

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

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

PROPOSED DRAFT GUIDELINES ON
INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

Comments at Step 3 (Replies to CL 2018/75-AMR)

Comments of Australia, Brazil, Canada, China, Colombia, Cuba, Egypt, Guyana, Indonesia, Iran, Japan, Kenya, Malaysia, Mexico, Morocco, Norway, United States of America, Consumers International, Health for Animal, International Association of Consumer Food Organization, International Feed Industry Federation, International Meat Secretariat and International Union of Food Science and Technology (IUFoST)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/75-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.

Comments on the proposed draft guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance

GENERAL COMMENT

GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3	MEMBER/OBSERVER
<p>Australia notes from the TFAMR5 that delegates sought clarity on the definition and scope of the food chain and Australia recognises the efforts of the EWG to address this issue. Australia however suggests that the definition and scope of food chain requires further modification to allow different regulatory systems and responsible competent authorities the flexibility to achieve the objective of integrated one-health monitoring and surveillance. Australia has provided alternative wording for Section 2 in the specific comments below.</p> <p>Australia understands the intent of having a stepwise or gradual approach to implementing monitoring and surveillance to allow countries to progress as their resources, capacity and systems develop. However, Australia would prefer the removal of the terms gradual or stepwise as there is an implication of hierarchy, even if not intended. Australia supports the principle of continuous improvement and enhancement and suggests that this approach captures the essence and intent of stepwise without the unintended hierarchy. Australia has provided alternative wording for Section 4 and Section 7 in the specific comments below.</p> <p>Australia does not support the inclusion of detailed information in Section 9.2 and recommends deletion of text in this section and make reference to relevant chapters in the OIE Codes on collection and reporting of data on sales and use. Australia has concerns that these guidelines are encroaching on the OIE remit for international reporting requirements for antimicrobial sales and use data. There is a risk that national competent authorities with responsibility for collecting and reporting antimicrobial sales and use data will be required to comply with multiple international standards setting bodies. There is currently no international consensus on the methods for collecting, analysing and reporting sales and use data and Codex guidelines are not subject to regular review. The OIE has a process in place to review and update standards as needed and should have sole responsibility for setting international standards for sales and use of antimicrobials in animals. Australia supports inclusion of a section on sale and use of antimicrobials on crops. Australia supports progression of the draft guidelines to Step 4.</p>	Australia
<p>Brazil continues not to agree with the stepwise approach as it is proposed in this new draft. Brazil is in favor of an incremental approach to be inserted into the document in each of the components for integrated surveillance, giving guidance to member countries on what would be the minimum elements to initiate an integrated surveillance program and how countries could increment their program.</p> <p>The table as proposed in section 7.3 with programs A, B and C continues to show three clearly distinct phases for the integrated surveillance program (former “initial, medium and advanced program” and “steps 1, 2 and 3”). This format creates a clear possibility of the categorization of member countries, that may lead to misinterpretation about the status of implementation of the program by countries and may be used inappropriately to generate barriers to trade.</p> <p>It is not in the mandate of Codex to categorize countries in a stepwise approach providing three different options from very basic to sophisticated. The mandate of Codex is to propose recommendations based on the principle of sound scientific analysis and evidence that protect the health of consumers and ensure fair practices in the food trade. Recommendations by Codex have to be applicable worldwide, taking into account countries capacities, giving particular attention to the impact on developing countries.</p> <p>General comments on the programs A, B and C of each of the components, in particular whether they fit the different situations of countries' capabilities to develop programs for integrated monitoring and surveillance of foodborne AMR:</p> <p>Brazil does not agree with the proposal of programs A, B and C and therefore Brazil is of the opinion that section 7.3 has to be deleted of the document, as explained in the general comments on the stepwise approach, and that the elements that provide an incremental approach should be inserted into the document in each of the relevant components for integrated surveillance.</p>	Brazil

GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3	MEMBER/OBSERVER
<p>Canada appreciates the efforts of the coordinators of these draft Guidelines to find a way to include the need for details on how surveillance systems can evolve over time. This information is one of the strengths of this document and is part of what delineates the content of this document from other WHO references. Canada is of the opinion that this beneficial information needs to be balanced with the concern that categorizing the development of monitoring and surveillance systems into different steps could potentially result in inappropriate trade barriers. Canada also notes that current language within the body of the text refer to several descriptors of this process such as: “design and implementation of programs should also evolve”, “gradual implementation”, “gradual approach”, “continuous enhancement”, “stepwise approach”; harmonization of this language is needed.</p> <p>Canada proposes that a basic description of an optimal/ideal integrated surveillance system be included in the body of the guidelines. Details regarding options for monitoring and surveillance enhancement over time can be included in an annex (or appendix). This is in line with the approach used in the Codex Guidelines for Risk Analysis of Foodborne AMR. The options for enhancement of surveillance (AMR, AMU, Integration of data, linkages with risk analysis) should be listed without headings to indicate phases/steps/stages.</p> <p>Canada believes that countries should be encouraged to continuously evolve their surveillance capacity to yield better data on AMU and AMR; and that it will be problematic for these guidelines to suggest that there is a minimum requirement for surveillance. Canada suggests a new principle be added to this effect, which is included in our specific comments.</p> <p>Canada suggests that consideration be given to the need to develop new definitions which are only specific to these Guidelines. Is this appropriate from a Codex standpoint? For example, “Prioritized antimicrobial agents” and “Risk-based approach to surveillance and monitoring of foodborne AMR”.</p> <p>Regarding the risk-based approach, Canada proposes to delete the section specific to this concept (i.e., Section 5). The entire document has reflection of a risk-based or science-based approach. In addition, in the introduction section of the document, the users of the document are encouraged to read the Codex Guidelines for Risk Analysis of Foodborne AMR, implying that a risk-based approach is a fundamental principle.</p> <p>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 these new Guidelines for Integrated Monitoring and Surveillance of Foodborne AMR.</p> <p>Canada proposes several structural changes (i.e., inclusion of Annex or Appendices) to the document to enhance the flow of the information as follows:</p> <ul style="list-style-type: none"> • Annex I - Details on AMR surveillance (move all of original Section 8 to here – Initiating Monitoring and Surveillance Activities) • Annex II – Details on AMU surveillance (move all of original Section 9 to here) • Annex III – Elements for Consideration for Monitoring and Surveillance Evolution over time (move all of the Table contents here, and put into text form instead of table form, remove the headings of “Program A”, “Program B”, and “Program C”). <p>Regulatory framework, policies and roles</p> <p>Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wide range of stakeholders. The level of engagement of stakeholders, including the food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals, farmers, professional associations, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance system. Stakeholders other than the competent authority, as previously described, may also carry out monitoring activities, for example, monitoring of AMU or AMR on a voluntary basis. Competent authorities may consider playing an active role in these stakeholder-based surveillance activities.</p> <p>An integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food-chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in relevant sectors should be included and collaborate in line with the NAP on AMR. The regulatory activities carried out by the competent authorities should be in response to policy objectives that are embedded in national strategies and NAPs on AMR.</p> <p>Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policy activities taken at a local level. Capacity building might help to ensure the implementation of interventions for AMR risk management.</p>	<p>Canada</p>

GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3	MEMBER/OBSERVER
<p>China agrees to using the stepwise approach, and suggests to add more details about the sampling plans and target microorganisms of crops/plants in section 7.3.</p> <p>China agrees that the definitions in GLIS need to align with the definitions in the COP (CXC 61-2005). Especially, the use of crops/plants should be unified in the whole text.</p> <p>China suggests through the whole text, always using “foodborne” to limit the scope of AMR, and the monitoring and surveillance program is both for foodborne AMR and AMU.</p>	China
<p>Para la tabla del numeral 7.3, línea 4, columna 2 Colombia propone: ANTIMICROBIAL RESISTANCE Target microorganisms, bacteria isolated Phenotypic testing of representative zoonotic/pathogens (e.g., Salmonella spp. and Campylobacter spp.), coagulase-positive Staphylococcus and indicator bacteria (e.g., E. coli and Enterococcus spp.) for resistance. Addition of testing for genetic determinants of resistance, mobile DNA elements (e.g. plasmids, transposons) and virulence factors Colombia propone incluir coagulase-positiva Staphylococcus ya que no se identifica Enterococcus spp., y asociar la detección de factores de virulencia.</p>	Colombia
<p>Cuba agradece las oportunidad de dar sus consideraciones sobre esta carta circular y apoya este documento por la importancia que tiene el seguimiento y la vigilancia integrados de la resistencia a los antimicrobianos transmitida por los alimentos..</p>	Cuba
<p>Egypt agrees with the proposal</p>	Egypt
<p>Guyana is in agreement with the contents of the proposed draft document without any amendment. We look forward to the finalizing of this draft document</p>	Guyana
<p>Indonesia agrees with the draft of Guideline on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance, but we propose suggestion: Option for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs. Indonesia has a deep concern regarding the implementation of the program categories which lead to the ranking of the codex members, it can be misled. Indonesia proposes to make general program needed for monitoring and surveillance only without categorization into several steps. STEP-wise approach may lead to trade issue</p>	Indonesia
<p>Japan considers that the contents of the table 7.3 needs to be in line with the objective of the guidelines, i.e. to monitor foodborne antimicrobial resistance, and to be more flexible allowing national situations including resource limitation in LMICs.</p> <p>For AMR monitoring:</p> <ul style="list-style-type: none"> λ Target microorganisms should be limited to “foodborne” pathogens and indicator bacteria. At least for PROGRAM A, flexibility should be given to the degree of inclusion of indicator bacteria according to the resource available. λ Prioritized antimicrobials tested should not include those ranked high importance for animal health, except for PROGRAM C, and in addition to antimicrobials listed on WHO list of CIA for Human Health, those on national lists (where available) should be considered in line with the definition of “prioritize antimicrobial agents” given in 3. Definitions. In order to reflect national needs, wording such as “as relevant to the national situation” should be added. <p>The part of Analysis and reporting seems to link to Section 10.4 to 12. However, some contents of the programs don’t directly correspond to the description of the sections. According to the development and elaboration of the sections, the program contents would need to be revised.</p>	Japan

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<p>Kenya proposes progressive or incremental approach which provides flexibility for implementation of integrated surveillance programs in line with the capacity and priorities of countries. There are also dynamics available in value chain for instance the capturing of data on AMU data. The risk of stepwise approach is categorization of compartmentalizing countries whereas the implementation should be based on countries abilities and priorities.</p> <p>Kenya proposes replacement of plants/crops with plants and consider using foods of plant origin.</p>	Kenya
<p>Le Maroc félicite les efforts fournis par le groupe de travail électronique (GTE) pour l'élaboration du projet des «DIRECTIVES SUR LE SUIVI ET LA SURVEILLANCE INTEGRES DE LA RESISTANCE AUX ANTIMICROBIENS D'ORIGINE ALIMENTAIRE CX/AMR 18/6/6» et supporte son adoption en tenant compte des recommandations du GTE pour la sixième session TFAMR06.</p>	Morocco
<p>The guidance reads well and it is a helpful tool for countries setting up integrated monitoring and surveillance systems foodborne AMR and AMU. It is also useful for countries when improving existing monitoring and surveillance systems. In our opinion it is important to collect data on foodborne AMR and AMU in a harmonized way globally. Norway support the step-wise approach given in the guidance, because this gives countries a useful tool to set up monitoring and surveillance in a timely manner.</p> <p>We have some amendments we consider of importance to the table on Antimicrobial Use due to the fact that there are differences between sales data and use data. The amendments would clarify this, they will be presented at the meeting as we were not able to submit them at this point due to technical restraints.</p>	Norway
<p>The U.S comments did not support inclusion of crops in a nationally harmonized, integrated surveillance system.</p> <p>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 the fundamental elements of AMR surveillance on crops and in the environment (e.g. sample sources, foodborne pathogens, antimicrobial agents). In addition, there appears to be a lack of standardized methods for the range of matrices involved. Additional research and methods development are needed in these sectors prior to the development of guidance in Codex Alimentarius. We suggest that a next step for integrated surveillance of foodborne AMR on crops and in the environment is to fill knowledge gaps on fundamental surveillance system components and develop appropriate, validated methods to ensure results are scientifically sound and sufficient for risk management.</p> <p>At this point, data on the occurrence of AMR in/on crops or in the environment are lacking, and the impact of AMR in crops or the environment on foodborne AMR is too difficult to discern. Focus should be maintained on the more direct interface between the public and food products of known risk (i.e., meat products), while maintaining consideration of surveillance of the environment and crops as aspirational. This approach would allow for a focus on clinically relevant AMR bacteria, which ideally are already being monitored and surveilled as part of other food safety programs</p>	USA
<p>In general, CI supports the draft Guidelines and believes it balances the need to be comprehensive while recognizing the different capacities of member countries.</p> <p>At the same time, CI believes the Guidelines should be strengthened by recognizing the potential role of the intensification of animal agriculture in the increase in antimicrobial use and associated resistance globally. Global sales of antimicrobials for use in food animals are expected to rise rapidly with much of this rise the result of increasing intensification in animal production systems. Large industrial farms are recognized as hotspots of antimicrobial resistance and this should be recognized by surveillance systems that aim to be risk based. Competent authorities need to have access to antibiotic use and microbiological data from industrial agriculture settings and the Guidelines should make this clear.</p>	Consumers International
<p><i>Acceptance and application by countries.</i> The guidelines are prescriptive. It will be a major challenge for even the most highly resourced countries to implement significant parts. Therefore, many countries will, by necessity, adopt a “pick and choose” approach. The recent Tripartite document, “Monitoring Global Progress on Addressing Antimicrobial Resistance” revealed that countries are implementing a range of surveillance programs consistent with their resources. The report reveals that lack of sufficient guidance is not a limitation to the development of a national surveillance program. The guidelines need to maintain flexibility in implementation to allow for differences. It would seem valuable to help countries understand that: 1) resistance surveillance is an input into risk assessment, 2) risk assessment precedes risk management, 3) surveillance reporting is not risk management.</p>	Healthforanimals

<p>GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3</p>	<p>MEMBER/OBSERVER</p>
<p><i>Purpose of surveillance.</i> The purpose of surveillance needs to be re-asserted and each clause needs to be assessed against the prime purpose. The purpose is to collect data that can be a useful input into the risk management and risk communication processes. The guidelines should provide a basic framework for foodborne AMR surveillance that is achievable globally. Surveillance programs should focus on the prevalence of foodborne resistant bacteria and the use of antimicrobial agents, to baseline data. This data can help explore potential relationships between the prevalence of resistant foodborne microorganisms and antimicrobial use or non-use as well as efficacy of risk management options. There remains insufficient knowledge about AMR in primary food production environments. Linking risk management and risk assessment/ risk profiles is fundamental to developing and implementing public health programs, including AMR surveillance and monitoring.</p> <p><i>Sales data.</i> The limitations of national antibiotic sales data to provide information on antibiotic use need to be clarified. Sales information does not necessarily co-relate to the quantities of antimicrobials used or to national resistance trends. It is inappropriate to present the use of such practices as the gold standard for medium and advanced systems. The ease of collecting such data and therefore the attractiveness of utilizing sales data as a starting point is clear; but without collecting information about on farm use it is not possible to provide accurate data on the type of use. Excessive focus on use misses the public health information that can inform risk assessment.</p> <p><i>Duplication.</i> The OIE, WHO, and CSLI publish guidance/ recommendations for surveillance of resistant foodborne bacteria and the use of antimicrobials in animals. The Codex guidelines should stay with the mandate and refrain from giving guidance on the practice of veterinary medicine – which is addressed by OIE.</p> <p><i>Visualize.</i> It is recommended to design and insert a diagram/illustration to show the role that surveillance should play to contribute to foodborne AMR outcomes.</p>	
<p>IACFO agrees with the EWG’s conclusions as summarized in the document, including that collection and analysis of data on sales and use of antimicrobials is an essential element of an integrated surveillance program. We also agree that crops/foods of plant origin should be included as well as animals, both in terms of monitoring and surveillance of antimicrobial usage and AMR, and that the immediate relevant environment of the food chain (soils where crops are grown, irrigation water, etc.) should also be considered in integrated monitoring and surveillance programs.</p> <p>We also emphasize that processing should be explicitly included, in addition to animal and food crop production, in integrated monitoring and surveillance programs. In addition to disinfectants, antimicrobial additives may be added to processed food items.</p> <p>These conclusions are consistent with the Terms of Reference for the work, to address the entire food chain. They are also consistent with the recent FAO/WHO expert meeting on foodborne antimicrobial resistance: Role of environment, crops and biocides, which concluded that “there is clear scientific evidence that foods of plant origin may serve as a vehicle of foodborne exposure to antimicrobial resistant bacteria.” It also concluded that “there is insufficient knowledge about the amounts and types of antimicrobials applied to crops and those used in terrestrial [production] and aquaculture.” It recommended that surveillance of antimicrobial usage and AMR in primary food production environments be implemented, and that terrestrial and aquatic primary food production system environments and products post-harvest also be considered for inclusion in integrated AMR programs.</p> <p>IACFO disagrees with excluding biocides from the scope. The document provides no justification for doing so. The recent FAO/WHO meeting summary report noted that bacteria with increased tolerance to biocides have been recovered from food production environments, and that chemical disinfectants are frequently used in food production and processing and are critical for food hygiene. It is scientifically plausible based on the available evidence that biocides play a role in AMR, and important to monitor AMR to biocides and biocide usage in order to better understand that role, as well as to preserve the use of critical food hygiene tools. The FAO/WHO meeting also noted that there is experimental evidence that certain microbiocides may co-select for AMR, although empirical data are lacking. Data from integrated monitoring and surveillance programs are needed to help fill critical data gaps.</p> <p>Biocides are used at various points throughout the food chain, including as disinfectants, food preservatives, feed preservatives, teat dips, and for decontamination of carcasses. In recognition of the contribution of biocides to antimicrobial resistance, a database on biocide (and metal) resistance genes has been developed and contains 470 experimentally verified resistance genes, which cover 41 biocides, 20 metals and 23 “other chemical compounds” toxic to bacteria (Cite 1). Researchers worldwide have pointed to the need to include biocides in efforts to address antimicrobial resistance (Cite 2).</p>	<p>International Association of Consumer Food Organizations</p>

<p>GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3</p>	<p>MEMBER/OBSERVER</p>
<p>Other authorities have noted that “any application that encompasses the widespread regular use of biocides at sub-lethal concentrations maintains a continuous selective pressure and thus increases the risk of selecting resistant bacteria. This may occur in a number of uses including ... food production...” (Cite 3).</p> <p>The step-wise approach of the document allows for national governments to prioritize other aspects over monitoring and surveillance of biocides/disinfectants, as noted in TFAMR5 paragraph 43 and 44.</p> <p>If biocides are excluded, it will be necessary to clarify what is meant by the term “biocides” and a justification for the exclusion should be provided.</p> <p>Cites:</p> <ol style="list-style-type: none"> 1. Pal C, Bengtsson-Palme J, Rensing C et al. BacMet: antibacterial biocide and metal resistance genes database. Nucleic Acids Res, 2014 Jan;43(Database issue):D737-43. Doi: 10.1093/nar/gkt1252. Epub 2013 Dec 3. 2. For example, Venter H, Henningsen ML, Begg SL. Antimicrobial resistance in healthcare, agriculture and the environment: the biochemistry behind the headlines. Essays Biochem 2017 Mar 3;61(1):1-10. Doi: 10.1042/EBC20160053. Print 2017 Feb 28. Deng W, Quan Y, Yang S et al. Antibiotic resistance in Salmonella from retail foods of animal origin and its association with disinfectant and heavy metal resistance. Microb Drug Resist 2017 Oct 17. Doi: 10.1089/mdr.2017.0127. [Epub ahead of print]. Romero JL, Grande Burgos MJ, Pérez-Pulido R et al. Resistance to antibiotics, biocides, preservatives and metals in bacteria isolated from seafoods: co-selection of strains resistant or tolerant to different classes of compounds. Front Microbiol 2017 Aug 31;8:1650. Doi: 10.3389/fmicb.2017.01650. eCollection 2017). 3. European Commission Directorate-General for Health & Consumers, Scientific Committee on Emerging and Newly Identified Health Risks. Assessment of the Antibiotic Resistance Effects of Biocides. 2009. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf 	
<p>Our members are firmly committed to ensuring the production of safe food for consumers through science-based practices, and we value the work of the Codex Alimentarius to ensure that science-based food safety practices are used in the international food trade.</p> <p>As stated in our previous comments to the Ad Hoc Intergovernmental Codex TFAMR, we believe that any national foodborne antimicrobial resistance surveillance system should possess a basic set of core competencies:</p> <ul style="list-style-type: none"> • Follow a science-based design approach and exhibit transparency in all aspects of the program. • Focus on the analysis of data trends rather than simply collecting and reporting bulk data. • Inform with data for outcomes-based actions to reduce the risk of foodborne antimicrobial resistance development. • Ensure data security and the confidentiality of all personal information. • Incorporate an integrated “One Health” approach within the mission of Codex for food safety. <p>In their work to create guidelines for the integrated monitoring and surveillance of foodborne antimicrobial resistance, it is important that the Codex TFAMR provides guidance to assist countries in identifying and developing flexible capacities to address the areas of greatest foodborne antimicrobial resistance risk in accordance with their national priorities and resources.</p> <p>The currently outlined stepwise approach in the draft document with programs A, B, and C in Chart 7.3 attempts to provide flexibility for an integrated approach to surveillance. At the same time, the programs are largely aspirational, highly prescriptive, and inappropriately categorize countries based on a set of artificially created steps. Surveillance guidance should be written to facilitate uniform implementation of basic surveillance principles, to assist in identifying possible risks, to establish country trends for use in benchmarking for improvement, and to inform to the overall risk analysis process.</p> <p>The data collected through the monitoring and surveillance of foodborne antimicrobial resistance should not imply or create any barriers to trade. A country’s position in the three programs for a step-wise implementation of an integrated surveillance process could easily be misinterpreted to create potential restrictions to trade. We recommend deleting the stepwise programs in Chart 7.3 and developing instead an incremental framework for the integrated monitoring and surveillance of foodborne antimicrobial resistance and antimicrobial drug use that is less aspirational and therefore, may be better achieved globally.</p>	<p>International Meat Secretariat</p>

GENERAL COMMENTS ON THE GUIDELINES GENERAL COMMENTS ON SECTION 7.3	MEMBER/OBSERVER
<p>The conclusion for the current draft surveillance guidelines states that crops/food of plant origin should be included in an integrated surveillance program of foodborne antimicrobial resistance. We believe that the inclusion of crops in the antimicrobial resistance surveillance guidance is premature because currently there is not readily available, validated, science-based information related to the antimicrobial resistance effects on crops and the environment.</p> <p>The summary report of the FAO/WHO Expert Meeting on Foodborne Antimicrobial Resistance, Role of the Environment, Crops, and Biocides held in in Rome, Italy in June of 2018 identifies data gaps that exist for the fundamental elements of antimicrobial resistance surveillance in crops and in the environment. There are still questions concerning the appropriate sample sources, bacteria, and the specific antimicrobial agents to monitor for the surveillance of foodborne antimicrobial resistance for crops and the environment.</p> <p>We advocate that the surveillance guidance from the Codex TFAMR should focus on the more direct interface between consumers and food products of known risk until more research information can be obtained regarding the potential of foodborne antimicrobial resistance from the use of antibacterial products in crops and the environment. Adequate information on antimicrobial drug use in crops, target bacteria, and use patterns should be allowed to develop before including crops in this Codex surveillance document.</p> <p>We propose that instead of including crops in the current integrated surveillance document, the Codex TFAMR should include a section in the document that specifically identifies the research needs for a better understanding of the potential for foodborne antimicrobial resistance from the use of antibacterial agents in crops. By identifying research gaps, countries could better understand how they might best evaluate and prioritize the risk of foodborne antimicrobial resistance in crops/food plants.</p> <p>We recommend deleting sections 9.2.2 and 9.2.4 found in the integrated surveillance guidance document that deal directly with antimicrobial reporting metrics. The precise metrics for reporting antimicrobial use data collection are still under careful consideration in many countries for use in their own national reporting systems, thereby, making consensus on this topic difficult to achieve for inclusion in a globally-focused Codex surveillance guidance document.</p> <p>Alternatively, we recommend providing specific language in Section 9.1 that directs countries to work to establish accepted and consistent technical units of measurement for reporting antimicrobial use data in their own national systems. Currently, the reporting of antimicrobial sales and/or use data may only be aspirational and not yet practically achievable in all countries.</p> <p>Risk analysis should follow a structured approach comprised of three distinct, but closely linked components: risk assessment, risk management and risk communication. We believe that Section 12 of the draft surveillance document concerning risk communication needs to be further developed to better outline a risk communication plan. The plan might reference the recommendations found in the 2017 WHO, AGISAR document, Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach which details reporting and outlines a risk communication plan that identifies human health implications, assesses communication capacity and leadership, establishes the key concerns of stakeholders and develops a format for creating key messaging for concerns. The value of effective risk communication would be to develop partnerships to achieve a commitment to activities to optimize responsible antimicrobial drug use and to function to better preserve the effectiveness of antimicrobial drugs, over time.</p> <p>We appreciate the need to achieve consensus for recommendations to best guide national food systems in implementing procedures for the monitoring and surveillance of foodborne antimicrobial resistance. Connecting foodborne bacterial resistance pathways can be a complex process. Bacteria possess the ability to share genetic material in a variety of ways. Data should provide information for risk assessment and subsequent risk management processes. Integrated monitoring and surveillance systems can be highly resource driven. The focus of the work of the Codex TFAMR should be to provide practical advice to countries to build a foodborne antimicrobial resistance surveillance system. The language in the Codex guidelines should provide flexibility for countries to monitor foodborne antimicrobial resistance based upon their currently available resources and to generate data to inform for the overall risk analysis process for establishing effective risk assessment, risk management, and risk communication.</p>	
IUFoST strongly supports these guidelines.	IUFoST

SPECIFIC COMMENTS

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
1. Introduction and purpose of the Guidelines	
Iran	
<p>1- Other guidelines including “Principles and guidelines for the conduct of microbiological risk management (MRM), CAC/GL 63-2007” can also be taken into account in introduction as a guideline for designing and implementation of this guideline.</p> <p>2- Although according to international agreements national standards and programs should not make barriers to trade, data related to imported foods and antimicrobial agents are so important and should be recorded and considered in national monitoring and surveillance programs. Antimicrobial resistance is a global and regional problem, so the regional problems, e.g. resistant microorganisms or antimicrobial residues in imported foods may lead to fail the surveillance programs.</p>	
World-wide recognition of the importance of antimicrobial resistance (AMR) as a public health threat has led to strong international calls for all countries to develop and implement national strategies and action plans that incorporate an integrated approach to risk management analysis . The political declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 committed member countries to developing multi-sectoral national action plans that involve all stakeholders within a “One Health” approach and to improving national systems of monitoring and surveillance of AMR and antimicrobial use (AMU).	Australia Risk assessment and risk communication should also be integrated to the greatest extent possible and therefore the term risk analysis is more appropriate.
For the purpose of these guidelines, “monitoring of AMR and AMU” is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and AMU related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity. “Surveillance of AMR and AMU” refers to the same activities when these are associated with a pre-defined risk mitigation plan or activity.	Australia Australia wishes to note again that the definitions of monitoring and surveillance in these guidelines are inconsistent with the definitions in the OIE Terrestrial and Aquatic Codes and also with the WHO AGISAR. Alignment with existing definitions will facilitate comparability of texts referred to in these guidelines.
For the purpose of these guidelines, “monitoring of AMR and AMU” is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and AMU related data to detect changes in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity. “Surveillance of AMR and AMU” refers to the same activities when these are associated with a pre-defined risk mitigation plan or activity and timely dissemination of AMR and AMU related data from defined populations.	Japan To be in line with Glossary of OIE Terrestrial Animal Health Code.
(1) While a number of activities in various sectors may be necessary to address AMR in totality, the scope of this Codex document is foodborne AMR risk. For the purpose of these guidelines, “monitoring of AMR and AMU” is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of (2) AMR-AMR in potential foodborne bacteria and AMU related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity. “Surveillance of AMR and AMU” refers to the same activities when these are associated with a pre-defined risk mitigation plan or activity	USA We suggest definitions for monitoring and surveillance be added to the definitions section as noted below. Change1: Focus within Codex scope. Change 2: The term ‘antimicrobial’ technically can include microorganisms other than bacteria (i.e. parasites), but justifiably needs to be limited for the purpose of these guidelines.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
For the purpose of these guidelines, “monitoring of AMR and AMU” is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and in potential foodborne bacteria and AMU related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity. “Surveillance of AMR and AMU” refers to the same activities when these are associated with a pre-defined risk mitigation plan or activity.	Healthforanimals To stay within scope of Codex, include in potential foodborne bacteria This needs to be done throughout the guidelines.
An integrated monitoring and surveillance system includes involves the coordinated and systematic collection of samples at appropriated stages along the food chain and the testing, analysis and reporting of AMR and AMU. In addition, including an integrated monitoring and surveillance system should include the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis and reporting of relevant epidemiological information from in humans, animals, foods, crops and environment to the greatest extent practical.	Australia Remove duplication and improve readability.
An integrated monitoring and surveillance system includes the coordinated and systematic collection of (1) data or samples at appropriated stages along the food chain and the testing, analysis and reporting of AMR and AMU, including the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and (2) the environment to the greatest extent practical.	Canada This paragraph contains one sentence with multiple concepts. Suggest dividing it into two sentences. Change1: Suggest adding “data or” to have “...coordinated and systematic collection of data or samples at...”. - In surveillance we collect data in addition to samples – for example on the AMU data. Change2: Editorial
An integrated monitoring and surveillance system includes the coordinated and systematic collection of samples at appropriated stages along the food chain and the testing, analysis and reporting of foodborne AMR and AMU, including the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and environment along the food chain to the greatest extent practical.	China
<u>For an integrated program for monitoring and surveillance of AMR in foodborne bacteria, testing of bacteria isolated form at least the following three sources is optimal: human (people in healthcare facilities, and in the community), animal derived food products, and food animals (sick and healthy). Depending on available resources, an AMR surveillance system for food borne bacteria can be implemented incrementally, or using focused priority study populations.</u> An integrated monitoring and surveillance system includes the coordinated and systematic collection of samples at appropriated stages along the food chain and the testing, analysis and reporting of AMR and AMU, including the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and environment to the greatest extent practical.	USA Delete existing paragraph 3 under Introduction and replace with new proposed text. We agree more work in the form of research is needed regarding developing methods and appropriate targets for monitoring and surveillance for crops and the environment. However, we believe the science in these areas have not matured enough for inclusion of crops and the environment in an integrated national surveillance system. The current statement is aspirational beyond the scope of Codex and existing scientific knowledge (foodborne AMR risk from crop and environmental sources are currently unknown).

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<p>The statement is also beyond what even well-resourced countries are currently doing. We note Incremental is also the term used in WHO AGISAR page 6.</p> <p>https://www.who.int/foodsafety/publications/agisar_guidance2017/en/ and WHO AGISAR also offers countries guidance on what should be in an integrated monitoring/surveillance program which is consistent with what well-resourced countries with mature monitoring/surveillance systems are currently doing.</p>
<p>An integrated monitoring and surveillance system includes the coordinated and systematic collection of samples at appropriated stages along throughout the food chain and the testing, analysis and reporting of AMR and AMU, including the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and environment to the greatest extent practical.</p>	<p>International Association of Consumer Food Organizations</p>
<p>An integrated monitoring and surveillance system includes the coordinated and systematic collection of samples at appropriated stages along the food chain and the testing, analysis and reporting of AMR and AMU, including the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices and the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and environment to the greatest extent practical.</p>	<p>International Feed Industry Federation</p> <p>The guidelines is focused on foodborne AMT (which is the remit of CODEX work). However, it appears that the monitoring and surveillance of AMR, particularly, is planned also on the environment, where the source may not be food (e.g. use of antibiotics as human medicine or pollution linked to the production of antibiotics). We think environmental compartment in this guidelines should be deleted or at least discussed (see paragraph 3 on the first page and the first paragraph of the scope chapter).</p>
<p>The data generated by integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides essential input to risk assessment and data for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistance resistant microorganisms and resistance determinants.</p>	<p>Australia</p>
<p>The data generated by integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides essential input to risk assessment and These data are also essential for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistance microorganisms and resistance determinants.</p> <p>It also contributes to the promotion and protection of public health by providing information to risk managers about, how resistant infections differ from susceptible infections, and the impact of interventions designed to limit the emergence spread of AMR.</p>	<p>Canada</p> <p>Edits to remove duplication and add clarity.</p> <p>Paragraphs 4 and 5 suggest these can be combined as they both address to what information arising from surveillance/monitoring are useful for.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
The data generated by integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides essential input to risk assessment and data for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about foodborne AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistance microorganisms and resistance determinants.	China
The data generated by integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides Furthermore it provides essential input to risk assessment and data for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistance microorganisms and resistance determinants.	Norway
The data generated by (1) appropriately targeted integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides (2) Data essential input to risk assessment and data for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize (3) any public health risk due to resistance microorganisms and resistance determinants foodborne AMR risk .	USA Change 1: Added to reinforce the need for initial assessment to determine what the regional foodborne AMR risks include. Change 2: Editorial. Change 3: Keep within Codex scope.
The data generated by integrated monitoring and surveillance systems provide information for the risk analysis of foodborne AMR. It provides essential input to risk assessment and data for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistance resistant microorganisms and resistance determinants.	International Feed Industry Federation
It also contributes to the promotion and protection of public health by providing information to risk managers about, how resistant infections differ from susceptible infections, and the impact of interventions designed to limit the emergence spread emergence, amplification and dissemination of AMR.	Australia Amplification and dissemination may more accurately reflect the complexity associated with AMU and selection pressure coupled with transmission within and between humans and animals etc. and AMR gene transfer between bacteria.
It also contributes to the promotion and protection of public health by providing information to risk managers about, how resistant infections differ from susceptible infections, and the impact of interventions designed to limit the emergence or spread of AMR.	Canada Para 4 and Para 5. Suggest these can be combined as they both address to what information arising from surveillance/monitoring are useful for. A word is missing. Add "or" as follows: "...limit the emergence or spread of AMR".
It also contributes to the promotion and protection of public health by providing information to risk managers about, how resistant infections differ from susceptible infections, and the impact of interventions designed to limit the emergence and spread of AMR	China

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
It also contributes to the promotion and protection of public health by providing information to risk managers about, how resistant AMR infections differ from susceptible infections, and the impact of interventions designed to limit the emergence spread selection and dissemination of foodborne AMR.	USA More precise terminology for determining risk.
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne foodborne AMR along the food chain at the national level. Such programs are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a comprehensive national food safety system.	Australia Consistent use of foodborne rather than food-borne.
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne foodborne AMR and AMU along the food chain at the national level. Such programs are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a comprehensive national food safety system	China
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne AMR along the food chain at the national level, <u>as well as methodology to collect harmonized data on AMU that to the extent possible are comparable across countries</u> . Such programs are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a comprehensive national food safety system.	Norway
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne AMR along throughout the food chain at the national level. Such programs are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a comprehensive national food safety system.	International Association of Consumer Food Organizations
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne AMR along the food chain (1) at the national level . Such (2) programs systems are a fundamental part of national strategies and plans to minimize foodborne (1) AMR and an important component of a comprehensive national food safety system. (3) <u>While these guidelines are aimed at action at national level, countries may consider creating multi-national or regional monitoring and surveillance systems to share laboratory, data management and other resources</u> .	Canada Change1: Delete "at the national level" as these guidelines are intended to assist governments to put surveillance programs in place and these programs could be put in place at a sub-national level if this suits the need of the government (i.e., provincial or state-level surveillance). Removal of "at the national level" keeps this flexibility in the text. Change2: For consistency and clarity for translation, suggest to always reference monitoring and surveillance systems as "systems" and not as "programs". With this in mind, the following editorial suggestion is proposed "Such systems programs are a ..." for this para. Similar changes are suggested for the rest of the documents as appropriate. Change3: Para 13 ("While these guidelines are aimed at..." is out of place. Suggest to enhance flow, that this paragraph be moved to Para 6 (i.e., to be the last sentence of Para 6).

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Each country should design and implement a system for monitoring and surveillance of foodborne AMR and AMU along the food chain that is appropriate to national circumstances. This should be informed by all available knowledge on priority foodborne food safety food safety risks due to associated with AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries and sectors.	Australia Improved clarity of meaning. The term foodborne is typically used in conjunction with hazard, as in foodborne hazard. Whereas the risk is related to food safety, as in food safety risks.
Each country should design and implement a system for monitoring and surveillance of foodborne AMR and AMU along the food chain that is appropriate to national circumstances. This should be informed by all available knowledge on priority foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries and or sectors.	Canada Replace “and” with “or” as follows: “...and the need for data comparability between countries and or sectors”. Rationale is that a comparison between sectors might not be one of the national objectives of the surveillance system.
Each country should design and implement a system for monitoring and surveillance of foodborne AMR and AMU along the food chain as well as monitoring and surveillance of AMU in agriculture and agaculture , that is appropriate to national circumstances. This should be informed by all available knowledge on priority foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries and sectors.	Norway
Each country should design and implement a system for monitoring and surveillance of foodborne AMR and AMU along throughout the food chain that is appropriate to national circumstances. This should be informed by all available knowledge on priority foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries and sectors.	International Association of Consumer Food Organizations
New scientific knowledge should be incorporated into integrated monitoring and surveillance programs as it becomes available to improve the design of the programs systems and to enhance analysis and utility of existing information and data. Design and implementation of programs systems should also evolve as AMR policies and priorities change at the national and international level.	Canada Replace “programs” with “systems” in three places in this paragraph.
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a gradual guide the implementation of monitoring and surveillance systems based on program objectives at the national level. Identification and implementation of priority activities should be followed by enhancements as the national situation permits resources and capacity develop . A gradual approach to monitoring Monitoring and surveillance system design should take into account broader capacity issues e.g. issues, including the availability of information on AMU in humans, animals and crops, human health care infrastructure, human data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended.
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a gradual implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as the national situation permits. A gradual approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AMU in humans, animals and crops, human health care infrastructure, human data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	Canada Delete “National” at the beginning of the sentence as this is redundant with other parts of the sentence as “likely to vary between countries” and “...at the national level”.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a gradual implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as the national situation permits. A gradual approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AMU in humans, animals and crops, human and animal health care infrastructure, human data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	China
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a gradual implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as the national situation permits. A gradual approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AMU in humans, animals and crops, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	USA Added to clarify intent.
These guidelines will contribute to the development and implementation of National Action Plans (NAP) on AMR that make the best use of available resources at the national level, with the goal of continuous improvement and enhancement as more scientific knowledge, technical capability, data and funding becomes available	Australia Australia recommends that the principle of continuous improvement and enhancement better reflects the meaning of stepwise and should be used in place of gradual or stepwise throughout the guidelines.
These guidelines will contribute to the development and implementation of National Action Plans (NAP) on AMR that make the best use of available resources at the national level, with the goal of continuous enhancement as more scientific knowledge, technical capability, data and funding becomes available.	Canada This paragraph "These guidelines will contribute..." is duplicative text on two fronts. Re-states the utility of the guidelines for national strategies and restates the issue of continuous enhancement. Delete this paragraph.
These guidelines will contribute to the development and implementation of National Action Plans (NAP) on foodborne AMR and AMU that make the best use of available resources at the national level, with the goal of continuous enhancement as more scientific knowledge, technical capability, data and funding becomes available.	China
These guidelines should also be used in conjunction with those already developed by other international standard-setting organizations especially the OIE standards related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code and advisory bodies especially such as the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) <i>Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach</i> , and OIE standards related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code.	Australia Australia recommends that the standards setting bodies such as the OIE Codes should be given precedent over advisory bodies such as the WHO AGISAR. There exist mechanisms in the OIE to update the aquatic and terrestrial codes, as such the OIE Codes remain up-to-date as new evidence emerges and scientific knowledge moves.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>These guidelines should also be used in conjunction with those already developed by other international standard-setting organizations. Several efforts currently exist to address AMR surveillance. Extensive, current and bodies especially comprehensive guidance are available through the World Organization for Animal Health (OIE) Chapters 6.2, 6.3, 6.7 and 6.8. The WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) <i>Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach</i> and OIE standards related to AMR and AMU published in and the Clinical & Laboratory Standards Institute (CLS) <i>Terrestrial Animal Health Code</i> and the <i>Aquatic Animal Health Code</i>.</p>	<p>USA</p> <p>The WHO is not an international standard setting organization where documents are developed through transparent processes and Member State input as are OIE, Codex and IPPC.</p>
<p>These guidelines should also be used in conjunction with those already developed by other the international standard-setting organizations organization OIE in the <i>Terrestrial Animal Health Code</i> and the <i>Aquatic Animal Health Codes</i>, and expert bodies especially like the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) <i>Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach</i>, and OIE standards related to AMR and AMU published in the <i>Terrestrial Animal Health Code</i> and the <i>Aquatic Animal Health Code</i>.</p>	<p>Healthforanimals</p> <p>A distinction should be made between OIE and WHO. OIE is the international standard setting body whose standards are set and signed-off by member states. WHO-AGISAR guidance is produced by an expert group. As a result, in the eyes of governments and international organizations (WTO) they do not carry the same (legal) weight.</p>
<p>While these guidelines are aimed at action at national level, countries may consider creating multi-national or regional monitoring and surveillance systems to share laboratory, data management and other resources.</p> <p>While these guidelines are aimed at action at <u>the</u> national level, countries may consider creating multi-national or regional monitoring and surveillance systems to share laboratory, data management and other resources.</p>	<p>Canada</p> <p>This paragraph is out of place. Suggest to enhance flow, that this paragraph be moved to Para 6 (i.e., to be the last sentence of paragraph 6).</p> <p>Editorial.</p>
2. Scope	
<p>These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including . <u>Each country's respective competent authority and non-government sector should apply the definition of food chain to include animals, crops and the environment according to each country's priorities and needs, so as to achieve the objective of integrated one-health monitoring and surveillance.</u></p>	<p>Australia</p> <p>Australia recommends not explicitly defining the food supply chain to include animals, crops, and environment, but rather, providing flexibility for each countries differing regulatory frameworks to achieve the objective of integrated one-health monitoring and surveillance.</p>
<p>These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the environment.</p>	<p>Brazil</p> <p>It is important to verify to which extent this document should include crops and environment. It clearly has to be related to the risks of foodborne AMR, based on science and evidence.</p>
<p>These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU (1) along the food chain, including animals, crops and the (2) <u>production</u> environment.</p>	<p>Canada</p> <p>Change1: Delete "along the food chain", as it has already been stated in the introduction what the scope of an integrated system includes (see para. 3), and also as this para already refers to 'foodborne'.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	Change 2: "the environment". How will environment be included? This is not consistent throughout the document. Consider "the production environment".
These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the related environment.	China
These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the environment. <u>The Identification and implementation of priority activities should be followed by enhancements as the national situation permits.</u>	Mexico It is proposed to include in the scope when mentioning that this guide covers the design and implementation of a monitoring and surveillance system of the AMR transmitted by food for food and the consumption of antimicrobials, that its design and implementation should be depending on the national situation of each country , so it can be adapted to different national sceneries making its implementation viable.
These guidelines cover the basic design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the environment as it relates to foodborne human health concerns.	USA While there is a need to address gaps in knowledge regarding crops and the environment, the topics are premature for inclusion in an integrated surveillance system. Further research is needed regarding appropriate methods and targets for monitoring and surveillance for foodborne AMR in crops and the environment.
These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the environment in relation to foodborne human health concerns.	Healthforanimals Stick to scope of Codex and the Task Force - foodborne AMR.
These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along throughout the food chain, including animals, crops and the environment.	International Association of Consumer Food Organizations
Though these guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans.	Colombia Validar la información en cuanto a lo señalado en el párrafo, ya que el mismo se entiende que dentro de la cadena agroalimentaria, no se propondrá un monitoreo o vigilancia de RAM en salud humana, sino que la información recopilada de dicha vigilancia servirá como insumo con el fin de ser asociados a los problemas que se puedan presentar en salud. De esta manera el texto estaría en concordancia con la definición Enfoque basado en el riesgo para la vigilancia y el seguimiento de la RAM transmitida por los alimentos.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Though these guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans. <u>Surveillance of local human foodborne illness cases helps establish priorities for sampling in food and sources of food. Foodborne AMR monitoring and surveillance data along with AMU data from human and animal sources, and other epidemiological information as described in CAC/GL 77 are useful inputs into a country's risk analysis framework to help inform effective risk management activities described in CAC/RCP 2005 (under revision)</u>	USA The added text helps countries understand how they should set priorities-based on human foodborne illness in the area (Codex scope). One could argue that there is little attribution data to implicate AMR foodborne illness in humans from crops and the environment, so advising countries to incorporate these into a national surveillance system is inconsistent with helping countries to prioritize in targeting limited resources on those areas of known risk.
The microorganisms covered by these guidelines are these pathogens and indicator bacteria of public health relevance.	Canada Delete "those", which is not needed.
The microorganisms covered by these guidelines are those foodborne pathogens and indicator bacteria of public health relevance.	China
The microorganisms covered by these guidelines are those foodborne pathogens and indicator bacteria of public health relevance.	Japan To stay within the scope of CODEX.
The microorganisms covered by these guidelines are those bacteria pathogens and indicator bacteria of public health relevance relevant to foodborne AMR risk .	USA For clarity and to keep within the scope of Codex.
The microorganisms covered by these guidelines are those pathogens and indicator bacteria organisms of public health relevance.	International Association of Consumer Food Organizations Indicator organisms may be fungi or other microbes besides bacteria.
Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines. In circumstances where a country may decide to include in the integrated system the monitoring and surveillance of biocides, the design and implementation should preferably be broadly consistent with these guidelines to facilitate comparability of data and analysis.	Brazil Exclude the last sentence, once it was decided to be out of the scope, so it does not seem to be logical that any recommendations should be included.
Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines. In circumstances where a country may decide to include in the integrated system the monitoring and surveillance of biocides, the design and implementation should preferably be broadly consistent with these guidelines to facilitate comparability of data and analysis.	Canada Regarding biocides/disinfectants, it is suggested that the language be consistent with the new Code of Practice language/descriptors. Surveillance should reflect what the Code of Practice requires.
Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines. In circumstances where a country may decide to include in the integrated system the monitoring and surveillance of biocides, the design and implementation should preferably be broadly consistent with these guidelines to facilitate comparability of data and analysis.	USA As biocides are excluded, it does not make sense to have further qualifying statements to follow.
These Implementation of these guidelines will provide aid in facilitate the utilization generation of appropriate AMR and AMU data from humans, animals, crops, the food and environment supply chain in order to conduct integrated integrate analysis of all these data data with other sectors including humans, animals, crops and the environment	Australia Provides flexibility for countries to implement integrated one-health surveillance with differing regulatory frameworks and competent authorities responsible for different sectors.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
These guidelines will provide aid in the utilization of appropriate AMR and AMU data from humans, animals, crops, food and related environment in order to conduct integrated analysis of all these data.	China
These guidelines will provide aid in the utilization of appropriate AMR and AMU data from humans, animals, crops, food and environment in order to conduct integrated analysis of all these data.	USA This statement appears repetitive and unnecessary.
Reporting of standardized and harmonized data generated through national monitoring and surveillance systems to international organizations and in return use of information generated from global monitoring and databases are is highly desirable aspects of integrated monitoring and surveillance systems at the national level desired .	Canada Suggest edits to remove redundant words as follows: "...and databases, is highly desired. are highly desirable aspects of integrated monitoring and surveillance systems at the national level."
Reporting of standardized and harmonized data generated through national monitoring and surveillance systems to international organizations and in return use of information generated from global monitoring and surveillance databases are highly desirable aspects of integrated monitoring and surveillance systems at the national level.	China
3. Definitions	
<u>Antimicrobial Resistance (AMR):</u> <u>The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species.</u> <u>Antimicrobial Resistance Determinant:</u> <u>The genetic element(s) encoding for the ability of microorganisms to withstand the effects of an antimicrobial agent. They are located either chromosomally or extra-chromosomally and may be associated with mobile genetic elements such as plasmids, integrons or transposons, thereby enabling horizontal transmission from resistant to susceptible strains.</u>	Colombia Se sugieren incluir estas dos definiciones tal cual como se establecen en el documento "Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance" CAC/GL 77-2011.
Definitions	Malaysia To include the definitions below: 1. Antibacterial ; 2. Antibiotic ; 3. Antimicrobial resistance (AMR); 4. Food chain. Align with the COP (CXC 61-2005)
Definitions	International Association of Consumer Food Organizations Add definitions for antimicrobial resistance, biocide, monitoring and surveillance of AMR and antimicrobial use (from intro).
<u>Antimicrobial agent:</u>	
Any substance of natural, semi-synthetic or synthetic origin that at <i>in vivo</i> concentrations kills or inhibits the growth of microorganisms by interacting with a specific target ^[1] . The term antimicrobial agent is collective for antiviral, antibacterial, antifungal and antiprotozoal agents. <u>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.</u>	USA Add this definition (from page 7 of CAC/GL 77 because it helps countries understand what they are surveying for-see comments under 8.4 in this document to see how the term can be used to provide guidance.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<i>Hazard:</i>	
A biological, chemical or physical agent in, or condition of, food with the <i>potential</i> to cause an adverse health effect ^[2] . For the purpose of these guidelines, the term hazard refers to foodborne AMR microorganism(s) and /or resistance determinant(s) ^[3] .	China
A biological, chemical or physical agent in, or condition of, food with the <i>potential</i> to cause an adverse health effect ^[2] . For the purpose of these guidelines, the term hazard refers to foodborne AMR microorganism(s) and /or resistance determinant(s) ^[3]	Japan To be in line with the scope of the guidelines.
A biological, chemical or physical agent in, or condition of, food with the <i>potential</i> to cause an adverse health effect ^[2] . For the purpose of these guidelines, the term hazard refers to AMR microorganism(s) and /or resistance determinant(s) ^[3] .	International Feed Industry Federation In the definition of hazard, we would propose not to use AMR microorganisms but similarly to what is written in paragraph 4 resistant microorganism (similar comment for the 6th bullet points of the principles).
<i>Crops/plants:</i>	
Crops/plants <u>A cultivated plant that is grown as food or feed, especially a grain, fruit, or vegetable.</u>	China
Crops/plants	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.
Crops/plants	International Association of Consumer Food Organizations Use “food crops” to differentiate from non-food crops (e.g., cotton, tulips).
<i>Prioritized antimicrobial agents:</i>	
Prioritized antimicrobial agents Medically important antimicrobials	Brazil To harmonize with the Code of Practice and not create a new/different definiton.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>Prioritized Medically Important antimicrobial agents:</u>	USA The U.S. originally offered a definition for “prioritized antimicrobial agents” because it was used throughout the document. Because “medically important antimicrobial agents” appeared in the last GLIS draft and has already been introduced in the CoP document, introducing another term here may be confusing. Harmonize definition in GLIS with CoP for medically important antimicrobial agents so we aren’t using multiple terms signifying the same thing.
<u>Prioritized antimicrobial agents:</u>	International Association of Consumer Food Organizations This phrase doesn’t exist in the document except here. Could also call them medically important (as the COP does).
For the purpose of integrated monitoring and surveillance, antimicrobial agents prioritized as being of importance to public health (1) e.g. according to according to the <i>WHO List of Critically Important Antimicrobials</i> (WHO CIA List) and where these exist, national lists based on national official risk analysis (2) and and a country’s unique situation.	Canada Change1: Replace “e.g.” with “according to” because the WHO list is not just an example, it is the main document of reference: “...importance to public health according to e.g. the WHO List...” Also, delete “national official risk analysis” because there are examples of countries which have their own science based lists, but which were not necessarily created based on a full risk analysis. Change2: Editorial.
For the purpose of integrated monitoring and surveillance, antimicrobial agents prioritized as being of importance to public human health e.g. the <i>WHO List of Critically Important Antimicrobials</i> (WHO CIA List) and where these exist, national lists based on national official risk analysis and country’s unique situation.	USA The WHO ranks based on importance to human health, so “human” may be more appropriate here.
For the purpose of integrated monitoring and surveillance, antimicrobial agents prioritized as being of importance to public health e.g. the WHO List of Critically Important Antimicrobials (WHO CIA List) and where these exist, national lists based on national official risk analysis and country’s unique situation.	Consumers International CX/AMR 18/6/6 Page 5 under Definitions: CI recommends deleting the definition for “Prioritized antimicrobial agents” because the term is not used in the Guidelines and it is similar to the definition of “Medically important antimicrobials” in CX/AMR 18/6/5.
<u>Risk-based approach to surveillance and monitoring of foodborne AMR:</u>	
<u>Risk-based approach to surveillance and monitoring and surveillance of foodborne AMR:</u>	China Editorial.
For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system along the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their (1) relationship with risks to human health potential for exposure to humans and foodborne AMR risk .	USA Change1: Increases clarity. Change2: Recommend incorporating the definitions of monitoring and surveillance within the definitions section. This will increase readability and improve flow of the introduction.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>(2) Monitoring of AMR and AMU: <u>The systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR in potential foodborne bacteria and AMU related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity.</u></p> <p>Surveillance of AMR and AMU: <u>The same activities as described in monitoring when these are associated with a pre-defined risk mitigation plan or activity</u></p>	
<p>For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system along throughout the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.</p>	<p>International Association of Consumer Food Organizations</p>
<p>3. Principles</p>	
<p>Thailand</p> <p>We are of the view that all principles as currently written are still ambiguous and needs a revision to be more logically comprehensive. In this relation, we humbly suggest that the common and proximity principles should be grouped together.</p> <p>For example, we propose rearranging and grouping of the broad principles and sub-principles as follows;</p> <p>Principle 1 Risk based approach (to include bullet 5 of current draft)</p> <ul style="list-style-type: none"> • Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance program for AMR, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health; <p>Principle 2 Monitoring and surveillance programs (to include bullet 1, 2, 4, 7 of current draft)</p> <ul style="list-style-type: none"> • An integrated monitoring and surveillance system for AMR should incorporate an “One Health” approach; • Monitoring and surveillance programs for AMR and AMU along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system; • Monitoring and surveillance programs should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies); • Monitoring and surveillance programs should incorporate to the extent practical capacity for epidemiological investigation and identification of new and emerging foodborne risks and trends; <p>Principle 3 Laboratories backup (to include bullet 8 of current draft)</p> <ul style="list-style-type: none"> • Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place and participate in external proficiency testing schemes (External Quality Assessment Schemes); <p>Principle 4 Monitoring and surveillance programs at National scale (to include bullet 3, 6, 9, 10, 11 of current draft)</p> <ul style="list-style-type: none"> • A national monitoring and surveillance program should be tailored to the domestic situation and may be designed and implemented according to a stepwise approach; • In using a stepwise approach, priority should be given to the most relevant elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> A national monitoring and surveillance system should harmonize laboratory methodology, data collection, analysis and reporting across all sectors as part of an integrated approach. Use of internationally recognized, standardized and validated antimicrobial susceptibility testing (AST) methods and harmonized interpretative criteria are essential to ensure that data are comparable at national level and to enhance an integrated approach to data management at the international level; Countries should strive to conduct research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance program (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants); Data generated from national monitoring and surveillance programs of AMR in imported foods should not be used to inappropriately generate barriers to trade. 	
<ul style="list-style-type: none"> An integrated monitoring and surveillance system for AMR should incorporate an “One Health” approach<u>approach to AMR</u> 	Canada Add “to AMR” at the end of the sentence, i.e., “... a One Health approach to AMR” to be consistent with phrasing used in the definitions.
<ul style="list-style-type: none"> An integrated monitoring and surveillance system for <u>foodborne AMR and AMU</u> should incorporate an “One Health” approach; 	China
<ul style="list-style-type: none"> Monitoring and surveillance programs for AMR and AMU along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system<u>program</u>; 	Canada Replace “program” with “system”
<ul style="list-style-type: none"> Monitoring and surveillance programs for AMR and AMU along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system <u>and should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies and should incorporate to the extent practical capacity for epidemiological investigation and identification of new and emerging foodborne risks and trends;</u> 	Egypt
<ul style="list-style-type: none"> Monitoring and surveillance programs for AMR and AMU along the food chain are a fundamental part <u>fundamental</u> of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system; 	USA
<ul style="list-style-type: none"> Monitoring and surveillance programs for AMR and AMU along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system; <u>[new bullet] Monitoring and surveillance programs for AMR and AMU require adequate resources to collect and analyze data and depend upon competent authorities’ access to sources of microbiological and antimicrobial use data.</u> 	Consumers International
<ul style="list-style-type: none"> Monitoring and surveillance programs for AMR and AMU along <u>throughout</u> the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system; 	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> A national monitoring and surveillance program should be tailored to the domestic situation and may be designed and implemented according to a stepwise approach with the objective of <u>continuous improvement and enhancement</u>; 	<p>Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended.</p>
<ul style="list-style-type: none"> A national monitoring and surveillance program should be tailored to the domestic situation and may be designed and implemented according to a stepwise <u>an incremental</u> approach; 	<p>Brazil</p>
<ul style="list-style-type: none"> A national monitoring and surveillance program system system should be tailored to the domestic situation and may be designed and implemented according to a stepwise approach; 	<p>Canada Refers to a “stepwise approach” which is different than the “gradual approach” mentioned in the introduction. Replace “program” with “system”.</p>
<ul style="list-style-type: none"> A national monitoring and surveillance program should be tailored to the domestic situation <u>national priorities</u> and may be designed and implemented according to a stepwise approach <u>incrementally from a range of options</u>; 	<p>USA “Incremental” is consistent with comments on paragraph 1 and we note is also the term used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/</p>
<ul style="list-style-type: none"> Monitoring and surveillance programs systems should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies); 	<p>Canada Replace “program” with “system”.</p>
<ul style="list-style-type: none"> Monitoring and surveillance programs should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies); 	<p>Egypt</p>
<ul style="list-style-type: none"> Monitoring and surveillance programs should aim to include data as national priorities dictate and resources permit on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies); 	<p>USA No country has resources to collect all of this data so edits inserted to make the document more practical.</p>
<ul style="list-style-type: none"> Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance program system for AMR, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health; 	<p>Canada Replace “program” with “system”.</p>
<ul style="list-style-type: none"> Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance program for AMR foodborne AMR and AMU, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health; 	<p>China</p>
<ul style="list-style-type: none"> In using a stepwise approach, priority Priority should be given to the most relevant <u>design</u> elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	<p>Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> In using a stepwise an incremental approach, priority should be given to the most relevant elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	Brazil
<ul style="list-style-type: none"> In using a stepwise-approach, priority should be given to the most relevant elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	Canada Also refers to a “stepwise approach.”
<ul style="list-style-type: none"> In using a stepwise approach, priority should be given to the most relevant elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism microorganisms and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	China
<ul style="list-style-type: none"> In using a stepwise an incremental approach, priority priorities within a country should be given to the most relevant elements from a public health perspective (e.g. defined combinations of the food commodities, the AMR microorganism bacteria and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	USA “Incremental” is consistent with comments on paragraph 1 and we note is also the term used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/ Additional edits for clarity.
<ul style="list-style-type: none"> In using a stepwise approach, priority should be given to the most relevant elements from a public health perspective (e.g. monitoring food production sectors known to have high levels of resistance, defined combinations of the food commodities, the AMR microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed to be analyzed); 	Consumers International
<ul style="list-style-type: none"> Monitoring and surveillance programs systems should incorporate to the extent practical capacity for epidemiological investigation and identification of new and emerging foodborne risks hazards/risks and trends; 	Canada Change1: Replace “program” with “system”. Change2: At the end, should also incorporate the word “hazard” as per the definition as follows: “...identification of new and emerging foodborne hazards/risks and trends”. Rationale, we may want to follow a hazard in surveillance before it becomes a risk.
<ul style="list-style-type: none"> Monitoring and surveillance programs should incorporate to the extent practical capacity for epidemiological investigation and identification of new and emerging foodborne risks and trends; 	Egypt
<ul style="list-style-type: none"> Monitoring and surveillance programs should incorporate to the best extent practical capacity for epidemiological investigation and identification of new and emerging foodborne AMR risks and trends; 	USA For clarity.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> A national monitoring and surveillance system should harmonize laboratory methodology, data collection, analysis and reporting across all sectors as part of an integrated approach. Use of internationally recognized, standardized and validated antimicrobial susceptibility testing (AST) methods and harmonized interpretative criteria are essential to ensure that data are comparable at national level and to enhance an integrated approach to data management and report at the international level; 	<p>Canada</p> <p>Having harmonized and comparable data at the national level are not just important to an integrated approach to data management at the international level, but are actually required for international reporting. Add words to address this as follows: "...integrated approach to data management and reporting at the international level".</p>
<ul style="list-style-type: none"> A national monitoring and surveillance system should strive to harmonize laboratory methodology, data collection, analysis and reporting across all sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated antimicrobial susceptibility testing (AST) methods and harmonized interpretative criteria are essential to ensure that data are comparable at national level and to enhance an integrated approach to data management at the international level; 	<p>USA</p> <p>As appropriate targets for sampling will vary across sectors, and "all sectors" is all-encompassing, the language is modified to be reflective of reality.</p>
<ul style="list-style-type: none"> Countries should strive to conduct research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance (1) program system (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants); (2) Countries should implement a monitoring and surveillance system, regardless of initial capacity, recognizing that the systems will be designed to suit national needs. Countries should be encouraged to demonstrate enhancements to their monitoring and surveillance system over time. These guidelines provide options for development or enhancements to monitoring and surveillance systems over time. 	<p>Canada</p> <p>Change1: Replace "program" with "system".</p> <p>Change2: New Principle: As per the general comments described above, suggest there is a need for a new principle (before the existing Principle 11) as follows: "Countries should implement a monitoring and surveillance system, regardless of initial capacity, recognizing that the systems will be designed to suit national needs. Countries should be encouraged to demonstrate enhancements to their monitoring and surveillance system over time. These guidelines provide options for development or enhancements to monitoring and surveillance systems over time."</p>
<ul style="list-style-type: none"> Data generated from national monitoring and surveillance(1) programs systems of AMR (2) in imported foods or AMU should not be used to inappropriately generate barriers to trade. The existing monitoring and surveillance system capacity also should not be used to inappropriately generate barriers to trade. 	<p>Canada</p> <p>Change1: Replace "program" with "system".</p> <p>Change2: It is not just AMR data that could be used to generate a barrier to trade, but also AMU data. Keep the principle more flexible by deleting the words "imported foods", particularly because AMU data in itself could be used to generate a trade barrier. Proposed new wording as follows: "...of AMR or AMU in imported foods should not be used to inappropriately generate..." It is also proposed that this Principle be not just about the data from the system, but also about the fact that the capacity of the system itself should not be used in appropriately as a barrier to trade. New proposed text to be added at the end of this Principle is as follows: "The existing monitoring and surveillance system capacity also should not be used to inappropriately generate barriers to trade."</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Data generated from national monitoring and surveillance programs of AMR <u>and AMU</u> in imported foods should not be used to inappropriately generate barriers to trade. 	China
<ul style="list-style-type: none"> Data generated from national monitoring and surveillance programs of AMR in imported foods should not be used to inappropriately generate barriers to trade. 	USA Grammatically inaccurate- a double-negative. 6. With respect to the collection of antimicrobial agent use (AMU) data, it is important to consider the current challenges and limitations of AMU data collection programs. Collection of on-farm AMU data is lacking in virtually all member countries and challenges remain in harmonizing this data. Further, estimates of drug sales are not a substitute for actual usage data on farms. Sales data alone do not indicate how the drugs are used and for what indications on the farm, nor do they reflect the ultimate amount of drug that may be purchased and used by the end user on the farm.
<ul style="list-style-type: none"> Data generated from national monitoring and surveillance programs of AMR in imported foods should not be used to inappropriately generate barriers to trade 	Consumers International
4. Risk-based approach	
Risk-based approach	Canada See Canada's general comments about this section. If this section is retained, Canada has specific comments below.
In applying a risk based approach to the design of an integrated monitoring and surveillance system, maximum use should be made of available information on foodborne AMR risks <u>hazards/risks</u> to human health at the national level.	Canada It is hard to comprehend this paragraph. Delete or clarify this paragraph. "Hazards" should also be added to this paragraph in addition to risks, as follows: "...foodborne AMR hazards/risks to human health..."
In applying a risk-based <u>risk-based</u> approach to the design of an integrated monitoring and surveillance system, maximum use should be made of available information on foodborne AMR risks to human health at the national level.	China
Integrated monitoring and surveillance of AMR and AMU in the food chain provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant <u>crops</u> and animal health.	Brazil
Integrated monitoring and surveillance of AMR and AMU in the food chain provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant <u>crop</u> and animal health.	China

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Integrated monitoring and surveillance of AMR and AMU in the food chain provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant and animal health.	USA Crops, not plants is the term for food, which is within Codex scope.
Integrated monitoring and surveillance of AMR and AMU when available in the food chain along with data regarding AMR transmission through food handling, environmental spread or other routes of transmission provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant crop and animal health.	USA Beyond AMU there are sources of AMR and one could argue determining routes of exposure are even more essential to effectively mitigating risk.
Integrated monitoring and surveillance of AMR and AMU in throughout the food chain, including the immediate relevant environment , provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant and animal health.	International Association of Consumer Food Organizations
While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs will may [initially] be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> .	USA “May” indicates less certainty of knowledge and is more appropriate in this sentence.
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on in a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human microbiological pathogens and pathogens , bacterial commensals and priority resistance determinants likely to transmit AMR to result in an adverse health outcome in humans.	Australia The hazard identification should also be linked to priority resistance determinants and the potential adverse outcome in humans, so as to be focusing effort and attention on pathogens and commensals of particular concern.
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i>. Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans.	Canada Information in this entire paragraph is available in the Guidelines for Risk Analysis for Foodborne AMR. This paragraph does not add content to these guidelines. Delete this paragraph.
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human foodborne microbiological pathogens and bacterial commensals likely to transmit AMR to humans.	China
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans, and antimicrobial resistance determinants .	Colombia Se sugiere la inclusión para mantener la coherencia tanto a lo largo del texto como con el documento “Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance” CAC/GL 77-2011.
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans humans via food .	Japan To be in line with the scope of the guidelines.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human microbiological microbiological bacterial pathogens and bacterial commensals likely to likely to that may transmit AMR to humans humans bacteria of human health concern .	USA Use of likely is too presumptive. The other edits are for clarity.
Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> . Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans.	International Association of Consumer Food Organizations
As countries improve and enhance their AMR systems and capabilities over time, a stepwise approach to monitoring and surveillance should increasingly incorporate risk-assessment factors as an important element in design of the program and analysis of data.	Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended.
As countries improve their AMR systems over time, a stepwise an incremental approach to monitoring and surveillance should increasingly incorporate risk-assessment factors as an important element in design of the program and analysis of data	Brazil
As countries improve their (1) AMR/ AMU systems over time, (2) a stepwise an approach to the development and implementation of monitoring and surveillance systems should increasingly incorporate risk-assessment factors as an important element in design of the program and analysis of data.	Canada Change1: Add "AMU" as follows: "...countries improve their AMR/AMU systems over time...". It is unclear here what "risk-assessment factors" are. Clarity on this phrase is requested. Change2: Revise "...a stepwise approach to monitoring and surveillance should increasingly incorporate risk assessment factors as..." to "...an approach to the development and implementation of monitoring and surveillance systems should increasingly incorporate risks to human health as...". "Stepwise" is not needed in this sentence.
As countries improve their AMR systems over time, a stepwise approach to monitoring and surveillance should increasingly incorporate gradually increase risk-assessment factors as an important element in design of the program and analysis of data.	USA Consistency with incremental implementation.
As countries improve their AMR systems over time, a stepwise approach to monitoring and surveillance should increasingly incorporate risk-assessment factors as an important element in design of the program and analysis of data.	International Association of Consumer Food Organizations
Potential foodborne AMR risks to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new (1) antimicrobial resistance genes, new food chain exposure pathways, changing patterns of AMU AMU in animals and humans . Any adjustments should be (2) properly publicly communicated with reference to methodological changes while retaining valid historical data for trend analysis.	Canada Change1: Revise "e.g. changes in test methodologies, new food chain exposure pathways, changing patterns of AMU" to "e.g. changes in test methodologies, new antimicrobial resistance genes, new food chain exposure pathways, changing patterns of AMU in animals and humans."Change2: Last sentence; suggest changing "properly" to "publically".

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Potential foodborne AMR risks to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new food chain exposure pathways, changing patterns of AMU. Any adjustments should be properly communicated with reference to methodological changes while retaining and potentially updating valid historical data for trend analysis.	USA Needed in the case of updated interpretive criteria that can drastically change AMR rates.
On a risk-based approach, the The revision of the monitoring and surveillance system should be conducted taking a risk based on approach and utilising information about hazards and risks incorporated in the risk analysis process as described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> .	Australia Editorial, improves clarity and readability.
On a risk-based approach, the The revision of the monitoring and surveillance system should be based on information about hazards and risks incorporated in the risk analysis process as described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> .	Canada Delete redundant phrase "On a risk-based approach".
On a risk-based approach, the revision of the monitoring and surveillance system should be based on information about hazards identification, exposure assessment, hazard characterization and risks risk characterization incorporated in the risk analysis assessment process as described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i> .	USA For consistency with CAC/GL 77.
6. Regulatory framework and roles	
5. Regulatory framework and roles	Canada Canada proposes several edits to this section to improve clarity and remove redundancies. The draft text is as follows, details regarding decisions made to arrive at this draft text can be found below.
Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the an integrated monitoring and surveillance program.	Australia Integration of the monitoring and surveillance program needs to be embraced by all sectors along the food supply chain.
Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals plant/crop advisors and consultants , farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance program.	Brazil

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance programsystem</p>	<p>Canada Replace “program” with “system” in two places.</p>
<p>Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, aquatic animal health professionals, plant health professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance program</p>	<p>Thailand To ensure all actors involved in the section of Regulatory framework and roles, we would like to add “aquatic animal health professional” in this section.</p>
<p>Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals crop advisors and consultants, farmers environmental professionals, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance program.</p>	<p>USA Crop advisors and consultants is more appropriate term and environmental professionals added for completeness of multi-disciplinary approach.</p>
<p><u>Competent authorities need access to sources of microbiological and antimicrobial use data. This should include access to livestock and crop production facilities when conducting epidemiological investigations of multidrug resistant foodborne outbreaks.</u> Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance program.</p>	<p>Consumers International The Guidelines assume that competent authorities will have access to data from all points in the food chain. In many countries, authorities do not have the legal authority to gather needed data. The Guidelines should make clear that this authority is important. Current Codex and OIE guidelines are very clear on the need for authority to regulate antimicrobial use through marketing authorization but are not similarly clear on the need for authority to collect data on how antimicrobials are used or on monitoring for resistance.</p>
<p>Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, plant health professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance program and the degree of integration. Ideally, all interested parties along throughout the food chain should contribute to the development and implementation of the monitoring and surveillance program.</p>	<p>International Association of Consumer Food Organizations</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
6.1. Policy and regulatory activities	
6.1. Policy and regulatory activities	Canada Remove two sub-section headings “6.1. Policy and regulatory activities” and “6.2. Other activities” since this whole section can readily encompassed by the one heading “Regulatory framework, policies and roles”.
A national integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant crop health, environmental and other relevant authorities. Other stakeholders in all relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	Brazil
A national (1) An integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders (2) in all relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs interventions for AMR risk management.	Canada Change1: Delete “national” as this is not how it has been described earlier in the document, i.e., “An national integrated...” Change2: Delete “all”, as it may become unwieldy to include all relevant stakeholders in policy and regulatory activities related to surveillance. Change3: Replace “programs” with “interventions”, as programs may not be readily understood in this context. Proposed text is as follows: “...ensure the implementation of programs interventions for AMR risk management.”
A national integrated monitoring and surveillance system for foodborne AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant crop health, environmental and other relevant authorities. Other stakeholders in all relevant sectors should be included and collaborate in line with the NAP on foodborne AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	China
A national integrated monitoring and surveillance system program for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in all relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	Colombia Unificar en el texto el cambio de la palabra “system” por “program” planteado en el anterior documento.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>A national integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant crop health, environmental and other relevant authorities. Other stakeholders in all relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.</p>	<p>USA Crops, not plants is the term for food, which is within Codex scope.</p>
<p>A national integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along throughout the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in all relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.</p>	<p>International Association of Consumer Food Organizations</p>
<p>The regulatory activities carried out by the competent authorities should be in response to policy objectives that are embedded in national strategies and NAPs on AMR. Guidance on developing national action plans are outlined in the <i>WHO Global Action Plan on Antimicrobial Resistance</i> and specific manuals developed by WHO, FAO and OIE such as the <i>Antimicrobial resistance: a manual for developing national action plans</i>.</p>	<p>Canada Delete these paragraphs, inclusive of “Guidance on developing national action plans are outlined in the WHO Global Action Plan on Antimicrobial Resistance and specific manuals developed by WHO, FAO and OIE such as the <i>Antimicrobial resistance: a manual for developing national action plans</i>. The use of antimicrobial agents in the food chain should be subject to regulation as described in the Code of practice to Minimize and Contain Antimicrobial Resistance and relevant OIE standards”. The rationale for this is that these documents are already referred to as reference material for these guidelines (or they should be) in the noted material right after the introduction (para 11). This material is too duplicative of what is noted in other Codex or WHO documents.</p>
<p>The regulatory activities carried out by the competent authorities should be in response to policy objectives that are embedded in national strategies and NAPs on foodborne AMR. Guidance on developing national action plans are outlined in the <i>WHO Global Action Plan on Antimicrobial Resistance</i> and specific manuals developed by WHO, FAO and OIE such as the <i>Antimicrobial resistance: a manual for developing national action plans</i>.</p>	<p>China</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
The use of antimicrobial agents in the food chain should be subject to regulation as described in the Code of practice to Minimize and Contain Antimicrobial Resistance and relevant OIE standards.	Canada Delete these paragraphs, inclusive of “Guidance on developing national action plans are outlined in the WHO Global Action Plan on Antimicrobial Resistance and specific manuals developed by WHO, FAO and OIE such as the Antimicrobial resistance: a manual for developing national action plans. The use of antimicrobial agents in the food chain should be subject to regulation as described in the Code of practice to Minimize and Contain Antimicrobial Resistance and relevant OIE standards”. The rationale for this is that these documents are already referred to as reference material for these guidelines (or they should be) in the noted material right after the introduction (para 11). This material is too duplicative of what is noted in other Codex or WHO documents.
6.2 Other activities	
6.2 Other activities	Canada Remove two sub-section headings “6.1. Policy and regulatory activities” and “6.2. Other activities” since this whole section can readily encompassed by the one heading “Regulatory framework, policies and roles”.
Stakeholders other than the competent authority, such as veterinarians, plant health professionals, farmers, consumer organizations, civil society, pharmaceutical industry or food and feed industry, retail retailers and others may carry out monitoring activities e.g. monitoring of AMU on a voluntary basis.	China
Stakeholders other than the competent authority, such as veterinarians, plant health professionals crop advisors and consultants , farmers, consumer organizations, civil society, pharmaceutical industry or food and feed industry, retail and others may carry out monitoring activities e.g. monitoring of AMU on a voluntary basis.	USA Crops rather than plants is the appropriate term for Codex scope.
Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated “One Health” approach in collaboration with other relevant authorities from the human, animal, plant crop and related environmental sectors.	China
Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated “One Health” approach in collaboration with other relevant authorities from the human, animal, food , plant and environmental sectors.	Colombia Incluir el sector de alimentos para completar las etapas involucradas en la vigilancia de RAM en la cadena agroalimentaria.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated “One Health” approach in collaboration with other relevant authorities from the human, animal, plant crop and environmental sectors, <u>recognizing that the science and resources available to address certain sectors may be more advanced than others.</u>	USA The added text helps ground the statement in reality.
7. A stepwise approach to the implementation of an integrated monitoring and surveillance program of foodborne AMR	
<p>Brazil</p> <p>Brazil continues not to agree with the stepwise approach as it is proposed in this new draft. Brazil is in favor of an incremental approach to be inserted into the document in each of the components for integrated surveillance, giving guidance to member countries on what would be the minimum elements to initiate an integrated surveillance program and how countries could increment their program.</p> <p>The table as proposed in section 7.3 with programs A, B and C continues to show three clearly distinct phases for the integrated surveillance program (former “initial, medium and advanced program” and “steps 1, 2 and 3”). This format creates a clear possibility of the categorization of member countries, that may lead to misinterpretation about the status of implementation of the program by countries and may be used inappropriately to generate barriers to trade.</p> <p>It is not in the mandate of Codex to categorize countries in a stepwise approach providing three different options from very basic to sophisticated. The mandate of Codex is to propose recommendations based on the principle of sound scientific analysis and evidence that protect the health of consumers and ensure fair practices in the food trade. Recommendations by Codex have to be applicable worldwide, taking into account countries capacities, giving particular attention to the impact on developing countries.</p>	
<p>Canada</p> <p>See Canada’s general comments about this section. For example, to include certain detailed contents in an annex, and to have a reconsideration regarding the term “stepwise”.</p>	
<p>Healthforanimals</p> <p><i>Stepwise approach.</i> 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.</p> <p>When drafting, the TFAMR needs to maintain flexibility in implementation to allow for differences.</p> <p>If this approach is maintained then suggest the word incremental is used.</p>	
7. A stepwise approach to the implementation of an integrated monitoring and surveillance program of for foodborne AMR <u>Implementation of an integrated monitoring and surveillance program based on the principle of continuous improvement and enhancement</u>	Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended. Australia believes that the principle of continuous improvement and enhancement captures the essence and intent of stepwise without the unintended hierarchy and is a workable compromise.
7. A stepwise <u>An incremental</u> approach to the implementation of an integrated monitoring and surveillance program of foodborne AMR	Brazil
7. A stepwise approach to the implementation of an integrated monitoring and surveillance program of foodborne AMR <u>and AMU</u>	China

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
7. A stepwise <u>An incremental</u> approach to the implementation of an integrated monitoring and surveillance program of foodborne AMR	USA “Incremental” is consistent with comments on paragraph 1 and we note is also the term used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/
A stepwise approach to the The design and implementation of an integrated monitoring and surveillance program based on the principle of continuous improvement and enhancement allows countries to develop a strategy and implement activities to progress according to their own time scales and is scales. It represents a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new available scientific information.	Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended. Australia believes that the principle of continuous improvement and enhancement captures the essence and meaning of stepwise without the unintended hierarchy.
A stepwise An incremental approach to the design and implementation of an integrated monitoring and surveillance program allows countries to develop a strategy and implement activities to progress according to their own time scales and is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new available scientific information.	Brazil
A stepwise An incremental approach to the design and implementation of an integrated monitoring and surveillance program allows countries to develop a strategy and implement activities to progress according to their own time scales and is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new available scientific information.	USA “Incremental” is consistent with comments on paragraph 1 and we note is also the term used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/
A stepwise An incremental approach to the design and implementation of an integrated monitoring and surveillance program allows countries to develop a strategy and implement activities to progress according to their own time scales and is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new available scientific information.	Healthforanimals Incremental is consistent with WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/
The implementation of a stepwise approach Implementation based on continuous improvement and enhancement should facilitate countries achieving their AMR monitoring and surveillance objectives in the achievement of initial stages and into the country's future as objectives on AMR and enable continuous improvement priorities evolve.	Australia Australia suggests that continuous improvement and enhancement should be an integral component of program design and implementation and not an outcome.
The implementation of a stepwise an incremental approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement.	Brazil
The implementation of a stepwise approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement. A stepwise approach may be utilized by some countries to properly implement applicable elements proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.	Malaysia Align with the COP (CXC 61-2005) on Principle 11.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
The stepwise approach to monitoring and surveillance of AMR and AMU that is presented in these guidelines is consistent with the <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach</i> , chapter 6.9 of the <i>OIE Terrestrial Animal Health Code</i> and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the <i>OIE Annual Report on the Use of Antimicrobial Agents in Animals</i> .	Australia Australia would prefer the removal of the term gradual or stepwise as there is an implication of hierarchy, even if not intended.
The stepwise incremental approach to monitoring and surveillance of AMR and AMU that is presented in these guidelines is consistent with the <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach</i> , chapter 6.9 of the <i>OIE Terrestrial Animal Health Code</i> and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the <i>OIE Annual Report on the Use of Antimicrobial Agents in Animals</i> .	Brazil
The stepwise approach to monitoring and surveillance of foodborne AMR and AMU that is presented in these guidelines is consistent with the <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach</i> , chapter 6.9 of the <i>OIE Terrestrial Animal Health Code</i> and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the <i>OIE Annual Report on the Use of Antimicrobial Agents in Animals</i> .	China Supplement official guidelines on surveillance and monitoring of AMR and AMU in plants and the environment.
The stepwise approach to monitoring and surveillance of AMR and AMU that is presented in these guidelines is consistent with the <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach</i> , chapter 6.3 and 6.4 of the <i>OIE Aquatic Animal Health Code</i> , chapter 6.8 and 6.9 of the <i>OIE Terrestrial Animal Health Code</i> and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the <i>OIE Annual Report on the Use of Antimicrobial Agents in Animals</i> .	Japan To include OIE code of Terrestrial Animal Code of AMR and Aquatic Animal Code of AMR and AMU.
7.1 Preliminary tasks/actions	
7.1.1. Establishing the monitoring and surveillance objectives	
The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders, should take into consideration national action plans, consider knowledge (1) of the domestic and international AMR and AMU situation and any existing AMR activities in the different sectors (animal, plant and human health sectors). Countries should identify the challenges that they currently face in the implementation of the activities. The following aspects should be defined (2) when setting objectives :	Canada Change1: Change "...consider knowledge of the AMR and AMU situation and any existing AMR or AMU monitoring activities..." to "...knowledge of the domestic and international AMR and AMU situation, and any existing AMR or AMU monitoring activities..." Change2: Add "when setting objectives" to the end of the last sentence of the para (i.e., after "...should be defined").

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders, should take into consideration national action plans, consider knowledge on the AMR and AMU situation and any existing AMR and AMU activities in the different sectors (animal, plant crop and human health sectors). Countries should identify the challenges that they currently face in the implementation of the activities. The following aspects should be defined:</p>	<p>China</p>
<p>The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders, should take into consideration national action plans, consider knowledge on the AMR and AMU situation and any existing AMR activities in the different sectors (animal, food, plant and human health sectors). Countries should identify the challenges that they currently face in the implementation of the activities. The following aspects should be defined:</p>	<p>Colombia</p> <p>Incluir el sector de alimentos para completar las etapas involucradas en la vigilancia de RAM en la cadena agroalimentaria.</p>
<p>The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders, should take into consideration available information on foodborne AMR risks to human health at the national level, national action plans, consider knowledge on the AMR and AMU situation data and any existing AMR activities to address AMR in the different sectors (animal related to food safety (animal, plant crop and human health sectors). Countries should identify the challenges that they currently face in the implementation of the activities. The following aspects should be defined:</p>	<p>USA</p> <p>Add clarity and prioritize foodborne AMR risk. Crop rather than plant is the appropriate term for Codex scope.</p>
<ul style="list-style-type: none"> The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk assessments and risk management, to obtain baseline information on AMR and AMU, to provide harmonized data that can be easily compared, exchanged, used or aggregated locally, nationally or internationally); <u>The aforementioned, as the legal situation and infrastructure of each country allow</u> <u>Identify the situation of the main food production and distribution system to regional and national level</u> 	<p>Mexico</p> <p>Change1: It is proposed in the preliminary actions to establish the objectives of monitoring and surveillance, in the referred to the "Primary reasons ... for the data collection ", to emphasize, to take into account the legal framework and infrastructure of each country; given that both concepts are criteria that must be taken into account to define the reason for monitoring, making viable in its implementation.</p> <p>Change2: Add after the second bullet, "• Identify the situation of the main food production and distribution system to regional and national level ". It's important within the first steps of the design and implementation of a monitoring and surveillance system of the RAM transmitted by food, identifying the characteristics of the main food productions as well as the food chain, at the regional and national level , allowing to guide the improvement in the accuracy of the objectives a food sampling design</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> The comprehensiveness of the surveillance and monitoring program program system (e.g., data representative of the national situation versus data representative of a regional situation, or data of convenience sampling); 	<p>Canada</p> <p>Change the content to “The comprehensiveness of the surveillance and monitoring system (e.g., geographic representation (national or regional), or data of convenience sampling)”.</p>
<ul style="list-style-type: none"> The comprehensiveness of the surveillance and monitoring program (e.g., whether data is representative of the national situation versus data representative of a regional situation foodborne AMR, or whether data of is obtained from random or convenience sampling); 	<p>USA</p> <p>Clarity.</p>
<ul style="list-style-type: none"> The setting of proposed timelines for reporting (e.g., reporting on an annual basis); 	<p>Canada</p> <p>Revise it as “The setting of proposed timelines for reporting (e.g., annual basis)”.</p>
<ul style="list-style-type: none"> The description of how the information will be communicated (e.g., shared in an annual report to interested stakeholders, publication and accessibility of data to enable further analysis, information exchange through networks). A confidentiality policy of to protect the data collected should be in place. 	<p>Australia</p>
<ul style="list-style-type: none"> The description of how the information will be communicated (e.g., shared in an annual report to interested stakeholders parties, publication and accessibility of data to enable further analysis, information exchange through networks networks or meetings). A confidentiality policy of the data collected should be in place. <u>Data requirements should be considered when setting monitoring and surveillance objectives, as this can impact data collection and reporting.</u> 	<p>Canada</p> <p>Change1: This last bullet is a separate point from the bullet about how the data should be communicated and should be moved to a separate bullet (bullet 4) as “The description of how the information will be communicated (e.g., shared in an annual report to interested parties, publication and accessibility of data to enable further analysis, information exchange through networks or meetings).”</p> <p>Change2: The original last sentence of the para on confidentiality is suggested to be listed as a new bullet (bullet 5) as “Data confidentiality requirements should be considered when setting monitoring and surveillance objectives, as this can impact data collection and reporting”.</p>
<ul style="list-style-type: none"> The description of how the information will be communicated (e.g., shared in an annual report to interested stakeholders, publication and accessibility of data to enable further analysis, information exchange through networks). A confidentiality policy of the data collected should be in place. <u>Other considerations include a comprehensive data management plan including a confidentiality policy of the data collected</u> 	<p>USA</p> <p>Depending on the situation and country, data may need greater management, protection, and investment beyond a confidentiality policy.</p>
7.1.2. Criteria for prioritization	
<p>7.1.2. Criteria for prioritization<u>Priority setting approach</u></p>	<p>Canada</p> <p>The sub-section heading does not reflect content. Revise the sub-heading as “7.1.2. Priority setting approach”.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>The establishment of the monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobials, (1) animal or plant species, food commodities types and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (2) (national or regional data as a priority) (in their jurisdiction) on AMR and AMU in different sectors.</p>	<p>Canada</p> <p>Change1: Expand the first sentence by changing “food commodities” with “animal or plant species, food types”.</p> <p>Change2: Replace “(national or regional data as a priority)” with “in their jurisdiction”.</p>
<p>The establishment of the monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobials, food commodities and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) and assess their appropriateness for obtaining valid data on AMR and AMU in different sectors.</p>	<p>China</p>
<p>The establishment of the monitoring and surveillance priorities for (1) microorganisms foodborne AMR bacteria and resistance determinants, antimicrobials, and antimicrobials in food commodities and sample sources should be informed by national, regional and international (2) scientific data and scientific knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on AMR and AMU in different sectors. (3) <u>A gradual approach should consider initial stages, as they are achieved while building subsequent stages. Criteria for prioritization may change based on past approaches and what is learned by them.</u></p>	<p>USA</p> <p>Change1: Suggest this change because we are proposing monitoring and surveillance for resistant microorganisms and determinants and antimicrobials in food commodities. As opposed to monitoring and surveillance for.....</p> <p>Change2: Adding “scientific” gives specificity to the type of data and knowledge that should be sought. We recommend deleting “national or regional data as a priority” because it has already been stated in the sentence above. Recommend adding sentences above as prioritization is not an immobile concept and is subject to change as information is gained and science proves or disproves concepts. It is important for countries to keep this mind as they plan a multi-staged approach.</p> <p>Change3: Recommend reminding the reader that this portion is a gradual approach and part of forming objectives and how to obtain them will include some of the following points, as they can be obtained.</p>
<p>The establishment of the monitoring and surveillance priorities for (1) microorganisms foodborne AMR bacteria and resistance determinants, antimicrobials, food commodities and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on AMR and AMU in different sectors.</p> <p><u>(2) A gradual approach should consider initial stages, as they are achieved while building subsequent stages. Criteria for prioritization may change based on past approaches and what is learned by them.</u></p>	<p>Healthforanimals</p> <p>Change1: Scope is food.</p> <p>Change2: Editorial.</p>
<p>Competent authorities should also consider public health implications of AMR, epidemiology of disease and resistance patterns, AMU patterns, information on food production systems, food distribution, consumption patterns and food exposure pathways.</p>	<p>Brazil</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Competent authorities should also consider public health implications of AMR, epidemiology of disease and resistance AMR patterns, AMU patterns, information on food production systems, food distribution, consumption patterns and food exposure pathways . <u>pathways including food handling and cultural practices.</u>	USA Added language to indicate practices that may contribute to cross-contamination.
Information from risk profiles and risk assessments, where these exist should also be used when establishing priorities.	Brazil
7.1.3 Infrastructure and resources	
7.1.3. Infrastructure and resources <u>resource considerations</u>	Canada Revise this sub-heading as “7.1.3. Infrastructure and resource considerations.
Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives and determine which of the programs described in section 7.3 of these Guidelines can effectively be implemented first and which additional activities could be implemented at a later stage given additional resources and other improvements.	Brazil
Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives and <u>use this to</u> determine which of the programs described in section 7.3 of these Guidelines can effectively be implemented first <u>where, when</u> and <u>how surveillance activities should begin and</u> which additional activities could be implemented at a later stage given additional resources and other improvements.	Canada Para 1, lines 2-3. Replace “...and determine which of the programs described in section 7.3 of these Guidelines can effectively be implemented first and...” with “... and use this to determine where, when and how surveillance activities should begin and...”
Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives and determine which of the programs described in section 7.3 of these Guidelines can effectively be implemented first and which additional activities could be implemented at a later stage given additional resources and other improvements. <u>All Objectives should include what will make a difference in AMR's effect on human health for foodborne illness.</u>	USA All objectives should include what will make a difference in AMR's effect on human health from foodborne illness” helps give clarity that there is an overall goal and all objects, whether implemented now or later should include this overarching concept of negative effect on human health from food.
Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives and determine which of the programs described in section 7.3 of these Guidelines can effectively be implemented first and which additional activities could be implemented at a later stage given additional resources and other improvements. <u>All objectives should include what will make a difference in AMR's effect on human health from foodborne illness.</u>	Healthforanimals Including this phrase will clarify that there is an overall goal and all objects, whether implemented now or later should include this overarching concept of negative effect on human health from food.
The evolution of surveillance and monitoring programs do not need to strictly follow the program in the order described in these guidelines; these are logical options for expansion which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both type types of data benefit from a joint analysis, is it will be most useful <u>for interpretation of results</u> if the both programs are aligned on its development <u>aligned</u>	Australia

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
The evolution of surveillance and monitoring programs do not need to strictly follow the program in the order described in these guidelines; these are logical options for expansion which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both type of data benefit from a joint analysis, is useful if the programs are aligned on its development.	Brazil
(1) The evolution of surveillance and monitoring programs do not need to strictly follow the program in the order described in these guidelines; these are These guidelines provide logical options for expansion of monitoring and surveillance activities which may require generally require increasing resources. (2) Programs Systems for AMU monitoring can proceed at a different rate than programs systems for AMR monitoring and surveillance and vice versa. However, as both type of data benefit from a joint analysis, is useful if the programs are aligned on its development.	Canada Change1: Simplify the first sentence to “These guidelines provide logical options for expansion of monitoring and surveillance activities which generally require increasing resources” (i.e., deleting the first part of the original sentence with additional revisions”). Change2: Replace “programs” with “systems” in two places of the second sentence. Change3: Delete the last sentence “However, as both types...” because the statement is not needed in this context.
The evolution of surveillance and monitoring programs do does not need to strictly follow the program in the order described in these guidelines; these are logical options for expansion which may require increasing resources resources and is meant to demonstrate an example approach . Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both type of data benefit from a joint analysis, is useful if the programs are aligned on its development	USA Clarify as example.
The evolution of surveillance and monitoring programs do not need to strictly follow the program in the order described in these guidelines; these are logical options for expansion which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both type of data benefit from a joint analysis, it is useful if the programs are aligned on its development as they are developed .	International Association of Consumer Food Organizations
In advance of launching surveillance activities, the competent authority should and interested stakeholders need to address laboratory capacity issues by carefully consider coordination coordinating the timing of sampling and laboratory testing. In addition, which interested stakeholders need to be involved in this coordination, and develop a plan for collation of the data in a central location management (e.g. As part of initial planning software, the competent authority hardware, technical expertise, etc.) should also consider in advance where harmonization and standardization are required to meet monitoring and surveillance objectives be developed .	Canada
In advance of launching surveillance activities, the competent authority should carefully consider coordination of sampling and laboratory testing, in involved , and develop a plan for collation of the data in a central location. As part of initial planning, the competent authority should also consider in advance where harmonization and standardization are required to meet monitoring and surveillance objectives.	USA

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
7.2 Initiating monitoring and surveillance activities	
7.2 Initiating monitoring and surveillance activities	Canada Detailed elements for considerations on AMR and AMU can be included in an Annex.
The design of a stepwise an incremental monitoring and surveillance system should consider the following principles:	Brazil
The design of a stepwise monitoring and surveillance system should consider the following principles: principles to meet monitoring and surveillance objectives	Canada Delete “stepwise” and also adding “to meet monitoring and surveillance objectives: “ at the end of the sentence (i.e., after “...following principles”).
The design of a stepwise monitoring and surveillance system should consider the following principles: tasks/actions:	Thailand We propose to replace the word “principles” with either “tasks” or “actions”.
The design of a stepwise an incremental monitoring and surveillance system should consider the following principles:	USA “Incremental” is consistent with comments on paragraph 1 and we note is also the term used in WHO AGISAR page 6 https://www.who.int/foodsafety/publications/agisar_guidance2017/en/
Antimicrobial resistance:	
Antimicrobial resistance resistance (Detailed elements for consideration can be found in Annex I):	Canada “Antimicrobial resistance” sub-section heading is suggested to be changed to “Antimicrobial resistance (Detailed elements for consideration can be found in Annex I)”.
<ul style="list-style-type: none"> Targeting the highest priority microorganisms, panels of antimicrobials for susceptibility testing, and high-risk (e.g., the food animal species which are primarily consumed in the country or evidence of AMR concern) food and commodities (see section 10 of these guidelines) based on country data or international recommendations; 	Canada Add “for susceptibility testing, and high-risk (e.g., the food animal species which are primarily consumed in the country or evidence of AMR concern) food” between “antimicrobials” and “commodities”.
<ul style="list-style-type: none"> Targeting the highest priority microorganisms, panels of antimicrobials and antimicrobials, commodities and related environment through the food chain (see section 10 of these guidelines) based on country data or international recommendations; 	China
<ul style="list-style-type: none"> Targeting the highest priority microorganisms, panels of antimicrobials antimicrobials, testing for genetic determinants of resistance and commodities (see section 10 of these guidelines) based on country data or international recommendations; 	Colombia Incluir la detección de determinantes de resistencia para dilucidar los posibles mecanismos que subyacen los perfiles de RAM.
<ul style="list-style-type: none"> Targeting the highest priority microorganisms foodborne bacteria, panels of antimicrobials and commodities (see section 10 of these guidelines) based on country data national priorities or international recommendations; 	USA Codex scope and for clarity.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Identifying <u>Understanding</u> the food production and distribution chain <u>to identify ideal</u> points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives<u>for sampling</u>; <u>Sample size and frequency to adequately detect and monitor trends in resistant bacteria recovered from sampled products.</u> 	<p>Canada</p> <p>Change1: Revise this bullet as “Understanding the food production and distribution chain to identify ideal points in the food chain for sampling”</p> <p>Change2: Add a new bullet as “Sample size and frequency to adequately detect and monitor trends in resistant bacteria recovered from sampled products.”</p>
<ul style="list-style-type: none"> Targeting the highest priority microorganisms, panels of antimicrobials and commodities (see section 10 of these guidelines) based on country data or international recommendations; Identifying the food production and distribution chain, points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives <u>including focus on sectors associated with high AMU and AMR such as intensive livestock production facilities</u>; 	<p>Consumers International</p> <p>Bullet 1 describes targeting of organisms and commodities, CI believes that targeting should also apply to points in the production chain specifically when there is evidence that certain segments (intensive versus extensive) are at higher risk of resistance and use.</p>
<ul style="list-style-type: none"> Establishing sampling methods, laboratory analysis and reporting protocols; building capacity where required; Establishing standardized and harmonized methodologies (e.g., laboratory testing for AST) and best practices with those used in other sectors. Establishing <u>laboratory protocols for</u> sampling methods, laboratory analysis and reporting protocols; building capacity where required;<u>standardized and harmonized methodologies (e.g., laboratory testing for AST) and best practices with those used in other sectors.</u> 	<p>Canada</p> <p>AMR Bullets 3 and 4. Merge these bullets as “Establishing laboratory protocols for sampling methods, laboratory analysis and reporting protocols; standardized and harmonized methodologies (e.g., laboratory testing for AST) and best practices with those used in other sectors.”</p>
<ul style="list-style-type: none"> Establishing standardized and harmonized methodologies (e.g., laboratory testing for AST) and best practices with those used in other sectors<u>sectors (e.g., laboratory testing for antimicrobial susceptibility).</u> 	<p>Australia</p>
<ul style="list-style-type: none"> Establishing standardized and harmonized methodologies (e.g., <u>bacteriological cultivation</u>, laboratory testing for AST) and best practices with those used in other sectors 	<p>China</p>
Antimicrobial use:	
Antimicrobial use <u>(Detailed elements for consideration can be found in Annex II)</u> :	<p>Canada</p> <p>Antimicrobial use” sub-section heading is suggested to be changed to “Antimicrobial use (Detailed elements for consideration can be found in Annex II)”.</p>
<ul style="list-style-type: none"> Identifying <u>Describing the</u> antimicrobial distribution chain from manufacturing or import to end-user including sales/use data providers;Identifying 	<p>Canada</p> <p>Change “Identifying” to “Describing the”.</p>
<ul style="list-style-type: none"> Identifying antimicrobial distribution chain from manufacturing or import to end-user including sales/use data providers; 	<p>USA</p> <p>This statement is unrealistically resource-intensive and goes beyond Codex scope of assuring food safety.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Identifying the sectors where collection of data would be more relevant relevant to the interpretation of AMR results; relevant to the interpretation of AMR results; 	Canada Add “to interpretation of AMR results” at the end of the bullet (i.e., after “more relevant”).
<ul style="list-style-type: none"> Initiating collection and reporting of antimicrobial sales (consumption) and use data in food producing animals and crops (see section 9 of these guidelines) if necessary building a legal framework framework; framework if necessary; 	Australia
<ul style="list-style-type: none"> Initiating collection and reporting of antimicrobial sales (consumption) and use data in food producing animals and crops (see section 9 of these guidelines) if necessary building a supportive legal framework; 	Canada Add “supportive” before “legal framework.”
<ul style="list-style-type: none"> Initiating collection and reporting of antimicrobial sales (consumption) and use AMU AMU data in food producing animals and crops (see section 9 of these guidelines) if necessary building a legal framework; as described in OIE chapter 6.8 as described in OIE chapter 6.8 	USA AMU is defined in comments above, so does not need to be further described here. A reference to OIE chapter 6.8 avoids duplication with OIE work and assures consistency if OIE changes standards in annual updates.
<ul style="list-style-type: none"> Implementing of monitoring and surveillance activities through pilot surveys in selected food sectors depending on prioritization (see section 10 of these guidelines). 	Canada This bullet may not necessarily to be here as it is a description of a staged approach, which would be the purpose of the new Annex on AMU.
<p>The phases described below are guidelines for development and enhancement of integrated monitoring and surveillance activities. These guidelines are intended to provide flexibility of options for stages of implementation and expansion, considering resources, infrastructure, capacities, and priorities of countries. They are not intended to provide prescriptive restrictive categories or steps, but rather a continuum of options for implementation. implementation and enhancement.</p>	Australia The principle of enhancement is captured by this small addition to the sentence.
<p>The phases described below are guidelines for development and enhancement of integrated monitoring and surveillance activities. These guidelines are intended to provide flexibility of options for stages of implementation and expansion, considering resources, infrastructure, capacities, and priorities of countries. They are not intended to provide prescriptive restrictive categories or steps, but rather a continuum of options for implementation.</p>	Brazil
<p>The phases steps described below are guidelines for development and enhancement of integrated monitoring and surveillance activities. These guidelines are intended to provide flexibility of options for stages of implementation and expansion, considering resources, infrastructure, capacities, and priorities of countries. They are not intended to provide prescriptive restrictive categories or steps, but rather a continuum of options for implementation.</p>	Thailand The word “phases” should be replaced with “steps”.
<p>The phases described below are guidelines for development and enhancement of integrated monitoring and surveillance activities. These guidelines are intended to provide flexibility of options for stages of implementation and expansion, considering resources, infrastructure, capacities, and priorities of countries. They are not intended to provide prescriptive restrictive categories or steps, but rather a continuum of options for implementation.</p>	USA The phases/steps are overly prescriptive, rather than offering a basic foundation and categorize countries, which is not the role of Codex. We recommend deletion of the chart in 7.3.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	<p>Brazil</p> <p>Brazil does not agree with the proposal of programs A, B and C and therefore Brazil is of the opinion that section 7.3 has to be deleted of the document, as explained in the general comments on the stepwise approach, and that the elements that provide an incremental approach should be inserted into the document in each of the relevant components for integrated surveillance.</p>
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	<p>Canada</p> <p>Canada suggests that the Table be replaced with headings and bullets, without categorization of the program/system. Here is an example using the general considerations, which could be applied to subsequent aspects of the table(s).</p> <p>General considerations:</p> <ul style="list-style-type: none"> • Scope and design based on: <ul style="list-style-type: none"> ○ Previous surveys or international experience and recommendations ○ Existing monitoring or surveillance findings ○ Epidemiology of antimicrobial-resistant bacteria in people ○ Refined based on risk profile or risk assessment findings, as available ○ Additional pro-active surveillance activities (e.g., pilot studies or point prevalence surveys) could be launched” <p>The table is suggested to be an Annex (i.e., “Annex III. Suggested elements for consideration for evolution of integrated monitoring and surveillance of foodborne AMR and AMU system”). Further suggested revisions of the Table are indicated in underlined/bold texts below at the end of the comments (see Table below).</p>
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	<p>USA</p> <p>Delete Chart: It is not Codex’s role to classify countries based on their implementation level of Codex guidance as described in general comments.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	Healthforanimals Do not include this chart. The stepwise approach will lead to a de facto categorization of countries. This type of categorization can be, and has been, misused to gain trade advantage. Specifying detailed and specific processes in Codex guidelines - often based on the experiences of developed countries - risks the sovereignty of countries to develop their specific plans. Such stepwise approaches are viewed with suspicion by member countries. It is therefore not useful to include the chart.
7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs	International Feed Industry Federation We would support deleting the chart. It is not Codex's role to classify countries based on their implementation level of Codex guidance as described in general comments.
TABLE ON ANTIMICROBIAL RESISTANCE	
ANTIMICROBIAL RESISTANCE	Brazil
ANTIMICROBIAL RESISTANCE	China Add more details about the sampling plans and target microorganisms of crops/plants. The panel of antimicrobials tested should also include OIE list and national list.
ANTIMICROBIAL RESISTANCE	International Association of Consumer Food Organizations The word "bacteria" and "bacterial" should be deleted and replaced with "microorganisms" and "microbial" since the document is about antimicrobial resistance which can occur in microorganisms in addition to bacteria. The word "program" should be deleted and replaced with "example" to be less prescriptive/rigid.
TABLE ON ANTIMICROBIAL RESISTANCE: PROGRAM A	
PROGRAM A	Brazil
PROGRAM A	USA Delete Chart: It is not Codex's role to classify countries based on their implementation level of Codex guidance as described in general comments.
PROGRAM EXAMPLE A	International Association of Consumer Food Organizations
TABLE ON ANTIMICROBIAL RESISTANCE: PROGRAM B	
PROGRAM B	Brazil

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
PROGRAM B	USA
PROGRAM EXAMPLE B	International Association of Consumer Food Organizations
TABLE ON ANTIMICROBIAL RESISTANCE: PROGRAM C	
PROGRAM C	Brazil
PROGRAM C	USA
PROGRAM EXAMPLE C	International Association of Consumer Food Organizations
PROGRAM C	International Feed Industry Federation Program C of the stepwise approach for the source of information is very much focused on animal production, while the plan is to cover all foodborne sources (similar comment for the sampling point, where we would imagine crop processors should also be controlled (not only slaughterhouses).
TABLE ON ANTIMICROBIAL USE	
ANTIMICROBIAL USE	Brazil
TABLE ON ANTIMICROBIAL USE: PROGRAM A	
PROGRAM A	Brazil
TABLE ON ANTIMICROBIAL USE: PROGRAM B	
PROGRAM B	Brazil
TABLE ON ANTIMICROBIAL USE: PROGRAM C	
PROGRAM C	Brazil
TABLE ON ANALYSIS AND REPORTING	
ANALYSIS AND REPORTING	Brazil
ANALYSIS AND REPORTING	Thailand The texts in the 2nd row (Link with risk management and risk assessment/risk profile) should be re-considered whether it needs the rearrangement to be in line with risk analysis concept (assessment/management/communication).
TABLE ON ANALYSIS AND REPORTING: PROGRAM A	
PROGRAM A	Brazil

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
TABLE ON ANALYSIS AND REPORTING: PROGRAM B	
PROGRAM B	Brazil
TABLE ON ANALYSIS AND REPORTING: PROGRAM C	
PROGRAM C	Brazil
7.4 Evaluation, review and adjustment or expansion of the monitoring and surveillance program	
7.4. Evaluation, review <u>Evaluation and adjustment or expansion</u> review of the monitoring and surveillance program	Canada This sub-section should be just for Evaluation and Review. Revise the sub-section heading as "Evaluation and review of the monitoring and surveillance system."
<ul style="list-style-type: none"> Indicators to effectively track the progress (implementation and effectiveness) of the monitoring and surveillance program; 	Canada Specify the progress by indicating "progress (implementation and effectiveness)".
<ul style="list-style-type: none"> Indicators to effectively track the progress of the monitoring and surveillance program; <u>Assessment of the program's objectives and their effect on human health from foodborne AMR.</u> 	Healthforanimals The core purpose of surveillance and monitoring is to assess effects on human health from foodborne AMR. It should therefore be mentioned explicitly.
<ul style="list-style-type: none"> Periodically evaluate the monitoring and surveillance program to ensure quality and that the results are a provide robust and reliable indicator of data on AMR or AMU; 	Norway
<ul style="list-style-type: none"> Periodically evaluate the monitoring and surveillance program to ensure quality and that the results are a robust and reliable indicator of AMR or AMU; 	USA This is an impractical statement. Even high resource countries have trouble reliably ensuring robust and reliable data for AMR and AMU. Such a statement is immature for global guidelines.
<ul style="list-style-type: none"> Periodically evaluate the monitoring and surveillance program to ensure quality and that the results are a robust and reliable indicator of AMR or AMU; 	Healthforanimals Risk profiling is not going to necessarily have a direct impact on food safety and human health. This concept is too broad and raises more questions than it solves.
<ul style="list-style-type: none"> Further detailed risk profiling based on preliminary monitoring and surveillance data 	Canada This bullet is not relevant and is suggested to be deleted.
<ul style="list-style-type: none"> Further detailed risk profiling based on preliminary monitoring and surveillance data 	USA Risk profiling may or may not be warranted.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Further detailed risk profiling based on preliminary monitoring <u>review of work to establish what has been learned</u> and surveillance data <u>were there are still information gaps in regard to AMR foodborne illness and its effect on human health;</u> 	<p>Healthforanimals A review of the program is important to ensure it is accomplishing a reduction in human health issues.</p>
<ul style="list-style-type: none"> Use the data generated from the evaluation of activities and risk profiling to adjust the monitoring and surveillance program if required or to expand to a wider scope of <u>foodborne</u> pathogens, foods and antimicrobials, taking into consideration resource allocation and priorities (refer back to preliminary actions); 	China
<ul style="list-style-type: none"> Use the data generated from the evaluation of activities and risk profiling to adjust the monitoring and surveillance program if required or program. For example, to expand to a wider refine the scope of pathogens, foods and antimicrobials, taking into consideration resource allocation and priorities (refer back to preliminary actions); 	<p>USA For clarity.</p>
<ul style="list-style-type: none"> Development and inclusion of new monitoring and surveillance tools (e.g. whole genome sequence to facilitate genomic characterization of bacteria). <u>Identification of how the monitoring and surveillance data have been used (e.g., for policy development, used to prompt implementing interventions, used to inform future research, to justify continued surveillance activities, used for risk profiling or risk assessment)</u> <u>Evaluate the resilience/adaptiveness the monitoring and surveillance system to meet the demands of new information, such as new emerging AMR patterns, new food products consumed, new antimicrobials entering the market</u> 	<p>Canada This bullet (“Development and inclusion...”) falls under stepwise implementation, rather than evaluation and review. Since a whole section is on stepwise implementation (i.e., Table or newly proposed Annex III), delete this bullet (consequently, this sub-section 7.4 is restricted to evaluation and review”. New bullets: Add two new bullets as follows:</p>
<ul style="list-style-type: none"> Development and inclusion of new monitoring and surveillance tools (e.g. whole genome sequence sequencing to facilitate genomic characterization of bacteria). 	China
<ul style="list-style-type: none"> Development and inclusion of new monitoring and surveillance tools (e.g. whole genome sequence to facilitate genomic characterization of bacteria microorganisms). 	International Association of Consumer Food Organizations
As resources and capacity may develop, and the design of the monitoring and surveillance program may change periodically, the competent authorities should ensure that all interested stakeholders are kept informed. <u>Aspects of this continual stakeholder engagement could be included in the review of the monitoring and surveillance system.</u>	<p>Canada Add a second sentence at the end of the paragraph.</p>
The expansion of activities should be done in alignment with the program design in order to continue to meet the monitoring and surveillance objectives in the country.	<p>Canada This last paragraph fits better to the suggested Annex III.</p>
8. Design of monitoring and surveillance programs for AMR	
8. Design of monitoring and surveillance programs for AMR	<p>Canada Suggest this section is presented as Annex I - Details of the design of monitoring and surveillance systems for AMR. Attention should be paid to avoid redundancy and to limit this section to details which are not provided earlier in this document.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
8. Design of monitoring and surveillance programs for AMR	Iran Detection of antimicrobial residues should also be considered in monitoring and surveillance programs, since a variety of resistance determinants may be transmitted by this way.
8. Design of monitoring and surveillance programs for AMR	Thailand We appreciated the useful texts added to this part. For reason of clarity, we propose that the essential components concerning to stepwise approach should be identified.
8.1 Elements of an integrated monitoring and surveillance programs for AMR	
8.1. Elements of an integrated monitoring and surveillance programs for AMR <u>To initiate an integrated monitoring and surveillance program for AMR the scope and design of AMR program can be informed by previous surveys or international experience and recommendations.</u> <u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, so that the scope and design can be based on monitoring findings, epidemiology of antimicrobial- resistant bacteria in people and refined based on risk profile findings or risk assessment findings, if appropriate. Additional pro-active surveillance activities (e.g. point prevalence surveys) could be launched or used, as appropriate.</u>	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.
To ensure that the monitoring and surveillance objectives are met, whatever the program or stage of implementation, an integrated program for monitoring and surveillance of foodborne AMR should strive to include and systematic systematically review the following design elements and technical characteristics:	USA Allow for flexibility in terminology.
To ensure that the monitoring and surveillance objectives are met, whatever the stage of implementation, an integrated program for monitoring and surveillance of foodborne AMR should strive to include and systematic review the following design elements and technical characteristics:	Consumers International Should imply conditionality it is not necessary to further qualify it with “strive to.”
<ul style="list-style-type: none"> List of target microorganisms based on public health relevance; (pathogens (foodborne pathogens and indicator bacteria) and resistance determinants and new information or emerging AMR hazards; 	China
<ul style="list-style-type: none"> List of target microorganisms based on public health relevance; (pathogens (foodborne pathogens and indicator bacteria) and resistance determinants and new information or emerging AMR hazards; 	Japan To be in line with the scope of the guidelines.
<ul style="list-style-type: none"> List of target microorganisms bacteria bacteria based on public health relevance; (pathogens and indicator bacteria) and resistance determinants and new information or emerging AMR hazards; 	USA For clarity.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> List of target microorganisms based on public health relevance; (pathogens and indicator bacteria) species) and resistance determinants and new information or emerging AMR hazards; 	International Association of Consumer Food Organizations
<ul style="list-style-type: none"> Laboratory testing methodology and quality assurance procedures that are appropriate, harmonized and standardized where possible; 	Australia
8.2 Types of design or sampling plans	
8.2. Types of design or sampling plans <u>Sampling design</u>	Australia Sampling plans are addressed in section 8.4, inclusion of sampling plans here is confusing for the reader.
<ul style="list-style-type: none"> Simple cross-sectional point prevalence surveys that can be used to collect basic information and compare between various populations at particular point of points in time; 	Australia
<ul style="list-style-type: none"> Investigative, targeted surveillance studies (e.g. pilot pilot studies to test collecting data from target new animal species); 	Australia
<ul style="list-style-type: none"> Short-term <i>ad hoc</i> pilot studies or projects can be used to test the feasibility of planned programs. They This type of sentinel surveillance can also enhance the overall technical and analytical value of a national program (e.g. use of new analytical methods); 	USA Pilot is a word typically used to describe this type of study/protection and indicates early steps/ studies should be viewed as learning exercises not regulatory processes. Added for clarity.
<ul style="list-style-type: none"> Sentinel surveillance, which relies on specific providers, healthcare facilities, laboratories, or other sources reporting a disease or condition under surveillance. 	USA To provide a description.
The design of the monitoring and surveillance program could involve new infrastructure only for the purpose of AMR or AMU (active surveillance) or where available information about AMR and AMU could be collected by an existing program which was designed for another purpose (passive surveillance) purpose.	USA The explanation appears targeted at resource availability versus accurate definitions of active and passive surveillance.
8.3 Sample sources for the collection of isolates for AMR testing	
Sources of samples for the collection of the isolates for AMR testing will be based on the objectives, the stage of implementation and the design of the monitoring and surveillance programs and will be determinate determined by the available resources and the national infrastructure. Data from the samples can be integrated with data from other sources (e.g. human isolates).	Australia
Sources of samples for the collection of the isolates for AMR testing will be based on the objectives, the stage of implementation and the design of the monitoring and surveillance programs and will be determinate by the available resources and the national infrastructure. Data from the samples can be integrated with data from other sources (e.g. human isolates).	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><u>To initiate an integrated monitoring and surveillance program for AMR sampling should be of a limited selection of animals, foods and crops at limited specific stages along the food chain (e.g., farm, crops, slaughterhouse, processing plants, retail).</u></p> <p><u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, so that sampling should be of a broader selection of animals, food and crops at higher number of stages along the food chain (e.g., farm, crops, slaughterhouse, processing plants, retail) and a broader range of direct and indirect food exposure pathways at all stages along the food chain.</u></p>	
Sources of samples for the collection of the isolates for AMR testing will be based on the objectives, the stage of implementation and the design of the monitoring and surveillance programs and will be determine determined by the available resources and the national infrastructure. Data from the samples can be integrated with data from other sources (e.g. human isolates).	USA
Samples should be to the extent possible representative of the population that is targeted and consider the biology of the bacterial species to increase the likelihood of detection and should be representative of given epidemiological unit (e.g. holding of origin, herd, flock).	USA Allow for flexibility.
Samples should be representative of the population that is targeted and consider the biology of the bacterial microbial species to increase the likelihood of detection and should be representative of given epidemiological unit (e.g. holding of origin, herd, flock).	International Association of Consumer Food Organizations
For plants crops , samples from priority crop species could also be taken at farm level.	Brazil
For plants, samples from priority crop species could also be taken at farm level	Canada See comments on paragraph 5.
For plants crops , samples from root, stem, leaf or fruit of priority crop species could also be taken at farm level.	China
For plants crops , samples from priority crop species could also be taken at farm level	USA Keep within Codex scope.
Although samples from both healthy animals and sick animals are useful for monitoring and surveillance, samples from healthy animals should be the primary focus because such samples can provide better measure of AMR in animals entering the human food supply chain. Isolates from sick animals are useful for detecting novel resistance patterns.	USA Sick animals should not be entering the food supply chain so outside Codex scope.
Although samples from both healthy animals and sick animals are useful for monitoring and surveillance, samples from healthy animals should be the primary focus because such samples can provide better measure of AMR in animals entering the human food supply chain. Isolates from sick animals are useful for detecting novel resistance patterns.	Healthforanimals These animals should not be entering the food supply so samples would then have to come from diagnostic labs which would be biased towards resistance. Therefore, this should be removed.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
For food producing animals at farm level, samples from animals and their related environment could include: faeces, feed, litter (bedding), dust, fluff, water, soil, etc. <u>For plants, samples from priority crop species could also be taken at farm level. At retail the most important plant-based food at a country or regional level should be sampled.</u>	Canada Add a second sentence “At retail the most important plant based foods at a country or regional level should be sampled.” and moving this revised paragraph “For plants, samples from priority crop species could also be taken at farm level. At retail the most important plant-based food at a country or regional level should be sampled.” after Paragraph 5 (“For food producing animals...”).
For food producing animals at farm level, samples from animals and their related environment could include: faeces, feed, litter (bedding), dust, fluff, water, soil, <u>sewage sludge, manure</u> , etc	China
For food producing animals at farm level, <u>the significance of environmental sampling for assessing risk from foodborne AMR is currently unknown, but research studies, as national priorities indicate and resources allow</u> , samples from animals and their related environment could include: faeces, feed, litter (bedding), dust, fluff, water, soil, etc.	USA To add clarity.
For food producing animals at farm level, <u>the significance of environmental sampling for assessing risk from foodborne AMR is currently unknown, but research studies could study, as national priorities indicate and resources allow</u> samples from animals and their related environment could include: faeces, feed, litter (bedding), dust, fluff, water, soil, etc.	International Feed Industry Federation Edit the paragraph for on-farm samples, as marked. Not every country is going to be able to take samples on farm (or needs to) and the significance and utility of such data is unknown.
At holding <u>processing</u> level (lairage and abattoir), samples can be taken from pen floor, truck/crate swabs, dust, etc.	Canada Replace “holding” with “processing”.
At the slaughter and post-slaughter stage, samples could taken at the evisceration point (e.g. ceacal contents, lymph nodes) <u>to provide an estimate of AMR arising at the farm level</u> , or after slaughter but before processing (e.g.carcass rinses and swabs) <u>to provide an estimate of contamination arising from the slaughter house</u> .	Canada Add “to provide an estimate of AMR arising at the farm level,” after “lymph nodes)” and also adding “to provide an estimate of contamination arising from the slaughter house” after “swabs)”
At the slaughter and post-slaughter stage, samples could <u>be</u> taken at the evisceration point (e.g.ceacal contents, lymph nodes) or after slaughter but before processing (e.g.carcass rinses and swabs).	China
At the slaughter and post-slaughter stage, samples could <u>be</u> taken at the evisceration point (e.g.ceacal contents, lymph nodes) or after slaughter but before processing (e.g.carcass rinses and swabs).	USA
At the slaughter and post-slaughter stage, samples could <u>be</u> taken at the evisceration point (e.g.ceacal contents, lymph nodes) or after slaughter but before processing (e.g.carcass rinses and swabs).	International Association of Consumer Food Organizations
At retail level, the types of food samples could include meat (beef, chicken, turkey, pork, etc.), (1) fish <u>fish and other sea food</u> , dairy product, other edible tissues (liver, kidney, etc.), vegetables <u>produce (fruits, vegetables, nuts, etc.) species</u> and processed food. The selection of foods for surveillance should reflect consumption patterns in the population and likely prevalence of AMR, but may be modified periodically in order to capture multiple commodities <u>or where products have been identified as high risk</u> .	Canada Change1: Change “fish” to “fish and other sea food” and “vegetables” to “produce (fruits, vegetables, nuts, etc.) species”. Change2: Add “or where products have been identified as high risk” at the end of the paragraph (i.e., after “commodities”).

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
At retail level, the types of food samples could include meat (beef, chicken, turkey, pork, etc.), fish, dairy product, other edible tissues (liver, kidney, etc.), vegetables grain, vegetables, fruits, and processed food of animal and plant origin . The selection of foods for surveillance should reflect consumption patterns in the population and likely prevalence of AMR, but may be modified periodically in order to capture multiple commodities.	China
At retail level, the types of food samples could include meat (beef, chicken, turkey, pork, etc.), fish, dairy product, other edible tissues (liver, kidney, etc.), vegetables and processed food. The selection of foods for surveillance should reflect consumption patterns in the population according to national priorities and resources and likely prevalence of AMR, but may be modified periodically in order to capture multiple commodities	USA To make the statement more practical.
Once the sampling structure is established established, consistency in sample types and methodology should be achieved for long-term consistency, comparability, and accurate interpretation of results the feasibility of conducting ad hoc pilot studies on a broader range of retail products may be considered.	USA There should be a statement stating that when sampling has commenced, it's imperative to maintain sampling of that sample type. For instance if carcass rinses are chosen then it's imperative to maintain that sampling point even if others are added, for consistency and proper comparisons it's important to maintain a level of consistency and not change sample type from year to year.
In an integrated program samples collected from food-producing animals should be taken from the same animal species as retail meat samples. An integrated program should cover samples from all stages of the different food chains including crops resources allow through incremental implementation.	USA To make the statement more practical.
The place where the food samples are collected should reflect the purchasing habits of the consumer (e.g. in open markets or chain stores) stores) as resources permit.	USA To make the statement more practical.
If possible, information on the origin of the animal or food (e.g. imported or domestic) and any other relevant information should be collected at the time of sampling. <u>Food-producing animals</u> Selection of animal populations should be relevant to a country's production system. Samples <u>should be representative of the population that is targeted and consider the biology of the bacterial species to increase the likelihood of detection and should be representative of given epidemiological unit (e.g. holding of origin, herd, flock). Samples taken from healthy animals should be prioritized and may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir.</u> <u>Crops</u> <u>The selection of crops should be risk-based and relevant to a country's production systems. Samples may be collected on-farm or during transport.</u>	Australia Australia suggests substantially re-writing section 8.3 and deleting text from paragraph 2, so as to be more consistent with the OIE Codes and the WHO AGISAR guidelines, in being less prescriptive and clearly delineating sampling from different sources. Australia recommends the following modifications for your consideration.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><u>Farm supplies</u> <u>Sampling of animal feed and organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system as they can be a source of resistant bacteria, such as Salmonella, which may be transferred to food-producing animals or be a source of crop contamination.</u></p> <p><u>Food</u> <u>Food sampling at processing/packing, wholesale or point-of-sale (retail) should be considered as part of the integrated monitoring and surveillance system and be consistent with national objectives, and include both domestically produced and imported food sources. Foodborne transmission is considered an important route for the transfer of AMR to humans.</u></p> <p><u>Environment</u> <u>Environmental sampling along the food supply chain should be considered as part of the integrated monitoring and surveillance system and be consistent with national objectives. The environment of animals and crops, processing and wholesale facilities and retail outlets may be a route for transfer or persistence of antimicrobial resistance.</u></p> <p><u>Table 1. Examples of sampling source, type and expected outputs</u></p>	

SPECIFIC COMMENTS																																			
Section/paragraph	Member/Observer/ rationale																																		
<p><u>Table 1. Examples of sampling source, type and expected outputs</u></p> <table border="1"> <thead> <tr> <th>Source</th> <th>Type</th> <th>Expected output</th> </tr> </thead> <tbody> <tr> <td>On-farm</td> <td>Animal faeces</td> <td>Prevalence of pathogens and resistant bacteria at animal population level. Infer relationship between AMR and AMU</td> </tr> <tr> <td rowspan="3">Slaughterhouse/abattoir</td> <td>Faeces</td> <td>Prevalence of pathogens and resistant bacteria in animals entering the food supply</td> </tr> <tr> <td>Caecum</td> <td>As above</td> </tr> <tr> <td>Carcass</td> <td>Prevalence of pathogens and resistant bacteria after carcass dressing, verification of effectiveness of process hygiene measures</td> </tr> <tr> <td>On-farm</td> <td>Crops</td> <td>Prevalence of pathogens and resistant bacteria originating from crops before processing</td> </tr> <tr> <td>Processing facility</td> <td>Food products</td> <td>Prevalence of pathogens and resistant bacteria after processing, verification of effectiveness of process hygiene measures</td> </tr> <tr> <td>Point of sale</td> <td>Food products</td> <td>Prevalence of pathogens and resistant bacteria originating from food, exposure data for consumers</td> </tr> <tr> <td rowspan="2">Various along the supply chain</td> <td>Animal feed</td> <td>Prevalence of pathogens and resistant bacteria originating from animal feed, exposure data for animals</td> </tr> <tr> <td>Fertilizer</td> <td>Prevalence of pathogens and resistant bacteria originating from fertilizers, exposure data for crops</td> </tr> <tr> <td>On or near farm</td> <td>Environment (faecal samples from wildlife and other animals in vicinity of cropping area)</td> <td>Prevalence of pathogens and resistant bacteria in animals in the vicinity of crops, exposure data for crops</td> </tr> <tr> <td>Various along the supply chain</td> <td>Environment (swabs, dust, water, bedding etc)</td> <td>Occurrence and persistence of pathogens and resistant bacteria in the environment</td> </tr> </tbody> </table>			Source	Type	Expected output	On-farm	Animal faeces	Prevalence of pathogens and resistant bacteria at animal population level. Infer relationship between AMR and AMU	Slaughterhouse/abattoir	Faeces	Prevalence of pathogens and resistant bacteria in animals entering the food supply	Caecum	As above	Carcass	Prevalence of pathogens and resistant bacteria after carcass dressing, verification of effectiveness of process hygiene measures	On-farm	Crops	Prevalence of pathogens and resistant bacteria originating from crops before processing	Processing facility	Food products	Prevalence of pathogens and resistant bacteria after processing, verification of effectiveness of process hygiene measures	Point of sale	Food products	Prevalence of pathogens and resistant bacteria originating from food, exposure data for consumers	Various along the supply chain	Animal feed	Prevalence of pathogens and resistant bacteria originating from animal feed, exposure data for animals	Fertilizer	Prevalence of pathogens and resistant bacteria originating from fertilizers, exposure data for crops	On or near farm	Environment (faecal samples from wildlife and other animals in vicinity of cropping area)	Prevalence of pathogens and resistant bacteria in animals in the vicinity of crops, exposure data for crops	Various along the supply chain	Environment (swabs, dust, water, bedding etc)	Occurrence and persistence of pathogens and resistant bacteria in the environment
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8.4 Sampling plans for AMR data collection																																			
8.4 Sampling plans for AMR data collection	<p>Iran</p> <p>In addition to points which should be considered in sampling, including Sample selection strategy, Frequency of collection of samples and Sample size, methods for sampling (e.g. sampling in aseptic conditions for microbiological testing) should also be defined in sampling plans.</p>																																		
8.4. Sampling plans for <u>foodborne</u> AMR data collection	<p>USA</p> <p>To keep with the scope of Codex.</p>																																		

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
8.4. Sampling plans for <u>foodborne</u> AMR data collection	Healthforanimals
<p>When designing monitoring and surveillance programs, representativeness of the data obtained is essential to ensure quality information. Irrespective of the stage, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under investigation (AUS) is representative of the target population and amenable to statistical analysis of temporal or regional trends.</p> <p><u>To initiate an integrated monitoring and surveillance program for AMR limited samples can be collected from the animal/crops/food (e.g., caecal contents vs. carcass swabs) at specific points in the food chain.</u></p> <p><u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, so sampling can be broadened to be fully representative of the national population of interest (e.g., surveillance of abattoirs according to slaughter volume) with stratification within animal species (e.g. broilers, layers, turkeys)</u></p>	<p>Brazil</p> <p>To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.</p>
<p>When designing monitoring and surveillance programs, representativeness of the data obtained is essential to ensure quality information. Irrespective of the stage, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under investigation (AUS) is representative of the target population and amenable to statistical analysis of temporal or regional trends.</p>	<p>Canada</p> <p>Delete "(AUS)".</p>
<p>When designing monitoring and surveillance programs, one should aim for representativeness of the data obtained is essential data to ensure quality information. Irrespective of the stage, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under investigation (AUS) is representative of the target population and amenable to statistical analysis of temporal or regional trends. <u>Methods and limitations to data interpretation should be fully described.</u></p>	<p>USA</p> <p>The language is overly prescriptive. What does "irrespective of the state" mean? Such a statement appears to be contradictory to incremental implementation. Some countries may need to evaluate samples collected for dual purposes as resources allow while they are building their surveillance system. Do not know what "AUS" is.</p>
<p>When designing monitoring and surveillance programs, representativeness of the data obtained is essential to ensure quality information. Irrespective of the stage, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under investigation (AUS) is representative of the target population and amenable to statistical analysis of temporal or regional trends.</p>	<p>International Feed Industry Federation</p> <p>Delete AUS - this abbreviation is not used anywhere else in the document.</p>
<p>The following elements should be defined <u>taken into consideration</u> when designing the sampling plan:</p>	<p>USA</p> <p>The section reads as elements that should be defined. See bullet 6. Even well-resourced countries have trouble can attest to having such clear statements about the amount of change the system is capable of detecting. Also, power is only applicable for studies that want to show an effect when one is really there. How does this apply to surveillance systems? Is there a hypothesis being tested?</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Target populations: animal/food/crops and related environment and target bacterial populations and resistance determinants; 	China
<ul style="list-style-type: none"> Target populations: animal/food/crops and target bacterial microbial populations and resistance determinants; 	International Association of Consumer Food Organizations
<ul style="list-style-type: none"> Point in the food chain where the samples will be taken taken (discrimination on domestic or imported for food and crops is needed); 	Japan To conduct of risk assess discrimination on domestic or imported is important.
<ul style="list-style-type: none"> Required sample size with estimates of statistical power to detect changes in antimicrobial resistance patterns with sufficient precisions and statistical power; precisions; 	Australia
<ul style="list-style-type: none"> Required sample size with estimates of statistical power to detect changes in antimicrobial resistance patterns with sufficient precisions and statistical power; 	Canada Delete "with estimates of statistical power".
<ul style="list-style-type: none"> Selection of strata or risk clusters to best meet surveillance objectives. <u>Qualification of sampling people (e.g. what training should be received).</u> 	China
<i>Sample selection strategy for collection of samples for AMR testing</i>	
Sampling may be active (prospective) or passive (samples collected for other purposes), random or systematic, statistically-based or convenience-based. Sentinel surveillance, which relies on specific providers, healthcare facilities, laboratories, or other sources reporting a disease or condition under surveillance, may also be employed.	Canada This paragraph is duplicative of Section 8.2. Suggest combining.
Examples of sampling strategies (Simple Random Sampling, Stratified Sampling, Systematic Sampling, etc.) are provided by Codex documents on food hygiene and methods of analysis and sampling.	Brazil It is important to make the adequate reference to the documents including in the footnote.
Examples of sampling strategies (Simple Random Sampling, Stratified Sampling, Systematic Sampling, etc.) are provided by Codex documents on food hygiene and methods of analysis and sampling.	Canada Provide the reference for paragraph.
<i>Frequency of collection of samples for AMR testing</i>	
For surveys and periodic studies, the frequency of testing should be decided on the basis of the defined objectives. The incidence and seasonality of the bacteria microbes or diseases under study should be considered. Samples can be collected monthly or periodically throughout the year from different sites, in sufficient numbers, to identify trends.	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<i>Sample size for collection of samples for AMR testing</i>	
Statistical methods should be used to calculate the number of samples or isolates needed for testing (sample size). The choice of sample size depends on the purpose of the study, on the desired precision for estimates of the prevalence of resistance and the magnitude of change in resistance to be detected over a specified period of time in a certain population. It further depends on the frequency of bacterial recovery, the initial or expected prevalence of resistance in that bacterial species and the size of the population to be monitored. It also depends on the desired level of statistical significance and power to detect a difference over time or between populations.	Canada Delete "It also depends on the desired level of statistical significance and power to detect a difference over time or between populations" as it is duplicative of the second sentence of the paragraph.
Statistical Consideration of statistical methods should be used to calculate are helpful for calculating the number of samples or isolates needed for testing (sample size). it is useful for a country to identify the most important AMR food safety issue(s) to monitor for changes to help inform sample size calculations. The choice of sample size depends on the purpose of the study, on the desired precision for estimates of the prevalence of resistance AMR and the magnitude of change in resistance AMR to be detected over a specified period of time in a certain population. It further depends on the frequency of bacterial recovery, the initial or expected prevalence of resistance AMR in that bacterial species and the size of the population to be monitored. It also depends on the desired level of statistical significance and power to detect a difference over time or between populations.	USA Rationale1: Countries may calculate an ideal number but then need to use convenience samples or smaller sample sizes as resources allow. Rationale2: Improve clarity (see added definition for "food safety issue in comments under definitions) and editorial.
Statistical methods should be used to calculate the number of samples or isolates needed for testing (sample size). The choice of sample size depends on the purpose of the study, on the desired precision for estimates of the prevalence of resistance and the magnitude of change in resistance to be detected over a specified period of time in a certain population. It further depends on the frequency of bacterial microbial recovery, the initial or expected prevalence of resistance in that bacteria species and the size of the population to be monitored. It also depends on the desired level of statistical significance and power to detect a difference over time or between populations.	International Association of Consumer Food Organizations
Example of sample size calculation can be found at national or international publications.	Brazil It is important to further elaborate and clarify which documents could be referenced.
Example of sample size calculation can be found at national or international publications.	Canada Reference(s) are needed for Paragraph.
8.5 Target microorganisms and resistance determinants	
8.5. Target microorganisms and resistance <u>resistance/virulence</u> determinants	China
8.5. Target microorganisms <u>bacteria</u> and resistance determinants	USA
Bacterial species should be chosen considering public health aspects, including the epidemiology of foodborne diseases, and should include both foodborne pathogens and indicator organisms of commensal bacteria.	Brazil

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>To initiate an integrated monitoring and surveillance program can be done by phenotypic testing of representative zoonotic/pathogens (e.g., Salmonella spp. and Campylobacter spp.) and indicator bacteria (e.g., E. coli and Enterococcus spp.) for resistance</u>	
Bacterial species should be chosen considering public health aspects foodborne AMR priorities , including the epidemiology of foodborne diseases, and should include both foodborne pathogens and indicator organisms of commensal bacteria bacteria as national priorities indicate and resources allow .	USA To reflect incremental implementation spirit of the document.
Bacterial Microbial species should be chosen considering public health aspects, including the epidemiology of foodborne diseases, and should include both foodborne pathogens and indicator organisms of commensal bacteria organisms .	International Association of Consumer Food Organizations
<u>For foods of animal origin, Salmonella is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance program. Other foodborne pathogens like Campylobacter should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. Vibrio, Staphylococcus aureus). For foods of plant origin, Salmonella is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance program. Other foodborne pathogens like Listeria, E. coli O157:H7 and Shigella should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. Staphylococcus aureus, Campylobacter, and Bacillus cereus).</u>	China
<i>Salmonella</i> is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance program. Other foodborne pathogens like <i>Campylobacter</i> should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. Vibrio Vibrio, coagulase-positive Staphylococcus).	Colombia Colombia sugiere incluir coagulase-positivo Staphylococcus, ya que no se identifica Enterococcus spp. y es necesario para análisis de brotes asociados a ETA en el país.
<i>Salmonella</i> is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance program. Other foodborne pathogens like <i>Campylobacter</i> should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (via food) (e.g. <i>Vibrio</i>).	Japan To be in line with the scope of the guidelines.
<i>Salmonella</i> is a key foodborne pathogen, found in humans and should therefore animal species and would make a good choice to be included in an integrated monitoring and surveillance program. Other foodborne pathogens like <i>Campylobacter</i> should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. <i>Vibrio</i>).	USA Less prescriptive.
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbor transferable resistance genes. Commensal bacteria such as <i>E. coli</i> and <i>Enterococcus faecium/faecalis</i> spp. should be used as indicators of Gram negative and Gram positive intestinal flora.	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, based on phenotypic testing of a broader range of pathogens and indicator bacteria for resistance, addition of testing for genetic determinants of resistance and mobile DNA elements (e.g. plasmids, transposons), AMR testing of animal/crops pathogens may be used to provide additional information about the selection pressure resulting from AMU</u>	
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbor transferable resistance genes. Commensal bacteria such as <i>E. Escherichia coli</i> and <i>Enterococcus faecium/faecalis spp.</i> should be used as indicators of Gram negative and Gram positive intestinal flora.	China
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbor transferable resistance genes. Commensal bacteria such as <i>E. coli</i> and <i>Enterococcus faecium/faecalis spp.</i> should be used as indicators of Gram negative and Gram positive intestinal flora <u>flora of terrestrial animals.</u>	Japan E. coli and Enterococcus spp. were not isolated from intestinal flora of aquatic animal.
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbor transferable resistance genes. Commensal bacteria such as <i>E. coli</i> and <i>Enterococcus faecium/faecalis spp.</i> should be used as <u>make appropriate</u> indicators of Gram negative and Gram positive intestinal flora	USA
Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may be a public health concern such as ESBL- AmpC and carbapenemase-producing strains and MDR strains.	Australia
Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may be a public health concern such as <u>ESBL-extended spectrum β-lactamase (ESBL)- AmpC and carbapenemase-producing strains and MDR strains.</u>	China
Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may be a public health <u>foodborne AMR</u> concern such as ESBL- AmpC and carbapenemase-producing strains and MDR strains.	USA To keep within Codex scope.
Tests for virulence factors, AMR genes, gene transferability and gene sequencing can also be applied as resources and capacity permits. <u>The risk based selection of target microorganisms may also be influenced by the presence of high priority AMR genes or mobile genetic elements and horizontal gene transfer in a given population. Target microorganisms for aquatic food sources should be determined based on available evidence and risk.</u>	Australia The selection of target microorganisms and associated resistance genes are intricately linked and selection should be based on risk. Australia also suggests an additional sentence including aquatic pathogens or aquatic indicator organisms as these appear to be overlooked; and these should also be based on evidence and risk.
8.6 Laboratories	
<ul style="list-style-type: none"> Isolate, identify, <u>to the species level</u>, type and further characterize target bacteria from the different sample types, by using internationally accepted reference methods or alternatively other analytical methods validated according to internationally accepted validation methodology; 	USA This is a critical requirement in order to appropriately apply most ECOFFs as the interpretive criteria.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Isolate, identify, type and further characterize target bacteria microorganisms from the different sample types, by using internationally accepted reference methods or alternatively other analytical methods validated according to internationally accepted validation methodology; 	International Association of Consumer Food Organizations
<ul style="list-style-type: none"> Be involved Participate in an external quality assurance systems system, including proficiency test testing in identification, typing, phenotypic and genotypic characterization and susceptibility testing of the microorganisms included in the monitoring and surveillance system; 	Australia
<ul style="list-style-type: none"> Be involved in an external quality assurance systems including proficiency test in identification, typing, phenotypic and genotypic characterization and susceptibility testing AST of the microorganisms included bacteria in the monitoring and surveillance system; 	USA Editorial, clarity.
<ul style="list-style-type: none"> Perform antimicrobial susceptibility testing AST using standardized and validated methods (at least phenotypic and selected genotypic methods to confirm selected phenotypes) methods; 	USA Written this implies that AST and genotypic methods should be done on all isolates. This is not a realistic expectation for most countries currently labeled as at Step A or B or even most C.
<ul style="list-style-type: none"> Have access to a national reference laboratory or an international laboratory (e.g. WHO-collaborative WHO or OIE-collaborative center) that can provide technical assistance if necessary. 	Japan In animal sector OIE collaborating centers have functioned as AMR international laboratory as same as WHO collaborative center in human sector.
8.7 Antimicrobial susceptibility testing	
8.7.1 Methods and interpretative criteria	
Susceptibility testing methods (disk diffusion or minimum inhibitory concentration (MIC) methodologies) standardized and validated by internationally recognized organizations such as the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI) should be used to ensure reliable and comparable data.	Healthforanimals EUCAST does not include veterinary isolates. It should not be included.
Quality control (QC) strains of bacteria should be used according to international recommendations e.g. from EUCAST or CLSI. The quality control QC strains of bacteria that are used should be designed to provide QC for all antimicrobial agents tested. The QC strains should be maintained and propagated according to the same recommendations, and results of the QC strains should be used to determine if results for other tested bacteria are valid before reporting the results.	USA Editorial.
Quality control (QC) strains of bacteria microorganisms should be used according to international recommendations e.g. from EUCAST or CLSI. The quality control strains of bacteria microorganisms that are used should be designed to provide QC for all antimicrobial agents tested. The QC strains should be maintained and propagated according to the same recommendations, and results of the QC strains should be used to determine if results for other tested bacteria microorganisms are valid before reporting the results.	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Interpretation of results for disc diffusion or MICs, should also be done according to EUCAST or CLSI standards and should include quantitative results (disk diffusion zone diameters or minimal inhibitory concentrations values) as well as categorization of the isolate (resistant, intermediate or susceptible, wild-type or non-wild type) and the cut off value used for interpretation.	Brazil
Interpretation of results for disc diffusion or MICs, should also be done according to EUCAST or CLSI standards and should include quantitative results (disk diffusion zone diameters with disk content of antimicrobials , or minimal inhibitory concentrations values) as well as categorization of the isolate (resistant or susceptible, wild-type or non-wild type) and the cut off value used for interpretation.	Japan It is necessary to record not only the disk diffusion zone but also the concentration of disk.
Interpretation of results for disc diffusion or MICs, should also be done (1) consistently according to internationally recognized standards such as EUCAST or CLSI standards, as appropriate per country , and should include quantitative results (disk diffusion zone diameters or minimal inhibitory concentrations values) as well as categorization of the isolate (2) (resistant, intermediate or susceptible, wild-type or non-wild type) based on clinical breakpoint and the cut-off / or epidemiological cutoff value used for interpretation. (ECOFF). If appropriate, data interpretations using both clinical breakpoint and ECOFFs can be very useful as temporal AMR trends are analyzed.	USA Change1: Language added for clarity and to emphasize the need for consistency. Change2: Text was added to clarify what interpretive categories are applicable to parenthetical just prior. The last sentence was added to be consistent with the recommendations of AGISAR and those of Simjee et al. (2018) The present and future surveillance of antimicrobial resistance in animals: principles and practices. Microbiol Spectrum 6(4) ARBA-0028-2017
Interpretation of results for disc diffusion or MICs, should also be done according to EUCAST or CLSI standards and should include quantitative results (disk diffusion zone diameters or minimal inhibitory concentrations values) as well as categorization of the isolate (resistant or susceptible, wild-type or non-wild type) and the cut-off clinical breakpoint and/or epidemiological cutoff value (ECOFF) used for interpretation	Healthforanimals EFSA have proposed ECOFF which CLSI have validated through the Vet05 WG. This is documented in the publically available minutes from CLSI.
Quantitative results are also necessary for the analysis of resistance patterns over the time and when retrospective data analysis is needed due to changes in clinical breakpoints or and epidemiological cut off values.	Brazil To harmonize with 8.7.3 using both parameters.
Quantitative results are also necessary for the analysis of resistance patterns over the time and when retrospective data analysis is needed due to changes in clinical breakpoints or epidemiological cut off values ECOFFs.	USA
The use of epidemiological cut off values ECOFFs , as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different origins (e.g. food, animal species). The use of clinical breakpoints may differ between animal species and countries but may be more adequate in case of treatment decisions related to pathogenic bacteria.	USA
The use of epidemiological cut-off values, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different origins (e.g. food, animal species). The use of clinical breakpoints may differ between animal species but may be more adequate in case of treatment decisions related to pathogenic bacteria organisms.	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Detailed information on interpretation of antimicrobial susceptibility test results and quality control can be found in Guideline 3.1 of the OIE Terrestrial Manual and the WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach.	Australia The OIE Terrestrial Manual also has information on interpretation and could be included here.
8.7.2 The panel of antimicrobials for susceptibility testing	
<p><u>To initiate an integrated monitoring and surveillance program include priority antimicrobials that have been ranked as highest priority for human health [e.g. as defined by WHO in the List of Critically Important Antimicrobials for Human Medicine or other relevant antimicrobials that have influence on the selection or co- selection of resistance.</u></p> <p><u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, could include a broader range of priority antimicrobials that have been ranked as critically and highly important for human health [as defined by WHO in the List of Critically Important Antimicrobials for Human Medicine and a broader range of other relevant antimicrobials that have influence in the selection and co-selection of for resistance. Additional antimicrobials that are specified in national risk prioritization exercises.</u></p> <p>The panel of antimicrobials for susceptibility testing should be harmonized as to ensure continuity and comparability of data, and attempts should be made to use the same antimicrobial class representatives across sample sources, across geographic regions, and over time.</p>	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.
The panel of antimicrobials for susceptibility testing should be harmonized as to ensure continuity and comparability of data, and attempts should be made to use the same antimicrobial class representatives across sample sources, across geographic regions, and over time.	Healthforanimals Different countries have different usage patterns. Antibiotic selection should be based on local usage data. Additionally, antibiotics within a class should be selected that would give the best selection of cross-resistance profiling.
The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the volumes that are used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance.	Healthforanimals Antimicrobials not used in veterinary medicine but with the potential for co-selection of resistance due to gene linkage should also be included e.g. chloramphenicol resistance in Salmonella.
The antimicrobials included in the panel should depend on the target bacteria microorganisms and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the volumes that are used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance.	International Association of Consumer Food Organizations
Suggested panel of antimicrobials by bacteria for inclusion for AST can be found at <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach.</i> National OIE and national list of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel.	China

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Suggested panel of antimicrobials by bacteria for inclusion for AST can be found at <i>WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach</i> . OIE List of Antimicrobials of Veterinary Importance and National list of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel.	Japan Animal lists need to be considered to be inclusive and informed by the types of antimicrobial agents when determining which antimicrobial agents to test for.
8.7.3 Concentration ranges of antimicrobials	
The concentration ranges to be used, should ensure that both epidemiological cut-off values ECOFFs and clinical breakpoints when available are included in order to make comparability of results with human data possible. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the QC strain(s) used for each antimicrobial agent.	USA Editorial, and to allow for resource disparities.
8.7.4 Characterization and subtyping of isolates	
Whenever possible characterization of bacterial microbial isolates (genus, species, and additional microbial subtyping) should be done.	International Association of Consumer Food Organizations
8.7.5 Molecular testing	
As resources allow, the use of molecular testing such as polymerase chain reaction (PCR), sanger-sequencing, pulsed-field gel electrophoresis (PFGE), multilocus sequence typing (MLST) or Whole Genome Sequencing (WGS), may contribute to the monitoring of AMR, the detection of resistance genes and epidemiological analysis.	Japan Molecular testing is expensive, so implementation should depend on capacity of each country.
The use of molecular testing such as polymerase chain reaction (PCR), sanger-sequencing Sanger-sequencing , pulsed-field gel electrophoresis (PFGE), multilocus sequence typing (MLST) or Whole Genome Sequencing (WGS), may contribute to the monitoring of AMR, the detection of resistance genes and epidemiological analysis.	USA Editorial – S should be capitalized for Sanger.
The use of molecular characterization such as WGS is also an important tool for the rapid detection of outbreaks, risk factors and epidemic source, investigation of transmission chains, detection of emergence and spread of new drug resistant strains; source attribution by linking to molecular monitoring of pathogen in humans, animals, food and related environment reservoirs reservoirs along the food chain .	China
For example of the use of molecular testing could be useful for the enhanced surveillance and early warning of resistant pathogens of high public health impact such as carbapenemase-producing <i>Enterobacteriaceae</i> .	USA
The application of molecular methods and the interpretation of the information derived from them will require multidisciplinary interpretation, global agreement on analytical and interpretational approaches, laboratory and technical capacity, data management and analytical platform to link epidemiological and microbiological information at national and international level. For appropriate and successful use of molecular surveillance data, national, international and cross-sector agreements on quality standards, analytical schemes and genomic type nomenclature for the bacterial pathogen or resistance determinants under monitoring should be established in collaboration with national and international reference laboratories.	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Training and professional development in bioinformatics and genomic epidemiology should be carried out for public human, animal, and environmental health microbiologists, and epidemiologists and risk managers about analysis, reporting, interpretation and use of integrated genomic epidemiology data.	USA Training for all of these is necessary. The next statement talks about costs being less for whole genome sequencing (WGS). WGS may cost less, but the management and analyses of these data will require the skills noted in this paragraph. This supports the importance of training and development noted above.
In some countries, using WGS costs less than using conventional microbiology, including isolation, detection and molecular typing. Countries without current AMR surveillance programs may consider focusing on WGS in developing surveillance programs. Countries taking this approach should do some surveillance using conventional microbiology to monitor for previously undetected resistance genes. WGS approaches to surveillance are particularly suited to data sharing and there are several international initiatives to collect and share WGS data.	Brazil
In some countries, using WGS costs less than using conventional microbiology, including isolation, detection and molecular typing. Countries without current AMR surveillance programs may consider focusing on WGS in developing surveillance programs. Countries taking this approach should do some surveillance using conventional microbiology to monitor for previously undetected resistance genes. WGS approaches to surveillance are particularly suited to data sharing and there are several international initiatives to collect and share WGS data.	USA The sole use of WGS data has not been recommended by other surveillance or proposed surveillance systems. WGS is useful in addition to traditional AST, but not yet suitable as a sole data source for surveillance. What would be the comparisons? How would other countries compare to this data? To properly conduct WGS, the surveillance system still has to include isolation and identification of the AMR bacterium, thus the cost differential between the “standard” phenotypic approaches and WGS may not be that great, especially when considering the analysis costs.
It is important that laboratories undertaking molecular characterization of isolates have quality assurance programs in place for the wet lab and dry lab components of the analysis. 8.8. Laboratories <ul style="list-style-type: none"> <u>Temperature, time between sample collection and testing, and storage of the samples are important aspects that may influence the results. During transport and storage of the samples measures to maintain sample integrity should be in place (e.g., time, temperature).</u> 	Canada 8.8. Laboratories Add a new bullet (as the last bullet) “Temperature, time between sample collection and testing, and storage of the samples are important aspects that may influence the results. During transport and storage of the samples measures to maintain sample integrity should be in place (e.g., time, temperature).”
9. Surveillance of national antimicrobial sales and use data in animals and crops	
9. Surveillance of national antimicrobial sales and use data in animals and crops	Canada Change this section to Annex II – Elements for Consideration for surveillance of antimicrobial consumption and use data.
9. Surveillance of national antimicrobial sales and use data in animals and crops	Iran Detection of antimicrobial residues can be considered as one of the Key aspects for developing surveillance of antimicrobial sales/use.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Surveillance <u>Collection</u> of national antimicrobial sales and use data in animals and crops	USA Inclusion of sales/use data in an integrated national surveillance system for AMR, though aspirational, is not yet practical in many countries, so not mature enough to include in a Codex guideline. Further, "integration", that is, clearly tying use to AMR along the food chain is very complex and subject to misinterpretation. Edits are made to provide guidance to collect data using less prescriptive language which is more appropriate for current circumstances, and editorial for appropriate grammatical structure.
9.1 Key aspects to consider when developing surveillance of antimicrobial sales/use data in animals and crops	
9.1 Key aspects to consider when developing surveillance of <u>collecting</u> antimicrobial sales/use data in animals and crops	USA Inclusion of sales/use data in an integrated national surveillance system for AMR, though aspirational, is not yet practical in many countries, so not mature enough to include in a Codex guideline. Further, "integration", that is, clearly tying use to AMR along the food chain is very complex and subject to misinterpretation. Edits are made to provide guidance to collect data using less prescriptive language which is more appropriate for current circumstances, and editorial for appropriate grammatical structure.
<u>To initiate an integrated monitoring and surveillance program the basic source can be: Sales data of antimicrobials intended for use in animals and crops collected from manufacturers, import/export, etc.</u> <u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, it could include direct source: Sales data of antimicrobials collected in addition from other sources like wholesalers, retailers, pharmacies, feed mills, other agricultural associations. Competent authorities could explore pilots for collection of antimicrobial use data from farmers, veterinarians, pharmacies, and End-user source: Collection of use data from veterinarian prescription, farmers use data, pharmacies and other sales data.</u> The following aspects should be taken into account when deciding on the approach to collect antimicrobial sales or use data.	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.
The following aspects should be taken into account when deciding on the approach to collect antimicrobial sales or use data AMU	USA
<ul style="list-style-type: none"> The distribution of antimicrobials for use in agriculture (animals and crops) within the country should be mapped and interested parties should be identified (e.g. marketing authorization holders, wholesalers, distribution centers, pharmacist, veterinarians, farmers, importers/exporters); <u>Decide on the type of data to be collected – i.e. sales or use data by animal species and crop type</u> 	Norway

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> • <u>If sales data investigate and describe the antimicrobial distribution system - e.g. from manufacturing or import to end-user including sales/use data providers in order to identifying the data source from where the sales data collected are reliable and is appropriate in terms of the stated objectives of the monitoring system;</u> • <u>If use data by animal species or crop type i investigate which data sources where use data would be available – e.g. farm records, veterinary records, prescriptions (veterinarians, pharmacies) in order to identifying the data source from where the use data collected are reliable and is appropriate in terms of the stated objectives of the monitoring system;</u> 	
<ul style="list-style-type: none"> • The <u>Identification of</u> distribution of antimicrobials for use in agriculture (animals and crops) within the country <u>country</u> and interested parties should be identified (e.g. marketing authorization holders, wholesalers, distribution centers, pharmacist, veterinarians, farmers, importers/exporters); 	USA
<ul style="list-style-type: none"> • The most appropriate points of data collection should be identified and the stakeholders that may provide the data at these points; 	Norway
<ul style="list-style-type: none"> • The <u>Identification of</u> most appropriate points of data collection should be identified and the stakeholders that may provide the data at these points; 	USA
<ul style="list-style-type: none"> • A protocol on the collection of data should be developed to captures qualitative and quantitative information on the antimicrobials; <u>The protocol and the data collection template should be tested in a pilot; the latter in order to test management of the data;</u> 	Norway
<ul style="list-style-type: none"> • A <u>Development of a</u> protocol on the collection of data <u>data</u> to captures qualitative and quantitative information on the antimicrobials; 	USA
<ul style="list-style-type: none"> • The <u>Identification of</u> antimicrobial agents, classes or sub-classes to be included in data reporting, based on current known mechanisms of antimicrobial activity and antimicrobial resistance data; 	USA
<ul style="list-style-type: none"> • The desired technical <u>Technical</u> units of measurement and indicators on antimicrobial consumption or <u>salesor</u> use should be established; 	Norway
<ul style="list-style-type: none"> • The <u>Establishment of</u> desired technical units of measurement and indicators on antimicrobial consumption or use should be established; 	USA
<ul style="list-style-type: none"> • The <u>Identification of the</u> type and number of crops and food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information; 	USA

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>The reporting of antimicrobial use data may be further organized by crop type, animal species, by route of administration (e.g. in-feed, in-water, injectable, oral, intramammary, intra-uterine, topical), by type of use (therapeutic vs non-therapeutic, pest-control in crops), etc.</p>	<p>China</p> <p>The reporting of antimicrobial use data may be further organized by crop type, animal species, by route of administration (e.g. in-feed, in-water, injectable, oral, intramammary, intra-uterine, topical), by type of use (therapeutic vs non-therapeutic, pest-control in crops), etc.</p> <p><u>The AMU data could be collected from:</u></p> <ul style="list-style-type: none"> • <u>A. WHOLESALERS & RETAILERS:</u> <ul style="list-style-type: none"> • <u>a. Sales data–Wholesalers.</u> • <u>b. Sales data–Retailers.</u> • <u>c. Purchase data–Wholesalers.</u> • <u>d. Purchase data–Retailers.</u> • <u>e. Purchase data–Agricultural cooperatives.</u> • <u>B. IMPORTS:</u> <ul style="list-style-type: none"> • <u>a. Import data–Customs declarations-Veterinary products.</u> • <u>b. Import data–Customs declarations-Active ingredients.</u> • <u>C. MARKETING AUTHORISATIONS HOLDERS:</u> <ul style="list-style-type: none"> • <u>a. Sales data–Marketing authorisations holders.</u> • <u>b. Sales data–Registration authorities.</u> • <u>D. VETERINARIANS:</u> <ul style="list-style-type: none"> • <u>a. Sales data-Veterinarians.</u> • <u>b. Veterinary prescriptions data–Sales.</u> • <u>c. Veterinary prescriptions data–Prescriptions.</u> • <u>d. Veterinary prescriptions data –Dispensing.</u> • <u>E. PHARMACISTS:</u> <ul style="list-style-type: none"> • <u>a. Sales data–Pharmacies.</u> • <u>b. Sales data–Farm shops/Agricultural suppliers.</u> • <u>c. Purchase data–Pharmacies.</u> • <u>F. FEED MANUFACTURERS:</u> <ul style="list-style-type: none"> • <u>a. Sales data–Feed mills.</u> • <u>b. Purchase data–Feed mills.</u> • <u>G. MANUFACTURERS:</u> <ul style="list-style-type: none"> • <u>a. Sales data–Industry trade associations.</u> • <u>b. Purchase data–Producer organizations.</u> • <u>H. FARMERS & OTHERS:</u> <ul style="list-style-type: none"> • <u>a. Antimicrobial use data–Farm records.</u> <p><u>Animal species considered to be food-producing animals vary between countries and how this difference could impact the data reported in the future when comparisons of antimicrobial agents used in milligrams by kilograms of live weight needed to understand will be possible. The categories below have been adjusted and contain the following species declared in the template:</u></p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
	<ul style="list-style-type: none"> • <u>A. POULTRY</u> • <u>a. Layers – commercial production for eggs</u> • <u>b. Broilers – commercial productions for meat</u> • <u>c. Other commercial poultry</u> • <u>d. Poultry – backyard</u> • <u>B. CATTLE</u> • <u>a. Cattle</u> • <u>b. Buffaloes (not Syncerus caffer)</u> • <u>C. SHEEP AND GOATS</u> • <u>a. Sheep</u> • <u>b. Goats</u> • <u>c. Sheep and goats (mixed flocks)</u> • <u>D. PIGS</u> • <u>a. Pigs – commercial</u> • <u>b. Pigs – backyard</u> • <u>E. FISH</u> • <u>a. Fish – aquaculture production</u> • <u>b. Fish – fish farmed in fresh water</u>
<ul style="list-style-type: none"> • The Organization of reporting of antimicrobial use data may be further organized by crop type, animal species, by route of administration (e.g. in-feed, in-water, injectable, oral, intramammary, intra-uterine, topical), by type of use (therapeutic vs non-therapeutic, pest-control in crops), etc 	USA
<ul style="list-style-type: none"> • The reporting of antimicrobial use data may should be further organized whenever possible by crop type antimicrobial agent (ideally) or antimicrobial class, animal crop type/animal species, by route of administration (e.g. foliar spray, in-feed, in-water, injectable, oral, intramammary, intra-uterine, topical), by type of use (therapeutic vs non-therapeutic (treatment, control, prevention, pest-control in crops), etc and indicatin (e.g., citrus greening, clinical mastitis, necrotic enteritis prevention) 	International Association of Consumer Food Organizations
9.2 Reporting of the national antimicrobial sales/use data for use in animals	
9.2 Reporting of the national antimicrobial sales/use data for use in animals	<p>Australia</p> <p>Australia recommends deletion of text on the reporting of the national antimicrobial sales/use data for use in animals and make reference to the OIE Codes on collection and reporting of data on sales and use.</p> <p>Australia has concerns that these guidelines are encroaching on the OIE remit for international reporting requirements for antimicrobial sales and use data. There is a risk that national competent authorities with responsibility for collecting and reporting antimicrobial sales and use data will be required to comply with multiple international standards setting bodies. There is currently no international consensus on the methods for collecting, analysing and reporting sales and use data and Codex guidelines are not subject to regular review. Conversely, the OIE has a process in place to review and update standards as needed.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>9.2. Reporting of the national antimicrobial sales/use data for use in animals <u>To initiate an integrated monitoring and surveillance program reporting can be done on overall amount sold for use in animals and crops by antimicrobial class; type of intended use (e.g. therapeutic/growth promotion); antimicrobial use data adjusted by information on estimated animal population size and area of crops, when these information is available. As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, reporting could be on overall amount sold for use in animals and crops by antimicrobial class, separate by type of use (therapeutic/growth promotion) and animal/plant species groups (e.g. terrestrial/aquatic food producing animals/companion animals). Competent authorities could explore voluntary or regulatory options for stratifying sales data to create estimates of sales by animal/plant species. Overall amount used in animals and crops by antimicrobial class, separate by type of use, and species group and route of administration. Antimicrobial use data presented using different indicators (e.g. DDD, DCD).</u></p>	<p>Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.</p>
9.2.1 International guidance on monitoring and surveillance of antimicrobial sales and use data in animals	
<ul style="list-style-type: none"> Continuous collection of antimicrobial consumption data by animal species 	<p>Japan According to AGISAR guidance, to clarify contents.</p>
9.2.2 Antimicrobial quantities (numerator)	
9.2.2. Antimicrobial quantities (numerator)	<p>USA Delete sections 9.2.2-9.3 Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>
To be further developed	USA
<ul style="list-style-type: none"> The minimum data collected should be the weight in kilograms of the active ingredient of the antimicrobial(s) used in food producing animals per year. It is possible to estimate total usage by collecting sales data, prescription data, manufacturing data, import and export data or any combination of these. 	<p>USA Delete sections 9.2.2-9.3 Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>
<ul style="list-style-type: none"> For active ingredients present in the form of compounds or derivatives, the mass of each active entity of the molecule should be recorded. For antimicrobial agents expressed in international units, the factor used to convert these units to mass of active entity should be stated. 	<p>USA Delete sections 9.2.2-9.3 Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animals. 	<p>USA</p> <p>Delete sections 9.2.2-9.3</p> <p>Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>
9.2.3 Animal population (denominator)	
Animal population (denominator)	<p>USA</p> <p>Delete sections 9.2.2-9.3</p> <p>Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>
To be further developed	USA
<ul style="list-style-type: none"> The desired denominator for reporting indicators of antimicrobial consumption or use should be determined in advance. This denominator should reflect the surveillance design and objectives. For example, the animal biomass is appropriate for national sales data, whereas 1,000 animal-days is an example of an appropriate denominator for antimicrobial use data from a sample of farms 	<p>USA</p> <p>Delete sections 9.2.2-9.3</p> <p>Metrics for data collection are still under consideration in countries and discussion and agreement on methodologies are not mature enough to be a part of this Codex guidance.</p>
<ul style="list-style-type: none"> For the estimated animal biomass, that can be exposed to antimicrobials should be calculated. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population; the methodology which has been adopted by other countries outside of the EU (e.g., Canada and Japan). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. 	<p>Japan</p> <p>Japan tried to calculate biomass by the EU method, but it has not adopted that method officially.</p>
<ul style="list-style-type: none"> For the estimated animal biomass, that can be exposed to antimicrobials should be calculated. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population; the methodology which has been adopted by other countries outside of the EU (e.g., Canada and Japan). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. 	USA

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> For the estimated animal biomass, that can be exposed to antimicrobials should be calculated. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population; the methodology which has been adopted by other countries outside of the EU (e.g., Canada and Japan). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. 	Thailand We are of the view that the methodology for calculation should harmonised to be suitable for the quantitative reporting of global antimicrobial use. The surveillance data from different areas, countries or regions can be more easily compared.
<ul style="list-style-type: none"> For the estimated animal biomass, that can be exposed to antimicrobials should be calculated. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population; the methodology which has been adopted by other countries outside of the EU (e.g., Canada and Japan). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals 	USA
<ul style="list-style-type: none"> For sampled farm data, the number of animals and the time they are under surveillance is critical context for reporting antimicrobial use data. Common denominators reported in the literature for sampled farm data include 1,000 animal days or 100 animal days. 	USA
<ul style="list-style-type: none"> The total number of food producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information 	USA
9.2.4 Units of measurement	
9.2.4 Units of measurement	Thailand The units of measurement should harmonised to be suitable for the quantitative reporting of global antimicrobial use. The surveillance data from different areas, countries or regions can be more easily compared.
9.2.4. Units of measurement	USA
To be further developed	USA
9.3 Reporting of the national antimicrobial sales/use data for use in crops	
9.3. Reporting of the national antimicrobial sales/use data for <u>Research needs to better understand potential foodborne AMR from use of antibacterial agents in crops</u>	USA This section is proposed because more research is needed on crops before guidelines for integrated surveillance can be articulated. See General Comments above.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
To be further developed	USA
<ul style="list-style-type: none"> • <u>Baseline information on what antimicrobials are registered</u> Competent authorities and stakeholders determine research gaps and national priorities for use <u>monitoring AMR</u> in which crops. • Studies regarding extent of AMR development from specific antibacterial agent use in the region can be conducted to address data gaps. For example, isolation and identification of total bacterial populations isolated from flower, leaf and soil samples applied with antimicrobial agents can be studied. • Multi-year, local sampling and testing for antimicrobial susceptibility can help assess the extent and distribution of AMR to help determine effectiveness of the antimicrobial agent and development of persistent AMR in the area. • Genetic analysis of isolates to understand the origins and diversity of AMR in bacteria can be explored for utility in bacterial disease management, bacterial strain tracking and informing the limiting of AMR spread in an area. 	USA Proposed new text This section is proposed because more research is needed on crops before guidelines for integrated surveillance can be articulated. See General Comments above.
<ul style="list-style-type: none"> • Collection of amounts sold/used in crops 	USA
<ul style="list-style-type: none"> ○ Option 1: overall amount sold for/used in crops by antimicrobial class, with the possibility to separate by crop type (eg. fruit trees, grains, vegetables); 	USA
<ul style="list-style-type: none"> ○ Option 2: overall amount sold for/used in food and feed crops by antimicrobial class, with the possibility to separate by crop type and specific crops; 	USA
<ul style="list-style-type: none"> ○ Option 3: overall amount sold for/used in food and feed crops by antimicrobial class, with the possibility to separate by crop type and specific crops, and specific disease and pathogen 	USA
<ul style="list-style-type: none"> • Collection of relevant data from farms and agriculture land where waste derived fertilizers and antimicrobials are applied as pest control products; 	USA
<ul style="list-style-type: none"> • Other plausible entry routes of antimicrobials in crop production such as but not limited to land application of biosolids, animal by products and municipal waste; 	USA
<ul style="list-style-type: none"> • Reporting of the national antimicrobial sales/use data for use in crops should consider collecting relevant data from farms and agriculture lands where waste derived fertilizers and antimicrobials as pest control products are applied 	USA
10. Other considerations for the implementation of the monitoring and surveillance program	
10.1 Sampling procedures	
Sampling procedures	Iran National or international standards may be used for sampling procedures.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Samples should be collected by persons authorized to do so (third party accreditation).	Canada This sub-section (first two paragraphs) is duplicative of quality controls identified in the original Section 8. Delete this sub-section. The information in the last paragraph is proposed to be placed in the previous Section 8 (see above).
Samples should be collected by persons authorized or suitably trained persons to do so (third party accreditation).	Japan Third party accreditation" is not feasible.
Samples should be collected by persons authorized to do so (third party accreditation).	USA This should be deleted as it appears to be too prescriptive.
Procedures should be put in place to ensure that collection of samples is carried out in accordance to the defined sampling strategy and to guarantee that traceability, security and quality management are maintained from collection through to analysis and storage.	Canada This sub-section (first two paragraphs) is duplicative of quality controls identified in the original Section 8. Delete this sub-section. The information in the last paragraph is proposed to be placed in the previous Section 8 (see above).
Procedures should be put in place to ensure that collection of samples is carried out in accordance to with the defined sampling strategy and to guarantee that traceability, security and quality management are maintained from collection through to analysis and storage.	USA
Temperature, time between sample collection and testing, and storage of the samples are important aspects that may influence the results. During transport and storage of the samples in the laboratory measures to maintain the cold chain should be implemented.	Canada The information in the last paragraph is proposed to be placed in the previous Section 8.
10.2 Collection and reporting of resistance data	
To ensure appropriate analysis of the integrated surveillance and monitoring program it is important that relevant information about the sampling procedure and the individual samples are collected and recorded in a national central database. The information collected and recorded may differ depending on the step that is designed and specific public health objectives.	Canada Para 1 and 2: The information about reporting (in the first two paragraphs) should be incorporated into Annex III (the original table) as there is a whole section dedicated to analysis and reporting.
To ensure appropriate analysis of the integrated surveillance and monitoring program it is important that relevant information about the sampling procedure and the individual samples are collected and recorded in a national central database. recorded.	USA It may not be practical at the beginning stages of a surveillance system to house a national central database.
The information collected and recorded may differ depending on the step that is designed and specific public health objectives foodborne AMR.	USA Keep within Codex scope.

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>Information for each individual sample should include:</p> <ul style="list-style-type: none"> • General description of the sampling design and randomization procedure • General information to identify the isolate, bacterial specie, serovar, other subtyping information as appropriate (e.g.: Phage type, molecular type, etc. • Specific information about the origin of the sample: food producing animal, plant/crop or food category, country of origin, type of sample, stage of sampling in the food chain, place, sampling, and isolation date, etc. • Specific information about the isolation of the bacteria and the AST: date of testing, specific information about the method, quantitative results (e.g. MICs in mg/L), etc. In the case of qualitative results interpretative criteria should be recorded. It is necessary to report the International standard used for the interpretation of the results. 	<p>Canada</p> <p>Para 3/Bullets. Much information is captured in Section 8 and suggest moving additional information to section 8.</p>
<ul style="list-style-type: none"> • General information to identify the isolate, bacterial specie, serovar, other subtyping information as appropriate (e.g.: Phage type, molecular type), virulence factors, etc. 	<p>China</p>
<ul style="list-style-type: none"> • General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate (e.g.: Phage type, molecular type, etc. 	<p>USA</p>
<ul style="list-style-type: none"> • General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate (e.g.: Phage type, molecular type, etc. 	<p>International Association of Consumer Food Organizations</p>
<ul style="list-style-type: none"> • Specific information about the origin of the sample: food producing animal, plant/crop or plant/crop, food or related environment category, country of origin, type of sample, stage of sampling in the food chain, place, sampling, and isolation date, etc. 	<p>China</p>
<ul style="list-style-type: none"> • Specific information about the origin of the sample: food producing animal, plant/crop crop or food category, country of origin, type of sample, stage of sampling in the food chain, place, sampling, and isolation date, etc. 	<p>USA</p> <p>Codex scope</p>
<ul style="list-style-type: none"> • Specific information about the isolation of the bacteria microbe and the AST: date of testing, specific information about the method, quantitative results (e.g. MICs in mg/L), etc. In the case of qualitative results interpretative criteria should be recorded. It is necessary to report the International standard used for the interpretation of the results. 	<p>International Association of Consumer Food Organizations</p>
10.3 Management of data	
<p>To properly manage test results and data generated through of the integrated monitoring and surveillance program, a database that guarantees security, confidentiality and integrity of data is needed. At national level, one common location of data is preferred, with one database for AMR information and one database for AMU in.</p>	<p>USA</p> <p>Too prescriptive.</p>
<p>The As appropriate the database should allow the appropriate extraction of data when required and for expansion as the integrated monitoring and surveillance system improves.</p>	<p>USA</p> <p>More flexible language.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
Ideally, isolate-level data should be collected and stored. at isolate. level stored (report separately each bacterial species and animal population/food combination)	Australia
Ideally, isolate-level data should be collected and stored. at isolate. level (report separately each bacterial microbial species and animal population/food combination)	International Association of Consumer Food Organizations
10.4 Analysis and reporting of results	
Analysis and reporting of results	Canada This information in this sub-section is suggested to be consolidated with the information in the Table (or Annex III).
<p><u>To initiate an integrated monitoring and surveillance program can be done by sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of quantities of antimicrobials intended for use in animals and crops. Collection of information of different sectors (e.g. humans, animal species, crops, environment), bacterial species, across regions or time, summary of key findings.</u></p> <p><u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, such as descriptive analysis and reporting of AMR data from the food chain and quantities of antimicrobials intended for use in humans, animals and crops. Isolate based data reporting (i.e. no aggregation); identification of sector specific risk/protective factors for AMU or risk/protective factors for AMR could be undertaken; sector specific quantitative epidemiological modelling of risk/protective factors for AMU or risk/protective factors for AMR could be undertaken. Integration of information and statistical modelling across sectors (e.g. humans, animal species, food, crops, environment), across bacterial species, across regions or time, or between use and resistance could be achieved by graphical display of harmonized data. These graphical displays could show multiple surveillance components at the same time (e.g., bacterial resistance in samples collected from several points along the food-chain up to humans, alignment with findings from whole genome sequencing, and relevant AMU practices).</u></p> <p>Reporting of results from the monitoring and surveillance system should be timely and preferably include information for each individual isolate, including information about microbiological methods used for isolation, the identification of the isolate, the bacterial species (serovar), specific information about the sampling (food category, place of sampling, sampling strategy, date of sampling), AST results, etc.</p>	Brazil To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.
Reporting of results from the monitoring and surveillance system should be timely and preferably include information for each individual isolate, including information about microbiological methods used for isolation, the identification of the isolate, the bacterial species (serovar), specific information about the sampling (food category, place of sampling, sampling strategy, date of sampling), AST results, etc	International Association of Consumer Food Organizations

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
When results of PFGE, MLST, WGS or other DNA analysis for an individual isolate are available, tests for genetic linkage and homogeneity can be carried out between the isolate and resistant bacteria isolated from humans, food, agricultural, livestock and aquatic products and environment.	USA This is presumptive. These analyses may be conducted on ALL isolates, not just the resistant ones. From a risk assessor's perspective evaluating data for pre-approval, %susceptible is just as useful as %resistant.
When results of PFGE, MLST, WGS or other DNA analysis for an individual isolate are available, tests for genetic linkage and homogeneity can be carried out between the isolate and resistant bacteria organisms isolated from humans, food, agricultural, livestock and aquatic products and environment.	International Association of Consumer Food Organizations
Results of AMR should be compared with results of AMU so that the along with other data can be used when implementing policies as described in CAC/GL 77 for risk analysis to ensure proper use of antimicrobials help inform appropriate risk management decisions commiserate with the risk.	USA More than AMU affects AMR and the results of monitoring/surveillance data should flow into the CAC/GL 77 risk analysis process to inform risk management decisions
Whenever possible, data from monitoring and surveillance of AMR should be analyzed though a One Health approach, combined with information on AMU in primary production (animals and crops) in national settings, and AMU in human medicine, and also the many food chain exposure pathways among people, animals, crops and their shared environment connecting resident bacterial populations	Japan Clarification based on the scope of these Guidelines. The words "food chain exposure pathways" are used in Section 5.
Whenever possible, data from monitoring and surveillance of AMR should be analyzed though a One Health approach, combined with information on AMU in primary production (animals and crops) in national settings, and AMU in human medicine, and also the many pathways among people, animals, crops and their shared environment connecting resident bacterial microbial populations	International Association of Consumer Food Organizations
10.5 Targeted investigation	
Targeted investigation	Canada Pilot studies or additional surveillance-based research were identified in the Table. Delete this section as these guidelines are not about how to conduct targeted investigations, but rather on monitoring and surveillance.
10.5. Targeted investigation	Japan Overlapping with Section 10.8
Targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g. incorporating real-time "Critical Resistance" Alert Systems.	Brazil There is a need to better clarify "Critical Resistance" Alert Systems

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p>Targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g. incorporating real time “Critical Resistance” Alert Systems.</p>	<p>Canada</p> <p>Pilot studies or additional surveillance-based research were identified in the Table. Delete this section as these guidelines are not about how to conduct targeted investigations, but rather on monitoring and surveillance</p>
<p>Targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g. incorporating real time “Critical Resistance” Alert Systems.</p>	<p>Japan</p>
<p>Targeted Targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed a helpful added source of information at national or local level levels as risk management response to surveillance activities national priorities indicate and actions, e.g. resources allow, incorporating real time “Critical Resistance” Alert Systems.</p>	<p>USA</p> <p>These guidelines provide monitoring/surveillance advice for generating data that would provide inputs into the risk analysis process described under CAC/RCP 77-2011. A risk manager would need to determine risk after evaluation of data through the CAC/RCP 77-2011 process, so risk management options do not appropriately fit in this surveillance guideline. Rather, collection of further data in a targeted way to help inform existing data may be helpful.</p>
10.6 Integrated analysis of results	
<p>Integrated analysis of results</p> <p>Combined analysis of results and data of a program of integrated monitoring and surveillance of antimicrobial resistance in foodborne bacteria comprises the synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system and epidemiological context.</p>	<p>Canada</p> <p>The placement of this section does not flow well. Suggest it be moved to Section 7.2 as a general principle section for integrated analysis. The details of this can be placed and consolidated with the information in the Table (Annex III).</p>
<p>Combined analysis of results and data of a program of integrated monitoring and surveillance of antimicrobial resistance in foodborne bacteria comprises aims to comprise the synthesis synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system and epidemiological context.</p>	<p>USA</p> <p>This is an aspirational statement and we would argue no country is currently doing this now.</p>
<p>Combined analysis of results and data of a program of integrated monitoring and surveillance of antimicrobial resistance in foodborne bacteria bacteria microorganisms comprises the synthesis synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system and epidemiological context.</p>	<p>International Association of Consumer Food Organizations</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<i>Integration of data from foodborne human isolates</i>	
Data from relevant human isolates should include data from those more relevant foodborne pathogens according to national epidemiological information (e.g. Salmonella, Campylobacter) <u>Salmonella, Campylobacter</u> and whenever possible <u>include indicator</u> commensal flora such as <i>E. coli</i> and potentially also Enterococcus <u>Enterococcus because of their ability to develop and disseminate AMR genes to other bacteria.</u> The surveillance of human clinical isolates should not only allow to follow trends in the occurrence of resistance to antimicrobials relevant for treatment but also to follow trends in the occurrence of resistance to other antimicrobials of public or animal health importance, and for the comparison with isolates from the food chain and the environment	USA Clarity
10.7 Detection and evaluation of emerging risks	
This could include the design of monitoring and surveillance system performance indicators and disease prevention metrics for the evaluation of public health benefits of system implementation, including definition of short-, medium-, long term indicators	Canada There seems a need to clarify the intention of this sub-section, because it may be more appropriate for evaluation of the monitoring and surveillance system rather than the identification of emerging risks. Delete this subsection.
This could include the design of monitoring and surveillance system performance indicators and disease prevention metrics for the evaluation of public health benefits of system implementation, including definition of short-, medium-, long term indicators. <u>The AMR risk should be compared within the objectives of monitoring and surveillance according to different data collected, and those with high AMR risk should be paid special attention in the following work.</u>	China
This could include the design of monitoring and surveillance system performance indicators and disease prevention metrics for the evaluation of public health benefits of system implementation, including definition of short-, medium-, long term indicators	Japan The sentence should be rephrased to explain “emerging risks”, “system performance indicators”, “disease prevention matrices” and etc.
10.8 Additional research and targeted investigation	
Additional research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies, point prevalence studies, surveys, etc. should be considered. Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions,	Canada Pilot studies or additional surveillance-based research were identified in the Table. Delete of this section.
Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions,	Australia Duplicative of section 10.5.
11. Evaluation of integrated surveillance programs	
Evaluation of integrated surveillance programs The evaluation of an integrated monitoring and surveillance system promotes the best use of data collection resources and provides assurance that systems operate effectively. Evaluation of systems also provides assurance the data and information reported is robust and surveillance objectives are being met. The steps in developing an evaluation framework include:	Canada Suggest that this information be consolidated and moved to the previous Section 7.4

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><u>To initiate an integrated monitoring and surveillance program can be done by prioritizing which AMR food safety hazard(s) need to be evaluated first. Risk managers/policy makers decide whether to develop a risk profile and conduct risk assessment based on the priority AMR food safety hazards.</u></p> <p><u>As the program increments additional activities could be implemented at a later stage given additional resources and other improvements, such as conducting risk profiles based on the priority AMR food safety hazards as needed. Launching of qualitative or quantitative risk assessments as needed; using monitoring and surveillance information to identify risk management options; using monitoring and surveillance information to evaluate risk management interventions to reduce risk; engaging in risk communication about priority AMR food safety risks. Periodic review and resetting of the risk analysis cycle as monitoring and surveillance data, and new technologies are analyzed and reported. Continuous input of risk assessment information to review and improve monitoring and surveillance as an essential contributor to risk management. Commissioning of ad hoc research projects for risk assessment and surveillance methodological improvement.</u></p> <p>The evaluation of an integrated monitoring and surveillance system promotes the best use of data collection resources and provides assurance that systems operate effectively. Evaluation of systems also provides assurance the data and information reported is robust and surveillance objectives are being met.</p>	<p>Brazil</p> <p>To be consistent with the general comment made by Brazil, that the incremental approach should be included in each component.</p>
12. Risk communication	
<p>As part <u>A program</u> of broader <u>integrated surveillance of foodborne AMR will generate information of interest to multiple stakeholders, including: government risk managers, physicians, veterinarians, farmers, food manufacturers, retailers and consumers. The implementation strategy is developed through an iterative process that feeds into the development of the risk communication plans plan and will necessarily evolve over time. Preliminary research and context analysis should identify the stakeholders and develop effective messages. A plan for national strategies implementation and NAPs leadership should be drawn up. Finally, there are specific requirements continuous evaluation will allow for communicating timely improvements to the results strategy. The timing of ongoing monitoring and surveillance communication is an important consideration as each stage of the program – industry will have different objectives including development of support for the program, consumers maintenance of the program, international organizations etc improvement, of the program and preparation for adverse event reporting.</u></p>	<p>USA</p> <p>Existing language appears to be very limited, identifying a message rather than describing the process, which is what is necessary for a guideline. Broader language summarized from the risk communication section from WHO AGISAR 2017 (http://apps.who.int/iris/bitstream/handle/10665/255747/9789241512411-eng.pdf?sequence=1) is suggested as new text.</p>
<p>The value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans, animals and plants/crops.</p>	<p>Canada</p> <p>It is hard to comprehend this paragraph. Suggest rewording or deleting it.</p>
<p>The value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans, animals and plants/crops.</p>	<p>China</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
<p><u><i>Communication between assessors and managers</i></u> Management must provide clear instructions for the risk issue that is to be analysed, together with the preferred method(s) of characterisation (e.g. person days of illness per year). Assessors must ensure that the managers have reasonable expectations of the assessment and may also advise of other potential information the assessment may provide that would help the management with their decision-making. There should be communication between the risk assessors and risk managers throughout the assessment process to ensure that the assessment is completed in a timely fashion and that the required resources are made available.</p> <p><u><i>Communication between assessors and stakeholders</i></u> It is extremely helpful to widely publicise the intended method of assessment, including model structure and assumptions at the earliest possible opportunity, together with an expression of flexibility in the eventuality of any new information or ideas. This allows stakeholders to provide input, improves transparency of the process and improves support for the assessment and any resultant risk management decision.</p> <p><u><i>Communication between managers and stakeholders</i></u> Risk managers will usually need to advise stakeholders of the intention to perform a risk analysis at the beginning of the project. At this stage, communication with stakeholders is an important opportunity to gather political and scientific support for the risk assessment, as well as a data gathering exercise. When the risk assessment has been completed, it is advisable to make the report publicly available with a reasonable comment period to ensure that there are no large errors in the assessment or additional data available. The World Wide Web is an excellent means for maximising the availability of the assessment and may include downloadable, self-contained versions of the risk assessment. Publishing comments received, together with any responses from the risk assessment and risk management teams, underlines the transparency of the process. These can be included in the final risk analysis document that explains the results of the risk assessment together with the risk management decision that has been made.</p>	
<p>The value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans, animals and plants/crops</p>	<p>USA</p>
<p>The value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce use of <u>the need for</u> antimicrobials and preserve the effectiveness of antimicrobial agents in humans, animals and plants/crops.</p>	<p>Healthforanimals Risk communication is about creating understanding about the necessity to reduce need for antibacterial through application of the other mentioned means: better hygiene, husbandry, nutrition vaccination, etc.</p>

SPECIFIC COMMENTS	
Section/paragraph	Member/Observer/ rationale
13. Training	
13. TrainingCapacity building – data collection, analysis, laboratory testing, and reporting	Canada There seems a need to clarify what the training covers. The Code of Practice is considered a good place to include training about practices to minimize and contain AMR. The contents of this section may suggest an alternative heading, i.e., “Capacity building – data collection, analysis, laboratory testing, and reporting.”
A tiered approach to the implementation of this guidance at the national level is recommended. Programs should aspire to use effectively available resources, technical capability and take advantage of potential for cross-sector integration while seeking continuous improvement. <u>Training involving all the relevant professional organizations, regulatory authorities, the antimicrobial and other relevant industries, research institutes, professional associations and other approved users is of importance to ensure consumer safety and, therefore, the protection of public health.</u>	China