

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**Agenda Item 6**

**CX/AMR 21/8/6-Add.1**

**September 2021**

**ORIGINAL LANGUAGE ONLY**

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

**Eighth Session  
(Virtual)**

**4-9 and 13 October 2021**

**GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF  
FOODBORNE ANTIMICROBIAL RESISTANCE**

**(At Step 4)**

Comments from

Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union (EU), Honduras, Indonesia, Iraq, Japan, Malaysia, Norway, Paraguay, Switzerland, Thailand, Uruguay, United States of America (USA), Consumers International, International Feed Industry Federation (IFIF), International Union of Food Science and Technology (IUFOST)

**Background**

1. This document compiles comments at Step 3 received through the Codex Online Commenting System (OCS) in response to CL 2021/59-AMR issued in July 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.
2. The comments submitted through the OCS are, hereby attached as an Annex and are presented in table format.

**GENERAL COMMENTS**

<b>COMMENT</b>	<b>MEMBER/OBSERVER</b>
<p>Brazil would like to congratulate the chair and co-chairs of the Electronic Working Group and of the Working Group for the excellent work done and recognize that the Guidelines as they are presented now in Appendix I of CX/AMR 21/8/6 have significantly improved, in an effort to achieve consensus at TFAMR8.</p> <p>Brazil is of the opinion that some changes to the document are still needed and that we need to keep many of the recommendations on a high level, considering that integrated monitoring and surveillance of foodborne AMR is a very complex and still evolving issue. Codex recommendations should be science based, practical, feasible and aiming to protect the health of consumers and ensure fair practices in the food trade. They should also allow for flexibility, since countries face different realities.</p>	<b>Brazil</b>
<p>Canada appreciates the efforts of the Working Group to develop the latest version of the document and supports the recommendations proposed by the Chair and co-Chairs of the WG, including the revisions made to Section 9.</p> <p>Canada finds that the document is streamlined and the level of detail throughout provides guidance which is not overly prescriptive. As the guidelines are further refined during the Task Force, it will be important to ensure the language used throughout the document is clear to provide guidance for practical implementation, and that the contents of the figure are aligned with the section headings.</p>	<b>Canada</b>
<p>Chile thanks all the work done by the Chair of the eWG and the Co chairs on taking into consideration all the comments received from members and observer. Chile thinks the document have several parts that are in good shape to be considered for step 5, however there some remaining issues that need to be revised in order to maintain the focus on foodborne AMR monitoring and surveillance.</p>	<b>Chile</b>
<p>Congratulations for the wonderful work from the chair and co-chairs. Thanks a lot for the opportunity to submit the comments from China. This version of the proposed Guidelines has been refined based on the previous work of the electronic working group. China will improve the process of this Guideline with all members and suggests that the Guidelines should emphasize that each country can gradually implement the integrated monitoring and surveillance of AMR and AMU according to its national conditions.</p>	<b>China</b>
<p>Es fundamental mencionar la necesidad de abordar mediante una planificada comunicación de riesgo para lograr la cooperación de las partes involucradas e interesadas mediante una socialización previa dado que se requerirá información de tal manera que se tengan claros los beneficios del programa y sus objetivos para la salud pública. Lo anterior debe aplicar solo para para la presentación de informes de resultados y se sugiere incluir en el programa en los aspectos previos de implementación.</p>	<b>Colombia</b>
<p>Cuba agradece la oportunidad de emitir sus criterios del documento: Directrices para el seguimiento y la vigilancia integrados de la resistencia a los antimicrobianos transmitida por los alimentos en respuesta a la CL 2021/59/OCS-AMR y despues de analizar el mismo, apoya lo descrito en estas directrices.</p>	<b>Cuba</b>
<p>Ecuador agradece al Comité del Codex por el esfuerzo para el desarrollo del Anteproyecto de Norma sobre las Directrices sobre el seguimiento y la vigilancia integrada en resistencia a los antimicrobianos- GLIS y pone en su conocimiento las siguientes observaciones generales:</p> <ul style="list-style-type: none"> <li>• El documento presenta claramente las directrices que se recomiendan y se debe considerar en los países para la implementación de seguimiento y vigilancia a las RAM y del uso de antimicrobianos – UAM; aún idealizado e inalcanzable para nuestro país.</li> <li>• Los componentes mencionados y las directrices engloban un trabajo integral de todos los actores implicados en el proceso del uso de los antimicrobianos y por su puesto del proceso de vigilancia del manejo responsable de los medicamentos, por ello sector público y privado debe complementarse para el intercambio de información que permita tener una visión clara de la RAM y su relación con el UAM.</li> </ul>	<b>Ecuador</b>
<p>Egypt commends the chair and co chairs of the EWG for the good work undertaken in developing those guidelines.</p>	<b>Egypt</b>
<p>The EU and its Member States (EUMS) appreciate very much the hard work of the Chair and Co-chairs and the substantial improvements achieved since the previous TFAMR7 meeting and acknowledge the revised draft provided as Annex to the working document CX/AMR 21/8/6.</p> <p>EUMS agree with the general concept in the guideline as explained by the Chair and Co-chairs, and as laid down in the terms of reference, namely to:</p>	<b>European Union</b>

COMMENT	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• include antimicrobial use within the scope of the document,</li> <li>• introduce antimicrobial use in the introduction without bringing in a formal definition for the term, and</li> <li>• introduce and apply the broad understanding of integrated monitoring and surveillance program(s)</li> </ul> <p>The EUMS agree with most of the revised wording and rearrangement of paragraphs, as this contributes to the clarification of the text. We also agree to not re-open discussions on the sections scope and definitions.</p> <p>While reviewing the revised draft guidelines, EUMS took into account points requested specifically by the chair and co-chairs. They are addressed in the comments on the specific paragraphs. Additionally, only those paragraphs have been commented where adjustments are suggested.</p>	
<p>Indonesia appreciates the work chaired by the Netherlands and co-chaired by Canada, Chile, China and New Zealand and support the development of guidelines on integrated monitoring and surveillance of foodborne AMR, since One Health approach for AMU and AMR requires harmonization in various aspects between human, animal and food systems at national and international levels.</p> <p>The challenge for the integrated system is the preparedness of each sector in responding to the AMR. Indonesia aware that while the human and animal health sectors have the available system to conduct AMR monitoring and surveillance, no guidelines is available for the plant/crops sector. Thus detail information under the section of plant/crops in the guideline is needed for MS to have flexibility and feasibility in the implementation.</p>	<b>Indonesia</b>
<p>Agree.</p>	<b>Iraq</b>
<ul style="list-style-type: none"> <li>• First, Japan thanks the EWG Chair and Co-chairs as well as members who gave comments for their efforts to move forward after the very limited discussion allowed at the TFAMR7. Japan shares the ambition with all of them of finalizing the draft for adoption at the CAC44.</li> <li>• Noting the discussion thus far about how much technical details and examples should be included, Japan reiterates that the guidelines to be developed should not and will never be able to be a substitute for a textbook. The guidelines should focus on the important elements and approaches to implement integrated monitoring and surveillance of foodborne AMR. Avoiding technical details will simplify the text which will help the readers to understand the key messages.</li> <li>• Japan is fully aware of the importance of AMU monitoring in order to understand the current situation and trend of use, and to provide useful input for the consideration of appropriate countermeasures against AMR development and spread.</li> <li>• In the animal sector, Japan has been conducting AMU monitoring for more than 20 years in close communication with and with advice from the OIE. This must be the same concerning the veterinary services of many other countries. Japan, thus, believes that these guidelines should avoid duplication with existing OIE work as much as possible. That will help to reduce the volume of the guidelines and to avoid confusion among users of the guidelines, in particular, in the animal-health sector.</li> <li>• For this reason, Japan proposes to delete some paragraph of Section9 to add a clear reference to the OIE standards.</li> </ul>	<b>Japan</b>
<p>Malaysia supports the Proposed draft Guidelines On Integrated Monitoring And Surveillance Of Foodborne Antimicrobial Resistance.</p>	<b>Malaysia</b>
<p>Norway appreciates the opportunity to provide our response to CL 2021/59/OCS. We would like to thank for the effort the Chair and Co-chair of the Electronic Working Group have put into preparing the proposed draft guidelines on the integrated monitoring and surveillance of foodborne antimicrobial resistance (GLIS).</p> <p>We are of the view that the GLIS reads well, and it will be a helpful tool for countries setting up integrated monitoring and surveillance systems foodborne AMR and AMU. It is important to have globally harmonized methods on how to design a monitoring and surveillance system. In general, we agree with the changes that have been made in the document, and we think the changes have clarified the text.</p> <p>Norway agrees with the Chair and the Co-chairs recommendations to:</p>	<b>Norway</b>

COMMENT	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• Not to re-open discussions on already agreed text in the sections on Introduction and purpose, Scope and Definitions.</li> <li>• Keep «antimicrobial use» in the introduction as it is essential and is used throughout the Guidelines.</li> <li>• Keep «antimicrobial use» within the scope of the document.</li> <li>• Ensure that the GLIS are a stand alone and future proofed document.</li> </ul> <p>We are looking forward to fruitful discussions at the 8th session of the TFAMR. In our view TFAMR8 should aim at sending the GLIS to the 44th session of CAC for final adoption.</p>	
Paraguay agradece el esfuerzo y los trabajos realizados por el Grupo de Trabajo Electrónico, asimismo informa que estamos de acuerdo con el documento presentado.	<b>Paraguay</b>
<p>Switzerland thanks the work of the Chair and co-chairs for the substantial improvement of the draft text. Also, we thank the participants of the electronic working group for their contributions during the webinars.</p> <p>Switzerland agrees with the general direction of the document and welcomes the improvements achieved in terms of content, structure and consistence with other relevant standards. Considering the urgent need for action against further emergence and spread of antimicrobial resistance throughout the food chain, our priority is to move the text forward. We believe the current version represents a robust compromise between the level of detail needed for the text to be "stand-alone" while avoiding being too prescriptive.</p> <p>Switzerland supports the aim that the guidelines should be stand-alone and future-proofed.</p> <p>Switzerland welcomes the convergence of the text with the wording already contained in existing OIE codes as proposed in the current version.</p>	<b>Switzerland</b>
<p>Uruguay agradece y felicita a los Países Bajos en su rol de presidente del Grupo de trabajo electrónico y a las copresidencias de Canadá, Chile, China y Nueva Zelandia, por el excelente trabajo realizado.</p> <p>A pesar de los importantes avances respecto a la última versión del documento, Uruguay es de la opinión que aún restan ser reconsiderados aspectos centrales del documento que atentan contra la claridad y aplicabilidad práctica por los países, en especial los menos desarrollados.</p> <p>La resistencia a los antimicrobianos es un tema sumamente complejo, en constante evolución y que está mereciendo la atención y el esfuerzo de diversos organismos internacionales, cada uno focalizado en su ámbito de acción y coordinando acciones en ámbitos superiores. Por tal motivo, entendemos que la labor del TFAMR no debe superponerse ni abarcar las competencias específicas de otros organismos como la OIE y el CIPF. Tal como fuera recomendado, y en beneficio de la claridad y aplicabilidad de estas directrices, sugerimos que las recomendaciones mantengan un carácter general y flexible, considerando la evolución constante de la resistencia a los antimicrobianos y a la labor específica que otros organismos internacionales vienen desarrollando.</p>	<b>Uruguay</b>
The United States is grateful for the work of the Netherlands and co-chairs to further revise the document. Our comments reflect the need to keep the guidance science and risk-based, offer flexibility to ensure advice is globally achievable, and stay within the Codex mandate to avoid becoming duplicative or contradictory with other international organizations.	<b>USA</b>
The document lacks information on the need for systems of competent inspection to identify sources leading to AMR, the need for quality control systems that include food safety procedures, and the necessary follow-up inspection and control steps to control or eliminate the sources leading to AMR. Without such information the document is likely to lead to extremely complicated sampling and monitoring work that has only academic interests , but no consumer protection functions.	<b>IUFOST</b>
<p>New Zealand would like to thank the chair and co-chairs for the work they have undertaken on the draft Guidelines on Monitoring and Surveillance of Foodborne Antimicrobial Resistance.</p> <p>New Zealand agrees with the following concepts and text proposed by the chairs and co-chairs.</p>	<b>New Zealand</b>

COMMENT	MEMBER/OBSERVER
<p>1) Ensure the guidelines are stand alone and future-proofed to the extent possible. To allow a stand-alone document, the concept of AMU must be retained. Section 9.3 has been extensively reviewed and shortened to ensure no contradiction with OIE documentation, while maintaining the wording that is applicable to data collection on AMU. New Zealand supports section 9.3 as it now stands.</p> <p>2) The concept of AMU should be first outlined in the introduction. Since AMU is used throughout the guidelines, an informal definition where the term is first used is more appropriate than keeping it where it was first defined in chapter 9.</p> <p>3) Retain the figure as it provides a good overview of the text and how each of the concepts are interrelated.</p> <p>New Zealand agrees that in some areas of the text, there are now multiple qualifiers which were introduced during the physical working group. The suggestions were made to attempt to soften the text, however, some sentences are now very difficult to read and other sentences have been softened where there should be no option.</p>	

## SPECIFIC COMMENTS

COMMENTS	MEMBER/OBSERVER
<b>1. INTRODUCTION AND PURPOSE</b>	
<p>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 within the framework of a “One Health” approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).</p> <p><u>Proposed text:</u></p> <p>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 contribute to a “One Health” approach, including the design and implementation of a national program for monitoring and surveillance of foodborne AMR.</p>	<p><b>Australia</b></p> <p>Modify the text to: "that contribute to a One Health approach", as these guidelines only cover the food safety components of the “One Health” approach and to match the title of the document., as follows:</p>
<p>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 within the framework of a “One Health” approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR <del>and antimicrobial use (AMU).</del></p>	<p><b>Brazil</b></p> <p>As Brazil has previously stated, we understand that “AMU monitoring” is a component of the “AMR monitoring and surveillance national programs”, and that adequate balance should be given in this sense. Deleting the reference to AMU in this sentence is consistent to the title of GLIS, as presented in the terms of reference of this TFAMR. It is important to highlight that deleting AMU from this sentence does not mean that GLIS should not be addressing the importance of AMU for national AMR programs. In fact, we agree that high level guidance on AMU should be retained in Section 9 and in other parts of GLIS that refer to AMU data.</p> <p>Brazil also understands that this is consistent to the Scope agreed in 2016 presented as a project document in CX/CAC 17/40/12 Add.2 - Proposal for new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance, where it states that “Effective public health AMR surveillance systems aiming at prevention and control of AMR should include surveillance of both antimicrobial resistance and antimicrobial use.”, confirming that AMU is part of an AMR surveillance system.</p>
<p>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 within the framework of a “One Health” approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).</p> <p><u>Proposed text:</u></p> <p>1. World -wide recognition of the importance of antimicrobial resistance (AMR) as a public health threat has led to calls for all countries to develop and implement national strategies and action plans within the framework of a “One Health” approach, including the design and implementation of national programs of integrated monitoring and surveillance of foodborne AMR.</p>	<p><b>Chile</b></p> <p>The One Health Approach was recommended by the Global Action Plan for the design and implementation of National Action Plans, where the integrated monitoring and surveillance is a component, and will contribute to the "One Health approach NAP".</p> <p>We propose to delete “and AMU” at the last part, because even when this guideline will address the AMU monitoring and surveillance under section 9, it should not be given the same relevance than AMR monitoring and surveillance that is in our view the scope that was ask to be consider for the development of this document.</p> <ul style="list-style-type: none"> <li>• Delete “Integrated” before OH, since One Health approach is already an integration. Redundant.</li> </ul>

COMMENTS	MEMBER/OBSERVER
	<ul style="list-style-type: none"> <li>Delete "Strong international". Codex documents should avoid adjectives that can be prescriptive in the trade arena after.</li> </ul>
<p>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 within the framework of a "One Health" approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).</p> <p><u>Proposed text:</u></p> <p>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 within the framework "One Health" approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR.</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests the addition of "to contribute" One health approach, and to delete the AMU approach. And therefore, we propose the following text:</p> <p><u>Rationale:</u> The AMU shouldn't have the same weight between AMR, because the Antimicrobial use monitoring is a complex step.</p>
<p>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 within the framework of a "One Health" approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).</p>	<p><b>European Union</b></p> <p>EUMS would like to emphasize the need to mention AMU in paragraph 1 and 2. This is unavoidable and needed since AMU is part of the scope of GLIS. The importance of AMU as an integral part of monitoring and surveillance program(s) within the One Health approach has also been underlined by the political declaration of the United Nations General Assembly (UNGA) in 2016.</p>
<p>1. World-wide recognition of the importance of antimicrobial resistance (AMR) as a public health threat has led <del>to strong international calls for</del> all countries to develop and implement national strategies and action plans within the framework of a "One Health" approach, including the design and implementation of national programs of monitoring and surveillance of foodborne <del>AMR and antimicrobial use (AMU)</del>AMR.</p>	<p><b>Japan</b></p> <ul style="list-style-type: none"> <li>Delete "to strong international call for" <u>Rationale:</u> "strong international call" is rather emotional and not suitable for technical guidelines.</li> <li>Delete "and antimicrobial use (AMU)"</li> </ul> <p><u>Rationale:</u> Considering the title of the guidelines which was based on the ToR agreed, it is inappropriate to treat AMU and AMR in an equal manner. In these guidelines, AMU monitoring should be treated as a contributor to the overall AMR surveillance.</p>
<p>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 within the framework of a "One Health" approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).</p>	<p><b>Norway</b></p> <p>It is crucial to fight AMR through the "One Health" approach. Data on use/consumption of antimicrobial agents, AMU, is a vital element for risk analysis undertaken prior to risk management activities. As AMU is part of the scope and essential throughout the GLIS, it is given that it is a part of paragraph 1 and 2 .</p> <p>The importance of AMU as an integral part of monitoring and surveillance program(s) within the One Health approach has also been underlined by the political declaration of the United Nations General Assembly (UNGA) in 2016.</p>

COMMENTS	MEMBER/OBSERVER
	This is in line with the WHO AGISARs scope of “integrated surveillance”, as underlined in the report "Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach Guidance from the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)" from 2017.
1. El reconocimiento mundial de la importancia de la resistencia a los antimicrobianos (RAM) como amenaza para la salud pública ha dado lugar a enérgicas llamadas internacionales para que todos los países desarrollen e implementen planes de acción y estrategias nacionales dentro del marco de un enfoque de «Una Salud», lo que incluye el diseño y la implementación de programas nacionales de seguimiento y vigilancia de la RAM transmitida por los <del>alimentos y el uso de antimicrobianos (UAM)</del> <u>alimentos</u> .	<b>Uruguay</b> Uruguay reconoce la importancia que tiene el buen uso de antimicrobianos en los distintos ámbitos (salud humana, animal, vegetal) en la lucha contra la resistencia a los antimicrobianos. Sin embargo, no creemos que éste deba ser priorizado en el objetivo de este documento y su inclusión en la introducción puede conducir a errores de interpretación a lo largo del documento.
1. <del>World-wide recognition of the importance of antimicrobial</del> <u>Antimicrobial</u> resistance (AMR) <del>as is a global public health threat has led to strong international calls for all countries to develop and implement national strategies and action plans within at the framework of human, animal, and environmental interface which necessitates a framework</del> “One Health” approach, <del>including the design, Monitoring and implementation of national programs of monitoring and surveillance programs can contribute to the food safety component of foodborne AMR and antimicrobial use (AMU)- a One Health approach for addressing this complex problem.</del>	<b>USA</b> The sentence as currently written is grammatically a run-on sentence and mentions the public health threat but not the One Health context. The information is also dated since the calls for National Action Plans came 6 years ago. Revisions are suggested to make the document more timeless and clearer. Codex is contributing to the food safety component of the One Health approach. Codex is not addressing all components of One Health. For example, the animal health component is not covered by Codex.
2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.	<b>Australia</b> Move paragraph 2 to section 9 which focuses on AMU.
<del>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</del>	<b>Brazil</b> Brazil suggests deleting this paragraph. A description of AMU should be included at the beginning of Section 9, as it had been proposed before. Brazil does not agree in having this description in the Introduction.
<del>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</del>	<b>Chile</b> Delete this paragraph. It is confuse and put sold data as the same as use data, when is not. Also can be contradictory with future OIE guidelines. All the information related to AMU should be kept at section 9 as a source of data that should be consider for the interpretation on the AMR monitoring and surveillance results.
<del>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</del>	<b>Japan</b> Japan suggests deleting the whole paragraph as it is odd to have such a technical definition at the front of the introductory section. IN stead, a description about AMU should be added in Section 9 (para 82 bis) where guidance for AMU monitoring is provided.



COMMENTS	MEMBER/OBSERVER
<p>2. A los fines de estas Directrices, por «uso antimicrobiano» y su sigla «UAM» se entiende los antimicrobianos a utilizar en animales o en plantas/cultivos, que se pueden obtener de los datos de antimicrobianos vendidos y/o usados en animales destinados a la producción de alimentos o plantas/cultivos.</p>	<p><b>Uruguay</b> En relación a nuestro comentario anterior, Uruguay sugiere eliminar este comentario de la introducción y trasladarlo a la sección 9, donde se aborda el uso de antimicrobianos.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</p>	<p><b>USA</b> We recommend more context on AMU and sales be placed under Section 9, where AMU is discussed, rather than inadequately mention it in passing in this section. Wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</p>	<p><b>Consumers International</b> Consumers International would like to thank the Chair and Co-chairs of the Working Group for their work to draft the “Guidelines On Integrated Monitoring And Surveillance Of Foodborne Antimicrobial Resistance”. Consumers International strongly supports the inclusion of data on antimicrobial use as part of integrated surveillance and thus support the proposed language in paragraphs 2, 3, and 4 of the Introduction. We also strongly support inclusion of guidance related to integrated surveillance in plants and the food production environment.  There are points in the document where CI does not completely agree with the proposed text, but after reviewing the past actions of the Task Force and Working Group we recognize these are often areas where there was much discussion and the text reflects compromise between conflicting viewpoints. In the spirit of compromise and recognizing the significant effort already made and the limited amount of time left to move the text forward, CI supports the current draft.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of AMR and AMU related data and information. Surveillance is 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. <u>Proposed text:</u> 3. 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 relevant data and trends from defined populations to inform risk assessment and in turn risk management actions that can be taken and to enable the measurement of their impact. An integrated program combines these two components.</p>	<p><b>Australia</b> Suggest the following changes for clarity and consistency:</p> <ul style="list-style-type: none"> <li>• Add the word foodborne to clarify that the scope of the guidelines is foodborne AMR, also for consistency with section 8.</li> <li>• Modification to text to remove the detail to streamline the text.</li> <li>• Addition to text to highlight the importance of risk assessment as well as risk management.</li> <li>• Addition to text to clarify what an integrated program is.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of <u>foodborne</u> AMR and AMU related data and information. Surveillance is 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 <u>risk-based</u> actions that can be taken and to enable the measurement of their impact.</p>	<p><b>Brazil</b></p> <p>Brazil suggests including “foodborne” and “risk-based”, for clarity and to be consistent with the Codex mandate.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of AMR <del>and AMU</del>-related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR <del>and AMU</del>-related data and trends from defined populations to inform <u>risk assessments which contribute to informing risk management</u> actions that can be taken <del>and to</del> <u>by risk managers</u>. <u>Data can help</u> enable the measurement of their <del>impact</del><u>impact of risk management</u>.</p>	<p><b>Chile</b></p> <p>All the information related to AMU should be kept at section 9 as a source of data that should be consider for the interpretation on the AMR monitoring and surveillance results and not be treated with the same importance or relevance as foodborne AMR monitoring and surveillance in this document, that can create the illusion that a country needs to implement both simultaneously. We suggest the same deletion through all section 1.</p> <p>The role of the data collected by the surveillance and monitoring programs in the risk analysis process must be clear and not lead to confusion.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of AMR and AMU related data and information. Surveillance is 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.</p> <p><u>Proposed text:</u></p> <p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of AMR related data and information. Surveillance is 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.</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests to delete the reference of “AMU” in the paragraph 3 (see Proposed text).</p> <p><u>Rationale:</u> We understand the surveillance consider the AMR and AMU, but nevertheless, the AMU is under the management of other international reference organism like OIE or IPPC. And is important the collecting AMR of AMR is part of the risk assessment and data of AMU is generated as a part of management risk. So, this mixed of concepts and actions can make confusing and suplications.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of <u>foodborne</u> AMR and AMU related data and information. Surveillance is 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 <u>risk based</u> actions that can be taken and to enable the measurement of their impact.</p>	<p><b>Japan</b></p> <ul style="list-style-type: none"> <li>• Add "foodborne" <u>Rationale:</u> It is “Foodborne” AMR which is the concern of these Codex guidelines. The mission of the Codex should be respected.</li> <li>• Add "risk based" <u>Rationale:</u> The data from surveillance should be used for risk analysis to develop an action, not be used directly for action.</li> </ul>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of AMR and AMU related data and information. Surveillance is 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.</p>	<p><b>Norway</b></p> <p>Norway supports keeping paragraphs 3 and 4 as agreed by the TFAMR because they apply the broad understanding of integrated monitoring and surveillance program(s) and define the concept of integrated monitoring and surveillance program(s) introduce.</p>

COMMENTS	MEMBER/OBSERVER
<p>3. A los efectos de estas Directrices, por seguimiento se entiende la obtención y el análisis de datos e información relacionados con la RAM y el UAM. Por vigilancia se entiende la medición, 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 el UAM de poblaciones definidas, que sirvan de fundamento para las medidas a tomar <u>basadas en riesgo</u> y permitan la medición de su impacto.</p>	<p><b>Uruguay</b></p> <p>Uruguay considera importante recalcar la necesidad de que los resultados obtenidos de la vigilancia y seguimiento deben ser evaluados en base al riesgo, previo a implementar medidas de gestión específicas.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of <u>AMR foodborne AMR, antimicrobial use (AMU) and/or antimicrobial sales</u>, and <u>AMU</u>-related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of <u>AMR and AMU-related</u> data and trends from defined populations to inform <u>risk assessments which contribute to informing risk management actions that can be taken and to by risk managers. Data can help</u> enable the measurement of <u>their impact</u><del>the impact of risk management measures</del>.</p>	<p><b>USA</b></p> <p>“Foodborne” is the mission of Codex and should be emphasized here in the introduction. The last statement is not accurate or consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011) as written. Wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text. Surveillance data provide information on trends and further inform risk assessments (as per CXG 77-2011).</p> <p>This sentence as written skips the critical stage of evaluating raw data from a surveillance system with other data through risk assessment as described in CXG 77-2011 before determining proportionate risk management actions.</p>
<p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR and AMU. The integrated program(s) 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, plants/crops and the food production environment.</p> <p><u>Proposed text:</u></p> <p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and within the food production environment, and the testing, analysis and reporting of AMR. The integrated program(s) 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, plants/crops and/or the food production environment.</p>	<p><b>Australia</b></p> <p>Suggest the following changes for clarity and consistency:</p> <ul style="list-style-type: none"> <li>• Addition of within the food production environment to be consistent with the scope of the document, and as this level of detail has been removed from principle 2.</li> <li>• Delete the reference to AMU, as the focus of the document is on AMR.</li> <li>• Modification to text to allow flexibility.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
<p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of <del>AMR and AMU</del>AMR. The integrated program(s) includes the alignment and harmonization of sampling, <u>where feasible</u>, testing, analysis and reporting methodologies and practices <u>along food of animal origin or plants/crops production chain</u> as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, plants/crops and the food production <del>environment</del><u>environment from the same food chain</u>.</p>	<p><b>Chile</b></p> <p>Since the different monitoring programs could be host by different government institutions or other stakeholders, the harmonization of sampling will not always be possible.</p> <p>The paragraph should explain better that the integration is not among everything is between the different steps of one food production chain (eg same animal species, same fruit) from farm to fork.</p>

COMMENTS	MEMBER/OBSERVER
<p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR and AMU. The integrated program(s) 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, plants/crops and the food production environment.</p> <p><u>Proposed text:</u></p> <p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR. The integrated program(s) 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, plants/crops and the food production environment.</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests and to delete the AMU approach for this Codex standard (see Proposed text).</p> <p><u>Rationale:</u> The AMU shouldn't have the same weight between AMR, because the Antimicrobial use monitoring is a complex step.</p>
<p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR and AMU. The integrated program(s) 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, plants/crops and the food production <del>environment</del><u>environment in a one health approach</u>.</p> <p><u>Proposed text:</u></p> <p>The integrated program(s) include(s) 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, plants/crops and the food production environment in a one health approach.</p>	<p><b>European Union</b></p> <p>EUMS suggest adding "in a one health approach" to the end of the second sentence. It would read as follows (see Proposed text):</p>
<p>4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR and AMU. The integrated program(s) includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices <del>as well as the so that an</del> integrated analysis of relevant epidemiological information from humans, animals, foods, plants/crops and the food production <del>environment</del><u>environment may be conducted</u>.</p>	<p><b>Japan</b></p> <p>Current description is far beyond the reality of many countries. Analysis of epidemiological information with surveillance results should be the next step.</p>
<p>4. <del>The integrated-Integrated</del> monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of <del>AMR and AMU results</del>. <del>The integrated</del> <del>program(s) includes program(s)</del>, <del>where feasible, include</del> the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from <del>humans</del><u>human foodborne illness data</u>, animals, foods, plants/crops and the food production environment.</p>	<p><b>USA</b></p> <p>Very few countries in the world are able to collect ongoing AMU data through a national program. What if a country cannot collect AMU data? This should be left at "results" for whatever a country can collect, with the addition of "where feasible". Foodborne illness data is the most important information to know for setting up foodborne AMR monitoring/surveillance programs.</p>

COMMENTS	MEMBER/OBSERVER
	If AMR and AMU must stay, the sentence should read “AMU and/or antimicrobial sales” and the following text should be added to acknowledge the difficulty in collecting AMU data. “While concurrent AMU data collection is desirable, when practical, monitoring and measuring actual AMU is complex and based on different data streams and sources than foodborne AMR.”
6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information <del>to risk managers about trends and may serve as inputs</del> for the <del>development of risk analysis processes including assessment which will inform the planning,</del> implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.	<b>Chile</b> The information gathered to surveillance and monitoring should informed the risk assessment process.
6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information to risk managers about trends and may serve as inputs for the risk analysis processes including implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants. <u>Proposed text:</u> 6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information about trends and may serve as inputs for the risk analysis processes including implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.	<b>Australia</b> Delete the reference to 'risk managers', as the data is initially used by risk assessors, who then provide information to risk managers. Suggest editing the text as follows (see Proposed text):
6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information to risk managers about trends and may serve as inputs for the risk analysis processes including implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.	<b>Costa Rica</b> <u>Position:</u> Our country requests to change the word “useful” for “useful”, and provide clarification for the “Additionally, these data may also be use for target epidemiological studies” <u>Rationale:</u> Our country rather the use of a neutral language and is important to be clear that part of the strategies is to be punctual about the information used and relate it to epidemiological studies of interest to be related to AMR.

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u></p> <p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be use for target epidemiological studies, food source attribution studies and research. Additionally, these data could provide information to risk managers about trends and may serve as inputs for the risk analysis processes including implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and <u>hypothesis generation for further</u> research. Additionally, these data provide information to risk managers about trends and may serve as inputs for <del>the risk analysis processes including assessment to inform</del> implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p><b>USA</b></p> <p>1) As written, it is not clear why the term "research" is listed. Text is provided in the first sentence for clarity. Data is useful for hypothesis testing for further research. 2) The text as written in the second sentence jumps from surveillance, which is hazard identification, to risk management, skipping the risk assessment stage which is inconsistent with CXG 77-2011 or CXG 30-1999. Text is added for clarity.</p>
<p>9. The design and implementation of monitoring and surveillance program(s) should be assessed based on their relevance to foodborne AMR priorities at the national and international level.</p> <p><u>Proposed text:</u></p> <p>9. The design and implementation of monitoring and surveillance program(s) should be assessed based on their relevance to foodborne AMR priorities at the national level, and where appropriate, at the international level.</p>	<p><b>Australia</b></p> <p>Modifications to the text to focus initially at the national level as the top priority, and then consider international priorities, as follows (see Proposed text):</p>
<p>9. The design and implementation of monitoring and surveillance program(s) should be assessed based on their relevance to foodborne AMR <u>situation and evolution of the</u> priorities at the national <del>and level and, when appropriate, also consider the</del> international level-.</p>	<p><b>Chile</b></p> <p>The relevance of the situation and evolution of foodborne AMR at national level should be prioritized before international situation. Each country should be able to assess when is appropriate to consider the international situation on their programs.</p>
<p>9. The design and implementation of monitoring and surveillance program(s) should be assessed based on their relevance to foodborne AMR priorities at the national <del>and international</del> level.</p>	<p><b>Japan</b></p> <p>Japan is not aware what is the foodborne AMR priority at international level means.</p>
<p>9. The design and implementation of monitoring and surveillance program(s) should be <del>assessed-re-assessed</del> based on their <u>ongoing</u> relevance <del>to when</del> foodborne AMR priorities <del>at the national and international level</del> evolve.</p>	<p><b>USA</b></p> <p>1) "Re-assessed" may be a more appropriate term if the point is ongoing evaluation.  2) The term evolve may be more proactive than "change".  3) "At the national and international level" is unnecessary and should be deleted as to not cause confusion if an issue is brought up at the international level and bears no pertinence to a country's national conditions or risk.</p>

COMMENTS	MEMBER/OBSERVER
<p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement includes: availability of information on AMU and AMR in humans, animals, plants/crops, availability of food consumption data, agriculture and aquaculture production data, and cross-sector laboratory proficiency and quality assurance and reporting.</p> <p><u>Proposed text:</u></p> <p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement covers: availability of information on AMR and AMU in humans, animals (terrestrial and/or aquatic animal data) and/or plants/crops, availability of food consumption data, and cross-sector laboratory proficiency and quality assurance and reporting.</p>	<p><b>Australia</b></p> <p>Modification to text to reduce duplication in terms, and to provide flexibility in relation to the scope of national program(s), as follows (see Proposed text):</p>
<p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement <del>includes: availability of</del> <u>may include: collecting more</u> information <u>or having new sources of data</u> on AMU and AMR in humans, animals, plants/crops, availability of food consumption data, agriculture and aquaculture production data, and <u>improvement in</u> cross-sector laboratory proficiency and quality assurance and reporting.</p>	<p><b>Canada</b></p> <p>The purpose of the proposed edits is to clarify the sentence and tie in continuous improvement more closely to the expansion of monitoring and surveillance activities. Cross-sector laboratory proficiency and quality assurance and reporting are different in nature from the expansion of data collection; hence, it is suggested to add “improvement” in the relevant part of the sentence.”</p>
<p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. <del>Continuous improvement includes: availability of information on AMU and AMR in humans, animals, plants/crops, availability of food consumption data, agriculture and aquaculture production data, and cross-sector laboratory proficiency and quality assurance and reporting.</del></p>	<p><b>Chile</b></p> <p>The availability of Data from different source it isn't what continuous improvement is. The phrase is prescriptive, and a list of things that doesn't necessarily reflect a continuous improvement.</p>
<p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement includes: availability of information on AMU and AMR in humans, animals, plants/crops, availability of food consumption data, agriculture and aquaculture production data, and cross-sector laboratory proficiency and quality assurance and reporting.</p> <p><u>Proposed text:</u></p> <p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement could include: availability of information on AMU and AMR in humans, animals, plants/crops, availability of food consumption data, agriculture and aquaculture production data, and cross-sector laboratory proficiency and quality assurance and reporting</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country request to include the verb “could”.</p> <p><u>Rationale (1):</u> Our country considers important the use a flexible language in the text of this codex standard.</p> <p><u>Rationale (2):</u> Our country rather the use of a neutral language and is important to be clear that part of the strategies is to be punctual about the information used and relate it to epidemiological studies of interest to be related to AMR.</p>

COMMENTS	MEMBER/OBSERVER
<p>10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement <del>includes</del> <u>is based on consideration of:</u> availability of information on AMU and AMR in humans, animals, <u>and</u> plants/crops; availability of food consumption <del>data,</del> <u>and</u> agriculture and aquaculture production data; <del>and</del> <u>and</u> cross-sector laboratory proficiency and quality assurance and reporting.</p>	<p><b>USA</b></p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in food should not be used to generate unjustified barriers to trade.</p>	<p><b>Australia</b> Australia supports the revised text.</p>
<p>12. These Guidelines should be applied in conjunction with the <i>Code of Practice to Minimize and Contain Antimicrobial Resistance</i> (CXC 61-2005) and the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> (CXG 77-2011). Design and implementation aspects of these Guidelines should <del>specifically</del> take into account the other relevant Codex texts <del>including</del> <u>including, but not limited to,</u> the <i>Principles and Guidelines for National Food Control Systems</i> (CXG 82-2013) or the <i>General Guidelines on Sampling</i> (CXG 50-2004).</p>	<p><b>Chile</b></p>
<p>12. These Guidelines should be applied in conjunction with the <i>Code of Practice to Minimize and Contain Antimicrobial Resistance</i> (CXC 61-2005) and the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance</i> (CXG 77-2011). Design and implementation aspects of these Guidelines should <del>specifically</del> <u>also</u> take into account <del>the</del> other relevant Codex <del>texts</del> <u>texts</u>, including the <i>Principles and Guidelines for National Food Control Systems</i> (CXG 82-2013) <del>or</del> <u>and</u> the <i>General Guidelines on Sampling</i> (CXG 50-2004).</p>	<p><b>USA</b></p>
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration those already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.</p> <p><u>Proposed text:</u></p> <p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. Where appropriate, these Guidelines should also take into consideration those already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.</p>	<p><b>Australia</b></p> <p>Australia supports moving the reference to the OIE to the start of this paragraph to reflect the relevance of the OIE standards to this guideline.</p> <p>Modification to text to provide clarity that the WHO and WHO-AGISAR guidelines are also to be taken into consideration "where appropriate", as follows (see Proposed text):</p>



COMMENTS	MEMBER/OBSERVER
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration those already developed by other advisory <del>bodies</del> <u>bodies, whenever applicable</u>, including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.</p>	<p><b>Brazil</b></p> <p>Brazil suggests including “whenever applicable” to be consistent with the reference to other documents and standards. It is important to include this concept, since it is too broad and unclear to “take into consideration guidelines already developed by other advisory bodies” without any boundaries or flexibility for countries to decide.</p>
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into <del>consideration those already developed by other advisory bodies including consideration, where appropriate</del>, the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.</p>	<p><b>Chile</b></p> <p>Since Codex Document has an impact on food trade we can’t leave an open window for documents developed from any advisory body, which are by the way not developed under members consensus. If there are other relevant document that should be take into consideration, it must be written after the AGISAR.</p>
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration those already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach. <u>When referring to these standards, keep consistent with the latest version of the standards.</u></p>	<p><b>China</b></p>
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration those already developed by other advisory <del>bodies</del> <u>bodies, when applicable</u> including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.</p>	<p><b>Japan</b></p> <p>Guidelines developed by other advisory bodies are non-mandatory. Flexibility should be clearly stated.</p>
<p>13. Cuando corresponda, se deben considerar las normas de otras organizaciones internacionales encargadas de dictar normas, incluidas las normas de la Organización Mundial de Sanidad Animal (las normas de la OIE). Al mismo tiempo, estas Directrices deben utilizarse teniendo en cuenta las ya desarrolladas <del>por otros</del> <u>por</u> organismos asesores, incluido el documento del Grupo Asesor de la Organización Mundial de la Salud (OMS) en Vigilancia Integrada de la RAM (AGISAR-OMS) titulado <i>Vigilancia integrada de la resistencia a los antimicrobianos en bacterias transmitidas por los alimentos: Aplicación del enfoque de Una Salud.</i></p>	<p><b>Uruguay</b></p> <p>A fin de diferenciar claramente el rol de las organizaciones internacionales encargadas de dictar normas con el de los organismos asesores, sugerimos eliminar la palabra “otros”.</p>
<p>13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration <del>these guidance</del> already developed by other advisory <del>bodies</del> <u>bodies</u>, including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach, <u>where appropriate</u>.</p>	<p><b>USA</b></p> <p>The phrase, “Where appropriate” is added at the beginning of the first sentence in reference to OIE, a recognized International Standard Setting Body. It definitely needs to be added in reference to WHO-AGISAR, which is not an international standard setting body.</p>

COMMENTS	MEMBER/OBSERVER
<b>2. SCOPE</b>	
<b>Scope</b>	<b>Switzerland</b> Switzerland supports the recommendation made by the chairs not to reopen this section as these were previously agreed in TFAMR06.
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain and the food production environment. <u>Proposed text:</u> 14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR along the food chain and within the food production environment.	<b>Australia</b> Delete the reference to AMU, as the focus of the document is on AMR, as follows (see Proposed text):
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR <del>and AMU</del> along the food chain and the food production environment.	<b>Brazil</b> Deleting reference to AMU in this specific sentence is consistent to our previous comment once AMU is considered a component of the AMR programs.
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR <del>and AMU</del> along the food chain and the food production environment.	<b>Chile</b> The document is for the integrated monitoring and surveillance of foodborne AMR, the AMU data is something that should be take into consideration for better interpretation of the results.
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain and the food production environment. <u>Proposed text:</u> 14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain and the food production environment.	<b>Costa Rica</b> <u>Position:</u> Our country requests and to delete the AMU approach for this codex standard. <u>Rationale:</u> The AMU shouldn't have the same weight between AMR, because the Antimicrobial use monitoring is a complex step. And this requesting is in line with para 7.
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR <del>and AMU</del> along the food chain and the food production environment.	<b>Japan</b> <u>Rationale:</u> AMU is part of an AMR surveillance system.
14. Estas Directrices abarcan el diseño y la implementación de uno o más programas integrados de seguimiento y vigilancia de la RAM transmitida por los alimentos <del>y del UAM</del> a lo largo de la cadena alimentaria y en el entorno de producción de alimentos.	<b>Uruguay</b> En línea con lo mencionado anteriormente, Uruguay sugiere eliminar la referencia al UAM de esta oración. El UAM es un componente de importancia en los programas integrados de control, pero no debería priorizarse particularmente en el ámbito de aplicación de este documento.
14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU <u>and/or sales data</u> along the food chain and the food production environment.	<b>USA</b> Wherever AMU is mentioned, "AMU and/or sales data" should be mentioned for clarity throughout the text.

COMMENTS	MEMBER/OBSERVER
<p>15. Although these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated program within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans—, <u>when available</u>.</p>	<p><b>Chile</b></p>
<p>15. Although these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated program within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans.</p> <p><u>Proposed text:</u></p> <p>15. Although these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated program within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans, when is possible.</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests the addition of “when is possible” in the end of para. 15.</p> <p><u>Rationale:</u> Our country prefers a flexible language in the text.</p>
<p>17. <b>Antimicrobials used as</b> biocides, including disinfectants, are excluded from the scope of these Guidelines.</p> <p><u>Proposed text:</u></p> <p>We therefore suggest the following amendment:</p> <p>Biocides, including disinfectants, are excluded from the scope of these Guidelines.</p>	<p><b>Norway</b></p> <p>In order to avoid misinterpretation and confusion regarding the term "antimicrobials" we suggest referring directly to biocides and disinfectants. In CXC 53/2003 there is a definition on Biocides.</p> <p>"Biocides—A chemical substance or micro-organism intended to destroy, deter, render harmless or exert a controlling effect on any harmful organism by chemical or biological means."</p>
<b>3. DEFINITIONS</b>	
<p><b>Definitions</b></p>	<p><b>Switzerland</b></p> <p>Switzerland supports the recommendation made by the chairs not to reopen this section as these were previously agreed in TFAMR06.</p>
<p><b>Antimicrobial agent:</b> Any substance of natural, semi-synthetic or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganisms by interacting with a specific target<sup>1</sup>.</p>	<p><b>USA</b></p> <p>This should be footnote #1 and further footnotes should be edited in the final document.</p>
<p><b>Hazard:</b> For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and/or resistance determinant(s), <u>in which resistance is expressed</u><sup>1</sup>.</p>	<p><b>Thailand</b></p> <p>Thailand would like to propose a text change of definition “hazard” to emphasize that resistance determinant(s) must enable microorganisms to exhibit phenotypic resistance to antimicrobials for clarity and consistency with CXG 77-2011. It can be read as “Hazard: For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and/or resistance determinant(s), in which resistance is expressed.”</p>
<p><b>One Health Approach:</b> A collaborative, multisectoral and trans-disciplinary approach working at the local, regional, national and global levels with the goal of achieving optimal health outcomes, recognizing the interconnection between humans, animals, plants and their shared environment.</p>	<p><b>Canada</b></p> <p>The definition of “One Health approach” in this document is slightly different from the definition in the CoP, which is (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text (CoP):</u> A collaborative, multisectoral, and trans-disciplinary approach working with the goal of achieving optimal health outcomes recognizing the interconnection between humans, animals, plants/crops, and their shared environment. It is recommended to use the same definition in both documents.</p>	
<b>4. PRINCIPLES</b>	
Principles	<p><b>Australia</b> Australia supports the removal of AMR and AMU to streamline the principles as this has previously been defined under the scope.</p>
Principles	<p><b>Switzerland</b> Switzerland supports the proposed changes made to this section as they contribute to consistency and clarity of the text.</p>
20.	<p><b>Norway</b> Norway agrees with the Chair and Co-chairs suggestion to remove both “AMR and AMU” in this, as long as this concept is captured within the “integrated monitoring and surveillance for foodborne AMR and AMU” in Paragraph 4 of the Introduction and in the scope of these Guidelines.</p>
<p><b>Principle 1:</b> Monitoring and surveillance program(s) should follow a “One Health” approach. <u>Proposed text:</u> Principle 1: Monitoring and surveillance program(s) should involve a “One Health” approach, where possible.</p>	<p><b>Australia</b> Modification to text to allow flexibility for countries, as follows (see Proposed text):</p>
<p><b>Principle 1:</b> Monitoring and surveillance <del>program(s) should follow</del> <u>program(s) contribute to</u> a “One Health” <del>approach</del> <u>approach for AMR prevention strategies</u>.</p>	<p><b>Brazil</b> Brazil suggests replacing “should follow” by “contribute to” and adding “for AMR prevention strategies” to provide a better distinction on the differences between the “One Health” approach framework related to the national AMR prevention strategies and the need on integrated monitoring and surveillance activities.</p>
<p><b>Principle 1:</b> Monitoring and surveillance program(s) should <u>contribute to the</u> follow a “One Health” <del>approach</del> <u>approach of the AMR National Action Plan</u>.</p>	<p><b>Chile</b></p>
<p><b>Principle 1:</b> Monitoring and surveillance program(s) should follow a “One Health” <del>approach</del> <u>approach and a stepwise approach according to the national situation</u>.</p>	<p><b>China</b> Different countries have different infrastructure, capacity and resources, it would be better to consider the country situation to establish the integrated monitoring and surveillance program.</p>
<p><b>Principle 1:</b> Monitoring and surveillance program(s) should follow a “One Health” approach. <u>Proposed text:</u></p>	<p><b>Costa Rica</b> <u>Position:</u> We requests the addition to the final of the principle “related in the foodborne AMR”. This clarification is in line the para 15.</p>

COMMENTS	MEMBER/OBSERVER
Principle 1: Monitoring and surveillance program(s) should follow a “One Health” approach related in the foodborne AMR.	<u>Rationale</u> : The scope of “One Health” is extremely broad, beyond the food chain, this document must work on the food chain under the mandate of CODEX and according the amendment requested in para 1.
<b>Principio 1:</b> Los programas de seguimiento y vigilancia deben <del>seguir el enfoque</del> <u>incluir todos los sectores y disciplinas a lo largo</u> de <del>«Una Salud»</del> <u>la cadena alimentaria</u> .	<b>Honduras</b> Incluso cuando el enfoque de "Una sola salud" se define en el documento, el concepto es más amplio que la definición y podría implicar aspectos que están fuera del mandato del Codex Alimentarius, por lo que el principio 1 debería de ser acorde al alcance del documento.
<b>Principle 2:</b> Monitoring and surveillance program(s) are an important part of national strategies to minimize and contain the risk of foodborne AMR. <u>Proposed text:</u> Principle 2: Monitoring and surveillance program(s) are an important part of national strategy(ies) to minimize and contain the risk of foodborne AMR.	<b>Australia</b> Australia supports moving this principle up to principle 3, and suggests editing the text as follows (see Proposed text):
<b>Principle 2:</b> Monitoring and surveillance program(s) are an important part of national strategies to <u>assess and then</u> minimize and contain the risk of foodborne AMR.	<b>Chile</b> Monitoring and surveillance are tools that provides data that will be used by countries to assess first and then mitigate.
<b>Principle 3:</b> Risk analysis <del>should</del> <u>can</u> guide the design, implementation and evaluation of monitoring and surveillance program(s).	<b>China</b>
<b>Principle 3:</b> Risk analysis should guide the design, implementation and evaluation of monitoring and surveillance program(s). <u>Proposed text:</u> Principle 3: Risk analysis should guide the design, implementation and evaluation of monitoring and surveillance program(s) and risk management actions.	<b>Australia</b> Addition to text to clarify the sequence in the approach, as follows (see Proposed text):
<b>Principle 4:</b> Monitoring and surveillance program(s) should include data on AMR and AMU, in relevant sectors as inputs into risk analysis. <u>Proposed text:</u> Principle 4: Monitoring and surveillance program(s) should include data on AMR, in relevant sectors as inputs into risk analysis.	<b>Australia</b> Delete the reference to AMU, as the focus of the document is on AMR, as follows (see Proposed text):
<b>Principle 4:</b> Monitoring and surveillance program(s) should <del>include</del> <u>be designed to generate</u> data on AMR and AMU, in relevant sectors <del>as inputs into</del> <u>to inform</u> risk analysis.	<b>Canada</b> Edits provided to enhance clarity of the principle.
<b>Principle 4:</b> Monitoring and surveillance program(s) should <del>deliver</del> include data on <u>foodborne</u> AMR <del>and AMU</del> <u>national situation and, when available, AMU or sales data</u> , in relevant sectors as inputs into risk analysis.	<b>Chile</b> Monitoring and surveillance programs are establish by countries in order to collect data, not to include it.

COMMENTS	MEMBER/OBSERVER
<p><b>Principle 4:</b> Monitoring and surveillance program(s) should <del>include</del> <u>generate</u> data on AMR and AMU, in relevant sectors as inputs into risk analysis.</p> <p><u>Proposed text:</u></p> <p><b>Principle 4:</b> Monitoring and surveillance program(s) should generate data on AMR and AMU in relevant sectors as inputs into risk analysis.</p>	<p><b>European Union</b></p> <p>EUMS suggest to replace wording “include” by the wording “generate”, as new data should be “generated” either based on sampling + laboratory investigations + evaluation (AMR) and/or data collection + evaluation (AMU).</p> <p>The sentence should read as follows (see Proposed text):</p>
<p><b>Principle 4:</b> Monitoring and surveillance program(s) should include data on <u>foodborne</u> AMR and AMU, in relevant sectors as inputs into risk analysis.</p>	<p><b>Japan</b></p> <p>“foodborne” should not be omitted.</p>
<p><b>Principle 4:</b> Monitoring and surveillance program(s) should include data on <u>foodborne</u> AMR <del>and AMU</del> <u>and, in as appropriate to national circumstances, AMU and/or antimicrobial sales and other related data from</u> relevant sectors as inputs into risk analysis.</p>	<p><b>USA</b></p> <p>The focus for Codex guidance should be foodborne AMR which poses a risk to food safety. Globally, most countries are unable to collect AMU data. Edits are made to make this principle more globally achievable.</p>
<p><b>Principle 5:</b> Monitoring and surveillance program(s) should be tailored to national priorities and <del>may</del> <u>should</u> be designed and implemented with the objective of continuous improvement as resources permit.</p>	<p><b>Canada</b></p> <p>It is recommended to replace “may” with “should”. Surveillance programs should always be evaluated, improved and refined over time.</p>
<p><b>Principle 5:</b> Monitoring and surveillance program(s) should be tailored to national priorities and may be designed and <del>implemented with</del> <u>implemented to allow</u> the <del>objective of</del> continuous improvement as resources permit.</p>	<p><b>Chile</b></p> <p>The continuous improvement should not be the objective of the surveillance program design.</p>
<p><b>Principle 5:</b> Monitoring and surveillance program(s) should be tailored to national priorities and may be designed and implemented <u>with the objective of to allow</u> continuous improvement as resources permit.</p>	<p><b>Japan</b></p> <p>Improvement is not an objective of designing and implementing the programs.</p>
<p><b>Principle 6:</b> Priority for implementation should be given to the most relevant foodborne AMR issues ((combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s)) to be analyzed from a public health perspective.</p>	<p><b>Australia</b></p> <p>Australia supports inclusion of this text as it provides clarity and reflects the Codex Guidelines for risk analysis of foodborne antimicrobial resistance (CXG 77-2011).</p>
<p><b>Principle 6:</b> Priority for implementation <u>of monitoring and surveillance program(s)</u> should be given to the most relevant foodborne AMR issues ((combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s)) to be analyzed from a public health perspective.</p>	<p><b>Canada</b></p> <p>Text added to improve clarity of the principle.</p>
<p><b>Principle 6:</b> Priority for implementation should be given to the most relevant foodborne AMR issues ((combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial <del>agent(s))</del> <u>agent(s) to which resistant is expressed</u> to be analyzed from a public health perspective.</p>	<p><b>Chile</b></p> <p>From GL 77</p>
<p><b>Principle 6:</b> Priority for implementation should be given to the most relevant foodborne AMR issues <del>((combinations (combinations</del> of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s)) to be analyzed from a public health perspective.</p>	<p><b>European Union</b></p> <p>EUMS note that there is an extra parenthesis in principle 6 to be deleted.</p>

COMMENTS	MEMBER/OBSERVER
<p><b>Principle 6:</b> Priority for implementation should be given to the most relevant foodborne AMR issues (<del>combinations-combinations</del> of the food commodities, <del>the microorganism-microorganisms</del> and resistance <del>determinants-determinants</del>, and the antimicrobial <del>agent(s)-agent(s)</del> to be <del>analyzed-analyzed</del>) from a <u>national</u> public health perspective.</p>	<p><b>USA</b> Add “national” as this principle begins with “priorities” and priorities should be for national contexts.</p>
<p><b>Principle 7:</b> Monitoring and surveillance program(s) should incorporate to the extent practicable, the identification of new and emerging foodborne AMR or trends and to <del>facilitate-inform</del> epidemiological investigation.</p>	<p><b>Chile</b></p>
<p><b>Principle 7:</b> Monitoring and surveillance program(s) should <del>incorporate-incorporate</del>, to the extent practicable, the identification of new and emerging foodborne AMR or trends and <u>should be designed</u> to facilitate epidemiological investigation.</p>	<p><b>USA</b></p>
<p><del>Principle 8: Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place.</del></p>	<p><b>China</b> The principle 8 can be deleted, it is already mentioned in section 8.5 laboratories.</p>
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to ensure that data are comparable, to facilitate sharing of data and to enhance an integrated approach to data management.</p> <p><u>Proposed text:</u> Principle 9: Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to ensure that data are comparable, to facilitate sharing of data and to enhance an integrated approach to data management, where appropriate.</p>	<p><b>Australia</b> Addition to text to allow flexibility for countries, as follows (see Proposed text):</p>
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to ensure that data are comparable, <del>to facilitate sharing of data</del> and to enhance an integrated approach to data management.</p>	<p><b>Brazil</b> Brazil suggests deleting “to facilitate sharing of data”, because the purpose of harmonizing is to ensure data are comparable to allow integration. “Sharing data” is unclear and outside the scope of this Task Force, therefore, this concept should not be included in a principle.</p>
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across sectors <del>according to national priorities and resources</del> as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria, where available, <del>is essential to ensure ensures</del> that data are comparable, <del>to facilitate-facilitates</del> sharing of data and <del>to enhance-enhances</del> an integrated approach to data management <u>and analysis</u>.</p>	<p><b>Canada</b> It is suggested to delete the text “according to national priorities and resources” since it is repetitive of Principle 5 which already states “program(s) should be tailored to national priorities... as resources permit”. Further minor edits are provided to enhance clarity and readability of the principle.</p>

COMMENTS	MEMBER/OBSERVER
	Addition of “and analysis” was made to the text. Harmonization and standardization are not only needed for just data management, but analysis as well. We cannot analyse the data if they are not comparable. In fact, we may be able to have non-harmonized data in our central repository, but we cannot integrate it.
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to <del>ensure</del> <u>facilitate</u> that data are comparable, <del>and to facilitate sharing the interpretation and report</del> of data and to enhance an integrated approach to data <del>management</del><u>management at national level</u>.</p>	<p><b>Chile</b> The harmonization should be focus on the reporting, interpretation and comparison, being more appropriate than to focus on sharing.</p>
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to ensure that data are comparable, <del>to facilitate sharing of data</del> and to enhance an integrated approach to data management.</p>	<p><b>Japan</b> Sharing of data is not suitable. This sentence is focused on facilitating data comparisons.</p>
<p><b>Principle 9:</b> Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across 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, is essential to <del>ensure that data are comparable, to</del> facilitate <del>sharing of comparable</del> data <u>interpretation</u> and <u>reporting, and</u> to enhance an integrated approach to data management.</p>	<p><b>USA</b> Sharing of data is outside the scope of this sentence. This sentence is focused on facilitating data comparisons. International harmonization documents typically discuss facilitating comparability over data sharing. The goal of data harmonization is to allow for comparable data interpretation. Data reporting is more appropriate here than the term “sharing”.</p>
<b>5. RISK-BASED APPROACH</b>	
<p>21. For the purpose of these Guidelines, a risk-based approach is <del>described in the development and implementation of monitoring and surveillance program(s) informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health-CXG 77</del></p>	<p><b>Chile</b> This Guideline can't establish a different concept regarding risk analysis, the 3 standards should link to each other and not be contradictory.</p>
<p>21. For the purpose of these Guidelines, a risk-based approach is the development and implementation of monitoring and surveillance program(s) informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health. <u>Proposed text:</u> 21. For the purpose of these Guidelines, a risk-based approach is the development and implementation of monitoring and surveillance program(s) informed by data and scientific knowledge on the likely occurrence of foodborne AMR potential risk to human health along the food.</p>	<p><b>Costa Rica</b> <u>Position:</u> Our country requests and amendment in the end of the para 21. <u>Rationale:</u> Our opinion is that is important to focus to risk-based approach. The hazards or other components are part of the process to determinate the potential risks from AMR.</p>



COMMENTS	MEMBER/OBSERVER
<p>21. <del>For the purpose of these Guidelines, a</del> risk-based approach <del>for microbial hazards</del> is described in the <del>development Principles</del> and <del>implementation of monitoring and surveillance program(s) informed by data and scientific knowledge on Guidelines for the likely occurrence</del> Conduct of foodborne AMR hazards along the food chain and their potential <del>Microbiological Risk Assessment (CXG 30-1999)</del>. <del>Microbiological risk assessment should be conducted according to pose risks to human health</del> a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.</p>	<p><b>USA</b></p> <p>The TFAMR should not be changing what a risk-based approach is and say that it is for the “purpose of these Guidelines”. Paragraph 21 is inconsistent with CAC GL 30 as written. Monitoring and surveillance data inform hazard Identification. They do not in themselves define a risk-based approach.</p> <p>It is better to reference existing Codex guidance, the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999) and insert text directly from it. Text is provided from Section 3, General Principle 3: “Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.”</p>
<p>22. Information from monitoring and surveillance program(s) including data from other sources when available, are important for risk assessment and risk management decision-making on the appropriateness of the control measures to minimize and contain foodborne AMR.</p> <p><u>Proposed text:</u></p> <p>22. Information from monitoring and surveillance program(s) including data from other sources when available, are important for risk assessment, which inform risk management decision-making, on the appropriateness of the control measures to minimize and contain foodborne AMR.</p>	<p><b>Australia</b></p> <p>Modification to text to provide clarity that risk assessment occurs prior to risk management, and informs risk management decisions, as follows (see Proposed text):</p>
<p>22. Information from monitoring and surveillance program(s) <del>including and available</del> data from other sources <del>when available</del>, are important for risk assessment and risk management decision-making on the appropriateness of the control measures to minimize and contain foodborne AMR.</p>	<p><b>Canada</b></p> <p>Edits provided to enhance clarity of the sentence.</p>
<p>22. Information from monitoring and surveillance program(s) including data from other sources when available, are important for <del>inform</del> risk assessment <del>and to procedure the follow step</del>, risk management decision-making on the appropriateness of the control measures to minimize and contain foodborne AMR-.</p>	<p><b>Chile</b></p> <p>It should be consistent along the GLIS, that the surveillance data should informed a risk assessment and then the results from this the risk management. Risk management should not be done only based in data.</p>
<p>22. Information from monitoring and surveillance program(s) including data from other sources when available, are important for <del>inform</del> risk assessment <del>and which lead to</del> risk management decision-making on the appropriateness of the control measures to minimize and contain foodborne AMR.</p>	<p><b>Japan</b></p> <p>The surveillance data should inform a risk assessment and then the results from such risk assessment is used to develop risk management measures.</p>
<p>22. Information from monitoring and surveillance program(s) <del>including data from as well as</del> other sources <del>when available</del> of information described under "Foodborne AMR Risk Assessment" in <del>CAC/GL-77</del>, are important for risk assessment and risk management decision-making <del>and may inform decisions</del> on the appropriateness of <del>the</del> control measures to minimize and contain foodborne AMR.</p>	<p><b>USA</b></p> <p>1) Text is added to be consistent with sources of information for risk analysis in CAC/GL-77 as the text as currently written does not provide clarity on what sources are being referenced.</p> <p>2) The appropriateness of a control measure is not always provided through surveillance so further clarification is provided.</p>

COMMENTS	MEMBER/OBSERVER
<p>23. When knowledge of AMR within a country is limited, monitoring and surveillance program(s) may initially be designed according to the relevant evidence 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 the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)</i>.</p> <p><u>Proposed text:</u></p> <p>23. When information or data on foodborne AMR within a country is limited, monitoring and surveillance program(s) may initially be designed according to the relevant scientific evidence 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 the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)</i>.</p>	<p><b>Australia</b></p> <p>Modification to text to improve clarity, as follows (see Proposed text):</p>
<p>23. When <del>knowledge information or data</del> of <u>foodborne</u> AMR within a country is limited, monitoring and surveillance program(s) may initially be designed according to the relevant <u>scientific</u> evidence that is available on AMR hazards and their potential to result in public health risks. AMR <del>food safety</del> <u>foodborne</u> issues may be identified on the basis of information arising from a variety of sources, as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)</i>.</p>	<p><b>Chile</b></p>
<p><del>23. When knowledge of AMR within a country is limited, monitoring and surveillance program(s) may initially information on hazards can be designed according to obtained from scientific literature; from databases such as those maintained by the food industry, government agencies and relevant evidence that is available on AMR hazards international organizations; and through solicitation of opinions of experts. Relevant information includes data from clinical studies; epidemiological studies and surveillance; laboratory animal studies; investigations of the characteristics of microorganisms and the interaction between microorganisms and their potential environment through the food chain from primary production up to result in public health risks, and including consumption; and studies on similar or related microorganisms and situations.</del> AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in the <i>Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)</i>.</p>	<p><b>USA</b></p> <p>The first sentence under paragraph 23 does not provide clarity or guidance. We recommend including text directly from CXG 30-1999 Section 4.3 that provides good guidance on what type of data countries should be seeking to include: "Information on hazards can be obtained from scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts.</p> <p>Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations."</p>
<p>24. The implementation and continuous improvement of an integrated monitoring and surveillance program(s) should improve the quality of data generated for risk analysis.</p> <p><u>Proposed text:</u></p> <p>24. The implementation and continuous improvement of an integrated monitoring and surveillance program(s) should improve the quality of data generated for risk analysis and risk management.</p>	<p><b>Australia</b></p> <p>Addition to text to clarify the sequence in the approach, as follows (see Proposed text):</p>
<p><del>24. The implementation and continuous improvement of an integrated monitoring and surveillance program(s) should improve the quality of data generated for risk analysis.</del></p>	<p><b>Canada</b></p> <p>This paragraph does not provide added guidance, rather it states a fact of monitoring and surveillance program(s). It is proposed to delete this sentence.</p>

COMMENTS	MEMBER/OBSERVER
24. The implementation and continuous improvement of an integrated monitoring and surveillance program(s) <del>should</del> <u>can</u> improve the quality of data generated for risk analysis.	<b>China</b>
<b>6. REGULATORY FRAMEWORKS, POLICY AND ROLES</b>	
<p>25. Integrated monitoring and surveillance program(s) requires good governance by the competent authorities. As part of national action plans (NAP) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain should ensure collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p> <p><u>Proposed text:</u></p> <p>25. Integrated monitoring and surveillance program(s) requires good governance by the relevant authorities. As part of national action plans (NAP) for AMR, the relevant authorities responsible for the monitoring and surveillance activities along the food chain within the food production environment, should ensure collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p>	<p><b>Australia</b></p> <p>For clarity and flexibility, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to replace 'competent' with 'relevant', as 'competent authorities' does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships.</li> <li>• Addition of 'within the food production environment' to be consistent with the scope of the document, and as this level of detail has been removed from principle 2.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
25. Integrated monitoring and surveillance program(s) requires good governance by the competent authorities. As part of national action plans (NAP) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain should ensure collaboration with human health, animal health, plant health, the environment and other relevant authorities, <u>as appropriate</u> .	<b>Chile</b>
25. Integrated monitoring and surveillance program(s) requires good governance by the competent authorities. As part of national action plans (NAP) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain should ensure collaboration with human health, animal health, plant health, <del>the</del> environment and other relevant authorities.	<b>USA</b>
26. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).	<p><b>Australia</b></p> <p>Delete 'of foodborne AMR and AMU' as this not required, it is covered under the scope.</p>
26. Activities related to monitoring and surveillance of foodborne <del>AMR and AMU</del> <u>AMR</u> should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).	<p><b>Brazil</b></p> <p>Deleting reference to AMU in this specific sentence is consistent to our previous comment once AMU is considered a component of the AMR programs.</p>
26. Activities related to monitoring and surveillance of foodborne AMR <del>and AMU</del> should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).	<b>Chile</b>
26. Las actividades relacionadas con el seguimiento y la vigilancia de la RAM transmitida por los alimentos <del>y el UAM</del> deben concernir a una amplia gama de partes interesadas que puedan contribuir al desarrollo, la implementación y la evaluación de programas integrados de seguimiento y vigilancia.	<p><b>Uruguay</b></p> <p>En base a lo ya comentado anteriormente, Uruguay sugiere remover la mención al UAM de la oración.</p>

COMMENTS	MEMBER/OBSERVER
<p>26. Activities related to monitoring and surveillance of foodborne AMR and AMU <a href="#">and/or sales data</a> should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).</p>	<p><b>USA</b></p> <p>Wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text.</p>
<p>27. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment and risk management decisions.</p> <p><u>Proposed text:</u></p> <p>27. Sharing of knowledge and data between stakeholders should be encouraged since it may improve the understanding of foodborne AMR, and inform risk assessments, and in turn risk management decisions, where appropriate.</p>	<p><b>Australia</b></p> <p>For clarity and flexibility, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Addition of 'between' to reflect business models of sharing responsibilities and solid partnerships.</li> <li>• Delete 'international and global' text, as internationally there is no agreed system for AMR data sharing.</li> <li>• Modification to text to provide clarity that risk assessment occurs prior to risk management, and informs risk management decisions.</li> <li>• Addition to text to allow flexibility for countries.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
<p>27. Sharing of <del>knowledge and data</del> <a href="#">knowledge</a> internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment and risk management decisions.</p>	<p><b>Brazil</b></p> <p>Brazil suggests deleting “and data” once this is still unclear and outside the scope of this Task Force, consistent with the comments provided for Principle 9.</p>
<p>27. Sharing of knowledge and data internationally and with stakeholders should be <del>encouraged</del> <a href="#">encouraged, when appropriate</a>, since it may improve the global understanding of foodborne AMR and inform risk assessment <del>and which enable</del> risk management decisions.</p>	<p><b>Chile</b></p>
<p>27. Sharing of knowledge and data internationally and with stakeholders <del>should be</del> <a href="#">is</a> encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment and risk management decisions.</p>	<p><b>China</b></p>
<p>27. Sharing of knowledge and data internationally and with stakeholders <a href="#">and the public</a> should be encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment <del>and as well as</del> risk management decisions.</p> <p><u>Proposed text:</u></p> <p>Sharing of knowledge and data internationally, with stakeholders and the public should be encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment as well as risk management decisions.</p>	<p><b>European Union</b></p> <p>EUMS suggest to add the public as a separate stakeholder to emphasize that data should be made available for all. Furthermore, a slight amendment is proposed for clarity as regards to “inform risk assessment as well as risk management decisions”. This should reflect the intended meaning, namely that conclusions are based on risk assessment and recommendations are leading to risk management decisions.</p> <p>The sentence should read (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p>27. Sharing of knowledge and <a href="#">reporting data internationally and with stakeholders</a> should be encouraged since it may improve the global understanding of foodborne AMR and inform risk <a href="#">assessment and risk management decisions analysis</a>.</p>	<p><b>USA</b></p> <p>The intent of this sentence is unclear. Data reporting covers all parties whether domestic, international, or stakeholders, so text is modified to reflect that. Data reporting informs risk communication in addition to risk assessment and risk management, so the term, “risk analysis” is more appropriate.</p>
<p>28. It is important for competent authorities to have access to all available sources of AMU data in their country.</p> <p><u>Proposed text:</u></p> <p>28. It is important for the relevant authorities to consider all available sources of relevant data in their country.</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships.</li> <li>• Modification to text as legal requirements are outside the remit of Codex, and it is important to consider all relevant data.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
<p>28. It is important for competent authorities to <del>have access to consider</del> all available sources of <del>AMU relevant</del> data in their country.</p>	<p><b>Chile</b></p>
<p>28. It is important for competent authorities to <del>have access to consider</del> all available sources of <del>AMU relevant</del> data in their country.</p>	<p><b>USA</b></p> <p>The sentence as written appears to prescribe what competent authorities should have access to, which delves into national legislation, which is beyond the role of Codex. Text is modified to put the onus on competent authorities to consider all data sources. What is the purpose of this sentence being limited to AMU data? All data should be considered.</p>
<p><b>7. PRELIMINARY ACTIITIES ON THE IMPLEMENTATION OF AN INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR FOODBORNE AMR</b></p>	
<p><u>Proposed text:</u></p> <p>7. Preliminary activities towards the implementation of an integrated monitoring and surveillance program(s) for foodborne AMR</p>	<p><b>Australia</b></p> <p>Australia supports the addition of preliminary activities to the title, as it streamlines the numbering system for the sub-sections.</p> <p>For clarity, suggest modification to the text, as follows (see Proposed text):</p>
<p><u><a href="#">28a bis The framework for integrated monitoring and surveillance program(s) is shown in Figure 1, which is intended to provide input to and be informed by the Guidelines for Risk Analysis [LX(1) of Foodborne Antimicrobial Resistance (CXG 77-2011) and Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005).</a></u></p>	<p><b>Canada</b></p> <p>It is proposed to add this paragraph to include reference to Figure 1 in the text. The figure is a key illustrative diagram but is not cited in the text. This would also be consistent with other Codex documents that include Figures, and where the text includes reference to the figures.</p>

COMMENTS	MEMBER/OBSERVER
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights the design for monitoring and surveillance program(s).</p> <p><u>Proposed text:</u></p> <p>29. Preliminary activities, performing monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous improvement allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights for the design and/or implementation of monitoring and surveillance program(s).</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to use the word performing as it provides clarity that these activities will be ongoing.</li> <li>• Modification to text as pilot studies have more benefits than just design.</li> </ul> <p>To incorporate the above changes, suggest editing the text, as follows (see Proposed text):</p>
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous <u>improvement</u> allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights the design for monitoring and surveillance program(s).</p>	<p><b>Brazil</b></p> <p>Include “improvement”.</p>
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). <u>The concept of Countries should strive for</u> continuous <del>allows countries to carry out improvement in</del> activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights <u>into</u> the design for monitoring and surveillance program(s).</p>	<p><b>Canada</b></p> <p>Edits provided to enhance clarity and readability. The word “improvement” was missing from continuous in the second sentence. Suggested text was inserted to place emphasis on countries striving for continuous improvement.</p>
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of <u>continuous continuity</u> allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights the design for monitoring and surveillance program(s).</p>	<p><b>China</b></p>
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous <u>improvement</u> allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights <u>into</u> the design <del>for of</del> monitoring and surveillance program(s).</p>	<p><b>European Union</b></p> <p>EUMS agree with the revised ordering of sentences and wording of the paragraph, but the language needs to be improved.</p> <p>The second and third sentences may read as follows (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u> The concept of continuous improvement allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights into the design of monitoring and surveillance program(s).</p>	
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous <u>improvement</u> allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights <u>into</u> the design <del>for of</del> monitoring and surveillance program(s).</p> <p><u>Proposed text:</u> The concept of continuous improvement allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights into the design for of monitoring and surveillance program(s).</p>	<p><b>Norway</b> Norway agrees with the revised ordering of the sentences; however we see that some wording is missing in the second and third sentence. We suggest the wording to be as follows (see Proposed text):</p>
<p>29. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s). The concept of continuous <u>improvement</u> allows countries to carry out activities <del>to and make</del> progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Undertaking pilot studies and testing may provide valuable insights <u>for</u> the design <del>for of</del> monitoring and surveillance program(s).</p>	<p><b>USA</b> The sentence structure was incomplete.</p>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p> <p><u>Proposed text:</u> Figure 1. Framework for integrated monitoring and surveillance program(s) for foodborne AMR along the food chain.</p>	<p><b>Australia</b> Edit this text to the following (see Proposed text): Modify the figure to the following:</p> <ul style="list-style-type: none"> <li>• Reduce the size of the AMU component box as the focus of this document is AMR. For this document, AMU is only a component of AMR, and the AMU component is related to work by other international bodies - the figure should be representative of this.</li> <li>• Edit the AMU component box to remove the detail, as shown below: AMU component</li> <li>• Program design</li> <li>• Sources of data</li> <li>• Collection and reporting of AMU data</li> </ul>

COMMENTS	MEMBER/OBSERVER
<del>Figure 1. Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</del>	<p><b>Brazil</b></p> <p>Brazil suggests deleting Figure 1 to avoid confusion or misinterpretation once it does not add value to the document and it does not present an adequate reflection of the Guidelines.</p>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p><b>Canada</b></p> <p>This figure is not cited in the text (see comment on new Paragraph 28a.(bis) and should be inserted, as well as in the footnote.</p>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p><b>Chile</b></p> <p>Delete AMU component from the figure. It is not accurate with the scope and can lead to mis interpretation of the component that need to be integrated.</p>
<p><b>Figure 1</b></p>	<p><b>Egypt</b></p> <p>Egypt wants to add the following comments on this figure:</p> <ul style="list-style-type: none"> <li>• Add "data management" to "AMA component" column and analysis and reporting of results.</li> <li>• Add "Design of an integrated monitoring and surveillance program for antimicrobial agents intended for use in animals or plants/crops" to "AMU component" column.</li> </ul>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p><b>European Union</b></p> <p>EUMS consider figure 1 as essential in order to provide a visual summary of the whole GLIS within the framework of Codex Alimentarius and its most relevant texts. Moreover, this figure contributes to the understanding of the components of GLIS and the interaction between them.</p>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p><b>Japan</b></p> <p>Delete this figure or at least substantially revise it by removing “AMU component” concept.</p> <p>After substantial discussion followed by changes of the draft guidelines, this figure does not depict the framework/flow of the guidelines. Especially, Japan reiterates that these guidelines are for AMR surveillance and that AMU monitoring is recommended in order to support the interpretation of AMR surveillance results. The parallel notation of AMR and AMU is not what we want.</p>
<p><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p><b>Norway</b></p> <p>Norway supports retaining figure 1 because this figure provides a visual summary of the concept "integrated monitoring and surveillance program (s) for foodborne AMR and AMU along the food chain". It also contributes to the understanding of the GLIS by displaying both the different components and their interactions.</p>



COMMENTS	MEMBER/OBSERVER
<p><b>Figure 1</b></p>	<p><b>Thailand</b></p> <p>Figure 1, Codex texts listed in the second item of figure note should be updated as “the Codex Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance” and “the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance”</p>
<p><del><b>Figure 1.</b> Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</del></p>	<p><b>USA</b></p> <p>Recommend deletion of the figure since preliminary activities are not consistent in presentation and lack parallel construction. Figures without in-depth figure captions must be intuitive and connect parts of a whole in a logical manner that allows the reader to better understand relationships that are difficult to textually explain. This figure does not meet these criteria. The Task Force should concentrate efforts on getting the text correct in the remaining time.</p>
<p><b>7.1 ESTABLISHING THE MONITORING AND SURVEILLANCE OBJECTIVES</b></p>	
<p>30. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programs, the AMR NAPs, relevant information on AMR and AMU in the country, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop and the environment). Competent authorities should identify the challenges they currently face during the implementation of these activities.</p> <p><u>Proposed text:</u></p> <p>30. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the authorities and stakeholders and should take into consideration existing food safety programs, the AMR NAPs, relevant information on AMR and AMU in the country, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop and the environment). Relevant authorities should identify the challenges they currently face during the implementation of these activities.</p>	<p><b>Australia</b></p> <p>Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):</p>
<p>30. The establishment of monitoring and surveillance objectives <del>should</del> <u>can</u> be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programs, the AMR NAPs, relevant information on AMR and AMU in the country, as well as any existing activities to address AMR in the different sectors (human, <u>food</u>, animal, plant/crop and the environment). Competent authorities should identify the challenges they currently face during the implementation of these activities.</p>	<p><b>China</b></p>

COMMENTS	MEMBER/OBSERVER
<p>30. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programs, the AMR NAPs, relevant information on AMR and AMU <u>and/or sales data</u> in the country, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop and the environment). Competent authorities should identify the challenges they currently face during the implementation of these activities.</p>	<p><b>USA</b> Wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text.</p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li>The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk <del>assessments and risk management</del><u>assessments</u>, to obtain baseline information).</li> </ul>	<p><b>Chile</b></p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li>The representativeness of the data collection (e.g., random or systematic sampling).</li> </ul> <p><u>Proposed text:</u></p> <ul style="list-style-type: none"> <li>The representativeness of the data collection (e.g., randomized samples; systematic sampling).</li> </ul>	<p><b>Australia</b> Modification to text as random samples do not equate to systematic sampling, this relates to the type of sampling plan, as follows (see Proposed text):</p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li>The representativeness of the data <del>collection (e.g., random or systematic sampling).</del></li> </ul>	<p><b>Chile</b> Sampling type should be choose by each country. The example should say Type of sampling, instead of propose samplings</p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li>The setting of <u>sampling design and</u> proposed timelines for sampling and reporting.: <u>Establish a methodology on how to handle and analyze the collected data</u></li> </ul>	<p><b>Chile</b> Is a point missing in 7.1 “Establish a methodology on how to handle and analyze the collected data”</p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li><u>A description of How</u> the information will be reported and communicated (e.g., publication of <del>report</del><u>report</u>) <u>and to whom</u>.</li> </ul>	<p><b>Canada</b> Delete to align text with the chapeau statement of Para 31. Text addition of “and to whom”. It is not just how the information will be reported, but who the information should be reported to.</p>
<p>31. The following aspects should be considered:</p> <ul style="list-style-type: none"> <li>A description of how the information will be reported and communicated (<del>e.g., publication of report</del>).</li> </ul>	<p><b>Chile</b> Example is not needed here, the text by itself is enough.</p>
<p><b>7.2 CONSIDERATIONS FOR PRIORITIZATION</b></p>	
<p>32. 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 systems, food distribution, food consumption patterns and food exposure pathways.</p>	<p><b>Australia</b> Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u></p> <p>32. When establishing monitoring and surveillance priorities, authorities should consider the epidemiology and public health implications of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways</p>	
<p>32. When establishing monitoring and surveillance priorities, competent authorities <del>should consider</del> <u>may consider, but not limited to,</u> the <u>national</u> epidemiology and public health implications of foodborne AMR, AMU patterns, information on food production systems, food distribution, food consumption patterns and food exposure pathways.</p>	<p><b>Chile</b></p> <p>For flexibility, AMU patterns and food consumption patterns are not easy to determine for low or middle income countries.</p>
<p>32. When establishing monitoring and surveillance priorities, competent authorities should consider the epidemiology and public health implications of foodborne AMR, AMU patterns, <u>and</u> information on food production systems, food distribution, food consumption patterns and food exposure <u>pathwayspathways to the extent data are available</u> .</p>	<p><b>USA</b></p> <p>Additional test added for flexibility.</p>
<p>33. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents 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 on AMR and AMU including data required for risk analysis or results of risk analysis.</p> <p><u>Proposed text:</u></p> <p>33. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents and sample sources should be informed by national, regional and international public health data and scientific evidence where it exists. Relevant authorities should identify existing data sources and data gaps, including data required for foodborne AMR risk analysis.</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships.</li> <li>• Modification to the text as the focus of the Guideline is foodborne AMR.</li> <li>• Remove the last part of the sentence as it not necessary.</li> </ul> <p>To incorporate the above changes, suggest editing the text, as follows (see Proposed text):</p>
<p>33. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents and sample sources should be informed by national, <u>and when appropriate,</u> regional and international public health data and <del>knowledge scientific evidence</del> where it exists. Competent authorities should identify existing data sources and gaps on <u>foodborne</u> AMR <del>and AMU</del> including data required for risk <del>analysis or results of risk analysis-</del></p>	<p><b>Chile</b></p>
<p>33. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents 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 on <u>foodborne</u> AMR and AMU including data <del>required</del> for <u>foodborne AMR</u> risk <del>analysis or results of risk analysis-</del> <u>as appropriate for national circumstances.</u></p>	<p><b>USA</b></p> <p>As written, the last sentence is unclear and appears prescriptive, particularly with the sentence preceding it that includes being informed by “international” public health data. For example, “data required” by whom? Text to allow for clarity and to keep within Codex scope of food safety is inserted.</p>
<p><b>7.3 INFRASTRUCTURE AND RESOURCES</b></p>	
<p>34. Once the objectives and priorities have been established, the competent authorities should determine the infrastructure, capacity and resources required to meet the objectives.</p>	<p><b>Australia</b></p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u> 34. Once the objectives and priorities have been established, the relevant authorities should determine the infrastructure, capacity and resources required to meet the objectives.</p>	<p>Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):</p>
<p>34. Once <del>the</del> objectives and priorities have been established, <del>the</del> competent authorities should determine the infrastructure, capacity and resources required to meet the objectives.</p>	<p><b>USA</b></p>
<p>35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. Antimicrobial use monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p>	<p><b>Chile</b> Sent to section 9.</p>
<p>35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. Antimicrobial use monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p> <p><u>Proposed text:</u> 35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. AMR monitoring and surveillance can proceed at a different rate than antimicrobial use monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p>	<p><b>Australia</b> Modification of text to put AMR first and AMU second to reflect the focus of the document is AMR, as follows (see Proposed text):</p>
<p>35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. <del>Antimicrobial use</del> <a href="#">Implementation of AMU</a> monitoring and surveillance can proceed at a different rate than <del>that of</del> AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p>	<p><b>Canada</b> It is recommended to add the proposed text to clarify that the sentence refers to implementation, which can proceed at different rates for AMR/AMU monitoring and surveillance.</p>
<p>35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. <del>Antimicrobial use</del> <a href="#">AMU</a> monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p>	<p><b>European Union</b> EUMS suggest to replace antimicrobial use with AMU. The second sentence would thus be: AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa.</p>
<p>35. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. <del>Antimicrobial use</del> <a href="#">AMU</a> monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.</p>	<p><b>Norway</b> Norway suggests to an editorial change in the second sentence. AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa.</p>

COMMENTS	MEMBER/OBSERVER
<p>36. As part of initial planning, the competent authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of integration or expansion of the AMR or AMU monitoring and surveillance activities within other ongoing activities.</p> <p><u>Proposed text:</u></p> <p>36. As part of initial planning, the relevant authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the relevant authorities should consider the possibilities of integration or expansion of the AMR monitoring and surveillance activities within other ongoing activities.</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships.</li> <li>• Delete the reference to AMU, as the focus of the document is on AMR.</li> </ul> <p>To incorporate the above changes, suggest editing the text, as follows (see Proposed text):</p>
<p>36. As part of initial planning, the competent authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of integration or expansion of the AMR <del>or AMU</del> monitoring and surveillance activities within other ongoing activities.</p>	<p><b>Chile</b></p>
<p>36. As part of initial planning, the competent authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of integration <del>or expansion of the</del> AMR or AMU monitoring and surveillance activities <del>within</del> <u>with</u> other ongoing activities.</p>	<p><b>USA</b></p>
<p>37. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data in a central repository.</p> <p><u>Proposed text:</u></p> <p>37. The relevant authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data in the appropriate repository.</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships.</li> <li>• Modification to text to provide countries with flexibility on how they will undertake data storage.</li> </ul> <p>To incorporate the above changes, suggest editing the text, as follows (see Proposed text):</p>
<p>37. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data <del>in</del> <u>into and out of</u> a central repository.</p>	<p><b>Canada</b></p> <p>Data from isolates are received into a central repository, but reporting happens out of the repository. Edits made to clarify the sentence.</p>
<p>37. The competent authorities <del>should</del> <u>may</u> also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data in a central repository.</p>	<p><b>Chile</b></p> <p>It is not clear which relevant stakeholders are referring in this paragraph, university labs?, suggest to add may for flexibility, since is something that the competent authority may or may not consider necessary.</p>

COMMENTS	MEMBER/OBSERVER
37. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data in a central <del>repository</del> <a href="#">repository for integrated monitoring and surveillance of foodborne AMR</a> .	<b>China</b> "a central repository" should be clarified its functions.
<b>7.4 KEY DESIGN ELEMENTS TO BE ESTABLISHED BEFORE INITIATING THE MONITORING AND SURVEILLANCE ACTIVITIES</b>	
38. <a href="#">Undertaking pilot studies and testing can provide valuable inputs into the design for monitoring and surveillance program(s)</a> . When designing the monitoring and surveillance program(s), the following elements should be considered:	<b>USA</b> Pilot studies are a helpful part of developing a broader program when resources are limited and there is a need to determine appropriate sampling, methods, and to identify logistical challenges.
39. AMR: <ul style="list-style-type: none"> <li>Standardized and/or harmonized methodologies for <del>sampling</del><a href="#">sampling, testing and testing reporting</a>.</li> </ul>	<b>Chile</b>
40. AMU:	<b>Chile</b> Move to section 9.
40. AMU: <ul style="list-style-type: none"> <li>Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.</li> </ul>	<b>Canada</b> It is recommended to move the first two bullets to Paragraph 86 since these are detailed elements that are better suited for later in the text.
40. AMU: <ul style="list-style-type: none"> <li>Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers, <a href="#">when available</a>.</li> </ul>	<b>Chile</b> Not easy or feasible by all country members.
40. AMU: <ul style="list-style-type: none"> <li><del>Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.</del></li> </ul>	<b>USA</b> Delete the first bullet in paragraph 40 as it is not feasible to collect such information in many countries. Further, this data appears to be a low priority compared to other data inputs.
40. AMU: <ul style="list-style-type: none"> <li>Identification of the <del>sectors where collection most appropriate points</del> of data <del>would be most relevant collection</del> and <del>efficient to meet monitoring and surveillance objectives</del> <a href="#">the stakeholders that can provide the data</a>.</li> </ul>	<b>Canada</b> This bullet has been moved from paragraph 86 to paragraph 40. The goal of paragraph 40 is to introduce the concept of data collection for AMU, with more details intended in Section 9, paragraph 86. Switching the first two bullets to paragraph 86 and moving this bullet from paragraph 86 achieves this objective.  See previous comment #88. It is recommended to move the first two bullets to Paragraph 86 since these are detailed elements that are better suited for later in the text.

COMMENTS	MEMBER/OBSERVER
<p>40. AMU:</p> <ul style="list-style-type: none"> <li>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 plants/crops or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide these data may be useful.</li> </ul>	<p><b>Australia</b></p> <p>Delete this final dot point as legal frameworks are beyond the mandate of Codex, it is not appropriate for this information to be included in this document.</p>
<p>40. AMU:</p> <ul style="list-style-type: none"> <li>An assessment of the need to establish a legal framework <u>may be useful</u> before initiating collection and reporting of <u>antimicrobial sales and use-AMU</u> data in food producing animals and <u>plants/crops or to start the plants/crops. The</u> collection of AMU data <u>could also be started</u> on a voluntary basis in agreement with stakeholders <u>that provide who have</u> these data <u>may be useful</u>.</li> </ul>	<p><b>Canada</b></p> <p>Edits provided to split the sentence into two sentences to enhance clarity and readability.</p>
<p>40. AMU:</p> <ul style="list-style-type: none"> <li><del>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 plants/crops or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide these data may be useful.</del></li> </ul>	<p><b>Chile</b></p> <p>Is not part of Codex to recommend the establishment of legal frameworks by countries, each country will evaluate if a legal framework is needed to accomplish what is recommended in Codex standards.</p>
<p>40. AMU:</p> <ul style="list-style-type: none"> <li><del>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 plants/crops or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide these data may be useful.</del></li> </ul>	<p><b>Japan</b></p> <p><u>Rationale:</u> It is beyond the mandate of this guideline to describe legal framework.</p>
<p>40. AMU:</p> <ul style="list-style-type: none"> <li><del>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 plants/crops or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide these data may be useful.</del></li> </ul>	<p><b>USA</b></p> <p>Delete the third bullet. If Codex makes recommendations, it should be implicit that competent authorities have the legal authority to carry out recommendations. It appears inappropriate for Codex to provide legal advice, legal guidance or suggest the need for a domestic legal framework.</p>
<p>41. Consideration may be given to additional information provided in the OIE Terrestrial Animal and Aquatic Health Codes.</p> <p><u>Proposed text:</u></p> <p>41. Consideration should be given to additional information provided in the OIE Terrestrial Animal and Aquatic Health Codes.</p>	<p><b>Australia</b></p> <p>Australia supports the addition of paragraph 41 to refer to the OIE Codes.</p> <p>For clarity, replace may with should to highlight the importance of referring to the OIE Codes, as follows (see Proposed text):</p>
<p>41. Consideration <del>may should</del> be given to additional information provided in the OIE Terrestrial Animal and Aquatic Health Codes.</p>	<p><b>Chile</b></p> <p>In order to avoid contradictions between food safety and animal health authorities regulations, consideration should be given to OIE codes.</p>

COMMENTS	MEMBER/OBSERVER
41. Consideration may be given to additional information provided in the OIE Terrestrial Animal <a href="#">Health Code</a> and Aquatic <a href="#">Animal Health CodesCode</a> .	<b>Thailand</b> A reference to the OIE standards should be corrected to be read as Terrestrial Animal Health Code and Aquatic Animal Health Code.
<b>8. COMPONENTS OF INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR AMR</b>	
Components of integrated monitoring and surveillance program(s) for AMR	<b>Switzerland</b> Switzerland supports the use of the term "should" in this chapter as "may" is not appropriate.
42. Integrated monitoring and surveillance program(s) for foodborne AMR should consider the following elements: <ul style="list-style-type: none"><li>Data management activities.</li></ul>	<b>Australia</b> Suggest adding a new point below this point: <ul style="list-style-type: none"><li>Available resources (human and financial)</li></ul> Additional text as it was a significant element that was missing. 'Available resources' dictate the size and detail of any plan. Although it is mentioned in some places of the document, it needs to be clearly acknowledged here as a practicality of any surveillance program.
42. Integrated monitoring and surveillance program(s) for foodborne AMR should consider the following elements: <ul style="list-style-type: none"><li><del>Data management activities.</del></li></ul>	<b>Canada</b> It is suggested to delete this bullet since it is unnecessary. There is a whole section (Section 10.1) dedicated to data management
43. The initial scope and design of the monitoring and surveillance program(s) for AMR may be informed by previous research or surveillance findings, by national priorities or by national and international experience and recommendations. As the AMR program develops, the scope and design may be adjusted based on one or more of the following factors: <u>Proposed text:</u> 43. The initial scope and design of the monitoring and surveillance program(s) for AMR may be informed by previous research or surveillance findings, by national priorities or by national and international experience and agreed recommendations. As the AMR program develops, the scope and design may be adjusted based on one or more of the following factors:	<b>Australia</b> Addition of the word agreed to reflect a consensus approach, as follows (see Proposed text).
43. The initial scope and design of the monitoring and surveillance program(s) for AMR <del>may should</del> be informed by previous research or surveillance findings, by national priorities or by national <del>and</del> <u>and/or</u> international experience and recommendations. As the AMR program develops, the scope and design may be adjusted based on one or more of the following factors:	<b>Canada</b> In this instance, "may" should be a "should" to provide useful guidance on what the initial scope and design of the program(s) should be informed by. Addition of "or" to be "and/or" as the scope and design of the program(s) could be informed by national experience alone, international experience alone, or both.
43. (...) <ul style="list-style-type: none"><li>Risk profile and risk assessment findings.- <a href="#">Evaluation of the integrated monitoring and surveillance program(s)</a></li></ul>	<b>Canada</b> Results of an evaluation are an important way to adjust the design of the program(s). This concept is missing from this list, hence, it is recommended to include it.



COMMENTS	MEMBER/OBSERVER
<b>8.1 SAMPLING DESIGN</b>	
<p>44. The design of monitoring and surveillance program(s) for AMR may build on or be integrated with existing monitoring and surveillance program(s), or may involve development of new infrastructures and activities only for the purpose of AMR data collection. If data are collected through existing programs designed for another purpose, this will need to be specified and the different methodologies and data interpretation methods should be described.</p> <p><u>Proposed text:</u></p> <p>44. The design of monitoring and surveillance program(s) for AMR may build on or be integrated with existing monitoring and surveillance program(s), or may involve development of new infrastructures and activities only for the purpose of AMR data collection. If data are collected through existing programs designed for another purpose, this will need to be specified and the different methodologies, data limitations and interpretation methods should be described.</p>	<p><b>Australia</b></p> <p>Addition of limitations as there are limitations to data interpretation, also for consistency with paragraph 47, as follows (see Proposed text):</p>
<p>44. The design of monitoring and surveillance program(s) for AMR may build on or be integrated with existing monitoring and surveillance program(s), or may involve development of new infrastructures and activities only for the purpose of AMR data collection. If data are collected through existing programs designed for another purpose, this will need to be specified and the <del>different</del> methodologies and data interpretation <del>methods</del> should be described.</p>	<p><b>Canada</b></p> <p>To enhance readability of the sentence.</p>
<p>44. The design of monitoring and surveillance program(s) for AMR may build on or be integrated with existing monitoring and surveillance program(s), or may involve development of new infrastructures and activities <del>only specifically</del> for the purpose of <del>foodborne</del> AMR data collection. If data are collected through existing programs designed for another purpose, this will need to be specified and the different methodologies and data interpretation methods should be described.</p>	<p><b>USA</b></p> <p>Text added to clarify that the specific new surveillance should be focused on foodborne AMR as described in the scope.</p>
<p>46. Once a sampling design is established, consistency in sample types and methodology is desirable to achieve <del>long-term, long-term</del> comparability and accurate interpretation of results, especially when new methodologies are added and the program is adjusted.</p>	<p><b>USA</b></p>
<b>8.2 SAMPLING PLANS</b>	
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>The procedure to collect a <u>representative</u> sample from the selected sample source(s) at the selected point(s) in the food chain.</li> </ul>	<p><b>China</b></p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>The procedure to collect a sample from the selected sample source(s) at the selected point(s) in the food <del>chain</del> <u>chain aiming for representativeness</u>.</li> </ul>	<p><b>European Union</b></p> <p>EUMS would like to thank for the proposed rewording, which needs some additional adjustment.</p> <p>In the first bullet point, the aspect ‘representative’ should not be deleted as it is very important to collect representative samples for proper analysis and interpretation of data, as otherwise accuracy of the analysis can be compromised and biased or misinterpretation of the data can appear.</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u> The procedure to collect a sample from the selected sample source(s) at the selected point(s) in the food chain aiming for representativeness.</p>	As a compromise, the sentence may read as follows (see Proposed text):
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>Sample size, statistical methods and underlying assumptions <del>e</del>(e.g., frequency of recovery, the initial or expected prevalence of AMR in that microorganism) of the data used to calculate the number of samples and isolates.</li> </ul>	<p><b>Brazil</b> Include the parenthesis at the beginning of the example in the second bullet.</p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>Sample size, statistical methods and underlying <del>assumptions e.g., frequency assumptions of recovery, the initial or expected prevalence of AMR in that microorganism) of the</del> data used to calculate the number of samples and isolates.</li> </ul>	<p><b>China</b></p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>Sample size, statistical methods and underlying assumptions <del>e</del>(e.g., frequency of recovery, the initial or expected prevalence of AMR in that <del>microorganism) microorganism and the size of the population to be monitored) of the</del> data used to calculate the number of samples and isolates.</li> </ul> <p><u>Proposed text:</u></p> <ul style="list-style-type: none"> <li>Sample size, statistical methods and underlying assumptions (e.g., frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored) of the data used to calculate the number of samples and isolates.</li> </ul>	<p><b>European Union</b> Furthermore, there is a missing parenthesis. As regards the second bullet point, we can agree with most of the revised wording. The aspect of the population size to be monitored is missing now. This should be included again. The sentence may read as follows (see Proposed text):</p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>Sample size, statistical methods and underlying assumptions <del>e</del>(e.g., frequency of recovery, the initial or expected prevalence of AMR in that microorganism) of the data used to calculate the number of samples and isolates.</li> </ul>	<p><b>USA</b></p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li>Statistical power, precision and <del>goals objectives</del> of testing.</li> </ul>	<p><b>European Union</b> As regards the third bullet point, for reasons of consistency, EUMS propose to use the term 'objectives' instead of 'goals', as the term 'objectives' is already used several times throughout the whole document.</p>
<p>47. The sampling plan should describe the following:</p> <ul style="list-style-type: none"> <li><del>Strength and Limitations to imitations that affect</del> data interpretation.</li> </ul>	<p><b>Canada</b> Sampling plans have strengths and limitations. Only limitations were noted in the bullet point, and thus, it would be important to also mention strengths. Additional edits were made to enhance clarity.</p>
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li><del>Whether the sampling</del>Sampling strategy <del>may be is</del> active (i.e. designed for AMR surveillance) or passive (i.e., using a system already in place).</li> </ul>	<p><b>Canada</b> Words added to the beginning of the sentence to better align the bullet with the chapeau sentence in Para 48.</p>

COMMENTS	MEMBER/OBSERVER
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li>• Selection of <del>strata (levels) or</del> risk clusters (groups) to best meet surveillance objectives.</li> </ul>	<p><b>Canada</b></p> <p>Suggest to delete the first half of this bullet on “strata (levels)” to simplify the sentence as this concept is already reflected in the paragraph.</p>
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li>• Prevalence and seasonality of the microorganisms under study.</li> </ul> <p><u>Proposed text:</u></p> <ul style="list-style-type: none"> <li>• Prevalence and seasonality of the microorganisms under study, if known.</li> </ul>	<p><b>Australia</b></p> <p>Addition to text to make the guideline realistic, as follows (see Proposed text):</p>
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li>• Standard operating procedures for sample collection: <ul style="list-style-type: none"> <li>○ Who should <del>be collecting</del> collect the samples.</li> </ul> </li> </ul>	<p><b>USA</b></p>
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li>• Standard operating procedures for sample collection: <ul style="list-style-type: none"> <li>○ Procedures for collection of samples in accordance with the defined sampling strategy and to guarantee that traceability, security (<u>including biosafety</u>) and quality assurance are maintained from collection through to analysis and storage.</li> </ul> </li> </ul>	<p><b>China</b></p>
<p>48. The following elements should be considered in the sampling plan:</p> <ul style="list-style-type: none"> <li>• Standard operating procedures for sample collection: <ul style="list-style-type: none"> <li>○ Procedures for storing and transporting the samples in order to maintain sample integrity.</li> </ul> </li> </ul> <p><u>Proposed text:</u></p> <ul style="list-style-type: none"> <li>○ Procedures for storing and transporting the samples in order to maintain sample integrity for testing.</li> </ul>	<p><b>Australia</b></p> <p>Addition to text to provide clarification, as follows (see Proposed text):</p>
<p>49. Initial implementation <del>might of the sampling plan may</del> include a limited selection of sample sources at one or more specific points along the food chain.</p>	<p><b>Canada</b></p> <p>Text added for clarity.</p> <p>Suggest to replace with “may” for consistency as the word “might” is not used frequently throughout the document.</p>
<p>50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in <del>eh</del> the food chain or food commodities to gradually be more representative of the population of interest.</p>	<p><b>Brazil</b></p> <p>Correction of “the”</p>

COMMENTS	MEMBER/OBSERVER
50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, <del>stages in eh-food chain or food</del> commodities <del>to gradually be more representative of or stages in the population of interest</del> food chain.	<b>Canada</b> Rearranging “food commodities” before “food chain” makes this sentence flow better. Suggest to delete the last phrase for simplicity and flexibility. Hypothetically, a program could start with one bacterial species, one animal species at one point in the food chain and be fully representative of the population of interest.
50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in <del>eh-the</del> food chain or food commodities to gradually be more representative of the population of interest.	<b>China</b>
50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in <del>eh-the</del> food chain or food commodities to gradually be more representative of the <del>population</del> populations of interest.	<b>European Union</b> Regarding the second sentence, EUMS note that "eh" should read "the". In addition, ‘s’ should be added to ‘populations’ (to change the word into plural) because in the first part of the sentence, different populations are listed.
50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in <del>eh-the</del> food chain or food commodities to gradually be more representative of the population of interest.	<b>Norway</b> We note that in the second sentence there is a need for an editorial correction by changing "eh" to "the".
50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in <del>eh-the</del> food chain or food commodities to gradually be more representative of the population of interest.	<b>USA</b>
<b>8.3 SAMPLE SOURCES</b>	
51. When identifying the sample sources to be included in the monitoring and surveillance program(s), consideration should be given to the major direct <del>and and, when scientific evidence exists,</del> indirect food exposure pathways.	<b>Chile</b> Consideration to indirect pathways must be scientific based.
51. When identifying the sample sources to be included in the monitoring and surveillance program(s), consideration should be given to the major direct and <del>scientifically relevant</del> indirect food exposure pathways.	<b>USA</b> Indirect food exposure pathways must be shown to be scientifically relevant to avoid conjecture of pathways that are not of importance or are confounded by other factors.
52. The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne AMR. <del>The prevalence of the bacterial species should be considered to maximize the likelihood of detection.</del>	<b>Canada</b> This statement is applicable to more than just samples from food producing animals. Suggest to move above the sub-title “Food producing animals”.
53. The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR. Possible sample sources are:	<b>Australia</b> Australia supports the revised text.

COMMENTS	MEMBER/OBSERVER
53. The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where there is <u>previous</u> science-based evidence that they could contribute to foodborne AMR. Possible sample sources are:	<b>Chile</b>
53. The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR. <u>For integration, samples should be collected from the same species at the different relevant points along the food chain.</u> Possible sample sources are:	<b>European Union</b> EUMS acknowledge that this paragraph was under great debate during the virtual meetings in June. We are still concerned about the wording, but agree that “science-based” is better than “evidence based”. EUMS suggest to move the sentence “For integration, samples from food-producing animals should be collected from the same species at the different relevant points along the food chain.” to up here since its content also reflects on food and food production environment, and to delete the term ‘from food-producing animals’ and the word ‘animal’ in it in order to cover also plant/crops.
53. The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food <del>chain where there is science-based evidence that they</del> <u>chain that</u> could contribute to foodborne AMR. Possible sample sources are: <u>Proposed text:</u> The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where that could contribute to foodborne AMR.	<b>Norway</b> Norway suggests to to rephrase the first sentence because there may be situations where there is not yet science based evidence. Sometimes the risk manager has reason to believe that AMR could be a hazard in a relevant stage of the food chain. According to the risk analysis, the risk manager may decide to take a preliminary risk management decision based on a risk profile. The next step is to make a risk assessment that provides the science-based evidence. However, there is a need to generate data so that the risk assessor is able to perform the risk assessment. Our suggested rephrasing is as follows (see Proposed text):
<ul style="list-style-type: none"> <li><b>Food producing animals</b></li> </ul> <p>Samples should be, to the greatest extent possible, representative of the animal species and epidemiological unit being targeted.</p>	<b>Costa Rica</b> <u>Position:</u> To delete the verb “Should” and use the verb “Could”. Samples could be, to the greatest extent possible, representative of the animal species and epidemiological unit being targeted. <u>Rationale:</u> This is according the capacity of the country, and we rather avoid a misunderstanding with the verb as a high commitment for the country.
<ul style="list-style-type: none"> <li><b>Food producing animals</b></li> </ul> <p><del>The prevalence of the bacterial species should be considered to maximize the likelihood of detection.</del></p>	<b>Canada</b> This statement is applicable to more than just samples from food producing animals. Suggest to move above the sub-title “Food producing animals”.
<ul style="list-style-type: none"> <li><b>Food producing animals</b></li> </ul> <p>Samples taken from healthy animals destined for slaughter may be collected on-farm, during lairage, or <del>at the</del> <u>at</u> slaughter. Collection of samples from animals not immediately entering the food chain may provide additional information on foodborne AMR at the population-level but may be a lower priority than those animals directly entering the food supply.</p>	<b>European Union</b> EUMS note that the word “the” must be deleted. Thus the sentence is: "during lairage, or at slaughter."

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> Samples taken from healthy animals destined for slaughter may be <del>collected on-farm, during lairage, or at the slaughter</del>collected. Collection of samples from animals not immediately entering the food chain may provide additional information on foodborne AMR at the population-level but may be a lower priority than those animals directly entering the food supply.</li> </ul>	<p><b>USA</b> <i>Category: SUBSTANTIVE</i></p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>2</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs.</li> </ul> </li> </ul>	<p><b>Chile</b> Feed [2]: No examples of sites for sampling, prescriptive.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, <u>rectal or cloacal swab</u>, feed<sup>2</sup> and/or feed ingredients, water, <del>litter, or bedding or</del> other relevant food production inputs.</li> </ul> </li> </ul>	<p><b>China</b> The bullet "food production animals" contains some of the food production environment samples, such as "litter or bedding", which should be moved to the bullet "food production environment", and "rectal or cloacal swab" could be added to the animal samples.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, <u>sample samples</u> may include faeces, feed<sup>2</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs.</li> </ul> </li> </ul>	<p><b>European Union</b> The word 'sample' should be in plural.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, <del>sample may include faeces, feed<sup>2</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs.</del></li> </ul> </li> </ul>	<p><b>USA</b></p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>2</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs.</li> </ul> </li> </ul>	<p><b>IFIF</b> Care should be taken when testing feed or feed ingredients on farm, as on farm contamination could impact test results.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>4</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs.  <del>FN14: The location of where the feed or feed ingredient is sampled, the manufacturing plant (feed mill), production site or farm, may provide additional information for understanding foodborne AMR.</del></li> </ul> </li> </ul>	<p><b>Chile</b></p>

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>14</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs. Consideration may be given to samples described in the OIE Terrestrial Animal and Aquatic Health Codes, specifically the chapters on Harmonisation of National AMR Surveillance and Monitoring Programmes <del>as well as on and</del> the Development and Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic animals.</li> </ul> </li> </ul>	<p><b>Canada</b></p> <p>To improve sentence structure, “and” is more appropriate here.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>14</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs. Consideration may be given to samples described in the OIE Terrestrial Animal <a href="#">Health Code</a> and Aquatic <a href="#">Animal Health CodesCode</a>, specifically the chapters on Harmonisation of National AMR Surveillance and Monitoring Programmes as well as on the Development and Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic animals.</li> </ul> </li> </ul>	<p><b>Thailand</b></p> <p>A reference to the OIE standards should be corrected to be read as Terrestrial Animal Health Code and Aquatic Animal Health Code.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At the farm-level, sample may include faeces, feed<sup>14</sup> and/or feed ingredients, water, litter or bedding or other relevant food production inputs. <del>Consideration-consideration</del> may be given to samples described in the OIE Terrestrial Animal and Aquatic Health Codes, specifically the chapters on Harmonisation of National AMR Surveillance and Monitoring Programmes as well as on the Development and Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic animals.</li> </ul> </li> </ul>	<p><b>USA</b></p> <p>On-farm sampling is under the mandate of OIE and Codex should not develop duplicative advice that may become contradictory or outdated as OIE standards, which are updated more frequently. The Physical Working Group in June 2021 agreed to make reference to OIE instead of duplicating advice here. Feed is included in OIE Chapter 6.8 section 6.8.4 so is duplicative to include in this Codex Guideline: (<a href="https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2018/en_chapitre_an_tibio_harmonisation.htm">https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2018/en_chapitre_an_tibio_harmonisation.htm</a> ).</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ <del>At lairage, sample may include rectal samples or fecal samples from pen floors or crates.</del></li> </ul> </li> </ul>	<p><b>USA</b></p> <p>Lairage samples are low priority compared to food samples, for foodborne AMR surveillance, which is Codex’s mandate. Lairage samples are better addressed under OIE, which has an on-farm mandate.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At slaughter, sample may include <del>for example, but not limited to,</del> carcass swabs, caecal contents or lymph nodes. In some animal species, caecal contents or lymph nodes may be representative of the pre-slaughter environment and may or may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter (e.g., carcass) may provide an estimate of contamination arising from the slaughterhouse.</li> </ul> </li> </ul>	<p><b>Chile</b></p>

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b> <ul style="list-style-type: none"> <li>○ At slaughter, <del>sample samples</del> may include <del>carcass swabs</del> <del>meat</del>, <del>poultry</del>, <del>seafood</del>, caecal contents or lymph nodes. In some animal species, caecal contents or lymph nodes may be representative of the pre-slaughter environment and may or may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter (e.g., carcass) may provide an estimate of contamination arising from the slaughterhouse.</li> </ul> </li> </ul>	<p><b>USA</b></p> <p>Meat, poultry, seafood samples would be the food products closest to consumption and of most risk to the consumer for foodborne AMR from food animals that could be collected at slaughter. Food samples are the priority for sampling for foodborne AMR risk under the Codex mandate. It is unclear why caecal samples and fecal samples from the floor are more important to collect than food samples for a Codex document. Please include, “meat, poultry, seafood” as agreed to at the Physical Working Group meeting in June 2021. “Carcass swab” is only one method of collection. It is not clear why carcass swab is mentioned but other sample types are not. Perhaps it is prudent to refer to product types (meat, poultry, seafood) versus listing every possible sample type or only mentioning one-carcass swab.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b></li> </ul> <p><del>For integration, samples from food-producing animals should be collected from the same animal species at the different relevant points along the food chain.</del></p>	<p><b>European Union</b></p> <p>The EUMS fully agree with the proposal from the Chair and co-chairs to use “should” instead of “may” with regards to the sentence “for integration”. To our understanding adequate and accurate integration is only possible when sampling is done from the same animal species along the food chain.</p> <p>For clarity and as already highlighted above, EUMS suggest to move this sentence to para 53, slightly amended (see comment in para 53).</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b></li> </ul> <p>For integration, samples from food-producing animals should be collected from the same animal species at the different relevant points along the food chain.</p>	<p><b>Norway</b></p> <p>Norway supports the proposal from the Chair and co-chairs to use “should” instead of “may” with regards to the sentence “for integration”. To our understanding adequate and accurate integration is only possible when sampling is done from the same animal species along the food chain.</p>
<ul style="list-style-type: none"> <li>• <b>Food producing animals</b></li> </ul> <p>For integration, samples from food-producing animals <del>should</del> <del>may</del> be collected from the same animal species at <del>the</del> different relevant points along the food chain, <del>though sampling may be expanded at slaughter or retail individually as resources allow.</del></p>	<p><b>USA</b></p> <p>There may be resources in one agency to sample at slaughter and not at another to sample at retail, so the text should not be prohibitive to expansion as resources allow in different points (different governmental agencies) at the food chain.</p>
<ul style="list-style-type: none"> <li>• <b>Food</b></li> </ul> <p>Food samples may be collected at processing, packaging, wholesale or retail. <del>Sample may include both domestically-produced and imported food sources.</del></p>	<p><b>Australia</b></p> <p>Delete 'Sample may include both domestically-produced and imported food sources.' to streamline the document and also to remove the focus on imported food (and any potential barriers to trade).</p>
<ul style="list-style-type: none"> <li>• <b>Food</b></li> </ul> <p>Food samples may be collected at processing, packaging, wholesale or retail. Sample may include <del>both</del> domestically-produced <del>and</del> <del>and</del>, <u>when appropriate</u>, imported food sources.</p>	<p><b>Chile</b></p>



COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li><b>Food</b></li> </ul> <p>Food samples may be collected at processing, packaging, wholesale or retail. <del>Sample may include both domestically produced and imported food sources.</del></p>	<b>International Feed Industry Federation</b>
<ul style="list-style-type: none"> <li><b>Food</b></li> </ul> <p>At the retail-level, food samples may include raw meat, fish or seafood, dairy products, other edible tissues, raw produce and other minimally processed animal products and produce. Food selection may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.</p>	<b>Thailand</b> <p>We noticed that food samples already covered raw meat, fish or seafood so we would like to ask for clarification of a term “raw produce”. Are fresh produces of plant origin (vegetables or fruits) fall into this term?</p>
<ul style="list-style-type: none"> <li><b>Food</b></li> </ul> <p>At the retail-level, food samples may include raw meat, <del>poultry</del>, fish or seafood, dairy products, other edible tissues, raw <del>produce produce</del>, and <del>other</del> minimally processed animal products and produce. Food selection may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.</p>	<b>USA</b>
<ul style="list-style-type: none"> <li><b>Plants/crops</b></li> </ul> <p>The selection of plants/crops should be risk-based and/or guided by the relevant standard setting bodies where <del>available</del>.</p> <p><u>Proposed text:</u></p> <p>The selection of plants/crops should be risk-based and/or guided by the relevant standard setting bodies where <u>required</u>.</p>	<b>Australia</b> <p>Edit the text as follows (see Proposed text):</p>
<ul style="list-style-type: none"> <li><b>Plants/crops</b></li> </ul> <p>Samples may be collected from farm, pre-harvest or post-harvest</p>	<b>Australia</b> <p>Remove details of sampling for plants/crops to reflect that this is the mandate of the relevant international standard-setting bodies, not Codex. If a country wishes to set up their own plant/crop AMR surveillance program, then what they choose to sample will be up to the country. It does not need to be set in this standard and will ultimately be guided by the relevant international standard-setting body, if required. Codex should not determine the agenda of other international standard-setting bodies.</p>
<ul style="list-style-type: none"> <li><b>Plants/crops</b></li> </ul> <p>Samples may be collected from farm, pre-harvest or post-harvest</p>	<b>Norway</b> <p>In order to make this a standalone document, Norway suggest the following added wording:</p> <p>At harvest and farm levels, sample options may include plants/crops, soils, fertilizers or irrigation water.</p> <p>At post-harvest level, samples may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water.</p>

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li><b>Plants/crops</b></li> </ul> <p>Samples may be collected from <del>farm</del><u>farms</u>, pre-harvest or post-harvest</p>	<p><b>USA</b></p>
<ul style="list-style-type: none"> <li><b>Food production environment</b></li> </ul> <p>Sample may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets<sup>15</sup>.</p> <p><u>Proposed text:</u></p> <p>Sample may include the immediate environment of food producing animals, plants/crops, processing, wholesale facilities or retail outlets.</p>	<p><b>Australia</b></p> <p>For clarity, suggest the following changes:</p> <ul style="list-style-type: none"> <li>Addition of the word immediate to better reflect the definition for food production environment.</li> <li>Modification to text to allow flexibility.</li> </ul> <p>To incorporate the above changes, suggest editing the text, as follows (see Proposed text):</p>
<ul style="list-style-type: none"> <li><b>Food production environment</b></li> </ul> <p>Sample may include the <u>immediate</u> environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets<sup>15</sup>.</p>	<p><b>Chile</b></p> <p>Examples are not needed. Even in a footnote constitute part of the document and can be prescriptive in the food trade.</p>
<ul style="list-style-type: none"> <li><b>Food production environment</b></li> </ul> <p><del>Sample</del><u>Samples</u> may <del>include be collected from</del> the environment of food producing animals and plants/crops, <del>processing</del><u>processing facilities</u>, wholesale facilities or retail outlets<sup>15</sup>.</p>	<p><b>USA</b></p> <p>The footnote should be deleted as currently, the value of including such sample types for a national-scale food safety surveillance system is lacking. See FAO/WHO expert meeting on foodborne antimicrobial resistance which describes the Role of environment, crops and biocides; Rome, 11-15 June 2018 (<a href="http://www.fao.org/documents/card/en/c/ca6724en/">http://www.fao.org/documents/card/en/c/ca6724en/</a>). The expert meeting found that gaps exist with regard to the fundamental elements of AMR surveillance on crops and in the environment (e.g. sample sources, foodborne pathogens, antimicrobial agents).</p> <p>In addition, there appears to be a lack of standardized methods for the range of matrices involved. Additional research and methods development are needed in these sectors prior to the development of guidance in Codex Alimentarius.</p> <p>We suggest that a next step for integrated surveillance of foodborne AMR on crops and in the environment is to fill knowledge gaps on fundamental surveillance system components and develop appropriate, validated methods to ensure results are scientifically sound and sufficient for risk management.</p> <p>Further information regarding the lack of knowledge on contribution in these areas is described by a 2021 report by the European Food Safety Authority: <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6651">https://www.efsa.europa.eu/en/efsajournal/pub/6651</a></p>
<ul style="list-style-type: none"> <li><b>Food production environment</b></li> </ul> <p>Sample may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets<sup>15</sup>.</p> <p><del>FN15: Dust, soil, water, organic fertilizers, sewage or manure in the farm environment or in surfaces of processing areas.</del></p>	<p><b>Chile</b></p>

COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> <li><b>Food production environment</b></li> </ul> <p>Sample may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets<sup>15</sup>.</p> <p>FN15: <del>Dust, soil, water, organic fertilizers, sewage or manure in the farm environment or in surfaces of processing areas.</del></p>	<p><b>China</b></p> <p>Because the definition of food production environment is very clear. The environment should be the immediate vicinity of the food chain.</p>
<ul style="list-style-type: none"> <li>Footnotes to para 53</li> </ul>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests to delete the footnotes 2 and 3.</p> <p><u>Rationale:</u> Our country requests to avoid confusions, and prefer a basic document as a codex standard to focus for the properly manage limit resources in our country. So, this kind of “example” expands the area of action related to monitoring or surveillance, and it can be a confused or interpreted as a requirement, and default a commitment for the system or program in the country.</p> <p>We consider all Codex standard documents need to be harmonized with the others documents from international reference organisms like OIE, AGISAR, etc.</p>
<b>8.4 TARGET MICROORGANISMS AND RESISTANT DETERMINANTS</b>	
<p>54. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and public health.</p>	<p><b>Australia</b></p> <p>Australia supports the revised text.</p>
<p>55. Bacterial species may include:</p> <ul style="list-style-type: none"> <li>Foodborne pathogens such as <i>Salmonella</i>, <i>Campylobacter</i> or other food borne pathogens depending on national <u>or, when appropriate,</u> or regional epidemiology and risks.</li> </ul>	<p><b>Chile</b></p>
<p>55. Bacterial species may include:</p> <ul style="list-style-type: none"> <li><b>Commensal bacteria</b> such as <i>Escherichia coli</i> and enterococci (e.g., <i>Enterococcus faecium</i> and <i>Enterococcus faecalis</i>), which can contaminate food and harbor transferable resistance genes.</li> </ul>	<p><b>Canada</b></p> <p>For consistency, we should refer to these as either “indicator” or “commensals”. In the scope we call them “indicator” bacteria (Para 16).</p> <p>These are examples. There are other enterococci found in food.</p>
<p>56. Target microorganisms from aquatic animals and food of non-animal origin should be determined based on available scientific evidence and relevance to public health.</p> <p><u>Proposed text:</u></p> <p>56. Target microorganisms from aquatic animals and food of non-animal origin should be determined based on available scientific evidence and relevance to public health, where possible.</p>	<p><b>Australia</b></p> <p>Suggest editing the text as follows (see Proposed text):</p> <p>Addition of where possible to allow flexibility. Target microorganisms for AMR surveillance in aquatic animals (as opposed to food products) can be difficult to select for in the field, particularly if vaccination and other measures are being implemented. This survey material should not be discounted on this basis.</p>
<p>56. Target microorganisms from aquatic animals and food of non-animal origin <del>should may</del> be determined based on available scientific evidence <del>and or</del> relevance to public <del>health.</del> <u>health and is important when it comes to contributing to new basic data on occurrence</u></p>	<p><b>Norway</b></p> <p>If the term “scientific evidence” is to be used, it must first be defined so that it is clear what is required for it to be science based. There is a need for surveys to obtain data that in the long run can contribute to “scientific evidence” via e.g. risk assessments.</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u> Target microorganisms from aquatic animals and food of non-animal origin may be determined based on available scientific evidence or relevance to public health and is important when it comes to contributing to new basic data on occurrence.</p>	<p>As the wording is now, such monitoring studies, ie mapping studies, are excluded from this guide, and can thus be used as a justification for not conducting such studies. That would be very unfortunate as we see it. Norway suggests the following changes to this para. (see Proposed text):</p>
<p>58. Monitoring and surveillance program(s) may begin with phenotypic susceptibility testing for AMR in representative foodborne pathogens and/or commensal bacteria. Options for expansion may include a broader range of foodborne pathogens, or commensal bacteria, testing for genetic determinants of resistance, virulence and mobile genetic elements.</p>	<p><b>Canada</b> See above comment. For consistency, we should refer to these as either “indicator” or “commensals”. In the scope we call them “indicator” bacteria (Para 16).</p>
<b>8.5 LABORATORIES</b>	
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>a. Bacterial isolation, identification (to species and serotype level), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.</p> <p><u>Proposed text:</u></p> <p>a. Bacterial isolation, identification (to species and serotype level, where relevant), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods, where possible, performed by trained personnel.</p>	<p><b>Australia</b> Modification to text to reflect that not all species/drug/bug combinations have standardised approaches, e.g. aquatic animals, as follows (see Proposed text):</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>b. Accreditation in accordance with national or international guidance or <del>have alternatively</del> <u>having</u> a quality management system in place.</p> <p><u>Proposed text:</u></p> <p>b. Accreditation in accordance with national or international guidance or alternatively having a quality management system in place.</p>	<p><b>European Union</b> EUMS suggest a minor alteration in order to promote the use of accredited methods. The sentence would thus be (see Proposed text):</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>c. Whenever possible participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).</p> <p><u>Proposed text:</u></p> <p>c. Whenever possible or available, participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).</p>	<p><b>Australia</b> Addition to text to reflect the practical situation, as follows (see Proposed text):</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p>	<p><b>Canada</b> Not necessary to include this qualifier as the term “should” in Paragraph 60 provides the necessary flexibility.</p>

COMMENTS	MEMBER/OBSERVER
<p>c. <del>Whenever possible participating</del> Participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).</p>	
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>c. Whenever possible participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the <del>microorganisms-microorganisms,</del> <u>where exists,</u> included in the monitoring and surveillance program(s).</p>	Chile
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>d. Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and recording time <del>between sample reception and analysis and traceability.</del></p>	<p><b>Canada</b></p> <p>Traceability is only used for this bullet. As well, this bullet is very hard to interpret and will not translate well. The “between” , “and”, and “and” is confusing. For simplicity, it is suggested to delete the last part of the bullet, since the key concept is captured in the remainder of the bullet.</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>d. Being equipped with facilities and having procedures to maintain sample <del>integrity including appropriate storage temperatures and recording time between sample reception and analysis and traceability</del> integrity.</p>	<p><b>Chile</b></p> <p>No need for the specificity. Every Quality management system will include this.</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>d. Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and <del>recording records that track the</del> time between sample reception and analysis and <u>ensure</u> traceability.</p>	USA
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>e. <del>Storing isolates and reference strains using methods that ensure viability and absence of change in the characteristics and purity of the strain.</del></p>	<p><b>Chile</b></p> <p>This recommendation is not always feasible, -80°C ids a major equipment and not always possible to have for storage of isolates and the reference strains are already included in the letter b. quality assurance system in place.</p>
<p>60. Laboratories participating in the monitoring and surveillance program(s) should consider:</p> <p>f. <del>Having access</del> Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary and carry out molecular <del>characterization</del> <u>where feasible</u> characterization.</p>	<p><b>Canada</b></p> <p>Text added to read with the chapeau sentence of Para 60. “Where feasible” was deleted as it is not necessary to include this qualifier since the verb “should’ provides the necessary flexibility.</p>
<b>8.6 ANTIMICROBIAL SUSCEPTIBILITY TESTING</b>	
Antimicrobial susceptibility testing	<p><b>Indonesia</b></p> <p>MS may not be familiar with the interpretation of MIC, and therefore the reference for resistance indicator should be made available for each of antimicrobial compound.</p>

COMMENTS	MEMBER/OBSERVER
<b>8.6.1 METHODS AND INTERPRETATIVE CRITERIA</b>	
61. Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by <a href="#">nationally or</a> internationally recognized organizations should be used where available.	<b>China</b> Some countries have their own national standards
61. <a href="#">Either phenotypic or genotypic methodologies may be considered for resistance determination;</a> Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) <a href="#">or genotypic methods</a> that are standardized and validated by internationally recognized organizations should be used where available- <del>2</del>	<b>European Union</b>
61. Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated <del>by</del> <a href="#">according to an</a> internationally recognized <del>organizations-protocols</del> should be used where available. <u>Proposed text:</u> 61. Susceptibility testing methods...that are standardized and validated according to an internationally recognized protocols should be used where available.	<b>Thailand</b> We would suggest text change of the validation of susceptibility testing methods in paragraph 61 and 62 to be in accordance with the internationally recognized protocols that will allow flexibility, feasibility and consistency with the text in Codex Procedural Manual, as follows (see Proposed text):
62. Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations.	<b>Australia</b> Delete paragraph 62 as it is not required, the necessary information is already included in paragraph 61.
62. Either phenotypic or genotypic methodologies <del>may</del> <a href="#">should</a> be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations.	<b>Canada</b> If this is left as a “may”, what other methods besides phenotypic and genotypic would be undertaken for AST? Leaving it as “may” could imply doing no susceptibility testing. It is recommended to replace “may” by “should”.
62. Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by <a href="#">nationally or</a> internationally recognized organizations.	<b>China</b>
62. Se podrán tener en cuenta metodologías fenotípicas o genotípicas a los efectos de las pruebas de sensibilidad y los métodos deben estar estandarizados y validados por organizaciones internacionales reconocidas.	<b>Colombia</b> Se propone eliminar este párrafo, debido a que no hay disponibilidad de técnicas moleculares para la identificación de determinantes de resistencia avaladas por organismos Internacionales, generalmente son técnicas “in house” que se estandarizan en el laboratorio. Así mismo, el numeral 61. hace referencia a los métodos fenotípicos, los cuales pueden estar avalados por CLSI e EUCAST, es decir aplican para esta condición de reconocimiento internacional como lo describe este numeral. Adicionalmente, en el numeral 8.6.4 se referencian las condiciones de los métodos moleculares.

COMMENTS	MEMBER/OBSERVER
<p><del>62. Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations.</del></p> <p><u>Proposed text:</u></p> <p>61. Either phenotypic or genotypic methodologies may be considered for resistance determination; Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) or genotypic methods that are standardized and validated by internationally recognized organizations should be used where available.</p>	<p><b>European Union</b></p> <p>EUMS suggest merging and rearranging the two paragraphs for clarity and to avoid duplication of wording. Furthermore, currently there is a discrepancy between 61 and 62. In 61 standardized etc. should be used, in 62, methods need to be standardized.</p> <p>The revised paragraph should read (see Proposed text):</p>
<p>62. Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated <del>by</del><u>according to an</u> internationally recognized <del>organizations</del><u>protocols</u>.</p> <p><u>Proposed text:</u></p> <p>62. Either phenotypic or genotypic methodologies ... need to be standardized and validated according to an internationally recognized protocols”</p>	<p><b>Thailand</b></p> <p>We would suggest text change of the validation of susceptibility testing methods in paragraph 61 and 62 to be in accordance with the internationally recognized protocols that will allow flexibility, feasibility and consistency with the text in Codex Procedural Manual, as follows (see Proposed text):</p>
<p>63. Quality control strains of bacteria should be included and used according to <u>national or</u> international standards where available to support validation of results.</p>	<p><b>China</b></p>
<p>63. Quality control strains of bacteria should be included and used according to international standards where available to support validation of <del>results</del><u>results and data harmonization</u>.</p>	<p><b>USA</b></p> <p>Quality control/assurance programs serve multiple purposes centered on data validity and interlaboratory comparability.</p>
<p>64. Interpretation of results for MICs or disk diffusion, should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.</p> <p><u>Proposed text:</u></p> <p>64. Interpretation of results for MICs or disk diffusion, should be undertaken according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, where possible, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.</p>	<p><b>Australia</b></p> <p>Delete consistently as there are not EUCAST tables etc. for every species/drug/bug combination, so it cannot be done consistently, particular for aquatic animals, as follows (see Proposed text):</p>
<p>64. Interpretation of results for MICs or disk diffusion, should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) <u>breakpoint</u> tables or <u>the</u> Clinical <u>and</u> Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.</p>	<p><b>Canada</b></p> <p>Wording changed as per EUCAST. Additional text added to improve sentence structure.</p>

COMMENTS	MEMBER/OBSERVER
<p>64. <del>Interpretation of. The results for MICs or disk diffusion, of the phenotypic AMR should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor The standards are available, program-specific interpretive criteria include those of the Clinical and Laboratory Standards Institute (CLSI) or categories may the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or national standards can be used.</del> <u>Interpretation of results for MICs or disk diffusion.</u></p>	<p><b>China</b> Based on the WHO standard, CLIS and EUCAST are accepted international standard. There are some difference between CLSI and EUCAST. Some countries have national standard for veterinary antimicrobial agents.</p>
<p>65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) which should be reported as wild-type <del>or</del> non-wild type or <u>by</u> clinical breakpoint which should be reported according to the interpretative category. The use of ECOFFs as interpretative criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpretative criteria or category used should be included in the <del>reporting, interpretation and</del> <u>reporting of the</u> data.</p>	<p><b>Canada</b> To enhance flow of sentence Text has been simplified for clarity.</p>
<p>65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) which <del>should</del> <u>can</u> be reported as wild-type or non-wild type or clinical <del>breakpoint which should be reported according to the interpretative category</del> <u>breakpoint</u>. The use of ECOFFs as interpretative criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpretative criteria or category used should be included in the reporting, interpretation and analysis of data.</p>	<p><b>China</b></p>
<p>65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) which should be reported as wild-type or non-wild type or clinical breakpoint which should be reported according to the <del>interpretative</del> <u>interpretive</u> category. The use of ECOFFs as interpretative criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The <del>interpretative</del> <u>interpretive</u> criteria or category used should be included in the reporting, interpretation and analysis of data.</p>	<p><b>USA</b></p>
<p>67. Quantitative results are <del>also</del> 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 <del>also</del> necessary for quantitative microbiological risk assessment.</p>	<p><b>Canada</b> The word “also” diminishes the importance of what is in this paragraph. Suggest to delete the two instances of “also”.</p>
<p>67. <del>Quantitative</del> <u>When are possible to be include in the monitoring and surveillance program(s), quantitative</u> 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 microbiological risk assessment.</p>	<p><b>Chile</b> The paragraph was informative and not a recommendation.</p>



COMMENTS	MEMBER/OBSERVER
<b>8.6.2 THE PANEL OF ANTIMICROBIALS FOR SUSCEPTIBILITY TESTING</b>	
<p><u>Proposed text:</u> 8.6.2. The selected antimicrobial panel for susceptibility testing</p>	<p><b>Australia</b> Modify the title for section 8.6.2 to provide more clarity around what information is included in this section, as follows (see Proposed text):</p>
<p>68. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized across the monitoring and surveillance program(s) 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.</p> <p><u>Proposed text:</u> 68. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized across the national monitoring and surveillance program(s) 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.</p>	<p><b>Australia</b> Add the word national to clarify that the panel is tailored to each countries' situation and priorities, as follows (see Proposed text):</p>
<p>68. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized <del>across</del> <u>within</u> the monitoring and surveillance program(s) as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, <u>within the country</u> and over time.</p>	<p><b>Chile</b></p>
<p>68. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized <del>across the</del> <u>within national</u> monitoring and surveillance program(s) 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.</p>	<p><b>USA</b> To clarify that this is not expected internationally to have a 'single global panel.'</p>
<p>70. The antimicrobials included may take into account the classes and uses in the relevant animal and plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if they are not used in animal and plant/crop production sectors.</p> <p><u>Proposed text:</u> 70. The antimicrobials included may take into account the classes and uses in the relevant animal and/or plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if they are not used in animal and/or plant/crop production sectors.</p>	<p><b>Australia</b> Modification to text to allow flexibility (see Proposed text):</p>
<p>71. Antimicrobials to be tested may be prioritized based on those that have been ranked with higher priority for human health, based on national context and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance.</p>	<p><b>Australia</b> Suggest editing the text as follows (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u> 71. Antimicrobials to be tested may be prioritized based on the national context and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance.</p>	<p>Delete the reference to higher priority for human health, as antimicrobials of lower priority/importance to human health are used a lot more frequently in human medicine across the whole population. High priority medicines are kept as a last line of defence and not used often or widely. As such, antimicrobials ranging from low to high importance to human health should be considered for inclusion in the panel.</p> <p>Also, Australia as an example, has an antimicrobial (macrolides) that is of high priority on global terms, but it is not of the same importance in Australia (i.e. not a national priority) due to the amount of resistance in the Australian human population.</p>
<p>71. Antimicrobials to be tested <del>may</del> <u>should</u> be prioritized based on those that have been ranked with higher priority for human health, based on national context and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance.</p>	<p><b>Canada</b></p> <p>Should is a more appropriate verb here as antimicrobials to be tested should be prioritized based on priority to human health, national context etc. It is recommended to replace “may” by “should”.</p>
<p>71. Antimicrobials to be tested may be prioritized based on <del>those that have been ranked with their</del> higher priority <u>ranking</u> for human health, based on national context and/or other relevant <del>antimicrobials that have an</del> influence on the selection or co-selection of resistance.</p>	<p><b>European Union</b></p> <p>EUMS would like to suggest a slight editorial amendment to improve reading and clarity: Antimicrobials to be tested may be prioritized based on their higher priority ranking for human health, based on national context and/or other relevant influence on the selection or co-selection of resistance.</p>
<p><b>8.6.4 MOLECULAR TESTING</b></p>	
<p>73. When possible, <u>or available,</u> molecular testing should be used <del>for-for:73 bis.</del> the identification and detection of resistance determinants and for epidemiological analysis according to country specific scenarios and resources-<u>.</u></p>	<p><b>Chile</b></p> <p>A chapeau where we clarify that when possible or available all the paragraph below may or should be done using the molecular testing instead of putting when possible or when available in each one of them.</p>
<p>73. When possible, molecular testing <del>should</del> <u>can</u> be used for the identification and detection of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.</p>	<p><b>China</b></p>
<p>73. <del>When-Whenever</del> possible, molecular testing should be used for the <del>identification and</del> detection <u>and characterization</u> of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.</p> <p><u>Proposed text:</u> Whenever possible, molecular testing should be used for the detection and characterization of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.</p>	<p><b>European Union</b></p> <p>EUMS agree with the changes made by the Chair and co-Chairs from “may” into “should” as molecular testing is recognized as the most valuable instrument for the identification and detection of resistance determinants and for epidemiological analysis. The flexibility which is needed to cover situations where molecular testing is not yet completely developed has been properly worded.</p> <p>To improve clarity, the following further amendments are suggested (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
73. When possible, molecular testing should be used for the identification and detection of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.	<b>Norway</b> Norway supports the proposal from the Chair and co-chairs to use “should” instead of “may” because molecular testing is recognized as the most valuable instrument for the identification and detection of resistance determinants and for epidemiological analysis.
73. When possible, molecular testing of bacterial isolates should be used for the identification and detection of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.	<b>USA</b> Isolates are required to determine if the bacteria are alive and viable, to conduct whole genome sequencing and other research.
74. Molecular characterization is a useful tool which may be used for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.  <u>Proposed text:</u> 74. Molecular characterization in conjunction with epidemiological information, may inform the determination of source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.	<b>Australia</b> Suggest the following changes: <ul style="list-style-type: none"> <li>• Delete the first sentence as outbreak investigations are outside of the scope of this guideline document.</li> <li>• Delete the word epidemic.</li> </ul> To incorporate the above changes, suggest editing the text as follows (see Proposed text):
74. Molecular characterization is a useful tool which may be used for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.	<b>Canada</b> Improves the readability of the sentence.
74. <del>Molecular characterization is a useful tool which may be used for the</del> The rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.	<b>Chile</b> No need to put adjectives, and unfortunately molecular testing is not available in the whole world.
74. Molecular characterization is a useful tool which may be used for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.	<b>Costa Rica</b> <u>Position:</u> Our country requests to eliminate the adjective “useful”, We rather an expression neutral for instrumental or operative laboratory practices (see Proposed text). <u>Rationale:</u> The qualifying adjective “useful” is redundant according the rest of sentence which may be use for.

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u></p> <p>74. Molecular characterization is a tool which may be used for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.</p>	
<p>74. Molecular characterization is a useful tool <del>which may be used</del> for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological <del>information, may inform</del> <u>information informs</u> the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.</p> <p><u>Proposed text:</u></p> <p>Molecular characterization is a useful tool for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information informs the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.</p>	<p><b>European Union</b></p> <p>Despite improvement of the text, which is acknowledged, we would prefer not to use the term “may” in both situations to better reflect the benefit of use of such techniques, namely for identification of clusters and understanding of the spread of AMR.</p> <p>The text should read as follows (see Proposed text):</p>
<p>76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and may be used for the early detection or detection of resistant microorganisms of high public health importance.</p> <p><u>Proposed text:</u></p> <p>76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and may be used for the detection or detection of resistant microorganisms of high public health importance.</p>	<p><b>Australia</b></p> <p>Delete the word early as early detection is not a practical or realistic, as follows (see Proposed text):</p>
<p>76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic <del>results and may be used for the early detection or detection of resistant microorganisms of high public health importance</del> <u>results</u>.</p>	<p><b>Canada</b></p> <p>The second half of Para 76 is duplicative of the second sentence of Para 74. It is suggested to delete the text in strike out to streamline the document.</p>
<p><del>76. Molecular testing may be useful in addressing. Addressing</del> or confirming inconclusive phenotypic results and may be used for the early detection or detection of resistant microorganisms of high public health importance.</p>	<p><b>Chile</b></p>
<p>77. <del>Molecular methods may allow. Allow</del> for the integration of resistance data with other relevant public health data (e.g., virulence determinants).</p>	<p><b>Chile</b></p>

COMMENTS	MEMBER/OBSERVER
<b>8.7 COLLECTION AND REPORTING OF RESISTANCE DATA</b>	
79. (...) a. Reference to the general description of the sampling design and <del>randomization procedure</del> <u>plan</u> .	<b>Canada</b> In some cases, there may not be a randomization procedure, it may be convenience sampling. Hence, it is suggested to delete “randomization procedure” at the end of the sentence.
79. (...) b. Specific information about the origin of the sample such as from what, where <u>how</u> and when the sample was collected.	<b>Chile</b>
79. (...) d. Specific information about the isolation of the bacteria and the AST (e.g., date of testing, method used, quantitative results). In the case of qualitative <del>results</del> <u>results</u> , interpretative criteria should be recorded.	<b>USA</b>
80. Reporting of results from the monitoring and surveillance <del>program</del> <u>program(s)</u> should be timely.	<b>China</b> To be consistent with the rest of the whole text.
80. La comunicación de los resultados provenientes del programa de seguimiento y vigilancia debe ser oportuna.	<b>Colombia</b> Se recomienda ampliar el concepto “timely” para el reporte de esos resultados, tal vez ejemplificando con un lapso de tiempo óptimo para tal fin.
<b>9. COMPONENTS OF INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR AMU</b>	
Proposed text: 9. AMU and sales data to be considered for integrated monitoring and surveillance program(s) for AMR	<b>Australia</b> Modify the title to define the purpose for the inclusion AMU and sales data, as follows (see Proposed text):
<u>Considerations on AMU as a component</u> <del>Components</del> of integrated monitoring and surveillance program(s) <u>to be considered for AMU/AMR data interpretation</u>	<b>Brazil</b> Brazil suggests amending the title of Section 9 for clarity and to be consistent with other comments of the context of the AMU program as part of an AMR program.
<del>Components of integrated</del> monitoring and surveillance program(s) for <del>AMU</del> <u>AMU or sales data</u> .	<b>Chile</b>
Components of integrated monitoring and surveillance program(s) for AMU	<b>European Union</b> EUMS support retaining the title of this section for the sake of consistency within the GLIS. Also deleting old Paragraph 82 seems to be logical and at the same time avoids redundancy.

COMMENTS	MEMBER/OBSERVER
<del>Components of integrated monitoring</del> <b>Monitoring</b> and surveillance program(s) for AMU	<b>Japan</b> <u>Rationale:</u> For the purpose of these guidelines for AMR, any AMU monitoring is to help analysis of AMR surveillance results. Having “AMU component” in the title of Section 9 is misleading as it gives an impression that “AMR surveillance” and “AMU monitoring” are at the same level/weight in the overall framework of the AMR surveillance.
Components of integrated monitoring and surveillance program(s) for AMU	<b>Norway</b> Norway supports retaining the title of this section in order to be consistent throughout the GLIS.
<del>Componentes de un programa integrado de seguimiento y vigilancia del UAM</del>	<b>Uruguay</b> Uruguay sugiere sustituir el título a “El UAM como un componente del programa integrado de seguimiento y vigilancia a ser considerado en la interpretación de datos de RAM”
<del>Components of integrated monitoring and surveillance program(s) for AMU</del> <b>AMU and/or sales data</b>	<b>USA</b> The title should be modified to be more consistent with other titles of sections and include both AMU and/or sales data as options to collect
<b>9.1 DESIGN OF AN INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR ANTIMICROBIAL AGENTS INTENDED FOR USE IN FOOD PRODUCING ANIMALS OR PLANTS/CROPS</b>	
Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops	<b>Australia</b> Move paragraph 2 to the beginning of section 9 as the focus of section 9 is AMU, as follows:  For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.
<del>Considerations on the AMU component and key elements for antimicrobial agents intended for use in food producing animals or plants/crops</del> <b>Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops</b>	<b>Brazil</b> Brazil suggests rewording the whole title of the topic 9.1 to align with the content of the paragraphs below once they do not provide details of the design of an AMU program, but they provide general high-level considerations, which we agree is adequate in this case. This rewording is also consistent with other comments of the context of the AMU program as part of an AMR program and the fact that this is still an evolving issue.
<del>Component d</del> <b>Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops</b> <u>esign</u>	<b>Canada</b> Edits to the title to abbreviate it, i.e., deleting the text in strike out would align 9.1, with the naming convention used in Section 8.1 “Sampling Design” to harmonize the document.

COMMENTS	MEMBER/OBSERVER
<p><del>Diseño de un programa integrado de seguimiento y vigilancia de agentes antimicrobianos a ser usado en animales destinados a la producción de alimentos o plantas/cultivos</del></p>	<p><b>Uruguay</b> Uruguay sugiere cambiar el título a “Consideraciones sobre el componente UAM y los elementos clave para los agentes antimicrobianos destinados a ser utilizados en animales o plantas / cultivos destinados a la producción de alimentos”, debido a que se ajusta mejor al contenido de la sección.</p>
<p><u>New paragraph xx. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.</u> <u>New paragraph xx.bis For the AMU component of the monitoring and surveillance program(s), including sources of sales/use data and the collection and reporting of AMU data in food-producing animals, the OIE’s Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.</u></p> <p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p>	<p><b>Brazil</b> Rationale for new paragraph xx - Brazil is of the opinion that the description of AMU should be included at the beginning of Section 9, as it had been proposed before. Brazil does not agree in having this description in the Introduction. Rationale for new paragraph xx.bis - Brazil suggests deleting paragraphs 94 and 97 and moving the concept of these paragraphs to the beginning of Section 9, so it is clear that it applies to the whole topic on AMU for food-producing animals and does not have to be repeated.</p>
<p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p> <p><u>Proposed text:</u></p> <p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The relevant authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p>	<p><b>Australia</b> Modification to text to replace competent with relevant, as competent authority does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):</p>
<p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p>	<p><b>Chile</b> 82 bis .AMU, when available, or sales data are important information to be consider in the interpretation of the results from the AMR monitoring and surveillance program(s) along with other relevant epidemiology data.</p>
<p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority <del>should</del> <u>needs</u> consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p>	<p><b>China</b></p>

COMMENTS	MEMBER/OBSERVER
<p>82. <a href="#">OIE Terrestrial Animal Health Code Chapter 6.9, Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-Producing Animals and Aquatic Animal Health Code Chapter 6.3, “Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Aquatic Animals” describe approaches for monitoring quantities of antimicrobial agents.</a></p> <p>82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.</p>	<p><b>Japan</b></p> <p><u>Rationale:</u> OIE codes for monitoring use and a description of antimicrobial use and sales should be referenced. CODEX should avoid duplication, as member states will be confused if there are different standards.</p>
<p>82. Each country may decide to collect different types of <del>data,</del> <u>data on</u> sales and/or use, according to their monitoring and surveillance objectives. <u>Collection of</u><del>The</del> antimicrobial sales data <del>collection</del> may evolve into <del>the</del> collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus <del>other types of</del> use data; this is reflected below.</p>	<p><b>USA</b></p> <p>Edits to clarify that sales data are not “other types of use data”.</p>
<p>83. Sales data may be a valuable indicator to monitor trends although it does not always reflect the actual use, administration or application.</p> <p><u>Proposed text:</u></p> <p>83. Sales data may be used as an indicator to monitor trends although it does not always reflect the actual use, administration or application.</p>	<p><b>Australia</b></p> <p>Remove the word valuable due to the assumptions that need to be made to infer usage trends from sales data, sales data could at best be used as an indicator, as follows (see Proposed text):</p>
<p>83. Sales data may be a valuable indicator to monitor trends although it does not always reflect the actual use, administration or <del>application</del> <u>application of antimicrobials</u>.</p>	<p><b>Canada</b></p> <p>There seems to be a word missing at the end of the sentence. Hence it is suggested to add “of antimicrobials” for clarity and completeness of the sentence, and to specify that the sales data does not reflect use of antimicrobials.</p>
<p>83. Sales data may be a valuable indicator to monitor trends although it does not always reflect the actual use, administration (<u>dosage or species/class</u>) or application.</p>	<p><b>USA</b></p> <p>Provides clarification that sales data may not reflect actual use due to the potential for certain antimicrobials to be approved for multiple species at various doses dependent on indication.</p>
<p>84. The collection of use data from farms/producers may be challenging but provide valuable insight on the magnitude of use and species-specific information on how and why antimicrobials are <del>being</del> <u>used/administered</u>.</p>	<p><b>Canada</b></p> <p>The term “use or used” is repeated three times in this sentence. It is Suggested to replace the term “used” at the end of the sentence with “administered” for improved readability.</p>
<p>84. <del>The</del> <u>When possible, the</u> collection of use data from farms/producers <del>may be challenging but</del> provide <del>valuable insight on</del> the magnitude of use and species-specific information on how and why antimicrobials are being used.</p>	<p><b>Chile</b></p> <p>Avoid adjectives.</p>



COMMENTS	MEMBER/OBSERVER
85. The choice of units of measurement for AMU <del>should</del> <u>needs</u> be established depending on method and scope of the data collection and the monitoring and surveillance objectives.	<b>China</b>
85. The choice of <del>units of measurement indicators</del> for AMU <u>reporting</u> should be established depending on <del>method and the</del> scope of the data collection and the monitoring and surveillance objectives. <u>Proposed text:</u> The choice of indicators for AMU reporting should be established depending on the scope of the data collection and the monitoring and surveillance objectives.	<b>Norway</b> Norway suggest to edit this para to add clarity. The sentence should read (see Proposed text):
85. The choice of units of measurement for AMU <u>and/or sales data</u> should be established depending on method and scope of the data collection and the monitoring and surveillance objectives.	<b>USA</b> Wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text.
86. The following elements should be considered when deciding on the approach to collect sales and/or use data.	<b>Australia</b> Delete this point and instead refer to the OIE standards, as AMU is the remit of the OIE. Noting that for plants the IPCC is yet to develop guidance/standards relevant to AMR and AMU.
86. The following elements <del>should</del> <u>need to</u> be considered when deciding on the approach to collect sales and/or use data.	<b>China</b>
86. The following elements should be considered when deciding on the approach to collect sales and/or use data: b. <del>Identification of the most appropriate points of data collection and the stakeholders that can provide the data.</del> <u>Proposed text:</u> b. <u>Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.b. (bis) Identification of the sectors where collection of data would be most relevant and efficient to meet monitoring and surveillance objectives.</u>	<b>Canada</b> Para 40 has the following: <ul style="list-style-type: none"> <li>Antimicrobial distribution chains, from manufacturing or import to end-user, including sales/use data providers.</li> <li>Identification of the sectors where collection of data would be most relevant and efficient to meet monitoring and surveillance objectives.</li> </ul> The goal of para. 40 was to introduce the concept, with more details intended in Section 9. But we actually have the reverse. Switched this bullet in 86 with the first two bullets of para 40.
86. The following elements should be considered when deciding on the approach to collect sales and/or use data: b. Identification of <del>the most appropriate the</del> points of data collection and the stakeholders that can provide <del>the data-</del> <u>data covering all sales and use in under surveillance nationally or by animal species, respectively</u>	<b>Norway</b> We suggest a modification to add clarity: Identification of the most appropriate points of data collection and the stakeholders that can provide data covering all sales and use in under surveillance nationally or by animal species, respectively.

COMMENTS	MEMBER/OBSERVER
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>b. Identification of the most appropriate points of data collection and the stakeholders <del>that</del><u>who</u> can provide the data.</p>	<p><b>USA</b></p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>c. Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) <del>and-or</del> quantitative information on the antimicrobials <del>intended for use</del><u>sold, prescribed or used</u> in food producing animals or plants/crops.</p>	<p><b>Norway</b></p> <p>We suggest a modification to add clarity: Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) or quantitative information on the antimicrobials sold, prescribed or used in food producing animals or plants/crops.</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>d. <del>Harmonization of the nomenclature</del><u>omencature</u> of antimicrobial agents <del>harmonized</del> with international standards where available.</p>	<p><b>Canada</b></p> <p>Edits provided to align the bullet with the chapeau statement in Para 86.</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>d. Nomenclature <del>of-for</del> antimicrobial agents harmonized with international standards where available.</p>	<p><b>Norway</b></p> <p>We suggest a minor change by changing "of" to "for".</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>e. <del>Identification, where possible, Identification</del> of the plant/crop type and species of food-producing animals for which the antimicrobials were intended to be used.</p>	<p><b>Canada</b></p> <p>We would suggest deleting “where possible” from the sentence since it is not necessary. The wording of the chapeau sentence (para 86) provides flexibility by noting the elements that should be considered.</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>e. Identification, where possible, of the plant/crop type and species of food-producing animals for which the antimicrobials were <del>intended to be sold, prescribed or</del> used.</p>	<p><b>Norway</b></p> <p>We suggest a modification to add clarity: Identification, where possible, of the plant/crop type and species of food-producing animals for which the antimicrobials were sold, prescribed or used.</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>g. <del>Information, where possible, Information</del> on antimicrobial dose, dosing interval and duration.</p>	<p><b>Canada</b></p> <p>We would suggest deleting “where possible” from the sentence since it is not necessary. The wording of the chapeau sentence (para 86) provides flexibility by noting the elements that should be considered.</p>
<p>86. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p> <p>g. Information, where possible, on antimicrobial dose, dosing interval and duration.</p>	<p><b>European Union</b></p> <p>EUMS acknowledge the aim for consistency with OIE wording when keeping “dose, dosing interval and duration” in bullet g.</p>
<p><b>9.2 SOURCES OF SALES/USE DATA</b></p>	

COMMENTS	MEMBER/OBSERVER
Sources of sales/use data	<b>Australia</b> Delete this detail and just keep para 94 that refers to the OIE standards, as AMU is the remit of the OIE. Noting that for plants the IPCC is yet to develop guidance/standards relevant to AMR and AMU.
Sources of <del>sales/use</del> sales data	<b>USA</b> Use and sales should be reversed to be consistent with the rest of the text.
87. <del>Options for sources</del> Sources of data may include:	<b>Canada</b> Since the verb “may” gives enough flexibility, the word “options” at the beginning of the sentence is redundant and could be deleted.
87. Options for sources of data may include:	<b>USA</b> The order of points a) and b) should be reversed to match the suggested change to the title of Section 9.2.
87. Options for sources of data may include: <ul style="list-style-type: none"> <li><b>Import data:</b> may be collected from the competent authorities that are in charge of registration of medicinal products or customs. Care must be taken to avoid double counting <del>with of the</del> sales data <del>in within the country and country, as well as for</del> those antimicrobials not intended for use within the country.</li> </ul>	<b>Canada</b> Edits provided to enhance sentence structure and clarity.
87. Options for sources of data may include: <ul style="list-style-type: none"> <li><b>Import data:</b> may be collected from the competent authorities <del>that are</del> in charge of registration of medicinal products or customs. Care must be taken to avoid double counting with sales data in the country and <del>these take into account that some imported</del> antimicrobials <del>may not be</del> intended for use within the country.</li> </ul>	<b>USA</b> Edits provided for clarity.
88. Data on quantities of antimicrobials sold or used within a country may differ. Differences may include loss during transport ( <del>pack (package</del> damage), storage (due expiry date) and administration (whole package not administered), stock purchased and held for future use, and fluctuations in animal or plant/crop populations.	<b>Canada</b> The word “pack” may not be well understood; “package” is more clear.
88. Los datos sobre las cantidades de antimicrobianos vendidos o utilizados dentro de un país pueden diferir. Las diferencias pueden provenir de las pérdidas durante el transporte (daños al embalaje), el almacenamiento (fecha de vencimiento cumplida) y la administración (falta de administración del envase completo), las existencias compradas y guardadas para uso futuro, y las fluctuaciones en la población animal o de plantas/cultivos.	<b>Colombia</b> De ser posible, se sugiere mencionar que algunas de estas diferencias en los datos sobre las cantidades de antimicrobianos utilizados también pueden corresponder a aquellos que han sido adquiridos de manera no controlada e incluso ilegal.
<b>9.3 COLLECTION AND REPORTING AMU</b>	
Collection and reporting of AMU	<b>Australia</b> Renumber to 9.2.

COMMENTS	MEMBER/OBSERVER
<p><b>Collection and reporting of AMU</b></p> <p><u>Proposed text:</u></p> <p>“According the collection and reporting AMU data, the Codex takes the reference to OIE (World Organization for Animal Health), as the competent international organism which establish the actions and documents related to monitoring and surveillance of AMU in animals (food producing animals). And, in addition, Codex takes as a reference to IPPC (International Plant Protection Convention) as the competent international organisms to establish the standard documents of monitoring and surveillance AMU in plants/crops.”</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country request to delete the para 86-88, and confirms to delete the section 9.3. and in concordance with some para like 53 And we propuse the next paragraph in substitution (See Proposed text):</p> <p><u>Rationale:</u> We consider this section is under the reference of OIE (animal Health and the AMU). The OIE is working with this data collection many years ago, support the countries in advancing then level of notification of AMU and OIE maintains a more frequent update of its reference’s documents. We consider pertinent to avoid now and the future duplication or incoherencies between international standard documents from CODEX and OIE according Animal Health issue. In Plant/Crops, is the same case, Codex standard documents needs wait for the development of the reference for the Internationals reference organism like IPPC.</p>
<p><b>Collection and reporting of AMU</b></p>	<p><b>European Union</b></p> <p>EUMS recognize that merging sections 9.3-9.5 has an added value in terms of joining actions pragmatically. Moreover, the current text keeps the balance between general advice for collection and reporting of AMU and the reference to OIE codes as the framework to be considered. Some further amendments are suggested below.</p>
<p><del>Collection and reporting of AMU</del></p>	<p><b>USA</b></p> <p>OIE codes for monitoring use and sales should be maintained in paragraphs 94 and 97 and the rest of section 9.3 (in this version) should be deleted. Codex should be referencing the international standard setting body with an on-farm mandate that has been working on collecting such data for many years and not run the risk of providing conflicting or contradictory advice with OIE. OIE is regularly updating OIE standards and guidance on AMU collection.</p> <p>Reference to OIE should be made here and further explanations should stop at Paragraph 88 to avoid duplication of efforts with OIE.OIE is also collecting data globally and constantly evaluating and improving the process. International standards for measuring antimicrobial pesticide use in crops do not exist so the TFAMR should not be prescribing these here.</p>
<p><b>COLLECTION OF DATA</b></p>	
<p><del>Collection of data</del></p>	<p><b>Canada</b></p> <p>These type of headings are not present within the AMR section and are not used in any other place within this document, and hence, it is suggested to delete them. As well, the title for 9.3 already clarifies “Collection and reporting of AMU”.</p>
<p><del>Collection of data</del></p>	<p><b>USA</b></p>

COMMENTS	MEMBER/OBSERVER
89. The data collection should <del>cover</del> <u>consider</u> the following elements:	<b>Brazil</b> Brazil suggests replacing the term “cover” by “consider” providing more flexibility, to align with other proposals for flexibility throughout the document, as agreed for example in Section 8 paragraph 42. Brazil is of the opinion that recommendations for Section 9 have to be flexible once AMU data collection is still an evolving issue, standards are not yet harmonized and there is still no worldwide consensus on measurements and indicators.
<del>89. The data collection should cover the following elements:</del>	<b>China</b> This paragraph has no substantive content.
89. The data collection should <del>cover</del> <u>consider</u> the following elements:	<b>Japan</b> To align with other proposals for flexibility throughout the document.
<del>89. The data collection should cover the following elements:</del>	<b>USA</b>
<b>THE NUMERATOR</b>	
<del>The numerator</del>	<b>Canada</b> These sub-headings are not used throughout the document. As well, with such a short paragraph, the sub-heading is not required as the following paragraph 90 discusses the numerator. Suggest to delete them.
<del>The numerator: <u>Antimicrobial quantities representing the amount of antimicrobial agents sold or used</u></del>	<b>Chile</b>
<del>The numerator</del>	<b>Japan</b> Delete the terminologies “Numerator” and “Denominator” <u>Rationale:</u> Although these terminologies “Numerator” and “Denominator” indicate that there will be calculation of “per unit use”, these guidelines don’t include such guidance. As they are not used anywhere in these guidelines, these terminologies should be deleted to avoid confusion.
<del>The numerator</del>	<b>USA</b>
90. Antimicrobial quantities representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used <u>during</u> the monitoring and surveillance period. In some cases this may be based on estimates.	<b>Brazil</b> Brazil suggests including “during” to add clarity to the paragraph.
90. <del>Antimicrobial quantities</del> <u>The numerator is the antimicrobial quantity</u> representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used <u>during</u> the monitoring and surveillance period. In some cases this may be based on estimates.	<b>Canada</b> Additional text added to complete the sentence and improve clarity. Word missing from the sentence, and added to improve sentence structure.

COMMENTS	MEMBER/OBSERVER
<p><del>90. Antimicrobial quantities representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used the monitoring and surveillance period. In some cases this may be based on estimates.</del></p>	<p><b>Chile</b></p>
<p>90. Antimicrobial quantities <del>representing</del> <u>represent</u> the amount of antimicrobial agents sold or <del>used</del> <u>used in food producing animals or in plants</u>. This is normally expressed as the weight in kilograms of the <del>antimicrobials</del> <u>antimicrobial</u> active ingredient which was sold or used <u>during</u> the monitoring and surveillance period. In some cases this may be based on estimates.</p> <p><u>Proposed text:</u></p> <p>90. Antimicrobial quantities represent the amount of antimicrobial agents sold or used in food producing animals or in plants. This is normally expressed as the weight in kilograms of the antimicrobial active ingredient which was sold or used during the monitoring and surveillance period. In some cases this may be based on estimates.</p>	<p><b>European Union</b></p> <p>An editorial adjustment is suggested for the second sentence.</p> <p>EUMS suggest to amend the first sentence. The paragraph should read as follows (see Proposed text):</p>
<p>90. Antimicrobial quantities representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used the monitoring and surveillance period. <del>In some cases this</del> <u>This</u> may be based on estimates.</p>	<p><b>Japan</b></p> <p>Delete “In some cases”, as estimation is not an exceptional cases, but almost always necessary in reality.</p>
<p>90. Antimicrobial quantities representing the amount of antimicrobial agents sold or <del>used</del> <u>used in food producing animals or in plants</u>. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used <u>during</u> the monitoring and surveillance period. <del>In some cases this</del> <u>For use data by species, defined daily dose animal by animal species may also be based on estimates</u> <u>used to express the numerator</u>.</p>	<p><b>Norway</b></p> <p>We suggest the following modification to add clarity:</p> <p>Antimicrobial quantities representing the amount of antimicrobial agents sold or used in food producing animals or in plants. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used during the monitoring and surveillance period. For use data by species, defined daily dose animal by animal species may also be used to express the numerator.</p>
<p><del>90. Antimicrobial quantities representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used the monitoring and surveillance period. In some cases this may be based on estimates.</del></p>	<p><b>USA</b></p>
<p>91. To calculate the numerator data should include identification of the antimicrobial product, the <del>number of packs</del> <u>quantity</u> sold or <del>used, the pack size</del> <u>used</u> and the strength per unit.</p>	<p><b>Canada</b></p> <p>The “number of packs” and “pack size” are terms that are more specific to antimicrobials used as drugs whereas “quantity sold or used” is more universal.</p>
<p><del>91. To calculate the numerator data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.</del></p>	<p><b>Brazil</b></p> <p>Brazil suggests deleting this paragraph once it is too prescriptive and there are other ways to calculate the amount of antimicrobial agents used or sold. Brazil does not agree in having prescriptive recommendations for Section 9 once AMU data collection is still an evolving issue, standards are not yet harmonized and there is still no worldwide consensus on measurements and indicators.</p>

COMMENTS	MEMBER/OBSERVER
<del>91. To calculate the numerator data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.</del>	<b>Chile</b>
91. To calculate the numerator data <del>should of</del> <u>AMU can</u> include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.	<b>China</b>
<del>91. To calculate the numerator data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.</del>	<b>Japan</b> Delete this paragraph. <u>Rationale:</u> Too detailed explanation for very common conduct.
91. To calculate the numerator data should include identification of the antimicrobial product, the <del>number of packs amount</del> sold or used, <del>the pack size,</del> and the strength per unit.	<b>Norway</b> We suggest the following modification to add clarity: To calculate the numerator, data should include identification of the antimicrobial product, the amount sold or used, and the strength per unit.
91. To calculate the <del>numerator numerator,</del> data should include identification of the antimicrobial product, <u>and the number of packs amount</u> sold or used, <del>the pack size and the strength per unit.</del> <u>Proposed text:</u> 91. To calculate the numerator, data should include identification of the antimicrobial product, and the amount sold or used.	<b>European Union</b> EUMS do not consider it essential to collect information on number of packs sold or used and pack size. To allow different ways of collecting the information this can be replaced by 'amount sold and used'. The sentence should read as follows (see Proposed text):
<del>91. Para calcular el numerador, los datos deben incluir la identificación del producto antimicrobiano, la cantidad de envases vendidos o utilizados, el tamaño del envase y la concentración por unidad.</del>	<b>Uruguay</b> Uruguay entiende que este párrafo es muy prescriptivo y sugiere eliminarlo. Existen otras metodologías para calcular el numerador de las ventas/uso de agentes antimicrobianos.
<del>91. To calculate the numerator data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.</del>	<b>USA</b>
<b>THE DENOMINATOR</b>	
<i>The denominator</i>	<b>Canada</b> These sub-headings are not used throughout the document. As well, with such a short paragraph the sub-heading is not required as the following paragraph 92 clearly discusses the denominator. Suggest to delete.
<i>The denominator: The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period</i>	<b>Chile</b>
<i>The denominator</i>	<b>Japan</b>
<i>The denominator</i>	<b>USA</b>

COMMENTS	MEMBER/OBSERVER
92. The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. <a href="#">Relevance to the food production system in the country should be considered.</a> The denominator provides the context for reporting and analyzing the sales and/or use data.	<b>Brazil</b> Brazil suggests including the sentence “Relevance to the food production system in the country should be considered.” to provide flexibility. Brazil is of the opinion that recommendations for Section 9 have to be flexible once AMU data collection is still an evolving issue, standards are not yet harmonized and there is still no worldwide consensus on measurements and indicators.
92. The <a href="#">denominator represents the</a> total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. The denominator provides the context for reporting and analyzing the sales and/or use data.	<b>Canada</b> Text added to enhance clarity and sentence structure.
<del>92. The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. The denominator provides the context for reporting and analyzing the sales and/or use data.</del>	<b>Chile</b>
92. The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. <a href="#">The denominator Such data</a> provides the context for reporting and analyzing the sales and/or use data.	<b>Japan</b>
<del>92. The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. The denominator provides the context for reporting and analyzing the sales and/or use data.</del>	<b>USA</b>
93. Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) <del>may</del> <a href="#">should</a> also be considered.	<b>Canada</b> If sales or use data is to be collected, then there should be consideration of the population the drugs are going into. Hence, it is suggested to replace “may” with “should”.
<del>93. Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) may also be considered.</del>	<b>Chile</b>
<del>93. Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) may also be considered.</del>	<b>Japan</b> Delete this paragraph. <b>Rationale:</b> For animals, no need/no use to go into such details as the countries follow OIE’s advices.
<del>93. Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) may also be considered.</del>	<b>USA</b>



COMMENTS	MEMBER/OBSERVER
94. For collection of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.	<b>Australia</b> Delete points 89-93 and just keep para 94 that refers to the OIE standards, as AMU is the remit of the OIE. Noting that for plants the IPCC is yet to develop guidance/standards relevant to AMR and AMU.
<del>94. For collection of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.</del>	<b>Brazil</b> Brazil suggests deleting paragraphs 94 and 97 and moving the concept of these paragraphs to the beginning of Section 9, so it is clear that it applies to the whole topic on AMU and does not have to be repeated.
94. For collection of data <u>on AMU</u> in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.	<b>Canada</b> Text added for clarity.
94. For collection <u>AMU or sales</u> of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.	<b>Chile</b>
<b>REPORTING OF DATA</b>	
<b>Reporting of data</b>	<b>Canada</b> Section 9.3 clarifies "Collection and Reporting of Data" this sub-heading is not needed for such a short section. This format is also not present in the rest of the document. Suggest to delete.
<b>Reporting of data</b>	<b>USA</b>
<del>95. Multiple units of measurement for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.</del>	<b>Chile</b>
<del>95. Multiple units of measurement for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.</del>	<b>Japan</b> Delete this paragraph. <u>Rationale:</u> For animals, no need/no use to go into such details as the countries follow OIE's advices. For plant, if needed, it should be clarified in para 96.
<del>95. Multiple units of measurement for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.</del>	<b>USA</b>
<del>96. For plants/crops, the information above is applicable and additional units of measurement may be established according to national priorities.</del>	<b>Chile</b> We do not know that, this is a food safety specialist ISSB not plant health specialist.
<del>96. For plants/crops, the information above is applicable and additional units of measurement may be established according to national priorities.</del>	<b>USA</b>

COMMENTS	MEMBER/OBSERVER
97. For reporting of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.	<b>Australia</b> Delete points 95 and 96 and just keeping para 97 that refers to the OIE standards, as AMU is the remit of the OIE. Noting that for plants the IPCC is yet to develop guidance/standards relevant to AMR and AMU.
<del>97. For reporting of data in food producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.</del>	<b>Brazil</b> Brazil suggests deleting paragraphs 94 and 97 and moving the concept of these paragraphs to the beginning of Section 9, so it is clear that it applies to the whole topic on AMU and does not have to be repeated.
97. For reporting of <u>AMU or sales</u> data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.	<b>Chile</b>
<b>10. INTEGRATED ANALYSIS AND REPORTING OF RESULTS</b>	
<b>10.1 MANAGEMENT OF DATA</b>	
98. To facilitate the management of data, database(s) should be structured, and where feasible, centralized to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance program(s) improves. <u>Proposed text:</u> 98. To facilitate the management of data, database(s) should be structured, and where feasible, coordinated to allow for easy extraction of data and appropriate analysis when required, and to accommodate planned expansion(s) of the integrated monitoring and surveillance program(s).	<b>Australia</b> Modification to text improve readability and allow flexibility, as follows (see Proposed text):
98. To facilitate the management of data, database(s) should be structured, and where feasible, centralized to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance program(s) improves. <u>Proposed text:</u> 98. To facilitate the management of data, database(s) should be structured, and where feasible or possible to centralized the data to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance program(s) improves.	<b>Costa Rica</b> <u>Position:</u> Our country requests and amendment to the para 98 (see Proposed text). <u>Rationale:</u> We consider important be clear and flexible in the context of this para. In developing countries there is not possible in a centralized way because there are many institutions involve in the monitoring and surveillance, and to centralize data implicates and a system or big platform to report/manage the data.
98. To facilitate the management of data, database(s) should be structured, and where feasible, centralized to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance program(s) <u>improves/evolves</u> .	<b>USA</b>
100. To facilitate the management of data, ongoing or regular validation of the data <u>may should</u> be performed.	<b>Canada</b> Ongoing or regular validation is a necessary part of the management of data for monitoring and surveillance program(s), hence, it is recommended to replace the verb "may" with "should".

COMMENTS	MEMBER/OBSERVER
100. To facilitate the management of data, ongoing or regular validation of the data <del>may</del> <u>should</u> be performed.	<b>European Union</b> EUMS suggest to replace “may” by “should” as unvalidated data has little value. The sentence should read: To facilitate the management of data, ongoing or regular validation of the data should be performed.
101. A description of sampling designs, stratification and randomization procedures per animal populations and plant/crop, food production environment or food categories should be recorded to link the data within and across monitoring and surveillance components.  <u>Proposed text:</u> 101. A description of sampling designs, stratification and randomization procedures per animal populations, plant/crop, food production environment or food categories should be recorded to link the data within and across monitoring and surveillance components.	<b>Australia</b> Modification to text to allow flexibility, as follows (See Proposed text):
101. A description of <del>the sampling designs</del> <u>designs and sampling plan, including any</u> stratification and randomization <del>procedures per animal populations and procedures, the animal,</del> plant/crop, food production environment or food categories should be recorded to link the data within and across monitoring and surveillance components.	<b>Canada</b> To provide added clarity to the sentence.
101. A description of sampling designs, stratification and randomization procedures per animal populations and plant/crop, food production environment or food categories <del>should</del> <u>needs to</u> be recorded to link the data within and across monitoring and surveillance components.	<b>China</b>
101. A description of sampling designs, stratification and randomization procedures <del>per</del> <u>according to</u> animal populations and plant/crop, food production environment or food categories should be recorded to link the data within and across monitoring and surveillance components.	<b>USA</b>
<b>10.2 ANALYSIS OF RESULTS</b>	
102. The data from the integrated monitoring and surveillance program(s) may be analyzed as described in CXG 77-2011 for risk assessment to then inform the development and implementation of risk management options and policies <del>to</del> <u>which could</u> drive responsible and prudent use of antimicrobials to address foodborne AMR.	<b>Canada</b> Suggest to replace “to” with “which could” as the implementation of risk management options and policies may not always drive responsible and prudent use.
102. The data from the integrated monitoring and surveillance program(s) may be analyzed as described in CXG 77-2011 for risk assessment <u>purposes and</u> <del>to then</del> inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials to address foodborne AMR.	<b>USA</b>
103. Analysis of data from the integrated monitoring and surveillance of AMR and AMU may include the assessment within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. When available, other contextual information such as epidemiological data may be considered.	<b>Australia</b> Modification to text for consistency with the rest of the document, as follows (see Proposed text):

COMMENTS	MEMBER/OBSERVER
<p><u>Proposed text:</u></p> <p>103. Analysis of data from the integrated monitoring and surveillance program(s) may include the assessment within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. When available, other contextual information such as epidemiological data may be considered.</p>	
<p>103. Analysis of data from the integrated monitoring and surveillance of <del>AMR and AMR</del>, AMU <u>or sales data and when available other contextual information such as epidemiological data</u> may include the assessment within <del>or between</del> sectors across the One Health spectrum, <u>when possible</u>, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. <del>When available, other contextual information such as epidemiological data may be considered.</del></p>	<p><b>Chile</b></p> <p>It is not always possible to assess the other sectors, because there is no data to compare.</p>
<p>103. Analysis of data from the integrated monitoring and surveillance of <del>AMR and AMR</del>, AMU <u>and/or sales data, and associated contextual data</u> may <del>include-include</del>, <u>when scientifically appropriate</u>, the assessment within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. <del>When available, other contextual information such as epidemiological data may be considered.</del></p>	<p><b>USA</b></p> <p>1) Wherever AMU is mentioned, 'AMU and/or sales data' should be mentioned for clarity throughout the text.</p> <p>2) Numbers from a monitoring and surveillance system mean little without contextual data, and any analysis must be scientifically appropriate when assessing across sectors as different sectors often generate incomparable data. Increases in AMR in salmonellae across different sectors temporally may be due to prevalence and persistence of strains with a propensity for drug resistant genes versus AMU, so contextual data is crucial to identify and mitigate risks. Considering risk assessment, one would have to take into account the environmental and biological factors that could affect an antimicrobial as it travels through the intestine of the target animal, food production environment, and food system-what this whole document is about.</p>
<p>104. The detailed methodology and the epidemiological context of the monitoring and surveillance program(s) should be considered for the analysis. Where data are available, exposure pathways among people, food producing animals, plants/crops and their shared environment connecting resident bacterial populations may be incorporated into the analysis.</p> <p><u>Proposed text:</u></p> <p>104. The detailed methodology and the epidemiological context of the monitoring and surveillance program(s) should be considered for the analysis. Where data are available, exposure pathways among people, food producing animals, plants/crops and/or their shared environment connecting resident bacterial populations may be incorporated into the analysis.</p>	<p><b>Australia</b></p> <p>Modification to text to allow flexibility, as follows (see Proposed text):</p>

COMMENTS	MEMBER/OBSERVER
<p>105. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of any relationship between AMU and AMR within or across the food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, and the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.</p> <p><u>Proposed text:</u></p> <p>105. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of any relationship between AMU and AMR within or across the food producing animals, plants/crops and/or human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, and the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.</p>	<p><b>Australia</b></p> <p>Suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to text to reflect the focus and purpose of the document is AMR.</li> <li>• Modification to text to allow flexibility.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
<p>105. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of <del>any</del> relationships between AMU and AMR within or across the food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the <del>understanding, and the investigation</del> understanding of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.</p>	<p><b>Canada</b></p> <p>Suggest to delete “any” and add a “s” to relationships to enhance clarity.</p> <p>Duplicative of the first part of the second sentence. Edits made to avoid repetition.</p>
<p>105. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of any relationship between AMU and AMR within or across <del>the</del> food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, and <del>in</del> the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.</p> <p><u>Proposed text:</u></p> <p>The paragraph should read as follows: Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of any relationship between AMU and AMR within or across food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, and in the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.</p>	<p><b>European Union</b></p> <p>Some editorial amendments are suggested (see Proposed text):</p> <p>EUMS agree with the use of “factors” instead of “drivers” as proposed during the PWG, especially because of the alignment with existing Codex texts.</p>

COMMENTS	MEMBER/OBSERVER
<p>105. <del>Data may originate from different Integrated monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches foodborne AMR should allow be harmonized across these sectors to assist in the understanding, and the investigation of relationships between AMR and AMU and/or sales data, including other factors that may influence the emergence and spread of AMR. When investigating any relationship between AMU and/or sales data and AMR within or across the food producing animals, plants/crops and human populations, provided that the choice of analytical approaches should be based on AMR and AMU and/or sales data that are representative of antimicrobials intended for use in the target populationpopulations. Integrated Data may originate from different monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding program(s), and the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR so comparability is an important consideration.</del></p>	<p><b>USA</b></p> <p>Sentences are reordered in the paragraph for clarity, but the words are the same. The choice of analysis can be based on data sources. For example, the use of qPCR data vs culture-based data can influence the way you interpret quantitative risk assessment models. Infectious dose models are based on culture data and using qPCR data will overestimate the risk. Because qPCR data is more sensitive, detecting molecules within a sample (often molecules that don't represent viable cells), you must transform the data so that it makes contextual sense within a culture-based framework. Similar concerns arise from an AMR perspective with respect to assay selection or data selection when working with AMU or AMR data.</p>
<p>106. AMR data from relevant human isolates may be considered for inclusion in the analysis and reporting based on information from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.</p>	<p><b>Canada</b></p> <p>See earlier comments on the use of “commensal” vs “indicator”.</p>
<p>106. AMR data from relevant human <del>isolates-isolates, when available,</del> may be considered for inclusion in the analysis and reporting based on information from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.</p>	<p><b>Chile</b></p>
<p>106. Se puede considerar la inclusión de aislados de humanos relevantes en el análisis y la comunicación de información sobre patógenos transmitidos por los alimentos que sean significativos según la información epidemiológica nacional y, toda vez que sea posible, floras comensales.</p>	<p><b>Colombia</b></p> <p>Cambiar el termino flora por microbiota</p>
<p>107. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance in humans, plants/crops and animals.</p> <p><u>Proposed text:</u></p> <p>107. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance between humans, plants/crops and/or animals.</p>	<p><b>Australia</b></p> <p>Suggest the following changes:</p> <ul style="list-style-type: none"> <li>• Modification to clarify that the trends can be a pattern across humans, plant/crops and animals, rather than a separate trend within each population.</li> <li>• Modification to text to allow flexibility.</li> </ul> <p>To incorporate the above changes, suggest editing the text as follows (see Proposed text):</p>
<p><del>107. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance in humans, plants/crops and animals.</del></p>	<p><b>Chile</b></p> <p>Repetition with 105</p>
<p>107. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance in humans, <u>food</u>, plants/crops and animals.</p>	<p><b>China</b></p>

COMMENTS	MEMBER/OBSERVER
<b>10.3 REPORTING OF RESULTS</b>	
<p>109. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders under the One Health approach should be encouraged.</p> <p><u>Proposed text:</u></p> <p>109. Transparent and open communication for the reporting of the results between the relevant authorities and the different stakeholders under the One Health approach should be encouraged.</p>	<p><b>Australia</b></p> <p>Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):</p>
<p>109. Transparent and open communication for the reporting of the results between the competent authorities and the <del>different-relevant</del> stakeholders <del>under the One Health approach</del> should be encouraged.</p>	<p><b>Chile</b></p> <p>It is not limited to the OH, in some cases stakeholders from economy will also relevant, or congress.</p>
<p>109. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders under the One Health approach <del>should be</del> <u>is</u> encouraged.</p>	<p><b>China</b></p>
<p>109. Transparent and open communication for the reporting of the results between the competent authorities and the different <del>stakeholders</del> <u>stakeholders including the public</u> under the One Health approach should be encouraged.</p> <p><u>Proposed text:</u></p> <p>109. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders including the public under the One Health approach should be encouraged.</p>	<p><b>European Union</b></p> <p>EUMS believe that data results should be made publicly available and thus suggest the following change (see Proposed text):</p>
<p>109. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders <u>including the public</u> under the One Health approach should be encouraged.</p> <p><u>Proposed text:</u></p> <p>Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders including the public under the One Health approach should be encouraged.</p>	<p><b>Norway</b></p> <p>We suggest adding some wording because these reports should be made publicly available (see Proposed text):</p>
<p>110. Results of integrated monitoring and surveillance program(s) <del>should</del> <u>need to</u> be reported regularly, where resources allow.</p>	<p><b>China</b></p>
<p>110. Results of integrated monitoring and surveillance program(s) should be reported regularly, where resources allow.</p> <p><u>Proposed text:</u></p> <p>110. Results of integrated monitoring and surveillance program(s) should be reported regularly established by the country and where resources allow it.</p>	<p><b>Costa Rica</b></p> <p><u>Position:</u> Our country requests the clarification of the par 110, and propose an amendment (see Proposed text).</p> <p><u>Rationale:</u> We consider important be clear and flexible in the context of this para.</p>

COMMENTS	MEMBER/OBSERVER
<p>111. When available, summary reports on the integrated monitoring and surveillance program(s) data across humans, animals, plants/crops, food and the food production environment may be made publicly available.</p> <p><u>Proposed text:</u></p> <p>111. When available, summary reports on the integrated monitoring and surveillance program(s) data across humans, animals, plants/crops, food and/or the food production environment may be made publicly available.</p>	<p><b>Australia</b></p> <p>Modification to text to allow flexibility, as follows (see Proposed text):</p>
<p>111. When available, summary reports on the integrated monitoring and surveillance program(s) data across humans, animals, plants/crops, food and the food production environment <del>may</del><u>should</u> be made publicly available.</p>	<p><b>Norway</b></p> <p>We are of the opinion that disclosure of such data is essential for further work to address AMR globally, thus "may" needs to be replaced by "should".</p>
<p>111. When available, <del>summary</del> reports on the integrated monitoring and surveillance program(s) data across humans, animals, plants/crops, food and the food production environment may be made publicly available.</p>	<p><b>USA</b></p> <p>Edited for flexibility on what types of reporting is conducted.</p>
<p><b>11. EVALUATION OF THE INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S)</b></p>	
<p>112. Evaluation of the integrated monitoring and surveillance program(s) provides assurance that the data and information reported are robust and the program objectives are being met. <del>The evaluation will also provide the best use of data collection resources.</del></p>	<p><b>Canada</b></p> <p>This statement is not always true of evaluation. Suggest to remove as evaluation provides input to make changes to improve what needs to be improved. For example this could be analysis and reporting.</p>
<p>112. Evaluation of the integrated monitoring and surveillance program(s) provides assurance that the data and information reported are robust and the program objectives are being met. The evaluation will also <del>provide</del><u>guide</u> the best use of data collection resources.</p>	<p><b>USA</b></p>
<p>113. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and changing patterns of AMU in humans, animals and plants/crops, and to respond to changing national needs.</p> <p><u>Proposed text:</u></p> <p>113. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and changing patterns of AMU in humans, animals and/or plants/crops, and to respond to changing national needs.</p>	<p><b>Australia</b></p> <p>Modification to text to allow flexibility, as follows (see Proposed text):</p>



COMMENTS	MEMBER/OBSERVER
113. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and changing patterns of AMU in humans, animals and plants/crops, and to respond to changing national <del>needs</del> <u>priorities</u> .	<b>Canada</b> Replace “needs” with “priorities” to be in line with the rest of the document.
113. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and <del>changing</del> <u>changing patterns</u> of AMU in humans, animals and plants/crops, and to respond to changing <u>in</u> national needs.	<b>Chile</b>
114. Competent authorities should develop a framework and plan to facilitate the evaluation and review of monitoring and/or surveillance activities, which may include the following: <u>Proposed text:</u> 114. Relevant authorities should develop a framework and plan to facilitate the evaluation and review of monitoring and/or surveillance activities, which may include the following:	<b>Australia</b> Modification to text to replace competent with relevant, as competent authorities does not provide the flexibility for countries with business models of sharing responsibilities and solid partnerships, as follows (see Proposed text):
114. (...) <ul style="list-style-type: none"> <li>Describe the monitoring and surveillance program(s) to be evaluated, including the objectives and desired outcomes. This may involve a subsection of the entire program(s) <del>(e.g., the sample collection, laboratories, analysis and reporting)</del>.</li> </ul>	<b>Chile</b> A subsection of the program can be also the monitoring program at farm level. It will depend how each country structure the program, which subsection will be. Examples are confusing.
114. (...) <ul style="list-style-type: none"> <li>Identify key stakeholders for <del>perform??</del>the evaluation.</li> </ul>	<b>Chile</b>
114. (...) <ul style="list-style-type: none"> <li>Consider <del>stakeholder-relevant stakeholders</del> input/feedback.</li> </ul>	<b>Chile</b>
114. (...) <ul style="list-style-type: none"> <li>Share evaluation outcomes with <u>relevant</u> stakeholders.</li> </ul>	<b>Chile</b>
115. If the design of the monitoring and surveillance program(s) changes or expands, adjustments should ensure the ability of the program(s) to identify trends over-time remains, that historical data are maintained and that the program continues to meet <del>the established</del> objectives.	<b>USA</b>
<b>12. TRAINING AND CAPACITY BUILDING</b>	
116. Training and capacity building are important components of the integrated monitoring and surveillance program(s) and should be supported where possible, by the competent authorities. <u>Proposed text:</u>	<b>Australia</b> Modification to text to allow flexibility, and also for consistency with changes throughout document, as follows (see Proposed text):

COMMENTS	MEMBER/OBSERVER
116. Training and capacity building are important components of the integrated monitoring and surveillance program(s) and should be supported where possible, by the relevant authorities.	
<p>117. Training of the relevant competent authorities should include different aspects of the monitoring and surveillance program(s): collection, analysis, interpretation and reporting of the data.</p> <p><u>Proposed text:</u></p> <p>117. Training of the relevant competent authorities should include different aspects of the monitoring and surveillance program(s): collection, analysis, interpretation and reporting of the data.</p>	<p><b>Australia</b></p> <p>Modification to text to allow flexibility, and also for consistency with paragraph 116 and changes throughout document, as follows (see Proposed text):</p>
117. Training of the relevant competent authorities <u>and stakeholders</u> should include different aspects of the monitoring and surveillance program(s), <u>e.g.</u> : collection, analysis, interpretation and reporting of the data.	<b>Chile</b>
118. Training of relevant stakeholders at the national level <u>is on different aspects of the monitoring and surveillance program(s) are</u> recommended.	<p><b>Canada</b></p> <p>Text added to clarify what type of training is necessary for stakeholders.</p>
<del>118. Training of relevant stakeholders at the national level is recommended.</del> 118. <u>Identify the priorities of training and capacity building to have a monitoring and surveillance program framework and design a plan to approach these priorities"</u>	<b>Chile</b>