CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Item 6 **CX/AMR 19/7/6-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Seventh Session

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

Comments at Step 3 (Replies to CL 2019/83-AMR)

Comments of Australia, Brazil, Canada, China, Egypt, Ghana, Iran, Iraq, Japan, Morocco, Norway, Republic of Korea, Switzerland, Uruguay, USA, CCTA, Consumers International, healthforanimals, International Feed Industry Federation and OIE

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/83-AMR issued in October 2019. 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 monitoring and surveillance of foodborne antimicrobial resistance

GENERAL COMMENT

GENERAL COMMENTS	MEMBER/OBSERVER
Australia commends the EWG Chair and co-Chairs in substantially advancing the proposed draft guidelines. Australia recommends that greater weight be given to the use of national lists of priority antimicrobials when developing and implementing national monitoring and surveillance systems. National lists of priority antimicrobials are based on local authorisations, availability, use patterns and risk assessments and should be given precedence where they are available. Specific comments are provided below. Australia has concerns that Sections 9.2.2, 9.2.3 and 9.2.4 are encroaching on the OIE remit for international reporting requirements for antimicrobial sales and use data in animals, which is the appropriate international body to develop standards for this activity. There is a risk that these guidelines will become redundant as national and international surveillance systems mature. As a consequence, national competent authorities with responsibility for collecting and reporting antimicrobial sales and use data may be required to comply with multiple international standards setting bodies. Australia therefore recommends deletion of these sections. Australia supports progression of the draft guidelines to Step 4.	**Australia**
Brazil would like to congratulate the EWG Chairs for their work in providing a new draft after discussions during the EWG. Brazil is of the opinion that the document still needs to improve so it turns into a document with practical guidance to member countries on this complex and still evolving issue that is the integrated monitoring and surveillance of foodborne AMR. Now having access to the whole document, it seems there is a need for it to be more concise, avoiding repetition of elements and in some parts detailed explanations, which can lead to misinterpretation or confusion. For member countries that have not yet implemented integrated monitoring and surveillance of foodborne AMR it would be difficult to prioritize and design a system based on "highly desired", "ideal" and "progressive/continuous improvement" elements or recommendations. Codex recommendations should be science based, practical, feasible and aiming to protect the health of the consumers and ensure fair practices in the food trade. Recommendations should focus on elements where scientific evidence supports a linkage with foodborne AMR risk to human health. Brazilian specific comments to the proposed draft are provided below.	**Brazil**
Canada appreciates the hard work that has taken place to create the current draft of the document; however, we believe this document should be very streamlined, clear and concise. Our overall perspective is that the document is too long and has much repetition. Canada believes the objectives for the creation of the Guidelines are two-fold: 1) to have a tool/reference for countries implementing surveillance for the first time 2) to have a tool/reference for countries expanding their activities. Canada believes the body of the Guidelines should be fairly high level, with detailed information on implementation placed in appendices, similar to the structure of the Codex Guidelines for Risk Analysis of Foodborne AMR. This approach would significantly facilitate the readability and flow of the document. The current draft of the Guidelines is attempting to be both a high-level guideline and an implementation tool, resulting in questions about the level of detail needed, questions about the range of the progressive implementation, and in duplication of material. For consistency of language/terminology in the document, the following should be reviewed: • Use of the words "harmonized" vs. "standardized" and how/when they occur in combination or separately. • Use of "environment" vs. "food production environment" vs. "production environment". • Canada proposes being clear throughout the document the distinction between "antimicrobial use" data and "antimicrobial consumption" data. The rationale is that "antimicrobial use" data refers to sources of data where detailed information is known about the use (e.g., farm-level records), whereas "antimicrobial consumption" often refers to sales data. • In an effort to make this document accessible to all parties, the document has attempted to use language to soften an approach to monitoring and surveillance development that is built from the ground up. The current document is difficult to read, complicated, and lacks a hierarchical direction. The practicality of developing a surveillance system has been lost with overly cautious language. As one solution for language considerations with respect to a "progressive approach", Canada recommends review of the World Health Organization's AGISAR Guidelines which recommends	**Canada**

GENERAL COMMENTS	MEMBER/OBSERVER
words/phrases such as: “suggested steps for progressing toward combined analysis and reporting”, “step towards”, “implemented in steps”, “implementation of subsequent components”, “incremental”, “evolve and develop” (see Section 3.5). Canada is also in favour of “component-based” monitoring and surveillance.	
Egypt would like to thank the EWG for this good work and submit the following comments: - In view of the Recommendations of The EWG to : • Revise the Guidelines to ensure consistency/harmonization in wording. • Avoid specific references to sections or chapters numbers, especially when referring to other documents (e.g. OIE, Codex standards) as these may change with new editions. Preferably, refer to the content of the chapter or section. • Align definitions with COP: Agree on a common definition for the term “food production environment”. • Revise Section 7 and Sections 8-10, where possible avoiding overlap, ensuring a clear link between the 3 areas presented in Figure 1 in Section 7 and the subsequent sections and ensuring that the progressive approach for the implementation of the monitoring and surveillance program is well reflected throughout the document. Consider moving some elements (e.g. technical descriptions in sections 8 and 9) to an Annex . Egypt agrees with the final wording and the definition for the term “food production environment” and the final of the wording section 7 and 8 and 10	**Egypt**
We agree with proposed draft and we have no comment.	**Iraq**
Morocco appreciates the work done by the EWG and the advice provided pursuant to the responses to the questions.	**Morocco**
Uruguay felicita la labor realizada por el Presidente y Vicepresidentes, y a su vez agradece la posibilidad de enviar cometnarios. Uruguay entiende que el borrador de documento aún requiere una discusión profunda entre los países. Entendemos además, que la revisión del documento por secciones como se realizó en el Grupo de trabajo electrónico, dificultó el análisis general del texto. En general, entendemos que debería revisarse la redacción de todo el documento, ya que aún se mantienen a lo largo del mismo, expresiones que le dan un carácter prescriptivo, condición que no debe contener un texto Codex. Por otro lado, pensamos que deberían revisarse aspectos claves del documento, como las definiciones de Seguimiento y Vigilancia, que son el centro del documento y que no resultan lo suficientemente claras para su comprensión/adopción. Entendemos, a su vez, que debería incentivarse una coordinación de esfuerzos con la Organización Internacional de Sanidad Animal (OIE), cuando se trate de aspectos concretos sobre la producción primaria animal, respetando sus competencias específicas. Por otro lado, existen aspectos del documento que entendemos que pueden ser muy valiosos para el desarrollo de planes de control de la Resistencia Antimicrobiana, pero que no reflejan el estado del arte de los países menos desarrollados, como por ejemplo, la recomendación de la utilización de la secuenciación genómica completa. Pensamos que deberían eliminarse este tipo de recomendaciones de este documento, los que podrían integrarse a un documento informativo.	**Uruguay**
We thank the EWG for the work that has been put into the document on a very complex subject for which the science is still evolving. We believe that the document as written describes what people wish a surveillance system could do versus giving practical advice to countries on how to conduct surveillance for an impactful understanding of the foodborne AMR situation in their countries. The document still needs much work to become practical Codex guidance. Regarding the term, progressive approach, the TFAMR may want to also consider harmonizing with terminology adopted by CCFICS CAC/GL82-2013 Principles and Guidelines for National food Control Systems. In CAC/GL82-2013, the terminology, “continuous improvement” is used under “Principle 9-Self Assessment and Review Procedures, which discusses the need for national food control systems to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective.	**USA**
The draft remains too complex, and overly prescriptive. In places it goes beyond the Terms of Reference given to it by the CAC. In places it recommends actions that could place countries at odds with their legal trade requirements. The draft directs resources to actions that are inconsistent with conditions within some countries, and not the best use of limited public resources. Recognizing the points above, it will be a challenge to achieve consensus on this draft unless a rewrite produces a simpler and less prescriptive version.	**healthforanimals**

GENERAL COMMENTS	MEMBER/OBSERVER
This is the preliminary feedback from the OIE - to be further developed during the working groups, and TFAMR7 plenary meeting; In general, we would like to see the OIE references, standards and guidelines clearly stated when mentioning issues related with animal health/veterinary medicine	**OIE**

SPECIFIC COMMENTS

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Introduction and purpose	**Morocco** Morocco concurs with the advice of the EWG in paragraph 3, 6 and 7 of the introduction.
1. 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 analysis~~surveillance. The political declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 committed Member Countries to developing multi-sectoral national action plans that involve all stakeholders within a "One Health" approach and to improving national systems of monitoring and surveillance of AMR and antimicrobial use (AMU).	**Canada**
1. 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~~ A One Health approach to risk analysis. ~~The political declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 committed Member Countries to developing multi-sectoral national action plans that involve all stakeholders within~~ A One Health approach is a ~~"One Health"~~ collaborative, transdisciplinary approach ~~and to improving national systems of~~ for addressing complex problems such as AMR that involve multiple crosses sectors. Foodborne AMR monitoring and surveillance ~~of AMR and~~ systems track changes in antimicrobial ~~use (AMU).~~ susceptibility of bacteria, providing data for risk assessments to inform risk analysis.	**USA** We recommend deleting the last sentence and replacing with new text. The political declaration language is already dated (3 years old) and the text does not sound consistent with other Codex texts. Additional language is proposed to help provide the purpose of the document for a smoother transition to paragraph 2.
1. 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 analysis. The political declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 committed Member Countries to developing multi-sectoral national action plans that involve all stakeholders within a "One Health" approach and to improving national systems of monitoring and surveillance of AMR and antimicrobial **agent** use (AMU).	**International Feed Industry Federation** For consistency with the Code of Practice we suggest to add the word agent.
2. For the purpose of these Guidelines, monitoring ~~refers to the collection~~ and ~~analysis of AMR and AMU related data and information. Surveillance is~~ surveillance generally refer to the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and AMU related data and trends from defined populations to inform actions that can be taken and to enable the measurement of their impact.	**Canada** Recognizing that the current text was a compromise between translation challenges of these words, Canada's proposed alternative would not make the distinction between monitoring vs. surveillance.
2. For the purpose of these Guidelines, monitoring refers to the collection and analysis of foodborne AMR and AMU related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of foodborne AMR and AMU related data and trends from defined populations to inform actions that can be taken and to enable the measurement of their impact.	**China**

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2. A los efectos de estas Directrices, ~~por~~ el seguimiento se ~~entiende~~ refiere a la ~~obtención~~ recopilación y ~~el~~ análisis de datos ~~e información~~ relacionados con la RAM y el UAM. ~~Por~~ La vigilancia amplía este seguimiento para informar las acciones que se ~~entiende~~ pueden tomar para reducir la ~~medición~~RAM, ~~la obtención, la recopilación, la validación, el análisis y la interpretación~~ en ~~forma sistemática, continua o repetida de datos y tendencias relacionados con la RAM y~~ algunos casos al enfocarse en el ~~UAM de poblaciones definidas~~UAM, ~~que sirvan de fundamento para las medidas a tomar~~ y ~~permitan~~ para permitir la medición de ~~su impacto.~~sus impactos	**Uruguay** Uruguay considera que las definiciones para seguimiento y vigilancia no son claras y que debería hacerse un esfuerzo por simplificarlas.
2. For the purpose of these Guidelines, monitoring refers to the collection and analysis of foodborne AMR and ~~AMU~~ antimicrobial use (AMU) related data and information. Surveillance is the systematic, continuous or repeated, ~~measurement,~~ collection, collation, validation, analysis and interpretation of foodborne AMR and AMU related data and trends from defined populations to inform actions that can be taken and to enable the measurement of their impact~~.~~. Monitoring and measuring actual AMU is complex and based on different data streams and sources than foodborne AMR. The science of the relationship between AMU and AMR in the production environment is still being developed,	**USA** “Foodborne” is inserted to specify within Codex scope. Additional text is added for clarity. The title of these Draft Guidelines states only foodborne AMR, consistent with what the Task Force was originally tasked to consider in its Terms of Reference. If these guidelines are meant for the integration of AMU in the production environment and foodborne AMR, they should reference the need for better science with respect to AMU-AMR relationships in the food production environment and connection with human foodborne AMR.
2. For the purpose of these Guidelines, monitoring refers to the collection and analysis and foodborne of AMR and AMU related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of foodborne AMR and AMU related data and trends from defined populations to inform actions that can be taken and to enable the measurement of their impact.	**International Feed Industry Federation** For consistency with the scope of the Code of Practice
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at ~~appropriated~~ appropriate stages throughout the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and ~~harmonization~~ harmonization/standardization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**Canada**
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages throughout the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, ~~crops~~ crops/plants and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated monitoring and surveillance system can be implemented progressively.	**China**

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3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages throughout the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**Egypt** Egypt agrees with the final advice of the eWG To keep “scientific evidence” in paragraph 3
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages throughout the food chain [1] and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**Norway** We suggest inserting a footnote with the definition of food chain the first time it is mentioned. The rationale being that this facilitates the readability of the paper, especially when crops and animals are deleted from paragraph 13 and feed is not mentioned in the same paragraph.
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages throughout the food ~~chain~~ chain[1] and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**Norway** We suggest inserting a footnote with the definition of food chain the first time it is mentioned. The rationale being that this facilitates the readability of the paper, especially when crops and animals are deleted from paragraph 13 and feed is not mentioned in the same paragraph. Footnote 1: Food chain Production to consumption continuum including, primary production (food producing animals, plants/crops, feed), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.
3. ~~An~~ Ideally, integrated monitoring and surveillance ~~system includes~~ systems include the coordinated and systematic collection of data or samples at appropriated stages ~~throughout~~ contributing to foodborne AMR risk along the food chain and the testing, analysis and reporting of AMR and AMU. An ideal integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, ~~an~~ integrated monitoring and surveillance ~~system~~ systems can be implemented progressively.	**USA** The word, “throughout” means everywhere. Alternate text is provided for practical guidance for countries to aim limited resources at areas of highest risk instead of stating that everything should be tested as the word “throughout” implies. Editorial changes are made at the beginning and end of the paragraph regarding monitoring and surveillance. Some countries may have a monitoring system and others may have surveillance systems so the beginning of the paragraph is edited for clarity. Regarding the definitions of monitoring and surveillance in paragrph (2) it may be inferred that the two are distinguished by a number of factors including intent, consistency, extent, intensity, validity and need for resources for data collection, analysis and reporting. The definition of monitoring is simply ‘collection and analysis…’ and that of surveillance is more comprehensive. In further bullets (3 and following), the language seems to roughly equate them as

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	'integrated … systems include … systematic collection of data or samples". So although the definitions in (2) appear to be distinct, in items (3) and following, the two terms seem to be used nearly equivalently, at least interchangeably.
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages ~~throughout~~ **throughout** the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. ~~Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources,~~ an integrated surveillance system can be implemented progressively.	**healthforanimals** "Throughout" implies every part from beginning to end. "Along" implies focus time and resources on areas with the greatest risk.
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages ~~throughout~~ along the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**International Feed Industry Federation** The word along describes better the objective of the guidelines
3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of data or samples at appropriated stages throughout the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, ~~crops~~ crops/plants and the food production environment. Depending on national priorities, food safety AMR issues, scientific evidence, capabilities and available resources, an integrated surveillance system can be implemented progressively.	**OIE**
4. The data generated by integrated monitoring and surveillance systems provide essential information for the risk analysis of foodborne AMR. These data are also essential for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends ~~and~~ for the planning, implementation and evaluation of risk mitigation measures to minimize ~~any foodborne~~ the public health risk due to resistant microorganisms and resistance ~~determinants~~determinants arising from food.	**Canada** "any foodborne public health risk" might be perceived as too expansive
4. The data generated by integrated monitoring and surveillance systems provide essential information for the risk analysis of foodborne AMR. These data are also essential for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about foodborne AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any foodborne public health risk due to resistant	**China**

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microorganisms and resistance determinants.	
4. The data generated by integrated monitoring and surveillance systems provide essential information for the risk analysis of foodborne AMR. These data are also essential for epidemiological studies, food source attribution studies ~~and~~ or other ~~operational research~~quantitative analyses. ~~It provides~~ In addition, data provide information to risk managers about AMR and AMU trends and as inputs for ~~the~~ risk assessment to inform risk management, which includes planning, implementation and evaluation of risk mitigation measures to minimize ~~any~~ foodborne AMR public health ~~risk due to resistant microorganisms and resistance determinants.~~ risk.	**USA** Text is edited for accuracy of terminology and clarity. There may not be a common understanding of "operational research" and the term may need to be defined if included. Surveillance data informs risk assessment which informs risk management, so text is added to clarify that important relationship. The term "any" implies "every" and is therefore, unrealistically comprehensive. The end of the sentence is superfluous so can be deleted.
4. The data generated by integrated monitoring and surveillance systems provide essential information for the risk analysis of foodborne AMR. These data are also essential for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about foodborne AMR and AMU trends as inputs to inform the risk assessment and for the planning, implementation and evaluation of risk mitigation measures to minimize any foodborne AMR public health ~~risk due to resistant microorganisms and resistance determinants~~risk.	**International Feed Industry Federation** For consistency with the scope of the Code of Practice, and to clarify the objectives of monitoring.
4.bis Reporting of ~~standardized and harmonized~~ data generated using both standardizedand internationally harmonized interpretive categories through national monitoring and surveillance systems ~~to~~ enables national awareness of trends over time. Data can also be shared with international organizations and, in return, use of information generated from global monitoring and surveillance databases is highly ~~desired~~desireable to work toward understanding global trends.	**USA** The primary aim of the guideline is to provide guidance to Member States on use of surveillance data for understanding their own circumstances. Global reporting is a secondary purpose. Text is added to help the reader understand these various purposes.
4.bis Reporting of standardized and harmonized data generated through national monitoring and surveillance systems to international organizations and, in return, use of information generated from global monitoring and surveillance databases is highly desired.	**healthforanimals** Take out because without proper aggregation (i.e. reporting by region rather than country), this will be seen to lead to trade barriers. (OIE has extensive experience with this challenge).
4.bis Reporting of ~~standardized and harmonized~~ data generated through national monitoring and surveillance systems ~~to~~ can be shared with international organizations and, in return, use of information generated from global monitoring and surveillance databases ~~is highly desired~~can highlight national and international awareness of trends over time.	**International Feed Industry Federation** To clarify the objective of the monitoring.
~~5. It also contributes to the promotion and protection of public health by providing burden of illness information to risk managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.~~	**Canada** Canada recommends deleting Para 5. The vast majority of monitoring and surveillance systems will not be generating data on burden of illness. These Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans; though an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans.
5. It also contributes to the promotion and protection of public health by providing burden of illness information to risk managers about, how infections caused by resistant bacteria differ from infections	**Ghana** Position: Ghana proposes the deletion of the first comma in paragraph 5 to read "It also contributes to the promotion and protection of public health by

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caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.	providing burden of illness information to risk managers about how infections caused by resistant bacteria differ from infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR. Rationale: The presence of the comma gives a different meaning to the provision
5. ~~It~~ The data also contributes to the promotion and protection of public health by providing burden of illness information to risk managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.	**Switzerland** "data" can also be considered plural.
5. ~~It~~ Data from monitoring and surveillance systems also ~~contributes~~ contribute to the promotion and protection of public health by providing ~~burden of illness~~ information on foodborne AMR to risk ~~managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria,~~ assessors and ~~the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR~~managers.	**USA** Surveillance data alone does not provide information needed to assess differences in burden of illness and other metrics between resistant and susceptible infections in people. Burden of illness refers to the impact of a health problem as measured by financial cost, mortality, morbidity, or other indicators. Surveillance data is combined with other data by risk assessors to conduct risk assessment, so it's important to include "risk assessors". Edits are made for clarification.
5. It also contributes to the promotion and protection of public health by providing burden of illness information to risk managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.	**CCTA** burden??
5. It also contributes to the promotion and protection of public health by ~~providing burden of illness~~ providing information to risk managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.	**healthforanimals** Take out "burden of illness" because it is more about cost/incidence of diseases and AMR is but one part of the full burden of illness picture.
5. It also contributes to the promotion and protection of public health by ~~providing burden of illness~~ providing foodborne AMR information to risk assessors and managers about, how infections caused by resistant ~~bacteria~~ microorganism differ from infections caused by susceptible ~~bacteria~~microorganism, and the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.	**International Feed Industry Federation** For clarification purposes.
6. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for ~~data on~~ AMU and ~~foodborne~~ AMR ~~throughout~~ arising through the food chain. Such systems are a fundamental part of national strategies and plans to minimize foodborne AMR and are an important component of a national food safety system.	**Canada** The mention of food twice in this phrase is redundant. Suggest to streamline the phrase and then use consistently throughout the document.
6. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for data on AMU and foodborne AMR throughout the food chain. Such systems are a fundamental part of national strategies and plans to minimize foodborne AMR and are an important component of a national food safety system.	**Egypt** Egypt agrees with the final advice of the eWG To keep the reference to the

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	"national food safety system" and delete the word "comprehensive" in paragraph6
6. Estas Directrices han sido elaboradas para colaborar con los gobiernos en el diseño y la aplicación de los sistemas de seguimiento y vigilancia de datos sobre el UAM y la RAM transmitida por los alimentos en toda la cadena alimentaria. Dichos sistemas constituyen una parte fundamental de las estrategias y los planes nacionales que buscan reducir al mínimo la RAM transmitida por los alimentos y son un componente importante de todo sistema nacional de inocuidad de los alimentos.	**Uruguay** Uruguay considera que la referencia a los sistemas nacionales de inocuidad de los alimentos debería ser eliminada. La importancia de los sistemas de seguimiento y verificación para minimizar la RAM y su vinculación con la inocuidad alimentaria, ya han sido suficientemente analizada y jerarquizada. Por otro lado, por sus características particulares, entendemos que no deberían considerarse un componente del sistema nacional de inocuidad de los alimentos.
6. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems ~~for data on~~ to gather AMU and foodborne AMR ~~throughout~~ data along the food chain. Such systems are a fundamental part of national strategies and plans to minimize foodborne ~~AMR and are an important component of a national food safety system~~AMR.	**USA** Reference to national food safety systems is in the remit of CCFICS, is covered elsewhere (CXG 82-2013), and outside the scope of the TFAMR. In addition, the GLIS could be stand alone in the absence of a comprehensive national food safety system. We also do not want to imply that countries without surveillance systems do not have food safety systems.
6. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for data collection on AMU and foodborne AMR ~~throughout~~ along the food chain. Such systems are a fundamental part of national strategies and plans to minimize foodborne AMR and are an important component of a national food safety system.	**International Feed Industry Federation** For clarification purposes.
7. While these Guidelines are primarily aimed at action at the national level, countries may also consider contribution to or creating international, or multi-national or regional, monitoring and surveillance systems to share laboratory, data management and other necessary resources.	**Egypt** Egypt agrees with the final advice of the eWG To keep both terms "international" and "multi-national" in paragraph 7and amend the sentence as proposed: "…countries may also consider contribution to or creating international, or multi-national or regional, monitoring and surveillance systems…"
7. While these Guidelines are primarily aimed at action at the national level, countries may also consider contribution to or creating international, or multi-national or regional, monitoring and surveillance systems to share laboratory, data management and other necessary resources.	**Ghana** Position: Ghana suggests the inclusion of "in accordance with countries' data governance policies to the last sentence of paragraph 7 to read as follows; While these Guidelines are primarily aimed at action at the national level, countries may also consider contribution to or creating international, or multi-national or regional, monitoring and surveillance systems to share laboratory, data management and other necessary resources in accordance with countries' data governance policies. Rationale: Data sharing should be in accordance with countries' data governance polices.
7. While these Guidelines are primarily aimed at action at the national level, countries may also	**USA**

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consider ~~contribution~~ contributing to or creating international, ~~or~~ multi-national or regional, monitoring and surveillance systems to share laboratory, data management and other necessary resources.	
7. While these Guidelines are primarily aimed at action at the national level, countries may also consider contribution to or creating international, or multi-national or regional, integrated monitoring and surveillance systems to share laboratory, data management and other necessary resources.	**OIE** international guidelines for AMU have been developed by OIE (ie, already exist, no need for countries to create them)
8. Each monitoring and surveillance system is designed to ~~ensure that it is appropriate~~ be relevant for ~~the~~ national ~~circumstances~~circumstances and priorities. The design should be informed by all available knowledge on foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries or sectors.	**Canada** Regarding "The design should be informed by all available knowledge on foodborne risks due to AMR…", consider replacing the word “risks” with either ‘hazards’ or ‘hazards and risks’, as often it is not known until synthesis of the surveillance data via risk assessment whether these are indeed ‘risks’ or not.
8. Each monitoring and surveillance system is designed to ensure that it is appropriate for the national circumstances. The design should be informed by all available knowledge on foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries or sectors.	**Ghana** Paragraph 8 Position: Ghana proposes “is” in the first sentence of paragraph 8 ‘be replaced with “should be” to read as: Each monitoring and surveillance system should be designed to ensure that it is appropriate for the national circumstances. The design should be informed by all available knowledge on foodborne risks due to AMR while taking into consideration the international dimensions of AMR and the need for data comparability between countries or sectors. Rationale: To make it mandatory and aligned with the context of the second sentence of the same paragraph.
8. Each monitoring and surveillance system ~~is~~ should be designed to ensure that it is appropriate for the national circumstances. The design should be informed by all available knowledge on foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries or sectors.	**Switzerland**
8. Each monitoring and surveillance system ~~is~~ should be designed to ensure that it is appropriate for the national circumstances. The design should be informed by all available knowledge on foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability ~~between~~ among countries or sectors.	**USA**
9. New scientific knowledge and methodology should be incorporated into integrated monitoring and surveillance programs as ~~it becomes~~ they become available to improve the design of the systems and to enhance analysis and ~~utility~~ reporting of existing information and data. Design and implementation of systems should also evolve as AMR policies and priorities change at the national and international level.	**Canada**
9. New scientific knowledge should be incorporated into integrated monitoring and surveillance programs as it becomes available to improve the design of the systems and to enhance analysis and utility of existing information and data. Design and implementation of systems should also	**USA** Edited language to “risk assessment policies” to be aligned with CAC/GL 77-2011 para 4.

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evolve as ~~AMR~~ risk assessment policies and priorities change at the national and international level.	
10. AMR scenarios are likely to vary between countries and these Guidelines should be used to foster a ~~gradual~~ progressive implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop. A ~~gradual~~ progressive approach to monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU in humans, animals and crops, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**Australia** Section 1, paragraph 10. Comment: Australia suggests replacing 'gradual' with 'progressive'. Rationale: Consistent with terminology used throughout the guidelines and particularly section 7.
10. AMR scenarios are likely to vary between ~~countries and these Guidelines should be used to foster a gradual implementation of monitoring and surveillance systems at the national level~~countries. Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop. ~~A gradual approach to~~ The development of monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU and AMR in humans, animals and crops, human health care infrastructure, human and animal clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**Canada** Given that the details of what is to be included in surveillance comes later in the document, Canada questions whether this Para is needed in the Introduction. "gradual implementation" and "gradual approach" as mentioned in this Para sound like it there is a recommendation to only implement monitoring and surveillance slowly. Recommend deleting reference to "gradual", as monitoring and surveillance activities could actually be implemented very quickly if the resources are available.
10. AMR scenarios are likely to vary between countries and these Guidelines should be used to foster a ~~gradual~~ progressive implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop. A gradual approach to monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU in humans, animals and crops, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**Switzerland** The term "progressive" is used in other parts of the Guidelines.
10. AMR scenarios are likely to vary ~~between~~ among countries and these Guidelines should be used to foster a ~~gradual~~ progressive implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop. A ~~gradual~~ progressive approach to monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU in humans, animals and crops, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	**USA** For consistency in terminology, "gradual" is changed to 'progressive"
10. AMR scenarios are likely to vary between countries and these Guidelines should be used to foster a ~~gradual~~ progressive implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop. A gradual approach to monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU in humans, animals	**OIE**

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and ~~crops~~crops/plants, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.	
11. These Guidelines should be applied in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005). Design and implementation aspects of these Guidelines should ~~specifically~~ take into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011), as well as other relevant Codex texts including the *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) whenever appropriate.	**Canada** The "specifically" somewhat contradicts the "whenever appropriate" at the end of the sentence.
12. These Guidelines should ~~also be used taking into consideration those already developed by other advisory bodies especially~~ consider the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) *Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach* and other international standard setting ~~organizations, specially~~ organizations and the standards of the ~~Organization of~~ World Organisation for Animal Health (OIE standards) related to AMR and AMU published in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code*. These documents include recommendations for improvements of monitoring and surveillance activities over time.	**Canada**
12. These Guidelines should also be used taking into consideration ~~those already~~ scientific advice developed by other ~~advisory bodies~~ international standard setting bodies, especially the OIE standards related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code.and by advisory bodies, such as the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) *Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach*. ~~and other international standard setting organizations, specially the standards of the Organization of Animal Health (OIE standards) related to AMR and AMU published in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code*.~~	**USA** Text is rewritten for technical accuracy. International standard-setting bodies such as OIE, Codex, and IPPC have international standing because text is developed transparently in these bodies with Member State input unlike those developed by non-transparent, expert groups, such as WHO AGISAR.
12. These Guidelines should also be used taking into consideration those already developed by ~~other advisory~~ international standard setting bodies especially the the OIE Standards related to AMR and AMU published by the Terrestrial Animal and Aquatic Health Codes, advisory bodies such as the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) *Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach*. ~~and other international standard setting organizations, specially the standards of the Organization of Animal Health (OIE standards) related to AMR and AMU published in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code*.~~	**International Feed Industry Federation** Priority should be on the standard setting bodies recognized for World Trade.
Scope	**Canada** Canada recommends that the Scope make the distinction that these Guidelines are for monitoring and surveillance activities. Guidelines for AMR research or other targeted studies should be out of scope of this document.

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13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU throughout the food chain, and the food production environment.	**Brazil** Brazil suggests adding “food” for clarity and consistency.
13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for ~~foodborne~~ AMR and AMU throughout the food chain, and the production environment.	**Canada** A suggestion for alternative wording for “production environment” is “sources of transmission”.
13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU throughout the food chain, and the production environment.	**Egypt** Egypt agrees with the final advice of the eWG To delete “including animals and crops” and to include it in the definition of food chain in Section 3. and To keep the current definition of food chain which refers to feed, therefore no need to specifically mention it in the scope.
13. Estas Directrices abarcan el diseño y la implementación de un sistema integrado de seguimiento y vigilancia de la RAM transmitida por los alimentos y del UAM en toda la cadena alimentaria y en el entorno de producción.	**Uruguay** Uruguay está de acuerdo con este párrafo, siempre que se mantenga la definición actual de Cadena alimentaria.
13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU ~~throughout~~ along the food chain~~, and the production environment.~~ .	**USA** “Throughout” means everything, so “along” is more appropriate terminology. Food chain includes production environment, so terminology is duplicative.
13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU throughout the food chain~~, and the production environment~~.	**healthforanimals** Take out “production environment” - It is already part of the food chain.
13. These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU ~~throughout~~ along the food chain, and the production environment.	**International Feed Industry Federation** For consistency in the documents.
~~*14.* These Guidelines focus on foodborne AMR.~~	**Canada** The concept is covered in Para 13.
15. Though these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) ~~would~~ should be ~~informed by~~ designed to align with data, trends and epidemiology regarding AMR and AMU in humans.	**Canada** Edits are proposed so as not to be separated if there is a possibility of integration at some point of the data collection, analysis and reporting of the data.
~~15. Though these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans.~~	**China**
15. ~~Though~~ Alhough these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology	**USA**

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regarding AMR and AMU in humans.	
16. The microorganisms covered by these Guidelines are those ~~foodborne~~ bacterial pathogens and indicator bacteria of public health ~~relevance~~relevance transmissible through food and the food production environment.	**Canada**
~~16~~15. The microorganisms covered by these Guidelines are those foodborne pathogens and indicator bacteria of public health relevance.	**China**
16. The microorganisms covered by these Guidelines are those foodborne ~~pathogens~~ bacteria and indicator bacteria of public health relevance.	**healthforanimals** Many of the recommendations in the document are referencing established methods for tracking AMR bacteria. There is scientific evidence to support the recommendation. The same is not true for other parasites, viruses and fungi.
16. The microorganisms covered by these Guidelines are those foodborne pathogens and indicator ~~bacteria~~ microorganism of public health relevance.	**International Feed Industry Federation** For consistency.
~~17~~16. Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these Guidelines. 17. Though these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans.	**China**
17. ~~Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these Guidelines.~~Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these Guidelines.	**Iran** Iranian committee agrees that biocides and disinfectants should be included in this guideline, because these agents are used vastly in food chain and their usage is unavoidable. According to some literatures, may biocide and disinfectant agents can induce microbial resistance and can be assumed as a hazard in infection prevention and control. Biocides are also mentioned in the current text (such as in paragraph for Reporting, para 63) This question has been raised and is requested to be replied why biocides ad disinfectants have been excluded in the scope
17~~. Antimicrobials used as .~~ biocides, including disinfectants, are excluded from the scope of these Guidelines.	**Norway** In order to avoid misinterpretation and confusion about terms we suggest referring directly to biocides and disinfectants.
17. Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these Guidelines.	**USA** This decision of the TFAMR should be reflected in the relevant section of the Code of Practice.
17. Antimicrobials agents used as biocides, including disinfectants, are excluded from the scope of these Guidelines.	**International Feed Industry Federation** For consistency with definitions in the Code of Practice.

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18. ~~Implementation of these Guidelines will facilitate the generation and use of appropriate AMR and AMU data from humans, animals, crops, food and production environment in order to conduct integrated analysis of all these data.~~	**Brazil** Brazil suggests deleting this paragraph because it is not related to the scope of the document and has already been covered in the Introduction section.
~~18. Implementation of these Guidelines will facilitate the generation and use of appropriate AMR and AMU data from humans, animals, crops, food and production environment in order to conduct integrated analysis of all these data.~~	**Canada** It unclear why the content of Para 18 is situated under “Scope”. This is not information about the scope of the Guidelines, but rather the value or what to do with the resulting data.
18. Implementation of these Guidelines will facilitate the generation ~~and use~~ of appropriate AMR and AMU data from ~~humans,~~ animals, crops, food and the food production environment in order to conduct integrated analysis of all these data.	**USA** "And use” should be deleted since the use is “to conduct integrated analysis” described at the end of this sentence. Human data is not being “generated” through these guidelines, though it would be fed into the risk assessment process later which the surveillance data also feeds.
18. Implementation of these Guidelines will facilitate the generation and use of appropriate AMR and AMU data from ~~humans,~~ animals, crops, food and food production environment in order to conduct integrated analysis of all these data.	**International Feed Industry Federation** For consistency with definitions in the Code of Practice.
18. Implementation of these Guidelines will facilitate the generation and use of appropriate AMR and AMU data from humans, animals, ~~crops~~crops/plants, food and production environment in order to conduct integrated analysis of all these data.	**OIE**
Definitions	**Canada** Canada suggests including a definition for "Indicator bacteria".
Definitions	**Morocco** Morocco takes note of the need to harmonize the definition of terms within the codex documents especially the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005), the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011), as well as other relevant Codex texts including the Principles and Guidelines for National Food Control Systems (CXG 82-2013) whenever appropriate.
Definitions	**International Feed Industry Federation** Proposal to make a link to the Code of Practice for the definitions used in both documents, in order to avoid discrepancy and to note the interlink between the two documents.
~~**Antimicrobial agent**~~**Antimicrobial agent**	**Iran** Biocide and disinfectant agents could be covered by this definition.
A plant or crop that is cultivated or harvested as food or feed.	**Canada** Canada suggests revision as definitions should not (on principle) contain the words they are defining.

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A plant or crop that is cultivated or harvested as food or feed.	**Ghana** Crops/plants Position: Ghana agrees to the definition of crops/plants in the Code of practice to minimize and contain foodborne Antimicrobial Resistance and proposes alignment of this definition with that in the Code of Practice under Agenda item 5. Rationale: Ensure consistency in both standards.
~~**Foodborne pathogen** A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and/or the biological products produced by the pathogen.~~	**Canada** This is already defined in GL 77.
A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and/or the biological products produced by the pathogen.	**Ghana** Foodborne pathogen Position: Ghana proposes “pathogen” in the definition be replaced with microorganism to read “A microorganism (bacteria, virus or fungus) present in food, which may cause human disease(s) or illness through consumption of food contaminated with the microorganism and/or the biological products produced by the microorganism”. Rationale: The word “pathogen” is included in the word being defined and therefore cannot be used to define the term if the aim is to enable a good understanding of the term.
~~**Food chain**~~	**Canada**
Food chain	**Ghana** Food Chain Position: Ghana proposes the deletion of feed in the definition of food chain. Production to consumption continuum including, primary production (food hygiene producing animals, plants/crops), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption. Rationale: The word “feed” is implied in the definition of crops/plants which is defined as “a plant or crop cultivated or harvested as food or feed”
~~Production to consumption continuum including, primary production (food producing animals, plants/crops, feed), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.~~	**Canada**
Production to consumption continuum including, primary production (food producing animals, ~~plants/crops~~plants/crops), ~~feed),~~ harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.	**USA** Feed is one input into the production of animals so its being listed out separately does not make sense if a country does an evaluation and finds other inputs to be of more significant risk. Singling it out as more important

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	than other risks in a definition, without an evaluation of foodborne AMR risk under local conditions could be misleading.
One Health approach ~~to AMR~~	**USA** This definition is applicable to One Health in general, not specific to AMR
Food production environment	**Egypt** Egypt agrees with the final proposals made by the the EWG: "The vicinity of food, feed, plants/crops/animals to be harvested or processed that could contribute to foodborne AMR".
Food production environment	**Ghana** Food Production Environment Position: Ghana supports the definition of "food production environment". Food Production Environment: The vicinity of food, feed, plants/crops, animals to be harvested or processed that could contribute to foodborne AMR. Rationale: It is appropriate.
The immediate vicinity of ~~food, feed, plants/crops, animals~~ food to be harvested or ~~processed that could contribute to~~ processed, where scientific evidence supports foodborne ~~AMR~~AMR risk to human health.	**Brazil** Brazil suggests a new text to provide clarity. It is important that definitions are aligned with the COP.
The vicinity of food, feed, plants/crops, animals to be harvested or processed that could contribute to emergence and transmission of foodborne AMR.	**Canada** For the future consideration of impacts of processing aids, disinfectants, etc.
La cercanía de alimentos, piensos, plantas/cultivos y animales a ser recolectados o procesados, que podría propiciar la RAM transmitida por los alimentos.	**Uruguay** Uruguay eta de acuerdo con la propuesta.
The immediate vicinity of ~~food, feed, plants/crops, animals~~ food to be harvested or processed ~~that could contribute to~~ where scientific evidence supports foodborne ~~AMR~~AMR risk to human health.	**USA** USA: Text is edited to be within Codex scope and to emphasize the need to ground the work in science and risk. Foodborne route is covered in the general term "food".
Principles	**Brazil** Brazil is of the opinion that this section on "Principles" could still improve to be more consistent to "principles" and proportionate to the scope of the document. Some of the principles still seem to be out of the scope of principles, redundant and could be more focused and concise.
~~19. These principles should be read in conjunction with the *Guidelines for Risk Analysis of Foodborne AMR*.~~	**Canada** The Introduction (Para 11) already states that the Guidelines should be read with the Codex Guidelines for Risk Analysis of Foodborne AMR.
Principle 1: An integrated monitoring and surveillance system for foodborne AMR and AMU should follow a "One Health" approach.	**Switzerland** The "one health" approach is defined in the proposed code of practice to minimize and contain foodborne AMR, the same text should be added

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	under definitions in this document or a reference provided to assure consistency in terminology.
Principle 1: An integrated monitoring and surveillance system for foodborne AMR and AMU should follow a "One Health" ~~approach~~approach for AMR.	**International Feed Industry Federation** Alignment with the definition.
Principle 2: Monitoring and surveillance systems for AMR and AMU throughout the food chain are a fundamental part of national strategies and plans to minimize foodborne ~~AMR and an important component of a national food safety program~~AMR.	**Brazil** Brazil suggests deleting the end of the sentence once it is out of the scope of this Task Force.
Principle 2: Monitoring and surveillance systems for AMR and AMU throughout the food chain are a fundamental part of national strategies and action plans to minimize ~~foodborne~~ impact of AMR in human health and an important component of a national food safety program.	**Canada** This principle captures much information which is covered in the Introduction. The material should be in only one place or the other for streamlining the document. Canada proposes that this information should be retained only here in the Principles. Impact goes beyond just the food chain.
Principle 2: Monitoring and surveillance systems for AMR and AMU throughout the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a national food safety program.	**Egypt** Egypt agrees with the final advice of the eWG To keep the sentence and to change "core" by "important"
Principio 2: Los sistemas de seguimiento y vigilancia de la RAM y del UAM a lo largo de la cadena alimentaria constituyen una parte fundamental de las estrategias y los planes nacionales que buscan reducir al mínimo la RAM transmitida por los alimentos ~~y son un componente importante de todo programa nacional de inocuidad de los alimentos.~~	**Uruguay** Uruguay considera que se debe eliminar la referencia al sistema nacional de seguridad de los alimentos.
Principle 2: Monitoring and surveillance systems for AMR and AMU ~~throughout~~ along the food chain are a fundamental part of national strategies and plans to minimize foodborne ~~AMR and an important component of a national food safety program~~AMR.	**USA** Reference to national food safety systems is in the remit of CCFICS, is covered elsewhere (CXG 82-2013), and outside the scope of the TFAMR. In addition, the GLIS could be stand alone in the absence of a comprehensive national food safety system.
Principle 2: Monitoring and surveillance systems for AMR and AMU ~~throughout~~ along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a national food safety program.	**International Feed Industry Federation** For consistency.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; ~~in order to facilitate reporting at~~ taking into consideration the need for international ~~level ant~~ harmonisation of methodologies to ~~ensure that data is comparable international standards should be considered~~facilitate reporting and comparability of data.	**Australia** Section 4, Principle 3 Comment: Australia suggests amending Principle 3 as follows: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered taking into consideration the need for international harmonisation of methodologies to

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	facilitate reporting and comparability of data. Rationale: Australia suggests a Codex guideline is not appropriate for advocating for international standards to be developed, but rather adherence to standards should they exist. Furthermore, this deleted sentence may become redundant if and when such standards are developed.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive ~~improvement~~ implementation considering international standards, as resources permit~~; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.~~;	**Brazil** Brazil suggests replacing “improvement” by “implementation” and modifyng the end of the sentence to provide more clarity.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.	**Canada** Principle 3 duplicates Para 10 of the Introduction. Suggest the content be retained as a Principle and deleted in the Introduction.
Principle 3: An integrated~~A national~~ monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit~~; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered~~.	**Canada** International reporting is elaborated upon later in the document. Suggest it can be deleted from Principle 3.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.	**Egypt** Egypt agrees with the final advice of the eWG to To keep “international standards”
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.	**Ghana** Principle 3 Position: Ghana proposes the deletion of the sentence after the semi colon in Principle 3. Rationale: It is not related to the rest of the text in principle 3 but a repetition of the second sentence of principle 9.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ~~ant~~ and to ensure that data is comparable international standards should be considered.	**Japan**
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.	**USA** The term “progressive implementation” has been used so it is better to keep the terminology consistent. The term “improvement” is a relative term. The last statement is edited for readability. Also, there are no standardized

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	methods for crops and many of the samples described in this draft guideline.
Principle 3: A national monitoring ~~and~~ and/or surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive ~~improvement~~ implementation as resources permit; in order to facilitate reporting and comparability at the international ~~level ant to ensure that data is comparable~~ level. Harmonization with international standards should be ~~considered~~considered when applicable.	**USA** A country could have monitoring or surveillance but may not have both; so perhaps "or" would be appropriate. Or state that "National monitoring and surveillance systems should … "
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; in order to facilitate reporting at the international ~~level ant to ensure that data is comparable~~ level. Harmonization with international standards should be ~~considered~~considered where appropriate if they are not used as a barrier to trade.	**healthforanimals** TFAMR should not underestimate the concerns of countries that reporting is mis(used) to create barriers for trade.
Principle 3: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of ~~progressive~~ continuous improvement as resources permit; in order to facilitate reporting at the international level ant to ensure that data is comparable international standards should be considered.	**International Feed Industry Federation** The word progressive implies a hierarchy, that could be misused. It is preferable to speak about a continuous process.
Principle 4: Monitoring and surveillance systems should include data on occurrence of AMR and patterns of AMU, ~~in all relevant sectors so as~~ to support risk analysis and policy initiatives (e.g. development of mitigation strategies).	**Brazil** Brazil suggests deleting "in all relevant sectors" because it is to broad and unclear to be in a principle.
~~**Principle 4:** Monitoring and surveillance systems should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies).~~	**Canada** Canada suggests deleting this Principle, as much of the content is already captured in Principles 1-3.
Principle 4: Monitoring and surveillance systems should include data on occurrence of foodborne AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies).	**China**
Principle 4: Monitoring and surveillance systems should include data on occurrence of AMR and patterns of AMU, in ~~all~~ relevant sectors so as to support risk ~~analysis~~ assessment and ~~policy initiatives (e~~analysis.~~g. development of mitigation strategies).~~	**USA** The statement is edited for technical accuracy and clarity as it is delving into areas covered by CAC/GL 77-2011. The raw data coming out of monitoring and surveillance programs do not directly result in policy initiatives. Monitoring and surveillance data feed risk assessments. Risk assessments are then used by risk managers to develop policy initiatives. From Codex Procedural Manual: Section IV para 14: "Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent."

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Principle 5: Risk analysis should be ~~a~~ guiding ~~principle in~~ the design, implementation and ~~review~~ evaluation of ~~a~~ national monitoring and surveillance systems for ~~AMR, with best practice being informed by expected benefits to public health~~ AMR and ~~in terms of preventing or minimizing the burden to human health~~AMU.	**Canada** Canada suggests deleting the latter part of Principle 5 as it is unclear what "best practices" are being referred to – best practices for surveillance vs. best practices for interventions?
Principle 5: Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance systems for foodborne AMR, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health.	**China**
Principle 5: Risk analysis should be a guiding principle in the design, implementation and review of ~~a~~ national monitoring and surveillance systems for AMR, with best practice being informed by expected benefits to public health ~~and~~ in terms of ~~preventing or~~ minimizing ~~the burden~~ foodborne AMR risk to human health.	**USA** Modified for Codex scope and practicality
Principle 5: Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance systems for AMR, with best practice being informed by ~~expected~~ benefits to public health and in terms of ~~preventing or~~ minimizing the ~~burden~~ foodborne AMR risk to human health.	**International Feed Industry Federation** To keep the principle within the scope of the guidelines.
Principle 5: Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance systems for AMR, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human and animal health.	**OIE**
Principle 6: Priority for implementation should be given to the most relevant ~~design elements~~ foodborne AMR issues to be analyzed from a public health perspective using a risk-based approach whereby the likelihood of AMR transmission to humans are highest (e.g~~.~~ ., defined combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed).	**Canada** It is unclear what "relevant design elements" means. Canada suggests an improvement would be to provide a description of what a public health perspective might be.
Principle 6: Priority should be given ~~to the most relevant design elements to be analyzed from a public health perspective~~ tofood safety issues as described in CAC/GL 77-2011 (e.g. defined combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed).	**USA** The combination in parentheses defines the food safety issue described in CAC GL77. It would be helpful to point the reader back to the "food safety issue" terminology and CAC GL77 that defines the parenthetical information to aid understanding and consistency between the different Codex documents.
Principle 7: Monitoring and surveillance systems should incorporate to the extent practicable, the capacity for epidemiological investigation and identification of new and emerging foodborne AMR hazards/risks and trends. ~~This could include research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance system (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants).~~	**Brazil** Brazil suggests deleting the second sentence because principles should be more concise, with no need for adding examples.

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~~**Principle 7:** Monitoring and surveillance systems should incorporate to the extent practicable, the capacity for epidemiological investigation and identification of new and emerging foodborne AMR hazards/risks and trends. This could include research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance system (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants).~~	**Canada** Canada suggests deleting Principle 7 as research is out of scope of the document.
Principle 7: Monitoring and surveillance systems should incorporate to the extent practicable, the capacity for epidemiological investigation and identification of new and emerging foodborne AMR hazards/risks and trends. This could include research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance system (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants).	**Egypt** Egypt agrees with the new proposal of the principle 7
Principio 7: Los sistemas de seguimiento y vigilancia deben incorporar, en la medida de lo posible, capacidad para la investigación epidemiológica y la identificación de tendencias y peligros/riesgos nuevos y emergentes de la RAM transmitida por los alimentos. ~~Esto podría incluir proyectos de investigación y estudios epidemiológicos para mejorar la capacidad técnica y la efectividad del sistema integrado de seguimiento y vigilancia (por ejemplo, nuevos métodos analíticos, estudios de atribución de origen, seguimiento de aportes indirectos a la cadena alimentaria, contaminación cruzada de alimentos, epidemiología molecular de clones emergentes y determinantes de resistencia).~~	**Uruguay** Uruguay considera que debería eliminarse la segunda parte del texto.
Principle 7: Monitoring and surveillance ~~systems should incorporate to the extent practicable, the capacity~~ provide raw data for further epidemiological ~~investigation~~ investigations and identification of ~~new and~~ emerging and re-emerging foodborne AMR ~~hazards/risks and~~ trends. ~~This could include research projects and epidemiological studies~~ Where practical, countries should strive to enhance the technical capability and effectiveness of the integrated monitoring and surveillance ~~system (e~~system~~.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants).~~	**USA** Edits are offered to help with clarity. Monitoring and surveillance are distinct activities from epidemiological investigations. They provide data that could be useful to epidemiologic investigations, but more explanation is needed if countries are being directed to incorporate epi investigations into monitoring/surveillance. Regarding the parenthetical example, Codex standards should be drafted in a sufficiently clear and transparent manner such that extensive explanatory material is not required for interpretation.
Principle 7: Monitoring and surveillance systems should ~~incorporate to the extent practicable, the capacity~~ help provide data for epidemiological investigation and identification of new and emerging foodborne AMR hazards/risks and trends. This could include research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance ~~system (e~~system~~.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants).~~	**International Feed Industry Federation** For clarification.
Principle 8: Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place and participate in external proficiency testing schemes (External Quality Assessment Schemes).	**Canada** Principles 8 and 9 reflect the same concept – harmonizing and standardizing. Canada proposes combining the two Principles with the

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	following language: “Use of standardized quality assurance systems and harmonized approaches to data collection and analysis will facilitate comparison of AMR findings across regions”.
Principle 8: Laboratories involved in monitoring and surveillance should ideally have effective quality assurance systems in place and participate in external proficiency testing schemes (External Quality Assessment ~~Schemes)~~Schemes) or have at least a plan to achieve this.	**OIE**
Principle 9: A national monitoring and surveillance system should strive to harmonize laboratory methodology, data collection, analysis and reporting across all sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria are essential to ensure that data are comparable and to enhance an integrated approach to data management and reporting at the international level.	**Brazil** Brazil suggests deleting “across all sectors” because it is to broad and unclear to be in a principle.
Principle 9: A national monitoring and surveillance system should strive to harmonize l~~a~~boratory methodology, data collection, analysis and reporting across all sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria are essential to ensure that data are comparable and to enhance an integrated approach to data management and reporting at the international level.	**Canada** Principles 8 and 9 reflect the same concept – harmonizing and standardizing. Canada proposes combining the two Principles with the following language: “Use of standardized quality assurance systems and harmonized approaches to data collection and analysis will facilitate comparison of AMR findings across regions”.
Principle 9: A national monitoring and surveillance system should strive to harmonize l~~a~~boratory methodology, data collection, analysis and reporting across all sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria are essential to ensure that data are comparable and to enhance an integrated approach to data management and reporting at the international level.	**Ghana** Principle 9 Position: Ghana proposes an additional text “in accordance to countries’ data protection policies” to principle 9 as follows; A national monitoring and surveillance system should strive to harmonize laboratory methodology, data collection, analysis and reporting across all sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria are essential to ensure that data are comparable and to enhance an integrated approach to data management and reporting at the international level, in accordance to countries’ data protection policies. Rationale: Sharing of data at the international level should be in accordance with countries’ data governance policies.
Principle 9: A national monitoring and surveillance system should strive to harmonize l~~a~~boratory methodology, data collection, analysis and reporting ~~across all sectors~~ according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria where available are essential to ensure that data are comparable and to enhance an integrated approach to data management and reporting at the international level.	**USA** “All sectors” should be deleted as the terminology is all encompassing. Adding “where available” adds clarity and allows for less prescriptive statement.

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Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to ~~[inappropriately]~~ generate barriers to trade.	**Brazil** Brazil suggests deleting “inappropriately” to provide clarity.
~~**Principle 10:** Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.~~	**Canada** Canada suggests deleting Principle 10 as we don’t believe it is a necessary provision for a Code of Practice document.
Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.	**Ghana** Position: Ghana supports the inclusion of “inappropriately” in principle 10 without any comment.
Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.	**Iran** In order to not misinterpretation, it is recommended to provide more detailed explanations about data collection from imported food. What could be the inappropriate data collection from imported food?
Principle 10: ~~Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.~~	**Norway** We are of the opinion that this is outside the scope of the guidelines, thus it should be deleted.
Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.	**Republic of Korea** Korea supports to move the concept of Principle 10 to another section of this document. For example, in the COP(CXC 61-2005), it is described in the Introduction.
Principio 10: Los datos generados a partir de los sistemas nacionales de seguimiento y vigilancia de la RAM sobre alimentos importados no deben usarse para obstaculizar el comercio ~~[en forma inadecuada]~~.	**Uruguay** Uruguay está de acuerdo con este principio, eliminando la última frase “en forma inadecuada”. Estamos de acuerdo con el concepto, pero entendemos que la oración es redundante.
Principle 10: Data generated from national monitoring and surveillance ~~system of~~ systems for AMR in imported foods should not be used to ~~[inappropriately]~~ generate barriers to trade, but rather to inform food safety.	**USA** By retaining the word “inappropriately” it gives the indication that there are appropriate instances where a country could use surveillance systems for AMR/AMU as a trade barrier. At the level of a finding at surveillance, there have been no risk assessments to indicate this would be an appropriate risk management step. Additional text explains the purpose for the data, which is the aim of Codex: to protect consumer health and ensure fair trade practices.
~~**Principle 10:** Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to [inappropriately] generate barriers to trade.~~	**Consumers International** CI opposes the retention of bullet point 10. The purpose of surveillance systems is consumer protection so if a surveillance system identifies a problem then action should be taken which may create a justified burden to trade. This is the whole point of developing international standards in contrast to domestic standards. If the bullet point, is retained the text should use the language related to barriers to trade in the Codex Procedural Manual which includes the phrase "unjustified burden to trade".

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	So the text would read "Data generated from national monitoring and surveillance system of AMR in imported food should not be used to generate unjustified barriers to trade. "
Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to ~~[inappropriately]~~ generate barriers to trade.	**healthforanimals** Take out the word “inappropriately”, otherwise it suggests there are “appropriate” instances where a country could date as a trade barrier. New EU legislation that includes specific clauses that could be applied extra-territorially have led to countries to be wary of secondary motives.
Principle 10: Data generated from national monitoring and surveillance system of AMR in imported foods should not be used to ~~[inappropriately]~~ generate barriers to trade.	**International Feed Industry Federation** There is no appropriate way to create barrier to trade.
20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system throughout the food chain that is informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards ~~at a step (or steps) in~~ along the food chain and their relationship with risks to human health.	**Brazil** Brazil suggests changes to improve clarity and consistency.
~~**Risk-based approach**~~ ~~20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system throughout the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.~~	**Canada** Canada proposes that this entire section be deleted. There are several points which could be incorporated as Principles but there is currently much duplication (e.g., see the content of Principles 5 and 6).
20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system ~~throughout~~ along the food chain that is informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.	**USA** "Throughout” should be replaced by “along” since “throughout” means “everything”. Foodborne should be added as a qualifier to keep in Codex scope.
20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system ~~throughout~~ along the food chain that is informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards at a step (or steps) in the food chain and ~~their relationship with risks~~ level of risk to human health.	**healthforanimals** For clarity.
20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system ~~throughout~~ along the food chain that is informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.	**International Feed Industry Federation** For consistency and to keep the document within its scope.
20. For the purpose of these Guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system throughout the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human and animal health.	**OIE**
~~21. Integrated monitoring and surveillance of AMR and AMU in the food chain, along with data regarding AMR transmission through food handling, environmental spread or other routes of transmission, provides essential information for risk assessment and risk management decision-~~	**Canada** While this is a general statement linking surveillance and risk analysis, Canada is of the perspective that it does not add much applicable content

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~~making on appropriate control measures in human, plant and animal health.~~	under this heading of “Risk-based approach”. Suggest to delete this paragraph. It also overlaps with Para 4.
21. ~~Integrated monitoring and surveillance of AMR and AMU in the food chain~~Integrated monitoring and surveillance of AMR and AMU in the food chain, along with data regarding AMR transmission through food handling, environmental spread or other routes of transmission, provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant and animal health.	**Iran** Low data and assessment are available in foodborne AMR in the world. It is recommended to establish an international data bank in codex framework for AMR induced by food chain to be accessed by all countries.
21. Integrated monitoring and surveillance of AMR and AMU in the food chain, along with data regarding AMR transmission through food handling, environmental spread or other routes of transmission, provides ~~essential~~ important information for risk assessment and risk management decision-making on appropriate control measures ~~in human, plant and animal~~ to protect human health.	**USA** The word “important” would be more appropriate here as there are other data that may be even more important, that is, essential. Plant and animal health are outside Codex scope so should be deleted.
21. Integrated monitoring and surveillance of AMR and AMU in the food chain, along with data regarding AMR transmission ~~through~~ along food handling, environmental spread or other routes of transmission, provides essential information for risk assessment and risk management decision-making on appropriate control measures in ~~human, plant and animal~~ human health.	**International Feed Industry Federation** For consistency and keep the document within its scope.
21. Integrated monitoring and surveillance of AMR and AMU in the food chain, along with data regarding AMR transmission through food handling, environmental spread or other routes of transmission, provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, animal, plant and ~~animal~~ environmental health.	**OIE**
~~22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs should [initially] be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*~~	**Canada**
22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs should [initially] be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	**Egypt** Egypt agrees with the final advice of the eWG to keep “relationship”.
22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs should [initially] be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising	**Ghana** Position: Ghana accepts the addition of the word “initially” to the second sentence of paragraph 22 Rationale: Knowledge on possible foodborne AMR is lacking in many countries and therefore it is prudent to structure the designs of national

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from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	surveillance and monitoring programs initially on available information on AMR hazards and risks. When more data becomes available the designs may be reviewed appropriately.
22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in ~~most~~ many countries. Consequently, most programs should [initially] be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	**Switzerland** The proportion of countries for which this aspect is true is hopefully declining. "Many" is a more flexible term to account for this.
22. While an integrated monitoring and surveillance system 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 programs should [initially] be designed according to the knowledge that is available on~~ Data stemming from human outbreaks from foodborne AMR ~~hazards~~ pathogens, and ~~their potential~~ studies providing information on what parts of the food chain are at highest risk for contributing to ~~result in public health risks.~~ foodborne AMR, inform national priorities for monitoring and surveillance. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	**USA** The most helpful piece of information for a country starting a surveillance system would be what the major causes of foodborne AMR illness in the country are. The word “possible” is unnecessary as anything, and therefore, everything is “possible”.
22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs should ~~[initially]~~ be designed according to the knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	**Consumers International** CI supports removing initially since programs should continue to be modified based on knowledge and public health risks not just initially.
22. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. ~~Consequently, most programs should [initially] be designed according to the knowledge that is available on~~ Data stemming from human outbreaks from foodborne AMR ~~hazards~~ and ~~their potential~~ studies providing information on what parts of the food chain are at highest risk for contributing to ~~result in public health risks~~foodborne AMR inform national priorities for monitoring and surveillance. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26 of the *Guidelines for Risk Analysis of Foodborne AMR.*	**International Feed Industry Federation** For clarification on the basis for prioritization.
~~23. Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the *Guidelines for Risk Analysis of Foodborne AMR*. Hazard identification should include human microbiological pathogens and bacterial commensals that may transmit AMR to humans.~~	**Canada** This Para speaks to activities which should be conducted within a risk assessment/risk profile. These activities are not needed for Guidelines for monitoring and surveillance of AMR. Canada proposes deleting this Para.

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23. Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the *Guidelines for Risk Analysis of Foodborne AMR*. Hazard identification should include human microbiological pathogens and bacterial commensals that may transmit AMR to humans.	**Switzerland** In general, I think the use of "etc." in a guideline is not very helpful. We should either spell out the options or use the wording "such as" to make it open.
23. Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included ~~on~~ in a risk profile as described in the *Guidelines for Risk Analysis of Foodborne AMR*. Hazard identification should include ~~human microbiological~~ foodborne pathogens and bacterial commensals that may transmit AMR to ~~humans~~humans through food.	**USA** Text is edited for Codex scope.
23. Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the *Guidelines for Risk Analysis of Foodborne AMR*. Hazard identification should include human microbiological foodborne pathogens and bacterial commensals that may transmit foodborne AMR to humans.	**International Feed Industry Federation** For consistency with the scope of the document.
~~24. As countries improve their AMR systems over time, an approach to the development and implementation of monitoring and surveillance systems should lead to an increased use of generated data for risk assessment.~~	**Canada** This Para states a logical outcome of better surveillance data. With this in mind, Canada suggests deleting this paragraph.
24. As countries improve their AMU and AMR data collection and analysis systems over time, and as there is improved understanding of the relationships between them and the impacts on foodborne AMR emergence, spread, maintenance and disappearance in the production environment, an approach to the development and implementation of monitoring and surveillance systems should lead to an increased use of generated data for risk assessment.	**USA**
25. Potential foodborne AMR risks to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new antimicrobial resistance genes, new food chain exposure pathways, changing patterns of AMU in humans and animals. Any adjustments should be communicated with reference to methodological changes while retaining valid historical data or when relevant updating historical data for trend analysis.	**Canada** Canada suggests that this is a Principle, rather than something to include under a “Risk-based approach”. Canada proposes to move this text to Principle 10. Alternatively, simplified text for Principle 10 could be: “Monitoring and surveillance programs will need to evolve with new methodology to stay relevant for national/international comparisons”.
25. ~~Potential foodborne~~ Foodborne AMR ~~risks~~ hazards to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, identification of new antimicrobial resistance ~~genes~~genes in bacteria, ~~new food chain~~ exposure ~~pathways~~pathways along the food chain, and changing patterns of AMU in humans and animals. Any adjustments should be communicated with reference to methodological changes while retaining valid historical data or when relevant updating historical data for trend analysis.	**USA** : Edits suggested for technical accuracy and flow. Monitoring informs on hazards rather than measuring risk, which needs to be done after data is put through the risk assessment process.
25. ~~Potential foodborne~~ Foodborne AMR ~~risks~~ hazards to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new antimicrobial resistance ~~genes~~determinants, new ~~food chain~~ exposure ~~pathways~~pathways along the food chain, changing patterns of AMU in humans and animals. Any adjustments should be communicated with reference	**International Feed Industry Federation** For alignment with definitions and clarification.

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to methodological changes while retaining valid historical data or when relevant updating historical data for trend analysis.	
25. Potential foodborne AMR risks to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new antimicrobial resistance genes, new food chain exposure pathways, changing patterns of AMU in ~~humans~~ humans, animals and ~~animals~~plants. Any adjustments should be communicated with reference to methodological changes while retaining valid historical data or when relevant updating historical data for trend analysis.	**OIE**
~~26. The revision of the monitoring and surveillance system should be based on information about hazards and risks incorporated in the risk analysis process as described in the *Guidelines for Risk Analysis of Foodborne AMR*.~~	**Canada** The content of this Para is already covered under Principle 5 and in the Introduction (Para 11). Suggest to delete for streamlining the document.
26. The revision of the monitoring and surveillance system should be based on scientific information about hazards and risks incorporated in the risk analysis process as described in the *Guidelines for Risk Analysis of Foodborne AMR.*	**USA** Text is added to emphasize Codex work is grounded in science.
26. The revision of the monitoring and surveillance system should be based on scientific information about hazards and risks incorporated in the risk analysis process as described in the *Guidelines for Risk Analysis of Foodborne AMR.*	**International Feed Industry Federation** Science based approach is necessary.
Regulatory framework, policy and roles	**Canada** There is a lot of redundancy in Paragraphs 27-30. Canada proposes that the current material be streamlined into three paragraphs. The main point is that a regulatory framework will assist with the establishment and support of monitoring and surveillance systems.
27. An integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities, including competent authorities responsible for food safety. ~~The~~ As part of a national AMR action plan, competent authorities should develop an overarching ~~policy~~ risk management framework ~~for~~ inclusive of monitoring and surveillance activities throughout the food chain in collaboration with ~~the~~ human health, animal health, plant health, environmental and other relevant authorities. ~~Other stakeholders in relevant sectors should be included and collaborate in line with the national action plan (NAP) on AMR.~~ Sharing of knowledge and data with international organizations and counterparts ~~can~~ may improve the relevance and effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	**Canada** Canada further proposes to move the final two sentences of this Para to be a new Principle 11 under Principles.
27. An integrated monitoring and surveillance system for foodborne AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities throughout the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in relevant sectors should be included and collaborate in line with the national action plan (NAP) on AMR. Sharing of knowledge	**China**

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and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	
27. An integrated monitoring and surveillance system for AMR and AMU requires good ~~governance~~ governance, sufficient legal powers and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities throughout the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in relevant sectors should be included and collaborate in line with the national action plan (NAP) on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at ~~local~~ local, regional, national and international level. Capacity building might help to ensure the implementation of programs for AMR risk management.	**Norway**
27. An integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should ~~develop~~ consider developing an overarching policy framework for monitoring and surveillance activities ~~throughout~~ based on national priorities along the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities, as appropriate. ~~Other stakeholders in relevant sectors should be included and collaborate in line with the national action plan (NAP) on AMR.~~ Sharing of knowledge and data with international organizations and counterparts can improve ~~the effectiveness~~ global understanding of ~~policies taken at local level~~foodborned AMR and its relationship with AMU, animal management and animal health. Capacity building ~~might help to ensure~~ can facilitate the implementation of programs for AMR risk ~~management~~assessment.	**USA** Edits are provided to make the language more pragmatic. Additional edits are provided to clarify purpose of sharing data better because it is unclear how sharing data with international organizations improves the effectiveness of policies at the local level. Stakeholders engagement is covered in the next paragraph (28) so is duplicative here and can be deleted. This document addresses risk assessment, not risk management, so the last word is edited to risk “assessment”.
27. An integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities ~~throughout~~ along the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in relevant sectors should be included and collaborate in line with the national action plan ~~(NAP)~~ on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of programs for AMR risk management.	**International Feed Industry Federation** For consistency and the NAP acronym is not used in the rest of the document.
28. ~~Competent~~ It is important for competent authorities ~~should need~~ to have access to all sources of antimicrobial use data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**Australia** Section 6; paragraph 28 Comment: Australia suggests the following to improve clarity and readability: Competent authorities should need It is important for competent authorities to have access to all sources of antimicrobial use data… Rationale: Editorial

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
28. ~~Competent authorities should need to have access to all sources of antimicrobial use data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration.~~ Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**Canada** Canada proposes to simplify this Para and eliminate the need to be overly specific of the parties involved.
28. Competent authorities should need to have access to all sources of antimicrobial use data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**Egypt** Egypt agrees with the final advice of the eWG to delete second sentence of paragraph 28 “This should include access to livestock and crop production facilities when conducting epidemiological investigations of multidrug resistant foodborne outbreaks” and rephrase the first part as “Competent authorities should need to have access to all sources of antimicrobial use data”. Move paragraph 29 above
28. ~~Competent authorities should need to have access to all sources of antimicrobial use data.~~ Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**Norway** The concept of the first sentence is in our opinion better incorporated with the suggested wording, sufficient legal powers in paragraph 27 first sentence.
28. Competent authorities should ~~need to~~ have access to ~~all~~ sources of antimicrobial use data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**Switzerland** "all" is perhaps too ambitious and may not be necessary.
28. ~~Competent authorities should need to have access to all sources of antimicrobial use data.~~ Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including ~~food industry~~those in the food, ~~food industry~~feed, and	**USA** Mandating access to microbiological and antimicrobial use data is outside the scope of Codex so the first sentence should be deleted. Confidentiality helps motivate participation.

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pharmaceutical ~~industry,~~ industries; veterinarians~~,~~; animal, public, and plant health and ~~environment~~ environmental professionals~~,~~; farmers~~,~~; professional associations~~,~~; civil society~~,~~; consumer ~~organizations,~~ and retail organizations; and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system. Stakeholder participation can be encouraged through confidentiality and data management policies that protect personal and proprietary information.	
~~28. Competent authorities should need to have access to all sources of antimicrobial use data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.~~	**healthforanimals** Delete for three reasons: 1) Mandating access to all data is not within the power of Codex. 2) National laws mean that authorities cannot obtain samples from all sources in their country. 3) Providing authorities access to production facilities is not a legal requirement to obtain microbiological and antimicrobial use data.
28. ~~Competent authorities should need to have access to all sources of antimicrobial use data.~~ Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**International Feed Industry Federation**
28. Competent authorities should need to have access to all sources of ~~antimicrobial use~~ AMU data. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of an integrated monitoring and surveillance system.	**OIE**
29. Stakeholders other than the competent authority, such as veterinarians, plant health professionals, farmers, consumer organizations, civil society, pharmaceutical industry or food and feed industry, retailers and others may carry out monitoring activities e.g. monitoring of AMU on a voluntary ~~basis~~basis in support of the national AMR/ AMU surveillance system.	**Canada**

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~~30. Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated "One Health" approach in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more advance than others.~~	**Canada** "Competent authorities responsible for food safety" has been added to Para 27.
30. Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated "One Health" approach in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more advance than others.	**Ghana** Paragraph 30 Position: Ghana proposes the replacement of "may consider playing", in the first sentence of paragraph 30 with "shall play" as follows; 30. Competent authorities responsible for food safety shall play an active role in design, analysis and reporting of these activities as part of an integrated "One Health" approach in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more advance than others. Rationale: These guidelines focus on food and therefore the competent authority for food safety must play an active role in these areas.
30. Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated "One Health" approach in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more ~~advance~~ advanced than others. Monitoring and surveillance are distinct activities from risk management or risk communication as described in CAC GL 77.	**USA** Edited for clarity and consistency with CAC/GL 77.
30. Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated "One Health" approach for AMR in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more advance than others.	**International Feed Industry Federation** Alignment with definition.
~~**A progressive approach for the implementation**~~ **Implementation of an integrated monitoring and surveillance system of foodborne AMR**	**Brazil** Brazil suggests rewording of the subtitle and merging paragraphs 31 and 32 for clarity and consistency with the proposed revision of Principle 3.
A progressive approach for the implementation of an integrated monitoring and surveillance system ~~of~~ for foodborne AMR	**Canada** Canada believes that this section requires a significant overhaul for streamlining and better flow as well as additional content. Canada suggests deleting most of the text for Section 7; however we have made additional notes below should some of the text be retained.
A progressive approach for the implementation of an integrated monitoring and surveillance system of foodborne AMR	**Morocco** Morocco takes note that a progressive approach for the design and implementation of an integrated monitoring and surveillance system will

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	enable countries develop strategies as well as implement activities based on country specific scenarios and resources. The revised text provides a good guidance to countries as they develop national AMR surveillance strategies. However, there is need for more data to provide appropriate evidence of the risk to human health due to foodborne AMR infections attributable to foods of plant origin
A ~~progressive~~ continuous approach for the implementation of an integrated monitoring and surveillance system of foodborne AMR	**healthforanimals** The word "progressive" suggests a level of performance. The use of a level of performance could enable countries to utilize this text to justify implementation of non-tariff trade barriers - because a country has not "progressed" its monitoring and surveillance program to a level that is acceptable to an importing country does not mean that the exporting country(s) is not providing an adequate level of protection for consumers or producing unsafe food. A WTO consistent and better concept is to employ a continuous model that builds on current food safety systems. This approach does not add a point of demarcation that could serve to justify a trade barrier and still achieves the objective of influencing the design of monitoring and surveillance systems.
A ~~progressive~~ continuous approach for the implementation of an integrated monitoring and surveillance system of foodborne AMR	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade.
31. ~~A progressive approach for the~~ The design and implementation of an integrated monitoring and surveillance system allows countries to develop a strategy as well as implement activities to progress according to country-specific scenarios and resources. It is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new scientific information. The ~~implementation of a~~ progressive ~~approach~~ implementation should facilitate the achievement of the country's objectives on AMR and enable ~~continuous~~ improvement and enhancement. It includes: preliminary activities, initiating monitoring and surveillance activities, and evaluation and review of the monitoring and surveillance system.	**Brazil** Brazil suggests merging paragraph 31 for clarity.
31. A progressive approach for the design and implementation of an integrated monitoring and surveillance system allows countries to develop a strategy as well as implement activities ~~to progress~~ according to country-specific scenarios and resources. It is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new scientific information. The implementation of a progressive approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement and enhancement.	**Canada**
31. ~~A progressive approach for the design and implementation of an integrated monitoring and surveillance system allows countries to develop a strategy as well as implement activities to progress according to country-specific scenarios and resources~~A progressive approach for the design and implementation of an integrated monitoring and surveillance system allows countries to	**Iran** It is recommended to state that each country should have at least one AMR laboratory in the field of food and domestic. This could be included mandatory or optional in national regulatories.

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develop a strategy as well as implement activities to progress according to country-specific scenarios and resources. It is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new scientific information. The implementation of a progressive approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement and enhancement.	
31. A progressive approach ~~for~~ to the design and implementation of an integrated monitoring and surveillance system allows countries to develop a strategy as well as implement activities to progress according to country-specific scenarios and resources. It is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new scientific information. The implementation of a progressive approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement and enhancement.	**USA**
31. A ~~progressive~~ continuous approach for the design and implementation of an integrated monitoring and surveillance system allows countries to develop a strategy as well as implement activities to progress according to country-specific scenarios and resources. It is a practical response to inevitable variations in monitoring and surveillance objectives, priorities, infrastructure, technical capability, resources and new scientific information. The implementation of a ~~progressive~~ continuous approach should facilitate the achievement of the country's objectives on AMR and enable continuous improvement and enhancement.	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade and keep the document within its scope.
32. ~~The progressive approach includes: preliminary activities, initiating monitoring and surveillance activities, and evaluation and review of the monitoring and surveillance system.~~	**Brazil** Brazil suggests merging paragraph 32 for clarity
32. The ~~progressive~~ continuous approach includes: preliminary activities, initiating monitoring and surveillance activities, and evaluation and review of the monitoring and surveillance system.	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade.
Figure 1. ~~Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR~~	**Brazil** Brazil suggests deleting the figure, once it does not add value and can lead to confusion or misinterpretation.
Figure 1. Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR	**Canada** Canada has the following comments on Figure 1: - figure does not demonstrate the linkage between the guidelines and the Code of Practice or GL 77 - the identification of key stakeholders and data providers is missing - it is unclear what is meant by "Gral. Considerations" - "Key design elements" does not touch on the design elements needed to establish and evaluate a monitoring and surveillance program - the order of the text in the figure does not reflect the order of the text in the rest of the document.
Figure 1. Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR	**Ghana** Figure 1 Ghana proposes AMC be added to AMU in the second box of the diagram as follows; AMU/AMC. Secondly, wherever AMU appears in the document,

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	if relevant, AMC should also be mentioned. Rationale: 1. AMU determinations are based on patient level data such as prescription records and the actual quantities of antimicrobial agents taken which in some countries (low income) may be lacking and do not facilitate AMU determination. WHO recommends AMC for countries with limited experience in data collection and where patient level data is lacking. As experience is built and more sophisticated data sources become available AMC should gradually give way to AMU in a progressive approach. 2. In support of the above proposal, the content of the text under 7.2.2 (Antimicrobial Use Program has information relating to AMC though not clearly defined as such).
Figure 1. Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR	**Republic of Korea** Korea proposes to add 'feedback arrow' from the box of "EVALUATION, REVIEW, ADJUSTMENT OR EXPANSION of the monitoring and surveillance system" to the box of "PRELIMINARY ACTIVITIES" or "INITIATING AND DEVELOPING MONITORING AND SURVEILLANCE ACTIVITIES" to express progressive improvement of an integrated monitoring and surveillance system. Korea suggests replacing 'Expansion of collection(2nd of "AMU")' with 'Types and reporting format' for consistency
~~**Figure 1**. Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR~~	**USA** We recommend deleting the figure as it goes beyond surveillance and is covered in CAC-GL 77-2011.
~~**Figure 1**. Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne AMR~~	**healthforanimals** Delete figure 1 because it is more confusing than enlightening. Better to insert a graphic that shows that M&S are inputs for risk management decisions.
33. The progressive ~~approach for~~ implementation of integrated monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and OIE standards and guidelines, especially the chapters on antimicrobial use in the *OIE Terrestrial Animal Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on the Use of Antimicrobial Agents in Animals*.	**Brazil** Brazil suggests rewording for clarity and consistency with the proposed revision of Principle 3.
~~33. The progressive approach for monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and OIE standards and guidelines, especially the chapters on antimicrobial use in the *OIE Terrestrial Animal*~~	**Canada** For streamlining purposes

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~~*Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on the Use of Antimicrobial Agents in Animals*.~~	
33. The progressive approach for monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and OIE standards and guidelines, especially the chapters on antimicrobial resistance and use in the *OIE Terrestrial Animal Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on the Use of Antimicrobial Agents in Animals*.	**Japan** To include OIE code of not only AMU but also AMR.
33. The progressive approach for monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with ~~the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and~~ OIE standards and guidelines, especially the chapters on antimicrobial use in the *OIE Terrestrial Animal Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on the Use of Antimicrobial Agents in Animals*.	**healthforanimals** Take out reference to AGISAR as it is not a standard setting organization like OIE. It is an advisory group whose outputs have not been agreed by all WHO member countries.
33. The ~~progressive~~ continuous approach for monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and OIE standards and guidelines, especially the chapters on ~~antimicrobial use~~ AMU in the *OIE Terrestrial Animal Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on the Use of Antimicrobial Agents in Animals*.	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade and consistent use of acronym.
33. The progressive approach for monitoring and surveillance of foodborne AMR and AMU presented in these Guidelines is consistent with the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*, and OIE standards and guidelines, especially the chapters on antimicrobial use in the *OIE Terrestrial Animal Health Code* and *OIE Aquatic Animal Health Code* and reporting options of the OIE's guidance for the collection of data on antimicrobial agents used in animals as described in the *OIE Annual Report on ~~the Use of Antimicrobial Agents~~ antimicrobial agents intended for use in Animals*.	**OIE**
34. The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders. It should take into consideration existing national food safety programs, national action plans (NAPs) and knowledge of the AMR and AMU food safety situation, as well as any existing activities to address AMR in the different sectors as related to foodborne AMR (animal, plant, food production environment and human health sectors). Competent authorities should identify the challenges that they currently face during the implementation of these activities.	**USA** Text is added to clarify that national food safety programs help provide a foundation for reducing the spread of antimicrobial resistant and susceptible bacteria in food, so serve as a helpful foundation. "Food safety" is added to keep within Codex scope.

SPECIFIC COMMENTS	
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34. The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders. It should take into consideration existing national food safety programs, AMR national action plans (NAPs) and knowledge of the AMR and AMU food safety situation, as well as any existing activities to address AMR in the different sectors (animal, plant, food production environment and human health sectors). Competent authorities should identify the challenges that they currently face during the implementation of these activities.	**healthforanimals** better clarity.
34. The establishment of monitoring and surveillance objectives is an important initial step in the design and implementation of activities. This should be done in a consultative manner by the competent authorities and stakeholders. It should take into consideration national action plans (NAPs) and knowledge of the AMR and AMU food safety situation, as well as any existing activities to address AMR in the different sectors in relation with foodborne AMR (animal, plant, food production, environment and human health sectors). Competent authorities should identify the challenges that they currently face during the implementation of these activities.	**International Feed Industry Federation** Use of acronyms and keeping the document within its scope.
The following aspects should be clearly defined:	**Canada**
The primary reasons objectives for the data collection (e.g., to evaluate trends over time and spaceregions, to provide data useful for risk assessments and risk management, to obtain baseline information on foodborne AMR and AMU, to provide harmonized data that can be easily compared, exchanged, used or aggregated locally, nationally or internationally).	**Canada**
The primary reasons for the data collection (e.g.,., to obtain baseline information on foodborne AMR and AMU, to evaluate trends over time and space, to provide data useful for risk assessments and risk management, to obtain baseline information on foodborne AMR and AMU, to provide harmonized data that can be easily compared, exchanged, used or aggregated locally, nationally or internationally).	**Norway** We suggest altering the order of examples to make it more logical
The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk assessments and risk management, to obtain baseline information on foodborne AMR AMU in the food production environment and AMUfoodborne AMR, to provide harmonized data that can be easily compared, exchanged, used or aggregated locally, nationally or internationally).	**USA**
The setting of proposed timelines (e.g., reporting on an annual basis). - Determination of where the data will be housed.	**Canada**
The setting of proposed timelines for sampling and reporting (e.g., reporting on an annual basis).	**Canada**
35. A confidentiality and data management policy should be put in place.	**Switzerland**
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health implications outcomes of foodborne AMR, AMU patterns,	**Australia** Comment: Australia suggests the following minor edit:

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information on food production systems, food distribution, food consumption patterns and food exposure pathways.	When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health implications outcomes of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways. Rationale: Australia prefers the more specific term 'outcome' which is evidence based, as opposed to 'implication' which may be more speculative or subjective.
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health ~~implications~~ outcomes of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways.	**Brazil** Brazil suggests rewording for clarity.
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health implications of foodborne AMR, AMU patterns, information on food production and processing systems, food distribution, food consumption patterns and food exposure pathways.	**China**
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health ~~implications~~ outcomes of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways.	**USA** Outcomes rather than implications is the more appropriate word regarding understanding health impacts.
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health ~~implications~~ outcomes of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways.	**healthforanimals** A public health outcome is a specific consequence related to foodborne AMR. Whereas, a public health implication is a speculative conclusion that is not explicitly drawn from the data. Codex member countries have an expectation that Codex will utilize the highest level of scientific integrity in its guidance(s); this edit improves the precision of the point and document.
36. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health ~~implications~~ outcomes of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways.	**International Feed Industry Federation** For clarification.
37. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobials, food commodities and sample sources should be informed by national, regional and international public health data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on AMR and AMU in different sectors. Information from risk profiles and risk assessments, where these exist, should also be used. 37 bis. When there are no existing national data to assist with prioritization, the suggested initial activities as per recommendations of the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) and the OIE's Terrestrial and Aquatic Animal Health Codes may be used.	**Canada**

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37. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobials, food commodities and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on foodborne AMR and AMU in different sectors. Information from risk profiles and risk assessments, where these exist, should also be used.	**China**
37. Monitoring and surveillance priorities for ~~microorganisms and resistance determinants~~foodborne AMR hazards, antimicrobials, food commodities and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on AMR and AMU in different sectors. Information from risk profiles and risk assessments, where these exist, should also be used.	**USA** Since hazards is defined earlier, it is simpler to use the term, “hazard”.
37. Monitoring and surveillance priorities for microorganisms and resistance determinants, ~~antimicrobials~~antimicrobial agents, food commodities and sample sources should be informed by national, regional and international data and knowledge where it exists. Competent authorities should identify existing data sources and gaps (national or regional data as a priority) on AMR and AMU in different sectors. Information from risk profiles and risk assessments, where these exist, should also be used.	**International Feed Industry Federation** Alignment with definitions.
~~**Infrastructure**~~ **Capacity and** ~~**resources**~~ **Infrastructure**	**Canada** Canada proposes that this section include identifying data or sample providers and mapping out the antimicrobial distribution system for the intended region for monitoring and surveillance activities.
38. Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the priority foodborned AMR public health objectives ~~and determine which of the~~ considering whether certain elements in ~~the programs described in Section~~ section 7.2 ~~can effectively be implemented first and which~~ could be implemented at a later stage when additional resources become available.	**USA** Edited for flow and clarity. We recommend moving this paragraph 38 to after 47 to improve flow.
38. Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives and determine which of the elements in the programs described in Section 7.2 can effectively be implemented first and which could be implemented at a later stage when additional resources become available.	**International Feed Industry Federation** Move after §47 for better logic in the document.
39. The evolution of surveillance and monitoring programs does not need to strictly follow the order described in these Guidelines; these are logical options for expansion, which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the programs are aligned during development to allow for temporal integrated analysis.	**Canada**
39. The evolution of ~~surveillance and~~ monitoring and surveillance programs does not need to strictly follow the order described in these Guidelines; these are logical options for expansion, which may	**China**

SPECIFIC COMMENTS	
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require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the programs are aligned during development to allow for integrated analysis.	
39. The evolution of ~~surveillance and~~ monitoring and surveillance programs does not need to strictly follow the order described in these Guidelines; these are logical options for expansion, which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the programs are aligned during development to allow for integrated analysis.	**Japan** For consistency with other parts.
39. The evolution of surveillance and monitoring programs does not need to strictly follow the order described in these Guidelines; ~~these are logical~~ rather, suggested options for expansion, which may require increasing ~~resources~~resources are provided. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the programs are aligned during development to allow for integrated ~~analysis~~analysis and refinement as improved understanding of the relationships between them becomes available.	**USA** Edited for flow and clarity.
~~39. The evolution of surveillance and monitoring programs does not need to strictly follow the order described in these Guidelines; these are logical options for expansion, which may require increasing resources. Programs for AMU monitoring can proceed at a different rate than programs for AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the programs are aligned during development to allow for integrated analysis.~~	**International Feed Industry Federation** Commentary.
40. In advance of launching the AMR monitoring and surveillance activities, in order to optimize resources and efforts, the competent authority should consider the possibilities of ~~integration~~ incorporation of the activities in already ongoing monitoring or surveillance programs ~~or~~ of other ~~activities. For example~~research activities (e.g., ~~on~~ ongoing monitoring of pathogenic foodborne ~~bacteria~~bacteria under food safety programs).	**Canada**
40. In advance of launching the AMR monitoring and surveillance activities, in order to optimize resources and efforts, the competent authority should consider the possibilities of integration of the activities in already ongoing monitoring or surveillance programs or other activities. For example, antimicrobial susceptibility testing could be added to on ongoing monitoring of ~~pathogenic~~ foodborne ~~bacteria~~pathogens.	**USA** Edited for clarity. Recommend moving paragraph 40 to follow 41 for better flow.
41. The competent authority should also carefully consider coordination of sampling and laboratory testing, in coordination with relevant stakeholders, and develop a plan for ~~collation~~ receiving, analyzing, and ~~analysis of~~ reporting the ~~data in a~~ anonymized data. A central ~~repository~~repository is desirable when feasible. As part of initial planning, the competent authority should also consider where harmonization and standardization are ~~required~~ apprpriate to meet monitoring and surveillance objectives.	**USA** Edited to clarify the data management needed to receive data, the importance that it protects confidentiality and also the distinct task of analyzing the data and providing reports. It may not always be possible to have a central repository. “Required” is prescriptive, so changed to “appropriate”.

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~~**Key design elements to be established before initiating the monitoring and surveillance activities**~~	**Canada**
~~42. When designing the monitoring and surveillance system, the following elements should be identified and established:~~	**Canada**
42. When designing the monitoring and surveillance system, the following elements should be ~~identified~~ considered and ~~established~~included to the extent practical:	**USA** Edited for flow and practicality.
42. When designing the monitoring and surveillance system, the following elements should be identified and established, where practical:	**International Feed Industry Federation**
~~43. Antimicrobial resistance:~~	**Canada**
43. Antimicrobial resistance:	**USA** Bullet 1: Edited for accuracy. Hazard is the appropriate term as that is what we are surveying for. Bullet 3: Representative sampling is not feasible in many circumstances and sectors. Standardized and harmonized methods are not even developed for some sectors. Bullet 4: Edited to make more practical. Bullet 5: It is not clear what “capacity requirements” means-should be deleted or explained.
The highest priority microorganisms, panels of antimicrobials and commodities (see Section 8) to be targeted based on any existing national data and international ~~recommendations~~data.	**Australia** Section 7, paragraph 43 Comment: Australia suggests the following edit to the first dot point: The highest priority microorganisms, panels of antimicrobials and commodities (see section 8) to be targeted based on any existing national and international recommendations data. Rationale: Australia suggests it is appropriate to use national and international data as a basis and applied to prevailing conditions in a country, rather than adopting international recommendations that may not be appropriate.
~~The highest priority microorganisms, panels of antimicrobials and commodities (see Section 8) to be targeted based on any existing national data and international recommendations.~~	**Canada**
The highest priority ~~microorganisms~~hazards, panels of antimicrobials and commodities (see Section 8) to be targeted based on any existing national ~~data~~ and international ~~recommendations~~data.	**USA** Edited for flow and practicality.
The highest priority microorganisms, panels of antimicrobials and commodities (see Section 8) to be targeted based on any existing national data and international ~~recommendations~~data.	**healthforanimals** Better to refer to data. Countries base their decisions on data, and less so

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	on recommendations from international entities. There is both a scientific logic and national legal rational for this
The highest priority microorganisms, panels of antimicrobials agents and commodities (see Section 8) to be targeted based on any existing national ~~data~~ and international ~~recommendations~~data.	**International Feed Industry Federation** Alignment with definitions.
~~The food production and distribution chain, points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives.~~	**Canada**
The food ~~production~~ production, processing and distribution chain, points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives.	**China**
The food production and distribution ~~chain,~~ points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives.	**International Feed Industry Federation**
~~Representative sampling methods, sampling plans, laboratory analysis and reporting protocols.~~	**Canada**
~~Representative sampling methods~~Sampling methods that are representative of the commodity, sampling plans, laboratory analysis and reporting protocols.	**USA**
~~Standardized and harmonized methodologies (e.g., laboratory testing) and best practices with those used in other sectors.~~	**Canada**
~~Standardized~~ The availability of standardized and harmonized methodologies (e.g., laboratory testing) and ~~best~~ potential for harmonizing methodologies and practices ~~with those used in other~~ across multiple sectors.	**USA**
~~Capacity requirements.~~	**Canada**
Capacity requirements.	**Switzerland** I suggest to expand this point so it is clear what kind of capacity we are referring to.
Capacity requirements.	**USA** It is not clear what “capacity requirements” means-should be deleted or explained.
~~44. Antimicrobial use:~~	**Canada**
~~Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.~~	**Canada**
Cadenas de distribución de los antimicrobianos desde su fabricación o importación hasta el usuario final, incluidos los proveedores de datos sobre ventas/uso.	**Uruguay** Uruguay considera que debe discutirse la viabilidad de incluir el usuario final dentro de la cadena de distribución.
~~Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data~~	**USA**

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~~providers.~~	
~~The sectors where collection of data would be most relevant and efficient to meet surveillance objectives.~~	**Canada**
The sectors where collection of data would be most relevant and efficient to meet monitoring and surveillance objectives.	**China**
~~The~~ Identification of the sectors where collection of data would be most relevant and efficient to meet surveillance objectives. For example, see OIE Terrestrial Animal Health Code Article 6.9.4 for information regarding efficient and practical sources of antimicrobial use data, including veterinary medicinal product registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and pharmaceutical industry associations. can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.	**USA**
~~An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and crops (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.~~	**Canada**
An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and ~~crops~~ crops/plants (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.	**China**
An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and crops (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.	**USA** This information is redundant with the next bullet. -On-farm antibiotic use data collection is within the mandate of OIE not Codex. Most appropriately, antibiotic use data collection is left out of this document with a reference to OIE Article 6.9.4. If Codex provides advice here, it should be consistent with what is in existing OIE, text rather than provide advice contrary or duplicative of OIE text. A reference to OIE is preferred since OIE chapters are continually updated. --It is beyond the mandate of Codex to provide legal advice, legal guidance or suggest the need for a domestic legal framework.
~~An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and crops (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.~~	**USA**
An assessment of the need to establish a legal framework before initiating collection and reporting of ~~antimicrobial sales and use~~ AMU data in food producing animals and crops (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.	**International Feed Industry Federation** For consistency reason and for consistent use of acronym.

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An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and ~~crops~~ plants/crops (see Section 9) or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide the data.	**OIE**
~~45. Undertaking pilot studies and testing can provide valuable inputs into the design for both AMR and AMU surveillance systems.~~	**Canada**
45. Undertaking pilot studies and testing can provide valuable inputs into the design for both foodborne AMR and AMU monitoring and surveillance systems.	**China**
~~**Initiating and developing an integrated monitoring and surveillance system**~~	**Canada**
~~46. When initiating and developing an integrated monitoring and surveillance system, the following three areas should be considered for progressive development: antimicrobial resistance program, antimicrobial use program and analysis and reporting.~~	**Canada**
46. When initiating and developing an integrated monitoring and surveillance system, the following three areas should be considered for progressive development: antimicrobial resistance program, antimicrobial use program and integration of programs for joint analysis and reporting.	**Switzerland**
46. When initiating and developing an integrated monitoring and surveillance system, the following three areas should be considered for progressive development: ~~antimicrobial resistance program~~AMR data collection, ~~antimicrobial use program~~ AMU data collection, and data analysis and reporting.	**USA** Edited for clarity.
46. When initiating and developing an integrated monitoring and surveillance system, the following three areas should be considered for ~~progressive~~ continuous development: ~~antimicrobial resistance~~ AMR program, ~~antimicrobial use~~ AMU program and analysis and reporting.	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade. Consistent use of acronyms.
47. The ~~phases~~ elements described below are guidelines for development and enhancement of integrated monitoring and surveillance system. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering resources, infrastructure, capacity, and priorities of countries.	**Australia** Comment: Australia suggests amending as follows: The phases elements described below are guidelines for development and enhancement of integrated monitoring and surveillance system. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering resources, infrastructure, capacity, and priorities of countries. Rationale: The components in Subsection 7.2.1 are not demarcated phases or successive steps, but elements that describe various actions. Australia suggests the term “phases” should be removed to avoid categorisation of countries and the potential for trade barriers to be created.
47. The ~~phases~~ elements described below are guidelines for development and enhancement of integrated monitoring and surveillance system. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering	**Brazil** Brazil suggests rewording for clarity.

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resources, infrastructure, capacity, and priorities of countries.	
~~47. The phases described below are guidelines for development and enhancement of integrated monitoring and surveillance system. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering resources, infrastructure, capacity, and priorities of countries.~~	**Canada**
47. The ~~phases~~ elements described below are guidelines for development and enhancement of integrated monitoring and surveillance ~~system~~systems. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering resources, infrastructure, capacity, and priorities of countries.	**USA** Elements rather than phases are described, so the sentence is edited accordingly.
47. The ~~phases~~ elements described below are guidelines for development and enhancement of integrated monitoring and surveillance system. These Guidelines are intended to provide a continuum of flexible options for implementation and expansion of the system, considering resources, infrastructure, capacity, and priorities of countries.	**International Feed Industry Federation** To avoid hierarchy between the system, which may lead to barrier to trade.
~~**Antimicrobial resistance program**~~	**Canada**
Antimicrobial resistance program	**Iran** In addition to the mentioned items, public awareness about antimicrobial resistance and training of professional experts as well as experimental programs are also recommended to be included in design of the AMR program
~~General considerations~~	**Canada**
~~48. The initial scope and design of the AMR program may be informed by previous surveys and by national and international experience and recommendations. As the AMR program develops, the scope and design may be refined and adapted as appropriate based on the following factors:~~	**Canada**
48. The initial scope and design of the AMR program may be informed by previous ~~surveys~~ surveys, scientific knowledge and by national and international experience and recommendations. As the AMR program develops, the scope and design may be refined and adapted as appropriate based on the following factors:	**USA**
~~Monitoring and surveillance findings.~~	**Canada**
~~Epidemiology of antimicrobial-resistant micro-organisms (primarily in humans, but also in the food chain, environment, etc.).~~	**Canada**
Epidemiology of antimicrobial-resistant micro-organisms (primarily in humans, but also in the food chain, food chain environment, etc.).	**International Feed Industry Federation** Alignment with definitions.
~~Risk profile and risk assessment findings.~~	**Canada**

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Risk profile and risk assessment findings.	**USA** Published papers, diagnostic data or other sources may be important sources of information to use in scoping and designing a program.
~~49.The competent authority may launch additional pro-active monitoring and surveillance activities such as point prevalence surveys or exploratory sampling to determine whether any modifications to the program are needed, e.g. whether a new food commodity should be incorporated into the core surveillance program.~~	**Canada**
49.The competent authority may launch additional pro-active monitoring and surveillance activities such as point prevalence surveys or exploratory sampling to determine whether any modifications to the program are needed, e.g. whether a new food commodity should be incorporated into the core monitoring and surveillance program.	**China**
~~Sampling sources and stages in the food chain~~	**Canada**
Sampling sources and stages in the food chain	**USA** This section B can be deleted as it is mostly covered in Section C and deletion will simplify the document. However, edits are offered in case the section is maintained.
Sampling sources and stages in the food chain	**healthforanimals** see comment at 50
~~50. When identifying the sampling sources to be included in the AMR monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure pathways throughout the food chain.~~	**Canada**
50. When identifying the sampling sources to be included in the AMR monitoring and surveillance program, consideration should be given to food and the major ~~direct and indirect~~ food based hazard release and exposure pathways ~~throughout the food chain~~where scientific evidence supports foodborne AMR risk to human health.	**USA** USA: As food is the closest sample type to the consumer and should be the priority consideration for sampling for foodborne AMR, it is important to emphasize the priority, so as not to confuse the reader. Additional text is provided to emphasize the need for any advice from Codex to be grounded in science and risk.”
~~50. When identifying the sampling sources to be included in the AMR monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure pathways throughout the food chain.~~	**healthforanimals** The paragraphs 50- 52 include concepts that are all part of the Sample Plan discussed in part C. The removal of this section should simplify the guidance for countries while preserving the integrity of objectives.
~~50. When identifying the sampling sources to be included in the AMR monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure pathways throughout the food chain.~~	**International Feed Industry Federation** Repeated in sampling plans.
51. The program can start by targeting a limited selection of sampling sources (e.g. limited number of food-producing animal species, crops/plant species, foods) at specific points in the food ~~chain (e~~chain.~~g. farm, harvest, slaughterhouses, processing plants, retail).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63

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	Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
~~51. The program can start by targeting a limited selection of sampling sources (e.g. limited number of food-producing animal species, crops/plant species, foods) at specific points in the food chain (e.g. farm, harvest, slaughterhouses, processing plants, retail).~~	**Canada**
51. The program can start by ~~targeting a limited selection~~ conducting antimicrobial susceptibility testing of ~~sampling sources~~ foodborne pathogenic bacteria in existing food safety programs (e.g. food, limited number of food-producing animal species, crops/plant species, foods) at specific points in the food chain (e.g. farm, harvest, slaughterhouses, processing plants, retail).	**USA** Text is modified to help clarify, that as many countries have existing testing for foodborne pathogens, they can build from those programs.
~~51. The program can start by targeting a limited selection of sampling sources (e.g. limited number of food-producing animal species, crops/plant species, foods) at specific points in the food chain (e.g. farm, harvest, slaughterhouses, processing plants, retail).~~	**healthforanimals** see comment above
~~51. The program can start by targeting a limited selection of sampling sources (e.g. limited number of food-producing animal species, crops/plant species, foods) at specific points in the food chain (e.g. farm, harvest, slaughterhouses, processing plants, retail).~~	**International Feed Industry Federation** Repeated in sampling plans.
52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances. ~~For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources such as feed, water, waste water, reclaimed water, sewage sludge, manure, surface water, etc.~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances. For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other ~~sources such as feed~~sources, ~~water, waste water, reclaimed water, sewage sludge, manure, surface water, etc~~where scientific evidence supports foodborne AMR risk to human health.	**Brazil** Brazil suggests a new text and deleting examples to provide clarity and consistency.
~~52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances. For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources such as feed, water, waste water, reclaimed water, sewage sludge, manure, surface water, etc.~~	**Canada**

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52. These sampling sources can be redefined according to changes in the country impacting the program, development of scientific knowledge, or other specific needs. Additional sampling sources and stages ~~in~~ along the food chain can be incorporated progressively according to priorities and resources as implementation advances. For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources ~~such~~ as ~~feed, water, waste water, reclaimed water, sewage sludge, manure, surface water, etc~~supported by scientific data.	**USA** Plans should consider changes in scientific knowledge in order to remain scientifically sound. Many of the examples are outside the scope of Codex and they add more confusion than clarity so should be deleted. For example, we can assume there will be plenty of bacteria in sewage and sludge, but it is unclear how spending limited resources on incorporating sewage and sludge, which are quite far from actual food in most countries, in an ongoing integrated national surveillance system will be helpful. Perhaps, these are areas better addressed in research studies. Additionally, some of the sample sources listed in the last line might be included in an outbreak investigation, but not likely feasible as part of a routine surveillance system.
~~52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances. For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources such as feed, water, waste water, reclaimed water, sewage sludge, manure, surface water, etc.~~	**healthforanimals** see comment above
~~52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances. For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources such as feed, water, waste water, reclaimed water, sewage sludge, manure, surface water, etc.~~	**International Feed Industry Federation** Repeated in sampling plans.
~~Sampling plans~~	**Canada**
Sampling plans 53bis In the development and selection of sampling plans, consideration should be given to the principles in the General Guidelines on Sampling (CAC/GL 50-2004).	**USA** USA: CAC/GL 50-2004 provides information on sampling plans.
53. The sampling plan should describe the sampling procedures required to obtain representative samples for collection from the animal/crops/food commodities or production environment, at the specific point in the food ~~chain (e~~chain~~.g. caecal content or carcass swabs from fattening pigs in slaughterhouses).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
53. The sampling plan should describe the sampling procedures ~~required~~ used to obtain representative samples for collection from the animal/crops/food commodities or production environment, at the specific point in the food ~~chain (e.g.~~ chain. For example, caecal content or carcass swabs from fattening pigs in ~~slaughterhouses)~~slaughterhouses will not represent on farm situation while carcass swabs from market hogs in the slaughterhouse will reflect the situation at the	**USA** : Additional text added for clarity.

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slaughter house.	
~~53. The sampling plan should describe the sampling procedures required to obtain representative samples for collection from the animal/crops/food commodities or production environment, at the specific point in the food chain (e.g. caecal content or carcass swabs from fattening pigs in slaughterhouses).~~	**Canada**
53. The sampling plan should describe the sampling procedures required to obtain representative samples for collection from the animal/crops/food commodities or production environment, at the specific point in the food chain (e.g. caecal content or carcass swabs from fattening pigs in slaughterhouses).	**healthforanimals** Prior to paragraph 53 and within part C, add the following: "53bis. In the development and selection of sampling plans consideration should be given to the principles in the General Guidelines on Sampling (CAC/GL 50-2004)." The inclusion of this reference to an existing Codex text can increase the acceptance of the overall document because the familiarity to the concepts.
53. The sampling plan should describe the sampling procedures required to obtain representative samples for collection from the ~~animal/crops/food commodities or~~ animal/plants/crops/food production environment, at the specific point in the food chain (e.g. caecal content or carcass swabs from fattening pigs in slaughterhouses).	**International Feed Industry Federation** For alignment with definitions.
54. As the program develops, the sampling plan should gradually broaden to be more representative of the national population of interest, with the ultimate goal of having a sampling plan representative of the national population. ~~For example, surveillance of abattoirs according to slaughter volume, with stratification within animal species (e.g. broilers, layers,) and sample size sufficient to establish prevalence or to detect changes.~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
~~54. As the program develops, the sampling plan should gradually broaden to be more representative of the national population of interest, with the ultimate goal of having a sampling plan representative of the national population. For example, surveillance of abattoirs according to slaughter volume, with stratification within animal species (e.g. broilers, layers,) and sample size sufficient to establish prevalence or to detect changes.~~	**Canada**
54. As the program develops, the sampling plan ~~should gradually broaden to~~ can be ~~more representative of the national population of interest, with the ultimate goal of having a sampling plan representative of the national population. For example, surveillance of abattoirs according~~ broadened to ~~slaughter volume, with stratification within animal species (e~~include additional food commodities presenting foodborne AMR risk.~~g. broilers, layers,) and sample size sufficient to establish prevalence or to detect changes.~~	**USA** It is unclear what "national population of interest" means. Edits are offered to simplify the text without becoming too prescriptive.
~~Target microorganisms~~	**Canada**

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55. The initial program may be based on phenotypic susceptibility testing for resistance of representative ~~zoonotic/pathogens (e~~zoonotic/pathogens.~~g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
55. The initial program may be based on ~~phenotypic~~ antimicrobial susceptibility testing for resistance of representative zoonotic/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne ~~pathogens (e~~pathogens, where scientific evidence supports foodborne AMR risk to human health.~~g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).~~	**Brazil** Brazil suggests a new text and deleting examples to provide clarity and consistency.
~~55. The initial program may be based on phenotypic susceptibility testing for resistance of representative zoonotic/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).~~	**Canada**
55. The initial program may be based on phenotypic susceptibility testing for resistance of representative zoonotic/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne pathogens (e.g. *Vibrio*, *Listeria monocytogenes*~~methicillin-resistant~~) and indicator bacteria~~*Staphylococcus* aureus (MRSA)) and indicator bacteria~~ *(e.g. Enterococcus* spp).	**China** To be consistent with Paragraph 87.
55. The initial program may be based on phenotypic susceptibility testing for resistance of representative ~~zoonotic/pathogens~~ foodborne/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).	**Japan** To use consistent terminology with the title of this guideline. “Foodborne pathogen“ is also used in CAC/GL 77 and AGISAR guideline.
55. The initial program may be based on ~~phenotypic~~ antimicrobial susceptibility testing ~~for resistance~~ of representative ~~zoonotic/pathogens~~ foodborne pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator or commensal bacteria (e.g., *Escherichia coli*~~)~~) of risk to human health. ~~The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).~~	**USA** The first sentence is edited for technical accuracy and to keep within Codex scope. Foodborne pathogens are within Codex scope. All zoonotic bacteria, such as those transmitted through animal-to-person contact or occupational exposure are not within Codex scope. The second sentence is not technically accurate as MRSA is not considered to be a foodborne pathogen and indicator bacteria are covered under the first sentence.
55. The initial program may be based on phenotypic susceptibility testing for resistance of	**healthforanimals** Clarity and the scope of Codex.

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representative zoonotic/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* ~~spp)~~spp) with risk to human health.	
55. The initial program may be based on phenotypic susceptibility testing for resistance of representative foodborne zoonotic/pathogens (e.g., *Salmonella* spp. and *Campylobacter* spp.) and indicator bacteria (e.g., *Escherichia coli*). ~~The program may be expanded by including a broader range of foodborne pathogens (e.g. methicillin-resistant *Staphylococcus* aureus (MRSA)) and indicator bacteria *(e.g. Enterococcus* spp).~~	**International Feed Industry Federation** To keep in the scope of the guidelines.. MRSA is not foodborne
56. Subsequent program development could include testing for genetic determinants of resistance and mobile DNA ~~elements (e~~elements.~~g. plasmids, transposons).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
~~56. Subsequent program development could include testing for genetic determinants of resistance and mobile DNA elements (e.g. plasmids, transposons).~~	**Canada**
56. Subsequent program development could include testing for ~~genetic determinants of~~ antimicrobial resistance determinants and mobile DNA elements (e.g. plasmids, transposons).	**International Feed Industry Federation** Alignment with definitions in the Code of Practice.
~~57. AMR testing of animal/plant pathogens could be used to provide additional information about the selection pressure resulting from AMU.~~	**Canada**
~~57. AMR testing of animal/plant pathogens could be used to provide additional information about the selection pressure resulting from AMU.~~	**USA** The text should be deleted. Animal and plant pathogens are beyond Codex scope and in the purview of OIE and IPPC. A One Health approach necessitates those working on food work with those working in other sectors, not that everything must be incorporated into one sector. It is not Codex's mission to conduct research on all contributors to selection pressure.
57. AMR testing of ~~animal/plant~~ animal/plant/crop pathogens could be used to provide additional information about the selection pressure resulting from AMU.	**International Feed Industry Federation** Alignment with definitions in the Code of Practice.
~~Antimicrobials tested~~	**Canada**
~~Antimicrobials~~ Antimicrobial agents tested	**Norway** Please follow up throughout the document

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Antimicrobials~~ Antimicrobial agents tested	**International Feed Industry Federation** Alignment with definitions in the Code of Practice.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by national lists of high priority antimicrobials for human health or the WHO in the *List of Critically Important Antimicrobials for Human Medicine*) and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**Australia** Section 7, paragraph 58 Comment: Australia suggests amending p58 to give priority to national lists of priority antimicrobials. 58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by national lists of high priority antimicrobials for human health or the WHO in the List of Critically Important Antimicrobials for Human Medicine) other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels. Rationale: National and/or regional lists of priority antimicrobials are based on local authorisations, availability, use patterns and risk assessments and should be given precedence where they are available. Australia's amendments are consistent with paragraph 102.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by national/regional lists or WHO in the *List of Critically Important Antimicrobials for Human Medicine*) and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**Brazil** Brazil suggests adding "national/regional lists" for clarity and consistency.
~~58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by WHO in the *List of Critically Important Antimicrobials for Human Medicine*) and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.~~	**Canada** If retained, Canada suggests for the choice of antimicrobials to be tested, there should be some relation to the antimicrobials used in animals/crops. Canada also has a question about the current text, whether the Para is implying that the WHO CIA list is the basis and only additional antimicrobials added are based on national lists? Canada requests clarification on how the antimicrobials are chosen.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by WHO in the *List of Critically Important Antimicrobials for Human ~~Medicine~~Medicine* and national lists (where they exist)) and other relevant antimicrobials that have an influence on the selection or co-selection of ~~resistance~~resistance as relevant to the national situation. ~~Additional~~ Broader range of priority antimicrobials ~~specified in national risk prioritization exercises~~ that have been ranked as critically and highly important for animal health (e.g. as defined by the OIE List of Antimicrobials of Veterinary Importance) may also be considered for inclusion in the ~~susceptibility testing panels.~~ panels as relevant to national	**Japan** Japan proposes to add "and national lists (where they exist)" to be consistent with 7.1.4 first bullet. Japan also proposes to add "as relevant to the national situation" to provide flexibility for implementation of integrated surveillance programs considering the capacity and priorities of countries. With reard to the addition of the last sentence, target microorganisms, bacteria isolated" animal/plant pathogens are included in Target organisms

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
situation.	(Paragraph 57). Therefore, the OIE List should be considered to take into account the animal health.
58. ~~Antimicrobials~~ Antimicrobial agents to be tested should be prioritized based on ~~antimicrobials~~ antimicrobial agents that have been ranked as highest priority for human health (e.g. as defined by WHO in the *List of Critically Important Antimicrobials for Human Medicine*) and other relevant ~~antimicrobials~~ antimicrobial agents that have an influence on the selection or co-selection of resistance. Additional ~~antimicrobials~~ antimicrobial agents specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**Norway** In order to be consistent with the definition and avoiding misunderstanding with want to add agents after antimicrobials. This should also be done throughout the document.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. by national/regional authorities or countries with similar prevailing conditions or as defined by national lists of important antimicrobials for humans and animals where they exist or, where national lists do not exist, the WHO in the *List of Critically Important Antimicrobials for Human Medicine*) and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**USA** National authorizations and lists developed in consideration of national use of antimicrobial agents and local risk of AMR should take precedence when available.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. ~~as defined~~ (e.g. by ~~WHO in the~~national/regional authorities or countries with similar prevailing conditions ~~*List of Critically Important Antimicrobials for Human Medicine*~~) and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**healthforanimals** The availability of medically important limited antimicrobials varies across countries. Utilizing national or regionally developed list(s) will yield the most relevant method.
58. ~~Antimicrobials to~~ Antimicrobial agents be tested should be prioritized based on antimicrobials agents that have been ranked as highest priority for human ~~health (e.g. as defined by WHO in the~~health ~~*List of Critically Important Antimicrobials for Human Medicine*)~~ and other relevant antimicrobials agents that have an influence on the selection or co-selection of resistance. Additional antimicrobials agents specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**International Feed Industry Federation** Alignment with definition of the Code of Practice. Prioritization may depend on local conditions.
58. Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked as highest priority for human health (e.g. as defined by WHO in the *List of Critically Important Antimicrobials for Human Medicine*~~)~~), the categorisation on the OIE List of antimicrobial agents of veterinary importance, and other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Additional antimicrobials specified in national risk prioritization exercises may also be considered for inclusion in the susceptibility testing panels.	**OIE**
~~**Antimicrobial use program**~~	**Canada**
Antimicrobial agents use program	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Source of antimicrobial use data~~	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Source of antimicrobial agents use data	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~59. The source of the data collected and the way the data are reported may vary between countries and may change as the implementation of the AMU program develops.~~	**Canada**
59. The source of the data collected and the way the data are reported may vary between countries and may change as the implementation of the AMU program develops. There are several AMU or sales data indicators that have been developed at varying levels for reporting, that is, at the animal-, flock-, farm or regional or national level. Each has its own characteristics, advantages and disadvantages, such as ease of data collection and computation.	**USA** USA: Text is added for clarity. Various data programs should be recognized and understood by the countries using them for monitoring.
~~60. A basic source of data regarding antimicrobials intended for use in animals and crops is the collection of antimicrobial sales data from manufacturers and importer/exporter data. Sales data of antimicrobials may be collected in addition, from other sources like wholesalers, retailers, pharmacies, feed mills or other agricultural associations.~~	**Canada**
60. A basic source of data regarding antimicrobials intended for use in animals and ~~crops~~ crops/plants is the collection of antimicrobial sales data from manufacturers and importer/exporter data. Sales data of antimicrobials may be collected in addition, from other sources like wholesalers, retailers, pharmacies, feed mills or other agricultural associations.	**China**
60. ~~A basic source of data regarding antimicrobials intended for use in animals and crops is the collection of antimicrobial sales data from manufacturers and importer/exporter data.~~ Sales data of antimicrobials may be collected ~~in addition,~~ from ~~other~~ sources ~~like~~ such as wholesalers, retailers, pharmacies, feed mills or other agricultural associations. Sales and distribution data may not be indicative of how antimicrobials are actually used. Sales data represent a summary of the product sold through various outlets, not the volume of product ultimately purchased by the end user for administration to animals.	**USA** Improve clarity and accuracy. Antimicrobial use data does not equate to antimicrobial sales data and sales data and “intentions” are difficult to objectively assess. Text added for clarity.
60. A basic source of data regarding ~~antimicrobials~~ antimicrobial agents intended for use in animals and ~~crops~~ plants/crops is the collection of antimicrobial agent sales data from manufacturers and importer/exporter data. Sales data of ~~antimicrobials~~ antimicrobial agents may be collected in addition, from other sources like wholesalers, retailers, pharmacies, feed mills or other agricultural associations.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
60. A basic source of data regarding antimicrobials intended for use in animals and ~~crops~~ plants/crops is the collection of antimicrobial sales data from manufacturers and importer/exporter data. Sales data of antimicrobials may be collected in addition, from other sources like wholesalers, retailers, pharmacies, feed mills or other agricultural associations.	**OIE**
~~61. Through pilot studies competent authorities could explore collection of antimicrobial use data from farmers, veterinarians and plant protection specialists.~~	**Canada**
61. Through pilot studies competent authorities could explore collection of ~~antimicrobial use~~ AMU data from farmers, veterinarians and plant protection specialists.	**International Feed Industry Federation** Consistent use of acronym.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~62. The AMU-program may evolve to include collection of AMU data from end-user sources , such as collection of use data from veterinary prescriptions and farmers records with increasing national coverage of the data.~~	**Canada**
62. The ~~AMU-program~~ program may evolve to include collection of AMU data from end-user sources , such as ~~collection of use data~~ from veterinary prescriptions and farmers records with increasing national coverage of the data.	**USA**
~~Reporting~~	**Canada**
Reporting	**Republic of Korea** Korea suggests replacing “Reporting” with “Types and reporting format” for clarification and consistency. Furthermore, specific title according to the text is preferred, and “Reporting(section 7.2.2. B.)” is duplicated and confused with “Analysis and reporting(section 7.2.3.)”. (Reference OIE terrestrial animal health code, chapter 6.9.4.)
~~63. The way of analyzing and reporting AMU data may vary depending on the type and source of the data collected, the level of detail of these data and the monitoring and surveillance objectives.~~	**Canada**
63. ~~The way of analyzing~~ Analysis and reporting of antimicrobial agent sales or AMU data may vary depending on the type and source of the data collected, the level of detail of these data and the monitoring and surveillance objectives.	**USA**
~~Reporting of overall amount of antimicrobial agents sold for use in animals and plants/crops may include:~~	**Canada**
~~Antimicrobial class.~~	**Canada**
Type of intended ~~use (e~~use~~.g. therapeutic/growth promotion).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
~~Type of intended use (e.g. therapeutic/growth promotion).~~	**Canada**
Type of intended use (e.g. therapeutic/growth promotion).	**USA** The current phrasing “intended use” under the first bold bullet implies the sales data equates to antimicrobial use.
~~Type of intended use (e~~Approved label indications~~.g. therapeutic/growth promotion).~~	**USA**
Type of intended use (e.g. ~~therapeutic/growth~~ treatment/prophylaxis/growth promotion).	**Consumers International** Both OIE and WHO along with numerous countries differ in their

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	recommendations with respect to treatment and prophylaxis. Data should be collected to determine the impacts of these recommendations
Type of intended use (e.g. therapeutic/growth promotion). Approved label indications	**healthforanimals**
~~Type of intended use (e.g. therapeutic/growth promotion).~~	**healthforanimals**
Type of intended use (e.g. therapeutic/growth promotion). approved lacel indications	**healthforanimals** Many antibiotics carry indications for multiple indications.
Type of intended use (e.g. ~~therapeutic/growth promotion)~~veterinary medical use/non-veterinary medical use).	**OIE**
Animal/plant species ~~groups (e.g~~groups. ~~terrestrial/aquatic food producing animals, type of vegetable, fruit).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
Animal/plant species groups (e.g. terrestrial/aquatic food producing animals, type of vegetable, fruit).	**Canada** Could these Guidelines provide recommendations for reporting to the animal species or stage of production? Canada suggests these Guidelines provide recommendations for reporting at these detailed levels.
~~Animal/plant species groups (e.g. terrestrial/aquatic food producing animals, type of vegetable, fruit).~~	**Canada**
~~Animal/plant~~ Animal/plant/crop species groups (e.g. terrestrial/aquatic food producing animals, type of vegetable, fruit).	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Route of administration.~~	**Canada**
~~Reporting of AMU data could be expanded as follows:~~	**Canada**
Reporting of AMU data could be expanded as follows:	**USA** Additional new dark bullet. Existing bullets refer to sales data only, thus on-farm use data could be separately addressed through pilot studies, so the second bold bullet was added.
~~Reporting~~ Pilot programs or other national efforts to collect on-farm AMU data to include dose, duration, indication •Reporting of AMU or antimicrobial sales data could be expanded as follows:	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Reporting of AMU data ~~could be expanded as follows~~should include plant and animal populations whenever possible. [New Bullet] Competent authorities should consider the the following additional reporting:	**Consumers International** The language on populations should be consistent with paragraph 124.
~~Adjusted by the estimated animal population size and land area used for plants/crops, when this information is available.~~	**Canada**
Adjusted by the estimated animal population size and land area used for plants/crops, when this information is available.	**USA** There is no global consensus on how such data will be collected, so it is premature to include this sentence.
~~Adjusted by the estimated animal population size and land area used for plants/crops, when this information is available.~~	**USA**
~~Adjusted by the estimated animal population size and land area used for plants/crops, when this information is available.~~	**Consumers International** Delete this sub-bullet and create a stand alone as proposed above.
~~Competent authorities could explore voluntary or regulatory options for stratifying sales data to create estimates of sales by animal/plant species.~~	**Canada**
~~Competent authorities could explore voluntary or regulatory options for stratifying sales data to create estimates~~ Estimates of sales by animal/plant ~~species~~species and by livestock production class (e.g. beef versus dairy cattle).	**Consumers International**
Competent authorities could explore voluntary or regulatory options for stratifying sales data to create estimates of sales by ~~animal/plant~~ animal/plant/crop species.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Overall amount used in animals and crops by antimicrobial class, stratified by type of use, species group and route of administration.~~	**Canada**
Overall amount used in animals and ~~crops~~ crops/plants by antimicrobial class, stratified by type of use, species group and route of administration.	**China**
Overall amount used in animals and ~~crops~~ plants/crops by antimicrobial class, stratified by type of use, species group and route of administration.	**OIE**
Antimicrobial use data presented using different ~~metrics (e.g~~metrics. ~~Defined Daily Doses (DDD), Defined Course Doses (DCD)).~~	**Australia** Section 7, paragraphs 51, 52, 53, 54, 55, 56 and 63 Comment: Australia suggests deleting the examples in each of the paragraphs. Rationale: These examples are best placed in Section 8 and 9, as appropriate, where there is greater detail and context provided. Removal of these examples will not compromise the intent or integrity of sections 7.2.1 and 7.2.2 but will simplify the guidance, remove unnecessary complexity and improve readability.
~~Antimicrobial use data presented using different metrics (e.g. Defined Daily Doses (DDD), Defined~~	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Course Doses (DCD)).~~	
Antimicrobial use and/or sales data presented using different metrics (e.g. Defined Daily Doses (DDD), Defined Course Doses (DCD)).	**USA** Sales data provides information on the amount of antibiotic available in the market but does not indicate whether the product was used or for what purpose. Many antibiotics have labels for multiple indications. Second open bullet under first dark bullet: The current phrasing "intended use" under the first bold bullet implies the sales data equates to antimicrobial use. First bullet under last dark bullet: USA: There is no global consensus on how such data will be collected, so it is premature to include this sentence. Additional editorial changes were made and an additional dark bullet was added-now second dark bullet. Existing bullets refer to sales data only, thus on-farm use data could be separately addressed through pilot studies, so the second bold bullet was added.
~~Antimicrobial use~~ AMU data presented using different metrics (e.g. Defined Daily Doses (DDD), Defined Course Doses (DCD)).	**International Feed Industry Federation** Consistent use of acronyms.
~~**Analysis and reporting**~~	**Canada**
~~Integrated analysis and reporting~~	**Canada**
~~64. The possibilities for integrated analysis and reporting of AMR and AMU data may differ between countries. Factors influencing the degree of integration include the level of development of the monitoring and surveillance system, type of data available, the extent of cross-sectorial collaboration, organizational and legal aspects for data sharing, etc.~~	**Canada**
64. The possibilities for integrated analysis and reporting of foodborne AMR and AMU data may differ between countries. Factors influencing the degree of integration include the level of development of the monitoring and surveillance system, type of data available, the extent of cross-sectorial collaboration, organizational and legal aspects for data sharing, etc.	**China**
64. The possibilities for integrated analysis and reporting of AMR and AMU data may differ ~~between~~ among countries. Factors influencing the degree of integration include the level of development of the monitoring and surveillance system, type of data available, the extent of cross-sectorial collaboration, organizational and legal aspects for data sharing, etc.	**USA**
~~65. The integrated analysis and reporting may start by including a sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of quantities of antimicrobials intended for use in animals and crops.~~	**Canada**
65. The integrated analysis and reporting may start by including a sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of quantities of antimicrobials intended for use in animals and ~~crops~~crops/plants.	**China**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
65. The integrated analysis and reporting may start by including a sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of quantities of ~~antimicrobials~~ antimicrobial agents intended for use in animals and ~~crops~~plants/crops.	**International Feed Industry Federation** Alignment with definitions of the Code of Practice.
65. The integrated analysis and reporting may start by including a sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of quantities of antimicrobials intended for use in animals and ~~crops~~plants/crops.	**OIE**
~~66. As the program develops:~~	**Canada**
~~More sectors may be included in the descriptive analysis.~~	**Canada**
~~Reporting of individual isolate AMR data (instead of aggregated data) may be considered.~~	**Canada**
~~Enhanced surveillance information may be included through active follow-up or collection of supplementary epidemiological data.~~	**Canada**
~~Linkage of information from various sources may increase to develop more comprehensive analysis across sectors.~~	**Canada**
~~Identification or quantitative epidemiological modelling of sector specific risk/protective factors for AMU or risk/protective factors for AMR can be undertaken.~~	**Canada**
Identification or quantitative epidemiological modelling of sector specific risk/protective factors for AMU or risk/protective factors for foodborne AMR ~~can~~ may be undertaken.	**USA** Edited to stay within Codex scope.
~~67. In the initial phase, analysis and reporting may include the collection of information from different sectors (e.g. humans, animal species, plants/crops, food production environment), bacterial species, across regions or time, and a summary of key findings.~~	**Canada**
68. Subsequent ~~advancement~~ progression could include integration of information and statistical or epidemiological modelling across the sectors (e.g. humans, animal species, food, plants/crops, food production environment), across bacterial species, across regions (geographical information systems) or time (trend analysis), or between use and resistance. Integration could include graphical display of harmonized data. Graphical charts could illustrate and compare multiple surveillance components at the same time (e.g., bacterial resistance in samples collected from several points along the food-chain up to humans, alignment with findings from whole genome sequencing, and relevant AMU practices).	**Australia** Section 7, paragraph 68 Comment: Australia suggests replacing ‘advancement’ with ‘progression’. Rationale: Consistent with progressive approach
~~68. Subsequent advancement could include integration of information and statistical or epidemiological modelling across the sectors (e.g. humans, animal species, food, plants/crops, food production environment), across bacterial species, across regions (geographical information systems) or time (trend analysis), or between use and resistance. Integration could include graphical display of harmonized data. Graphical charts could illustrate and compare multiple surveillance components at the same time (e.g., bacterial resistance in samples collected from several points~~	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~along the food-chain up to humans, alignment with findings from whole genome sequencing, and relevant AMU practices).~~	
68. Subsequent advancement could include integration of information and statistical or epidemiological modelling across the sectors (e.g. humans, animal species, food, plants/crops, food production environment), across bacterial species, across regions (geographical information systems) or time (trend analysis), or between ~~use~~ AMU and ~~resistance.~~ AMR. Integration could include graphical display of harmonized data. Graphical charts could illustrate and compare multiple surveillance components at the same time (e.g~~., bacterial resistance~~ . AMR in samples collected from several points along the food-chain up to humans, alignment with findings from whole genome sequencing, and relevant AMU practices).	**USA**
~~69. Advanced analytics may be a link between surveillance data and surveillance-based research.~~	**Canada**
69. Advanced analytics may be a link between monitoring and surveillance data and monitoring and surveillance-based research.	**China**
69. Advanced analytics may be a link between surveillance data and surveillance-based research.	**Switzerland** Please clarify what is meant by "advanced analytics"
69. Advanced analytics may be ~~a~~ used to link between surveillance data and surveillance-based research.	**USA**
~~Link with risk analysis processes~~	**Canada** It is unnecessary to explain risk analysis activities in these Guidelines for monitoring and surveillance.
~~Link with risk analysis processes~~	**International Feed Industry Federation** Outside the scope of the term of reference.
~~70. Monitoring and surveillance data can be progressively included in risk analysis activities (risk management and assessment/risk profiling activities) such as:~~	**Canada**
70. Monitoring and surveillance data can be progressively included in risk analysis activities (risk management and assessment/risk profiling activities) such as:	**USA** The fourth and the fifth bullets should be modified as monitoring and surveillance data feed risk profiling and risk assessments to determine risk prior to developing risk management options. Monitoring and surveillance data give information on hazards, not risk, and must feed the risk assessment process as described in CAC/GL 77. Risk managers can then use data from risk assessments to develop proportionate risk management options. Presence/absence or trends identified through a monitoring/surveillance system does not establish risk in itself.
~~70. Monitoring and surveillance data can be progressively included in risk analysis activities (risk management and assessment/risk profiling activities) such as:~~	**healthforanimals** Delete all section B because this is guidance on risk management. This is not in the TOR.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
70. ~~Monitoring and surveillance data can be progressively included in risk analysis activities (risk management and assessment/risk profiling activities) such as:~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Prioritizing which AMR food safety hazard(s) need to be evaluated first.~~	**Canada**
Prioritizing which foodborne AMR ~~food safety~~ hazard(s) need to be evaluated first.	**USA**
~~Prioritizing which AMR food safety hazard(s) need to be evaluated first.~~	**healthforanimals**
~~Prioritizing which AMR food safety hazard(s) need to be evaluated first.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Decision-making by risk managers/policy makers on whether to develop a risk profile or conduct a risk assessment based on the priority AMR food safety hazards.~~	**Canada**
Decision-making by risk managers/policy makers on whether to develop a risk profile or conduct a risk assessment based on the priority foodborne AMR ~~food safety~~ hazards.	**USA**
~~Decision-making by risk managers/policy makers on whether to develop a risk profile or conduct a risk assessment based on the priority AMR food safety hazards.~~	**healthforanimals**
~~Decision-making by risk managers/policy makers on whether to develop a risk profile or conduct a risk assessment based on the priority AMR food safety hazards.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Conducting qualitative or quantitative risk assessments as needed.~~	**Canada**
~~Conducting qualitative or quantitative risk assessments as needed.~~	**healthforanimals**
~~Conducting qualitative or quantitative risk assessments as needed.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Identify risk management options, including informing interventions for disease prevention and control and to evaluate risk management interventions to reduce risk.~~	**Canada**
~~Identify~~ Evaluate risk management ~~options, including informing~~ interventions ~~for disease prevention and control and~~ to ~~evaluate risk management interventions to~~ reduce risk.	**USA**
~~Identify risk management options, including informing interventions for disease prevention and control and to evaluate risk management interventions to reduce risk.~~	**healthforanimals**
~~Identify risk management options, including informing interventions for disease prevention and control and to evaluate risk management interventions to reduce risk.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Risk communication about priority AMR food safety risks.~~	**Canada**
~~Risk~~ Engaging in risk communication with risk managers about priority foodborne AMR ~~food safety risks~~hazards.	**USA**
~~Risk communication about priority AMR food safety risks.~~	**healthforanimals**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~Risk communication about priority AMR food safety risks.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Periodic review and refinement and update of risk analysis in light of new data reported and new technologies.~~	**Canada**
~~Periodic review and refinement and update of risk analysis in light of new data reported and new technologies.~~	**healthforanimals**
~~Periodic review and refinement and update of risk analysis in light of new data reported and new technologies.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~Commissioning of *ad hoc* research projects for targeted data collection and for risk assessment and surveillance methodological improvement.~~	**Canada**
Commissioning of *ad hoc* research projects for targeted data collection and for risk assessment and surveillance methodological ~~improvement~~improvement to refine the system to target priority risks.	**USA**
~~Commissioning of *ad hoc* research projects for targeted data collection and for risk assessment and surveillance methodological improvement.~~	**healthforanimals**
~~Commissioning of *ad hoc* research projects for targeted data collection and for risk assessment and surveillance methodological improvement.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~71. Risk assessment findings can continuously be used to review and improve the monitoring and surveillance system.~~	**Canada**
71. ~~Risk assessment findings can continuously be used to review and improve the monitoring and surveillance system.~~	**International Feed Industry Federation** Outside of the scope of the terms of reference.
~~**Evaluation, review and adjustment or expansion of the monitoring and surveillance program**~~	**Canada**
~~**Evaluation, review**~~ **Review and adjustment or expansion of the monitoring and surveillance program**	**USA** As “evaluation” and “review” mean the same thing, they appear duplicative, so the word, “review” is likely enough.
~~72. Evaluation and review of the monitoring and surveillance activities are needed to ensure the objectives are being met and that planned activities are being achieved. The evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies and to respond to changing national needs as determined by risk analysis.~~	**Canada**
72. ~~Evaluation and review~~ Review of the monitoring and surveillance activities are needed to ensure the objectives are being met and that planned activities are being ~~achieved~~implemented effectively. The ~~evaluation and~~ review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies and to respond to changing national needs as determined by risk ~~analysis~~analysis and national priorities.	**USA**
~~73. The competent authority should develop a framework and plan to facilitate the evaluation and~~	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~review of monitoring and surveillance activities (see Section 11) which could include the following aspects:~~	
~~Indicators to effectively track the progress of the monitoring and surveillance program.~~	**Canada**
~~Periodic evaluation of the monitoring and surveillance program to ensure quality and that the results are a robust, representative and a reliable indicator of AMR or AMU.~~	**Canada**
~~Use of the data generated from the evaluation of activities and risk profiling to adjust the monitoring and surveillance program if required, for example to expand to a wider scope of pathogens, foods and antimicrobials, taking into consideration resource allocation and priorities.~~	**Canada**
Use of the data generated from the evaluation of activities and risk profiling to adjust the monitoring and surveillance program if required, for example to expand to a wider scope of foodborne pathogens, foods and antimicrobials, taking into consideration resource allocation and priorities.	**USA**
Use of the data generated from the evaluation of activities and risk profiling to adjust the monitoring and surveillance program if required, for example to expand to a wider scope of foodborne pathogens, foods and ~~antimicrobials~~antimicrobial agents, taking into consideration resource allocation and priorities.	**International Feed Industry Federation** Focus on the scope of the document. Alignment with definition of the Code of Practice
~~Development and inclusion of new monitoring and surveillance tools (e.g. whole genome sequencing to facilitate genomic characterization of bacteria).~~	**Canada**
Development and inclusion of new monitoring and surveillance tools (e.g. whole genome sequencing to facilitate genomic characterization of bacteria).	**USA** The qualifier regarding national circumstances is needed as whole genome sequencing (last bullet) requires resources that all countries may not have, and do not need to start an initial surveillance program.
~~74. As resources and capacity may increase, and the design of the monitoring and surveillance program may change periodically, the competent authorities should ensure that all interested stakeholders are kept informed. Adjustments or changes in the program should strive to ensure that the ability of the program to identify trends over the time remains.~~	**Canada**
74. As resources and capacity may increase, and the design of the monitoring and surveillance program may change periodically, the competent authorities should ensure that all interested stakeholders are kept informed. Adjustments or changes in the program should strive to ensure that the ability of the program to identify trends over ~~the~~ time remains.	**USA**
~~75. The expansion of system should be done in alignment with the program design in order to continue to meet the monitoring and surveillance objectives in the country.~~	**Canada**
75. The expansion of a system should be done in alignment with the program design in order to continue to meet the monitoring and surveillance objectives ~~in~~ of the country.	**USA**
Design of a monitoring and surveillance program for AMR	**Republic of Korea**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Korea proposes to describe the texts of section 8(Design of a monitoring and surveillance program for AMR) as an Appendix for clear understanding and readability.
Elements of an integrated monitoring and surveillance program for AMR	**Ghana** Position: 1. Ghana proposes that “sampling design” as in bullet 1, paragraph 76 should be replaced with sampling plan. Rationale: Section 8.2 elaborates on bullet point 1, Section 8.1 and for consistency in terminology this amendment is necessary. 2. Ghana proposes a restructuring of bullet 2 (Section 8.1) to read: • Sample sources (incl. type of samples) as informed by sampling methodology for the collection of isolates to test AMR. Rationale: Sample sources will depend on sampling methodology Position: Ghana proposes the information under sampling design (8.2) Sample sources (8.3) and Sampling plan (paragraph 85) be captured as sub-clauses under Sampling design for simplicity and to avoid the repetition of text in these sections of the document. Rationale: The heading Sampling design (Section 8.2) is a broad terminology and includes sampling plans, sample sources amongst others. Sampling design and samples sources can be captured as sub clauses under sampling design.
76. To ensure that the monitoring and surveillance objectives are met, ~~whatever the stage of implementation,~~ an integrated program for monitoring and surveillance of foodborne AMR should include and systematically review the following design elements and technical characteristics:	**Australia** Section 8, paragraph 76 Comment: Australia suggests amendment as follows 76. To ensure that the monitoring and surveillance objectives are met, whatever the stage of implementation, an integrated program for monitoring and surveillance of foodborne AMR should include and systematically review the following design elements and technical characteristics: Rationale: Australia has some concern that referring to ‘stage of implementation’ infers a level of performance and therefore may have trade implications. Australia is of the opinion that deletion does not undermine the intent and meaning of the paragraph.
76. To ensure that the monitoring and surveillance objectives are met, ~~whatever the stage of implementation,~~ an integrated program for monitoring and surveillance of foodborne AMR should include and systematically review the following design elements and technical characteristics:	**Brazil** Brazil suggests deleting “whatever the stage of implementation” for clarity.
76. To ensure that the monitoring and surveillance objectives are met, ~~whatever the stage of implementation,~~ an integrated program for monitoring and surveillance of foodborne AMR ~~should~~ should, according to national priorities and resources, include and systematically review the following design elements and technical characteristics:	**USA** -The introductory sentence is edited for clarity and to reemphasize the importance of national priorities. -2nd bullet-editorial

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	Text is offered to replace the following phrase that may not be possible initially: 'that are statistically robust enough to provide the desired level of statistical significance and power to detect differences over time or between populations' and replaced. The term “commensal” and “other genetic elements” are added for clarity.
76. To ensure that the monitoring and surveillance objectives are ~~met, whatever the stage of implementation,~~ met an integrated program for monitoring and surveillance of foodborne AMR should include and systematically review the following design elements and technical characteristics:	**International Feed Industry Federation** To avoid hierarchical evaluation of the continuous program.
Sampling plans ~~(representativeness,~~ (i.e. documents describing frequency, sample size, sampling points etc.) that are statistically robust enough to provide the desired level of statistical ~~significance~~ significance, representativeness and power to detect differences over time or between populations.	**Switzerland**
Sampling plans (representativeness, frequency, sample size, etc.) designed so that ~~are statistically robust enough to provide the desired level of statistical significance and power to detect differences~~ when resources allow, trends over time ~~or between populations.~~can be detected.	**USA**
Sample sources ~~(incl.~~ (including type of samples) and sampling methodology for the collection of isolates to test AMR.	**Canada**
Sample ~~sources (incl. type~~ sources, types of ~~samples)~~ samples, and sampling methodology for the collection of isolates to test AMR.	**USA**
Target microorganisms based on public health relevance (foodborne pathogens and indicator or commensal bacteria) and resistance determinants taking into account new information on emerging foodborne AMR hazards.	**USA**
Target microorganisms based on public health relevance (foodborne pathogens and indicator bacteria) and resistance determinants taking into account new information on emerging foodborne AMR hazards.	**International Feed Industry Federation** Keep focus on the scope of the guidelines.
Antimicrobials susceptibility to be ~~tested~~ monitored and genes or other genetic elements (e.g.,SNPs) to be detected.	**USA**
~~Antimicrobials to be tested~~ Antimicrobials and genes to be ~~detected~~monitored.	**healthforanimals** Clarity
~~Antimicrobials~~ Antimicrobial agents to be tested and ~~genes~~ antimicrobial resistance determinants to be detected.	**International Feed Industry Federation** Alignment with definitions of the Code of Practice.
Laboratory testing methodologies and quality control/assurance procedures that are ~~appropriate,~~ harmonized and standardized.	**Brazil** Brazil suggests deleting “appropriate” for clarity.
77. Monitoring and surveillance programs may include, but are not limited, to the following types of design for sample collection:	**healthforanimals** Countries with limited resources can expand existing pathogen sampling

SPECIFIC COMMENTS	
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	programs. This would save money, time, and possibly improve adoption of monitoring for AMR.
77. Monitoring and surveillance programs may include, but are not limited, to the following types of design for sample collection~~.~~ : "Integrate sampling into existing pathogen monitoring systems."	**healthforanimals** Add new bullet point at top "Integrate sampling into existing pathogen monitoring systems."
77. Monitoring and surveillance programs may include, but are not limited, to the following types of design for sample collection:	**International Feed Industry Federation** Insertion first bullet after §77: • integrate sampling into existing pathogens monitoring systems
~~Cross-sectional~~ Integrate sampling into existing pathogen monitoring systems. •Cross-sectional point prevalence surveys. These surveys can be used to collect basic information and compare between various populations at particular points in time.	**USA**
Investigative, targeted surveillance and short-term *ad hoc* pilot studies. These studies can be used, for example, to obtain data on specific subpopulations or data on animal/plant species or foodstuffs that cannot be justified for inclusion in routing, ongoing surveillance. Short-term *ad hoc* pilot studies can also be used to test the feasibility and reliability of planned programs, changes in laboratory or data management methodologies, etc.	**Canada** Canada suggests moving this bullet to the top of this list. This is in line with what the WHO AGISAR recommends as a place to start.
Investigative, targeted surveillance and short-term *ad hoc* pilot studies. These studies can be used, for example, to obtain data on specific subpopulations or data on animal/plant species or foodstuffs that cannot be justified for inclusion in ~~routing~~routine, ongoing surveillance. Short-term *ad hoc* pilot studies can also be used to test the feasibility and reliability of planned programs, changes in laboratory or data management methodologies, etc.	**USA**
Investigative, targeted surveillance and short-term *ad hoc* pilot studies. These studies can be used, for example, to obtain data on specific subpopulations or data on ~~animal/plant~~ animal/plant/crop species or ~~foodstuffs~~ food that cannot be justified for inclusion in routing, ongoing surveillance. Short-term *ad hoc* pilot studies can also be used to test the feasibility and reliability of planned programs, changes in laboratory or data management methodologies, etc.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Sentinel surveillance which relies on selected reporting sites or specific providers, (laboratories. farms, veterinarians, plant health professionals, etc.) and can be used to obtain high quality data on resistance that cannot be obtained through a passive system. - Comprehensive surveillance (e.g., consensus-based).	**Canada**
Sentinel surveillance which ~~relies on selected reporting sites or specific providers~~is active rather than passive surveillance, ~~(laboratories. farms, veterinarians, plant health professionals, etc.)~~ involves the identification and regular testing of one or more populations of known health or immune status in a specified geographical location to detect the occurrence of infection or infestation. It can be used to obtain high quality data on resistance that cannot be obtained through a passive system.	**USA** An initial bullet is added to clarify countries can build on existing systems. The definition for sentinel surveillance is revised to be more consistent with OIE Article 1.4.4.5 p. 6 (http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/chapitre_surveillance_general.pdf) If there is a Codex definition, that would probably be even more applicable.
Sentinel surveillance which relies on selected reporting sites or specific providers, (laboratories~~.~~, farms, veterinarians, plant health professionals, etc.) and can be used to obtain high quality data on	**CCTA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
resistance that cannot be obtained through a passive system.	
78. The design of a monitoring and surveillance program may involve new infrastructure and activities only for the purpose of AMR ~~or~~ (i.e., active surveillance) or, where available, information about AMR may be collected through existing programs designed for another ~~purposes~~purposes (i.e., passive surveillance). For example, detection of AMR in microorganisms isolated in foodborne outbreaks investigations.	**Canada**
78. The design of a monitoring and surveillance program may involve new infrastructure and activities only for the purpose of AMR or where available, information about AMR may be collected through existing programs designed for another purposes. For example, detection of AMR in microorganisms isolated in foodborne outbreaks investigations.	**Switzerland** It is not clear what is meant by "new infrastructure"
78. The design of a monitoring and surveillance program may involve new infrastructure and activities only for the purpose of AMR or where available, information about AMR may be collected through existing programs designed for another purposes. For example, detection of AMR in microorganisms isolated in foodborne ~~outbreaks investigations.~~ outbreak investigations may provide information about hazards, pathways, releases or exposures not detected through other surveillance data streams.	**USA**
~~79. Sources of samples for AMR testing will depend on the objectives and the design of the monitoring and surveillance program, as well as the stage of implementation. Available resources and the national infrastructure may also impact decisions regarding the source and collection of samples.~~	**Canada** Duplicative of text in Section 7 (Para 37).
79. Sources of samples for foodborne AMR testing will depend on the objectives and the design of the monitoring and surveillance program, as well as the stage of implementation. Available resources and the national infrastructure may also impact decisions regarding the source and collection of samples.	**USA**
80. An integrated program should reflect the food production in the country and cover samples from all stages of the different food chains. In an integrated program, samples collected from production and retail for a given species should be ~~from~~ representatives of the ~~same species~~supply chain, e.g. samples from food-producing animals should be taken from the same animal species and supply chain as retail meat samples.	**Australia** Section 8, paragraph 80 Comment: Australia suggests amendment as follows 80. An integrated program should reflect the food production in the country and cover samples from all stages of the different food chains. In an integrated program, samples collected from production and retail for a given species should be from the same species representative of the supply chain, e.g. samples from food-producing animals should be taken from the same animal species and supply chain as retail meat samples.
80. An integrated program should reflect the food production in the country and cover samples ~~from all stages~~ of the different food chains. In an integrated program, samples collected from production and retail should be from the same species, e.g. samples from food-producing animals should be taken from the same animal species as retail meat samples.	**Brazil** Brazil suggests deleting “from all stages” once this is to broad and can lead to confusion.
80. An integrated program should reflect the food production in the country and cover samples from	**Canada**

SPECIFIC COMMENTS	
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all relevant stages of the different food chains. In an integrated program, samples collected from production and retail should be from the same species, e.g. samples from food-producing animals should be taken from the same animal species as retail meat samples.	
80. An integrated program should ~~reflect the food production in the country and cover samples from all stages~~ begin with a sampling strategy focusing on foods of ~~the different food chains~~known foodborne AMR risk closest to consumption. ~~In an integrated program~~As resources allow or data identify potential foodborne AMR safety hazards, ~~samples collected from production and retail should~~ sampling can be ~~from~~ expanded to other commodities or earlier in the ~~same species, e~~food chain.~~g. samples from food-producing animals should be taken from the same animal species as retail meat samples.~~	**USA** Edits are provided to help countries prioritize foodborne AMR risks for surveillance.
~~81. If possible, the origin of the animal or food, crop (e.g. imported or domestic) and any other relevant information should be collected at the time of sampling.~~	**Canada** This is duplicative of what is in Section 8.8.
81. If possible, the origin of the animal or food, crop ~~(e.g. imported or domestic)~~ and any other relevant information should be collected at the time of sampling. To fully understand surveillance value the relationship between AMR and AMU should be further evaluated.	**USA** These do not seem to be useful examples. The authority would want to identify the specific origin in order to identify local source of AMR pathogens, not just “domestic or imported”? Additional text added for further clarification on the need to understand interrelationships.
81. If possible, the origin of the animal or food, crop (e.g. imported or domestic) and any other relevant information should be collected at the time of sampling. To fully understands surveillance value, the science-based interrelationship between AMR and AMU should be evaluated.	**healthforanimals** There is not a linear relationship between volume of antimicrobials available or used and reducing AMR. Some efforts to reduce the use of antibiotics are having negative animal welfare effects, with no effect on AMR.
81. If possible, the origin of the animal or food, ~~crop~~ plant/crop (e.g. imported or domestic) and any other relevant information should be collected at the time of sampling.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
81. If possible, the origin of the animal or food, ~~crop~~ plant/crop (e.g. imported or domestic) and any other relevant information should be collected at the time of sampling.	**OIE**
82. Considerations for the selection of possible sample ~~sources~~ sources, where scientific evidence supports foodborne AMR risk to human health, at different points of the food chain are described below:	**Brazil** Brazil suggests adding for clarity and consistency.
82. Considerations for the selection of possible sample sources at different points of the food chain are described below:	**USA** Sampling of most of the sources in the third paragraph under food-producing animals is impractical and listing them is unnecessary. Language is provided to clarify under plants/crops that there is no science describing an AMR foodborne illness from use of antibacterial pesticides in crops.

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	The routine, systematic collection of the samples sources listed under “farm supplies” and “plants/crops” is challenged by the lack of adequate scientific information, including sampling strategies and validated methods. The recommendation to include them at this time as core elements of a national surveillance system is not practical or feasible. The end product is of utmost importance. Sampling this far away from the point of use product really spreads resources too thin and is more of an issue for research to focus on. These guidelines for surveillance need to target areas of highest risk for foodborne AMR. Further research could be helpful with respect to these sample sources, in particular understanding the exposure pathway and impact on public health. Under, “Food”, not all animal or crop products will have an international source. The second paragraph is a duplicative, but more prescriptive concept is already captured in the third paragraph, so it is unnecessary. Under “Environment”, edits are offered to make the text consistent with Codex scope. For example, wildlife feces and dust are more fit for research studies than an integrated national surveillance system.
82. ~~Considerations for the selection of possible sample sources at different points of the food chain are described below:~~	**healthforanimals**
82. Considerations for the selection of possible sample sources at different points of the food chain are described below:	**healthforanimals** Delete all. These are ideas for a country to study but lack scientific merit to recommend that all Codex member countries should undertake these studies as part of their monitoring and surveillance program for antimicrobial resistance. The bulleted points do not present a clear and demonstrable benefit to public health or food safety.
82. Considerations for the selection of possible sample sources at different points of the food chain are described below:	**International Feed Industry Federation** Questioning on keeping this paragraph, as there is no scientific merit to recommend all these studies to all CODEX members. In addition, the different section do not provide clear and demonstrable benefit to public health and food safety. If kept, the following changes should be made:

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Food producing ~~animals~~animals (including aquatic and terrestrial animals)	**Canada**
~~Food producing animals~~	**healthforanimals**
Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g~~. holding of origin.~~., farm, herd, ~~flock)~~flock, aquaculture net-pen). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection.	**Canada**
Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population of animals being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection.	**USA**
~~Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection.~~	**healthforanimals**
Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the animal population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection.	**International Feed Industry Federation** For clarity.
Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial ~~populations~~populations and the interrelationship between AMR and AMU.	**Australia** Section 8, paragraph 82, Food producing animals Comment: Australia suggests amending as follows Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection. Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial populations and the interrelationship between AMR and AMU.

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	At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc. At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc. Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse information on the effectiveness of process hygiene measures. Rationale: Deleted sections for farm level and lairage samples should be moved to environment as these come from the production environment. Additional changes reflect the benefit of collecting these samples.
~~Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial populations.~~	**healthforanimals**
~~At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.~~	**Australia** Section 8, paragraph 82, Food producing animals Comment: Australia suggests amending as follows Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection. Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial populations and the interrelationship between AMR and AMU. At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc. At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc.

SPECIFIC COMMENTS	
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	Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse information on the effectiveness of process hygiene measures. Rationale: Deleted sections for farm level and lairage samples should be moved to environment as these come from the production environment. Additional changes reflect the benefit of collecting these samples.
At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.	**Canada** This bullet would be better placed in the section about the Environment.
At farm level, samples could include a variety of samples in the ~~food-producing~~ food production environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.	**Japan** "Food production environment" has been defined in Section 3 Definitions. The term should be used for consistently with the definition.
At farm level, samples could include a variety of samples in the food-producing environment~~: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.~~ .	**USA**
~~At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.~~	**healthforanimals**
At farm level, samples could include a variety of samples in the ~~food-producing~~ food production environment~~: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc.~~ .	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc.~~	**Australia** Section 8, paragraph 82, Food producing animals Comment: Australia suggests amending as follows Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection. Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial populations and the interrelationship between AMR and AMU. At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil,

SPECIFIC COMMENTS	
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	sewage, sludge, manure, etc. At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc. Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse information on the effectiveness of process hygiene measures. Rationale: Deleted sections for farm level and lairage samples should be moved to environment as these come from the production environment. Additional changes reflect the benefit of collecting these samples.
~~At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc.~~	**healthforanimals**
~~At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc.~~	**International Feed Industry Federation**
Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide ~~an estimate of contamination arising from~~ information on the ~~slaughterhouse~~effectiveness of process hygiene measures.	**Australia** Section 8, paragraph 82, Food producing animals Comment: Australia suggests amending as follows Selection of animal populations should be relevant to the country's production system. Samples should be, to the greatest extent possible, representative of the population being targeted as well as representative of a given epidemiological unit (e.g. holding of origin, farm, herd, flock). The prevalence of the bacterial species should be considered in order to maximize the likelihood of detection. Samples taken from healthy animals destined to slaughter may be collected on-farm, during transport or lairage, or at the slaughterhouse/abattoir. Collection of samples from animals not immediately entering the food chain can provide population level information on animal health and bacterial populations and the interrelationship between AMR and AMU. At farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, etc. At the lairage, prior to slaughter, samples could be taken from pen floors, truck/crate swabs, dust, etc. Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse information on the effectiveness of process hygiene measures. Rationale: Deleted sections for farm level and lairage samples should be moved to environment as these come from the production environment. Additional changes reflect the benefit of collecting these samples.
~~Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse.~~	**Brazil** Brazil suggests deleting because it is not applicable to all species and can lead to confusion.
Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are ~~only~~ representative of the pre-slaughter environment and may <u>or may</u> not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the ~~slaughterhouse~~<u>dressing process or the slaughterhouse environment</u>.	**Canada**
~~Samples such as caecal contents or lymph nodes could be taken post-slaughter. In some species, these samples are only representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter but before processing (e.g. carcass, rinses and swabs) may provide an estimate of contamination arising from the slaughterhouse.~~	**healthforanimals**
Plants/crops	**Australia** Section 8, paragraph 82, Plants/crops Comment: Australia suggests amending as follows: The selection of crops should be risk-based and relevant to a country's production systems. Samples may be collected on-farm, during transport or at processing facility. At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered. At post-harvest level, samples may be taken during transport, processing and packaging and could include samples of the plant/crop, surfaces, dust, washing or cooling water, etc. Rationale: The deleted sentences are more appropriately placed in the

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	environment section (manure, soil, water, sludge etc) or the food section (post processing and packaging).
The selection of crops should be risk-based and relevant to a country's production systems. Samples may be collected on-farm, during transport or at processing facility.	**Australia**
~~The selection of crops should be risk-based and relevant to a country's production systems.~~	**Canada** In the Introduction (Para 8), there is the recommendation that the design be based on all available knowledge on foodborne risks due to AMR" and Principle 6 describes a "risk-based approach" (with the new language modifications). Hence, "Risk-based" does not need to be duplicated here (also note that it is not included under "Food producing animals").
The selection of ~~crops~~ crops/plants should be risk-based and relevant to a country's production systems.	**China**
Scientific data describing foodborne AMR risk from use of antibacterial pesticides in crops are lacking and require further development. A blanket recommendation to incude crops in a national AMR surveillance system over other areas where the science is better established is not warranted.The selection of crops should be risk-based and relevant to a country's production ~~systems~~systems and AMR food safety risks. Appropriate samples and methodologies still need to be developed.	**USA**
~~The selection of crops should be risk-based and relevant to a country's production systems.~~	**healthforanimals**
The selection of ~~crops~~ plants/crops should be risk-based and relevant to a country's production systems.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
The selection of ~~crops~~ plants/crops should be risk-based and relevant to a country's production systems.	**OIE**
~~At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.~~	**Australia**
At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered. Samples could include crops on the farm, or samples could be collected during transport, processing and packaging.	**Canada**
At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.	**Canada** This bullet would be better placed in the section about the Environment
~~At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.~~	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~At harvest and farm level, samples could include crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.~~	**healthforanimals**
At harvest and farm level, samples could include ~~crops~~plants/crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
At harvest and farm level, samples could include ~~crops~~plants/crops, soils, and when appropriate irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered.	**OIE**
~~At post-harvest level, samples may be taken during transport, processing and packaging and could include samples of the plant/crop, surfaces, dust, washing or cooling water, etc.~~	**Australia**
At the post-harvest level, samples may be taken during transport, processing and packaging and could include samples of the plant/crop, surfaces, dust, washing or cooling water, etc.	**Canada** "surfaces, dust, washing or cooling water, etc." is also the production environment. Canada suggests this be moved to the section on Environment below.
At post-harvest level, samples may be taken during transport, processing and ~~packaging and could include samples of the plant/crop, surfaces, dust, washing or cooling water, etc~~packaging.	**USA**
~~At post-harvest level, samples may be taken during transport, processing and packaging and could include samples of the plant/crop, surfaces, dust, washing or cooling water, etc.~~	**healthforanimals**
~~**Farm supplies**~~	**Brazil** Brazil suggests deleting this bullet because relevant elements are already reflected in the first bullet for “Food producing animals”.
Farm ~~supplies~~ inputs	**Canada** Canada suggests “Farm inputs” for clarity; however, we note that sampling farm inputs is very aspirational in nature and might be difficult for many countries to include. This could be part of passive surveillance (using samples collected for other purposes) but might not be included in core surveillance activities.
~~**Farm supplies**~~	**USA**
~~**Farm supplies**~~	**International Feed Industry Federation** Focus should be at the end of the food chain.
~~Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system, as they can be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of crop contamination.~~	**Brazil** Brazil suggests deleting this bullet because relevant elements are already reflected in the first bullet for “Food producing animals”.
Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production ~~inputs~~inputs (e.g., ~~should~~ bedding), may be considered as part of the	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
integrated monitoring and surveillance system, as they ~~can~~ may be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of crop contamination.	
~~Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system, as they can be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of crop contamination.~~	**USA**
~~Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system, as they can be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of crop contamination.~~	**healthforanimals**
~~Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system, as they can be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of crop contamination.~~	**International Feed Industry Federation** Focus should be at the end of the food chain.
Sampling of animal feed including regular feed, medicated feed and animal organic fertilizers, and other relevant food production inputs, should be considered as part of the integrated monitoring and surveillance system, as they can be a source of resistant bacteria, such as *Salmonella*, which may be transferred to food-producing animals or be a source of ~~crop~~ plant/crop contamination.	**OIE**
Food sampling at processing/packing, wholesale or point-of-sale (retail) should be considered as part of the integrated monitoring and surveillance system and include both domestically produced and imported food sources, where appropriate.	**USA**
~~Food sampling at processing/packing, wholesale or point-of-sale (retail) should be considered as part of the integrated monitoring and surveillance system and include both domestically produced and imported food sources.~~	**healthforanimals**
~~The place where the food samples are collected should reflect the production system in the country and the purchasing habits of the consumer (e.g. in open markets or chain stores).~~	**USA**
~~The place where the food samples are collected should reflect the production system in the country and the purchasing habits of the consumer (e.g. in open markets or chain stores).~~	**healthforanimals**
At retail level, the types of food samples could include raw meat (beef, chicken, turkey, pork, etc.), fish or seafood, dairy products, or other edible tissues (liver, kidney, muscle, fat, lung, etc.), raw produce (fruits, vegetables, nuts, etc.) and other minimally processed food. The selection of foods for surveillance should reflect production and consumption patterns in the population and the likely prevalence of AMR but may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.	**Canada** Canada proposes replacing this text or referencing WHO AGISAR Section 1.3.2 which states: “The selection of foods for surveillance (beef, chicken, turkey, pork, etc.) should reflect consumption patterns in the population and likely prevalence of antimicrobial resistance, but may be modified from year to year in order to capture multiple commodities. It is helpful to collect food samples that reflect the purchasing habits of the consumer (e.g. in open markets or chain stores).”

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At retail level, the types of food samples could include raw meat (beef, chicken, turkey, pork, etc.), fish or seafood, dairy products, or other edible tissues (liver, kidney, muscle, fat, lung, etc.), raw produce (fruits, vegetables, nuts, etc.) and other minimally processed food. The selection of foods for surveillance should reflect production and consumption patterns in the population and the likely prevalence of AMR but may be modified periodically in order to capture multiple commodities, seasonality, or ~~where products have been identified as high risk~~wevents that may increase risk of AMR contamination.	**USA**
~~At retail level, the types of food samples could include raw meat (beef, chicken, turkey, pork, etc.), fish or seafood, dairy products, or other edible tissues (liver, kidney, muscle, fat, lung, etc.), raw produce (fruits, vegetables, nuts, etc.) and other minimally processed food. The selection of foods for surveillance should reflect production and consumption patterns in the population and the likely prevalence of AMR but may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.~~	**healthforanimals**
~~**Environment**~~	**Brazil** Brazil suggests deleting this bullet because relevant elements are already reflected in the first bullet for “Food producing animals”.
Food Production Environment	**Canada**
Food Production Environment	**USA**
~~Sampling of the food production environment along the food chain (environment of animals and crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc.~~	**Brazil** Brazil suggests deleting this bullet because relevant elements are already reflected in the first bullet for “Food producing animals”.
~~Sampling of the food production environment along the food chain (environment of animals and crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc.~~Sampling of the food production environment along the food chain (environment of animals and crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc. At the farm level, samples could include a variety of samples in the food-producing environment: faeces, feed, litter (bedding), dust, fluff, water, soil, sewage, sludge, manure, sediment below aquaculture sites, etc. For plants, as the pre-harvest level, food production environment samples could include soils, and when appropriate, irrigation water. Sampling soil amendments such as manure and sewage sludge should also be considered. At the post-harvest level, samples could include surfaces, dust, washing	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
or cooling water, etc.	
Sampling of the food production environment along the food chain (environment of animals and crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance ~~system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc~~system.	**USA**
~~Sampling of the food production environment along the food chain (environment of animals and crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc.~~	**healthforanimals**
Sampling of the food production environment along the food chain (environment of animals and ~~crops~~plants/crops, processing, wholesale facilities and retail outlets) could be considered as part of the integrated monitoring and surveillance system and may include: faecal samples from wildlife and other animals in vicinity of cropping areas, dust, water, bedding, etc.	**International Feed Industry Federation** Alignment with the definition of the Code of Practice.
83. Once a sampling structure is established, consistency in sample types and methodology should be ~~achieved~~ maintained for long-term, comparability and accurate interpretation of results. ~~The feasibility of conducting *ad hoc* pilot studies on a broader range of retail products may be considered.~~	**Canada** This should be in Section 7 rather than here.
83. Once a sampling structure is established, consistency in sample types and methodology should be achieved for long-term, comparability and accurate interpretation of results, to the extent practical as new methodologies are added. The feasibility of conducting *ad hoc* pilot studies on a broader range of retail products may be considered.	**USA** Text is added for clarification and feasibility.
83. Once a sampling ~~structure~~ plan is established, consistency in sample types and methodology should be achieved for long-term, comparability and accurate interpretation of results. The feasibility of conducting *ad hoc* pilot studies on a broader range of retail products may be considered.	**Switzerland** Same terminology as used before It could be considered to move this para to section 8.2
83. Once a sampling structure is established, consistency in sample types and methodology should be achieved for long-term, comparability and accurate interpretation of results. The feasibility of conducting *ad hoc* pilot studies on a broader range of retail products may be considered, where practical and as new methodologies become available.	**International Feed Industry Federation** To emphasize the context of continuous improvements.
Sampling plans	**Canada** Regarding Para 84-85, Canada notes that we would like to have animal and plant pathogens included, should resources permit and if in line with national priorities.
84. When designing a monitoring and surveillance program, representativeness of the data obtained is essential to ensure quality information. Adequate sample size and design must be considered to enable valid interpretation of the data and comparability of the results and to ensure that data obtained from the selected population under investigation is representative of the target population and amenable to statistical analysis of temporal or regional trends. Methods and limitations to data	**Canada** Canada proposes to include the following two bullet points under the existing text in Para 84: o Statistical power, precision, and goals of testing (sampling for detection, precision of point estimates versus ability to detect changes

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Section/paragraph	**Member/Observer/ rationale**
interpretation should be fully described and specified.	over time). o Statistical methods should be used to calculate the number of samples or isolates needed for testing. Sample size will depend on the purpose of the monitoring and surveillance, the desired precision for estimates of the prevalence of AMR and the magnitude of change in AMR to be detected over a specified period of time in a certain population. It will further depend on the frequency of recovery of the bacteria, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored. Examples of sample size calculation can be found in national or international publications.
85. The following elements should be defined when designing the sampling plan:	**USA** Under “Target populations”, “food, feed or environment” are not “populations”, so title changed to “Target samples” Bullets 8&9 are very similar. We have provided an alternate bullet to capture the thought in both bullets. Sampling methods designed to achieve the desired level of detection and provide a large enough tested population to assure confidence in the result, including for when you need to identify a rare event. Further, regarding the bullet starting with “Required sample size…”, calculating an 'ideal' sample size presents several challenges and instead programs need to sample what is practical and what they can afford. The statement regarding authorized sample collectors requiring third party accreditation is too prescriptive and best be deleted. The last bullet is edited as it is too prescriptive as written.
85. ~~The following elements~~ In the development and selection of sampling plans, consideration should be ~~defined when designing~~ given to the ~~sampling plan~~principles in the General Guidelines on Sampling (CAC/GL 50-2004):	**International Feed Industry Federation** For alignment with other CODEX texts.
Sampling strategy: Active or passive surveillance, or monitoring.	**USA**
~~Examples of sampling strategies (Simple Random Sampling, Stratified Sampling, Systematic Sampling, etc.) are provided in Codex documents on food hygiene and methods of analysis and sampling (e.g. *General Guidelines on Sampling* (CXG 50-2004))~~	**Australia** Section 8, paragraph 85, dot point 1 Comment: Australia suggests deletion of the examples of sampling strategies in dot point 1 and the revised text would read as follows: Sampling strategy: Active or passive surveillance. Sampling may be active (prospective) or passive (samples collected for other purposes), random or systematic, statistically-based or convenience-based. Sentinel surveillance may also be employed.

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	Examples of sampling strategies (Simple Random Sampling, Stratified Sampling, Systematic Sampling, etc.) are provided in Codex documents on food hygiene and methods of analysis and sampling (e.g. General Guidelines on Sampling (CXG 50-2004)). Rationale: The sampling strategies presented in the referenced Codex texts are for a specific purpose that may not be applicable to these guidelines. In particular, CXG 50-2004 is for the purpose of compliance testing against specific Codex commodity standards and are not general examples of sampling strategies for monitoring and surveillance.
Target populations: Animals, plants/crops, food, ~~feed or~~ feed, environment~~.~~, or epidemiological units of interest.	**Canada**
Target ~~populations~~samples: Animals, plants/crops, food, feed or environment.	**USA**
Target populations: Animals, plants/crops~~, food, feed or environment.~~ .	**International Feed Industry Federation** Not populations.
~~Epidemiological units.~~	**Canada**
Frequency of sampling.	**Switzerland** Reference could also be made to timing, seasonality with reference to practical sampling considerations
~~For surveys and periodic studies, the~~ The frequency of testing should be decided on the basis of the defined objectives. The incidence and seasonality of the microorganisms or diseases under study should be considered. Samples can be collected monthly or periodically throughout the year from different sites, in sufficient numbers, to identify trends.	**Canada**
~~Statistical power and goals of testing (precision of point estimates versus sensitivity to change over time).~~	**Canada** Canada proposes including this under Para 84 instead.
~~Required sample size (number of isolates/samples) to detect changes in antimicrobial resistance patterns with sufficient precision and statistical power.~~	**Canada** Duplicative of previous bullet.
~~Required sample size (number of isolates/samples) to detect changes in antimicrobial resistance patterns with sufficient precision and statistical power.~~	**USA**
Required sample size (number of isolates/samples) to detect changes in ~~antimicrobial resistance~~ foodborne AMR patterns with sufficient precision and statistical power.	**International Feed Industry Federation** Consistent use of acronym.
~~Statistical methods should be used to calculate the number of samples or isolates needed for testing Sample size will depend on the purpose of the study, the desired precision for estimates of the prevalence of AMR and the magnitude of change in AMR to be detected over a specified period of time in a certain population. It will further depend on the frequency of recovery, the initial or~~	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~expected prevalence of AMR in that microorganism and the size of the population to be monitored; Examples of sample size calculation can be found in national or international publications.~~	
Statistical methods should be used to calculate the number of samples or isolates needed for testing Sample size will depend on the purpose of the study, the desired precision for estimates of the prevalence of foodborne AMR and the magnitude of change in prevelance of AMR to be detected over a specified period of ~~time in a certain population.~~ time. It will further depend on the frequency of recovery, the initial or expected prevalence of AMR in ~~that microorganism~~ the microorganism(s) of interest and the size of the population to be monitored~~; Examples of sample size calculation can be found in national or international publications~~.	**USA**
Statistical methods should be used to calculate the number of samples or isolates needed for ~~testing~~ testing. Sample size will depend on the purpose of the study, the desired precision for estimates of the prevalence of AMR and the magnitude of change in AMR to be detected over a specified period of time in a certain population. It will further depend on the frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored; ~~Examples~~ examples of sample size calculation can be found in national or international publications.	**CCTA**
Statistical methods should be used to calculate the number of samples or isolates needed for testing Sample size will depend on the purpose of the study, the desired precision for estimates of the prevalence of foodborne AMR and the magnitude of change in foodborne AMR to be detected over a specified period of time in a certain population. It will further depend on the frequency of recovery, the initial or expected prevalence of foodborne AMR in that microorganism and the size of the population to be monitored; Examples of sample size calculation can be found in national or international publications.	**International Feed Industry Federation** Keep focus on the scope of the guidelines.
Statistical methods should be used to calculate the number of samples or isolates needed for ~~testing~~ testing. Sample size will depend on the purpose of the study, the desired precision for estimates of the prevalence of AMR and the magnitude of change in AMR to be detected over a specified period of time in a certain population. It will further depend on the frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored; Examples of sample size calculation can be found in national or international publications.	**OIE**
Selection of strata (levels) or risk clusters (groups) to best meet surveillance objectives. - Development of standard operating procedures for sample collection. - 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 assurance/management are maintained from collection through to analysis and storage. - Procedures for storing and transporting the samples (time between sample collection and testing and temperature during transport and storage) in order to maintain sample integrity. - Development of training material/manual/program using the standard operating procedures.	**Canada**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Selection of strata (levels) or risk clusters (groups) to best meet surveillance objectives.	**Canada** Canada proposes to move this to be a sub-bullet of the second bullet (Target populations) under Para 85.
Samples should be collected by trained persons ~~authorized to do so (e~~following the standard operating procedures~~.g. third-party accreditation).~~	**Canada**
Samples should be collected by suitably trained persons ~~authorized~~ to do ~~so (e~~so~~.g. third-party accreditation).~~	**Japan** Authorization with" third party accreditation" is not feasible in many countries. Such strict requirement will hinder the surveillance activity.
~~Samples should be collected by trained persons authorized to do so (e.g. third-party accreditation).~~	**USA**
~~Procedures for storing and transporting the samples (time between sample collection and testing and temperature during transport and storage) in order to maintain sample integrity.~~	**Canada** Moved up.
~~Procedures should be put in place to ensure that collection of samples is carried out in accordance with to the defined sampling strategy and to guarantee that traceability, security and quality assurance/management are maintained from collection through to analysis and storage.~~	**Canada** Moved up.
Procedures ~~should be put~~ for sample collections in ~~place to ensure that collection of samples is carried out in~~ accordance with ~~to~~ the defined sampling strategy ~~and to guarantee that~~ such as how traceability, security and quality assurance/management are maintained from collection through to analysis and storage.	**USA**
Procedures should be put in place to ensure that collection of samples is carried out in accordance with ~~to~~ the defined sampling strategy and to guarantee that traceability, security and quality assurance/management are maintained from collection through to analysis and storage.	**CCTA**
Procedures should be put in place to ensure that collection of samples is carried out in accordance ~~with~~ to the defined sampling strategy and to guarantee that traceability, security and quality assurance/management are maintained from collection through to analysis and storage.	**OIE**
Target microorganisms and resistance determinants	**Ghana** Position: Ghana proposes an addition to the Paragraph 88 to read: 88. Commensal intestinal bacteria including Escherichia coli and Enterococcus faecium/faecalis can contaminate food and harbor transferable resistance genes. These species can serve as indicators of Gram negative and Gram-positive intestinal microflora from terrestrial animals respectively, with potential risk for resistance. Rationale: E coli and E. faecalis/faecium are known microbes on terrestrial animals (food and humans) with a risk of transferring resistant genes. Their presence is an indicative risk for resistance.
86. In order to target appropriate bacterial species and resistance determinants, the bacteria's relevance to public health must be considered. ~~Bacterial species studied should include both foodborne pathogens and indicator organisms or commensal bacteria.~~	**USA** Indicator organisms are not generally thought of as also being foodborne pathogens and therefore are not targeted for their relevance to public health.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
87. *Salmonella* is a key foodborne pathogen to be included in an integrated monitoring and surveillance program as it is found in human and animal species. The inclusion of *Campylobacter* (*C. coli, C. jejuni*) is also strongly advised, as well as other food borne pathogens depending on national or regional epidemiology and ~~risks (e~~risks~~.g. *Vibrio, Listeria monocytogenes)*.~~	**Brazil** Brazil suggests deleting because it is not necessary and can lead to confusion.
87. *Salmonella* is a key foodborne pathogen to be included in an integrated monitoring and surveillance program as it is found in human and animal species. The inclusion of *Campylobacter* (*C. coli, C. jejuni*) is also strongly advised, as well as other food borne pathogens depending on national or regional epidemiology and risks (e.g. *Vibrio, Listeria monocytogenes)*.	**Canada** Should “food consumption patterns” be included here?
87. Terrestrial Foodborne Pathogens: *Salmonella* is a key foodborne pathogen to be included in an integrated monitoring and surveillance program as it is found in human and animal species. The inclusion of *Campylobacter* (*C. coli, C. jejuni*) is also strongly advised, as well as other food borne pathogens depending on national or regional epidemiology and ~~risks (e.g.~~ risks~~*Vibrio, Listeria monocytogenes)*~~.	**Canada**
87. *Salmonella* is a key foodborne pathogen to be included in an integrated monitoring and surveillance program as it is found in human and animal species. The inclusion of *Campylobacter* (*C. coli, C. jejuni*) is also strongly advised, as well as other food borne pathogens depending on national or regional epidemiology and ~~risks (e~~risks~~.g. *Vibrio, Listeria monocytogenes)*.~~	**USA** The examples are unnecessary and there is little information about foodborne AMR priorities globally from these specific examples.
88. Commensal intestinal bacteria ~~-~~including *Escherichia coli* and *Enterococcus faecium/faecalis* can contaminate food and harbor transferable resistance genes. These species can serve as indicators of Gram-negative and Gram-positive intestinal microflora from terrestrial animals respectively. Aquatic Foodborne Pathogens: e.g., Vibrio: Crop/Plant target bacteria:	**Canada**
88. Commensal intestinal bacteria including *Escherichia coli* and *Enterococcus faecium/faecalis* can contaminate food and harbor transferable resistance genes. These species can serve as indicators of ~~Gram-negative and Gram-positive~~ potential intestinal ~~microflora~~ pathogenic flora from terrestrial ~~animals respectively~~animals.	**USA** They serve as indicators for pathogenic bacteria. They are not indicators of Gram negative or positive bacteria
88. Commensal intestinal bacteria including *Escherichia coli* and *Enterococcus faecium/faecalis* can contaminate food and harbor transferable antimicrobial resistance ~~genes~~determinants. These species can serve as indicators of ~~Gram-negative and Gram-positive~~ intestinal microflora from terrestrial animals respectively.	**International Feed Industry Federation** Alignment with the definition of the Code of Practice.
89. Target microorganisms for aquatic animals and food of non-animal origin should be determined based on available scientific evidence and risk.	**USA** Available science is appropriate terminology since we do not have targets at this point.
89. Target microorganisms for aquatic animals and food of non-animal origin should be determined based on available scientific evidence and risk.	**International Feed Industry Federation** Keep scientific basis for the guidelines.
90. Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may present a public health ~~concern (i.e~~concern.	**China**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~extended spectrum beta lactamases (ESBL) - AmpC beta-lactamases (AmpC) and carbapenemase-producing strains and multidrug-resistant strains).~~	
90. Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may present a public health ~~concern (i.e~~concern. ~~extended spectrum beta lactamases (ESBL) - AmpC beta-lactamases (AmpC) and carbapenemase-producing strains and multidrug-resistant strains).~~	**USA** Public health priorities may change over time so the example should be deleted to make the guidance more timeless.
90. Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may present a public health ~~concern (i.e~~concern. ~~extended spectrum beta lactamases (ESBL) - AmpC beta-lactamases (AmpC) and carbapenemase-producing strains and multidrug-resistant strains).~~	**International Feed Industry Federation** The public health concern will depend on the country.
~~92. The selection of target microorganisms should also be influenced by the presence of high priority AMR genes or mobile genetic elements and horizontal gene transfer in a given population.~~	**USA** This bullet is duplicative of paragraph 91.
Laboratories	**Ghana** 8.6. Laboratories Position: Ghana recommends an addition to bullets 1 and 2 under Section 8.6 (Laboratories) to read: Bullet 1 Laboratories participating in the monitoring and surveillance program should: • Perform bacterial isolation, identification (to species level), typing, phenotypic and genotypic characterization and antimicrobial susceptibility testing (AST) using standardized and validated methods and have trained personnel in the methods used with support from a national reference laboratory. Rationale: In some countries, capacities in participating laboratories is limited to bacterial isolation, identification to species and antimicrobial susceptibility testing (AST) or less. Capacities for typing and genotypic characterization simply does not exist. Support from reference laboratories is paramount to the achievement of the mandatory requirement in bullet 1. Bullet 2 • Be accredited in accordance with national and/or international regulations or have in place a validated Standard Operating Procedure on AST in operation for the monitoring purposes. Rationale: A validated standard operating procedure on AST does not guarantee its operation and thus the need for evidence demonstrating an operational validated SOP failing accreditation.
93. Laboratories participating in the monitoring and surveillance program ~~should~~should ideally:	**OIE**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Perform bacterial isolation, identification (to species level), typing, phenotypic and genotypic characterization and antimicrobial susceptibility testing (AST) using standardized and validated methods and have trained personnel in the methods used.	**USA** The first bullet should be deleted here because it is covered below. It is the only method-centric bullet in the list.
~~Perform bacterial isolation, identification (to species level), typing, phenotypic and genotypic characterization and antimicrobial susceptibility testing (AST) using standardized and validated methods and have trained personnel in the methods used.~~	**USA**
Be accredited in accordance with national and/or international ~~regulations~~ guidance/procedures or have a validated Standard Operating Procedure on ~~AST for the monitoring purposes in place~~AST.	**Canada**
Be accredited in accordance with national and/or international regulations or have a validated Standard Operating Procedure ~~on AST~~ for the monitoring purposes in place.	**USA**
Participate in an external quality assurance system testing including proficiency testing in identification, typing, phenotypic and genotypic characterization and AST of the microorganisms included in the monitoring and surveillance program.	**Canada**
Have access to a national reference laboratory or an international laboratory (e.g. WHO-collaborative ~~center)~~ center or OIE collaborating centers) that can provide technical assistance if necessary.	**Japan** In animal sector OIE collaborating centers have functioned as AMR international laboratory as same as WHO collaborative center in human sector.
~~Be equipped with facilities and have procedures to maintain sample integrity (e.g. storage temperature and time between sample reception and analysis) and traceability.~~	**Canada** This is addressed sufficiently in the fourth bullet above.
~~Be equipped with facilities and have procedures to maintain sample integrity (e.g. storage temperature and time between sample reception and analysis) and traceability.~~	**USA** The last bullet appears duplicative of the bullet regarding accreditation.
Methods and interpretative ~~criteria~~categories	**USA** The CLSI and other standard setting organizations have officially changed their terminology from criteria to categories.
94. Susceptibility testing methods (disk diffusion or minimum inhibitory concentration (MIC) methodologies) that are standardized and validated by internationally recognized organizations ~~such as the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI)~~ should be used to ensure reliable and comparable data.	**USA** CLSI and EUCAST are not equivalent, so better to reference "internationally recognized organizations" instead of making them sound equivalent in the first paragraph. For example, CLSI-VAST is the only organization with standards and methods for testing and interpreting bacteria of animal origin. This does not exist for EUCAST. Neither have standards/methods for crops or "environment".
94. Susceptibility testing methods ~~(disk diffusion or minimum~~ (minimum inhibitory concentration (MIC) methodologies) that are standardized and validated by recognized organizations ~~such as the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI)~~ should be used to ensure reliable and comparable data.	**healthforanimals** Disk diffusion is not recommended by CLSI Vet 05 Report. References to the one or the other organization should be avoided to increase acceptability of the texts.
94. Susceptibility testing methods (disk diffusion or minimum inhibitory concentration (MIC) methodologies) that are standardized and validated by recognized organizations ~~such as the~~	**International Feed Industry Federation** Avoid reference to local examples.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~European Committee on Antimicrobial Susceptibility Testing (EUCAST) or Clinical and Laboratory Standards Institute (CLSI)~~ should be used to ensure reliable and comparable data.	
95. Quality control strains of bacteria should be used according to international ~~standards e.g~~standards, where available. ~~from EUCAST or CLSI.~~ The strains used should be designed to provide quality control for all antimicrobial agents tested. The quality control strains should be maintained and propagated according to the same recommendations, and results of the quality control strains should be used to determine if results for other tested bacteria are valid before interpreting and reporting the results.	**USA** Standards do not exist for many of the sample types described in this document. EUCAST and CLSI should be deleted as they are not equivalent.
95. Quality control strains of bacteria should be used according to international ~~standards e.g~~standards. ~~from EUCAST or CLSI.~~ The strains used should be designed to provide quality control for all antimicrobial agents tested. The quality control strains should be maintained and propagated according to the same recommendations, and results of the quality control strains should be used to determine if results for other tested bacteria are valid before interpreting and reporting the results.	**International Feed Industry Federation** Avoid reference to local examples.
96. Interpretation of results for disc diffusion or minimum inhibitory concentrations (MICs), should also be done consistently according to EUCAST rational documents or CLSI standards, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value (ECOFF) (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or ~~susceptible) used for interpretation~~susceptible). Data interpretations using ECOFFs can be very useful as for the temporal analysis of AMR trends. The interpretative category used, ECOFF or clinical breakpoint, should be included in the reporting, interpretation and analysis of data.	**Canada**
96. Interpretation of results for disc diffusion and disk content for antimicrobials or minimum inhibitory concentrations (MICs), should also be done consistently according to EUCAST rational documents or CLSI standards, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value (ECOFF) (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or susceptible) used for interpretation. Data interpretations using ECOFFs can be very useful as for the temporal analysis of AMR trends. The interpretative category used, ECOFF or clinical breakpoint, should be included in the reporting, interpretation and analysis of data.	**Japan** It is necessary to record not only the disk diffusion zone but also the concentration of disk.
96. Interpretation of results for disc diffusion or minimum inhibitory concentrations (MICs), should also be done consistently according to EUCAST ~~rational documents~~ tables or CLSI standards, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value (ECOFF) (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or susceptible) used for interpretation. Data interpretations using ECOFFs can be very useful as for the temporal analysis of AMR trends. The interpretative category used, ECOFF or clinical breakpoint, should be included in the reporting, interpretation and analysis of data.	**USA** Interpretive categories published by EUCAST are found in tabular format not in rational documents.

SPECIFIC COMMENTS	
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96. Interpretation of results for disc diffusion or minimum inhibitory concentrations (MICs), should also be done consistently according to EUCAST rational documents or CLSI standards, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value ~~(ECOFF)~~ (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or susceptible) used for interpretation. Data interpretations ~~using ECOFFs~~ can be very useful as for the temporal analysis of AMR trends. The interpretative category ~~used, ECOFF or~~ clinical breakpoint, should be included in the reporting, interpretation and analysis of data.	**healthforanimals** References to the one or the other system should be avoided to increase acceptability of the texts.
96. Interpretation of results for disc diffusion or ~~minimum inhibitory concentrations (~~MICs, should also be done consistently, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value (ECOFF) (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or susceptible) used for interpretation. Data interpretations using ECOFFs can be very useful as for the temporal analysis of AMR trends. The interpretative category used, ECOFF or clinical breakpoint, should be included in the reporting, interpretation and analysis of data.~~MICs), should also be done consistently according to EUCAST rational documents or CLSI standards, and should include quantitative results (disk diffusion zone diameters or MIC values). Categorization of the isolate should also be done based on the epidemiological cut off value (ECOFF) (wild-type or non-wild type) and when available based on clinical breakpoint (resistant, intermediate or susceptible) used for interpretation. Data interpretations using ECOFFs can be very useful as for the temporal analysis of AMR trends. The interpretative category used, ECOFF or clinical breakpoint, should be included in the reporting, interpretation and analysis of data.~~	**International Feed Industry Federation** Consistent use of acronym. Avoid reference to local examples.
98. Quantitative results are also necessary for the analysis of resistance patterns over time and when retrospective data analysis is needed due to changes in clinical breakpoints or ECOFFs. Quantitative results are also necessary for quantitative microbial risk assessment.	**Canada** This additional text ties monitoring and surveillance data into quantitative risk assessment.
99. The use of ECOFFs, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different origins (e.g. food, animal species). The use of clinical breakpoints may differ between animal species but may be adequate in the case of treatment decisions related to pathogenic bacteria.	**USA** While ECOFFs most often provide optimum sensitivity, this may not be the case if an ECOFF is not completely accurate or the ECOFF and susceptible clinical breakpoint are the same. Further, clinical breakpoints for animal species are relevant for animal health veterinary decision and not relevant for human foodborne AMR, and therefore outside Codex scope.
~~99. The use of ECOFFs, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different origins (e.g. food, animal species). The use of clinical breakpoints may differ between animal species but may be adequate in the case of treatment decisions related to pathogenic bacteria.~~	**USA**
99. The use of ECOFFs, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different origins (e.g. food, animal	**CCTA** or "interpretative" as in 118

SPECIFIC COMMENTS	
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species). The use of clinical breakpoints may differ between animal species but may be adequate in the case of treatment decisions related to pathogenic bacteria.	
100. ~~Detailed information on interpretation of AST results and quality control are described in the~~ *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health ~~Approach~~Approach* describes interpretive criteria in Appendix 3.	**USA** Edited to specify where information can be found in AGISAR.
100. ~~Detailed information on interpretation~~ The evolving science of ~~AST results and quality control are described in~~ understanding the causal risk links from animal production to human food needs increased research to give informed advice on managing resistance bacteria originating in animals.~~*WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*.~~	**healthforanimals** Delete because reference to a past non-Codex document is not acceptable to all (see earlier comment). Add because important to note where science is lacking or more research needs to be done.
100. Detailed information on interpretation of AST results and quality control are described in appendix 3 of the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*.	**International Feed Industry Federation** For clarification.
The panel of ~~antimicrobials~~ antimicrobial agents for susceptibility testing	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
101. The panel of antimicrobials for susceptibility testing should be harmonized as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.	**Canada** The panel of antimicrobials for susceptibility testing should be "harmonized" with what?
101. The panel of antimicrobials for susceptibility testing should be harmonized ~~as~~ to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.	**Canada**
101. The panel of antimicrobials for susceptibility testing should be harmonized as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.	**Switzerland** It is not clear whether harmonization should be achieved within or between programs
101. If phenotypic testing is done, the panel of antimicrobials for susceptibility testing should be harmonized across the national monitoring and surveillance program. The panel of antimicrobials for susceptibility testing should be harmonized as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.	**USA** Text added to provide needed clarity.
101. The panel of ~~antimicrobials~~ antimicrobial agents for susceptibility testing should be harmonized as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
102. The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the quantities used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Antimicrobials not used in veterinary medicine, but which have the potential for co-	**Canada** The first sentence of this Para contradicts Para 58. Canada feels that there is better language here and suggests reconsidering the language in Para 58.

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selection of resistance due to gene linkage can also be included (e.g. chloramphenicol resistance in *Salmonella*.).	
102. National lists of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel. In addition, suggested panels of antimicrobials by bacteria for inclusion for AST can be found in the WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach. The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the ~~quantities~~ classes of antimicrobials used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Antimicrobials ~~not used in veterinary medicine, but~~ which have the potential for co-selection of resistance due to gene linkage can also be ~~included (e.g~~included. ~~chloramphenicol resistance in *Salmonella*.).~~	**USA** Moved some text from para 103 below. (Moved 2nd sentence to the beginning of paragraph 102. Moved 1st sentence in para 103 to after this 2nd sentence and begin it with 'In addition'.
102. The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the quantities used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Antimicrobials not used in veterinary medicine, but which have the potential for co-selection of resistance due to gene linkage can also be included (e.g. chloramphenicol resistance in *Salmonella*.).	**USA** Replaced “quantities” with “classes of antimicrobials” because if critically important antimicrobials are used in small quantities, competent authorities should still want to know the resistance profiles for these classes. The document goes beyond veterinary medicine, so the phrase, “not used in veterinary medicine” is irrelevant. The example should be deleted because countries will need to determine their priorities for inclusion based on local conditions and resources. The example is unnecessary.
102. The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the quantities used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected~~. Antimicrobials not used in veterinary medicine, but which have the potential for co-selection of resistance due to gene linkage can also be included (e.g. chloramphenicol resistance in *Salmonella*.).~~	**healthforanimals** Delete: necessary detail.
102. The ~~antimicrobials~~ antimicrobial agents included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these ~~antimicrobials~~ antimicrobial agents and should allow for the tracing of isolates with particular patterns of resistance. The ~~antimicrobials~~ antimicrobial agents included should also take into account the quantities used in the relevant agricultural sectors and their influence in the selection or co-selection of resistance. ~~Antimicrobials~~ Antimicrobial agents that would give the best selection of cross-resistance profiling should be selected. ~~Antimicrobials~~ Antimicrobial agents not used in veterinary medicine, but which have the	**International Feed Industry Federation** Alignment with definition of the Code of Practice.

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potential for co-selection of resistance due to gene linkage can also be included (e.g. chloramphenicol resistance in *Salmonella*.).	
102. The antimicrobials included in the panel should depend on the target bacteria and the clinical or epidemiological relevance of these antimicrobials and should allow for the tracing of isolates with particular patterns of resistance. The antimicrobials included should also take into account the quantities used in the relevant ~~agricultural~~ animal and plant production sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Antimicrobials not used in veterinary medicine, but which have the potential for co-selection of resistance due to gene linkage can also be included (e.g. chloramphenicol resistance in *Salmonella*.).	**OIE** "and their influence in the selection or co-selection of resistance" - this is a "moving target", and therefore very challenging to define.
103. Suggested panels of antimicrobials by bacteria for inclusion for AST can be found in the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*. OIE List of Antimicrobials of Veterinary Importance and National lists of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel.	**Japan** Animal lists need to be considered to be inclusive and informed by the types of antimicrobial agents when determining which antimicrobial agents to test for.
~~103. Suggested panels of antimicrobials by bacteria for inclusion for AST can be found in the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*. National lists of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel.~~	**USA** Edits suggested for readability. Move 2nd sentence to the beginning of paragraph 102. Move 1st sentence after this 2nd sentence and begin it with 'In addition".
103. Suggested panels of ~~antimicrobials~~ antimicrobial agents by bacteria for inclusion for AST can be found in the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*. National lists of important ~~antimicrobials~~ antimicrobial agents can also be used to guide the selection of ~~antimicrobials~~ antimicrobial agents to be included in the panel.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
103. Suggested panels of antimicrobials by bacteria for inclusion for AST can be found in the *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health ~~Approach~~Approach* and the OIE List of Antimicrobial Agents of Veterinary Importance. National lists of important antimicrobials can also be used to guide the selection of antimicrobials to be included in the panel.	**OIE**
Concentration ranges of ~~antimicrobials~~antimicrobial agents	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
104. The concentration ranges used, should ensure that both ECOFFs and clinical breakpoints, when available, for animal species/bacteria/drug combinations, are included in order to allow comparability of results with human data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) (QC strain(s)) used for each antimicrobial agent.	**USA**
104. The concentration ranges used, should ensure that both ECOFFs and clinical breakpoints, when available, are included in order to allow comparability of results with human and animal data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) (QC strain(s)) used for each antimicrobial agent.	**OIE**

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105. Examples of suggested ranges of concentrations of antimicrobials can be found at CLSI and EUCAST and also at *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*. Data on concentration ranges are often maintained by the national competent authority and the product licensing process.	**USA** Companies produce data on concentration ranges during product licensing and it may be interpreted, but not collected by WHO.
105. Examples of suggested ranges of concentrations of ~~antimicrobials~~ antimicrobial agents can be found at CLSI and EUCAST and also at *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach*.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
106. Whenever possible characterization of bacterial isolates (genus, species, and additional microbial subtyping) should be undertaken.	**Canada** There should be separation of requirements for pathogens vs. commensal/indicator bacterial species.
106. ~~Whenever possible~~ Beyond genus and species characterization of bacterial ~~isolates (genus~~isolates, ~~species, and~~ additional microbial ~~subtyping) should~~ subtyping may be undertaken.	**USA** If the capacity is not in place to identify the bacteria, then AMR data is misleading at best. Basic infrastructure should be established as a prerequisite to AMR monitoring and surveillance.
Molecular testing	**Brazil** Brazil is of the opinion that this whole section is very detailed and should be revised to be more concise, keeping only relevant elements, that are of practical guidance for member countries.
Pruebas moleculares	**Uruguay** Uruguay considera que los párrafos 108 al 116 que corresponden a este punto, deberían simplificarse.
108. Molecular testing such as polymerase chain reaction (PCR), micro and nano arrays, Sanger-sequencing, ~~pulsed-field gel electrophoresis (PFGE),~~ multilocus sequence typing (MLST) or whole genome sequencing (WGS), may be used for the detection of resistance determinants and epidemiological analysis	**USA** PFGE is not used to detect AMR determinants.
109. Molecular characterization such as WGS is also an important tool for use in the rapid identification of clusters, outbreak investigations, helpign to inform determination of epidemic source and transmission chains, detection of emergence and helping with investigation of the spread of new resistant strains or resistance determinants; and helping to inform source attribution by linking ~~to~~ with epidemiologic data and case control studies along with molecular monitoring of pathogens or resistant microorganisms or resistance determinants in humans, animals, food and environmental reservoirs.	**USA** Edits are made for clarity as some of the statements may overstate what molecular testing does. Finding a gene in 2 different places does not mean one caused the other. Epidemiologic data and case control studies can help but the finding through monitoring data is insufficient scientific evidence for source attribution
110. ~~The use of molecular testing may be useful for the~~ 'Molecular testing, in particular WGS, is invaluable to enhanced surveillance and early ~~warning~~ detection of resistant microorganisms of high public health impact ~~such as ESBL/AmpC/carbapenemase-producing~~ where resources permit.~~*Enterobacteriaceae*~~.	**USA** Edits are made to clarify that WGS is simply the most current, preferred method of molecular testing. "Detection" is a more appropriate term than "warning". Public health priorities may change. Providing an example is unnecessary.
111. The application of molecular methods and the interpretation of the information derived from them is by nature multidisciplinary. ~~Global agreement on methods, quality standards, analytical~~	**Australia** Section 8, paragraph 111

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~~schemes, genomic type nomenclature for microorganisms or resistance determinants and interpretational approaches should be established to prevent variability in the interpretation of molecular test results.~~ Laboratory and technical capacity, data management data sharing and analytical platforms to link epidemiological and microbiological information at national and international level are ~~also~~ important considerations.	Comment: Australia suggests amending as follows; 111. The application of molecular methods and the interpretation of the information derived from them is by nature multidisciplinary. Global agreement on methods, quality standards, analytical schemes, genomic type nomenclature for microorganisms or resistance determinants and interpretational approaches should be established to prevent variability in the interpretation of molecular test results. Laboratory and technical capacity, data management data sharing and analytical platforms to link epidemiological and microbiological information at national and international level are also important considerations. Rationale: Australia suggests a Codex guideline is not appropriate for advocating for global agreement to be reached, but rather adherence to consensus based internationally recognised methods and quality standards etc, should they exist.
~~111. The application of molecular methods and the interpretation of the information derived from them is by nature multidisciplinary. Global agreement on methods, quality standards, analytical schemes, genomic type nomenclature for microorganisms or resistance determinants and interpretational approaches should be established to prevent variability in the interpretation of molecular test results. Laboratory and technical capacity, data management data sharing and analytical platforms to link epidemiological and microbiological information at national and international level are also important considerations.~~	**USA** USA: Suggest moving first sentence to beginning of 112. The rest of the paragraph includes items that should be addressed in other expert fora rather than addressed broadly in this guidance.
~~112. Basic training and professional development in bioinformatics and genomic epidemiology should be carried out for microbiologists, risk assessors, epidemiologists and risk managers to facilitate the typing, interpretation, reporting, and use of integrated genomic epidemiology data.~~	**China**
112. Basic training and professional development in bioinformatics and genomic epidemiology should be carried out for microbiologists, risk assessors, epidemiologists and risk managers to facilitate the ~~typing~~typing of isolates, interpretation, reporting, and use of integrated genomic epidemiology data.	**Switzerland**
112. The application of molecular methods and the interpretation of the information derived from them is by nature multidisciplinary. Basic training and professional development in bioinformatics and genomic epidemiology should be carried out for microbiologists, risk assessors, epidemiologists and risk managers to facilitate the typing, interpretation, reporting, and use of integrated genomic epidemiology data.	**USA**
112. Basic training and professional development in bioinformatics and genomic epidemiology should ideally be carried out for microbiologists, risk assessors, epidemiologists and risk managers to facilitate the typing, interpretation, reporting, and use of integrated genomic epidemiology data.	**OIE**
~~113. In some countries, using WGS may cost less than using conventional AST and typing. Countries without current AMR monitoring or surveillance programs may consider WGS when developing their programs. Countries taking this approach should validate WGS findings with~~	**China**

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~~conventional AST. WGS approaches to surveillance are particularly suited to allow for comparison of molecular data sharing and there are several international initiatives to collect and share WGS data.~~	
113. In some countries, using WGS may cost less than using conventional AST and typing. Countries without current AMR monitoring or surveillance programs may consider WGS when developing their programs. Countries taking this approach should ~~validate~~ evaluate WGS findings in comparison with conventional ~~AST~~AST methods implemented in their country. WGS approaches to surveillance are particularly suited to allow for comparison of molecular data sharing and there are several international initiatives to collect and share WGS data.	**USA**
114. There are limitations to the applicability of WGS data to the risk assessment process when no correlative AST data exist. These can include whether the presence of a resistance determinant in a given isolate or sample is in fact casual of a resistant foodborne pathogen hazard and if a resistance determinant confers a clinically relevant resistance phenotype. When acquired resistance genes are identified and correlative AST data does not exist, laboratories should confirm phenotypic expression using AST.	**Canada** It is unclear what is meant by the use of the word “casual” here.
~~114. There are limitations to the applicability of WGS data to the risk assessment process when no correlative AST data exist. These can include whether the presence of a resistance determinant in a given isolate or sample is in fact casual of a resistant foodborne pathogen hazard and if a resistance determinant confers a clinically relevant resistance phenotype. When acquired resistance genes are identified and correlative AST data does not exist, laboratories should confirm phenotypic expression using AST.~~	**China**
114. There are limitations to the applicability of WGS data to the risk assessment process when no correlative AST data exist. These can include whether the presence of a resistance determinant in a given isolate or sample is in fact ~~casual~~ causal of a resistant foodborne pathogen hazard and if a resistance determinant confers a clinically relevant resistance phenotype. When acquired resistance genes are newly identified and validated, correlative AST data ~~does~~ do not exist, laboratories should confirm phenotypic expression using AST.	**USA** Genotypic validation with phenotypic AST is a critical step as WGS matures into a useful and powerful surveillance tool.
~~115. It is important that laboratories undertaking molecular characterization of isolates have quality assurance programs in place for the wet and dry laboratory components of the analysis.~~	**China**
116~~. There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain organism and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC.~~. Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of resistance data with other relevant data for public health such as virulence determinants.	**Australia** Section 8, paragraph 116 Comment: Australia suggests amending as follows: 116. There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain organism and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC. Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of

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	resistance data with other relevant data for public health such as virulence determinants. Rationale: By their very nature the deleted sentences are commentary on methods development and are therefore not guidance material, and should be omitted.
~~116. There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain organism and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC. Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of resistance data with other relevant data for public health such as virulence determinants.~~	**China**
116. There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain ~~organism~~ organisms and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC. Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of resistance data with other relevant data for public health such as virulence determinants.	**CCTA**
116. ~~There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain organism and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC.~~ Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of resistance data with other relevant data for public health such as virulence determinants.	**healthforanimals** These two sentences are speculative and do not add meaningful guidance. The statement may or may not come to fruition, but it does not add direction for a country or context that could help improve their surveillance and monitoring programs. The remaining sentences in this paragraph are fine.
116. ~~There is substantial scientific knowledge which indicates that predicting the resistance phenotype from WGS data is now possible with a high level of accuracy for certain organism and genes. New approaches are also coming through with the application of machine learning techniques for the determination of MIC.~~ Once sequence data are generated and stored (with appropriate metadata) these data can be used for retrospective surveillance (e.g. in the case of newly discovered resistance determinants). The use of WGS also allows the integration of resistance data with other relevant data for public health such as virulence determinants.	**International Feed Industry Federation** Speculative and not adding guidance.
117. The information collected and recorded may differ depending on the step in the production chain, sampling design and the specific ~~public health~~ surveillance objectives.	**Canada**
117. The information collected and recorded may differ depending on the step in the production chain, sampling design and the specific ~~public health~~ AMR food safety objectives.	**USA** Keep within TFAMR Scope.
Specific information about the origin of the sample: food producing animal ~~species~~species and production class (e.g. layers or chickens raised for meat), epidemiological unit, plant/crop,	**Consumers International** Antimicrobial use and resistance varies by the production class of animals

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environmental or food category, country of origin, type of sample, stage of sampling in the food chain, date and place of sampling, and isolation date, etc. Information on antimicrobial use in the production environment of the sample.	within a given species so this information is important for surveillance systems. Whenever possible data on what antibiotics are used in a production environment should be collected to help better understand the connection between use and resistance. For samples collected at retail any product labeling such as organic, biological, or raised without antibiotics should be noted.
General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate (e.g.: , phage type, molecular type, etctype).).	**Canada**
Specific information about the isolation of the bacteria and the AST: date of testing, specific information about the methods used, quantitative results (e.g. MICs in mg/L), etc. In the case of qualitative results interpretative criteria categories should be recorded (e.g. AST results including criteria categories used to identify resistant or non-wild type isolates). It is also necessary to report the International standard used for the interpretation of the results.	**USA** Change 'criteria' to 'categories' to be consistent with changes to terminology that CLSI and other standard setting organizations have officially made.
119. Reporting of results from the monitoring and surveillance program should be timely and preferably include information on individual isolates, specific information about sampling and methods as describe described above.	**Canada**
119. Reporting of results from the monitoring and surveillance program should be timely and preferably include information on individual isolates, specific information about sampling and methods as describe described above.	**CCTA**
120. Antimicrobial susceptibility testing methods and interpretive criteria categories should be clearly described, and differences transparently explained to show where data may and may not be directly comparable.	**USA** Change 'criteria' to 'categories' to be consistent with changes to terminology that CLSI and other standard setting organizations have officially made.
120. 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.	**CCTA** or "interpretative" as in 118
120. Antimicrobial susceptibility testing AST methods and interpretive criteria should be clearly described, and differences transparently explained to show where data may and may not be directly comparable.	**International Feed Industry Federation** Consistent use of acronym.
121. 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 bacteria isolated from humans, food, agricultural, livestock and aquatic products and the environment.	**Canada**
121. 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 bacteria isolated from humans, food, agriculturalplant production, livestock and aquatic products and environment.	**OIE**

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122. The *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach* provides detailed information about ~~interpretation of antimicrobial susceptibility results,~~ data analysis and reporting.	**USA** It would not be appropriate to cite a WHO document (not a laboratory standard) as a source of AST interpretive standards which could change considerably over time. Edited to limit this sentence to the data analysis and reporting aspect covered under WHO.
122. The *WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach* provides detailed information about interpretation of ~~antimicrobial susceptibility~~ AST results, data analysis and reporting.	**International Feed Industry Federation** Consistent use of acronym.
Collection of national antimicrobial sales and use data in animals and plants/crops	**Brazil** Brazil is of the opinion that this whole section 9 needs to be carefully revised once the AMU data collection is still an initial and evolving issue, standards are still being harmonized and there is still no consensus on measurements and indicators, for example. Only elements where scientific evidence supports a linkage with foodborne AMR risk to human health should be kept. Recommendations have to be of practical guidance for member countries, be science based, feasible and based on Codex main objectives, to protect the health of the consumers and ensure fair practices in the food trade.
Collection of ~~national~~ antimicrobial sales and use data in animals and plants/crops	**Canada**
Collection of national antimicrobial sales and use data in animals and plants/crops	**Morocco** General comments Morocco takes note of the work of the EWG and makes the following general comments: • Reporting of AMU in animals is guided by the OIE and it will be advisable to make cross reference to the terrestrial and aquatic animal health code. • The calculation of biomass is work in progress by the OIE and this information will be accessible on the OIE website. • Recommend deletion of section 9.2 since it is well summarized in 7.2.2(B) • The extent to which antimicrobial use in plant production selects for the emergence and maintenance of antimicrobial resistant (AMR) organisms in plant production is unclear. Surveillance and further testing are needed to conduct comprehensive risk assessments and to monitor progress in implementing more sustainable plant health practices that reduce reliance on antimicrobials . • Countries should be encouraged to support research in foodborne AMR due to foods derived from plants.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	• The proposals contained/outlined in section 9.3 are derived from the OIE template for reporting AMU in animals. It is not certain if the same methodology will apply for reporting AMU in plants. • The international Plant Protection Convention (IPPC) should consider developing guidelines on AMU in plants to enable countries report on use of antimicrobials in the plant health sector. • This section in essence is still under development and most countries will not be able to implement surveillance in plants.
Obtención de datos nacionales de ventas y uso de agentes antimicrobianos relativos a animales y plantas/cultivos	**Uruguay** Respecto a los párrafos 123-136 correspondientes a este punto, Uruguay considera que debe contemplarse el trabajo ya realizado por la OIE en este aspecto y complementarlo si fuera necesario, a través de una iniciativa conjunta.
Collection of national antimicrobial sales ~~and~~ and/or use data ~~in animals and plants/crops~~	**USA** This change to 'and/or' should be made throughout the document to remain consistent and to prevent confusion since sales and use are not the same. Data characterizing the foodborne AMR risk from use of antimicrobial in crops is still scant and limited to contamination that would be covered in food hygiene. Specific sectors should be deleted in the title to leave countries the option of collecting this data in crops if a risk is found rather than requiring it as a core element for routine, systematic collection as part of a national surveillance system.
Collection of national ~~antimicrobial sales and use~~ AMU data in animals and plants/crops	**International Feed Industry Federation** Consistent use of acronym.
Elements of an integrated monitoring and surveillance program for ~~antimicrobial sales/use data~~ AMU	**International Feed Industry Federation** Consistent use of acronym.
123. The following aspects should be taken into account when deciding on the approach to collect ~~antimicrobial sales or use data~~AMU.	**International Feed Industry Federation** Consistent use of acronym.
Identification of how antimicrobials are distributed for use in agriculture (animals and ~~crops)~~ crops/plants) within the country. Contributing parties, including marketing authorization holders, wholesalers, distribution centers, pharmacists, veterinarians, farmers and importers/exporters should be identified as part of this process.	**China**
Identification of how antimicrobials are distributed for use in agriculture ~~(animals and crops)~~ as applicable within the country. Contributing parties, including marketing authorization holders, wholesalers, distribution centers, pharmacists, veterinarians, farmers and importers/exporters should be identified as part of this process.	**USA** Data characterizing foodborne AMR risk from use of antimicrobials on crops is lacking.
Identification of how ~~antimicrobials~~ antimicrobial agents are distributed for use in agriculture (animals and ~~crops)~~ plants/crops) within the country. Contributing parties, including marketing authorization	**International Feed Industry Federation** Alignment with definitions of the Code of Practice.

SPECIFIC COMMENTS	
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holders, wholesalers, distribution centers, pharmacists, veterinarians, farmers and importers/exporters should be identified as part of this process.	
Identification of how antimicrobials are distributed for use in agriculture (animals and ~~crops)~~ plants/crops) within the country. Contributing parties, including marketing authorization holders, wholesalers, distribution centers, pharmacists, veterinarians, farmers and importers/exporters should be identified as part of this process.	**OIE**
Establishment of the principles for ensuring confidentiality of data supplied ~~at national level~~ (e.g. personal or proprietary data)Development of a protocol on the collection of data to ~~captures~~ capture qualitative and quantitative information on the antimicrobials.	**Canada** The confidentiality could apply at multiple levels, not just national.
Establishment of the principles for ensuring confidentiality of data supplied at national level (e.g. personal or proprietary ~~data)Development~~ data). Development of a protocol on the collection of data to ~~captures~~ capture qualitative and quantitative information on the antimicrobials.	**CCTA**
Establishment of the principles for ensuring confidentiality of data supplied at national level (e.g. personal or proprietary data)Development of a protocol on the collection of data to captures qualitative and quantitative information on the ~~antimicrobials~~antimicrobial agents.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Establishment of the principles for ensuring confidentiality of data supplied at national level (e.g. personal or proprietary ~~data)Development~~ data). Development of a protocol on the collection of data to ~~captures~~ capture qualitative and quantitative information on the antimicrobials.	**OIE** The protocol for the collection of antimicrobial use data in animals at the national level has been clearly established by the OIE.
Nomenclature of the antimicrobial agents should comply with international standards where ~~available~~available (i.e., ATCvet code).	**Canada**
~~Nomenclature of antimicrobial agents should comply with international standards where available.~~	**USA** There are legal and language differences in the way countries name antimicrobials and this bullet is unnecessary and goes beyond the scope for setting up a surveillance system.
~~Nomenclature of antimicrobial agents should comply with international standards where available.~~	**healthforanimals** There are legal and linguistic differences between countries describing the names of antimicrobials and related terminology. The attempt to align nomenclature can lead to a trade barrier due to misinterpretation.
~~Nomenclature of antimicrobial agents should comply with international standards where available.~~	**International Feed Industry Federation** Not necessary.
Nomenclature of antimicrobial agents should comply with international standards ~~where~~ when available.	**OIE**
Establishment of the technical units of measurement and indicators of antimicrobial sales or use The units used for reporting sales and use should be based on internationally accepted methods, to enable interpretation and data sharing globally.	**Switzerland** This is an important point that should also be considered in section 8.1.
Establishment of the technical units of measurement and indicators of antimicrobial sales or ~~use The units used for reporting sales and use should be based on internationally accepted methods, to enable interpretation and data sharing globally~~use.	**USA** There is currently no global consensus for measuring use in various sectors.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Establishment of the technical units of measurement and indicators of ~~antimicrobial sales or use~~ AMU. The units used for reporting sales and use should be based on internationally accepted methods, to enable interpretation and data sharing globally.	**International Feed Industry Federation** Consistent use of acronym.
Identification of the type and number of crops and food-producing animals by species, type of production and their weight in kilograms ~~for food production~~ per year (as relevant to the country of production) is essential basic ~~information~~information (see 9.2.3).	**Canada**
Identification of the type and number of ~~crops~~ crops/plants and food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.	**China**
Identification of the type and number of crops and food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is ~~essential basic information~~important information that should be collected where possible and where appropriate for the national context.	**USA** Data characterizing foodborne : AMR risk from use of antimicrobials on crops is lacking.
Identification of the type and number of ~~crops~~ plants/crops and food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Identification of the type and number of ~~crops~~ plants/crops and food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.	**OIE**
The ~~way of organizing the~~ reporting of antimicrobial sales or use data may be further organized by crop type, animal species, animal categories, age groups, and by route of administration (e.g. in-feed, foliar spray, in-water, injectable, oral, intramammary, intra-uterine, topical), type of use (therapeutic vs non-therapeutic, pest-control in crops), etc.	**Canada**
The way of organizing the reporting of antimicrobial sales or use data may be further organized by crop type, animal species, animal categories, age groups, and by route of administration (e.g. in-feed, foliar spray, in-water, injectable, oral, intramammary, intra-uterine, topical), type of use (therapeutic vs non-therapeutic, pest-control in ~~crops)~~crops/plants), etc.	**China**
The way of organizing the reporting of antimicrobial sales or use data may be further ~~organized~~ organized, as appropriate, by crop type, animal species, animal categories, age groups, and by route of ~~administration (e~~administration.~~g. in-feed, foliar spray, in-water, injectable, oral, intramammary, intra-uterine, topical), type of use (therapeutic vs non-therapeutic, pest-control in crops), etc.~~	**USA** Route of Admin. is a well-understood term and examples are unnecessary. Regarding type of use, we don't have definitions for some of these terms, so better to replace examples with "labeled indication of use".
The way of organizing the reporting of ~~antimicrobial sales or use~~ AMU data may be further organized by crop type, animal species, animal categories, age groups, and by route of administration (e.g. in-feed, foliar spray, in-water, injectable, oral, intramammary, intra-uterine, topical), type of use (therapeutic vs non-therapeutic, pest-control in ~~crops)~~plants/crops), etc.	**International Feed Industry Federation** Consistent use of acronym. Alignment with definition of the Code of Practice
The way of organizing the reporting of antimicrobial sales or use data may be further organized by ~~crop~~ plant/crop type, animal species, animal categories, age groups, and by route of administration	**OIE**

SPECIFIC COMMENTS	
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(e.g. in-feed, foliar spray, in-water, injectable, oral, intramammary, intra-uterine, topical), type of use (therapeutic vs non-therapeutic, pest-control in crops), etc.	
Reporting of the ~~national~~ antimicrobial sales/use data for use in animals	**Canada**
Reporting of the national ~~antimicrobial sales/use~~ AMU data for use in animals	**International Feed Industry Federation** Consistent use of acronym.
International guidance on monitoring and surveillance of ~~antimicrobial sales and use~~ AMU data in animals	**International Feed Industry Federation** Consistent use of acronym.
124. The following international guidance should be taken into consideration when developing a national surveillance and monitoring system for ~~antimicrobial sales or use~~ AMU data in animals:	**International Feed Industry Federation** Consistent use of acronym.
~~WHO:~~ ~~*WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach (2017)*.~~	**USA** Section on WHO moved further down.
~~The AGISAR guidance provides details for:~~	**USA**
~~Surveillance of national antimicrobial sales data.~~	**USA**
Surveillance of national antimicrobial agent sales data.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Surveillance of antimicrobial consumption by animal species.~~	**USA**
Surveillance of antimicrobial agent consumption by animal species.	**International Feed Industry Federation** Alignment with definition of the Code of Practice
~~Continuous collection of antimicrobial consumption data by animal species.~~	**USA**
Continuous collection of antimicrobial agent consumption data by animal species.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Collection of data from a sample of farms.~~	**USA**
~~Stratification of sales data.~~	**USA**
~~The relevant Chapter of the OIE Terrestrial Animal Health code provides~~ These provide information about the sources of antimicrobial data (basic, direct, end-use and other sources) and about the types and reporting formats of antimicrobial usage data.	**Canada**
The relevant Chapter of the OIE Terrestrial Animal Health code provides information about the sources of antimicrobial agent data (basic, direct, end-use and other sources) and about the types and reporting formats of ~~antimicrobial usage~~ AMU data.	**International Feed Industry Federation** Alignment with definition of the Code of Practice. Consistent use of acronym
The OIE *Annual report on antimicrobial agents intended for use in animals* provides a detailed template for the collection of AMU data ~~on antimicrobials used~~ in animals, with different options for the level of reporting of antimicrobial agent data. The information can be divided as follows:	**International Feed Industry Federation** Consistent use of acronym. Alignment with definition of the Code of Practice

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Option 1: Quantities and usage patterns of antimicrobial agents ~~sold for/used~~ used in food-producing animals overall by antimicrobial class, with the possibility to separate by type of use.	**healthforanimals** Sales data gives an estimation of the maximum volume of antimicrobial available for use. However, sales data does not equal amount used in animals
Option 2: Quantities and usage patterns of antimicrobial agents ~~sold for/used~~ used in food producing animals by antimicrobial class, with the possibility to separate by type of use and species group.	**healthforanimals** same as above
Option 3: Quantities and usage patterns of antimicrobial agents ~~sold for/used~~ used in food producing animals by antimicrobial class, with the possibility to separate by type of use, species group and route of administration.	**healthforanimals** same as above
Whenever possible the above data should be provided with an estimate of the animal population that has been exposed to the ~~antibiotics~~ antimicrobial agent (see below).	**International Feed Industry Federation**
125. Data on quantities of antimicrobials sold and used at the national level may differ. Proper analysis of the data collected, and additional information may be necessary to understand these differences. For example, differences in data source, different data providers, stocks in some points of the supply chain could be reason for differences between sales and use data.	**Canada**
o WHO: WHO-AGISAR Guidelines for Integrated Surveillance of AMR in Foodborne Bacteria: Application of a One Health Approach (2017). The AGISAR guidance provides details for: • Surveillance of national antimicrobial sales data. • Surveillance of antimicrobial sales and/or use by animal species. • Continuous collection of antimicrobial sales and/or use data by animal species. • Collection of data from a sample of farms. • Stratification of sales data. When collecting data on quantities of antimicrobials used or sales data, it is important to recognize that sales data dose not equate to the quantity used in animals. Further, reporting of the data should include a description of data collection, methodologies, and limitations so that accurate context of the data is accurately conveyed. 125. Data on quantities of antimicrobials sold ~~and~~ and/or used at national level may differ. Proper analysis of the data collected, and additional information may be necessary to understand these differences. For example, differences in data source, different data providers, stocks in some points of the supply chain could be reason for differences between sales and use data. Further, sales data	**USA** Text added for clarification.

SPECIFIC COMMENTS	
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are not equivalent to the quantity used in animals and multiple measurements may be needed to properly understand quantities used at a national level.	
125. Data on quantities of antimicrobials sold and used at national level may differ. Proper analysis of the data collected, and additional information may be necessary to understand these differences. For example, differences in data source, different data providers, stocks in some points of the supply chain could be reason for differences between sales and use data.	**International Feed Industry Federation** For ensuring protection of proprietary data: Include §125bis: Disclosure of the data should include a discussion and details of the limits of the data collected and presented for AMU and the methods and sources that were marshalled to deliver the data.
125. Data on quantities of ~~antimicrobials~~ antimicrobial agents sold and used at national level may differ. Proper analysis of the data collected, and additional information may be necessary to understand these differences. For example, differences in data source, different data providers, stocks in some points of the supply chain could be reason for differences between sales and use data.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Antimicrobial agent quantities (numerator)	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
126. ~~Numerator~~ The numerator in the context of antimicrobial data consumption represents the amount of antimicrobials sold or used	**Canada**
126. Numerator in the context of antimicrobial data consumption represents the amount of estimates of antimicrobials sold or ~~used~~ used.	**USA** Countries may collect sales and/or use data. Further clarity is added.
126. Numerator in the context of antimicrobial data consumption represents the amount of antimicrobials sold or ~~used~~ used.	**CCTA**
126. Numerator in the context of antimicrobial agent data consumption represents the amount of antimicrobials agents sold or used	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
126. Numerator in the context of antimicrobial data ~~consumption~~ use represents the amount of antimicrobials sold or used	**OIE**
127. The minimum data collected to estimate the amount of antimicrobials should be the weight in kilograms of active ingredient of the antimicrobial(s) intended for use in food-producing animals per year~~. It is possible to estimate total usage by collecting~~ . Collecting sales data, prescription data, manufacturing data, import and export data or some combinations of ~~these.~~ these is also possible, though they are not equivalent to sales data.	**USA** Edited for technical accuracy.
127. The minimum data collected to estimate the amount of ~~antimicrobials~~ antimicrobial agents should be the weight in kilograms of active ingredient of the ~~antimicrobial(s)~~ antimicrobial agent(s) intended for use in food-producing animals per year. It is possible to estimate total usage by collecting sales data, prescription data, manufacturing data, import and export data or some combinations of these.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
129. Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are ~~important~~ desirable elements to ~~include~~ collect, if resources and infrastructure allow, when ~~assessing antimicrobial usage~~ developing an antimicrobials use monitorign system in food-producing animals.	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
129. Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are important elements to include when assessing ~~antimicrobial usage~~ AMU in food-producing animals.	**International Feed Industry Federation** Consistent use of acronym.
130. The denominator in the context of antimicrobial consumption is the animal population at risk ~~for~~ of being treated (with antimicrobials).	**Canada**
130. Total sales or use of antimicrobials is dependent on several variables including the number of animals and size of animals in the population, differences in physiology and weight, and differences in how animal species metabolize drugs. Use of a denominator can be used to provide a more nuanced estimate. The denominator in the context of antimicrobial ~~consumption~~ sales/and/or use data is the animal population at risk for being treated (with antimicrobials).	**healthforanimals** Proposed revision to provide better contextualization.
130. The denominator in the context of antimicrobial agent consumption is the animal population at risk for being treated (with ~~antimicrobials)~~antimicrobial agents).	**International Feed Industry Federation**
130. The denominator in the context of antimicrobial ~~consumption~~ use is the animal population ~~at risk for being treated (with~~ potentially exposed to antimicrobials).	**OIE**
131. Variables such as number of animals per farm/species/categories/production, average weight of the animals in the population, or differences in how animal species metabolize antimicrobials are important for the interpretation and assessment of the amount of antimicrobials sold or used (numerator). A denominator representing the animal population at risk of being treated with the antimicrobials should enable a better overview/indication of the consumption data and should facilitate the reporting and the comparability of data. The denominator chosen should be representative to the species, production type, etc.	**Canada**
131. Variables such as number of animals per farm/species/categories/production, weight of the animals in the population, or differences in how animal species metabolize antimicrobials are important for the interpretation and assessment of the amount of antimicrobials sold or used (numerator). A denominator representing the animal population at risk of being treated with the antimicrobials should enable a better overview/indication of the ~~consumption~~ sales and/or use data and should facilitate the reporting and the comparability of data. The denominator chosen should be representative to the species, production type, etc.	**USA** Edits made for consistent terminology use.
131. Variables such as number of animals per farm/species/categories/production, weight of the animals in the population, or differences in how animal species metabolize ~~antimicrobials~~ antimicrobial agents are important for the interpretation and assessment of the amount of ~~antimicrobials~~ antimicrobial agents sold or used (numerator). A denominator representing the animal population at risk of being treated with the ~~antimicrobials~~ antimicrobial agents should enable a better overview/indication of the consumption data and should facilitate the reporting and the comparability of data. The denominator chosen should be representative to the species, production type, etc.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
132. The desired denominator for reporting of antimicrobial sales or use should be determined in advance. This denominator should consider the country's available data on animal populations and animal weights and reflect the surveillance design and objectives. Examples, of denominators that may be appropriate depending on the type of data collected include the animal biomass for national	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
sales data, or 1,000 ~~animal-days for antimicrobial use data from a sample~~ animal-days total weight of ~~farms~~marketed animals, animal years, weight of commodity/food, kg liveweight sold or slaughtered, or number of birds placed (poultry only). The denominator chosen should be appropriate to the species. Countries should prioritize the standardization this data for the purposes of longitudinal trends analysis within their country.	
132. The desired denominator for reporting of antimicrobial sales or use should be determined in advance. This denominator should consider the country's available data on animal populations and animal weights and reflect the surveillance design and objectives. Examples, of denominators that may be appropriate depending on the type of data collected include the animal biomass for national sales data, or 1,000 ~~animal-days for antimicrobial use data from a sample~~ animal-days,total weight of ~~farms~~marketed animals, animal years, weight of commodity/food, kg live weight sold or slaughtered, or number of birds placed (poultry only). The denominator chosen should be appropriate to the species. Countries should prioritize the standardization this data for the purposes of longitudinal trends analysis within their country.	**healthforanimals** Application of a denominator is for the benefit the Codex member country and their NAP, not for international comparisons.
132. The desired denominator for reporting of ~~antimicrobial sales or use~~ AMU should be determined in advance. This denominator should consider the country's available data on animal populations and animal weights and reflect the surveillance design and objectives. Examples, of denominators include the animal biomass for national sales data, or 1,000 animal-days for ~~antimicrobial use~~ AMU data from a sample of farms.	**International Feed Industry Federation** Consistent use of acronym.
The estimate of animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation~~, therefore~~ .The calculation of the national animal population is desirable for reporting at the national ~~level~~level and should be established as part of the national action plan. ~~The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.~~	**Australia** Section 9, paragraph 132, dot point 1 Comment: Australia suggests amending as follows: The estimate of animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation., therefore The calculation of the national animal population is desirable for reporting at the national level and should be established as part of the national action plan. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population. Rationale: The deleted text is commentary in nature and not suitable for

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	guidance. The denominator should be established as part of the national action plan and used for purposes detailed in the national action plan.
The estimate animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. ~~The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.~~	**Brazil** Brazil suggests deleting these examples. OIE recommended standards should be the reference for Codex documents.
The ~~estimate~~ estimated animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.	**Canada**
The ~~estimate~~ estimated animal biomass of food producing species at risk of being treated with antimicrobials ~~should~~ may be calculated. The OIE ~~provides~~ is currently working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals~~. Different productions~~ , however different production practices and ~~slaughtering or~~ marketing weights make it challenging to develop one biomass calculation method that would be equally applicable to every national situation~~, therefore calculation of the national animal population is desirable for reporting at national level. .The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.~~	**USA** Text is added for clarity. There is currently no global consensus on biomass calculations. OIE's approach is specific for global estimates and may or may not be appropriate for national estimates. ADD and biomass calculations are difficult because the ESVAC method is not appropriate to apply to different countries' situations where animal weights vary. It is not appropriate to cite references to specific countries/regions versus internationl guidance.
The estimate animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. The European Surveillance of Veterinary	**CCTA** The estimated ?

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.	
~~The estimate~~ he estimated animal biomass ~~of food producing species at risk of being treated with~~ that can be exposed to antimicrobials should be calculated. Several national health agencies have d developed methodologies for the calculation of such animal populations. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population. Additionally, OIE is working to provide a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals.	**healthforanimals**
The estimate animal biomass of food producing species at risk of being treated with antimicrobials should be calculated. The OIE provides a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. ~~The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.~~Th	**healthforanimals** Inappropriate to reference specific regions/countries.
The estimate animal biomass of food producing species at risk of being treated with ~~antimicrobials~~ antimicrobial agents should be calculated. The OIE ~~provides~~ is in the process of providing a biomass denominator suitable for global reporting of quantities of antimicrobial agents intended for use in animals. Different productions practices and slaughtering or marketing weights make it challenging to develop one biomass calculation that would be equally applicable to every national situation, therefore calculation of the national animal population is desirable for reporting at national level. ~~The European Surveillance of Veterinary Antimicrobial Consumption project has provided a methodology for the calculation of such animal population for sales data reported at EU level; this methodology~~	**International Feed Industry Federation** Alignment with definition of the Code of Practice. Clarification. Avoid reference to local examples

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~has been adopted by other countries outside of the EU (e.g., Canada). Furthermore, the US Food and Drug Administration recently published a proposal for the estimation of the animal population.~~	
For sampled farm data, the number of animals and the time they are under surveillance is critical context for reporting antimicrobial use data. Time-specific components (e.g., animal years or 1,000 animal-days) and components incorporating animal weights (e.g., total weight of animals marketed) are possible considerations. Common denominators reported in the literature for sampled farm data include 1,000 ~~animal-days or~~ animal-days,100 animal-days~~.~~, or total number of animals treated.	**USA** The denominators reported in literature so far are limited to a few countries or subregions and their legislation. It could be very difficult for this model to apply globally. An additional example is also used in the literature.
For sampled farm data, the number of animals and the time they are under surveillance is critical context for reporting ~~antimicrobial use~~ AMU data. Common denominators reported in the literature for sampled farm data include 1,000 animal-days or 100 animal-days.	**International Feed Industry Federation** Consistent use of acronym.
For sampled farm data, the number of animals and the time they are under surveillance is critical context for reporting antimicrobial use data. Common denominators reported in the literature for sampled farm data include 1,000 animal-days or 100 animal-days.	**OIE** Proposal to move the 1000 animal-days or 100 animal-days to the units of measurement section, instead of having them as common denominators.
Other examples of denominators may be the total weight of slaughtered or marketed animals, animal years, kg live weight sold or slaughtered~~, etc~~.	**Canada**
~~Other~~ The source the denominator data should, generally, be aligned with the year or time period as the numerator data; • The quality of the denominator should be comparable to the numerator. A high variation in the quality of the denominator data is undesirable for interpretation. • The denominator calculation should be comprehensively and transparently described, easily reproducible based on appropriate, publicly available data sources, and results should be compared to those obtained using other existing methodologies where possible. The selected methodology should be applied consistently in subsequent years to allow for an analysis of temporal trends. • Member should strive to apply the denominator method consistently over time and across species, as appropriate. The method should be disclosed with the data and include any changes to the method from the previous period. •Other examples of denominators may be the total weight of slaughtered or marketed animals, animal years, kg live weight sold or slaughtered, etc.	**USA**
Other examples of denominators may be the total weight of slaughtered or marketed animals, animal years~~, ~~,weight of commodity/food kg live weight sold or slaughtered, etc. Countries should prioritize the standardization of this data for the purposes of longitudinal trends analysis within their country.	**healthforanimals** The literature missed this important denominator, which is increasingly used in the food chain use. Regarding the second sentence, it is important to highlight that the application of a denominator is there to benefit the Codex member country and their national action plan, not for international comparisons.
Other examples of denominators may be the total weight of slaughtered or marketed animals, animal years, ~~kg live~~ weight ~~sold or slaughtered~~of food produced, etc. Countries should prioritise the standardisation of this data for the purpose of longitudinal trend analysis within their territory.	**International Feed Industry Federation** Clarification.

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The total number of food-producing animals by species, ~~type of~~ production class and animal weight in kilograms for food production per year (as relevant to the country of production) is important information that should be collected where possible.	**USA** Antimicrobial drug use data collection arguably goes beyond Codex's mandate and into OIE. OIE chapters are updated more often than Codex and as there is little global consensus on measurements of use, careful consideration be given as to the level of detail that should be included in this guideline.
The total number of food-producing animals by species, type of production and animal weight in kilograms for food production per year (as relevant to the country of production) is important information that should be collected where possible. • The quality of the denominator should be comparable to the numerator. A high variation in the quality of the denominator data is undesirable for interpretation. • Member should strive to apply the denominator method consistently over time and across species, as appropriate. The method should be disclosed with the data and include any changes to the method from the previous period.	**healthforanimals** ADD IN NEW BULLET POINT The denominators reported in literature so far are limited to a few countries or subregions and their legislation. They rely on having a firm understanding of the number of animals produced within the country. It could be very difficult for this model to apply globally.
133. Standardized units of measurement for reporting antimicrobial sales and use in specific food producing animal species should be used. Any selected metrics for reporting can bias results for certain animal species and standardized metrics should represent a national consensus on relevance and availability of data points for species in the national database. More information can be found in OIE Chapter 6.8	**USA** Antimicrobial drug use data collection arguably goes beyond Codex's mandate and into OIE. OIE chapters are updated more often than Codex and as there is little global consensus on measurements of use, careful consideration be given as to the level of detail that should be included in this guideline.
133. Standardized units of measurement for reporting ~~antimicrobial sales and use~~ AMU in specific food producing animal species should be used	**International Feed Industry Federation** Consistent use of acronym.
134. Examples of units are: mg of active substance/kg of animal biomass, number of Defined Daily Doses for animals ~~(DDDvet)~~(DDDvet)/1000 animal-days, number of Defined Course Dose for animal ~~(DCDvet), etc~~(DCDvet)/1000 animal-days.	**Canada**
134. Examples of units are: mg of active substance/kg of animal biomass, number of Defined Daily Doses for animals (DDDvet), number of Defined Course Dose for animal (DCDvet), etc.	**USA** If DDDvet and DCDvet are used, references should be added for these terms. These terms may be calculated differently and it would be helpful to provide references.
135. Units of measurement described in international guidelines to collect antimicrobial use and/or sales data should be used where possible (OIE instructions for collecting antimicrobial use data).	**USA** OIE guidance/templates are not only for 'use' data collection, but many countries are using them for reporting sales data too.
135. Units of measurement described in international guidelines to collect ~~antimicrobial use~~ AMU data should be used where possible (OIE instructions for collecting ~~antimicrobial use~~ AMU data).	**International Feed Industry Federation** Consistent use of acronym.
Reporting of the ~~national~~ antimicrobial sales/use data for use in plants/crops	**Canada**
Reporting of the national ~~antimicrobial sales/use~~ AMU data for use in plants/crops	**International Feed Industry Federation** Consistent use of acronym.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
136. The following aspects should be taken into account when deciding on the approach to collect ~~antimicrobial sales or use~~ AMU data:	**International Feed Industry Federation** Consistent use of acronym.
Baseline information on what ~~antimicrobials~~ antimicrobial agents are registered for use in which plants/crops.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Collection of amounts sold/used in plants/crops:	**USA** Inclusion of use of antimicrobials in crops in a national surveillance system is premature as public health impacts from use of antimicrobials on crops needs to be assessed prior to developing science-based guidance. See report from FAO at TFAMR6: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-06%252FWD%252Fam06_02e.pdf "In order to develop science-based recommendations to mitigate the negative public health impacts of AMR, the use of antimicrobials in plant production resulting in occupational exposure, food, and environmental contamination need to be assessed. FAO will continue to work on this area together with WHO and OIE." The first 2 bullets appear to be duplicative, except that the first bullet appears to be more than food crops. The last bullet includes information that is not easily collected-specific disease and pathogen. There are no plant pathogens shared to humans, so what pathogen data is to be collected? The last 3 bullets in particular are unclear. What are relevant data? These bullets provide little clarity on the types of data to be collected for a national surveillance system for foodborne AMR. There is a concern that several of these data elements would go outside the scope of Codex. The last 3 bolded bullets should be deleted as they are not relevant to antimicrobial use/sales data. The last bullet is editorial.
Collection of amounts sold/used in ~~plants/crops~~plants/crops such as:	**USA**
~~**Option 1**: Overall amount sold for/used in plants/crops by antimicrobial class, with the possibility to separate by plant/crop type (e.g. fruit trees, grains, vegetables, field vegetables vs greenhouse vegetables, nuts).~~	**USA**
Option 2: Overall amount sold for/used in food and feed crops by antimicrobial class, with the possibility to separate by plant/crop type and specific ~~crops~~crops (e.g., apple orchards, walnuts, greenhouse tomatoes).	**Canada**
~~**Option 2**:~~ Overall amount sold for/used in food ~~and feed~~ crops by antimicrobial class, with the possibility to separate by plant/crop type and specific crops.	**USA**

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Option 2: Overall amount sold for/used in food and feed ~~crops~~ plants/crops by antimicrobial class, with the possibility to separate by plant/crop type and specific ~~crops~~plants/crops.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~**Option 3**: Overall amount sold for/used in food and feed crops by antimicrobial class, with the possibility to separate by plant/crop type and specific crops, and specific disease and pathogen.~~	**USA**
Option 3: Overall amount sold for/used in food and feed crops by antimicrobial class, with the possibility to separate by plant/crop type and specific crops, and specific disease and pathogen. [New Bullet] Whenever possible the above data should be provided with an estimate of the acreage of crops that have been exposed to the antimicrobials.	**Consumers International** Adding an additional bullet on plant populations makes this consistent with paragraph 124.
Option 3: Overall amount sold for/used in food and feed ~~crops~~ plants/crops by antimicrobial class, with the possibility to separate by plant/crop type and specific ~~crops~~plants/crops, and specific disease and pathogen.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
~~Collection of relevant data from farms and agriculture land where waste derived fertilizers and antimicrobials as pest-control products are applied.~~	**USA**
Collection of relevant data from farms and ~~agriculture~~ plant production land where waste derived fertilizers and antimicrobials as pest-control products are applied.	**OIE**
~~Other plausible entry routes of antimicrobials in crop production such as but not limited to land application of biosolids, animal by-products and municipal waste.~~	**USA**
Other plausible entry routes of ~~antimicrobials~~ antimicrobial agents in ~~crop~~ plant/crop production such as but not limited to land application of biosolids, animal by-products and municipal waste.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
Other plausible entry routes of antimicrobials in ~~crop~~ plant production such as but not limited to land application of biosolids, animal by-products and municipal waste.	**OIE**
Reporting of the national antimicrobial sales/use data for use in ~~crops~~ crops/plants should consider collecting relevant data from farms and agriculture lands where waste derived fertilizers and antimicrobials as pest-control products are applied.	**China**
~~Reporting of the national antimicrobial sales/use data for use in crops should consider collecting relevant data from farms and agriculture lands where waste derived fertilizers and antimicrobials as pest-control products are applied.~~	**USA**
Reporting of the national ~~antimicrobial sales/use~~ AMU data for use ~~in crops~~ in plants/crops should consider collecting relevant data from farms and agriculture lands where waste derived fertilizers and ~~antimicrobials~~ antimicrobial agents as pest-control products are applied.	**International Feed Industry Federation** Consistent use of acronym. Alignment with definitions of the Code of Practice
Reporting of the national antimicrobial sales/use data for use in ~~crops~~ plants should consider collecting relevant data from farms and ~~agriculture~~ plant production lands where waste derived fertilizers and antimicrobials as pest-control products are applied.	**OIE**
138. To properly manage test results and data generated through of the integrated monitoring and surveillance program, a digital database that guarantees security, confidentiality and integrity of data is needed. At a national level, one common location of data is preferred~~, with one database for AMR information and one database for AMU information.~~ .	**USA** The last phrase is repetitive regarding AMR with paragraph 137 above and not practical regarding AMU from different sectors.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
138. To properly manage test results and data generated ~~through of~~ throughout the integrated monitoring and surveillance program, a digital database that guarantees security, confidentiality and integrity of data is needed. At a national level, one common location of data is preferred, with one database for AMR information and one database for AMU information.	**CCTA**
138. To properly manage test results and data generated through ~~of~~ the integrated monitoring and surveillance program, a digital database that guarantees security, confidentiality and integrity of data is needed. At a national level, one common location of data is preferred, with one database for AMR information and one database for AMU information.	**OIE**
142. For AMR ideally, data should be collected and stored at isolate level with each bacterial species and sample source reported to the database separately.	**Canada** This contradicts Para 137.
143. Results of AMR monitoring and surveillance should be compared with results of AMU monitoring and surveillance to evaluate trends over ~~time and that the~~ time, between regions, across host species, across bacterial species or across drug classes. The data can be used as described in CAC/GL 77/2011 for risk analysis purposes and to inform the development and implementation of appropriate risk management options and policies to ensure responsible and prudent use of antimicrobials and to address foodborne AMR.	**Canada** We will not achieve that with the collection of AMU/AMR data only. It will be necessary to better understand the on-farm management risk factors which may affect AMU and we will need to better understand the human component.
143. Results of AMR monitoring and ~~surveillance should be compared with results of AMU~~ sAMU monitoring and surveillance may be examined to evaluate trends over time and that the data can be used as described in CAC/GL 77/2011 for risk ~~analysis purposes~~ assessment and to inform the development and implementation of appropriate risk management options and policies to ensure responsible and prudent use of antimicrobials and to address foodborne AMR.	**USA** Edited for technical accuracy.
143. Results of AMR monitoring and surveillance should be compared with results of AMU monitoring and surveillance to evaluate trends over time and that the data can be used as described in CAC/GL 77/2011 for risk analysis purposes and to inform the development and implementation of appropriate risk management options and policies to ensure responsible and prudent use of ~~antimicrobials~~ antimicrobial agents and to address foodborne AMR.	**International Feed Industry Federation** Alignment with definition of the Code of Practice.
144. Results of foodborne AMR and AMU monitoring and surveillance should be published annually where resources allow. When available, summary reports about AMR in humans, agricultural, livestock and aquatic products and environment can be published.	**China**
~~144. Results of AMR and AMU monitoring and surveillance should be published annually where resources allow. When available, summary reports about AMR in humans, agricultural, livestock and aquatic products and environment can be published.~~	**USA** Delete bullet. Rationale: This is addressed in next section.
144. Results of AMR and AMU monitoring and surveillance should be published annually where resources allow. When available, summary reports about AMR in humans, ~~agricultural~~plant production, livestock and aquatic products and environment can be published.	**OIE**
145. Data from the samples and use data can be integrated with data from other sources (e.g. human isolates).	**Canada** Canada suggests moving this point up to become Para 144.
145. Data from the samples and use data can be integrated with data from other sources (e.g. human isolates).	**Ghana** Paragraph 145

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
	Position: Ghana proposes the replacement of the text at the beginning of paragraph 145 with Foodborne AMR, and AMU/AMC data as follows; 145. Foodborne AMR and AMU/AMC data can be integrated with data from other sources (e.g. human isolates). Rationale: To ensure clarity of this paragraph.
145. Data from the samples and use data can be integrated with data from other sources (e.g. human ~~isolates)~~isolates) for comparative analysis and reporting.	**Switzerland**
~~145. Data from the samples and use data can be integrated with data from other sources (e.g. human isolates).~~	**USA** Delete as intent is unclear and appears superfluous.
146. Combined analysis of ~~results and~~ data ~~of a program of~~ from integrated monitoring and surveillance of AMR in foodborne bacteria ~~comprises~~ can include the comparison and synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail ~~foods,~~ foods and the environment. The detailed methodology of the surveillance system and epidemiological context should also be ~~incorporated to~~ considered in the analysis. Where data ~~is~~ are available, exposure pathways among people, animals, crops and their shared environment connecting resident bacterial populations could be incorporated to the analysis.	**Canada**
146. Combined analysis of results and data of a program of integrated monitoring and surveillance of AMR in foodborne bacteria comprises the comparison and synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment. The detailed methodology of the monitoring and surveillance system and epidemiological context should also be incorporated to the analysis. Where data is available, exposure pathways among people, animals, crops and their shared environment connecting resident bacterial populations could be incorporated to the analysis.	**China**
146. Combined analysis of results and data of a program of integrated monitoring and surveillance of AMR in foodborne bacteria comprises the comparison ~~and synthesis of AMU in humans, animals and crops and AMR data~~ across ~~all sectors~~ teh One Health spectrum, including humans, food-producing animals, plants/crops, retail foods, and the environment. The detailed methodology of the surveillance system and epidemiological context should also be incorporated ~~to~~ into the analysis. Where data is available, exposure pathways among people, animals, crops and their shared environment connecting resident bacterial populations could be incorporated ~~to~~ into the analysis.	**USA** Delete 'and synthesis of AMU in humans, animals, and crops and AMR data'. Delete the 2nd and 3rd sentence and Paragraph 147. Rationale: Focus text on the overarching objective of the analysis.
146. Combined analysis of results and data of a program of integrated monitoring and surveillance of AMR in foodborne bacteria comprises the comparison and synthesis of AMU in humans, animals and crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment. The detailed methodology of the surveillance system and epidemiological context should also be incorporated to the analysis. Where data ~~is~~ are available, exposure pathways among people, animals, crops and their shared environment connecting resident bacterial populations could be incorporated to the analysis.	**CCTA** "Data" is a plural noun … synthesis ??

SPECIFIC COMMENTS	
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146. Combined analysis of results and data of a program of integrated monitoring and surveillance of AMR in foodborne bacteria comprises the comparison and synthesis of AMU in humans, animals and ~~crops~~ plants/crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and ~~the~~ food production environment. The detailed methodology of the surveillance system and epidemiological context should also be incorporated to the analysis. Where data is available, exposure pathways among people, animals, ~~crops~~ plants/crops and their shared environment connecting resident bacterial populations could be incorporated to the analysis.	**International Feed Industry Federation** Alignment with definitions of the Code of Practice. Focus on the scope of the guidelines
146. Combined analysis of results and data of a program of integrated monitoring and surveillance of AMR in foodborne bacteria comprises the comparison and synthesis of AMU in humans, animals and ~~crops~~ plants/crops and AMR data across all sectors including humans, food-producing animals, plants/crops, retail foods, and the environment. The detailed methodology of the surveillance system and epidemiological context should also be incorporated to the analysis. Where data is available, exposure pathways among people, animals, ~~crops~~ plants/crops and their shared environment connecting resident bacterial populations could be incorporated to the analysis.	**OIE**
147. The data may originate from different monitoring and surveillance systems, and comparability is an important factor to ~~consider in the design of the monitoring and surveillance program~~consider. The choice of analytical approaches should allow the investigation of the relationship between use and resistance within the animal, plant/crops and human populations, as well as additional associations between equivalent data within all relevant populations, provided that AMR and AMU data are representative. Appropriate statistical analysis such as univariate ~~(logistic regression)~~ and multivariate analysis (e.g., logistic regression) should be used to ensure accuracy.	**Canada**
147. The data may originate from different monitoring and surveillance systems, and comparability is an important factor to consider in the design of the monitoring and surveillance program. The choice of analytical approaches should allow the investigation of the relationship between use and resistance within the animal, ~~plant/crops~~ crops/plants and human populations, as well as additional associations between equivalent data within all relevant populations, provided that AMR and AMU data are representative. Appropriate statistical analysis such as univariate (logistic regression) and multivariate analysis should be used to ensure accuracy.	**China**
147. The data may originate from different monitoring and surveillance systems, and comparability is an important factor to consider in the design of the monitoring and surveillance program. ~~The choice of analytical approaches should allow the investigation of the relationship between use and resistance within the animal, plant/crops and human populations, as well as additional associations between equivalent data within all relevant populations, provided that AMR and AMU data are representative. Appropriate statistical analysis such as univariate (logistic regression) and multivariate analysis should be used to ensure accuracy.~~	**USA** USA: Delete 2nd and 3rd sentences. Rationale: Unnecessary level of detail, does not provide any guidance, and not useful to risk assessors.
148. Integrated monitoring and surveillance of foodborne AMR should be aligned with surveillance in human populations to ~~ensure comparability of results and inferring~~ assist in understanding relationships between foodborne AMR and ~~AMU~~AMU in food production. Key considerations for data analysis include analysis of relevant ~~human isolates to include data from significant~~ foodborne	**USA** If the goal is to ensure comparability, countries may never start a surveillance program. Since different strains of bacteria are often found in

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
pathogens according to national epidemiological information (e.g. *Salmonella*, *Campylobacter*) and, whenever possible, commensal flora such as *E. coli* and *Enterococcus*. Integration of results with surveillance of human clinical isolates should facilitate identifying trends in resistance to specific antimicrobials important for human treatment, as well as identify trends in the occurrence of resistance to other antimicrobials of human and animal importance. The surveillance of ~~human isolates~~ foodborne pathogens will allow comparison with isolates from the food chain and environment.	different sectors and different drugs are used, it is not possible to "ensure" comparability. "Human" isolates is not clear.
148. Integrated monitoring and surveillance of foodborne AMR should be aligned with surveillance in human populations to ensure comparability of results and inferring relationships between AMR and AMU. Key considerations for data analysis include analysis of relevant human isolates to include data from significant foodborne pathogens according to national epidemiological information (e.g. *Salmonella*, *Campylobacter*) and, whenever possible, commensal flora such as *E. coli* and *Enterococcus*. Integration of results with surveillance of human clinical isolates should facilitate identifying trends in resistance to specific ~~antimicrobials~~ antimicrobial agents important for human treatment, as well as identify trends in the occurrence of resistance to other ~~antimicrobials~~ antimicrobial agents of human and animal importance. The surveillance of human isolates will allow comparison with isolates from the food chain and environment.	**International Feed Industry Federation** Alignment with the definition of the Code of Practice.
149. Isolates obtained for AMR surveillance ~~should~~ could also include representative isolates from sporadic and outbreak foodborne disease cases.	**Canada**
149. Isolates obtained for AMR surveillance should also include representative isolates from sporadic cases and ~~outbreak~~ outbreaks of foodborne ~~disease cases~~disease.	**Switzerland**
~~149. Isolates obtained for AMR surveillance should also include representative isolates from sporadic and outbreak foodborne disease cases.~~	**USA** This statement is not clear. What if through surveillance, sporadic or outbreak strains are not found?
150. Guidance on conducting antimicrobial resistance surveillance of human isolates is provided by the WHO Global Antimicrobial Resistance Surveillance System (GLASS).	**Canada** Canada recognizes that GLASS priorities are broader than foodborne. WHO AGISAR would be a better reference here.
~~150. Guidance on conducting antimicrobial resistance surveillance of human isolates is provided by the WHO Global Antimicrobial Resistance Surveillance System (GLASS).~~	**USA** GLASS is outside Codex scope.
150. ~~Guidance on conducting antimicrobial resistance surveillance of human isolates is provided by the WHO Global Antimicrobial Resistance Surveillance System (GLASS).~~	**International Feed Industry Federation** Out of the scope of the terms of reference.
~~**Additional research and targeted investigation**~~	**Canada** Canada proposes that Additional research and targeted investigation is beyond the scope of guidelines for monitoring and surveillance.
Additional research and targeted investigation	**USA** This section is outside scope of surveillance and is ideally deleted.
~~**Additional research and targeted investigation**~~	**International Feed Industry Federation** Out of the scope of the terms of reference.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
~~151. Additional research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies, point prevalence studies, surveys, etc. should be considered.~~	**Canada**
151. Additional research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies, point prevalence studies, surveys, etc. ~~should be considered.~~ is beyond the scope of this document.	**USA**
~~151. Additional research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies, point prevalence studies, surveys, etc. should be considered.~~	**healthforanimals** Delete because this is commentary - not guidance.
151. ~~Additional research in the national setting to improve the understanding and knowledge of AMR e.g. food source attribution studies, point prevalence studies, surveys, etc. should be considered.~~	**International Feed Industry Federation** Out of the scope of the terms of reference.
152. Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions~~, e.g. incorporating real-time "Critical Resistance" Alert Systems.~~	**Brazil** Brazil suggests deleting this example, once it is outside the scope of this document.
~~152. Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g. incorporating real-time "Critical Resistance" Alert Systems.~~	**Canada**
152. ~~Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response~~ Understanding causal links from animal production to ~~surveillance activities~~ human foodborne illness needs further research and ~~actions, e~~advancement to give informed advice on managing AMR risk originating in food animals.~~g. incorporating real-time "Critical Resistance" Alert Systems.~~	**USA** This is outside scope so should be deleted. Alternative text is provided regarding the need for further research.
~~152. Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g. incorporating real-time "Critical Resistance" Alert Systems.~~	**healthforanimals** Delete because this is commentary - not guidance.
152. ~~Other targeted investigation which is not included in the routine AMR monitoring and surveillance program may be needed at national or local level as risk management response to surveillance activities and actions, e.g~~. ~~incorporating real-time "Critical Resistance" Alert Systems.~~	**International Feed Industry Federation** Out of the scope of the terms of reference.
Evaluation of the integrated surveillance programs	**Canada**
153. The evaluation of an integrated monitoring and surveillance system promotes the best use of data collection resources and provides assurance that systems operate effectively. Evaluation of systems also provides assurance that the data and information reported ~~is~~ are robust and surveillance objectives are being met.	**Canada**
153. The evaluation of an integrated monitoring and surveillance system promotes the best use of data collection resources and provides assurance that systems operate effectively. Evaluation of systems also provides assurance the data and information reported ~~is~~ are robust and surveillance objectives are being met.	**CCTA**
154. The steps in developing an evaluation framework include:	**Switzerland** I think the first bullet should also be the most important criteria, this is not currently the case. I would start with the second point.

SPECIFIC COMMENTS	
Section/paragraph	**Member/Observer/ rationale**
Risk communication	**Canada** We are missing a couple of steps of getting the data from surveillance into the risk analysis process. There is communication of surveillance findings, which is different than risk communication. Data from surveillance is only a part of the risk communication piece. Canada suggests that text be developed to reflect this.
155. The implementation strategy of the monitoring and surveillance system should include the development ~~a~~ of a risk communication plan which defines the objectives, the evaluation process and allows for timely improvement of the plan.	**China**
~~155. The implementation strategy of the monitoring and surveillance system should include the development a of risk communication plan which defines the objectives, the evaluation process and allows for timely improvement of the plan.~~	**USA** Delete Paragraphs 155 and 156. Rationale: Risk communication is part of risk analysis as defined in CAC/GL 77. Risk communication is beyond the scope of a program on integrated surveillance and monitoring of AMR and is the result of risk analysis process.
155. ~~The implementation strategy of the monitoring and surveillance system should include the development a of risk communication plan which defines the objectives, the evaluation process and allows for timely improvement of the plan.~~	**International Feed Industry Federation** Covered by CAC/GL 77.
156. Risk communication processes should allow the development of partnerships between the competent authorities and stakeholders. Such partnerships should facilitate communication between parties and the involvement and commitment of stakeholders in the development and implementation of the AMR monitoring and surveillance activities and other related risk management options.	**Canada** Canada suggests that Para 156 come after 157 for improved flow.
~~156. Risk communication processes should allow the development of partnerships between the competent authorities and stakeholders. Such partnerships should facilitate communication between parties and the involvement and commitment of stakeholders in the development and implementation of the AMR monitoring and surveillance activities and other related risk management options.~~	**USA**
156. ~~Risk communication processes should allow the development of partnerships between the competent authorities and stakeholders. Such partnerships should facilitate communication between parties and the involvement and commitment of stakeholders in the development and implementation of the AMR monitoring and surveillance activities and other related risk management options.~~	**International Feed Industry Federation** Covered by CAC/GL 77.
Training and capacity building	**Canada** As currently written, Canada feels that this section does not add much guidance. We suggest that including a reference to the developing Code of Practice would be appropriate here.
159. A ~~tiered~~ progressive approach to the implementation of this guidance at the national level is recommended. Programs should aspire to use effectively available resources, technical capability and take advantage of potential for cross-sector integration while seeking continuous improvement.	**USA**