific to be listed in this section
§28. • training in ~~new methodologies for~~ molecular analysis of resistance;	**Canada** Third bullet needs clarity as to which user this would apply to. This bullet would not apply to all users. Also suggest deleting "new technologies for"
§28. • the current scientific understanding on the ability of antimicrobial agents to select for resistant microorganisms that may contribute to animal, plant/crop, or human health problems; and	**USA** Edited for clarity.
§28. • the current scientific understanding on the ability of antimicrobial agents to select for resistant microorganisms that may contribute to animal, plant/crop, or human health problems; and	**Healthforanimals**
§28. • the need to observe responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice. • Categorization of antimicrobials according to importance in human health (e.g., the WHO CIA list).	**Canada** Suggest adding a new bullet (as the last bullet) "Categorization of antimicrobials according to importance in human health (e.g., the WHO CIA list)"
§28. • the need to observe responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations / registrations and professional advice.	**USA** “Registrations” is the appropriate term for crops.
§28. • the need to observe responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional public health advice.	**International Association of Consumer Food Organizations** “Professional advice" is too broad and could include, for example, economic advice

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Knowledge gaps and research	
§29. The ~~relevant~~ authorities or agencies should encourage public and private research to:	**Australia** The proposed change provides flexibility in countries' systems
§29. The relevant authorities should encourage public and private research to:	**Brazil** Items on research on behaviour change and on cost-positive interventions to reduce the need of antimicrobial agents should be included in this paragraph
§29. • improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize ~~the~~ dosage regimens and ~~their~~ efficacy;	**USA**
§29. • further develop protocols to ~~predict~~asses, ~~during~~ the ~~authorization process, the~~ impact of the proposed ~~use~~ uses of ~~the~~ antimicrobial agents on the rate and extent of resistance development; and	**USA**
§29. • develop and encourage good animal production and nutritional strategies and plant/crop production best management practices and alternative methods to prevent and treat infectious diseases that would reduce the need to use antimicrobial agents	**International Feed Industry Federation** Same remark as before, otherwise, add, including implementation of nutritional strategies.
§29. • determine the potential transfer to fresh produce and other plants/crops of resistant microorganisms and determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers.	**Canada** It is hard to comprehend "...or selected for during the use of production practices". Suggest rewording it.
§29. • improve the knowledge ~~and~~ of the role of the environment and its impact on the transfer and persistence of antimicrobial agents.	**USA** Edited for clarity
§29. • determine the potential for transfer to animals of resistant microorganisms and determinants due to agricultural chemical use. • determine suitable resistance determinants and bacteria to serve as indicators of resistance development within specific production environments.	**USA** Adding this bullet point would enhance the research list by recognizing that suitable indicator bacteria are necessary for determining the development of AMR within specific production environments.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§29. • determine the potential transfer to animals of resistant microorganisms and determinants due to agricultural chemical use. • determine suitable resistance determinants and bacteria to serve as indicators of resistance development within specific production environments.	**Healthforanimals** This would enhance the research list by recognizing that suitable indicator bacteria are necessary for determining the development of AMR within specific production environments.
§29. • determine the potential transfer to animals of resistant microorganisms and determinants due to *agricultural chemical* use.	**International Feed Industry Federation** Agricultural chemical should be defined if kept in the text
§30. Research should be conducted, as resources permit, on ~~antimicrobials, their metabolites, and risks of foodborne resistant~~ AMR microorganisms ~~and resistance determinants~~ in the primary production environment, and ~~if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment leading to~~ foodborne AMR risk.	**Indonesia**
§30. Research should be conducted, as resources permit, on antimicrobials, their metabolites, and risks of foodborne ~~resistant microorganisms~~ pathogens and resistance determinants in the primary production environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among ~~microorganisms~~ foodborne pathogens in the environment leading to foodborne AMR risk.	**Healthforanimals** The Codex mandate is for food safety and trade. There are many microorganisms that are foodborne and have no impact on food safety. This document should focus on those items that are related to foodborne illness – not all microorganisms.
Collection and destruction of unused or out-of-date antimicrobial agents	
§31. The ~~relevant~~ authorities or agencies should ~~develop~~ progress effective procedures for the safe collection and destruction of unused or out-of-date antimicrobial agents.	**Australia** The proposed change provides flexibility in countries' systems.
§31. The relevant authorities should develop effective procedures for the safe collection and destruction of counterfeit, illegally marketed, unused or out-of-date antimicrobial agents.	**USA** Addresses other categories of products that should be removed from the market.
§31. The relevant authorities should develop effective procedures for the safe collection and destruction of counterfeit, illegally marketed and work with relevant organizations to determine most appropriate method of disposal of unused or out-of-date antimicrobial agents.	**Healthforanimals** Like the WHO observations about the growth in trafficking of fake medicines, the animal health space suffers from this as well and government action to reduce this impact and destroy product is needed. Additionally, while national authorities providing information on disposal or take-back of unused products, few, if any, regulatory agencies take responsibility for this type of action.
Responsibilities of Manufacturers and Marketing Authorization Holders	
General comment	**Canada** Under this section, suggest adding text specifying manufacturing standards/practices to minimize contamination of surface waters from effluent containing active pharmaceutical ingredients.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Marketing authorization of antimicrobial agents	
§33. Only officially licensed/authorized antimicrobial agents should be marketed, and then only through distribution ~~systems in accordance with national legislation~~systems.	**Brazil**
§33. Only officially licensed/authorized antimicrobial agents should be marketed, ~~and then only~~ through distribution systems in accordance with national legislation.	**USA** Redundant
§~~33. Only officially licensed/authorized antimicrobial agents should be marketed, and then only through distribution systems in accordance with national legislation.~~	**International Feed Industry Federation** Out of scope of Terms of Reference and covered by OIE.
§33. • Only antimicrobial agents meeting the quality standards of the importing country should be exported from a country in which the products were produced;	**Brazil** Considering the importance of the content and for better understanding these should be separate paragraphs and not bullets of a single paragraph.
§33. • ~~Only antimicrobial agents meeting the quality standards of the importing country should be exported from a country in which the products were produced;~~	**USA** Outside the mandate of Codex
§33. • ~~Only antimicrobial agents meeting the quality standards of the importing country should be exported from a country in which the products were produced;~~	**International Feed Industry Federation**
§33. • The information necessary to evaluate the amount of antimicrobial agents marketed should be provided to the national regulatory authority.	**Brazil** Considering the importance of the content and for better understanding these should be separate paragraphs and not bullets of a single paragraph.
§33. • ~~The information necessary to evaluate the amount of antimicrobial agents marketed should be provided to the national regulatory authority~~.	**International Feed Industry Federation**
§34~~. Package size and~~ . the concentration and composition of antimicrobial formulations should be adapted as far as possible to the approved indications of use in order to avoid improper dosing, overuse and leftovers.	**Malaysia** Malaysia generally agrees with the current structure of the draft of COP (CXC61-2005)
§~~34. Package size and the concentration and composition of antimicrobial formulations should be adapted as far as possible to the approved indications of use in order to avoid improper dosing, overuse and leftovers.~~	**USA** Outside the mandate of Codex
§34. ~~Package size and the concentration and composition of antimicrobial formulations should be adapted as far as possible to the approved indications of use in order to avoid improper dosing, overuse and leftovers.~~	**International Feed Industry Federation** Out of scope of Terms of Reference and covered by OIE.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Advertising	
§35. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise ~~medically~~ critically important antimicrobials to producers.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§35. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not ~~advertise medically important~~ advertise antimicrobials to producers.	**Norway**
§35. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of ~~Advertising and to not advertise medically important antimicrobials to producers~~Advertising.	**USA** Redundant with para 25.
§35. ~~It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers.~~	**International Feed Industry Federation** Out of scope of Terms of Reference and covered by OIE.
§~~36. Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged.~~	**Indonesia** Indonesia proposes to delete this para as it is not too relevant to the scope of the code of practice
§~~36. Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged.~~	**USA** Redundant with para 25.
§36. ~~Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged.~~	**International Feed Industry Federation** Out of scope of Terms of Reference and covered by OIE.
Training	
§37. It is the responsibility of the marketing authorization holders to participate ~~in the~~ and/or to provide training of users of antimicrobial agents as defined in paragraph 28.	**Canada** Suggest changing "to participate" to "to participate and/or to provide"

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Research	
§38. ~~It is the responsibility of the marketing~~ Marketing authorization holders should be encouraged to support the development of research as defined in paragraph 29, as appropriate.	**USA** Marketing authorization holders have a primary responsibility to provide data as required in national legislation. Some aspects of para 38 go beyond these intrinsic responsibilities.
§38. It is the responsibility of the marketing authorization holders to support the development of research required to register the compound and appropriate assess the safety and efficacy of the product as defined in paragraph 29, as appropriate.	**Healthforanimals** Marketing authorization holders are required to provide the information regulators need to make an independent review of the safety and efficacy of an animal health product. This specific information required is outlined in national legislation
§39. Research on the development of new antimicrobials, ~~safe and effective~~ alternatives to the use of antimicrobials, rapid diagnostics and vaccines should be ~~performed.~~performed and engaged the related industry participation	**Indonesia**
Responsibilities of wholesale and retail distributors	
§40. Wholesalers and retailers distributing ~~medically~~ critically important antimicrobial agents for human medicine should only do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled. §41. Distributors should encourage compliance with the national guidelines on the responsible use of ~~medically~~ critically important antimicrobial agents for human medicine and should keep records of all antimicrobials supplied according to the national regulations including, for example:	**Australia** For paragraphs 40 and 41. Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§40. Wholesalers and retailers ~~distributing medically important~~ distributing antimicrobial agents should only do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled.	**Norway**
§41. Distributors should encourage compliance with the national guidelines on the responsible use of medically important antimicrobial agents and should keep records of all antimicrobials supplied according to the national regulations ~~including, for example:~~in accountable way.	**Indonesia**
§41. Distributors should encourage compliance with the national guidelines on the responsible use ~~of medically important~~ of antimicrobial agents and should keep records of all antimicrobials supplied according to the national regulations including, for example:	**Norway**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§41. • ~~name of prescribing veterinarian or other suitably trained and authorized person~~	**USA** Maintaining records on individual prescribers or producers is not the responsibility of wholesalers or retail distributors. Additionally, the recording of personal information should not be done without proper protocols to assure privacy protection. A section on confidentiality would need to be put in. This appears to go far beyond Codex's role even though it was included in the 2005 Code. Should defer to OIE to cover as appropriate.
§41. • ~~name of user~~	**USA** Maintaining records on individual prescribers or producers is not the responsibility of wholesalers or retail distributors. Additionally, the recording of personal information should not be done without proper protocols to assure privacy protection. A section on confidentiality would need to be put in. This appears to go far beyond Codex's role even though it was included in the 2005 Code. Should defer to OIE to cover as appropriate.
§~~42. Distributors should support the training of users of antimicrobial agents as defined in paragraph 28.~~	**USA** Distributors are responsible for providing information for the appropriate label use of the product and for providing technical information on the drug product makeup and safety/efficacy studies. Training of veterinary professionals on responsible antimicrobial use and the risk of developing AMR should come from approved continuing education programs to ensure accuracy.
Responsibilities of Veterinarians[1] and Plant/Crop Advisors or Consultants	
Responsibilities of Veterinarians, aquatic animal health professional[7] and Plant/Crop Advisors or Consultants	**Thailand** The revised Code should define the responsibilities of all actors in the entire food chain. Therefore, we would like to add "aquatic animal health professional" in this section.
Responsibilities of Veterinarians[7] and Plant/Crop ~~Advisors or Consultants~~ Professionals and other Professionals Authorized to Administer Antimicrobial Agents	**Consumers International**
Responsibilities of Veterinarians[7] and Plant/Crop Advisors or Consultants	**Healthforanimals** Duplication. The OIE, FAO and WHO publish guidance and recommendations for the use of antimicrobials in animals, plants and humans respectively. Codex documents should refrain from giving or stating guidance on animal populations, or the practice of veterinary medicine, when it is already addressed by OIE.

[1] Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Responsibilities of ~~Veterinarians[7] and Plant/Crop Advisors~~ Professionals Authorized to Administer or ~~Consultants~~ Direct the Use of Antimicrobial Agents	**International Association of Consumer Food Organizations** Antimicrobial agents may be used throughout the food chain, not just in food producing animals or on crops.
§43. Veterinarians and plant/crop advisors or consultants should identify new or recurrent disease problems and develop alternative strategies to prevent or treat infectious ~~disease~~disease where possible. These may include, but are not limited to, biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination where applicable/available.	**Australia** The proposed change accounts for differing availability of alternative strategies in countries.
§43. ~~Veterinarians~~ Veterinarians, aquatic animal health professional and plant/crop advisors or consultants should identify new or recurrent disease problems and develop alternative strategies to prevent or treat infectious disease. These may include, but are not limited to, biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination where applicable/available.	**Thailand**
§43. Veterinarians and plant/crop advisors or consultants should identify new or recurrent disease problems and develop alternative strategies to prevent or treat infectious disease. These may include, but are not limited to, biosecurity, improved or altered production practices, and safe and effective alternatives to antimicrobial agents, including vaccination where applicable/available.	**Consumers International**
§45. National action plans may include recommendations to develop species or sector-specific guidelines. Professional organizations ~~should~~ could develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents~~. National action plans may include recommendations to develop species or sector-specific guidelines~~.	**Australia** Re-ordering of the sentences indicates the objective (species or sector-specific guidelines) and which actor will potentially undertake this work (professional organizations).
§47. Antimicrobial agents should only be used when necessary, as only as long as necessary, and in an appropriate manner:	**Australia** This provides explicit labelling requirements for veterinarians and reflects variation in global labelling requirements. Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§47. Antimicrobial agents should only be ~~used~~ prescribed or administered when necessary, as only as long as necessary, and in an appropriate manner:	**Brazil**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§47. • A prescription or order for application and any accompanying advice notes or similar documents for ~~medically~~ critically important antimicrobial agents for human medicine should indicate the dose, the dosage intervals, the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered depending on the dosage and the characteristics of the individual or population to be treated;	**Australia**
§47. • A prescription or order for application for medically important antimicrobial agents should indicate the dose, the dosage intervals, the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered depending on the dosage and the characteristics of the individual or population to be treated; in accordance with national legistation;	**Brazil**
§47. • A prescription or order for application ~~for medically important~~ for antimicrobial agents should indicate the dose, the dosage intervals, the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered depending on the dosage and the characteristics of the individual or population to be treated;	**Norway**
§47. • A prescription or order for application for medically important antimicrobial agents should ~~indicate the dose, the dosage intervals, the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered depending on the dosage and the characteristics of the individual or population to be treated;~~follow label indications. • ~~A prescription or order for application for medically important antimicrobial agents should indicate the dose, the dosage intervals, the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered depending on the dosage and the characteristics of the individual or population to be treated;~~	**Healthforanimals** Outside codex mandate and in OIE mandate Outside Codex food safety mandate and in the OIE mandate
§47. • The quantity of the antimicrobial provided to the end-user should be ~~limited only~~ appropriate for the intended administration ~~concerned~~based on the experience of the veterinarian or crop advisor or consultant. Prescriptions should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;	**USA** Revised to account for professional oversight.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§47. • ~~The quantity of the antimicrobial provided to the end-user should be limited only for the administration concerned. Prescriptions should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;~~	**Healthforanimals** Outside codex mandate and in OIE mandate limited vet access make this challenging in many geographies
§47. • All ~~medically~~ critically important antimicrobial agents for human medicine should be prescribed or applied and used according to label directions or veterinary directive and the conditions stipulated in the national legislation.	**Australia**
§47. • All ~~medically important~~ antimicrobial agents should be prescribed or applied and used according to label directions and the conditions stipulated in the national legislation.	**Norway**
§47. • All medically important antimicrobial agents should be prescribed or applied and used according to label ~~directions and the conditions stipulated in the national legislation~~directions.	**USA** Legislation may not be applicable in some countries.
§47. • All medically important antimicrobial agents should be prescribed or applied and used according to label directions ~~and the conditions stipulated in the national legislation~~.	**Healthforanimals** National legislation not existant in some countries
§48. For food-producing animals, the appropriate use of ~~medically~~ critically important antimicrobial agents for human medicine in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§48. For food-producing animals, the appropriate use of medically important antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical ~~disease and for reasons of animal welfare~~disease.	**Indonesia** Proposes the elimination of phrase "and for reason of animal welfare" since it is outside the codex mandate

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§48. For food-producing animals, the appropriate use ~~of medically important~~ of antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	**Norway**
§48. For food-producing animals, the appropriate use of medically important antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical ~~disease and for reasons of animal welfare~~disease.	**USA** Outside the mandate of Codex.
§48. For food-producing animals, the appropriate use of medically important antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, and the accurate diagnosis, based on adequate diagnostic procedures~~.~~ ~~There~~ . Infrequently, there will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	**Consumers International**
§48. For food-producing animals, the appropriate use of medically important antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian, the conditions of the marketing authorization, and the accurate diagnosis, based on adequate diagnostic procedures. ~~There will~~ Infrequently, there may be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.	**International Association of Consumer Food Organizations**
§49. ~~To be further developed: a paragraph describing~~ The proposal to describe the diagnosis and treatment of ~~plants~~plants should be carefully considered.	**Australia** The Code of Practice would be best to reference other key texts for this purpose rather than potentially duplicating information.
§49. To be further developed: a paragraph describing the diagnosis and treatment of plants.	**China** The crop health professionals have responsibilities for the diagnosis and treatment of plants. The use of antimicrobial agents for treatment of plant disease should be under the direction of plants health professionals. The treatment of plants should avoid the development or co-selection of antimicrobial resistance

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§50. • o the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected whenever possible/appropriate; based on antimicrobial susceptibility testing;	**Brazil**
§50. • o the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected first whenever possible/appropriate;	**Canada** Suggest adding "first" after "selected"
§50. • o the importance of the antimicrobial agents to human ~~and veterinary~~ medicine; and,	**Canada** Suggest revising "human and veterinary medicines" to "human medicine" because it is for minimizing human health adverse effects.
§50. • If the label conditions allow for flexibility, the veterinarian or plant/crop ~~advisor or consultant~~ health professional should consider a dosage 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.	**Consumers International**
Off-label use	
§51. 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 appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period. ~~Off-label use~~ Fluoroquinolones, colistin and third and fourth generations of ~~medically important antimicrobial agents~~ cephalosporins should ~~not~~ be ~~permitted~~ urgently prohibited for use as growth ~~promotion~~promotors.	**Australia** The proposed text provides alignment with the outcomes of the OIE World Assembly 2018 and is an important message to capture within the Code of Practice.
§51. 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 appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period. Off-label use of medically important antimicrobial agents should only be used in treatment or prevention situations warranted by susceptibility results. Medically important antimicrobial agents should not be permitted for growth promotion, on or off-label.	**Canada** Suggest replacing the last sentence by two sentences. The rationale is that there are two separate points here.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§51. 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 appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period~~. Off-label use of medically important antimicrobial agents should not be permitted for growth promotion~~.	**Indonesia**
§51. 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 appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period. Off-label use ~~of medically important~~ of antimicrobial agents should not be permitted for growth promotion.	**Norway**
§51. For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with ~~the~~ applicable national legislation including the appropriate and/or approved withdrawal periods to be used. ~~It is the veterinarian's responsibility to~~ Veterinarians should define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period. Off-label use of medically important antimicrobial agents should not be permitted for growth promotion.	**USA** 1. Whose legislation would be "the" legislation. Edits make the statement more globally appropriate. 2. To be consistent with "medically important antimicrobial" term in definition section,
§51. For food-producing animals, the off-label use of a veterinary antimicrobial agent should be avoided but may be permitted in appropriate circumstances and should comply with the national legislation including the appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period. Off-label use of medically important antimicrobial agents should not be permitted for growth ~~promotion~~promotion or disease prevention.	**Consumers International**
§51. For food-producing animals, the off-label use of a veterinary antimicrobial agent should generally be avoided but may be permitted in exceptional and appropriate circumstances and should comply with the national legislation including the appropriate and/or approved withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of use including the ~~therapeutic~~ treatment regimen, the route of administration, and the duration of the administration and the withdrawal period. Off-label use of medically important antimicrobial agents should not be permitted for growth promotion, or for routine disease prevention or control.	**International Association of Consumer Food Organizations**
§52. Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary ~~agents~~agents in food producing species.	**Australia** The proposed change reflects the risk in the food chain.
§52. Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of ~~veterinary~~ medically important antimicrobial agents.	**USA** To be consistent with definitions above.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§53. ~~Medically~~ Critically important antimicrobials for human medicine should not be used off-label for plants/crops.	**Australia** Critically important antimicrobials for human medicine to replace medically important antimicrobials. 'Critically important antimicrobials' are referred throughout the CAC/GL 77-2011 text. This approach will also take into account highest category within national lists and provide flexibility for low-to-middle-income countries. The Code of Practice is to be read in conjunction with CAC/GL 77-2011, which is one of two, other key Codex texts.
§~~53. Medically important antimicrobials should not be used off-label for plants/crops.~~	**Indonesia** Indonesia suggest to delete para 53, as it is redundant with the general principle
§53~~. Medically important~~ . antimicrobials should not be used off-label for plants/crops.	**Norway**
Record keeping and recording	
§54. For food-producing animals and plants/crops, records on antimicrobial agent prescription or administration should be kept in conformity with national legislation or best management practice guidelines.	**Brazil**
§54. For food-producing animals and plants/crops, records on antimicrobial agent administration should be kept ~~in conformity with national legislation~~ as specified by regulatory authorities or ~~best management practice guidelines~~industry/stakeholder/professional associations.	**USA** Often, national legislation is not the only guidance that veterinarians/crop advisors follow. Industry or stakeholder guidance should also be mentioned.
§54. For food-producing animals and plants/crops, records on antimicrobial agent administration should be kept in conformity with national legislation or best management practice guidelines. In particular, for investigation of antimicrobial resistance, veterinarians and plant/crop advisors or ~~consultants or suitably trained persons authorized in accordance with national legislation~~ consultants should:	**Japan** To remove duplicates. See the footnote 7.
§54. • record the quantitative not just susceptible/intermediate/resistant antimicrobial susceptibility testing ~~results~~results (MICS and zone diameters);	**USA** Important for trend analysis and detection of AMR emergence
§54. • record the antimicrobial used, the dosage regimen and the duration; investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report ~~it~~them, as appropriate, to the regulatory authorities (through a pharmacovigilance system, if available).	**USA**
§~~55. Veterinarians and plant/crop advisors or consultants should also periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions.~~	**USA** Out of scope of Codex. OIE is the appropriate body to provide recommendations on the practice of medicine, and IPPC for on-farm crop practices.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Training	
§56. Professional organizations including societies, associations and relative organizations should participate in the development and/or delivery of training of users of antimicrobial agents as defined in paragraph 28.	**China** The veterinary professional societies, associations and relative organizations have responsibilities to establish standards and guidelines for training and education of users of antimicrobial agents.
Responsibilities of food producers	
Responsibilities of food animal and plant/crop producers	**Canada** Suggest revising the section heading as "Responsibilities of food animal and plant/crop producers".
Responsibilities of food and feed producers	**FEFAC** It may not be that clear that this chapter (at least some elements of it) apply also to feed producers.
	International Feed Industry Federation Does this also involves (primary) feed producers? If not straightforward, then it should be specified (food and feed producers)
	Consumer Goods Forum Para 57 – para 60: We would suggest that for clarity, given the focus on the farm side of the manufacturing chain in the points and text in paras 57, 58 and 59, that the titles proceeding the para 60 refers to primary producers. Currently the distinction between 'food producers' and the 'food processing industry is not clear'.
§57. Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks. They should call on the assistance of veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation. ~~All participants involved in primary production of food have an important role to play in preventing disease and ensuring the responsible and prudent use of antimicrobial agents to minimize risk of foodborne AMR.~~	**Australia** The last sentence of this paragraph is a duplication of paragraph 2 in the Introduction.
§57. Producers ~~are responsible for~~ should work to reduce risk by implementing health programmes on their farms to prevent and manage disease outbreaks. They should call on the assistance of veterinarians, plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation. All participants involved in primary production of food have an important role to play in preventing ~~disease~~ disease, to reduce the need to use antimicrobial agents and when necessary ensuring the responsible and prudent use of antimicrobial agents to minimize risk of foodborne AMR.	**USA** Language is more in line with Codex language/tone.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§58. Producers of food animals and food of plant origin have the following responsibilities: • to isolate sick animals and dispose of dead or dying animals or plants/crops promptly under conditions approved by ~~relevant authorities~~authorities or agencies; • to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product labels ~~and~~ and/or national legislation; • To ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate ~~food~~food or water; • To assist the ~~relevant~~ authorities or agencies in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.	**Australia** The proposed actions listed are appropriate to producers of food-producing animals and foods of plant origin. The proposed change provides flexibility in countries' systems. The addition reflects the focus on the environment. The proposed change provides flexibility in countries' systems.
§58. • to isolate sick animals and dispose of dead or dying animals or diseased plants/crops promptly under conditions approved by relevant authorities; • to address infection prevention and control measures regarding contacts ~~between people,~~ between veterinarians, plant/crop advisor or consultants, breeders, ~~owners~~farm owners and their children, ~~children~~ pets and wildlife and the food-producing animals or plants/crops treated; • to keep adequate records of all antimicrobial agents used, including the following: o number of animals treated;	**Canada** Suggest deleting "people" and revising "owners and children" to "farm owners and their children, pets and wildlife" "Number of animals treated" needs to be deleted as it is duplicative of sub-bullet 3 (=date of administration; species and number of animals).
§58. • ~~to~~ use antimicrobial agents only when necessary, under the supervision of a veterinarian or plant/crop advisor or consultant when required, and not as a replacement for good management and farm hygiene practices, or other disease prevention methods; • ~~to~~ implement a health plan in cooperation with the veterinarian, plant/crop advisors or consultants, or other suitably trained person authorized in accordance with national legislation that outlines measures to prevent disease; • ~~to~~ use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop advisors or consultants or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site;	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**

• ~~to~~ isolate sick animals and dispose of dead or dying animals or plants/crops promptly under conditions approved by relevant ~~authorities~~authorities or as appopriate;
• ~~to~~ comply with the storage conditions of antimicrobial agents according to the approved product labelling;
• ~~to~~ address infection prevention and control measures regarding contacts between people, veterinarians, plant/crop advisor or consultants, breeders, owners, children and the food-producing animals or plants/crops treated;
• ~~to~~ comply with the recommended withdrawal periods or pre-harvest intervals to ensure that residue levels in or on the food do not present a foodborne AMR risk for the consumer;
• to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product ~~labels and national legislation~~labels;
• to inform the veterinarian, plant/crop advisor or consultant, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or failures of antimicrobial applications, as appropriate;
• to maintain ~~all~~ relevant clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.
• to keep adequate records of all antimicrobial agents used, including the following:
  ○ name of the antimicrobial agent/active ~~substance and batch number~~substance;
  ○ ~~daily dose and number of treatment days;~~
  ○ quantity and duration of the antimicrobial agent administered.
• To assist as resources are available the relevant authorities in surveillance programs related to antimicrobial use and foodborne antimicrobial resistance, with the assurance of data security and confidentiality as appropriate.
	Rationale: labelling is done in accordance with national legislation so duplicative
	Allow for flexibility.
	The batch number is too prescriptive to include.
	Redundant with following bullet
	Edited to better define an appropriate role for producers.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**Canada** This paragraph (the fourth sentence) describes "probiotics", "prebiotics", "competitive exclusion products", etc. There should be a careful consideration of promoting alternatives that may not be effective (as indicated in General comments). Suggest providing a Codex or FAO reference for the third sentence "This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices"
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**Japan** The definition of “antibiotics” includes naturally derived substances but does not include semi-synthetic and synthetic ones. Japan is of the view that a term used here should cover any substance of natural, semi-synthetic and synthetic origin.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to medically important antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**USA** To focus limited resources on areas of public health concern.
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts ~~in disease prevention~~ to prevent or minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as ~~prebiotics, probiotics)~~ prebiotics) should be considered.	**Consumers International**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of ~~vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of~~ vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**FEFAC** The two last sentences address the same concept. The second option is in FEFAC's opinion more appropriate.
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to medically important antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that ~~have been clinically proven to be safe and efficacious~~are authorized, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**Healthforanimals** Change1: A distinction should be made on which type of antimicrobial is being considered. Change2: Replace ‘clinically proven to be safe and efficacious’ with ‘are authorized ‘. The term authorized encompasses the core principles of safety, efficacy and quality - the cornerstone of regulatory review. Being clinically proven to be safe and efficacious are but two of the many requirements to be achieved prior to authorization. The measures listed - probiotics, prebiotics, intestinal bacterial flora – all require some form of authorization.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts ~~in disease prevention~~ to prevent or minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, production conditions, nutrition, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. ~~Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.~~	**International Association of Consumer Food Organizations** Last sentence redundant with previous sentence
§59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production and nutritional strategies (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as ~~adequate~~ appropiate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.	**International Feed Industry Federation** For the term adequate it should be changed to appropriate as mentioned in principle 2.
§60. Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants. Food processing industry, food retailers and consumers should take necessary action in accordance with the *Principles and guidelines for the conduct of microbiological risk management*.	**Brazil** As this is a general statement, not directly related to the “responsibilities of producers”, this paragraph should be inserted after paragraph 10, in the beginning of section 5.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§~~60. Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants.~~ ~~Food processing industry, food retailers and consumers should take necessary action in accordance with the *Principles and guidelines for the conduct of microbiological risk management*.~~	**Indonesia** Suggests to eliminate para 60 since it is only general statement and has already concern issue included in introduction
§60. Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants. Food processing industry, food retailers and consumers should take necessary action in accordance with the *Principles and guidelines for the conduct of microbiological risk management*.	**Japan** These paragraphs are general issues on responsible use of antimicrobial agents and therefore should be put in section 5 after paragraph 11 rather than “Responsibilities of food producers”

§60. Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants.
Manufacturers of foods (including secondary processors, distributors and caterers / food services) have the following responsibilities:
• To apply only cleaning agent / sanitizers / disinfectants that are ‘fit for purpose’ to be used in a food production environment
• To ensure that chemicals are stored, handled and used according to the manufacturer’s instructions and - when used according to the validated cleaning regime – not introduce food safety, compliance or quality hazards. The following accompanying information may be used as pre-requisites
  ○ Cleaning agent / sanitizers / disinfectants specification
  ○ Storage Instructions (Instructions to minimize by-product build-up and physical separation of chemicals)
• In line with Good Manufacturing Practices, food safety management systems (e.g. HACCP) to determine and implement a methodology for assessing efficiency of cleaning, sanitizing or disinfection processes and presence of traces in the food product
• To ensure the minimizing traces of cleaning chemicals, sanitizers and disinfectants on food contact surfaces considering
	Consumer Goods Forum
	We suggest that the following text be included in the document after para 60, so as to include address the gap in the current document regarding the use of cleaning chemicals.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
○ Cleaning frequency / duration / sequence; ○ cleaning agents, sanitizers and disinfectants composition (e.g. active substances) ○ Cleaning process parameters (equipment used, concentration of chemicals, time, temperature, physical parameters); ○ Responsibilities, documentation, visual aids, training / qualification requirements; ○ Necessary monitoring or verification activities • Ensure safe chemical disposal by following manufacture instructions • Ensure documented staff training which covers the aspects of both health and safety and the cleaning, sanitizing or disinfection process.	
6. Practices during production, processing, storage, transport, retail and distribution of food	
6. Practices during production, processing, storage, transport, retail and distribution of food Food should be produced and handled in such a way as to minimize the presence and growth of microorganisms, which apart from having the potential to cause spoilage and foodborne illnesses can also carry AMR determinants. Slaughterhouses and processing plants should follow good manufacturing practices and the Hazard Analysis and Critical Control Points (HACCP) principles. The Codex General Principles of Food Hygiene (CAC/RCP 1-1969. Rev. 4 - 2003) is a useful reference in this respect.	**Canada** The suggested paragraph is as follows (see comment for 60bis)
6. Practices during production, processing, storage, transport, retail and distribution of food	**China** This part should include "\wholesale" and "catering" into the food chain. The catering industry has a responsibility to provide safe and reliable food to prevent the presence and spread of drug-resistant microorganisms in food. Therefore, the responsibility of catering industry should be added to the chapter of responsibility of food production and processing.
6. Practices during production, processing, storage, transport, retail and distribution of food	**Thailand** To enhance the prudent use of antimicrobial, we view that the related international standards and guidelines for each step of food production should be taken into consideration and referred, where applicable and necessary.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§~~60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.~~ §60. Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne antimicrobial resistance. While such efforts mainly focus on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays a significant role in preventing transmission and spread of resistant bacteria and resistance determinants. Food processing industry, food retailers and consumers should take necessary action in accordance with the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007). The absence of Good Hygiene Practices (GHPs) in food production can occur at different stages of the production carrying high levels of microbiological contamination of food. These micro-organisms may be resistant or not. Better hygiene and infection prevention measures are essential to limit the development and spread of antimicrobial-resistant infections and multidrug-resistant bacteria. Therefore, specific processing steps, as described in various Codes of Hygienic Practice for specific foods, should be complied by food producers.	**Brazil** As this is a general statement, not directly related to the “responsibilities of producers”, paragraph 60 should be inserted in this section. Include the paragraph beginning with "The absence of Good Hygiene Practices..."
§60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.	**Canada** This para is highly technical: bacteriostatic vs. bactericidal, which is also affected by other factors such as concentrations and time. It is suggested that this paragraph be replaced by a general paragraph advising to apply good manufacturing practices and HACCP principles for minimizing the load of microorganisms (thus AMR) along the food chain. Line 1. Suggest clarifying the term "technological treatments" as it is unclear what is meant by it.
60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.	**China** Strengthen and detailly define the responsibilities for each practice during production, processing, storage, transport, retail and distribution of food. Control of environment during the food processing to avoid the dissemination of resistant microorganisms. Control of food safety by catering industry. The catering industry has a responsibility to provide safe and reliable food to prevent the presence and spread of drug-resistant microorganisms in food. Therefore, the responsibility of catering industry should be added to the chapter of responsibility of food production and processing.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
§~~60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.~~	**USA** This paragraph should be deleted. As written, it makes conclusions and does not provide guidance. Further, according to the summary of the FAO/WHO expert meeting on foodborne antimicrobial resistance: Role of environment, crops and biocides Rome, 11-15 June 2018, it appears data gaps exist with regard to biocides, which appears this paragraph is addressing, and impact on foodborne AMR risk.
§60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.	**International Feed Industry Federation** Only antibiotics (as defined above)?

§60ter. Control of post-production contamination: Post-production contamination should not be underestimated. It can occur in the different stages of the production and consumption chain, in which food handlers have an important responsibility to avoid contamination of food with microorganisms that can be carriers of resistance genes. Food contamination usually occurs at times of increased handling, in meat during slaughter or processing. In ready-to-eat foods, the real risk is presumed cross-contamination, directly between raw and processed foods or indirectly through contaminated hands, surfaces or utensils and vectors.
Manufacturers of foods (including secondary processors, distributers and caterers/foodservices) have the following responsibilities:
• To apply only cleaning agent/sanitizers/disinfectants that are 'fit for purpose' to be used in a food production environment
• To ensure that chemicals are stored, handled and used according to the manufacturer's instructions and - when used according to the validated cleaning regime – not introduce food safety, compliance or quality hazards. The following accompanying information may be used as pre-requisites
  ○ Cleaning agent/sanitizers/disinfectants specification
  ○ Storage Instructions (Instructions to minimize by-product build-up and physical separation of chemicals)
• In line with Good Manufacturing Practice, food safety management systems (e.g. Hazard Analysis Critical Control Points) to determine and implement a methodology for assessing efficiency of cleaning, sanitizing or disinfection processes and presence of traces in the food product
• To ensure the minimizing traces of cleaning chemicals, sanitizers and disinfectants on food contact surfaces considering
	Australia
	The suggested text addresses a gap in the current document at section 6 regarding cleaning processes in relation to food production.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
○ Cleaning frequency/duration/sequence; ○ cleaning agents, sanitizers and disinfectants composition (e.g. active substances) ○ Cleaning process parameters (equipment used, concentration of chemicals, time, temperature, physical parameters); ○ Responsibilities, documentation, visual aids, training/qualification requirements; ○ Necessary monitoring or verification activities • Ensure safe chemical disposal by following manufacture instructions • Ensure documented staff training which covers the aspects of both health and safety and the cleaning, sanitizing or disinfection process.	
§~~60ter. Control of post-production contamination~~60ter. ~~: Post-production contamination should not be underestimated. It can occur in the different stages of the production and consumption chain, in which food handlers have an important responsibility to avoid contamination of food with microorganisms that can be carriers of resistance genes. Food contamination usually occurs at times of increased handling, in meat during slaughter or processing. In ready-to-eat foods, the real risk is presumed cross-contamination, directly between raw and processed foods or indirectly through contaminated hands, surfaces or utensils and vectors.~~	**Brazil**
§60ter. Control of post-production contamination: Post-production contamination should not be underestimated. It can occur in the different stages of the production and consumption chain, in which food handlers have an important responsibility to avoid contamination of food with microorganisms that can be carriers of resistance genes. Food contamination usually occurs at times of increased handling, in meat during slaughter or processing. In ready-to-eat foods, the real risk is presumed cross-contamination, directly between raw and processed foods or indirectly through contaminated hands, surfaces or utensils and vectors.	**China** The “Five Keys to Safer Food” is for promoting safe food handling behaviors and educate all food handlers, including consumers. It is suggested incorporating “Five Keys to Safer Food” for food handlers along the food chain as well. It is suggested adding the following sentences at the end of 60ter: In addition, food business operators have to provide specific instructions and training on good hygienic practices, including those for minimizing cross-contamination. The WHO Five Keys to Safer Food can be followed by food handlers to minimize the transmission of foodborne AMR.
§60ter. Control of post-production contamination: Post-production contamination should not be underestimated. It can occur in the different stages of the production and consumption chain, in which food handlers have an important responsibility to avoid contamination of food with microorganisms that can be carriers of resistance genes. Food contamination usually occurs at times of increased handling, in meat during slaughter or processing. In ready-to-eat foods, the real risk is presumed cross-contamination, directly between raw and processed foods or indirectly through contaminated hands, surfaces or utensils and vectors~~.~~. This Code of Practice should be read in conjunction with the Codex General Principles of Food Hygiene (CAC/RCP 1-1969)	**USA** This paragraph should be further revised. As written, it makes conclusions and does not provide guidance. Suggest adding reference to Codex General principles of food hygiene which addresses this area.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
7. Communication to consumers	
7. Consumer Practices and Communication to consumers	**International Association of Consumer Food Organizations**
§61. Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne ~~AMR~~ disease and ways to minimize the risk of infection.	**USA** This section is not about foodborne AMR, but about foodborne pathogens in general. Introducing AMR is inappropriate and adds unnecessary stress to consumers without providing useful information. Risk communication should provide consumers with information that can help them make a more informed decision and food preparation practice.
§61. Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne ~~AMR~~ pathogens and ways to minimize the risk of infection.	**Healthforanimals** This section is not about foodborne AMR, but about foodborne pathogens in general. Introducing AMR is inappropriate and adds unnecessary stress to consumers without providing useful information. Risk communication should provide consumers with information that can help them make a more informed decision and food preparation practice.
§61. Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne ~~AMR~~ illness and ways to minimize the risk of infection.	**International Feed Industry Federation** Delete AMR, foodborne pathogens don't need to be resistant to cause illness.
§61. • ~~Identifying all the stakeholders~~Ensuring that label claims relevant to use of antimicrobials and ~~having a common message;~~foodborne AMR (e.g., "no antibiotics") are meaningfully defined/documented, truthful and not misleading • Identifying all the stakeholders and having a common message;	**International Association of Consumer Food Organizations**
§63. The best way for consumers to prevent foodborne AMR is through proper food handling. The *WHO Five Keys to Safer Food Manual* can be used to teach consumers how to minimize foodborne bacteria in their food. 64. The consumers have responsibilities of (1) learning food safety knowledge on how to minimize and contain antimicrobial resistance by active participation in training; (2) improving the skills of identifying food quality; (3) promoting the dissemination of correct information to avoid adverse opinions; (4) maintaining a sense of justice, supervision, feedback and reporting on violations of food safety laws and regulations; (5) cooperating with the government and relevant academic institutions to carry out food safety related investigations.	**China** 64. The consumers have responsibilities of (1) learning food safety knowledge on how to minimize and contain antimicrobial resistance by active participation in training; (2) improving the skills of identifying food quality; (3) promoting the dissemination of correct information to avoid adverse opinions; (4) maintaining a sense of justice, supervision, feedback and reporting on violations of food safety laws and regulations; (5) cooperating with the government and relevant academic institutions to carry out food safety related investigations.
§63. The best way for consumers to prevent foodborne ~~AMR~~ illness is through proper food handling. The *WHO Five Keys to Safer Food Manual* can be used to teach consumers how to minimize foodborne bacteria in their food.	**International Feed Industry Federation**