CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/AMR 17/5/6-Add.1**

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Fifth Session

PROPOSED DRAFT GUIDELINES ON INTEGRATED SURVEILLANCE OF ANTIMICROBIAL RESISTANCE

Comments at Step 3 (Replies to CL 2017/82-AMR)

Comments of Albania, Australia, Brazil, Canada, China, Colombia, Cuba, Indonesia, Kenya, Russian Federation, Thailand, United States of America, IACFO, Health for Animal, IMS, CI, FAO, ICGMA and OIE

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/82-AMR issued in September 2017. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

Explanatory notes on the appendix

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

ANNEX I

Comments on the Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance

GENERAL COMMENT

GENERAL COMMENTS	MEMBER/OBSERVER
ok.	**Albania**
• Australia supports an integrated surveillance approach for foodborne AMR to inform decision making and containment activities. • Australia supports the improved clarity of purpose provided in section 2 of the guidelines. • Australia supports the revised definition of integrated approach, recognising that surveillance and monitoring of antimicrobial use (AMU) and analysis of AMU data for risk analysis is detailed in the OIE Codes. • Australia supports the continued leadership of the OIE regarding monitoring the use of antimicrobials in food producing animals and surveillance of AMR in live animals. • Australia supports the inclusion of 'monitoring' in the title of the guidelines, in conjunction with an alignment of surveillance and monitoring definitions with the OIE and WHO (see specific comments below). • Australia supports discussion of the inclusion of examples to illustrate the step-wise approach. The examples would be best placed in an annex to the guidelines. • Australia supports discussion of the collection and analysis of data on the use of antimicrobials, with a focus on crops and environment to avoid duplication of the OIE Code.	**Australia**
Brazil congratulates the EWG coordinators for their work and would like to express that Brazil supports the recommendations, however emphasizes that examples to illustrate the stepwise approach should be included in a Codex information document, and not as part or annex of these Guidelines. Brazil would also like to submit its specific comments on the proposed draft, for the paragraphs as listed below.	**Brazil**
1. Canada considers the document should be stand alone and emphasize the mandate of Codex (while referring to other relevant documents). 2. A better definition of integrated surveillance is needed. The integrated surveillance definition could be structured as (i) integrated sampling and design and (ii) integrated analysis and reporting. 3. Intersection with risk assessment and risk analysis. Canada supports the intersection between surveillance and risk assessment/risk analysis. However, the document would benefit on more details on how risk assessment/risk analysis will inform surveillance, particularly because risk assessment is focused on a specific question asked by risk managers, rather than a general question. 4. Scope: (i) To align with the Code of Practice document and other efforts on antimicrobial resistance, Canada would like to emphasize the focus of the integrated monitoring and surveillance on medically important antimicrobial agents. (ii) How to incorporate human antimicrobial use and resistance into integrated surveillance is an area requiring more input. (ii) Crops and environment – Canada recognizes the importance of crops and the environment and as such, Canada considers these should be in scope but ranked according to national priorities of potential hazards. 5. The current definitions for "Monitoring of antimicrobial resistance" and "Surveillance of antimicrobial resistance" need to be expanded upon for clarity and should be referenced. It should be recognized that the mandate of the organization conducting the activity may affect the decision as to whether surveillance vs. monitoring is implemented. Technical Detailed Comments Purpose of these guidelines Bullets on Risk Analysis and Risk Communication are broad and should be further expanded since other bullets contain specific information. Use of this document Suggest mentioning specifically the OIE chapters for ease of access.	**Canada**

GENERAL COMMENTS	MEMBER/OBSERVER
Framework China suggests that the proposed guidelines can be divided into a main body and an appendix. The main content of this guidelines should focus on monitoring and surveillance of antimicrobial resistance (AMR) and the use of antimicrobial agents (AMU). The appendix includes bacteria, antimicrobials, AMR determinants, sampling, and examples for stepwise approach, etc., which can be updated regularly. The concept of "Integration" "Integration" should include two aspects, monitoring and surveillance of antimicrobial resistance (AMR) and the use of antimicrobial agents (AMU), and each aspect includes coordinated and systematic designing, sampling, testing, data analysis and reporting. Monitoring and surveillance should appear simultaneously in the title. According to the need, these two words can appear singly or simultaneously in the text. Nodes for monitoring and surveillance The nodes for monitoring and surveillance should be around the food chain of animal and plant origin. For example, food chain of animal origin covers feed, food animals (farms), animal products (slaughterhouses), processing plants, supermarkets, etc. Target microorganisms The target microorganisms should mainly focus on foodborne pathogens; The target microorganisms for animals and crops should be separately specified. For example, for foodborne pathogens from animal sources, the target microorganisms should be *Salmonella*, *Campylobacter* and *Yersinia* for swine, *Salmonella* and *Campylobacter* for chicken, *Escherichia coli* O157, *Salmonella* and *Campylobacter* for bovine, and *Salmonella*, *Campylobacter* and *Vibrio parahaernolyticus* for aquatic products; The indicator organisms (e.g. *Escherichia coli* and *Enterococcus*) can be included in an integrated monitoring and surveillance programme, but the results should not be exaggeratedly interpreted; Suggest delete "and carbapenemase" in paragraph 4 in section 10.6. Index of monitoring and surveillance for target microorganisms Bacterial resistance phenotype and virulence are the major index of monitoring and surveillance for target microorganisms. The results of specific resistance determinants of bacteria are only for reference. The panel of antimicrobials for susceptibility testing The antimicrobials for susceptibility testing should be the common antimicrobial agents for each foodborne pathogen. The list can be placed in the appendix. It is not suitable to copy the list of WHO AGISAR Guidelines which includes the common antimicrobial drugs for pathogenic bacteria that are related to hospitals and communities.	**China**
Colombia, agradece el trabajo realizando por el GTe y desea realizar la siguientes observaciones generales • En diversos apartes del documento se menciona el enfoque de ¨Una Salud¨, mientras que en otros se utiliza el término ¨Salud Única¨, se sugiere estandarizar el término para todo el documento. Adicionalmente se sugiere aclarar cuál es el alcance del Codex en el marco del enfoque de ¨Una Salud¨. • En términos generales se observan problemas de traducción al español en el contexto del documento. • Se sugiere evaluar la pertinencia del término ¨seguimiento¨, el cual se utiliza en diferentes apartados del documento, ya que se considera que el término ¨monitoreo¨ es más apropiado. • Se sugiere revisar el alcance de las palabras ¨bacterias¨ y ¨microorganismos¨ en el contexto del documento, ya que el espectro del segundo es más amplio y se refiere no solamente a las bacterias sino a todo el universo de microorganismos susceptibles de desarrollar resistencia.	**Colombia**
Cuba apoya en principio este documento por la importancia que tiene en ayudar a los gobiernos en el diseño y la implementación de programas de monitoreo y vigilancia de la RAM a través de los alimentos a lo largo de la cadena alimentaria a nivel nacional.	**Cuba**

GENERAL COMMENTS	MEMBER/OBSERVER
1) “Stepwise Approach” is a very important principle in these guidelines. Given the diverse situations in member countries, flexibility in designing stepwise approach should be allowed. Therefore, Japan proposes to clarify that stepwise approach shown in section 9 is an example. 2) In order to avoid inconsistency with the OIE Terrestrial Animal Health Code, each element concerning animal origin in “10. Design of monitoring and surveillance programmes” should be compliant with OIE Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes.	**Japan**
Kenya appreciates the work presented by the EWG chaired by the Netherlands and co-chaired by Chile, China and New Zealand for member countries to comment on the Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance. We do take note of the report by the EWG conclusions and recommendations. We however reserve to comment on the draft standard at this level until the plenary session during the meeting. However, we support the progression of the work.	**Kenya**
Thailand would like to thank chair and co-chair for taking consideration our comments previously submitted. We have considered in detail of the Proposed draft Guidelines on integrated surveillance of antimicrobial resistance (CX/AMR 17/5/6) and appreciate the opportunity to provide comments for further discussion in the 5th Session of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR5) as follows; 1. Thailand support the inclusion of “monitoring and” in the title of the Guideline. This term reflect all activities as defined in the scope. 2. In item 3. Use of this document, Thailand is still of the view that this draft Guidelines should include the list of the documents relevant and related to antimicrobial resistance (AMR) and antimicrobial use (AMU) from the specialized international bodies. Moreover, some sections need further clarification and should be clearly defined to specific issue in the document such as the relevant section of WHO GLASS food borne pathogen; this is to make the draft easy to read and follow. 3. Thailand would like the TFAMR to defined only definitions which are used in the draft Guidelines. For the consistency, we would like to request the TFAMR to harmonize the meaning of the identical definitions that appear in this draft document and proposed draft revision of CAC/RCP61-2005. 4. Thailand is of the opinion that there are too many principles in this document. We suggested that the common and proximity principles could be grouped together. In order to clearly understand, some broad principles should added sub-principles. A clear set of principles will give us immediate focus and clarity on the Codex work on AMR in the future. 5. To ensure all actors involved in the section of Regulatory framework and roles, Thailand would like to stress once again that it is necessary to add the medicated feed manufacturer in this section.	**Thailand**
Consumers International (CI) would like to express our appreciation to the Netherlands, New Zealand, China, and Chile for the excellent work in pulling together this draft. CI supports the draft but would like to make a few recommendations for where it could be strengthened.	**Consumers International** *Category: SUBSTANTIVE*
FAO appreciates the work done by the working group and the great progress made on this develop this first draft of the surveillance guidance document. We welcome the recommendation for further discussions in a number of areas and based on feedback form our country level activities support that there needs to be further discussion and consideration of monitoring and surveillance on food crops, aquaculture systems and the environment.	**FAO**
The International Asociation of Consumer Food Organizations (IACFO) is grateful for this opportunity to comment on the Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance (the draft surveillance guidelines), and thanks the working group, in particular the co-chairs, for bringing together this important document. We agree with the conclusions of the Electronic Working Group as summarized in paragraph 8. We commend the working group for improving and widening the scope of the draft surveillance guidelines to cover the monitoring and surveillance of AMR all along the food chain, including foods of animal and plant origin and the environment, and the use of antimicrobials in animals and crops, although additional attention is needed to ensure that the widened scope is reflected in all sections. We also recommend that the scope be further expanded to explicitly cover additional points along the food chain, such as in food processing.	**International Association of Consumer Food Organizations**

GENERAL COMMENTS	MEMBER/OBSERVER
We generally suggest that further consideration be given to substituting “microbial” and “microbe” for “bacterial” and “bacteria” throughout the document, including in sections 1, 6, 7, 9, 10, and 13. It would be helpful to include more examples on how the stepwise approach can address sectors other than animal production. For example, sales data for use of antimicrobial agents on crops and in processing should also be collected, in addition to those sold for/used in animals. The report of the Physical Working Group on Antimicrobial Resistance (CX/CAC 17/49/12 Add. 2) clearly states that effective AMR surveillance systems need to be cross-sectoral, with surveillance conducted utilizing data from crops as well as from humans, animals, and food. Similarly, the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011) includes both food-producing animals and crops in its statement about the use of antimicrobial agents providing a potentially important risk factor for selection and dissemination of AMR microorganisms and determinants. The Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance also state that surveillance of use of antimicrobial agents should, to the extent possible, include all antimicrobial agents used in food-producing animal and crop production, and that ideally such surveillance should provide data per animal species or crop. Although the quantity of antimicrobials used for crop production is calculated to be relatively low in comparison to that used in livestock production [cite 5], there is interest in expanding the use of antimicrobials on crops [cite 6], and such uses may contribute to the development of resistance. Sources cited: (5) Food and Agriculture Organization of the United Nations, “The FAO Action Plan on Antimicrobial Resistance 2016-2020,” Rome, 2016. (6) For example, in January 2016 the U.S. Environmental Protection Agency (EPA) received a request to grant an emergency exemption allowing the use of more than 1 million pounds of the medically important antimicrobial oxytetracycline as a pesticide to suppress citrus greening disease in Florida (81 FR 4624), which it granted in March 2017 (82 FR 13245); and then in April 2017 the petitioner requested that the EPA permanently register oxytetracycline to approve its ongoing use as a pesticide on a variety of citrus crops (82 FR 17256). We disagree with excluding biocides from the scope of this document. We are not aware of any scientific justification for excluding biocides, since “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…” [see cite 1 below]. Biocides are used at various points along the food chain, including as disinfectants, food preservatives, in animal husbandry (as feed preservatives and for specific applications such as 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. It contains 470 experimentally verified resistance genes, which cover 41 biocides, 20 metals, and 23 “other chemical compounds” that are toxic to bacteria. [cite 2] Researchers worldwide have pointed to the need to include biocides in efforts to address antimicrobial resistance.[cite 3] Furthermore, we note that excluding biocides from the scope of the document would be inconsistent with the approach taken in the Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) [cite 4], which does not exclude biocides. Sources cited: (1) 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. (2) 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. (3) 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.	

GENERAL COMMENTS	MEMBER/OBSERVER
(4) Codex Alimentarius Commission, Ad Hoc Codex Intergovernmental Task Force on Antimicrobial Resistance, Fifth Session Agenda Item 4, CX/AMR 17/5/5, September 2017. Finally, we recommend that further consideration be given to ensuring that appropriate conflict of interest safeguards are in place when deciding to establish, establishing, implementing, and monitoring a surveillance policy or programme, consistent with the conclusions of a recent World Health Organization consultation.[cite 7] Sources cited: (7) World Health Organization, "Addressing and Managing Conflicts of Interest in the Planning and Delivery of Nutrition Programmes at Country Level," Geneva, 2016.	
The International Meat Secretariat (IMS) appreciates the opportunity to offer our comments concerning Step 3 on the Proposed Codex Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance (CL 2017/82/OCS-AMR). IMS members are committed to protecting the health and well-being of their animals and to producing high quality, safe meat for consumers. Our members also promote responsible and judicial antimicrobial drug use practices. IMS offers the following general considerations for core competencies for Codex to consider when developing guidelines for integrated surveillance and monitoring of foodborne antimicrobial resistance (AMR): • Adhere to a science-based approach when developing a monitoring and surveillance system for AMR. • Focus the analysis of surveillance data on identifying trends rather than simply collecting and reporting bulk data. This focus toward trends will allow for better benchmarking to achieve continued improvements. • Ensure data security and confidentiality for all personal information collected in the process. • Reference existing Codex and international texts where advice exists, and do not attempt to recreate overly prescriptive measures for an integrated AMR surveillance system. • Utilize a risk-based approach, whenever possible, to develop monitoring and surveillance guidelines for AMR. Focus only on those functions, as risk management and risk communication are separate functions. • Consider the ecology of bacterial resistance as well as any sources of resistance that may have contaminated food products. • Operate the integrated surveillance system guidelines within the scope of foodborne AMR, utilizing a One Health approach for the overall risk management of AMR. • Consider the use of national lists or consensus-based guidelines to prioritize antimicrobial drugs for surveillance and monitoring. Scope of Integration: As stated in the draft document, the scope of the Codex guidelines for AMR surveillance is "to cover the design and implementation of an integrated monitoring and surveillance program for AMR and antimicrobial use along the food chain, including animals and crops. These guidelines do not cover design and implementation of monitoring and surveillance of AMR and antimicrobial use in humans." Scientific justification for including crops has not been provided. Data gaps currently exist for the information on the antimicrobial classes and application methods for crops as well as evidence of the transfer of resistance determinants between bacteria associated with crops. Much of the necessary information for antimicrobial drug use in crops is currently not available to use in designing an effective and efficient antimicrobial resistance surveillance system for crops. Adequate information on antimicrobial drug use in crops, target bacteria, and use patterns should be allowed to develop before including crops in the Codex surveillance program for foodborne. Nevertheless, the discussion on the addition of plants in the Code of Practices document should be reflected in the Surveillance document. Additionally, there are instances in which the draft AMR surveillance guidelines refer to the adequacy of human health infrastructures and reporting that is clearly outside of the agreed upon scope of the document for the surveillance of foodborne AMR as well as outside of the Codex food safety mandate. The work of Codex should be aligned; but, not duplicative of the work of other international organizations, such as the World Organization for Animal Health (OIE), and the World Health Organization (WHO).	**International Meat Secretariat**

SPECIFIC COMMENTS

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
PROPOSED DRAFT GUIDELINES FOR THE INTEGRATED [MONITORING AND] SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE	
PROPOSED DRAFT GUIDELINES FOR THE INTEGRATED ~~[MONITORING AND]~~ MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE	**Thailand** Thailand support the inclusion of "monitoring and" in the title of the Guideline. This term reflect all activities as defined in the scope *Category: SUBSTANTIVE*
PROPOSED DRAFT GUIDELINES FOR THE INTEGRATED [MONITORING AND] SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE	**International Association of Consumer Food Organizations** We agree with including monitoring in the title of the Guidelines. *Category: SUBSTANTIVE*
1.Introduction	
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. The political Declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 commits member countries to developing multi-sectoral national action plans that involve all stakeholders within a "One Health" approach and to improve national systems of monitoring and surveillance of antimicrobial resistance and the use of antimicrobials[1].	
	USA Paragraph 1 – We do not understand what footnote 1 at the end of the paragraph adds and suggest deletion *Category: TECHNICAL*
	USA • The United States congratulates the eWG, and especially the co-chairs, for a well-written, comprehensive document to address antimicrobial resistance (AMR) surveillance that took into consideration the many comments submitted. • The United States' comments address those areas that we believe are written to a more aspirational level than what current scientific understanding can support, and therefore, a Codex document, should espouse. • While it is important to consider the various sources of foodborne AMR within the CAC/GL 77 risk analysis process, it is not appropriate to attempt to address all risks from all sources in this surveillance guidance. It is important for Codex, and Codex members, to prioritize.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	• In addition, we believe the TFAMR should refer to existing Codex and other international standards where advice exists, such as with residue avoidance, food hygiene, and animal feed (See Codex Code of Practice on Good Animal Feeding: http://www.fao.org/docrep/012/i1379e/i1379e06.pdf). • It is a resource challenge to develop a national surveillance system for well-described risks from foodborne AMR. The United States believes it is premature to develop Codex guidance for integrated surveillance of foodborne AMR in poorly defined areas such as crops and the environment without further scientific data [See "Review of Antimicrobial Resistance in the Environment and Its Relevance to Environmental Regulators", Singer, et. al. (2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5088501/]. • As Codex is based on science- and risk-based principles, the TFAMR should await the results from the request for scientific advice in areas where there are data gaps or limited data, such as potential risk to human health of foodborne AMR due to antimicrobial use on crops. • Adequate information on the antimicrobials, target bacteria, food commodities, use patterns, and other agroecological parameters is critical to the design of effective and efficient surveillance systems. This information is currently lacking for antimicrobial use on crops. Among the areas where data gaps exist are: o Information on the antimicrobial classes and application methods used on crops o Types of crops and agricultural settings where antimicrobials may be used o Information on the selection and dissemination of resistant bacteria associated with antimicrobial use on crops o Evidence of the transfer of resistance determinants between bacteria associated with crops

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	○ Evidence of a causal link for human foodborne illness due to antimicrobial resistant plant pathogens • While antimicrobial use (AMU) is an important factor for resistance development, the development and spread of AMR does not just involve the use of antimicrobial drugs. Connecting information regarding what antimicrobial agents were used on the farm, what resistance developed, what resistance may have already been present, what resistance survived the process of slaughter and/or processing, and what resistance may have contaminated food products derived from an animal or plant is complex. Risk communication from results of a surveillance system must be careful to consider the ecology of resistance and other external sources that could have contaminated food products. • There are many pathways among people, animals, and the environment connecting resident bacterial populations in one population or setting to those in other populations or settings. The ability of bacteria to move from one setting to another, sometimes over large geographic distances and among the different populations, makes it difficult to know with certainty where resistant strains of bacteria originated. Bacteria have the ability to share genetic material in a variety of ways so it is important for any information that comes in through surveillance to be fed into the risk analysis process described in CAC/GL 77-2011 to sort out the complexities for effective risk management strategies. • It is appropriate to focus on foodborne AMR for this guidance, which is within Codex scope and the established objectives and terms of reference of the TFAMR. There are references to AMU data collection throughout the document, but it is only described for on-farm AMU data. The Task Force should consider whether articulating on-farm AMU data collection efforts in this document is prudent, in light of the fact that OIE has existing consensus-driven standards that are reviewed and updated annually, and the potential for what is put in the Codex guidelines to become outdated.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	In addition, AMU in humans also contributes to antimicrobial drug resistance and clinical prescribing practices play a role in the development of AMR. There needs to be coordination regarding human and animal AMU data sources for a truly One Health approach. • A step-wise approach may be useful, but steps should be described in ways that are helpful for resource-constrained countries and can be flexible given their priority foodborne AMR risks. Even high resource countries have not been able to implement complex integrated surveillance plans and flexibility needs to be incorporated in a Codex document to allow countries to adapt to changing science and resource priorities. ○ • The Task Force will need to address harmonizing definitions and terminology across both the surveillance and code of practice documents at some point as the documents are further developed.
A monitoring and surveillance programme for tracking changes in the AMR of bacteria throughout the food chain, combined with epidemiological information from humans and data on the use of antimicrobials (AM) in humans and animals, is an essential component of a comprehensive national food safety system.	
A monitoring and surveillance programme for tracking changes in the AMR of ~~bacteria throughout the food chain,~~ bacteria **at defined points of the food chain eg: at farm, at slaughter, at retail,** combined with epidemiological information from humans and data on the use of antimicrobials (AM) in humans and animals, is an essential component of a comprehensive national food safety system.	**Australia** Rationale: The use of the term 'throughout the food supply chain' lacks the clarity and specificity required for harmonisation and integration of monitoring and surveillance activities
A monitoring and surveillance programme for tracking changes in the AMR of bacteria throughout the food chain, combined with epidemiological information from ~~humans~~ humans, animals, and other sectors, and data on the use of antimicrobials (AM) in humans and animals, is an essential component of a comprehensive national food safety system.	**USA** Rationale: A comprehensive national system needs to include epidemiological data beyond human data and antibiotic use data.
A monitoring and surveillance programme for tracking changes in the AMR of ~~bacteria~~ microbes throughout the food chain, combined with epidemiological information from humans and data on the use of antimicrobials (AM) in humans and throughout the food chain including in animals, crops, and food processing, is an essential component of a comprehensive national food safety system.	**International Association of Consumer Food Organizations**
~~A monitoring and surveillance programme for tracking changes in the AMR of bacteria throughout the food chain, combined with epidemiological information from humans and data on the use of antimicrobials (AM) in humans and animals, is an essential component of a comprehensive national food safety system.~~ A monitoring and surveillance programme for tracking changes in the AMR of bacteria throughout the food chain, combined with epidemiological information from humans and data on the use of antimicrobials (AM) in humans, animals and plants and monitoring in the environmental, are essential components of a comprehensive national food safety system.	**OIE**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Each country should design and implement a programme for monitoring and surveillance of foodborne AMR and monitoring of use of AMs "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 counties and sectors.	
Each country should design and implement a programme for monitoring and surveillance of foodborne AMR and monitoring of use of AMs "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 counties and sectors.	**FAO** The repeated use of "along the food chain" does not fully reflect the complex and non-linear nature of the food chain and its multiple linkages and inter-relationships, particularly in the context of AMR. We suggest that the Task Force considers using terms in addition to "along the food chain", e.g. "in the food chain" or "associated with the food chain" etc, depending on the context and to illustrate the non linearity where appropriate..
Monitoring and surveillance information on AMR along the food chain provides an essential input to risk assessment and decisions by risk managers on control measures to minimise any public health risks due to this exposure pathway. New scientific knowledge should be incorporated in monitoring and surveillance programmes as it becomes available so as to enhance the utility of existing information and data. Design and implementation of programmes should also evolve as AMR policies change at the national and international level.	
Monitoring and surveillance information on AMR along the food chain provides an essential input to risk assessment and decisions by risk managers on control measures to minimise any public health risks due to ~~this exposure pathway~~**AMR microorganisms and their resistance determinants**. New scientific knowledge should be incorporated in monitoring and surveillance programmes as it becomes available so as to enhance the utility of existing information and data. Design and implementation of programmes should also evolve as AMR policies change at the national and international level.	**Australia** Rationale: The public risk arises due to the consequences associated with resistance rather than the exposure pathway. *Category: SUBSTANTIVE*
Monitoring and surveillance information on AMR along the food chain provides an essential input to risk assessment and decisions by risk managers on control measures to minimise any public health risks due to this ~~exposure~~ consequence pathway. New scientific knowledge should be incorporated in monitoring and surveillance programmes as it becomes available so as to enhance the utility of existing information and data. Design and implementation of programmes should also evolve as AMR policies change at the national and international level.	**ICGMA** The exposure to commensal bacterial, antibiotic resistant or not, is not equal to understanding the consequence of an infection that could lead to treatment failure. The Taskforce should focus more on consequence pathways instead of just exposure. An exposure that can be treated is a lesser concern than consequence of antibiotic resistant bacterial infection that leads to treatment failure. *Category: SUBSTANTIVE*
Monitoring and surveillance information on AMR along the food chain provides an essential input to risk assessment and decisions by risk managers on control measures to minimise any ~~public~~ human health risks due to this exposure pathway. New scientific knowledge should be incorporated in monitoring and surveillance programmes as it becomes available so as to enhance the utility of existing information and data. Design and implementation of programmes should also evolve as AMR policies change at the national and international level.	**OIE** *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
2. Purpose of these guidelines	
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance programmes for food-borne AMR along the food chain at the national level. Such programmes are a fundamental part of national strategies and plans to minimize foodborne AMR. The information generated from these programmes provides essential inputs to:	
These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance programmes for food-borne AMR along the food chain at the national level. Such programmes are a fundamental part of national strategies and plans to minimize foodborne AMR. The information generated from these programmes provides essential inputs ~~to~~to **risk analysis**:	**Brazil** *Category: SUBSTANTIVE*
Estas directrices han sido concebidas para ayudar a los gobiernos en el diseño y la aplicación de los programas de seguimiento y vigilancia de la RAM transmitida por los alimentos a lo largo de la cadena alimentaria a nivel nacional. Dichos programas constituyen una parte fundamental de los planes y las estrategias nacionales que buscan reducir al mínimo la RAM transmitida por los alimentos. La información que generan estos programas ofrece aportes esenciales para el Análisis de Riesgos, con respecto a los siguientes temas:	**Colombia** Todos los ítems mencionados responden o aportan a alguno de los tres componentes del AR, por tanto no debería mencionarse este como ítem independiente. *Category: TECHNICAL*
• **Risk analysis**	
Risk analysis of foodborne antimicrobial resistance	**Australia** *Category: SUBSTANTIVE*
~~Risk analysis~~	**Brazil** *Category: SUBSTANTIVE*
~~El análisis de riesgos~~	**Colombia** *Category: TECHNICAL*
• **Assessing trends in occurrence of food borne AMR and AMR determinants (resistant clones, plasmids or genes)**	
Assessing trends in occurrence of food borne AMR and AMR determinants (resistant clones, plasmids or genes) • Setting public health goals related to AMR	**Consumers International** Section 2 Purpose of these guidelines, CI recommends that an additional bullet “Setting public health goals related to AMR” be included in this section. Justification: While setting public health goals could be included under risk analysis like most of the other bullets, it is a specific task for which public health monitoring is needed. *Category: SUBSTANTIVE*
• **Providing epidemiological information in case of outbreaks and in incidents of AMR in humans**	
~~Providing epidemiological information in case~~ Investigation of outbreaks and in incidents of AMR in humans	**Australia** *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Providing epidemiological information in case of outbreaks and in incidents of AMR infections in ~~humans~~ humans, to support targeted, risk based management decisions.	**FAO** In developing awareness on AMR there has been a lot of confusion amongst consumers at to what is resistant. Therefore throughout the text suggest it is important to clarify what is AMR where appropriate. In this case suggest inclusion of the word 'infections' after AMR. However it is also suggested to make the link here to risk: "Providing epidemiological information to support targeted, risk based management decisions" *Category: TECHNICAL*
• **Providing data for assessing the impact of control measures at different parts of the food chain in mitigating foodborne risks to consumers**	
~~Providing data for assessing~~ Assessing the impact of control measures at different parts of the food chain in mitigating foodborne risks to consumers	**Australia** *Category: SUBSTANTIVE*
• **Availability of information for assessment of risks to animal and plant health**	
~~Availability of information for assessment of~~ Assessing the risks to animal and plant health	**Australia** *Category: SUBSTANTIVE*
Availability of information for assessment of risks to animal ~~and~~ [and plant ~~health~~health]	**ICGMA** ICGMA does not support developing guidelines for monitoring AMR in plants at this time. While we recognize that plants/crops are included within the scope of the guidelines, we do not believe sufficient data currently exists on the contribution of antimicrobials use in plants to AMR to allow the pWG to develop monitoring and surveillance guidelines in a manner consistent with Codex's high bar for scientific evidence and risk-based standards. We encourage the Taskforce to wait for the results of requested scientific advice, and avoid work on areas where data gaps exist like in plants. Should sufficient data be made available or presented through this scientific review, we would support revisiting the bracketed text. *Category: SUBSTANTIVE*
• **Guiding and evaluating risk management decisions on more effective or new control measures, either regulatory or non-regulatory**	
Guiding and evaluating risk management decisions ~~on more effective~~ result of evaluation or new control measures, either regulatory or non-regulatory	**OIE** *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
• **Providing data inputs to epidemiological studies, food source attribution studies and other operational research**	
EProviding data inputs to epidemiological pidemiological studies, food source attribution studies and other operational research	**Australia** *Category: SUBSTANTIVE*
• **Risk communication**	
The guidance provided in this document will contribute to design and implementation of National Action Plans (NAP) that make the best use of available resources at the national level, with the goal of continuous enhancement as more technical capability, data and funding becomes available. As such, these guidelines will assist in promoting a step-wise approach to design and implementation in different countries, both for resistance to, and use of AMs.	
The guidance provided in this document will contribute to design and implementation of National Action Plans (NAP) that make the best use of available resources at the national level, with the goal of continuous enhancement as more technical capability, data and funding becomes available. As such, these guidelines will assist in promoting a step-wise approach to design and implementation in different countries, both for resistance to, and use of AMsNAPs.	**Australia** *Category: EDITORIAL*
La orientación brindada en este documento ayudará a diseñar e implementar Planes los programas de Acción Nacional (PAN) seguimiento y vigilancia de la RAM transmitida por los alimentos a lo largo de la cadena alimentaria para aprovechar al máximo los recursos disponibles a nivel nacional, con el objeto de mejorarlos continuamente a medida que se cuente con más fondos, más datos y mayor capacidad técnica. Así, estas directrices serán de utilidad para promover un enfoque gradual para el diseño y la implementación de dichos planes programas en los distintos países, tanto en relación con la resistencia a los antimicrobianos como con respecto a su uso.	**Colombia** El objetivo del documento es “ayudar a los gobiernos en el diseño y la aplicación de los programas de seguimiento y vigilancia de la RAM transmitida por los alimentos a lo largo de la cadena alimentaria a nivel nacional” lo cual difiere del diseño e implementación de los Planes de Acción Nacionales para la RAM. No obstante cabe aclarar que las orientaciones si pueden apoyar en la implementación o desarrollo de acciones enmarcadas en el plan de acción nacional para todo lo demás.
The guidance provided in this document will contribute to design and implementation of National Action Plans (NAP) 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. As such, these guidelines will assist in promoting a step-wise approach to design and implementation in different countries, both for resistance to, and use of AMs.	**USA** Rationale: Science should inform enhancements of national plans. *Category: TECHNICAL*
The guidance provided in this document will contribute to design and implementation of National Action Plans (NAP) that make the best use of available resources at the national level, with the goal of continuous enhancement as more technical capability, data and funding becomes available. As such, these guidelines will assist in promoting a step-wise stepwise approach to design and implementation in different countries, both for resistance to, and use of AMs.	**FAO** Stepwise appears in both hyphenated word and non-hyphenated forms in the text. Suggest to harmnize throughout. *Category: EDITORIAL*
The guidance provided in this document will contribute to design and implementation of National Action Plans (NAP) that make the best use of available resources at the national level, with the goal of continuous enhancement as more scientific evidence, technical capability, data and funding becomes available. As such, these guidelines will assist in promoting a step-wise approach to design and implementation in different countries, both for resistance to, and use of AMs.	**ICGMA** As noted in other comments related to plants, our understanding of AMR is still evolving. These guidelines should recognize this fact and the fact that new scientific evidence is and will continue to emerge. *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
3. Use of this document	
	Thailand Use of this document, Thailand is still of the view that this draft Guidelines should include the list of the documents relevant and related to antimicrobial resistance (AMR) and antimicrobial use (AMU) from the specialized international bodies. Moreover, some sections need further clarification and should be clearly defined to specific issue in the document such as the relevant section of WHO GLASS food borne pathogen; this is to make the draft easy to read and follow. *Category: EDITORIAL*
Application of these guidelines should be in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005)[2]. Design and implementation aspects of these guidelines should specifically take into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) as well as taking into account other relevant Codex texts including: *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013).	
Application of these guidelines should be in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005)[2]. Design and implementation aspects of these guidelines should specifically take into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) as well as taking into account other relevant Codex texts including: *Principles and Guidelines for National Food Control Systems* (CAC/GL ~~82-2013).~~ 82-2013) whenever appropriate.	**USA** Rationale: The document should be flexible for countries to adopt practices as appropriate for their national conditions. *Category: TECHNICAL*
These guidelines should also be used in conjunction with those already developed by other international standard-setting organisations and international bodies especially the WHO-AGISAR "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach" and relevant chapters of the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code.	
These guidelines should also be ~~used~~ read in conjunction with ~~those already developed by~~ Codex Guideline 77 - Risk Analysis for Foodborne Antimicrobial Resistance and other ~~international standard-setting organisations~~ relevant Codex texts and ~~international bodies especially~~ relevant Chapters of the OIE Terrestrial and Aquatic Animal Health Codes. In addition the WHO-AGISAR guideline "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach" ~~and relevant chapters of the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code~~can also be considered.	**USA** Rationale: Codex texts should be read in conjunction with other standards developed through transparent processes of review and consensus by Member Countries such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e.,Codex, OIE, and the International Plant Protection Convention (IPPC)]. Expert-derived technical recommendations may also be considered where relevant. The WHO uses an expert group without Member State review. Codex guidelines, which carry trade implications, should not give trade status to what is in the WHO document, but rather note that the information can be considered. *Category: TECHNICAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
These guidelines should also be used in conjunction with ~~those already developed by~~ Codex Guideline 77 and other ~~international standard-setting organisations~~ relevant Codex texts and ~~international bodies especially~~ relevant chapters of the OIE Terrestrial and Aquatic Animal Health Code, the WHO-AGISAR guideline, "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach" ~~and relevant chapters of the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code~~may also be considered.	**ICGMA** It is critical that Codex texts be read in conjunction with one another. In addition to Codex standards, only other international standards developed in a manner consistent with Codex process and procedures (e.g., based on sound science and developed transparently) should be referenced. In this case, we have concerns about the WHO reference as WHO uses expert bodies to drive technical recommendations that may not be considered by member states or developed in a transparent manner. Thus, they should be considered, but members states should only be directed to use OIE and Codex standards. *Category: SUBSTANTIVE*
These guidelines should also be used in conjunction with those already developed by other international standard-setting organisations and international bodies especially the WHO-AGISAR "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach" and ~~relevant chapters of the~~ OIE standards published in the Terrestrial Animal Health Code (2017) in particular Chapters 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programs and 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents in food-producing animals and in the Aquatic Animal Health ~~Code.~~ Code (2017) 6.3 Monitoring of the quantities and usage patterns of agents used in aquatic animals, 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programs fort aquatic animals	**OIE** *Category: TECHNICAL*
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a step-wise approach to programme design and implementation at the national level. Identification and implementation of priority baseline activities should be followed by enhancements as the national situation permits. A step-wise approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AM use, adequacy of human health care infrastructure and reporting, availability of food consumption data and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a step-wise approach to programme design and implementation at the national level. Identification and implementation of priority baseline activities should be followed by enhancements as the national situation permits. A step-wise approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AM use, ~~adequacy~~ availability of human ~~health care infrastructure and reporting~~health-data, availability of food consumption data and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**USA** Rationale: Human health care infrastructure is beyond the scope of Codex. *Category: TECHNICAL*
National AMR scenarios are likely to vary between countries and these guidelines should be used to foster a step-wise approach to programme design and implementation at the national level. Identification and implementation of priority baseline activities should be followed by enhancements as the national situation permits. A step-wise approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AM ~~use~~use food animal and plant production as well as humans, adequacy of human health care infrastructure and reporting, availability of food consumption data and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**FAO** Propose to indicate what it is that we need AM use data - which sectors? *Category: TECHNICAL*

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 step-wise approach to programme design and implementation at the national level. Identification and implementation of priority baseline activities should be followed by enhancements as the national situation permits. A step-wise approach to monitoring and surveillance should take into account broader capacity issues e.g. availability of information on AM use, adequacy of human health care infrastructure and reporting, availability of food consumption data and ~~agriculture~~ animal and plant production data, and cross-sector laboratory proficiency and quality assurance.	**OIE** *Category: EDITORIAL*
Information provided from monitoring and surveillance of AMR along the food chain should be combined with information on the amounts and types of antimicrobial agents that are used to best inform risk management decisions.	
Information provided from monitoring and surveillance of AMR along the food chain should be combined with information on the amounts and types of antimicrobial agents that are used to best inform risk management decisions~~.~~ While these guidelines are aimed at national level action, countries may consider creating multi-national or regional surveillance system to share laboratory, data management and other resources	**Consumers International** CI recommends that an additional paragraph be added at the end of this section. “While these guidelines are aimed at national level action, countries may consider creating multi-national or regional surveillance system to share laboratory and other resources.” Justification:While the focus of this document is to provide guidance on national action plans, it may be helpful to mention the potential benefits of multi-national or regional efforts. Countries may choose to share laboratory and data management efforts to reduce the needed resources.
4. Scope	
These guidelines cover the design and implementation of an integrated monitoring and surveillance program for AMR and antimicrobial use (AMU) along the food chain, including animals and crops.	
These guidelines cover the design and implementation of an integrated monitoring and surveillance program for AMR and antimicrobial use (AMU) along the food chain~~, including animals and crops~~.	**Australia** Rationale: Australia questions the inclusion of live animals in the scope of these guidelines. The intention of integrated surveillance is joining systems rather than duplicating activities. The inclusion of live animals appears to be duplication of the OIE Standards and current AMR activities. The scope should remain with the food sector.
After Paragraph 1, add a paragraph: The monitoring and surveillance programme should focus on foodborne pathogens which have risks to human.	**China**
These guidelines cover the design and implementation of an integrated monitoring and surveillance program for foodborne AMR and antimicrobial use (AMU) along the food chain, including animals and crops.	**USA** Rationale: The scope of work for the Task Force (and Codex) is foodborne AMR. The rest of the sentence beyond food chain is duplicative. Scientific justification for including crops has not been provided.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
These guidelines cover the design and implementation of an integrated monitoring and surveillance ~~program~~ programme for AMR and antimicrobial use (AMU) along the food chain, including ~~animals~~ food from animal (terresterial and ~~crops.~~ aquatic) and plant origin.	**FAO** Created by merging other changes together
These guidelines cover the design and implementation of an integrated monitoring and surveillance program for AMR and antimicrobial use (AMU) along the food chain, including ~~animals and~~ animals, crops, and food processing.	**International Association of Consumer Food Organizations** Also see our general comments about expanding scope to explicitly cover additional points along the food chain such as in food processing; and our disagreement with excluding biocides. While many countries have not yet developed robust systems for surveillance of AMR in crops and the environment, or in processing, these areas constitute potentially important sources of AMR that may affect human and animal health. Their inclusion in the guidelines is in keeping with the One Health approach, and provides an important framework that can be further refined as additional scientific data become available. Moreover, the stepwise approach adopted by the guidelines allows countries to prioritize surveillance of antimicrobial use in crops, the environment, and processing based on the tools and data available at the national and local level. Therefore, existing data and implementation gaps should not serve as a barrier to inclusion of crop and environmental surveillance in the guidelines.
These guidelines cover the design and implementation of an integrated monitoring and surveillance program for AMR and antimicrobial use (AMU) along the food chain, including animals and ~~crops~~plants.	**OIE**
These guidelines do not cover design and implementation of monitoring and surveillance of AMR and AMU in humans.	
~~These~~ Though these guidelines do not cover design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system would be informed by data, trends and epidemiology regarding foodborne AMR illness in humans.	**USA** Rationale: An understanding of the AMR foodborne bacteria causing AMR foodborne illness in humans is necessary to inform what the priorities are for foodborne AMR surveillance in food products. An integrated system needs to be informed by data from ill humans.
A monitoring and surveillance programme for AMR and AMU along the food chain within the context of overall risk management of AMR (One Health approach) will include design elements, analysis of data and reporting that are common to, and integrated with AMR monitoring and surveillance systems for human and animal health, as well as environmental monitoring	
A monitoring and surveillance programme for AMR and AMU along the food chain within the context of overall risk management of AMR (One Health approach) will include design elements, analysis of data and reporting that are common to, and as appropriate integrated with AMR monitoring and surveillance systems for human and animal health, as well as relevant environmental monitoring,	**USA** Rationale: The focus of this TFAMR should be to give advice on building foodborne AMR surveillance. It is too simplistic to state everything can be integrated.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	"As appropriate" and "relevant" are added because there are different samples, methodologies, and bacteria to appropriately test in the environment, different animal species, and people. Everything is not comparable and capable of integration, but all data needs to be put in context and considered.
A monitoring and surveillance programme for AMR and AMU along the food chain within the context of overall risk management of AMR (One Health approach) will include design elements, analysis of data and reporting that are common to, and integrated with AMR monitoring and surveillance systems for human and animal health, as well as environmental monitoring,	**FAO** The words surveillance systems and surveillance programmes seemed to be used interchangable throughout the document. The differences should be defined, or all references should be made to one or the other wording. Also programme not program...both versions appear in the text
Reporting of data to international organisations and use of information generated from global monitoring and databases are highly desirable aspects of integrated monitoring and surveillance at the national level..	
Reporting of data to international organisations and use of information generated from global monitoring and databases are highly desirable aspects of integrated monitoring and surveillance at the national level.	**Canada** Scope Paragraph 4. Suggest text addition: "Reporting of standardized/harmonized data to international organisations…" The goal should be to strive for comparable data for international reporting.
Reporting of data <u>generated through national surveillance and monitoring programmers</u> to international organisations and <u>in return the</u> use of information generated from global monitoring and databases are highly desirable aspects of integrated monitoring and surveillance at the national level.	**FAO** Edited to clarify the connection with national level surveillance activities
AMs used as biocides, including disinfectants, are excluded from the scope of these guidelines	
AMs used as biocides, including disinfectants, are excluded from the scope of these guidelines~~.~~<u>. In circumstances where monitoring and surveillance of biocides are undertaken, the design and implementation should be broadly consistent with these guidelines to facilitate comparability of data and analysis.</u>	**Australia** Rationale: Australia agrees that antimicrobials used as biocides, including disinfectants, are outside the scope of these guidelines. However, if monitoring and surveillance of biocides are undertaken by countries, then these activities should be broadly consistent with these guidelines. Australia suggests inclusion of an additional sentence that reflects this for consistency of approach to surveillance and monitoring activities which will facilitate the comparability of data with particular regard to co-selection of resistance determinants.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~AMs~~ Antimicrobials used ~~as~~ asviricides, de-wormers, coccidiostats (including ionophores), and biocides, including disinfectants, are excluded from the scope of these guidelines.	**USA** Rationale: The focus should be on antibacterials here and excluding these other items *Category: TECHNICAL*
AMs used as biocides, including disinfectants, are excluded from the scope of these ~~guidelines~~guidelines except where there is evidence that their use contributes to the spread of resistance to medically important antibiotics.	**Consumers International** CI recommends that the final sentence with respect to biocides be modified as follows (addition underlined): AMs used as biocides, including disinfectants, are excluded from the scope of these guidelines except where there is evidence that their use contributes to the spread of resistance to medically important antibiotics. Justification: There is growing evidence that the use of biocides in food processing can co-select for bacteria that are resistant to medically important antibiotics. Whole Genome Sequencing (WGS) can be used to look for linkages between biocide use and resistance to antimicrobial agents so adding biocide resistance to surveillance can be fairly straightforward when WGS is used. A risk-based approach to surveillance as proposed in the draft should not ignore a known risk. *Category: SUBSTANTIVE*
~~AMs used as biocides, including disinfectants, are excluded from the scope of these guidelines.~~	**International Association of Consumer Food Organizations** See our general comment about the lack of scientific justification for excluding biocides, including disinfectants; and that excluding biocides would be inconsistent with the Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005). *Category: SUBSTANTIVE*
5. Definitions	
Add a definition for "AMR determinant".	**China**
5. Definitions	**Thailand** Thailand would like the TFAMR to defined only definitions which are used in the draft Guidelines. For the consistency, we would like to request the TFAMR to harmonize the meaning of the identical definitions that appear in this draft document and proposed draft revision of CAC/RCP61-2005.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
5. Definitions	**FAO** Definitions will need to be harmonized across all codex AMR texts. *Category: EDITORIAL*
5. Definitions	**International Association of Consumer Food Organizations** It would be helpful to list the terms being defined in alphabetical order. *Category: EDITORIAL*
5. Definitions Antimicrobial resistance (AMR): The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species. Biocide: [definition to be developed]	**International Association of Consumer Food Organizations** A definition for "antimicrobial resistance" should be added, consistent with the definition in the Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005). A definition of "biocide" should also be developed and included. *Category: SUBSTANTIVE*
One Health approach: **An internationally-recognised approach to designing and implementing programmes, policies, legislation and research on AMR in which multiple sectors communicate and work together to achieve better public health outcomes (WHO reference)**	
An internationally-recognised approach to designing and implementing programmes, policies, legislation and research on AMR in which multiple sectors communicate and work together to achieve better public health outcomes (WHO reference)	**Australia** Definitions need to be harmonised across Codex texts including CX/AMR 17/5/5 Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance *Category: SUBSTANTIVE*
One Health approach: should be re-defined, considering human, animal and environment at the same time.	**China**
One Health approach:	**Thailand** This definition needs further elaboration of working area in order to be consistent with existing WHO definition. *Category: TECHNICAL*
~~An internationally-recognised approach to designing~~ A collaborative, multi-sectorial and ~~implementing programmes~~trans-disciplinary approach - working at the local, ~~policies~~regional, ~~legislation~~ national and ~~research on AMR in which multiple sectors communicate and work together to achieve better public~~ global levels with the goal of achieving optimal health ~~outcomes (WHO reference)~~outcomes, recognizing the interconnection between people, animals, plants, and their shared environment.	**USA** Rationale: The definition is edited for consistency with the definition in the Code of Practice. *Category: TECHNICAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
An internationally-recognised approach to designing and implementing programmes, policies, legislation and research on AMR in which multiple sectors communicate and work together to achieve better public health outcomes (WHO reference)	**Consumers International** One Health: CI recommends that this be clarified to mention human, animal, and environmental health, which are usually included in definitions of “One Health”. *Category: SUBSTANTIVE*
One Health approach:	**FAO** The One Health Approach is often referred to as a concept and is broader than AMR. It is also about achievingor maintianling helath in sectors other than public health such as animal health and ecosystem health and promotes addressing problems in a holistic manner. This definition falls short on a number of these aspects. Is there a need to define One Health is this document and suggest the Task Force consider capturing the conceptrual aspects in para 1 of the introduction. *Category: SUBSTANTIVE*
An ~~internationally-recognised approach~~ internationally-recognized collaborative and trans-disciplinary approach, working at the local, regional, national, and global levels, with appropriate conflict of interest safeguards, to designing and implementing programmes, policies, legislation and research on AMR in which multiple ~~sectors~~ sectors, recognizing the interconnecton between people, animals, plants, and their shared environment, communicate and work together to minimize the development and spread of antimicrobial resistant organisms and achieve ~~better~~ optimal public health outcomes (WHO reference)	**International Association of Consumer Food Organizations** We note that the definitions in this document, and in the Proposed Draft Revision of the Code of Practice to Contain and Minimize Antimicrobial Resistance, should be consistent. For example, the definition of the “One Health” approach is not consistent between those two documents. Furthermore, whenever collaborative approaches are suggested, it is important to ensure that appropriate conflict of interest safeguards are included. A recent WHO consultation concluded that Member States have duty to ensure that undue influence, either actual or perceived, for interests other than the public good is not exerted on individuals or institutions responsible for public decision-making, in order not to affect integrity and public trust. Our suggested revision integrates elements from both proposed definitions and addresses conflict of interest concerns. *Category: SUBSTANTIVE*
~~An internationally-recognised approach to designing and implementing programmes, policies, legislation and research on AMR in which multiple sectors communicate and work together to achieve better public health outcomes (WHO reference)~~Involving coordination among numerous international sectors and actors, including human and veterinary medicine, agriculture, finance, environment and well-informed consumers (Global action plan definition).	**OIE** *Category: TECHNICAL*
Antimicrobial agent:	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Any substance of natural, semi-synthetic or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganisms by interacting with a specific target (ref. CAC/GL 77-2011)	
Antimicrobial agent:	**FAO** In the course of FAO activities with the food and agriculture sector we have received feedback that the definition in the Codex text is not clear enough for it to be understood that it does not include all forms of antimicrobials (biocides, disinfectants, organic acids, plant extracts etc). thus consideration should be given to adding clarity to the definition as it relates to Codex texts overall, It is already a step foreward that the Scope has clearly indicated that biocides are excluded. Some other definitions under consideration in other fora also indicate what is included such a definition e.g. Use G7, G7 – CVOs Second Forum – AMR – 5 October 2017, definition (http://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf) 'naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity to kill or inhibit the growth of micro-organisms at concentrations attainable in vivo. The term antimicrobials is a collective for anti-virals, anti-bacterials (i.e., antibiotics), anti-fungals, and anti-protozoals
Any substance of natural, semi-synthetic or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific ~~target~~ target. The term antimicrobial is a collective for antiviral, antifungal, and antiprotozoal agents. (ref. CAC/GL 77-2011)	**International Association of Consumer Food Organizations** The definition of "antimicrobial agent" in the Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) has an additional helpful sentence clarifying that the term antimicrobial includes antiviral, antifungal, and antiprotozoal agents, that should be added, both for clarification and harmonization with the definition in the Code.
Priority antimicrobial agents: **Antimicrobial agents prioritized as being a public health concern. e.g. the WHO list of critically important antimicrobials.**	
Antimicrobial agents prioritized as being a public health concern. e.g. the WHO list of critically important antimicrobials[3].	**Australia** Comment: Australia suggests inclusion of country specific lists in the example.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Rationale: Consistent with Table 1. Priority antimicrobials and foods as defined at the national level are included in Step 1 of Table 1. In circumstances where countries do not have a list of priority antimicrobial agents, then the WHO list can be used a guide.
Antimicrobial agents prioritized for monitoring as being a public health concern. ~~e.g.~~ considering the WHO list of critically important antimicrobials[3]~~.~~, national and international data, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways.	**Brazil** *Category: SUBSTANTIVE*
Priority antimicrobial agents: The priority antimicrobial agents should primarily consider the list of antimicrobials used for animals and plants in OIE and each country.	**China**
Antimicrobial agents prioritized as being ~~a~~ of concern to public health concern. e.g. National lists or the WHO list of critically important antimicrobials[3].	**USA** Rationale: Some countries have their own lists appropriate for their unique national needs and conditions that take precedence over the WHO list. Pathogens, AMU, and AMR may vary by country and countries need to assess risks based on their national priorities. *Category: TECHNICAL*
~~Priority antimicrobial agents:~~	**Consumers International** CI recommends that this term be modified or removed since it is not a term used in the WHO list of critically important antimicrobials. The word “priority” is used with respect to “highest priority critically important antimicrobials” and “high priority critically important antimicrobials.” The draft Code of Practice document includes the term “medically important antimicrobials” which are defined by WHO as “Antimicrobial classes used in human medicine, and therefore listed on the WHO CIA List where they are categorized according to specified criteria, as “important”, “highly important” or “critically important” for human medicine. Categorization criteria, definitions for the categories and a complete list of medically important antimicrobials are available on the WHO website. “ Source - WHO Guidelines On Use Of Medically Important Antimicrobials In Food-Producing Animals *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Antimicrobial agents prioritized as being a public health concern. e.g. the WHO list of critically important antimicrobials[3].~~	**Consumers International** CI proposes removing this definition or modifying it to match language used in the WHO CIA list. *Category: SUBSTANTIVE*
~~Antimicrobial agents prioritized as being a public health concern. e.g. the WHO list of critically important antimicrobials[3].~~ Medically Important Antimicrobials: Antimicrobial agents important for therapeutic use in humans as determined by risk assessment."	**ICGMA** This aligns with the definition from the Proposed Draft Code of Practice. Some countries have their own list and/or utilize risk assessment to determine inclusion or exclusion. The World Health Organization (WHO) list is not risk assessment based or a consensus list. It is important that Codex's documents reflect its commitment to the application of risk assessment to inform its work and its consensus based process. Some countries have national lists that use risk assessment and determined certain drugs to be important for treating bacterial infections in people. *Category: SUBSTANTIVE*
Antimicrobial agents prioritized as being a ~~public~~ human health concern. e.g. the WHO list of critically important antimicrobials[3].	**OIE** *Category: EDITORIAL*
Antimicrobial agents prioritized as being a public health concern. e.g. the WHO list of critically important antimicrobials[3] and the OIE list of antimicrobials of veterinary importance regarding animal health..	**OIE** *Category: TECHNICAL*
Hazard: **A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.**	
A biological, chemical or physical agent in, or condition of, food with the *potential* to cause an adverse health effect.	**Brazil** Brazilian comment: This definition is currently under revision by Codex. *Category: SUBSTANTIVE*
A biological, chemical or physical agent in, or condition of, food with the *potential* to cause an adverse health effect~~.~~. For the purpose of these guidelines, the term "hazard" means AMR microorganisms and/or determinant(s) in/on food with the potential to cause an adverse health effect.	**Japan** Rationale: CAC/GL 77-2011 para. 13 refers to "hazard" as "AMR microorganisms and/or determinant(s)." While maintaining the Codex definition of "hazard" throughout Codex, a specific definition of "hazard" for the purposes of these draft guidelines should be in line with CAC/GL 77-2011. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Hazard~~:	**ICGMA** see next comment. *Category: SUBSTANTIVE*
~~A biological, chemical or physical agent in, or condition of, food with the *potential* to cause an adverse health effect.~~	**ICGMA** Hazard is already defined in the Codex procedural manual. Reference may be made, but this document should only define those terms specific to the document. *Category: SUBSTANTIVE*
Risk-based approach: **For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance programme along the food chain that is informed by data and scientific knowledge on the likely level of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.**	
For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance programme along the food chain that is informed by data and scientific knowledge on the likely level of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health animal, and plant health.	**USA** Rationale: Risks should be defined for this document to include the One Health approach.
For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance programme along the food chain that is informed by data and scientific knowledge on the likely ~~level~~ occurance of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.	**FAO** The use of the word 'level' suggests quantification not just occurrence which may not be feasible *Category: TECHNICAL*
Integrated approach to monitoring and surveillance: **For the purpose of these guidelines, a fully integrated approach to the design and implementation of a monitoring and surveillance system includes:**	
the bullet point 1 should include AMU.	**China**
~~For the purpose of these guidelines, a fully integrated approach to the design and implementation of a monitoring and surveillance system includes:~~	**USA** *Category: TECHNICAL*
For the purpose of these guidelines, ~~a fully~~ a integrated approach to the design and implementation of a monitoring and surveillance system includes:	**FAO** The qualification of the word 'integrated' with 'fully' is not necessary and just adds unclarity *Category: EDITORIAL*
• The coordinated and systematic sampling, testing, analysis and reporting of AMR along the food chain	
The coordinated and systematic sampling, testing, analysis and reporting ~~of~~ of **foodborne** AMR along the food chain	**Brazil** *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~The coordinated and systematic sampling, testing, analysis and reporting of AMR along~~ Tracks changes in the ~~food chain~~antimicrobial susceptibility of foodborne bacteria, Combined with data on the use of antimicrobials in humans and animals, and epidemiological data on various sources of resistance, provides information for the risk analysis process and is an essential component of a comprehensive national food control system. Promotes and protects public health by providing information to risk managers about bacterial resistance trends, how resistant infections differ from susceptible infections, and the impact of interventions designed to limit the spread of resistance.	**USA** Rationale: The description for integrated surveillance is aspirational but not practical. Codex should give countries advice on what can actually be done. Even high-resource countries such as the United States cannot do what is written here. It is much too simplistic to say we can aggregate data from all sources, collate, and then inform risk management advice across ALL sectors. *Category: TECHNICAL*
• Alignment and harmonisation of sampling, testing, analysis and reporting methodologies and practices in humans, animals, plants and the environment to the greatest extent practical	
~~Alignment and harmonisation of sampling, testing, analysis and reporting methodologies and practices in humans, animals, plants and the environment to the greatest extent practical~~	**USA** *Category: TECHNICAL*
• Integrated analysis of all monitoring and surveillance data and other information on AMR and AMU so as to inform effective risk management across all sectors	
Integrated analysis of ~~all~~ monitoring and surveillance data and other information on AMR and AMU so as to inform effective risk ~~management across all sectors~~ management	**Canada** *Category: EDITORIAL*
~~Integrated analysis of all monitoring and surveillance data and other information on AMR and AMU so as to inform effective risk management across all sectors~~	**USA** *Category: TECHNICAL*
~~Integrated~~ Combined analysis of all monitoring and surveillance data and other information on AMR and AMU so as to inform effective risk management across all sectors	**FAO** Suggest it is best to not include words being defined in a definiton to avoid circularity
Monitoring of antimicrobial resistance: **The systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of antimicrobial resistance related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity.**	
Monitoring of antimicrobial resistance:	**Australia** Comment: Australia suggests aligning the monitoring and surveillance definitions with those of the OIE Terrestrial and Aquatic Animal Health Code and the WHO definition of public health surveillance. http://www.oie.int/index.php?id=169&L=0&htmfile=glossaire.htm http://www.who.int/topics/public_health_surveillance/en/ Rationale: These guidelines reference and are intended to be used in conjunction with the OIE Codes and the WHO-AGISAR but have quite different definitions of surveillance and monitoring.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	The OIE and WHO places a focus on surveillance being systematic, continuous and ongoing and the OIE defines monitoring with a focus on the intermittency of observations to detect changes in health status of populations. The focus of the definitions in these draft guidelines is rather on the presence or absence of pre-defined risk mitigation activities. There is no definition of activities that are ad hoc or intermittent in nature which could potentially encompass monitoring activities in the retail food space, including cross-sectional surveys.
need to be re-defined.	**China**
Monitoring of antimicrobial resistance:	**USA** Hazard – Suggest deleting the definition. Rationale: It is already defined in the Codex Procedural Manual and it is better to define terms specific to this document here.
~~The systematic, continuous or repeated, measurement, collection, collation, validation, analysis~~ Surveillance and ~~interpretation of antimicrobial resistance related data in defined populations when these activities~~ monitoring – Active (targeted) surveillance and monitoring are ~~not associated with a pre-defined risk mitigation plan or activity~~core parts of national AMR surveillance programmes. Passive surveillance and monitoring may offer additional information. Cooperation between all Member Countries conducting AMR surveillance should be encouraged. Surveillance and monitoring of AMR is necessary to: assess and determine the trends and sources of AMR in bacteria; detect the emergence of new AMR mechanisms; provide the data necessary for conducting risk analyses as relevant to animal and human health; provide a basis for policy recommendations for animal and human health; provide information for evaluating antimicrobial prescribing practices and for prudent use recommendations; assess and determine effects of actions to combat antimicrobial resistance.	**USA** Monitoring of AMR and Surveillance of AMR - The United States suggests consistency with other international fora. Another possibility is to quote the purpose from OIE Ch. 6.7 as:
Surveillance of antimicrobial resistance: **The systematic, continuous or repeated measurement, collection, collation, validation, analysis, interpretation and timely dissemination of antimicrobial resistance related data from defined populations when these activities are associated with a pre-defined risk mitigation plan or activity.** ***Note: These data will likely be used in a dynamic manner in the planning, implementation and evaluation of risk mitigation actions.***	
need to be re-defined.	**China**
~~Surveillance of antimicrobial resistance:~~	**USA**
~~The systematic, continuous or repeated measurement, collection, collation, validation, analysis, interpretation and timely dissemination of antimicrobial resistance related data from defined populations when these activities *are* associated with a pre-defined risk mitigation plan or activity.~~	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Rationale: It is unclear where the definition for "monitoring of AMR and surveillance of AMR are from and it may be useful to use agreed-to text from an existing reference.
6. Principles	
Add a principle: Foodborne pathogens should be the primary focus for monitoring and surveillance of antimicrobial resistance.	**China**
	Thailand Thailand is of the opinion that there are too many principles in this document. We suggested that the common and proximity principles could be grouped together. In order to clearly understand, some broad principles should added sub-principles. A clear set of principles will give us immediate focus and clarity on the Codex work on AMR in the future.
These principles should be read in conjunction with the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CAC/GL 77-2011).	
These principles should be read in conjunction with the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CAC/GL ~~77-2011).~~ 77-2011)) and relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes.	**USA** Rationale: The principles make reference to areas covered by OIE
• **Monitoring and surveillance programmes for AMR should be a core component of a national food safety system;**	
Monitoring and surveillance programmes should include patterns of use of ~~AMs~~ AMs, along with data on subsequent development of foodborne AMR risk so as to support risk ~~analysis and policy initiatives~~analysis;	**USA** Rationale: AMU alone cannot inform risk analysis without contextual data. The collection of AMU data can be very resource intensive and not practical for resource constrained countries. Countries would also have to gather contextual information to effectively use such data to design effective and appropriate risk management strategies. Also, this section is redundant to the OIE's Chapter 6.8 - Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-Producing Animals. Delete "policy initiatives" as outside the scope.
Monitoring and surveillance programmes should include patterns of use of AMs so as to support risk analysis and policy initiatives;	**Canada** The bullet only mentions that 'patterns of use of AMs' should be included in monitoring and surveillance. Canada suggests that additionally frequency and quantities of AMs should be included. *Category: SUBSTANTIVE*
Monitoring and surveillance programmes ~~should~~ may include patterns of use of ~~AMs~~ AMs, along with data on subsequent development of foodborne AMR risk so as to support risk analysis and policy initiatives;	**ICGMA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	The collection of antimicrobial use data can be very resource intensive and not practical for resource constrained countries. Countries would also have to gather contextual information to effectively use such data to design effective and appropriate risk management strategies. Finally, we note that this section is redundant to the OIE's Chapter 6.8 - Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-Producing Animals. *Category: SUBSTANTIVE*
• **Monitoring and surveillance programmes should include patterns of use of AMs so as to support risk analysis and policy initiatives;**	
• **Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance programme for AMR, with best practice being informed by expected benefits in terms of minimising the burden of human illness;**	
Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance programme for AMR, ~~with best practice being informed by expected benefits in terms of minimising the burden of human illness;~~	**FAO** A number of factors including costs, feasibility etc contribute to decision on best practice. While benefits to human health are highly important it is not the only issue that informs best practice. As this second half of the sentence does not add clear information and the use of risk analysis already conveying th eimportance to human health suggest it can be deleted *Category: EDITORIAL*
Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance programme for AMR, with best practice being informed by expected benefits in terms of <u>preventing or</u> minimising the burden of human illness;	**International Association of Consumer Food Organizations** The concept of prevention should be incorporated. *Category: SUBSTANTIVE*
• **Programmes for monitoring and surveillance of AMR should incorporate an integrated approach ("One Health");**	
Programmes for monitoring and surveillance of AMR should <u>aspire or attempt to</u> incorporate an integrated approach ("One Health");	**ICGMA** this is aspirational, it should be communicated as such. Two options are presented in this edit. *Category: SUBSTANTIVE*
Programmes for monitoring and surveillance of AMR should <u>aspire to</u> incorporate an integrated approach ("One Health");	**USA** Rationale: It may not be immediately possible, effective or efficient to combine data from human, animal and environmental sources, however the aspiration to include all relevant information could be described.
• **A national monitoring and surveillance programme should be tailored to the domestic situation and be designed and implemented according to a step-wise approach;**	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
A national monitoring and surveillance programme should be tailored to function in the domestic situation and be designed and implemented according to a step-wise approach;	**USA** Rationale: Provides further clarity and defines flexibility to function within the resources of each country
A national monitoring and surveillance programme should be tailored to the domestic situation and may be designed and implemented according to a step-wise approach;	**FAO** A step wise design and implementation should not be mandatory. Edited for flexibility.
• **In using a step-wise approach, priority should be given to the most relevant elements from a public health perspective (e.g. combinations of bacterial species/ food to be analysed);**	
In using a step-wise approach, priority should be given to the most relevant ~~elements~~ risks from a public health perspective (e.g. combinations of ~~bacterial species/~~ food commodity, the AMR microorganism and determinants and the antimicrobial agent(s) to ~~be analysed);~~which resistance is expressed.)	**USA** Rationale: The language provided is from Principle 6 CAC/GL 77-2011 for consistency
• **Monitoring and surveillance programmes should incorporate capacity for epidemiological investigation and identification of new and emerging foodborne risks;**	
Monitoring and surveillance programmes should incorporate to the extent practical, a capacity for epidemiological investigation and identification of new and emerging foodborne ~~risks~~risks and trends;	**Brazil**
Monitoring and surveillance programmes ~~should~~ may incorporate to the extent practical, a capacity for epidemiological investigation and identification of new and emerging foodborne ~~risks~~risks and trends;	**USA** Rationale: Monitoring and surveillance programs should look for trends beyond just emerging resistance. A risk manager would want to know about increases and decreases in resistance trends to evaluate efficacy of risk management.
Monitoring and surveillance programmes should incorporate to the extent practical, a capacity for epidemiological investigation and identification of ~~new and emerging~~ foodborne ~~risks~~risks and trends;	**ICGMA** The use of “emerging” suggest that bacterial resistance in a monitored population only increases. However, this is not the case, The National Antimicrobial Resistance Monitoring System (NARMS) and other national authorities reporting systems have reported significant declines. The decreases should be equally important as increases for risk managers because decreases reveal insight on efficacy of risk management. The proposed change can help risk communications to accurately reflect the potential risk that may or may not be present for specific bacteria. It is important for risk managers to understand the efficacy of interventions and that would include understanding why there are decreasing and/or emerging risks.
• **Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place and participate in external proficiency testing;**	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
• **Laboratory methodology, data collection, analysis and reporting should be aligned and harmonised across all sectors in national AMR systems as part of an integrated approach;**	
~~Laboratory methodology, data collection, analysis and reporting should be aligned and harmonised across all sectors in national AMR systems as part of an integrated approach~~**All sectors in national AMR/AMU monitoring and surveillance system should strive to align and harmonise laboratory methodologies, data collections, analyses and reports**;	**Japan** Rationale：These guidelines should be formulated to provide a framework that countries may implement in accordance with their capabilities, budget. *Category: SUBSTANTIVE*
Laboratory methodology, data collection, analysis and reporting should be ~~aligned and harmonised across all sectors~~ harmonized in national AMR systems to the greatest extent practical as part of an integrated ~~approach~~approach use of standardized and validated antimicrobial susceptibility testing methods and harmonised interpretive criteria are essential to ensure that data are comparable;	**USA** Rationale: The statement as it stands is too simplistic, not implementable, and misses a key opportunity to be descriptive. Aligned across all sectors? How does this factor the need to take different sample types from different species? *Category: TECHNICAL*
• **Ad hoc operational research projects and epidemiological studies should be carried out to enhance the technical capability and effectiveness of the monitoring and surveillance programme (e.g.new analytical methods, food source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);**	
~~Ad hoc operational research~~ Research projects and epidemiological studies should be ~~carried out~~ encouraged to enhance the technical capability and effectiveness of the monitoring and surveillance programme (e.g.new analytical methods, food source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);	**Brazil** *Category: SUBSTANTIVE*
Ad hoc operational research projects and epidemiological studies should be carried out to enhance the technical capability and effectiveness of the monitoring and surveillance programme (e.g.new analytical methods, food source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);	**Canada** (Page 7). First bullet. “Ad hoc operational research projects and epidemiological studies should be carried out”. Canada suggests text be added to indicate that these additional projects and studies be based on resource availabilities and national priorities. *Category: SUBSTANTIVE*
~~Ad hoc operational research projects~~ Countries should strive to conduct science and hypothesis-driven epidemiological studies should ~~be carried out~~ to enhance the technical capability and effectiveness of the monitoring and surveillance programme (e.g.new analytical methods, food source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);	**USA** Rationale: The statement is aspirational and will be difficult for resource poor countries to do initially. “Ad hoc” is too vague and could mislead. Good epidemiological work relies on science. *Category: TECHNICAL*
~~Ad hoc operational research projects~~ Countries should strive to conduct evidence and hypothesis-driven epidemiological studies ~~should be carried out~~ to enhance the technical capability and effectiveness of the monitoring and surveillance programme (e.g.new analytical methods, food source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);	**ICGMA** “Ad hoc” is too vague and could mislead. Good epidemiological work relies on evidence.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
• **National programmes should strive to harmonise components, methodologies and interpretative criteria with international guidance so as to enhance an integrated approach to information management at the international level;**	
National programmes should strive to harmonise components, methodologies and interpretative criteria with ~~international~~ according to applicable internationally recognized, consensus-based surveillance guidelines such as CAC/GL 77 and OIE codes guidance so as to enhance an integrated approach to inform risk assessment and risk information management at the international level;	**USA** Rationale: References are provided for other consensus-based surveillance guidance and clarifying language is provided as to why the harmonization is needed.
• **Data generated from national monitoring and surveillance programmes of AMR in imported foods should not be used to inappropriately generate barriers to trade.**	
~~Data~~ Status of the implementation and data generated from national monitoring and surveillance programmes of AMR in imported foods should not be used to inappropriately generate barriers to trade.	**Brazil** *Category: SUBSTANTIVE*
Data generated from national monitoring and surveillance programmes of AMR in ~~imported foods~~ should not be used to inappropriately by trading partners to generate barriers to trade.	**USA** Rationale: All monitoring/surveillance data taken as a whole, help illustrate trends, identify priority risks, and are inputs to inform the overall risk analysis process. AMR data on imported food should not be taken individually to be used as barriers to trade
~~Data generated from national monitoring and surveillance programmes of AMR in imported foods should not be used to inappropriately generate barriers to trade.~~	**Consumers International** CI recommends deleting this bullet as it just restates a major principle of Codex that standards not be used inappropriately to hinder trade. There is no reason to believe that surveillance of AMR creates a special risk of inappropriate trade barriers.
7. Risk-based approach	
7. Risk-based approach	**Canada** Risk-based approach The bullets should be numbered as they are referred to by number in the first paragraph below the bullets.
7. Risk-based approach	**International Meat Secretariat** We are striving for a risk-based approach. The goal should always be a risk-based approach instead of a hazard-based approach. If we condone the use of a hazard-based approach for some, even for the “time being” we create an opportunity for countries to remain in a hazard-based mind set. We should encourage all countries to strive for a risk-based approach, and leave any mention of hazard-based approaches out of the discussion.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
The *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) incorporate the following steps:	
• **Preliminary risk management activities** • **Risk assessment** • **Identification and selection of risk management options** • **Implementation of control measures** • **Monitoring and review.** • **Risk communication**	
In applying a risk based approach to the design of a monitoring and surveillance programme (equivalent to step 5 in the Codex risk analysis framework), maximum use should be made of available information on foodborne AMR risks to human health at the national level.	
In applying a risk based approach to the design of a monitoring and surveillance ~~programme (equivalent to step 5 in the Codex risk analysis framework)~~programme, maximum use should be made of available information on foodborne AMR risks to human health at the national level.	**USA** Rationale: This reference is unclear *Category: TECHNICAL*
In applying a ~~risk based~~ risk-based approach to the design of a monitoring and surveillance programme (equivalent to step 5 in the Codex risk analysis framework), maximum use should be made of available information on foodborne AMR risks to human health at the national level.	**FAO** *Category: EDITORIAL*
Integrated monitoring and surveillance of AMR in the food chain provides essential information for risk assessment and risk management decision-making on appropriate control measures.	
Integrated monitoring and surveillance of AMR in the food chain provides essential information for risk assessment and risk management decision-making on appropriate control ~~measures~~measures in both human and animal health.	**Australia** *Category: SUBSTANTIVE*
While monitoring and surveillance programmes 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 programmes will [initially] be designed according to the knowledge that is available on AMR hazards (and their determinants) and their potential to result in public health risks.	
While monitoring and surveillance programmes 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 programmes will [initially] be designed according to the knowledge that is available ~~on~~ for the initial step in which risk managers identify and briefly describe the AMR ~~hazards (and their determinants)~~ risk caused by the food safety issue, i.e., the defined combination of the hazard(s) (AMR microorganisms and ~~their potential~~ / or determinant(s)), the antimicrobial agent(s) to ~~result~~ which resistance is expressed and the food commodity in ~~public health risks~~which the hazard is identified. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of CAC/GL-77	**USA** Rationale: Re-written to be consistent with CAC/GL-77 in defining the food safety issue and initial steps for risk manager. *Category: TECHNICAL*
While monitoring and surveillance programmes should ideally be designed according to knowledge of possible ~~food-borne~~ foodborne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programmes will [initially] be designed according to the knowledge that is available on AMR hazards (and their determinants) and their potential to result in public health risks.	**FAO** *Category: EDITORIAL*
This knowledge should be included on a risk profile (ref. CAC/GL 77-2011)). Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~This knowledge~~ Knowledge and information on foodborne AMR hazards, risk factors etc should be included on a risk profile (ref. CAC/GL 77-2011)). Hazard identification should include human microbiological pathogens and bacterial commensals likely to transmit AMR to humans.	**FAO** the particular knowledge that the definative article "this" refers to is unclear. Is it foodborne AMR *Category: EDITORIAL*
As countries improve their AMR systems over time, a step-wise approach to monitoring and surveillance should increasingly incorporate risk-assessment factors as an important element in design of the programme and analysis of data.	
As countries improve their AMR systems over time, a step-wise approach to monitoring and surveillance should increasingly incorporate risk-assessment factors as an important element in design of the programme and analysis of data.	**Canada** Paragraph 6. "the increasingly incorporation of risk assessment factors". Canada supports the intersection between surveillance and risk assessment, but details and examples of this in the context of this paragraph would be useful. *Category: SUBSTANTIVE*
As countries improve their AMR systems over time, a step-wise approach to monitoring and surveillance should increasingly incorporate ~~risk-assessment~~ risk assessment factors as an important element in design of the programme and analysis of data.	**FAO** *Category: EDITORIAL*
Potential foodborne AMR risks to human health are subject to change over time and monitoring and surveillance should be adjusted as new information becomes available e.g. changes in test methodologies, new food chain exposure pathways, changing use patterns of AM. Any adjustments should be properly communicated with reference to methodological changes.	
Potential foodborne AMR risks to human health are subject to change over time and monitoring and surveillance should be adjusted as new information becomes available e.g. changes in test methodologies, new food chain or environmental exposure pathways, changing use patterns of AM. Any adjustments should be properly communicated with reference to methodological changes.	**OIE** *Category: TECHNICAL*
8. Regulatory framework and roles	
	Canada Regulatory framework and roles It is suggested that stakeholders identified in this section should align with those of the Code of Practice because the COP identifies the responsibilities associated with each stakeholder including the surveillance. *Category: SUBSTANTIVE*
	Thailand To ensure all actors involved in the section of Regulatory framework and roles, Thailand would like to stress once again that it is necessary to add the medicated feed manufacturer in this section.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Activities related to monitoring and surveillance of AMR should involve not only the Competent Authority, but also a wider range of stakeholders in various roles. The level of integration of stakeholder roles including food industry, pharmaceutical industry, veterinarians, farmers, professional associations, retail and others will depend on the level of step-wise development of the programme and the degree of integration. Ideally, all stakeholders along the food chain should contribute to the development and implementation of the monitoring and surveillance system.	
Activities related to monitoring and surveillance of AMR should involve not only the Competent Authority, but also a wider range of stakeholders in various roles. The level of integration of stakeholder roles including food industry, pharmaceutical industry, medicated feed industry, veterinarians, farmers, professional associations, retail and others will depend on the level of step-wise development of the programme and the degree of integration. Ideally, all stakeholders along the food chain should contribute to the development and implementation of the monitoring and surveillance system.	**Thailand** *Category: EDITORIAL*
Activities related to monitoring and surveillance of AMR should involve not only the Competent Authority, but also a wider range of ~~stakeholders~~ interested parties in various roles. The level of integration of ~~stakeholder~~ interested party roles including food industry, pharmaceutical industry, veterinarians, farmers, professional associations, civil society and consumer organizations, retail and others will depend on the level of step-wise development of the programme and the degree of integration. Ideally, all ~~stakeholders~~ interested parties along the food chain should contribute to the development and implementation of the monitoring and surveillance system.	**Consumers International** CI recommends that "civil society and consumer organizations" be included in the list of stakeholders. We also ask the drafters to consider using the term "interested parties" instead of "stakeholders" to be consistent with other Codex documents. *Category: SUBSTANTIVE*
Activities related to monitoring and surveillance of AMR should involve not only the Competent Authority, but also a wider range of stakeholders in various roles. The level of integration of stakeholder roles including food industry, pharmaceutical industry, veterinarians, farmers, professional associations, retail and others will depend on the level of step-wise development of the programme and the degree of integration. Ideally, all stakeholders along the food chain should contribute to the development and implementation of the monitoring and surveillance ~~system~~programme.	**FAO** Change system to programme for consistency *Category: EDITORIAL*
Activities related to monitoring and surveillance of AMR should involve not only the Competent Authority, but also a wider range of stakeholders in various roles, with appropriate conflict of interest safeguards. The level of integration of stakeholder roles including food industry, pharmaceutical industry, veterinarians, farmers, professional associations, ~~retail~~ retail, consumers and others will depend on the level of step-wise development of the programme and the degree of integration. Ideally, all stakeholders along the food chain should contribute to the development and implementation of the monitoring and surveillance system.	**International Association of Consumer Food Organizations** First, we suggest that consumers also be explicitly mentioned as a stakeholder contributing to the development and implementation of the monitoring and surveillance system. And second, we suggest "with appropriate conflict of interest safeguards" be added to the sentence, to address the duty to ensure that undue influence, either actual or perceived, for interests other than the public good is not exerted on activities related to monitoring and surveillance of AMR.
8.1 Regulatory policy framework	
8.1 ~~Regulatory policy framework~~ Policy and regulatory activities	**FAO** We understand this section is supposed to address the policy framework that determines what regulatory activities should be carried out. But there is the potential for exacerbating the confusion between what is "policy" and what is "regulation".

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	It may be beneficial to reframe this as just “Policy framework”, as it is already under the larger section of “Regulatory framework and roles”. If the paragraph is aimed to cover also “regulatory activities” stricto sensu, a better title would be “Policy and regulatory activities”
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health and environmental sectors. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal <u>health, plant</u> health and environmental sectors. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	**Thailand** *Category: EDITORIAL*
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health and environmental sectors. Sharing of knowledge <u>and capacity building</u> with international counterparts might improve the effectiveness of ~~policies taken at~~ local ~~level~~<u>programs for AMR risk management</u>.	**USA** Rationale: Local policy-making is beyond the food safety mandate of Codex and this document. *Category: TECHNICAL*
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health and environmental sectors. Sharing of knowledge <u>and data</u> with international counterparts ~~might~~ <u>and organizations can</u> improve the effectiveness of policies taken at local level.	**Consumers International** CI recommends strengthening the last sentence in the first paragraph to make it more consistent with the eleventh bullet under Principles which emphasizes the need for a harmonized approach. *Category: SUBSTANTIVE*
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal <u>and plant</u> health and environmental sectors<u>, and other relevant stakeholders in line with the National Action Plan on AMR</u>. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	**FAO** The National Action Plans on AMR being developed by countries should be developed in a One Helath manner and addressing this kind of collaboration. All of these aspects should be integrated so we think in this context in making explicit reference to national action plans is a useful reminder for countries. Also depending on the country situation other stakeholders may need to be involved so flexibility for this should be in the text
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal ~~health~~ <u>health, food processing, crop</u> and	**International Association of Consumer Food Organizations** In keeping with the broader scope and the One Health approach, additional sectors should be included.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
environmental sectors. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	*Category: SUBSTANTIVE*
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should provide an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health plant and environmental sectors. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	**OIE** *Category: TECHNICAL*
Integrated monitoring and surveillance programmes for AMR at the national level require good governance and co-ordination by the relevant Competent Authorities if they are to be effective and sustainable. The Competent Authorities responsible for food safety should ~~provide~~ develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health and environmental sectors. Sharing of knowledge with international counterparts might improve the effectiveness of policies taken at local level.	**OIE** *Category: EDITORIAL*
The regulatory activities carried out by the Competent Authorities should be in response to policy objectives that are embedded in national strategies and action plans for managing AMR. Guidance on developing national action plans are outlined in the WHO Global action plan on antimicrobial resistance (reference Global Action Plan on Antimicrobial Resistance, WHO, 2015).	
The regulatory activities carried out by the Competent Authorities should be in response to policy objectives that are embedded in national strategies and action plans for managing AMR. Guidance on developing national action plans are outlined in the WHO Global action plan on antimicrobial resistance (reference Global Action Plan on Antimicrobial Resistance, WHO, 2015).	**FAO** WHO, FAO and OIE have developed a manual for the development of National action plans as well as some other tools which may be useful to reference here http://www.who.int/antimicrobial-resistance/national-action-plans/en/ *Category: TECHNICAL*
The regulatory activities carried out by the Competent Authorities should be in response to policy objectives that are embedded in national strategies and action plans for managing AMR. Guidance on developing national action plans are outlined in the WHO Global action plan on antimicrobial resistance developed by the WHO in closed collaboration with FAO and OIE (reference Global Action Plan on Antimicrobial Resistance, WHO, 2015).	**OIE** *Category: TECHNICAL*
The use of antimicrobial agents in the food chain should be subject to regulation as described in *Code of practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005; under review) and relevant OIE standards.	
The use of antimicrobial agents in the food chain should be subject to regulation as described in *Code of ~~practice~~ Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005; under review) and relevant OIE standards.	**FAO** *Category: EDITORIAL*
The use of antimicrobial agents in the food chain should be subject to regulation as described in *Code of practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005; under review) and ~~relevant~~ OIE ~~standards~~Terrestrial Animal Health Code (2017) Chapter, 6.9 – Responsible and prudent use of antimicrobial agents in veterinary medicine and Aquatic Animal Health Code (2017) Chapter 6.2 Principles for responsible and prudent use of antimicrobial agents in aquatic animals.	**OIE** *Category: TECHNICAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
8.2 Non-regulatory activities	
~~8.2 Non-regulatory activities~~	**USA** *Category: TECHNICAL*
8.2 ~~Non-regulatory~~ Other activities	**FAO** The term term “non-regulatory activities” might create some confusion. We would suggest including “Other activities” instead *Category: EDITORIAL*
Stakeholders other than the Competent Authority may carry out non-regulatory monitoring activities e.g. monitoring of the use of AMs on a voluntary basis by non-government stakeholders such as veterinarians, farmers and the pharmaceutical industry.	
~~Stakeholders other than the Competent Authority may carry out non-regulatory monitoring activities e.g. monitoring of the use of AMs on a voluntary basis by non-government stakeholders such as veterinarians, farmers and the pharmaceutical industry.~~	**USA** Rationale: This information is covered under CAC/RCP 61 and OIE and does not belong in this surveillance document. *Category: TECHNICAL*
~~Stakeholders~~ Interested parties other than the Competent Authority may carry out non-regulatory monitoring activities e.g. monitoring of the use of AMs on a voluntary basis by non-government stakeholders such as ~~veterinarians~~veterinarian organizations, ~~farmers~~ farmer organizations, consumer and civil society organizations, and the pharmaceutical industry.	**Consumers International** CI recommends that the phrase “interested parties” be used instead of “stakeholders” and civil society organizations be included in the list of “interested parties.” We recommend that farmers and veterinarians not be included as potential stakeholder here but instead include organizations of farmers and veterinarians. Justification: In the U.S., civil society organizations have developed marketing labels on antibiotic use (e.g. Certified Responsible Antibiotic Use) that require producers who wish to use the label to report antibiotic use data. There are also several initiatives based out of universities that collect data on antimicrobial use. Individual antibiotic users or prescribers are not actually the appropriate group to collect data on use. Instead, associations of farmers and veterinarians may play a role. Farmers and veterinarians should be consulted when developing monitoring systems, but as individuals would not be able to create monitoring programs. *Category: SUBSTANTIVE*
Stakeholders other than the Competent ~~Authority~~ Authority, such as veterinarians, farmers and the pharmaceutical industry, may carry out ~~non-regulatory~~ other monitoring activities e.g. monitoring of the use of AMs on a voluntary ~~basis by non-government stakeholders such as veterinarians, farmers and the pharmaceutical industry.~~basis. b	**FAO** Edited for clarity and in line with comment on title. *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Competent authorities responsible for food safety should play an active role in design, analysis and reporting of non-regulatory activities as part of an integrated "One Health" approach.	
Competent authorities responsible for food safety should play an active role in design, analysis and reporting of non-regulatory activities as part of an integrated "One Health" approach.	**Canada** (Page 8). Non-regulatory activities. Paragraph 2. The bullet indicates that "Competent authorities responsible for food safety should play an active role in design, analysis and reporting of non-regulatory activities". Canada notes that in some circumstances, the competent authorities may have no role in non-regulatory activities. *Category: SUBSTANTIVE*
~~Competent authorities responsible for food safety should play an active role in design, analysis and reporting of non-regulatory activities as part of an integrated "One Health" approach.~~	**USA** *Category: TECHNICAL*
Competent ~~authorities~~ Authorities responsible for food safety should play an active role in design, analysis and reporting of non-regulatory activities as part of an integrated "One Health" approach.	**FAO** *Category: EDITORIAL*
9. A stepwise approach to integrated monitoring and surveillance programme of AMR	
Suggest elaborating examples for stepwise approach, target bacteria, a panel of antimicrobials for susceptibility testing, AMR determinants, and put them in the appendix.	**China**
9. A stepwise approach to integrated monitoring and surveillance programme of AMR	**Consumers International** CI recommends that the working group take into consideration the recommendations on sampling priorities included in the WHO-AGISAR Integrated Surveillance document which lists retail samples as second priority after human samples with samples from healthy food animals as the third priority, and sick food animals the fourth (WHO-AGISAR Integrated Surveillance Pages 8-9). *Category: SUBSTANTIVE*
9. A stepwise approach to integrated monitoring and surveillance programme of AMR	**International Meat Secretariat** Reporting of sales data tells us nothing if we do not have distribution or use data. This number can be grossly misinterpreted by stakeholders within and outside of each country. *Category: SUBSTANTIVE*
A stepwise approach to guidance on design and implementation of integrated monitoring and surveillance programmes allows countries to progress according to different time scales and this is a practical response to inevitable variations in infrastructure, technical capability and budgets level. Clear guidance on a stepwise approach should also facilitate continuous improvement.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
A stepwise approach to guidance on design and implementation of integrated monitoring and surveillance programmes allows countries to progress according to different time scales and ~~this is a practical response~~ respond to inevitable variations in infrastructure, technical capability and budgets level. Clear guidance on a stepwise approach should also facilitate continuous improvement.	**Australia** *Category: EDITORIAL*
The stepwise approach on the monitoring and surveillance of AMR and the use of AMs that is presented in these guidelines references WHO AGISAR Guidelines for integrated surveillance of AMR in foodborne bacteria[1] and reporting options of OIE Guidance for the collection of data on antimicrobial agents used in animals[2]).	
The stepwise approach ~~on the~~ to monitoring and surveillance of AMR and the use of AMs that is presented in these ~~guidelines references WHO AGISAR Guidelines for integrated surveillance of AMR in foodborne bacteria~~guidelines[4] and reporting options of OIE Guidance for the collection of data on antimicrobial agents useishould be read in conjunction with Codex Guideline 77 - Risk Analysis for Foodborne Antimicrobial Resistance and relevant Chapters of the OIE Terrestrial and Aquatic Animal Health Codes including reporting options of OIE Guidance for the collection of data on antimicrobial agents used in ~~animals~~animals 5). In addition, the WHO-AGISAR guideline, "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria; Application of a One Health Approach" should also be considered.[5]) ~~.~~	**USA** Rationale: Codex texts should be read in conjunction with other standards developed through transparent processes of review and consensus by Member Countries such as those recognized under the World Trade Organization (WTO) SPS agreement [i.e. Codex, OIE, and International Plant Protection Convention (IPPC)]. Expert-derived technical recommendations may also be considered where relevant. The WHO uses an expert group without Member State review; Codex guidelines, which carry trade implications, should not give trade status to what is in the WHO document, but rather note that the information can be considered. Rationale: The WHO AGISAR Guidelines are not consensus-based but rather formed by expert groups. *Category: TECHNICAL*
The stepwise approach on the monitoring and surveillance of AMR and the use of AMs that is presented in these guidelines references WHO AGISAR ~~Guidelines for integrated surveillance of AMR in foodborne bacteria~~*Guidelines for integrated surveillance of AMR in foodborne bacteria*[4] and reporting options of OIE Guidance for the collection of data on antimicrobial agents used in animals[5]).	**FAO** Title of document in italics to differentiate from text. *Category: EDITORIAL*
The stepwise approach on the monitoring and surveillance of AMR and the use of AMs that is presented in these guidelines references WHO AGISAR Guidelines for integrated surveillance of AMR in foodborne bacteria[4] and reporting options of OIE ~~Guidance~~ standards for the collection of data on antimicrobial agents used in animals[5]).	**OIE** *Category: TECHNICAL*
Pre-requisites	
Pre-requisites	**Canada** A stepwise approach to integrated monitoring and surveillance programme of AMR (Page 8). Pre-requisites.

[1] http://apps.who.int/iris/bitstream/10665/255747/1/9789241512411-eng.pdf?ua=1
[2] http://www.oie.int/fileadmin/Home/fr/Our_scientific_expertise/docs/pdf/AMR/Survey_on_monitoring_antimicrobial_agents_Dec2016.pdf

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	If it is possible to recommend non WHO, FAO, or OIE references, Canada recommends that this section should also acknowledge the excellent recommendations adopted in the EU for indicators of AMR and AMU (ECDC, EFSA and EMA Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals).
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[3]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment.	
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs ~~e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) ~~and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment.	**Australia** duplication *Category: EDITORIAL*
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment.	**Canada** Canada suggests also that a stepwise approach might advance at different paces for different aspects of surveillance. For example, antimicrobial use surveillance might advance to Step 2 prior to AMR surveillance or vice-versa.
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure ~~pathways will enhance risk profiling and risk assessment~~.	**Canada** *Category: EDITORIAL*
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food ~~exposure pathways will enhance risk profiling and risk assessment~~exposure.	**Canada** *Category: EDITORIAL*

[3] http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia/en/

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
El seguimiento y la vigilancia deberían concentrarse en las especies bacterianas prioritarias y/o los determinantes de la RAM, los AM prioritarios (por ejemplo, la lista de la OMS de antimicrobianos de importancia crítica para la medicina humana [referencia [6]]) y una gama de fuentes de muestra conforme se determine a nivel nacional. El establecimiento de prioridades debería estar fundamentado en datos nacionales e internacionales y en conocimientos que incorporen aspectos relativos a la salud pública, epidemiología y patrones de UAM, información sobre sistemas de producción agrícola, patrones de consumo de alimentos y vías de exposición de ~~alimentos a fin de mejorar el trazado de perfiles de riesgos y la evaluación de riesgos~~alimentos.	**Colombia** Si bien el resultado de los programas de seguimiento y vigilancia aportarían información importante para la generación de perfiles y evaluaciones de riesgo, no se considera necesario incluirlo en este apartado del documento.
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment~~.~~ **. An example of stepwise approach is shown below.**	**Japan** Rationale：Refer to the General Comments. *Category: SUBSTANTIVE*
Monitoring and surveillance should focus on ~~priority bacterial species~~ the food commodity, the AMR microorganism and ~~or~~ determinants ~~of AMR, priority AMs e.g~~and the antimicrobial agent(s) to which resistance is expressed as described in CAC/GL 77. ~~WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level.~~ Establishing priorities should be informed by national and international data and knowledge that incorporates public health aspects, epidemiology and AMU patterns, information on agricultural production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment.	**USA** Rationale: The WHO CIA list was done by an expert group and not risk or consensus-driven, while some national lists are. Because this is a public health initiative, it should focus on antimicrobials that are medically important for human therapy. The term “medically important” instead of “priority” should be used throughout the document to avoid confusion. ‘Highest priority’ as monitoring should be to the range of medically important antimicrobials as per local country needs.
Monitoring and surveillance should focus on priority bacterial species and or determinants of AMR, priority AMs e.g. WHO list of critically important antimicrobials for human medicine (reference[6]) and a range of sample sources as determined at the national level. Establishing priorities should be informed by national and international data and knowledge that incorporates ~~public~~ human health aspects, epidemiology and AMU patterns, information on ~~agricultural~~ animal and plant production systems, food consumption patterns and food exposure pathways will enhance risk profiling and risk assessment.	**OIE** *Category: EDITORIAL*
Step 1	
	Canada (Page 8). Pre-requisites. Step 1. First bullet. Canada agrees with the principle of the bullet but suggests that the current wording of this bullet needs some more clarity to enhance the utility of this bullet as a Step 1 item. The current wording raises the question of whether surveillance is being conducted to detect a rare event (in most cases resistance to these CIA drugs is fairly rare) or to provide a cross-section of prevalences of resistance.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	The design for the surveillance program would be very different and a larger sample size would be needed for the former. For clarity, this bullet should refer to the WHO terminology “critically important”, if that is what is meant. Secondly, there are 15 drug classes in the WHO CIA list; some of which are not on standard panels for testing. Hence refinement of the wording “range” would provide useful guidance for this bullet as a Step 1 item.
• **Monitoring of AMR to a range of priority AMs that have been ranked as highest priority for human health [as defined by WHO in the list of CIAs for human medicine, reference].**	
Monitoring of AMR to a range of ~~priority~~ AMs that have been ranked as highest priority for human health [as defined by ~~WHO~~ national lists of priority AMs or as detailed in the WHO list of CIAs for human medicine, reference].	**Australia** Rationale: Priority AMs will vary from country to country and the WHO list of CIA should only be used as a guide in circumstances where a priority list has not been developed.
Monitoring of AMR to a range of ~~priority~~ medically important AMs that have been ranked as highest priority for human health [~~as defined by WHO in~~ [Consideration can be given to national lists, risk-based lists, consensus-based guidelines or the WHO list of CIAs for human medicine, reference].	**ICGMA** Because this is a public health initiative, it should focus on antimicrobials that are medically important for therapy to people based on risk assessment. It would be beneficial for the Taskforce to use “medically important antimicrobial” throughout instead of two similar terms. Regarding the second insertion, if a country has a risk-based list that can take precedence, this list would be consistent with the Codex principles and should be consulted. Lastly, we note that the WHO CIA list was completed by an expert group and not risk or consensus-driven. The Taskforce should consider this as it advances these guidelines.
• **Testing of representative pathogen and indicator bacteria for resistance.**	
Testing of representative pathogen and indicator bacteria for resistance.	**Canada** Second bullet. General guidance on how to select the bacterial species for inclusion would be useful. Could refer to WHO AGISAR document here. *Category: SUBSTANTIVE*
Testing of representative pathogen and / or indicator bacteria for ~~resistance~~resistance as appropriate for national priorities and available resources.	**USA** Rationale: The ecology of resistance is complex and testing of indicator or commensal bacteria may not be the best use of resources to understand the risk and trends in a population.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	The relationship between specific drug class resistance among commensals and pathogens is complex, nuanced, and has many confounding factors. Suggesting that countries look at commensal bacteria may shift resources away from higher priority pathogens. *Category: TECHNICAL*
Testing of representative ~~pathogen and indicator bacteria~~ pathogens for ~~resistance~~resistance as appropriate based on national priorities and resources.	**ICGMA** Per EUCAST, it covers human health and does not have a veterinary section, suggest deleting EUCAST and keeping CLSI only since CLSI has a veterinary specific sub-committee and expertise. *Category: SUBSTANTIVE*
• **Sampling from a limited number of food exposure pathways at limited stages along the food chain e.g. slaughterhouse or retail meats.**	
Sampling from a limited number of food exposure pathways at ~~limited~~ specific stages along the food chain e.g. slaughterhouse or retail meats.	**Australia** *Category: EDITORIAL*
Sampling from a limited number of food exposure pathways at limited stages along the food chain e.g. slaughterhouse or retail meats.	**Canada** Third bullet. “Sampling from a limited number of food exposure pathways at limited stages along the food chain e.g. slaughterhouse or retail meats” is unclear. Suggest substituting ‘food exposure pathway” with “food animal commodities”. *Category: SUBSTANTIVE*
Sampling from a limited number of food exposure pathways at limited stages along the food chain e.g. slaughterhouse or retail ~~meats~~meats and produce.	**Consumers International** CI recommends retail sampling of produce that may have been produced with antimicrobials at this point. Could also sample crops at processing. *Category: SUBSTANTIVE*
Sampling from a limited number of food sources and exposure pathways at limited stages along the food chain e.g. slaughterhouse or retail meats.	**FAO** Edited for clarity
• **Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use.**	
Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals by antimicrobial ~~class~~agent, with the possibility to separate by type of use.	**Brazil** *Category: SUBSTANTIVE*
Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use.	**Canada** Fourth bullet: “Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use”.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Even though the word 'possibility' is in the bullet, this is likely not a Step 1 possibility. Only very advance surveillance systems can provide this level of detail, though it is dependent on what is meant by 'type of use'. Suggest that this be Step 2 or 3. *Category: SUBSTANTIVE*
Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals and food and feed crops by antimicrobial class, with the possibility to separate by type of use.	**Consumers International** Consistent with the mandate to include corps CI recommends that monitoring of sales for use in crop production should be included here. *Category: SUBSTANTIVE*
Aggregation of national sales data for AMs e.g. collection of data on overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of ~~use~~use (eg. by species, purpose (growth promotion, treatment).	**FAO** Suggest that some clarity needed around type of use e'g' use for plants, animals, for what purpose e.g. growth promotion, treatment etc. *Category: TECHNICAL*
• **Analysis and reporting of data from the food chain.**	
Analysis and reporting of data from the food chain.	**Canada** Fifth bullet. Suggest adding in ways to report the data (metrics for AMR and AMU) *Category: SUBSTANTIVE*
Step 2	
• **Scope and design elements informed by a risk profile**	
	Canada Step 2. First bullet. It is unclear about what is meant by 'scope and design elements informed by a risk profile'. Details and examples would be useful here. *Category: SUBSTANTIVE*
• **Monitoring and surveillance of AMR to a broader range of priority AMs 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, reference].**	
Monitoring and surveillance of AMR to a broader range of priority AMs that have been ranked as critically and highly important for human health [as defined by ~~WHO~~ national lists of priority AMs or as detailed in the WHO list of Critically Important Antimicrobials for human medicine, reference].	**Australia** Rationale: Priority AMs will vary from country to country and the WHO list of CIA should only be used as a guide in circumstances where a priority list has not been developed. *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Monitoring and surveillance of AMR to a broader range ~~of priority AMs that have been ranked as critically and highly~~ of medically important ~~for human health [as defined by WHO in the list of Critically Important Antimicrobials for human medicine~~antimicrobials, ~~reference].~~ with consideration given to national lists or consensus-based guidelines	**USA** Rationale: If a country has a national list that can take precedence. The WHO CIA list was done by an expert group and not consensus-driven. *Category: TECHNICAL*
Monitoring and surveillance of AMR to a broader range of priority AMs 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, reference].Local information sources such as national critically important antimicrobials or important or commonly used veterinary antimicrobials may also be considered.	**FAO** In progressing through the steps it is suggested that other information also be considered in refining or expanding the list of AMs considered e.g Knowledge of commonly used vet drugs should also play into AM selection. *Category: TECHNICAL*
• **Testing of a range of pathogens determinants and indicator bacteria for resistance.**	
Testing of a range of pathogens determinants ~~and~~ or indicator bacteria for resistance.	**USA** *Category: EDITORIAL*
• **Sampling from a number of food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products and other related sources (e.g. feed, water)..**	
Sampling from a number of food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products and other related sources (e.g. feed, water).	**Canada** Fourth bullet. It is suggested to not include collecting feed and water samples for AMR surveillance into Step 2 even as examples of other sources to sample. These really should be Step 3; once foodborne AMR sampling is sufficient in scope and detail. *Category: SUBSTANTIVE*
Sampling from a number of food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products and other related sources (e.g. feed, water). •Sampling of healthy animals on farm and sampling of crop fields where antimicrobials have been applied.	**Consumers International** CI recommends including sampling of healthy animals on farm as second tier activity consistent with the WHO-AGISAR priorities for sampling. On farm sampling may also include sampling of crop fields. *Category: SUBSTANTIVE*
Sampling from a number of food sources and exposure pathways along the food chain e.g. red meat, poultry, aquaculture products and other related sources (e.g. feed, ~~water)~~water, waste water and effluent).	**FAO** Included some additional examples of related sources.
• **Pro-active surveillance activities as informed by monitoring and human epidemiology**	
Pro-active surveillance activities as informed by monitoring and human epidemiology.	**Canada** Fifth bullet. Suggest clarifying what ‘pro-active surveillance activities’ are. Clarity on how ‘human epidemiology’ would drive pro-active surveillance activities would be beneficial. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Pro-active surveillance activities as informed by monitoring and human foodborne AMR illness epidemiology.	**USA** Rationale: Language added to stay within scope of Task Force work *Category: TECHNICAL*
• **Alignment of food chain methodologies and practices with those used in other sectors.**	
Alignment of food chain methodologies and practices with those used in other sectors.	**Canada** Sixth bullet. The current text reads “Alignment of food chain methodologies and practices with those used in other sectors”. As written, it is unclear what other sectors are food chain methodologies being proposed to align with. Examples here would help clarify what is meant. *Category: SUBSTANTIVE*
~~Alignment of food chain methodologies and practices with those used in other sectors.~~	**USA** Rationale: As written this activity appears to be risk management rather than surveillance. *Category: TECHNICAL*
• **Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group.**	
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM ~~class~~agent, with ~~separation~~ the possibility to separate by type of use and species group.	**Brazil** *Category: SUBSTANTIVE*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group.	**Canada** Seventh bullet. Canada suggests that separation of AM data into species groups is more likely a Step 3 process rather than Step 2. *Category: SUBSTANTIVE*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group~~.~~. Collection of data on amount sold for/used on crop production by AM class with separation by crop and type of use.	**Consumers International** *Category: SUBSTANTIVE*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group.	**FAO** It would be useful here and in the subsequent step to clarify what is meant by @ type@
• **Integrated analysis and reporting of data from the food chain, and other sources as available**	
Integrated analysis and reporting of data from the food chain, and other sources as available.	**Canada** Eighth bullet. Providing some guidance on what ‘integrated analysis and reporting’ would be beneficial.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	This is a place where examples would be very useful. Or insert a reference here to the AGISAR document. *Category: SUBSTANTIVE*
Step 3	
Step 3	**Canada** Step 3. Suggest including testing of veterinary pathogens. Understanding what is happening in these pathogens will inform antimicrobial stewardship and help with knowing where AMR determinants may be arising. Step 3. Suggest Step 3 have an additional bullet to address the comprehensiveness of surveillance activities. It could generally be written such as 'expansion of comprehensiveness of surveillance activities to encompass more geographic regions, more aspects of the food production continuum, or more sampled sites to ensure representativeness of the data, more types of animal productions (organic, conventional), more bacterial species, more drugs to be tested, etc.' *Category: SUBSTANTIVE*
Step 3	**Russian Federation** Also, we propose to include into this Step the following provision: "monitoring of adverse effects to human health associated with the organism exposure to the target pathogen resistant (or co-resistant) to antimicrobial drugs, with the purpose of subsequent assessment of the disease severity and probability of negative effects" *Category: SUBSTANTIVE*
• **Scope and design elements informed by a risk profile and risk assessment.**	
• **Monitoring and surveillance of AMR to a broad range of AMs that are important for human health [as defined by WHO list of Critically Important Antimicrobials, reference].**	
Monitoring and surveillance of AMR to a broad range of AMs that are important for human health [as defined by national lists of priority AMs or as detailed in the WHO list of Critically Important Antimicrobials, reference].	**Australia** Rationale: Priority AMs will vary from country to country and the WHO list of CIA should only be used as a guide in circumstances where a priority list has not been developed. *Category: SUBSTANTIVE*
Monitoring and surveillance of AMR to a broad range of AMs that are important for human health [as defined by ~~WHO list of Critically Important Antimicrobials, reference~~]national lists or consensus-based guidelines.	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Rationale: If a country has a national list, that can take precedence. The WHO CIA list was done by an expert group and not consensus-driven. *Category: TECHNICAL*
Monitoring and surveillance of AMR to a broad range of AMs that are important for human health [as defined by WHO list of Critically Important Antimicrobials, reference].	**FAO** As indicated under step 3 other lists such as a national CIA list or list of veterinary importan antimicrobials should also be considered, *Category: SUBSTANTIVE*
• **Testing of a wide range of pathogen bacteria / determinants and indicators for susceptibility.**	
Testing of a wide range of pathogen bacteria ~~/ determinants~~ and indicators for susceptibility.	**FAO** unclear what ""determinants" adds to sentence *Category: EDITORIAL*
• **Sampling from a range of direct and indirect food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products, food plants, animal feed, waste water.**	
Sampling from a range of direct and indirect food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products, food plants, animal feed, waste water~~.~~ <u>, and human and animal waste (biosolids, manure, and other waste-based fertilizers) used in feed and food production.</u>	**Consumers International** Since these guidelines are to take into account the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011), CI recommends that this document use language consistent with CAC/GL 77-2011 with respect to environmental monitoring. Specifically CAC/GL 77-2011 includes specific risk management language with respect to waste management and the use of animal and human waste in crop production. CI recommends that the guidance include under monitoring of the environment sampling of "human and animal waste (biosolids, waste-water, manure, other waste-based fertilizers) when used in feed and food production. *Category: SUBSTANTIVE*
Sampling from a range of direct and indirect food exposure pathways along the food chain e.g. red meat, poultry, aquaculture products, ~~food~~ <u>[food plants</u>~~,~~<u>,]</u> animal feed, waste water.	**ICGMA** See earlier comments on plants. Support keeping this text in brackets until additional scientific advice is available. *Category: SUBSTANTIVE*
• **Pro-active surveillance activities as informed by monitoring and human epidemiology.**	
Pro-active surveillance activities as informed by monitoring and human <u>foodborne AMR illness</u> epidemiology.	**USA** Rationale: Language added to stay within scope of Task Force work

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Pro-active surveillance activities as informed by monitoring and human epidemiology. • Sampling using longitudinal studies, metagenomics, and studies examining biocides and other food chain risk factors for AMR.	**Consumers International** CI recommends that the third step of surveillance and monitoring include reference to longitudinal studies, metagenomics studies, biocides and other risk factors for resistance. *Category: SUBSTANTIVE*
• **Alignment of food chain methodologies and practices with those used in other sectors.**	
~~Alignment of food chain methodologies and practices with those used in other sectors.~~	**USA** Rationale: As written this activity appears to be risk management rather than surveillance *Category: TECHNICAL*
• **Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration..**	
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration.	**Brazi** Brazil believes that the collection of data on use of antimicrobial agents would be more appropriate than by class of antimicrobials. Antimicrobial agents have different doses, so the quantity of antimicrobials used should also be related to the number of doses that can be used in a given species. The aggregate number per class does not allow refinement of this data. *Category: SUBSTANTIVE*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM ~~class~~agent, with ~~separation~~ the possibility to separate by type of use and species group and route of administration.	**Brazil** *Category: SUBSTANTIVE*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration.	**Canada** Seventh bullet. Suggest considering the addition of farm-level or veterinary prescription level data for Step 3. *Category: SUBSTANTIVE*
Aggregation of national ~~and~~ and/or regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration.	**Thailand** *Category: EDITORIAL*
Aggregation of national and regional sales data for AMs e.g. collection of data on overall amount sold for/used in animals by AM class, with separation by type of use and species group and route of administration, including farm- and herd-level use when possible.	**International Association of Consumer Food Organizations** Step 3 currently falls short of the best available practices with respect to monitoring of antimicrobial use. Specifically, Step 3 includes only collection of national and regional antimicrobial use, but does not recommend individual farm- or herd-level reporting.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Information on antimicrobial consumption for individual farms or herds can be extremely useful. Requiring reporting of farm-level data in the Netherlands has revealed, among other things, that consumption of antimicrobial agents can vary by as much as two orders of magnitude (i.e., 100-fold) between farms.[cite 9] Herd-level antimicrobial usage is also tracked in Denmark.[cite 10] The availability of this type of data will enhance surveillance efforts and should be included in the guidelines at Step 3. Sources cited: (9) Bos MEH, Taverne FJ, et al., "Consumption of Antimicrobials in Pigs, Veal Calves, and Broilers in The Netherlands: Quantitative Results of Nationwide Collection of Data in 2011," PLOS One, October 21, 2013. (10) Dupont N, Stege H, "Vetstat- Monitoring usage of antimicrobials in animals." www.icar.org/documents/aarhus_2013/Manuscripts/Dupont.pdf. *Category: SUBSTANTIVE*
• **Integrated analysis and reporting of data from the food chain and other sectors ("One Health" approach).**	
Integrated analysis and reporting of data from the food chain to evaluate with animal, human and ~~other sectors ("One~~ relevant environmental aspects for a "One Health" ~~approach)~~approach.	**USA** Rationale: Animal, human and environmental sectors are outside Codex scope but an integrated approach is one that should be added to other data streams, not be duplicative of them. The Codex component should complement the other pieces. *Category: TECHNICAL*
• **Period review and resetting of the risk analysis cycle as monitoring and surveillance data, together with new technology, is analysed and reported**	
~~Period~~ Periodic review and resetting of the risk analysis cycle as monitoring and surveillance data, together with new technology, is analysed and reported.	**Australia** *Category: EDITORIAL*
~~Period~~ Periodic review and resetting of the risk analysis cycle as monitoring and surveillance data, together with new technology, is analysed and reported.	**USA** *Category: EDITORIAL*

SPECIFIC COMMENTS

Section/paragraph	**Member/Observer/ rationale**

Table 1: Description of steps

Step	**Scope**	**Programme**	**Design**	**Analysis and reporting**
1	Priority AMs and foods as defined at national level	Monitoring of pathogens / indicators in a limited range of foods for susceptibility to priority AMs Collection of national AM sales/use data as available	Informed by previous surveys and international experience and recommendations	Limited to monitoring data from the food chain
2	Priority AMs and representative foods	Monitoring of a range of pathogens / pathogen determinants and indicators in a number of foods along the food chain Surveillance Collection of national AM sales/use by type of use and species group	Informed by risk profile Alignment of methodologies across sectors Pro-active surveillance as informed by monitoring Review and resetting of design as needed	Co-ordinated and systematic analysis and reporting of data from along the food chain
3	AMs, foods and pathogens / determinants as determined by risk profile	Monitoring of a range of pathogens / pathogen determinants and indicators in a range of foods along the food chain; monitoring of indirect sources Surveillance Collection of national and regional AM sales/use by type of use and species group, and route of administration	Based on risk profile Alignment of methodologies across sectors Pro-active surveillance as informed by monitoring and human health epidemiology 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 methodological improvement	Co-ordinated and systematic analysis and reporting of data from along the food chain Integration of data from human sources in co-ordinated analysis and reporting

Table 1: Description of steps	**Thailand** The last sentence in Step 3: Programme should be revised as follows; Surveillance Collection of national and/or regional AM sales/use by type of use and species group, and route of administration *Category: EDITORIAL*
Table 1: Description of steps	**Canada** (Page 9). Table 1. Some thoughts for harmonization in the document.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Step 1. Column on Program – only includes surveillance of food? Not animals – at slaughter or on farm? Step 2. Currently has 'review and resetting of design as needed" which didn't appear in the Step 2 bullets above. Suggest it should be added to Step 2 bullets above.
Step 2 - Design: Revise "Alignment of Harmonize methodologies across sectors for sample types in humans, animals and retail meats, to the extent possible"	**USA** Rationale: It is not possbile to harmonize methoddologies across all ectors. It is better to be specific and give some guidance to countries on wht is achievable
Table 1: Description of steps	**FAO** This table is not cross referenced in the text yet. Could be added earlier in the section
	International Association of Consumer Food Organizations Similar to the previous comment, in step 3, under the "Programme" column, add "including farm- and herd-level use when possible" at the end of the paragraph.
10. Design of monitoring and surveillance programmes	
10. Design of monitoring and surveillance programmes	**Canada** Design of monitoring and surveillance programmes (Page 10). 10.1. Prerequisites to design. Canada considers that the first step is for the country to decide the objectives of their surveillance program and to link this with their national action plan. The second step is to map out details of Steps 1-3, in consultation with their stakeholders using the information described in bullets under 10.1.1 and 10.1.2. Currently, Canada notes there is overlap between 10.1.1 and 10.1.2 and suggest refining of the two lists or combining the two lists under a more generic heading.
Many options are available in regard to design of integrated monitoring and surveillance programmes for AMR. The design will be primarily determined by the resources available and the technical capability of the Competent Authorities. An ability to change the design in response to new policy objectives, changes in scientific knowledge and risk assessment is a key attribute for ensuring continuous improvement of the programme. Design should proactively introduce new elements and measures in a timely manner so as to minimise food-borne transmission of AMR.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Many options are available in regard to design of integrated monitoring and surveillance programmes for AMR. The design will be primarily determined by the risk management objectives, the resources available and the technical capability of the Competent Authorities. Prioritization of design elements (e.g., bacteria, food products, and antimicrobial agents) should be a function of the risk manager, and not the surveillance system administration. An ability to change the design in response to new ~~policy~~ risk management objectives, changes in scientific knowledge and risk assessment is a key attribute for ensuring continuous improvement of the programme. Design should proactively introduce new elements and measures in a timely manner so as to minimise food-borne transmission of AMR.	**USA** Rationale: It should be clarified here that the prioritization of the AMR bacteria/food/antimicrobial is a function of the risk manager, and not the surveillance system administration. *Category: TECHNICAL*
10.1 Prerequisites to design	
10.1.1 Step-wise approach	
10.1.1 ~~Step-wise~~ Stepwise approach	**Australia**
A step-wise approach is key to ensuring continuous enhancement of a monitoring and surveillance programme. The following aspects should be taken into account in deciding on an appropriate initial step in design and implementation:	
A step-wise approach is key to ensuring continuous enhancement of a monitoring and surveillance programme~~,~~ however it is essential as enhancements are made to consider the importance of historical data to determine trends. The following aspects should be ~~taken into account~~ factored in ~~deciding on~~ arriving at an appropriate initial step in design and implementation:	**USA** Rationale: As methods and data interpretation change, it is important to give proper context. Additional bullets help add contextual information. *Category: TECHNICAL*
• **Public health infrastructure and knowledge of AMR**	
~~Public~~ Human health infrastructure and knowledge of AMR	**OIE** *Category: EDITORIAL*
Public health infrastructure and knowledge of AMR Capacity of the Food Safety Control System Other relevant national circumstances	**USA** Rationale: Focus on antimicrobials important for therapeutic use in human medicine and additional information from research for consideration. *Category: TECHNICAL*
• **Veterinary infrastructure**	
Veterinary infrastructure . Veterinary drugs infrastructure	**Indonesia** Indonesia proposed additional aspect should be taken: “Veterinary Drugs Infrastructure” *Category: TECHNICAL*
~~Veterinary~~ Animal health infrastructure	**OIE**
• **Pharmaceutical infrastructure and distributions systems**	
• **Existing national survey data**	
• **National strategies and action plans**	
• **Budget**	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Budget	**Canada** (Page 10). 10.1.1. Bullet for budget. Suggest adding here also human resources and expertise.
• **Laboratory capacity and performance**	
• **Type of agricultural, aquatic and livestock production systems and practices**	
Type of ~~agricultural~~plant, aquatic and livestock production systems and practices	**OIE**
• **Other relevant national circumstances, including historical data**	
10.1.2 Information sources	
The Competent Authorities responsible for food safety should consider all available information on:	
• **Existing national [and international] surveys and/or programmes (regulatory and voluntary)**	
Existing data from various sources e.g. national ~~[and international]~~ and international surveys and/or programmes (regulatory and voluntary), researches	**Thailand** *Category: EDITORIAL*
• **Type and use of AMs along the food chain**	
Type and use of medically important AMs along the food chain	**ICGMA** Monitoring resources should be focused on AMs important for use in human medicine.
• **Food-borne pathogens occurring in each exposure pathway**	
~~Food-borne~~ Foodborne pathogens occurring in each exposure pathway	**FAO**
• **Food supply and distribution systems**	
~~Food~~ Results of food value chain analyses, including food supply and distribution systems	**FAO** Suggest to add some specificity as to what is to be considered. *L*
• **Food consumption patterns and habits**	
• **Foodborne illness data in humans [and animals] that has been attributed to AMR**	
• **International guidance published by international organisations**	
~~International guidance published by~~ Published international ~~organisations~~ guidance	**Canada**
International standards and guidance published by international organisations	**OIE**
As with infrastructure and capability considerations above, the extent of the information available and the ability to access and integrate this information will depend on the national situation and the information needs of the initial step that is taken in monitoring and surveillance.	
10.1.3 Risk profile	
10.1.3 Risk profile	**Canada** (Page 11). 10.1.3. Canada supports risk profile activities. However in this context, this could be a very time-consuming process as proposed as a pre-requisite for surveillance.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	The current structure of a risk profile is for the purpose of answering a specific question, rather than a general approach across all antimicrobial use practices, resistance hazards, in all food animal species. *Category: SUBSTANTIVE*
In 10.1.3 Risk profile, delete the bullet points 10 and 11 which are duplicated with the bullet points 4 and 5.	**China**
10.1.3 Perfil de riesgos	**Colombia** Debería remitirse al CAC/GL 77-2011 y nombrar únicamente aquellos aspectos que ese documento no tenga explícitamente contemplados, especialmente en el APÉNDICE 1.
Developing a risk profile from available information on hazards and risks (CAC/GL 77-2011) is an important prerequisite to design and should include quantitative information on the likely presence of hazards and associated information, including:	
• **Lists of critically important (CZ) antimicrobials**	
~~Lists of critically important (CZ) antimicrobials~~	**Australia** Rationale: Australia suggests deleting as there is no context of what this list represents and there appears to be duplication with 10.1.3 dot point 7, *Category: SUBSTANTIVE*
• Lists of critically important ~~(CZ) -~~ antimicrobials	**Brazil** *Category: SUBSTANTIVE*
Lists of critically important ~~(CZ) antimicrobials~~antimicrobials (CIAs)	**Thailand** *Category: EDITORIAL*
Lists of critically important (CZ) antimicrobials	**USA** What is CZ? *Category: EDITORIAL*
Lists of critically important ~~(CZ)~~ antimicrobials	**ICGMA** Not clear what CZ refers to or means. *Category: EDITORIAL*
Lists of ~~critically important (CZ) antimicrobials~~priority antimicrobial agents	**International Association of Consumer Food Organizations** It is not clear how “Lists of critically important (CZ) antimicrobials” (first bullet) is distinct from “Lists of [antimicrobials] prioritized as important for public health” (seventh bullet).

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Critically important antimicrobials are generally presented as a subset of antimicrobials important for public health. We suggest the bullet should read "Lists of priority antimicrobial agents," which is more inclusive, as well as consistent with the term used in the definitions section. *Category: SUBSTANTIVE*
• **Emerging foodborne AMR threats**	
• **Changing antimicrobial use patterns**	
~~Changing antimicrobial~~ Use patterns of antimicrobials along the food chain any any information on changing use patterns	**FAO** As this bullet and bullet 8 are similar, suggest that they are combined *Category: EDITORIAL*
• **Epidemiology of potential transmission of resistance form food to humans**	
Epidemiology of potential transmission of resistance ~~form~~ from food to humans	**Australia** *Category: EDITORIAL*
Epidemiology of potential transmission of resistance ~~form~~ organisms (or determinants) from food to humans	**FAO** resistance is not transferred to humans but to microorganisms. In communication outreach it has become apparent that there is some confusion about what is actually resistant to suggest to not take shortcuts and refer to antimicrobial resistant organisms *Category: TECHNICAL*
• **Factors affecting foodborne AMR human exposure e.g. food chain hygiene, cooking of foods.**	
• **The likely presence of foodborne microbiological hazards (foodborne AMR microorganism and /or determinants) along the food chain(s) to be monitored**	
• **Lists of AMs prioritised as important for public health**	
~~Lists of AMs prioritised as important for public health~~	**International Association of Consumer Food Organizations** This bullet is no longer needed, as it is included in the revised first bullet, "Lists of priority antimicrobial agents" *Category: SUBSTANTIVE*
Lists of AMs prioritised as important for ~~public~~ human health	**OIE** *Category: EDITORIAL*
• **Use patterns of AMs along the food chain**	
~~Use patterns of AMs along the food chain~~	**FAO** Covered in an earlier bullet *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
• **Indirect pathways for contamination of food**	
• **Factors affecting human exposure to foodborne hazards e.g. food chain hygiene, cooking of foods**	
~~Factors affecting human exposure to foodborne hazards e.g. food chain hygiene, cooking of foods~~	**FAO** proposed to delete for consistency with change in bullet 5 which now covers this point *Category: TECHNICAL*
• **Epidemiology information on potential transmission of resistance from food to humans**	
• **Any risk assessment information that is available**	
Risk profiling will utilise the above sources and any other relevant information to describe the potential foodborne risks of transmission of AMR in the particular food chain setting. The extent of the risk that is undertaken will depend on the national situation and the design and implementation step that is being initiated. In many situations, very little risk-based information will be available to draw on and the risk profile will be primarily based on an accumulation of information on hazards and likely exposure through the food chain.	
Risk profiling will utilise the above sources and any other relevant information to describe the potential foodborne risks of transmission of AMR in the particular food chain setting. The extent of the risk that is undertaken will depend on the national situation and the design and implementation step that is being initiated. In ~~many~~ situations, where very little risk-based information ~~will be~~ is available to draw on ~~and~~ the initial risk profile ~~will~~ may be ~~primarily based on~~ an accumulation of information on hazards and likely exposure through the food chain. As additional information becomes available the risk profile may be revised to reflect risk-based information.	**USA** Rationale: The statement as written reflects the current availability of data, but given that the guideline may be used for many years, we recommend these edits to reflect current and future states. *Category: TECHNICAL*
Risk profiling will utilise the above sources and any other relevant information to describe the potential foodborne risks of transmission of AMR in the particular food chain setting. The extent of the risk profiling that is undertaken will depend on the national situation and the design and implementation step that is being initiated. In many situations, very little risk-based information will be available to draw on and the risk profile will be primarily based on an accumulation of information on hazards and likely exposure through the food chain.	**USA** It appears that this word was inadvertently left off. *Category: EDITORIAL*
10.2 Elements of an integrated monitoring and surveillance programmes	
10.2 Elements of an integrated monitoring and surveillance programmes	**Canada** (Page 11). 10.2 Elements of an integrated monitoring and surveillance programmes It is considered to strive for statistical robustness as indicated in the first paragraph under 10.2. Under the third bullet, we should also strive to statistically evaluate trends in AMU over time if national sales data (census data) are not available.
Whatever the step that is utilised, an integrated programme for monitoring and surveillance of AMR along the food chain should strive to include systematic development of the following design elements and technical characteristics:	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
• **Monitoring structure for the food chain**	
• **Sample sources and sampling methodology**	
• **Sampling plans (representativeness, frequency, sample size, etc) that are statistically robust to determine trends in AMR over time**	
• **List of target microorganisms; (pathogens and indicators) and resistance determinants**	
• **Laboratory testing methodology and quality assurance**	
• **Data management including method of Data analysis, sharing and reporting**	
Data management including method of ~~Data~~ data analysis, sharing and reporting	**Australia**
10.3 Types of structure design	
10.3 Types of structure design	**Canada** (Page 11). 10.3. Types of structure design. Canada proposes a title change to this section "Surveillance and Monitoring Program Design". This section as written does provide material required to meet the intended goal for on-going longitudinal surveillance (which is what Step 3 is aiming for). Overall, this subsection needs further elaboration.
• **Monitoring programmes may include the following types of design or studies: Simple cross-sectional point prevalence surveys that can be used to collect basic information and compare between various populations at particular point of time**.	
Monitoring programmes may include the following types of design or studies: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** *Category: EDITORIAL*
• **Longitudinal monitoring to routinely and continuously collect data for a long period of time. The limitations of longitudinal studies are related to their greater complexity and cost compared with point prevalence surveys, but provide valuable information on trends. In the most simple circumstances one or two target microorganisms can be intensively monitored at regular intervals, e.g. every other year.**	
• **Investigative, targeted surveillance studies**	
• **Short-term *ad hoc* studies or projects that can enhance the overall technical and analytical value of a national programme e.g. use of new analytical methods.**	
10.4 Sample sources	
10.4 Sample sources	**Canada** (Page 12). Under 10.4 Sample sources: The type of samples in this section could be categorized more clearly into 'Samples from animals and related sources' and 'Samples from food', for example by using bullet points for these two categories.
10.4 Sample sources	**Australia** Comment: Australia questions the inclusion of testing of live animals as this duplicates activities covered by OIE standards. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
In 10.4 Sample sources, add a description of sample sources from crops.	**China**
Sources of samples will be determined by the step that is designed. Data from the samples can be integrated with data from other sources e.g. human isolates.	
Sources of samples will be determined by the monitoring and surveillance step ~~that is designed~~under consideration. Data from the samples can be integrated with data from other sources e.g. human isolates.	**Australia** *Category: EDITORIAL*
Samples from animals and related sources along the food chain should include:	
Samples from crops and related sources along the food chain should include crops, soil, and water, including irrigation water. Samples from animals and related sources along the food chain should include:	**International Association of Consumer Food Organizations** This section should be expanded in keeping with the broader scope of the document to include all uses of antimicrobials and all sectors. Crops may be exposed to antimicrobials through sources that are not related to food-producing animals, including antimicrobials applied as pesticides. Therefore, crop sampling, including irrigation water, should be considered separately from sampling related to food-producing animals.
Samples from animals and plants and related sources along the food chain should include:	**OIE**
Samples from food-producing animals (e.g. faeces), feed, litter, water, soil, etc. taken at farm or crops. Although samples from both healthy animals and sick animals are useful for surveillance, samples from healthy animals should be the primary focus for monitoring and surveillance because such samples can provide an unbiased measure of AMR in source animals for the human food supply. Samples collected from food-producing animals should be taken from the same animal species as retail meat food samples in an integrated programme	
Samples from food-producing animals (e.g. faeces), feed, litter, water, soil, etc. taken at farm or crops. Although samples from both healthy animals and sick animals are useful for surveillance, samples from healthy animals should be the primary focus for monitoring and surveillance because such samples can provide an unbiased measure of AMR in source animals for the human food supply. Samples collected from food-producing animals ~~should~~ may be taken from the same animal species as retail meat food samples in an integrated programme; however, one cannot assume that there is a relationship between what is found on farm and at retails because of the many processing steps that occur between the farm and at retail level	**USA** Rationale: The statement as written appears to assume that what is found on farm will correlate with what is found at retail and that is not scientifically supportable. *Category: TECHNICAL*
Samples from food-producing animals (e.g. faeces), feed, litter, water, soil, etc. taken at ~~farm or crops~~farm. Although samples from both healthy animals and sick animals are useful for surveillance, samples from healthy animals should be the primary focus for monitoring and surveillance because such samples can provide an unbiased measure of AMR in source animals for the human food supply. Samples collected from food-producing animals should be taken from the same animal species as retail meat food samples in an integrated programme	**USA** Rationale: The introductory sentence states the information pertains to animals then mentions crops which is out of place. *Category: EDITORIAL*
Samples from food-producing animals (e.g. faeces), feed, litter, water, soil, waste water, liquid and solid effluent etc. taken at farm or crops. Although samples from both healthy animals and sick animals are useful for monitoring and surveillance, samples from healthy animals should be the primary focus for monitoring and surveillance because such samples can provide an unbiased measure of AMR in source animals for the human food supply. Samples collected from food-producing animals should be taken from the same animal species as retail meat food samples in an integrated programme	**FAO** Change made for consistency and also suggest to include more example of sample types *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Samples from food-producing animals (e.g. faeces), feed, litter, water, soil, etc. taken at farm or crops. Although samples from both healthy animals and sick animals are useful for surveillance, samples from healthy animals should be the primary focus for monitoring and surveillance because such samples can provide an unbiased measure of AMR in source animals for the human food supply. Samples collected from food-producing animals should be taken from the same animal species as retail meat food samples in an integrated programme	**International Association of Consumer Food Organizations** The sentence "samples from food-producing animals… taken at farm or crops" may require revision, as it is not immediately clear how a sample from food-producing animals would be taken from crops.
Samples from food-producing animals ~~(e.g. faeces), feed, litter, water, soil, etc. taken at farm or crops. Although samples from both healthy animals and sick animals are useful for surveillance, samples from healthy animals~~ should be ~~the primary focus for~~ chosen in accordance in accordance with OIE Terrestrial Animal Health Code (2017) Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programs and ~~surveillance because such samples can provide an unbiased measure~~ OIE Aquatic Animal Health Code (2017) Chapter 6.4 Development and harmonization of ~~AMR in source animals~~ national antimicrobial resistance surveillance and monitoring programs for ~~the human food supply. Samples collected from food-producing animals should be taken from the same animal species as retail meat food samples in an integrated programme~~aquatic animals.	**OIE** *Category: TECHNICAL*
At holding stage, sample can be taken from holding pen floor, truck/crate swabs, dust, etc.	
At holding stage, ~~sample~~ samples can be taken from holding pen floor, truck/crate swabs, dust, etc.	**Australia** *Category: EDITORIAL*
In the post-slaughter stage, samples can be caecal contents, carcass rinsates and swabs, lymph nodes, etc.	
The types of food samples include meat (beef, chicken, turkey, pork, etc.), fish, dairy product, other edible tissues (liver, kidney, etc.), vegetables, processed food. The selection of foods for surveillance should reflect consumption patterns in the population and likely prevalence of AMR, but may be modified from year to year in order to capture multiple commodities.	
Samples from food processing and related sources along the food chain should include food samples, processing water, wastewater, and the processing environment. The types of food samples include meat (beef, chicken, turkey, pork, etc.), fish, dairy product, other edible tissues (liver, kidney, etc.), vegetables, processed food. The selection of foods for surveillance should reflect consumption patterns in the population and likely prevalence of AMR, but may be modified from year to year in order to capture multiple commodities.	**International Association of Consumer Food Organizations** Sampling during food processing should also be included, including processing water. *Category: SUBSTANTIVE*
Food samples should reflect the purchasing habits of the consumer (e.g. in open markets or chain stores).	
10.5 Sampling plans	
10.5 Sampling plans	**Brazil** Brazil suggests that the sampling plans be further developed in this document. It is not enough to cite examples of how sampling can be performed, since countries should adopt the same rule for the establishment of the monitoring samples.
When designing monitoring and surveillance programmes, representativeness of the data obtained is essential to ensure quality information. Irrespective of the step, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under study is representative of the whole population and amenable to statistical analysis of temporal trends.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
When designing monitoring and surveillance programmes, representativeness of the data obtained is essential to ensure quality information. Irrespective of the step, an adequate sampling design is required to interpret data and compare results, and to ensure that data obtained from the selected population under study is representative of the whole population and amenable to statistical analysis of temporal trends.	**Canada** (Page 12). 10.5 Sampling plans. First paragraph. “the selected population under study is representative of the whole population”. Being representative of the whole population may not be necessary. Suggest replacing with “representative of the target population”.
Examples of sampling methods are: Simple Random Sampling (SRS), Stratified Sampling, Systematic Sampling, etc[4].	
The following elements should be defined when designing the sampling plan:	
• **Samples selection strategy: retrospective/prospective**	
• **Target animal populations/food/crops**	
Target animal ~~populations/food/crops~~ populations/food/plants	**OIE** *Category: EDITORIAL*
• **Selected epidemiological units (flocks, holding)**	
• **Frequency of sampling**	
• **Statistical power and goals of testing (precision of point estimates versus sensitivity to change over time**	
Statistical power and goals of testing ~~(precision~~ (e.g. detection of specific resistance genotypes), precision of point ~~estimates versus~~ estimates, sensitivity to change over ~~time~~time etc	**FAO** *Category: EDITORIAL*
Statistical power and goals of testing (precision of point estimates versus ~~sensitivity~~ sensitivity) to change over time	**OIE** *Category: EDITORIAL*
• **Sampling size with estimates of statistical power to detect changes in antimicrobial resistance patterns.**	
• **Number of isolates/samples**	
• **Selection of strata or risk clusters**	
Selection of strata or risk clusters	**Canada** Seventh bullet: The bullet currently reads “selection of strata or risk clusters”. Canada suggests that more details or examples would be useful. *Category: EDITORIAL*
• **Point in the food chain where the samples will be taken**	
Selection strategy and principle	
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.	

[4] Guidance on sampling methods is provided by the Codex documents CCFH and CCMAS

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
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~~ foodborne illness under surveillance, may also be employed.	**USA** Rationale: The additions help to frame the statement within the scope of work *Category: TECHNICAL*
Frequency of sampling	
Frequency of sampling	**Canada** Frequency of sampling. Samples could also be taken as per the production cycles of the animal such as once per flock/herd or at select multiple times for a flock/herd; for example, at chick placement on a broiler farm and then again at pre-harvest.
For surveys and periodic surveillance studies, the frequency of testing should be decided on the basis of the incidence and seasonality of the bacteria or diseases under surveillance. Samples can be collected monthly or periodically throughout the year from different sites, in sufficient numbers, to identify trends.	
Sampling size	
Sampling size	**Canada** (Page 13).Under 10.5, sampling size Example of sample size calculation can be found at EFSA Technical specification on harmonised monitoring AMR 2012; 10(6):2742. The following link can be inserted: (https://www.efsa.europa.eu/en/efsajournal/pub/3686). Particularly for step 1 and 2, the sampling size may be a balance between the desired precision and budgetary constraints. Knowledge of this discrepancy is important; particularly for understanding the results. Also, if greater stratification of the data or more exploration of risk factors is desired; then the sample size will have to increase.
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 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; depends on the initial or expected prevalence of resistance and the size of the population to be monitored; depends on the desired level of statistical significance and power to detect a difference.	
Example of sample size calculation can be found at EFSA Technical specification on harmonised monitoring AMR 2012; 10(6):2742.	
~~Example of sample size calculation can be found at EFSA Technical specification on harmonised monitoring AMR 2012; 10(6):2742.~~	**Brazil**
Example of sample size calculation can be found at EFSA Technical specification on harmonised monitoring AMR 2012; 10(6):2742~~.~~ **. and OIE Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes; Table 1: Sample size estimates for prevalence in a large population.**	**Japan** Rationale：Refer to the General Comments.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Example of sample size calculation can be found at EFSA Technical specification on harmonised monitoring AMR 2012; 10(6):2742.~~	**FAO** Suggest that references be to international sources where they exist rather than regional or national ones. eg [OI E's Terrestial Animal Health Code Chapter 6.7, Hamonisation of Natinal Antimicrobial Resistance Surveillance and Monitoring Programs http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_antibio_harmonisation.pdf.].
10.6 Target microorganisms and resistance determinants	
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.	
Bacterial species should be chosen considering ~~public~~ human health aspects, including the epidemiology of foodborne diseases, and should include both foodborne pathogens and indicator organisms of commensal bacteria.	**OIE** *Category: EDITORIAL*
***Salmonella* is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance programme. 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. *Staphylococcus*, *Clostridium* or *Vibrio)*.**	
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbour transferable resistance genes. Commensal *E. coli* and *Enterococcus* spp should be used as indicators of Gram negative and Gram positive intestinal flora.	
Indicator organisms of commensal intestinal bacteria may contaminate food and can harbour transferable resistance genes. Commensal *E. coli* and *Enterococcus* ~~spp~~ spp. should be used as indicators of ~~Gram negative~~ Gram-negative and ~~Gram positive~~ Gram-positive intestinal flora.	**FAO** *Category: EDITORIAL*
Whenever possible the monitoring and surveillance programme 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.	
Tests for virulence factors, AMR genes, gene transferability and gene sequencing can also be applied.	
10.7 Laboratories	
In 10.7 Laboratories, add one bullet point: The laboratory should have the corresponding qualification and capability.	**China**
Laboratories participating in the monitoring and surveillance program should:	
• **isolate, identify and type target bacteria from the different matrices, by using internationally accepted reference methods or alternatively other analytical methods validated according to internationally accepted validation methodology;**	
• **be accreditated in accordance with national and/or international regulations**	
	FAO specifying a requirement for laboratory "accreditation" – is onerous and unnecessary, especially if a laboratory is capable of 'using internationally accepted reference methods' (1st bullet point), is able to 'perform AST using standardized and validated methods' (4th bullet point); and has 'access to a national reference laboratory or international laboratory' (last bullet point).

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	It also disregards the step at which a country's monitoring and surveillance system is at....while eventually it may be accredited it may not be at the outset. *Category: SUBSTANTIVE*
• **be involved in a quality assurance systems including proficiency test in identification, typing and susceptibility testing of the microorganisms included in the monitoring and surveillance system;**	
be continuously involved in a quality assurance systems including proficiency test in identification, typing and susceptibility testing of the microorganisms included in the monitoring and surveillance system;	**Australia** *Category: EDITORIAL*
• **perform antimicrobial susceptibility testing using standardised and validated methods (both phenotypic and/or genotypic);**	
• **store isolates for a period of time by methods that ensure viability and absence of change in strain properties;**	
• **have access to a national reference laboratory or an international laboratory (e.g. WHO-collaborative centre) able to provide technical assistance if necessary.**	
10.8 Antimicrobial susceptibility testing	
10.8.1 Methods and interpretative criteria	
Susceptibility testing methods (disk diffusion or minimum inhibitory concentration (MIC) methodologies) standardized and validated by internationally recognised organizations such as European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI) should be used to ensure reliable data.	
Susceptibility testing methods ~~(disk diffusion or~~ reporting a minimum inhibitory concentration (MIC) ~~methodologies)~~ that are standardized and validated by internationally recognised organizations such as European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI) should be used to ensure ~~reliable~~ reliability and comparability of data.	**Australia** Rationale: Disk diffusion methods do not allow the detection of a 'reduced susceptible population' and thus will not allow for examination of susceptibility trends over time. *Category: SUBSTANTIVE*
Susceptibility testing methods (disk diffusion or minimum inhibitory concentration (MIC) methodologies) standardized and validated by internationally recognised organizations such as ~~European Committee on Antimicrobial Susceptibility Testing (EUCAST) or~~ Clinical and Laboratory Standards Institute (CLSI) should be used to ensure reliable data.	**USA** *Category: TECHNICAL*
Quality control (QC) strains of bacteria should be used according to international recommendations e.g. from EUCAST. The quality control 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 the other bacteria tested are valid before reporting the results.	
Quality control (QC) strains of bacteria should be used according to international recommendations e.g. from ~~EUCAST~~EUCAST **or CLSI**. The quality control 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 the other bacteria tested are valid before reporting the results.	**Japan** Rationale：In the previous paragraph, it is stated that susceptibility testing methods should be standardized by not only EUCAST but also CLSI. Therefore QC strain from CLSI should also be added. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Quality control (QC) strains of bacteria should be used according to international recommendations e.g. from EUCAST. The quality control 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 the other bacteria tested are valid before reporting the results.	**USA** Rationale: There is no 'EUCAST MIC testing method' per se, but rather just a reference to an ISO method which is the CLSI method. Reference to a 'standardized and validated' method is sufficiently explanatory that quality control is a central component to any surveillance protocol. Further explanation is warranted to explain the two potential interpretive categories available for surveillance depending on the scope and objective of the program.
Interpretation of results for disc diffusion or MICs, should also be done according to EUCAST or CLSI standards and should include the quantitative results (disk diffusion zone diameters or minimal inhibitory concentrations values) as well as the categorisation of the isolate (resistance or susceptible).	
Interpretation of results for disc diffusion or MICs, should also be done according to EUCAST or CLSI standards and should include the quantitative results ~~(disk diffusion zone diameters or minimal~~ (minimal inhibitory concentrations values) as well as the categorisation of the isolate ~~(resistance~~ (resistant or susceptible).	**Australia** Rationale: Disk diffusion methods do not allow the detection of a 'reduced susceptible population' and thus will not allow for examination of susceptibility trends over time. *Category: SUBSTANTIVE*
In 10.8.1 Methods and interpretative criteria, Paragraph 3, "……as well as the categorisation of the isolate (resistance or susceptible)" should be revised to "……as well as the categorisation of the isolate (susceptible, intermediate or resistant)".	**China**
Interpretation of results for disc diffusion or MICs, should also be done according to ~~EUCAST~~ EUCAST recommendations or CLSI standards and should include the quantitative results (disk diffusion zone diameters or minimal inhibitory concentrations values) as well as the categorisation of the ~~isolate (resistance~~ isolates. isolates. Epidemiological cutoff values are used for wild type or ~~susceptible)~~non-wild type. Clincial breakpoints must be used for susceptible, intermediate, or resistant classifications	**USA** *Category: TECHNICAL*
Primary quantitative data should be maintained in order to allow comparability of results e.g. with human data, for early recognition of emerging resistance or reduced susceptibility and in order to maximize ability to analyse and compare results across sample sources.	
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.	
The use of epidemiological cut-off values, rather than 'clinical' breakpoints, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance.	
Detailed information on interpretation of antimicrobial susceptibility test results and Quality control can be found at WHO AGISAR Guidelines for Integrated surveillance of AMR in foodborne bacteria.	
Detailed information on interpretation of antimicrobial susceptibility test results and Quality control can be found at WHO AGISAR Guidelines for Integrated surveillance of AMR in foodborne bacteria~~.~~ OIE Terrestrial and Aquatic Animal Health Codes, and the 2011 Clinical and Laboratory Standards Institute (CLSI) VET05 Report (Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin; A Report)	**USA** Rationale: There are a variety of helpful references that could be useful to the reader. *Category: TECHNICAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
10.8.2 The panel of antimicrobials for susceptibility testing	
10.8.2 The panel of antimicrobials for susceptibility testing	**Thailand** A minimum set of panel of antimicrobial agents for susceptibility testing with target bacteria should be developed. This will be useful for AMR monitoring and surveillance programmes. *Category: TECHNICAL*
The panel of antimicrobials for susceptibility testing should be harmonised as to ensure continuity and comparability of data, and attempts should be made to use the same antibiotic class representatives across sample sources, across geographic regions, and over time.	
The panel of antimicrobials for susceptibility testing should be ~~harmonised as~~ selected taking into consideration national patterns of use and to the greatest extent possible harmonised to ensure continuity and comparability of data~~, and attempts.~~ Attempts should be made to use the same antibiotic class representatives across sample sources, across geographic regions, and over time.	**Australia** Rationale: The patterns of use and the prioritisation of antimicrobials important for human use will differ between countries. Australia suggests these guidelines be sufficiently flexible to allow for country specific priorities whilst recognising that harmonisation of AM panels and comparability of data within and between countries is critically important.
The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of the antimicrobials and should allow for the tracing of isolates with particulars patterns of resistance.	
Suggested panel of antimicrobials by bacteria for inclusion for AST can be found at WHO AGISAR Guidelines for Integrated surveillance of AMR in foodborne bacteria.	
~~Suggested panel~~ Clinically important antimicrobial classes used in human and veterinary medicine should be monitored. However, the number of tested antimicrobials ~~by bacteria for inclusion for AST can~~ may have to be ~~found at WHO AGISAR Guidelines for Integrated surveillance~~ limited according to the financial resources of ~~AMR in foodborne bacteria.~~the country	**USA** Rationale: The language is consistent with OIE Terrestrial Animal Health Code Ch. 6.7. *Category: TECHNICAL*
Suggested panel of antimicrobials by bacteria for inclusion for AST can be found at WHO AGISAR Guidelines for Integrated surveillance of AMR in foodborne ~~bacteria~~bacteria(http://apps.who.int/iris/bitstream/10665/255747/1/9789241512411-eng.pdf?ua=1) and OIE Aquatic Animal Health Code (2017) Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programs fort aquatic animals and Terrestrial Animal Health Code (2017) Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programs	**OIE** *Category: TECHNICAL*
10.8.3 Concentration ranges of antimicrobials	
The concentration ranges to be used, should ensure that both epidemiological cut off values and clinical breakpoints are included in order to make possible comparability of results with human data. 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.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
The concentration ranges to be ~~used,~~ used should ensure ~~that both~~ that epidemiological cut off values ~~and clinical breakpoints~~ are ~~included in order to make possible comparability of results with human data.~~ included.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.	**Australia** Rrationale: This text needs to be reworded so that it supports the use of epidemiological cut-off values, as it currently contradicts Section 10.8.1. Section 10.8.1 states the use of epidemiological cut-off values should be used as interpretive criteria rather than clinical breakpoints. *Category: SUBSTANTIVE*
Examples of suggested ranges of concentrations of antimicrobials can be found at WHO Agisar Guidelines for Integrated surveillance of AMR in foodborne bacteria.	
~~Examples of suggested~~ More detailed information regarding specific tests and ranges of concentrations of antimicrobials can be found at WHO Agisar Guidelines for Integrated surveillance of AMR in foodborne bacteria, OIE Terrestrial and Aquatic Animal Health Codes, and the 2011 Clinical and Laboratory Standards Institute (CLSI) VET05 Report (Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin; A Report).	**USA** Rationale: There are a variety of helpful references that could be useful to the reader. *Category: TECHNICAL*
Examples of suggested ranges of concentrations of antimicrobials can be found at WHO Agisar Guidelines for Integrated surveillance of AMR in foodborne ~~bacteria~~bacteria(http://apps.who.int/iris/bitstream/10665/255747/1/9789241512411-eng.pdf?ua=1).	**OIE** *Category: EDITORIAL*
10.8.4 Characterisation of isolates	
Whenever possible characterization of bacterial isolates (genus, species, and additional microbial subtyping) should be done. ***To be further elaborated***	
In 10.8.4 Characterisation of isolates, “(genus, species, and additional microbial subtyping)” should be revised to (genus, species, virulence and additional microbial subtyping).	**China**
To be further elaborated ・Serotyping of *Salmonella*.	**Japan** Rationale：Since Salmonella show different antimicrobial susceptibility depending on the serotype, it is desirable to confirm the serotype. *Category: TECHNICAL*
10.8.5 Molecular testing	
10.8.5 Molecular testing	**Australia** Comment: The guidelines should provide high level guidance on the following for WGS analysis: • Human resource-skills required • Hardware required • Data storage and management • Data analysis and reporting • Accreditation

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Rationale: Codex guidelines should not include detailed guidance on molecular methods but rather high level principles and resources needed. Australia recognises that many countries do not have the capacity to develop molecular testing capabilities in the short to medium term but recognise that guidance is required on the resources and quality parameters needed. *Category: SUBSTANTIVE*
10.8.5 Molecular testing	**FAO** Some text to be considered in further elabotrating this section Molecular testing done to characterize resistant pathogens, focusing on those showing multidrug resistance (MDR) and extreme drug resistance (XDR). Pathogens showing MDR and XDR to critically important Antimicrobials should be prioritized. Countries are encouraged to identify pathogens common to sub-regions or regions presenting an increasing critical challenge of AMR, and can initiate regional efforts utilizing molecular testing to generate regional pools of data that can be used in prevention of cross-border transmission of resistant pathogens. Molecular characterization of pathogens showing MDR and XDR should also be used in development of effective vaccines and alternative treatment methods *Category: SUBSTANTIVE*
Use of molecular testing such as Whole Genome Sequencing (WGS), detection of genes of resistance. ***To be further elaborated***	
Use of molecular testing such as Whole Genome Sequencing (WGS), detection of genes of resistance.	**Russian Federation** We propose to include into paragraph 10.8.5 «Molecular analysis» the following: “there is an urgent need to implement much wider usage of the Molecular Genetic Methods for the study of microorganisms (including amplification technologies and methods of whole-genome sequencing based on the NGS technology) in order to effectively identify the most significant determinants of resistance for their subsequent localization (within mobile genetic elements, plasmids, etc.) which is of particular epidemiological significance.” *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Use of molecular testing such as Whole Genome Sequencing (WGS), detection of genes of resistance. Whole genome sequencing (WGS) combined with bioinformatic tools can be an effective tool to monitor antimicrobial resistance. 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.	**Consumers International** CI suggests the following language based on the WHO-AGISAR Integrated Surveillance document *Category: SUBSTANTIVE*
11. Surveillance of national antimicrobial sales data for use in animals	
11. Surveillance of national antimicrobial sales data for use in animals	**Canada** Surveillance of national antimicrobial sales data for use in animals (Page 14). Canada suggests that other sources of antimicrobial use data (not just national sales data) should be included in this document. *Category: SUBSTANTIVE*
11. Surveillance of national antimicrobial sales data for use in animals	**Thailand** The term “use”, “consumption” and “sales” in this section should be considered. *Category: SUBSTANTIVE*
11. Surveillance of national antimicrobial sales data for use in ~~animals~~the food chain	**International Association of Consumer Food Organizations** This entire section, including sections 11.1 and 11.2, should be expanded beyond animals, in keeping with the broader scope of the document to address all uses of antimicrobials. *Category: SUBSTANTIVE*
This chapter on antimicrobial use should be read in conjunction with:	
• **Chapter 2.3 (Surveillance of use of antimicrobials in animals) and chapter 2.4. Data management to support surveillance of antimicrobial use of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) guidance on Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria,**	
Chapter 2.3 (Surveillance of use of antimicrobials in animals) and chapter 2.4. Data management to support surveillance of antimicrobial use of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) guidance on Integrated Surveillance of Antimicrobial Resistance in Foodborne ~~Bacteria,~~Bacteria((http://apps.who.int/iris/bitstream/10665/255747/1/9789241512411-eng.pdf?ua=1).	**OIE** *Category: EDITORIAL*
• **Chapter 6.8 (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) of the 2016 OIE Terrestrial Animal Health Code and the Guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals, as included in the OIE Annual report on the use of antimicrobial agents in animals.**	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Chapter 6.8 (Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals) of the ~~2016~~ 2017 OIE Terrestrial Animal Health ~~Code~~ Code, Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animal and the Guidance for completing the OIE template for the collection of data on antimicrobial agents used in ~~animals~~animals(http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_AMUse_Template_Final_2017.xls), as included in the OIE Annual report on the use of antimicrobial agents in ~~animals.~~ animals (http://www.oie.int/fileadmin/Home/fr/Our_scientific_expertise/docs/pdf/AMR/Survey_on_monitoring_antimicrobial_agents_Dec2016.pdf).	**OIE** *Category: TECHNICAL*
11.1 Key aspects to consider when developing surveillance of antimicrobial sales data	
The distribution of antimicrobials for use in animals within the country should be identified.	
The distribution of antimicrobials for use in ~~animals~~ the food chain within the country should be identified.	**International Association of Consumer Food Organizations** This section should be expanded beyond animals, in keeping with the broader scope of the document to address all uses of antimicrobials. *Category: SUBSTANTIVE*
The most appropriate points of data collection should be identified.	
A protocol on the collection of data should be developed.	
A protocol on the collection of data should be developed. Sales and distribution data submitted by drug sponsors and summarized through reporting are not indicative of how antimicrobial drugs are actually used in animals and may represent an estimate of the volume of product sold or distributed to various outlets and not the volume of product purchased or used by the end user.	**USA** Rationale: Need to make this statement for clarity. Sales data, at best, reflects an estimate of the antimicrobials marketed over a given period of time and reporting often varies in the level of sophistication, based upon the resources available to a reporting country.
The estimated animal biomass that can be exposed to antimicrobials should be calculated. [In the EU the ESVAC project has provided a methodology for the calculation of such animal population. The FDA has recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a worldwide estimate of the animal population for country.]	
The estimated animal biomass that can be exposed to antimicrobials should be calculated. [In the EU the ESVAC project has provided a methodology for the calculation of such animal population. The FDA has recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a worldwide estimate of the animal population for country.]	**Thailand** The methodology for the calculation should be based on the final recommendations of the international or intergovernmental organization such as OIE, FAO and WHO.
~~The~~ [The estimated animal biomass that can be exposed to antimicrobials should be calculated~~. [In the EU the ESVAC project has provided a methodology for the calculation of such animal population. The FDA has recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a worldwide estimate of the animal population for country.~~]]	**USA** Rationale: The sentence is unclear. Does “can be exposed” mean that the biomass is potentially exposed, or does it mean a threshold beyond which additional biomass exposure would be problematic?

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
The estimated crop and animal biomass that can be exposed to antimicrobials should be calculated. [In the EU the ESVAC project has provided a methodology for the calculation of such animal population. The FDA has recently published a proposal for the estimation of the animal population and the OIE is currently working to provide a worldwide estimate of the animal population for country.]	**International Association of Consumer Food Organizations** This section should reflect that the scope has been broadened beyond animals.
The estimated animal biomass that can be exposed to antimicrobials should be calculated. [In the EU the ESVAC project has provided a methodology for the calculation of such animal ~~population~~population(http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500224492.pdf). The FDA has recently published a proposal for the estimation of the animal population ((https://www.fda.gov/downloads/animalveterinary/safetyhealth/antimicrobialresistance/ucm571099.pdf) and the OIE is currently working to provide a ~~worldwide estimate~~ global and regional estimates of ~~the animal population~~ antimicrobial agents intended for ~~country~~use in animals adjusted for biomass of relevant animal populations.~~]~~	**OIE** *Category: TECHNICAL*
11.2 Reporting of the national antimicrobial sales data for use in animals	
11.2 Reporting of the national antimicrobial sales data for use in animals	**Brazil** Brazil believes that the collection of data on use of antimicrobial agents would be more appropriate than by class of antimicrobials. Antimicrobial agents have different doses, so the use quantity of antimicrobials used should also be related to the number of doses that can be used in a given species. The aggregate number per class does not allow refinement of this data.
11.2 Reporting of the national antimicrobial sales data for use in animals	**FAO** Sales data may also be relevant to other sectors e.g. plants/crops *Category: TECHNICAL*
11.2 Reporting of the national antimicrobial sales data for use in ~~animals~~the food chain	**International Association of Consumer Food Organizations** This section should reflect that the scope has been broadened to include the entire food chain and not just animals. *Category: SUBSTANTIVE*
The OIE [5] provides a detailed template for the collection of data on antimicrobials used in animals, with different options for the level of reporting of antimicrobial data. The information can be divided as follows:	
The OIE [8] provides a detailed template for the collection of data on antimicrobials used in (terrestrial and aquatic) animals, with different options for the level of reporting of antimicrobial data. The information can be divided as follows:	**FAO** Clarify that animals refers to both terresterial and aquatic *Category: EDITORIAL*

[5] OIE Annual report on the use of antimicrobial agents in animals

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Data collection on sales of antimicrobials throughout the food chain, including in animals, crops, and in food processing, should be developed. The OIE [8] provides a detailed template for the collection of data on antimicrobials used in animals, with different options for the level of reporting of antimicrobial data. The information can be divided as follows:	**International Association of Consumer Food Organizations** This section needs to be further developed to address reporting of national antimicrobial sales data for use in the entire food chain (not only food-producing animals). *Category: SUBSTANTIVE*
• **Baseline information**	
• **Option 1; overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use**	
Option 1; overall amount sold for/used in animals by antimicrobial ~~class~~agent, with the possibility to separate by type of use	**Brazil** *Category: SUBSTANTIVE*
• **Option 2; overall amount sold for/used in use animals by antimicrobial class, with the possibility to separate by type of use and species group**	
Option 2; overall amount sold for/used in use animals by antimicrobial ~~class~~agent, with the possibility to separate by type of use and species group	**Brazil** *Category: SUBSTANTIVE*
• **Option 3; overall amount sold for/used in animals by antimicrobial class, with the possibility to separate by type of use, species group and route of administration**	
Option 3; overall amount sold for/used in animals by antimicrobial ~~class,~~ agent with the possibility to separate by type of use, species group and route of administration	**Brazil** *Category: SUBSTANTIVE*
Whenever possible the above data should be provided with an estimate of the animal population that can be exposed to the antibiotics (see above).	
The AGISAR guidance provides details on the collection of:	
• **Surveillance of national antimicrobial sales data**	
• **Surveillance of antimicrobial consumption by animal species**	
• **Continuous collection of consumption data by animal species**	
• **Collection of data from a sample of farms**	
• **Stratification of sales data**	
Stratification of sales data	**FAO** Data on sales and use of antimicrobials for use in other agriculture sectors (crop production, apiculture, other) should also be included (with the possiblity to separate by species and provide an estimate of the population that can be exposed) should be incorporated into surveillance and monitoring programs. *Category: EDITORIAL*
12. Implementation of the monitoring and surveillance programme	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
12.1 Sampling procedures	
Samples should be collected by persons authorised to do so (third party accreditation – ref. CCFICS).	
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.	
Temperature and duration of transport, and storage of the samples are important aspects as it may influence the results. During transport and storage of the samples in the laboratory measures to maintain the cold chain should be implemented.	
12.2 Collection and reporting of data	
To ensure an appropriate analysis of the integrated surveillance and monitoring programme it is important that relevant information about the sampling procedure and the individual sample is collected and recorded.	
The information collected and recorded may differ depending on the step that is designed and specific public health objectives.	
Information for each individual sample should include:	
• **General description of the sampling design and randomisation procedure**	
• **General information to identify the isolate, bacterial specie, serovar, etc**	
• **Specific information about the origin of the sample: food producing animal or food category, country of origin, type of sample, stage of sampling in the food chain, place, date of sampling and isolation, etc.**	
Specific information about the origin of the sample: ~~food producing animal or food category,~~ country of origin, type of sample, stage of sampling in the food chain, place, date of sampling and isolation, etc.	**International Association of Consumer Food Organizations** This should address samples other than those from food-producing animals or food products derived from food-producing animals. *Category: SUBSTANTIVE*
Specific information about the origin of the sample: food producing animal <u>species and production type,</u> or food category, country of origin, type of sample, stage of sampling in the food chain, place, date of sampling and isolation, etc.	**OIE** *Category: TECHNICAL*
• **Specific information about the isolation of the isolate and the AST: date of testing, specific information about the method, quantitative results (e.g. MICs in mg/L), etc. In case of qualitative results interpretative criteria should be recorded.**	
Specific information about the isolation of the isolate and the AST: date of testing, specific information about the method, quantitative results (e.g. MICs in mg/L), etc. In case of qualitative results interpretative criteria should be recorded. <u>[Data on sales and use of antimicrobials for use in other agriculture sectors (crop production, apiculture, other) (with the possiblity to separate by species and provide an estiamte of the population that can be exposed) should be incorporated into surveillance and monitoring programs.</u>	**FAO** Insert- need to cover other aspects of ag, including capturing emerging uses that may not be overed *Category: TECHNICAL*
Specific information about the isolation of the isolate and the ~~AST~~<u>Antibiotic Sensitivity Testing (AST)</u>: date of testing, specific information about the method, quantitative results (e.g. MICs in mg/L), etc. In case of qualitative results interpretative criteria should be recorded.	**OIE** *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
12.3 Management of data	
12.3 Management of data	**Canada** Implementation of the monitoring and surveillance programme (Page 16). 12.3. Management of data. This section should also consider AMU information. Canada suggests that one common database may not be possible for both AMU and AMR data. Having two databases may be more practical for these very different types of data. *Category: SUBSTANTIVE*
To properly manage test results and data of the integrated monitoring and surveillance programme, a database that guarantees the security, confidentiality and integrity of the data is needed. At national level, one common database is preferred.	
To properly manage test results and data of the integrated monitoring and surveillance programme, a database that guarantees the security, confidentiality and integrity of the data is needed. At national level, ~~one common~~ the database ~~is preferred~~from different sources should be interconnected.	**Brazil** *Category: SUBSTANTIVE*
The database should allow the appropriate extraction of data when required and for expansion as the integrated monitoring and surveillance system improves. Ongoing validation of the data should be ensured.	
Ideally, data should be stored at isolate level including information about.	
Ideally, data should be stored at isolate level including information about.	**Australia** Comment: Incomplete sentence *Category: EDITORIAL*
Ideally, data should be stored at isolate level including information about.	**Brazil** The last sentence needs to be clarified in relation to “isolate level” and further developed. *Category: SUBSTANTIVE*
Ideally, ~~data~~ data, and associated metadata, should be stored at isolate level ~~including information about~~.	**FAO** The sentence seems unfinished. *Category: TECHNICAL*
12.4 Analysis and reporting of results	
12.4 Analysis and reporting of results	**Canada** 12.4. Analysis and reporting of results. Suggest including more information here about reporting AMU data. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
12.4 Analysis and reporting of results	**Russian Federation** We propose to include into the “Expected results” section 12.4 of the “Data Management” the following: “Knowledge accumulation and the use of research data for risk assessment and development of measures for its minimization.” *Category: SUBSTANTIVE*
12.4 Analysis and reporting of results	**FAO** The guidelines rightly places emphasis on the need for reporting but is rather silent on the use of nationally generated data/results, which should primarily be to inform/support AMR risk management decisions at the national level. Reporting, especially to global databases, should be considered a secondary albeit critically important objective. *Category: SUBSTANTIVE*
12.4 Analysis and reporting of results	**FAO** We suggest inclusion of a paragraph on the required/recommended “policy, regulatory and institutional arrangements for analysis and reporting of results”, at the national level and internationally, esp since the goal is integrated analysis *Category: TECHNICAL*
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.	
Antimicrobial susceptibility testing methods and interpretive criteria should be clearly described and differences transparently explained to show where data may and may not be directly comparable.	
WHO AGISAR Guidelines provides detailed information about interpretation of antimicrobial susceptibility results, data analysis and reporting.	
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, agricultural, livestock and aquatic products and environment.	
When results of PFGE **(pulsed-field gel electrophoresis)**, 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, agricultural, livestock and aquatic products and environment.	**Japan** Rationale：Spell out is necessary
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, ~~agricultural~~plants, ~~livestock~~ animals and aquatic products and environment.	**OIE** *Category: EDITORIAL*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Results of AMR should be compared with results of AMU so that the data can be used when coming up with policies to ensure proper use of antimicrobials.	
Information provided from monitoring and surveillance of AMR should be analyzed combined with information on the amounts of antimicrobial agents that are used in primary production in national settings, especially with regard to direct use associated with the food chain. Sources of such data include	
Information provided from monitoring and surveillance of AMR should be analyzed combined with information on the amounts of antimicrobial agents that are used in primary production in national settings, especially with regard to direct use associated with the food chain. Sources of such data include	**Australia** comment: last sentence incomplete *Category: EDITORIAL*
Information provided from monitoring and surveillance of AMR should be ~~analyzed combined with information on the amounts of antimicrobial agents~~ viewed through a One Health lens that ~~are used in primary production in national settings~~includes not only AMU human and animal medicine, ~~especially with regard to direct use associated with~~ but also the ~~food chain. Sources of such data include~~ many pathways among people, animals, and their shared environment connecting resident bacterial populations.	**USA** Collecting national AMU data from farms is resource intensive. And connecting information regarding what antimicrobials were used in animals on the farm, what resistance developed, what resistance may have already been present, what resistance survived the process of slaughter and processing, and what resistance may have contaminated food products derived from the animal that was found through a surveillance system must consider the ecology of resistance and other external sources that could have contaminated animal products. The development and spread of AMR does not just involve the use of antimicrobial drugs. There are many pathways among people, animals, and the environment connecting resident bacterial populations in one population or setting to those in other populations or settings. The ability of bacteria to move from one setting to another, sometimes over large geographic distances and among the different populations, makes it difficult to know with certainty where resistant strains of bacteria originated. Bacteria have the ability to share genetic material in a variety of ways. *Category: TECHNICAL*
Results of AMR monitoring and surveillance should be published annually. When available, summary reports about AMR in humans, agricultural, livestock and aquatic products and environment can be published.	
Results of AMR monitoring and surveillance should be published annually. When available, summary reports about AMR in humans, ~~agricultural~~animals, ~~livestock~~ plants and aquatic products and environment can be published.	**OIE** *Category: EDITORIAL*
12.5 Targeted investigation	
Targeted investigation which is not included in the routine AMR monitoring and surveillance programme 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.	
Targeted investigation which is not included in the routine AMR monitoring and surveillance programme 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.	**USA** Paragraph 1 – "Critical Resistance Alert System" needs more explanation

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Rationale – It is not clear what this is. *Category: TECHNICAL*
13. Review	
13.1 Integrated analysis of results	
13.1 Integrated analysis of results	**Canada** Review (Page 16). 13.1. Suggest further elaborating this section. Examples would be very useful here. *Category: SUBSTANTIVE*
Combined analysis of results and data of a programme of integrated surveillance of antimicrobial resistance in foodborne bacteria comprises the bringing together of antimicrobial use in humans and animals and antimicrobial resistance data across all sectors including humans, food-producing animals, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system	
Combined analysis of results and data of a programme of integrated surveillance of ~~antimicrobial resistance in~~ AMR foodborne bacteria ~~comprises the bringing together~~ involves synthesis of ~~antimicrobial use~~ AMU in humans and animals and ~~antimicrobial resistance~~ AMR data across all sectors including humans, food-producing animals, retail foods, and the environment, ~~and also~~ provision of the detailed methodology of the surveillance system and epidemiological context	**USA** Rationale: The statement does not include anything beyond r AMR and AMU can lead to inaccurate interpretation of data. See rationale provided above for 12.4. “Involves” is more appropriate grammatically than “comprises”. *Category: TECHNICAL*
Combined analysis of results and data of a programme of integrated surveillance of antimicrobial resistance in foodborne ~~bacteria~~ microbes comprises the bringing together of antimicrobial use in humans and ~~animals~~ in the food chain and antimicrobial resistance data across all sectors including humans, food-producing animals, crops, food processing, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system	**International Association of Consumer Food Organizations** This section should better reflect the expanded scope of the document. *Category: SUBSTANTIVE*
Combined analysis of results and data of a programme of integrated surveillance of antimicrobial resistance in foodborne bacteria comprises the bringing together of antimicrobial use in ~~humans and~~ humans, animals and plants and antimicrobial resistance data across all sectors including humans, food-producing animals, plants, retail foods, and the environment, and also provision of the detailed methodology of the surveillance system	**OIE** *Category: EDITORIAL*
Integration of data from foodborne human isolates	
Data from relevant human isolates should include data from those foodborne pathogens more relevant according to national epidemiological information (e.g. Salmonella, Campylobacter) and whenever possible commensal flora such as E. coli and potentially also Enterococcus from healthy humans. 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.	

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Data from relevant human isolates should include data from ~~those~~ priority foodborne pathogens ~~more relevant~~ according to national epidemiological information (e.g. Salmonella, Campylobacter) and whenever possible commensal flora such as E. coli and ~~potentially also Enterococcus from healthy humans~~potentially Enterococcus. 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** Rationale: Countries are looking for guidance on where to utilize scarce resources. Collecting isolates from healthy humans does not appear to be a priority area on which to spend resources designated for foodborne AMR surveillance. *Category: TECHNICAL*
Data from relevant human isolates should include data from those foodborne pathogens more relevant according to national epidemiological information ~~(e.g. Salmonella, Campylobacter)~~ (*e.g. Salmonella, Campylobacter*) and whenever possible commensal flora such as E. coli and potentially also Enterococcus from healthy humans. 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.	**FAO** *Category: EDITORIAL*
Data from relevant human isolates should include data from those foodborne pathogens more relevant according to national epidemiological information (e.g. Salmonella, Campylobacter) and whenever possible commensal flora such as E. coli and potentially also Enterococcus from healthy humans. 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~~ human or animal health importance, and for the comparison with isolates from the food chain and the environment.	**OIE** *Category: EDITORIAL*
Isolates obtained for antimicrobial resistance surveillance should also include representative isolates from sporadic and outbreak foodborne disease cases.	
Guidance on conducting antimicrobial resistance surveillance among isolates from humans is provided by the WHO Global Antimicrobial Resistance Surveillance System (GLASS).	
13.2 Detection and evaluation of emerging risks ***To be further elaborated.***	
In 13.2 Detection and evaluation of emerging risks, suggest detecting and evaluating of emerging risks according to the guidelines for risk assessment CAC/GL77-2011.	**China**
	FAO Some text for consideration As data generated from monitoring and surveillance activities increases, deliberate efforts should be made to put in place methods and systems that will enable the use of such data to detect and evaluate emerging risks in order to minimize the likelihood of development and spread of AMR. *Category: SUBSTANTIVE*

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
13.3 Ineffective use	
13.3 Ineffective use	**Australia** Comment: The OIE Chapter 6.9 Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine and the Aquatic Animal Health Code, Chapter 6.2, Principals for the Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals covers this aspect adequately and should be referenced in this section. Rationale: Consistency with OIE standards *Category: SUBSTANTIVE*
~~13.3 Ineffective use~~	**USA** Rationale: Pharmacovigilance is duplicative of what is being revised in CAC/RCP 61 and OIE Ch. 6.9. *Category: TECHNICAL*
13.3 Ineffective use	**FAO** The purpose and added value of this paragraph, and the intended message are unclear – consider deleting or rewording to clearly convey the intended message more clearly. *Category: TECHNICAL*
The Competent Authority should have in place a pharmacovigilance programme for the reporting of adverse reactions to antimicrobials containing veterinary medicinal products and antimicrobial agents, including lack of the expected efficacy, so that this information can be used to review use with respect to the potential for AMR.	
~~The Competent Authority should have in place a pharmacovigilance programme for the reporting of adverse reactions to antimicrobials containing veterinary medicinal products and antimicrobial agents, including lack of the expected efficacy, so that this information can be used to review use with respect to the potential for AMR.~~	**USA** *Category: TECHNICAL*
The Competent <u>National</u> Authority should have in place a pharmacovigilance programme for the reporting of adverse reactions to antimicrobials containing veterinary medicinal products and antimicrobial agents, including lack of the expected efficacy, so that this information can be used to review use with respect to the potential for AMR.	**OIE** *Category: EDITORIAL*
13.4 Operational research	
Investment in operational research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies.	
14. Risk communication	
14. Risk communication	**USA** General Comment: The Task Force should consider the appropriateness of including a risk communication section since risk communication is a part of the risk analysis process and currently contained within CAC/GL 77. Monitoring and surveillance is one contributor to risk assessment contained within CAC/GL77.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
As part of broader risk communication plans for national strategies and action plans, there are specific demands in regards to communicating the results of ongoing surveillance programme – industry, consumers, international organisations etc. ***To be further developed.***	
Ref Codex Risk Analysis principles for governments and CAC/GL 77-2011.	
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 and animals.	
~~Value~~ The value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce inappropriate use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans and animals.	**USA** Rationale: With changes in animal populations and disease conditions, the goal should be to reduce inappropriate use rather than total quantity used. Considerations might include an increase in animal population or high disease incidence.
Value of consultative and risk communication processes in developing partnerships and achieving commitment to activities to optimize and reduce inappropriate use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans and animals.	**ICGMA** Eliminating use does not eliminate disease, suffering, or food safety risks. The goal should be to support responsible use of medicines in all settings.
To be further developed.	
~~*To*~~ *Consultative and risk communication processes should clearly describe the antimicrobial susceptibility testing methods, emerging genotypic approaches, and interpretive criteria used in surveillance. Differences should be* ~~*further developed*~~*transparently explained to show where data may and may not be comparable*.	**USA** Rationale: Results of monitoring and surveillance data and their interpretation can be confusing and lead to faulty conclusions if not clearly and transparently explained.
15. Training	
15. Training	**Australia** Comment: last sentence is incomplete
15. Training	**Australia** Comment: The OIE Chapter 6.9 Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine covers this aspect adequately and should be referenced in this section. Rationale: Consistency with OIE standards
A tiered approach to implementation at the national level is required, proportional to each step. Programmes should aspire to effective use of available resources, technical capability and potential for cross-sector integration while seeking continuous improvement.	
~~A~~ Competent authorities should undertake training using a tiered approach to implementation at the national ~~level is required~~level, proportional to each step. ~~Programmes should aspire to effective use of available resources, technical capability and potential for cross-sector integration while seeking continuous improvement.~~	**USA** Rationale: The statement is too prescriptive for a Codex document that has trade implications.
Training programs should include capacity to train the relevant personnel of the relevant competent authority in the different aspects of the monitoring and surveillance programme. This should also include capacity to train personnel in the capture, analyse and reporting of the monitoring and surveillance data.	