

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Eighth Session

GUIDELINES ON

INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

(AT STEP 4)

Comments at Step 3 (Replies to CL 2021/33-AMR)

Comments of Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, European Union, Ghana, Jamaica, Japan, Morocco, Nigeria, Norway, Republic of Korea, Singapore, Thailand, Uruguay, United States of America (USA), Healthforanimals, International Dairy Federation (IDF/FIL) and International Feed Industry Federation (IFIF)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/33-AMR issued in April 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 **Annex I** and are presented in table format.
3. All comments submitted in reply to this CL will be included in an Annex to the report of the Working Group on the revision to the COP that met in June 2021.

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

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Australia supports the progression of the Guidelines with a view to final adoption at CAC44 in November 2021. Australia recommends the main point for discussion is the level of detail on AMU in the document.</p> <p>Australia recommends increasing the reference to the OIE standards, and having less content in the Guidelines about AMU, in order to remain consistent with the work of the OIE.</p> <p>Overall Australia supports the current level of detail provided in the Guidelines, except regarding AMU and plant health (refer to other comments for details).</p> <p>Australia supports consistency of the Guidelines with other Codex documents, such as the Code of Practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005), particularly in regard to the definitions.</p>	<p>Australia</p>
<p>Many parts of the Guidelines were not yet discussed in plenary and members face a huge challenge ahead, if we ambitiously aim to finish our task at TFAMR8, with a view to final adoption by the 44th Session of the Codex Alimentarius Commission (CAC44) (November 2021).</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. Recommendations should focus on where there is scientific evidence that foodborne AMR could pose risk to human health. They should also allow for flexibility, since countries face different realities.</p> <p>Major areas for improvement are Sections 8 and 9, recalling that these sections have not been previously discussed in plenary and are core sections to the document. Section 8 on AMR is still detailed and some of the examples should be deleted, since recommendations should be science based, practical and feasible, and that priorities vary regionally and can change over time. Section 9 on AMU should be carefully revised and shortened, 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. It is also important to avoid duplication, overlap and conflicts with the ongoing work and efforts by OIE related to this topic.</p>	<p>Brazil</p>
<p>Overall, Canada finds that the document is more streamlined and the level of detail throughout, including the use of examples, is sufficient to provide guidance to countries without being overly prescriptive. The softer language around “options” in this version of the document provides greater flexibility for uptake by users.</p> <p>Canada supports the inclusion of the figure as it not only depicts the major components needed for consideration when implementing integrated monitoring and surveillance of foodborne AMR, but also illustrates how the other codex texts (Code of Practice and Guidelines for Risk Analysis) are intended to work together. It will be important to ensure, as the document progresses, that the contents of the figure continue to be aligned with the section headings.</p>	<p>Canada</p>
<p>Costa Rica noted this document needs continue a deep and detailed review, specially for being a technical document related with a integrated context to other documents and the practical activities of the countries.</p> <p>Costa Rica considers it important to avoid duplicating, overlapping guidelines established by international tripartite organizations such as the OIE in matters of surveillance of antimicrobial use patterns (AMU), as well as avoiding repetitions on the integrated surveillance that is referred to and well developed in through the WHO (AGISAR). We consider it important that the Codex Alimentarius, through GLIS, should create a framework of reference to the guidelines given by these international organizations, thus allowing to the country members the sufficient flexibility and clarity for its implementation and improvement over the time.</p>	<p>Costa Rica</p>
<p>En el acápite 2. Ámbito de aplicación en el punto 15 se plantea que: Estas Directrices abarcan el diseño y la implementación de uno o más programas integrados de seguimiento y vigilancia a lo largo de la cadena alimentaria y en el entorno de producción de alimentos.</p> <p>Da la idea que en el documento las directrices abarcaran el seguimiento y la vigilancia en todos los entornos de producción incluida la industria y es en toda la cadena alimentaria incluido el procesamiento hasta el consumo, sin embargo, cuando se refiere a planes de muestreo y otros aspectos el documento se enfoca a muestras procedentes de animales y plantas/cultivos.</p>	<p>Cuba</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Consideramos que se debe aclarar en un inicio que se propone comenzar con un seguimiento y vigilancia de los alimentos obtenidos de la producción de animales y plantas/cultivos y a continuación lo referido en el punto 49: a medida que se desarrollen los programas, se puede ampliar el plan de muestreo a los efectos de que incluya otros productos alimentarios.</p> <p>Debe aclararse en el punto 49 respecto al plan de muestreo que resulte gradualmente más representativo de la población de interés. ¿A qué población se refiere: a la bacteriana o a los consumidores expuestos a alimentos en los que se identifican bacterias RAM?</p> <p>En acápite 8.3. Fuentes de las muestras en punto 50. Al identificar las fuentes de las muestras a incluir en el programa de seguimiento y vigilancia, se deberá considerar la principal exposición directa e indirecta de los alimentos. Definir cuál se considera la exposición directa y la indirecta.</p> <p>En el acápite 8.6.1. Métodos y criterios de interpretación punto 65. En relación con la categorización por los puntos de corte clínicos refiere que: puede diferir entre las especies animales. Es preciso aclarar que esta interpretación sería para el estudio en animales y en el estudio de alimentos el punto de corte a utilizar es el definido para humano pues los datos que se generen son para evaluar el riesgo para la salud humana producidos por la RAM transmitida por los alimentos, lo que estaría en correspondencia con el acápite 8.6.3. Rangos de concentración de los agentes antimicrobianos punto 72. Se utilizarán rangos de concentración que garanticen la aplicación tanto de los valores ECOFF como de los puntos de corte clínicos, cuando existan, a fin de permitir que los resultados sean comparables con datos humanos.</p>	
<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 y pone en su conocimiento las siguientes observaciones generales al documento:</p> <p>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 UAM.</p> <p>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.</p>	<p>Ecuador</p>
<p>Mixed Competence European Union Vote</p> <p>The European Union and its Member States (EUMS) would like to provide the following comments in response to CL 2021/33/OCS:</p> <p>3.1 General comments on:</p> <p>a. the overall content of the Guidelines and the points necessary for discussion by the 8th Session of the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR08) (October 2021) with a view to their final adoption by the 44th Session of the Codex Alimentarius Commission (CAC44) (November 2021); EUMS: The revised version has much improved. We welcome the shortening and simplification of the text. We can agree with the overall content of the draft Guidelines as currently drafted. Further discussions should concentrate on certain specific elements especially in chapters 1, 8 and 9.</p> <p>b. major areas for improvement or inclusion to complement existing provisions in the Guidelines as needed; EUMS: Some improvements are still needed in the introduction, as well as in chapters 8 and 9. Our main concern is linked with the future role of molecular testing. In shaping the text further, it should be taken into account that methods develop and 'susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) may be replaced by genotypic methods. Therefore, we suggest to introduce more flexibility in the text and highlight the need to use methods standardized and validated by internationally recognized organizations, where available. The details are highlighted in our specific comments in Annex II.</p> <p>c. whether references to (i) other international organizations and (ii) antimicrobial use (AMU) are appropriately addressed in the Guidelines considering that, while developed within a One Health Approach, the Guidelines are intended for food safety and aim to ensure that Codex Members are aware of what is needed for monitoring and surveillance of foodborne AMR and AMU, while complementing and remaining consistent with the work of other international organizations; and EUMS: In our view, references to (i) other international organisations and (ii) antimicrobial use (AMU) are appropriately addressed.</p> <p>d. whether overall the level of detail provided in the Guidelines is appropriate and the balance needed to ensure that the Guidelines are actively used by Members has been achieved</p>	<p>European Union</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>EUMS: In our view, the overall level of detail is useful and provides, after some further refinement, a very useful basis for implementation of monitoring and surveillance of antimicrobial resistance and antimicrobial use in the food chain offering the necessary flexibility to be adapted to the national situation, either to start monitoring and surveillance systems or to improve the existing ones.</p> <p>3.2 Specific comments on key aspects identified by the EWG under the following sections that will assist in the finalization of the Guidelines, while taking into account the agreements made by TFAMR07 (2019) on provisions which are common to both the Code of practice to minimize and contain foodborne antimicrobial resistance (COP) (CXC 62-2005) and the Guidelines:</p> <p>Section 1: Comments on the description of AMU in the introduction rather than the inclusion of a formal definition on AMU in Section 3.</p> <p>EUMS: Whereas we acknowledge that a definition for AMU would be useful, taking into account that finding a consensus for such definition would be very challenging, we support the proposal to introduce a description of AMU in the introduction instead of developing a formal definition for it. The current text for AMU is acceptable. Additional comments to section 1 to para 7, 10, 11 and 14 are provided in the draft text provided in Annex II.</p> <p>Sections 2, 3, 5, 6, 11 and 12: Any (i) outstanding issue(s) or (ii) particular point(s) that need refinement for accuracy and/or to improve coherence of the text including consistency with the COP and the Guidelines for Risk Analysis Principles for Foodborne AMR (CXG 77-2011).</p> <p>EUMS: We have no further comments on these sections and can agree with proposed text.</p> <p>Section 4: Confirm that the revisions to Principles 8 and 9 and removal of part of Principle 2 and all of Principle 10 to the Introduction now provides the flexibility requested by Members and observers.</p> <p>EUMS: As a compromise, we can agree with the drafted principles (including principles 1-7) with the following comments:</p> <p>Principle 8. We can accept the current wording of principle 8.</p> <p>Principle 9. Whereas we would prefer to refer to the comparability of data internationally because this is an important aspect, we can support principle 9 as currently drafted and accept as a compromise that international comparability is described in the introduction.</p> <p>Principle 10. We acknowledge that principle 10 has been deleted as it does not fit within the scope of the guidelines and that as a compromise, text has been included in the introduction.</p> <p>Section 7: Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain. Comments on the proposal to retain and revise the figure in order to provide a unique overview of the framework presented in the Guidelines. CL 2021/33/OCS-AMR 2</p> <p>EUMS: We support to retain the figure as drafted. As regards the content of section 7, we welcome the shortening and simplification of the text. Specific comments to section 7 been included in the text provided in Annex II.</p> <p>Sections 8, 9 and 10: Any (i) outstanding issue(s) or (ii) particular point(s) that need refinement for accuracy and/or to improve coherence of the text including consistency with the COP and the Guidelines for Risk Analysis of Foodborne AMR, noting that: the level of detail has been reduced to that which was considered essential to provide the intended audience with an overview of the key aspects of monitoring and surveillance with the removal of the overly technical, detailed or prescriptive information and examples except for those necessary for clarity of the text.</p> <p>EUMS: We welcome the shortening and simplification of the text. Specific comments to sections 8 and 9 have been inserted in the text provided in Annex II.</p> <p>3.3 Other comments not covered under points 3.1 – 3.2 that may be of relevance to Codex Members or Observers.</p> <p>EUMS: The current draft text provides a very good basis to finalise the draft guidelines in the forthcoming 8th session of TFAMR.</p>	
<p><u>Proposal:</u> The document title should read: GUIDELINES ON THE INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE AND ANTIMICROBIAL USE”</p> <p><u>Rationale:</u></p>	<p>Ghana</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<ul style="list-style-type: none"> The title of the guideline should reflect content and scope to be effective. There are several instances where reference is made to AMU in the document such that it cannot be omitted in the title; Section 1 (Introduction) makes several references to AMU, the whole of section 9 focuses on AMU. Section 2 (Scope) of the guideline clearly mentions that both AMR and AMU are covered in the guideline and thus inappropriate to leave AMU out of the title. As per Principle 16 of the draft COP agreed at TFAMR07 and Principle 7 of the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL77-2011) the goal of an integrated monitoring and surveillance program may not be realized focusing only on AMR surveillance. 	
<p>Japan shares the ambition with all of them of finalizing the draft for adoption at the CAC44.</p> <p>Japan, however, notes that there has not been enough discussion for the development of the surveillance guidelines during past meetings. It is necessary to go through the entire draft and examine how the guidelines will be used and what they should include.</p> <p>Japan considers that there should be a clarification of the meaning of “integrated monitoring and surveillance program.” Japan’s understanding is that the guidelines are to provide ways to make results from different monitoring programs along the food chain comparable so that integrated analysis will be possible. Currently, the phrase “integrated monitoring and surveillance program” is mostly followed by the phrase “for AMR and AMU.” But sometimes it is followed by the phrase “for AMR” and other times followed by the phrase “for AMU.” Overall, this demonstrates a lack of clarity as to what is intended to be integrated.</p> <p>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. Thus, Japan is not against including AMU monitoring in these guidelines.</p> <p>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 focus on the non-animal sector to fill existing gaps for integrated surveillance of the entire food-chain and to 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.</p> <p>For this reason, Japan proposes to delete Section 9.3, 9.4 and 9.5 concerning the animal sector and to add a clear reference to the OIE standards.</p>	<p>Japan</p>
<p>Nigeria commends the electronic Working Group (EWG) for the work done so far however it is important that the EWG reconsiders its scope and align with the Terms of Reference provided by the Codex Alimentarius Commissions in 2016. We are concerned that current draft Guidance on Integrated Surveillance of Antimicrobial Resistance (GLIS) includes areas that will add complexity, reduce risk-based resource allocation for regulators, and further delay the completion of the document.</p> <p>Removing items, such as antimicrobial use, and prioritizing the scope to focus on surveillance of antimicrobial resistance creates an option that could enable adoption at Step 5/8 of this document at the next task force meeting. This document should focus on guidance to establish the core components of a surveillance system for foodborne antimicrobial resistance.</p> <p>The new definitions proposed are important because of the recommendation on data interpretation.</p>	<p>Nigeria</p>
<p>Combatting AMR requires a One Health approach in which all relevant sectors cooperate, especially health, agriculture, aquaculture and environment. We strongly believe that scaling up efforts through the already existing cooperation between the Tripartite plus organizations (FAO, WHO, OIE and UNEP), are important. It is important that Codex takes part in the common fight to combat AMR.</p> <p>We are of the view that the proposed Guideline is a step in the right direction, it reads well and 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 surveillance system. As these guidelines are intended for use by countries that at present do not have AMR surveillance systems, the level of detail seems sufficient. We are looking forward to fruitful discussions and hopefully there will be progress in the meetings ahead of the session and at the 8th session of the TFAMR. In our view TFAMR should aim at sending the Guidelines to the 44th session of CAC for final adoption</p> <p>The proposed Guidelines reflects many of the most important and relevant parts of the monitoring and surveillance of foodborne AMR. We would support cross referencing WHO-, OIE-, FAO- and IPPC- documents, where relevant. Furthermore, we are of the view that data on use/consumption of antimicrobial agents is a vital element for risk analysis undertaken prior to risk management activities, and an important part of integrated monitoring and surveillance systems foodborne AMR and AMU.</p>	<p>Norway</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>1. We are of the view that the use of the term “animals” and “food-producing animals” should be considered to fit with its context throughout the document.</p> <p>2. We would like to express our concern on the texts related to plants/crops as there are different AMR and AMU patterns in different countries and the limited availability of scientific information on AMU and AMR in plants/crops. We are of the view that the specific content related to AMU and AMR in plants/crops should be considered the flexibility and feasibility for the implementation of member countries before inclusion to the document. Moreover, we propose the deletion of the detailed information that mentioned to plants/crops throughout the document.</p>	<p>Thailand</p>
<p>Uruguay agradece el trabajo desarrollado por los Países Bajos en su rol de presidente del Grupo de trabajo electrónico y de las copresidencias de Canadá, Chile, China y Nueva Zelandia, para lograr esta nueva versión del documento.</p> <p>Observaciones Generales:</p> <p>Uruguay considera que a pesar del esfuerzo realizado por adecuar el documento a las necesidades de los países, aún restan consensuarse aspectos fundamentales sobre los que es necesario profundizar en el debate.</p> <p>Creemos que la imposibilidad de discutir el documento en plenaria en la última reunión del TFAMR puede haber atentado en ese sentido.</p> <p>En nuestra opinión, el tratamiento que aún mantiene el Uso de Antimicrobianos, no sólo sigue estando fuera de los objetivos iniciales del trabajo, sino que además y tal como está tratado a lo largo del documento, dificulta la adopción de la directriz por los países, sobre todo los menos desarrollados.</p> <p>Dado que las menciones al tema y su abordaje se encuentran a lo largo de todo el documento, pensamos que es más razonable incluirlo como una observación general y que el mismo sea revisado nuevamente en profundidad.</p>	<p>Uruguay</p>
<p>We believe it would be important to work from the draft submitted through this Circular Letter at the physical Working Group (PWG) meeting in June 2021 rather than having to consider a new draft for the PWG meeting. Specific comments are also provided below in the relevant sections of the draft GLIS.</p> <p>Part c) References of Paragraph 3.1 in CL2021/33/OCS-AMR:</p> <p>The United States would like to note that the One Health approach, includes the health of humans, animals, and the environment. Since the charge to TFAMR is limited to foodborne AMR and the Codex food safety mandate, it will contribute to the overall One Health approach, but is not a One Health approach in itself. Work must be implemented in coordination with human, animal, and environmental health sectors for a One Health approach, rather than Codex providing guidelines for all antimicrobial resistance (AMR)-related concerns. Edits are provided in the first paragraph to help clarify that the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) is addressing the food safety component of One Health.</p> <p>(i) International standard-setting bodies (ISSB’s) such as Codex, the World Organization for Animal Health (OIE), and the International Plant Protection Convention (IPPC) have international standing because standards are based on science and developed through open and transparent procedures involving a wide range of stakeholders, generally resulting in consensus. Codex, OIE and IPPC are recognized in the World Trade Organization’s Agreement on the Application of Sanitary and Phytosanitary Measures as the relevant international standard-setting organizations. Advisory or expert groups that develop documents without Member State input or transparency do not carry the same weight as ISSB’s. Therefore, references to ISSB’s (Codex and OIE) should be first. Paragraphs 13 and 14 should be switched.</p> <p>(ii) Regarding antimicrobial use (AMU), there is no global consensus on the details of metrics. Some countries are still trying to develop appropriate metrics. Further, OIE has ongoing work for global measurement of AMU and the TFAMR runs the risk of being inconsistent with or duplicative of ongoing work at the OIE. The description of AMU in the draft does not clearly distinguish AMU data (which few countries are collecting) and sales data (which the majority of countries are collecting). See specific comments under Section 9 for additional context. The United States recommends keeping information about AMU in section 9 and not including a description under Section 1 because the current description in section 1 is inadequate and lengthening it in the introduction would appear out of place. It is also worth noting that the TFAMR Terms of Reference focus on consideration of the development of guidelines for surveillance of AMR, not AMU. Section 9 should make reference to OIE and be kept at a high level by ending with Section 9.2. Wherever AMU is mentioned in the document, the text should state “AMU and/or sales data” to avoid confusion. There is much confusion around these terms globally and Codex should not add to the confusion in its guidance.</p>	<p>USA</p>

GENERAL COMMENTS	MEMBER/OBSERVER
<p>Part d) Level of Detail of Paragraph 3.1 in CL2021/33/OCS-AMR:</p> <p>The United States appreciates further work done on the document. We continue to have concerns with the document, particularly Sections 8 and 9. As written, few countries, if any, are achieving what is in the current Draft Guidelines. The sections go beyond what is scientifically known to have food safety implications and reflect a level of resources, infrastructure, technical expertise, and scientific methodologies not yet achieved by many high resource countries. Areas requiring further research are mixed with what is necessary for a basic surveillance system for foodborne AMR. As currently written, it is not clear that the priority sample type to be collected to survey for foodborne AMR is food.</p> <p>The draft as written is not globally achievable. For example, few if any countries are currently carrying out monitoring and surveillance of AMR in sewage and sludge as part of a national monitoring system for foodborne AMR. Additionally, fundamental data and information that would inform the elements of integrated national surveillance systems in crops is still in development (e.g. sample sources, target microorganisms, sample design, laboratory testing methodology, data analysis and reporting). Simply to state that countries should do it without telling them how does not provide guidance. It would be most appropriate to revisit areas where there is limited science once there is a sound scientific basis to inform methodologies.</p> <p>APPENDIX I: Report of the Electronic Working Group (For information)</p> <p>Regarding paragraph 20 under Recommendations, the United States appreciates the work that has been done to streamline the document. While language to have sample types as “optional” allows flexibility, inclusion does not help provide clarity to countries that are beginning a surveillance program, and need this guidance the most. Countries need guidance on priorities to focus limited resources. Some of the examples in Section 8 go well beyond practicality or application for assuring safe food and preventing and minimizing foodborne AMR, the purpose of Codex, and these guidelines. Inclusion of examples such as sludge, sewage, and dust, for example, under “food animals” (with no mention of actual food, that is, meat samples), does not reflect what most countries include in national monitoring programs for foodborne AMR.</p> <p>For a Codex document, examples should focus on high priority needs to assure safe food, where there is scientific evidence of foodborne AMR risk, such as food itself, which is closest to consumption. It is not that the other sample types may not be useful for understanding the ecology of AMR in the broader context through further research, but they are not essential to ongoing surveillance to assure safe food. Codex does not need to specify every sample type important for understanding AMR, just those that are globally achievable to assure safe food. As written, it is unclear what the priorities are to assure safe food—guidance that countries need.</p> <p>Furthermore, the information in Section 9 should be high level and stop at Section 9.2. It does not need to duplicate OIE or run counter to the ongoing work at OIE to improve antimicrobial use data collection. Countries are also doing work on developing appropriate metrics for antimicrobial use and it is premature for Codex to provide guidance that ties countries down to what a few countries or regions may be doing. Codex should not develop duplicative or contrary guidance to OIE as OIE is updating their guidance regularly. Any TFAMR guidance may be outdated quickly.</p>	
<p>General Comments</p> <p>The IDF believes that there is significant work still required in order to reach consensus on the draft GLIS.</p> <p>The draft GLIS, as written, is not globally achievable. For example, few if any countries are currently carrying out monitoring and surveillance of AMR in sewage and sludge as part of a national monitoring system for foodborne AMR.</p> <p>The IDF finds parts of the draft GLIS to be problematic, particularly sections 8 and 9. These sections seemingly go beyond what is scientifically known to have food safety implications and reflect a level of resources, infrastructure, technical expertise, and scientific methodologies not yet achieved by many high resource countries let alone developing nations. Areas requiring further research are mixed in with what is necessary for a basic surveillance system for foodborne AMR. As currently written, it is not even clear that the priority sample type to be collecting to survey for foodborne AMR is food.</p> <p>The IDF looks forward to continued development of the draft GLIS at TFAMR 8.</p>	<p>IDF/FIL</p>

SPECIFIC COMMENTS

Section/paragraph	Member/Observer/ rationale
1. Introduction and purpose	
Brazil is of the opinion that description of AMU should only stay as it is already presented at the beginning of Section 9. It should not be in the Introduction nor as a formal definition in Section 3.	Brazil
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 an integrated that are a component of a "One Health" approach for the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU)."	Australia Australia recommends the use of 'component of a One Health approach' as the document is only focusing on the food safety aspects of a One Health approach. This will also provide flexibility for member countries.
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 an integrated "One Health" approach <u>approach, emphasizing the need</u> for the design and implementation of national programs of integrated monitoring and surveillance of foodborne AMR and antimicrobial use (AMU) <u>AMR</u> .	Brazil Brazil would like to make a clear distinction on the differences between the "One Health" approach framework related to the national action plans and the need on "integrated" monitoring and surveillance activities to be implemented by members, to avoid confusion and misinterpretation. 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 guidance on AMU should be retained in Section 9 and in other parts of GLIS that refer to AMU data.
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 for and the design and implementation of national programs of integrated monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).	Chile
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 an integrated "One Health" approach for the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).	Ghana Position: Ghana proposes a rearrangement of the paragraphs in Section 1. <u>Rationale:</u> This will ensure coherence and promote readers' understanding of the ideas and main points.
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 an integrated "One Health" approach for the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).	Japan "Strong international call" is rather emotional and not suitable for technical guidelines. Redundant. One Health approach already includes the concept of integration.

Section/paragraph	Member/Observer/ rationale
<p>1. World-wide recognition of the importance of antimicrobialAntimicrobial resistance (AMR) 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 human, animal and environmental interface which necessitates a framework of an integrated “One Health” approach for the design-approach. 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.</p>	<p>USA Rationale: 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 clear that Codex is contributing to the food safety component of the One Health approach. Codex is not addressing the animal health component of One Health, for example.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals (<u>terrestrial and aquatic</u>) or plants/crops, which may include the quantities of antimicrobials sold and/or the quantities used.</p>	<p>Australia Australia supports the inclusion of a description of AMU in the introduction rather than a formal definition for AMU in Section 3. Australia recommends inclusion of extra detail around animals for consistency with the Code of Practice introduction. Australia recommends the deletion of ‘both’, as ‘and/or’ is later used in the sentence.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>Brazil Brazil is of the opinion that description of AMU should only stay as it is already presented at the beginning of Section 9. It should not be in the Introduction nor as a formal definition in Section 3.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>Chile Delete</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>China The description of AMU in the introduction is more acceptable than inclusion of a formal definition on AMU in Section 3.</p>
<p>2. A los fines de estas Directrices, por «uso antimicrobiano» y su sigla «UAM» se entiende las cantidades previstas de uso de antimicrobianos en animales o en plantas/cultivos, que pueden incluir tanto las cantidades de antimicrobianos vendidas como las cantidades de antimicrobianos usadas.</p>	<p>Colombia Se propone establecer una definición del uso antimicrobiano en el numeral 3 sobre definiciones ya que esta, tiene una gran relevancia como componente esencial dentro de los programas de seguimiento y vigilancia integrada de la RAM y se usa a lo largo del documento. Conforme a lo documentado en el numeral 14. Sección 3: Definiciones para las observaciones. Una definición formal puede afectar otros documentos de códex.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>Japan Japan suggests deleting the whole paragraph as it is odd to have such a technical definition at the front of the introductory section. Instead, a description about AMU should be added in Section 9 (para 82 bis) where guidance for AMU monitoring is provided.</p>

Section/paragraph	Member/Observer/ rationale
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in <u>food-producing</u> animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>Thailand</p> <p><u>General comment:</u> We are of the view that the use of the term “animals” and “food-producing animals” should be considered to fit with its context throughout the document. For clarity and consistency with the definition of the COP, Thailand proposes to replace the term “animals” with “food-producing animals”.</p> <p><u>Specific comment for paragraph 2:</u> Moreover, we prefer to include a description of antimicrobial use in this section as it was previously mentioned in paragraph 1.</p>
<p>2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may include both the quantities of antimicrobials sold and/or the quantities used.</p>	<p>USA</p> <p><u>Rationale:</u> The description in Section 1 for AMU is not adequate. 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. Instead, wherever AMU is mentioned, “AMU and/or sales data” should be mentioned for clarity throughout the text.</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 assessments and, in turn, risk management</u> actions that can be taken, and to enable the measurement of their impact."</p>	<p>Australia</p> <p>Australia recommends addition of the word ‘foodborne’ to provide clarity that the Guidelines only relate to foodborne AMR.</p> <p>Australia recommends modifying the text to match the Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL 77-2011).</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of <u>foodborne</u> AMR and AMU antimicrobial use (AMU) related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of 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>Brazil</p> <p>Brazil suggests including “foodborne” and “risk-based”, for clarity and to be consistent with the Codex mandate. Since Brazil asked for deletion of “antimicrobial use” in paragraph 1 and deletion of paragraph 2, “antimicrobial use” would be mentioned for the first time in actual paragraph 3, needing the description and acronym.</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>Ghana</p> <p><u>Position:</u> Ghana supports a description of the term “antimicrobial use” and its abbreviation AMU in the Section 1 rather than the inclusion of a formal definition in Section 3.</p> <p><u>Rationale:</u> AMU is mentioned severally in the introduction and purpose of the guideline as well as in other sections of the document. The definition is not conventional therefore, it is important that it is defined early in the Guideline document to ensure it is not confused with the conventional definition.</p>

Section/paragraph	Member/Observer/ rationale
<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>Japan “Foodborne” is the mission of this guideline. The data from surveillance should be utilized for risk analysis not for directly action.</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, 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>Republic of Korea Korea removes the comma between "repeated" and "measurement".</p>
<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 proporcionen <u>información para el análisis de fundamento riesgo</u> para las-la adopción de <u>medidas a tomar de gestión</u> y permitan la medición de su impacto.</p>	<p>Uruguay Los resultados de la vigilancia y seguimiento deben proporcionar información para el análisis de riesgo. Las decisiones de gestión surgirán a partir de este análisis, tal como está descrito en el párrafo 23 de este documento.</p>
<p>3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of <u>AMR-foodborne AMR, antimicrobial use (AMU), 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 AMR and AMU related data and trends from defined populations to inform <u>risk assessments which in turn inform risk management</u> actions that can be taken and to <u>by risk managers. Further data can help</u> enable the measurement of their impact <u>the impact of risk management</u>.</p>	<p>USA Rationale: “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. Surveillance data provide information on trends and further inform risk assessments (as per CXG 77-2011). 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 so is not risk-based.</p>
<p>4. 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. 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 (<u>terrestrial and aquatic</u>), foods, crops/plants and the food production environment.</p>	<p>Australia Australia recommends inclusion of extra detail around animals for consistency with the introduction of the Code of Practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005).</p>
<p>4. 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, <u>where feasible</u>, AMU. 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, crops/plants and the food production environment <u>from the same food chain</u>.</p>	<p>Chile</p>

Section/paragraph	Member/Observer/ rationale
<p>4. 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. Integrated program(s) includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the so that an integrated analysis of relevant epidemiological information from humans, animals, foods, crops/plants and the food production environment<u>environment may be conducted.</u></p>	<p>Japan 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. 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. 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, crops/plants<u>plants/crops</u> and the food production environment.</p>	<p>Republic of Korea Korea suggests that crops/plants replace with plants/crops for consistency.</p>
<p>4. Uno o más programas integrados de seguimiento y vigilancia incluyen la obtención coordinada y sistemática de datos o muestras en las etapas correspondientes a lo largo de la cadena alimentaria, y la prueba, el análisis y la presentación de informes sobre resultados del seguimiento y la <u>vigilancia de la RAM</u> y el UAM. Asimismo, incluyen la coordinación y la armonización de prácticas y metodologías de muestreo, pruebas, análisis y presentación de informes, así como el análisis integrado de la información epidemiológica pertinente relativa a humanos, animales, alimentos, cultivos/plantas y el entorno de producción de alimentos.</p>	<p>Uruguay Debe quedar claro que los programas de seguimiento y vigilancia deben aportar información para el análisis de riesgo. Los informes de la situación de la RAM, deberían someterse a ese análisis.</p>
<p>4. 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 results. <u>Integrated program(s)-program(s), where feasible,</u> 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<u>human foodborne illness data,</u> animals, foods, crops/plants and the food production environment.</p>	<p>USA <u>Rationale:</u> 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. 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.”</p>
<p>5. Depending on national priorities, AMR food safety issues, scientific evidence, capabilities and available resources, integrated monitoring and surveillance program(s) should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s).</p>	<p>Chile This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s). Move to paragraph 4</p>
<p>5. Depending on national priorities, AMR food safety issues, scientific evidence<u>evidences,</u> capabilities and available resources, integrated monitoring and surveillance program(s) should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s).</p>	<p>China</p>

Section/paragraph	Member/Observer/ rationale
<p>5. Depending on national priorities, AMR food safety issues, scientific evidence, capabilities and available resources, integrated monitoring and surveillance program(s) should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s).</p>	<p>Ghana <u>Position:</u> In the proposed rearrangement of the paragraphs in section 1, paragraph 10 should follow paragraph 5 since they both speak to the continuous improvement of the monitoring and surveillance program (s)</p>
<p>5. En función de cuáles sean las prioridades a nivel nacional, de las cuestiones de la RAM con relación a la inocuidad de los alimentos, de las pruebas científicas, de las capacidades y de los recursos disponibles, <u>sería deseable que</u> los programas integrados de seguimiento y vigilancia deben experimentar <u>experimenten</u> una mejora constante, conforme lo permitan los recursos. Ello no implica que un país tenga que implementar tanto el seguimiento como la vigilancia en todas las etapas o áreas cubiertas por los programas.</p>	<p>Uruguay</p>
<p>5. Depending on national <u>National</u> priorities, AMR food safety issues, scientific evidence, capabilities and available resources, <u>help guide the development of</u> integrated monitoring and surveillance program(s) <u>which</u> should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s).</p>	<p>USA <u>Rationale:</u> Edited for clarity. National priorities are one factor, but do not dictate what the food safety issues and other factors may be. It is not necessary to repeat AMR and AMU. If they are to be repeated, then the phrase should be rewritten as “foodborne AMR, AMU, and antimicrobials sales”.</p>
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis of foodborne AMR. They also provide information on the impact of interventions designed to limit the emergence, selection, and dissemination 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 AMR and AMU trends and can serve as inputs for risk assessments which inform risk management for the planning, implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p>Australia Australia recommends modifying the text to match the Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL 77-2011).</p>
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis of foodborne AMR. They also provide information on the impact of interventions designed to limit the emergence, selection, and dissemination 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 AMR and AMU trends and for the development of risk assessment and for the planning, implementation, and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p>Chile</p>
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis of foodborne AMR. They also provide information on the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research <u>researches</u>. Additionally, these data provide information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p>China</p>

Section/paragraph	Member/Observer/ rationale
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis of foodborne AMR. They also provide information on the impact of interventions designed to limit the emergence, selection, and dissemination 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 AMR and AMU trends and for risk assessment for the planning, implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p>Japan Providing information about AMR and AMU is obvious. What should be mentioned is that the information contributes to risk assessment for future planning of measures.</p>
<p>6. Los datos generados por los programas integrados de seguimiento y vigilancia brindan información valiosa para el análisis de riesgos de la RAM transmitida por los alimentos. Además, proporcionan información acerca del impacto que producen las intervenciones concebidas para limitar la aparición, la selección y la propagación de la RAM transmitida por los alimentos. Estos datos pueden asimismo ser útiles para estudios epidemiológicos, estudios de atribución del origen de alimentos e investigaciones. Además, brindan información a los encargados de la gestión de riesgos acerca de las tendencias de la RAM y del UAM y para el análisis de riesgo que permita la planificación, la implementación y la evaluación de medidas de mitigación de riesgos, a los efectos de reducir al mínimo el riesgo para la salud pública transmitido por los alimentos debido a los microorganismos resistentes y a los determinantes de resistencia.</p>	<p>Uruguay</p>
<p>6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis of foodborne AMR. They also provide information on the potential impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and hypothesis generation for further research. Additionally, these data provide information to risk managers about AMR and AMU trends and can serve as inputs for risk assessment which inform risk management which may include for the planning, implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.</p>	<p>USA <u>Rationale:</u> 1) Due to the complexity of AMR many interventions implemented may not have a measurable impact. 2) The text as written 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.</p>
<p>7. While this document’s focus is on foodborne AMR, there is an implicit connection between the goal of addressing foodborne AMR with the goal of reducing foodborne illness, and thus a connection to the national food safety control system.</p>	<p>European Union EUMS: Whereas we would have preferred to keep principle 2 as originally drafted, highlighting that monitoring and surveillance program(s) for AMR and AMU along the food chain and the food production environment are an important part of national strategies to minimize the risk of foodborne AMR and contribute to a national food control system, we can accept as a compromise that the latter aspect is introduced in the introduction in para 7.</p>
<p>7. While this document’s focus is on foodborne AMR, there is an implicit connection between the goal of addressing foodborne AMR with the goal of reducing foodborne illness, and thus a connection to the national food safety control system. <u>Proposal:</u> Ghana proposes the deletion of “while this document’s focus is on foodborne AMR” in the first line of paragraph 7.</p>	<p>Ghana <u>Rationale:</u> Data generated by an integrated monitoring and surveillance programs provide information for risk analysis as well as information on the impact of interventions designed to limit the emergence and spread of foodborne AMR. Principle 16 of the COP also mentions monitoring and surveillance of foodborne AMU and AMR among the critical factors to consider when developing risk management measures and evaluating the effectiveness risk management measures implemented.</p>

Section/paragraph	Member/Observer/ rationale
	Shifting the focus of the Guideline document to AMR is not in line with the requirements of the COP nor the goals of an integrated monitoring and surveillance program and must be deleted
7. While this document’s focus is on foodborne AMR, there is an implicit connection between the goal of addressing foodborne AMR with the goal of reducing foodborne illness, and thus a connection to the national food safety control system.	USA Not clear what this paragraph adds/aims to achieve, but it doesn’t seem to do any harm.
8. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance program(s). They provide a continuum of flexible options for implementation and expansion, considering resources, infrastructure infrastructures, capacity capacities, and priorities of countries. Each monitoring and surveillance program should be designed to be relevant for national, and when appropriate, regional circumstances. While these Guidelines are primarily aimed at action at the national level, countries may also consider creating or contributing to international, multi-national or regional, monitoring and surveillance program(s) to share laboratory, data management and other necessary resources.	China
8. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance program(s). They provide a continuum of flexible options for implementation and expansion, considering resources, infrastructure, capacity, and priorities of countries. Each monitoring and surveillance program should be designed to be relevant for national, and when appropriate, regional circumstances. While these Guidelines are primarily aimed at action at the national level, countries may also consider creating or contributing to international, multi-national or regional ,regional monitoring and surveillance program(s) to share laboratory, data management and other necessary resources.	Republic of Korea Korea removes the comma between "regional" and "monitoring".
8. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance program(s) program(s) of foodborne AMR and AMU. They provide a continuum of flexible options for implementation and expansion, considering resources, infrastructure, capacity, and priorities of countries. Each monitoring and surveillance program should be designed to be relevant for national, and when appropriate, regional circumstances. While these Guidelines are primarily aimed at action at the national level, countries may also consider creating or contributing to international, multi-national or regional, monitoring and surveillance program(s) to share laboratory, data management and other necessary resources.	Republic of Korea Korea would like o add to 'of foodbourne AMR and AMU at the end of the first sentence for the clarity.
8. Estas Directrices han sido elaboradas para colaborar con los gobiernos en el diseño y la implementación de programas de seguimiento y vigilancia. Brindan flexibilidad continua flexibilidad para su implementación y expansión, de acuerdo con los recursos, la infraestructura, la capacidad y las prioridades de los países. Cada programa de seguimiento y vigilancia debe ser concebido de manera tal que se pueda aplicar a las circunstancias nacionales y, cuando corresponda, regionales. Si bien estas Directrices apuntan principalmente a que se tomen medidas a nivel nacional, los países pueden asimismo considerar la posibilidad de crear o colaborar con programas internacionales, multinacionales o regionales de seguimiento y vigilancia, para compartir recursos de laboratorio, la gestión de datos y otros recursos necesarios.	Uruguay
9. Design and implementation of monitoring and surveillance program(s) should also be assessed on their relevance when foodborne AMR priorities change at the national and international level.	Australia Australia recommends deletion of the last part of the text to streamline the document.

Section/paragraph	Member/Observer/ rationale
<p>9. Design and implementation of monitoring and surveillance program(s) should also be assessed on their relevance when foodborne AMR situation and priorities change at evolves at the national and international level.</p>	<p>Chile</p>
<p>9. Design and implementation of monitoring and surveillance program(s) should also be assessed on their relevance when foodborne AMR priorities change at the national and international level.</p>	<p>Japan Japan is not aware what is the foodborne AMR priority at international level means.</p>
<p>9. Design and implementation of monitoring and surveillance program(s) should also be assessed-re-assessed based on their ongoing relevance when foodborne AMR priorities change at the national and international level evolve.</p>	<p>USA <u>Rationale:</u> 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>
<p>10. A continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities, broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.</p>	<p>European Union EUMS: The aspect of identification and implementation of priority activities, as mentioned in the previous version, is not sufficiently covered by the current text. Therefore, the sentence ‘Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop’ should be retained. As a compromise, the current text could be adapted to include ‘identified priorities’. It would read as follows: ‘A continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities, broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.’</p>
<p>10. A continuous improvement of the monitoring and surveillance program(s) should take into account broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.</p>	<p>Ghana <u>Position:</u> In the proposed rearrangement of the paragraphs in section 1, paragraph 10 should follow paragraph 5 since they both speak to the continuous improvement of the monitoring and surveillance program (s)</p>
<p>10. A continuous improvement of the monitoring and surveillance program(s) should take into account broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.</p>	<p>Singapore Specific observation: Under para 10, the issues to consider for continuous improvement of integrated monitoring and surveillance programme include particularly agriculture production data. Comment: Both agriculture and aquaculture production data should be included. <u>Justification:</u> Limiting the consideration issue to agriculture can result in discrepancy when the guideline also makes references to international standards in aquatic animals (para 14) and recommendation of target microorganisms in aquatic animals (para 57).</p>

Section/paragraph	Member/Observer/ rationale
<p>10. A continuous Continuous improvement of the monitoring and surveillance program(s) should take into account broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.</p>	<p>USA</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade. <u>Proposed change:</u> "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>Australia Australia recommends deletion of 'imported' as data could be from imported or domestic food.</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.</p>	<p>Brazil Brazil agrees to the proposal to have this sentence in the Introduction, but suggests deleting "imported", once the recommendation should not be limited to referencing only the AMR programs on imported food. It should also address the domestic food AMR programs.</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade..</p>	<p>Chile</p>
<p>11. Los datos generados a partir de los programas nacionales de seguimiento y vigilancia de la RAM sobre alimentos [importados] no deben usarse para crear obstáculos injustificados al comercio. De acuerdo con lo establecido en el Acuerdo MSF, lo propuesto en el numeral 11 ya se contempla en dicho Acuerdo, adicionalmente, se encuentra como uno de los objetivos del Codex Alimentarius.</p>	<p>Colombia</p>
<p>11. Los datos generados a partir de los programas nacionales de seguimiento y vigilancia de la RAM sobre alimentos importados no deben usarse para crear obstáculos injustificados al comercio.</p>	<p>Ecuador Ecuador solicita eliminar los corchetes en la palabra importados y mantener el párrafo.</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.</p>	<p>European Union EUMS: While we maintain our view that the scope of the guidelines should exclude trade related aspects, we can accept para 11 as a compromise for deleting principle 10. The square-bracketed term 'imported' should be deleted as the same rules should apply for all data from national programs.</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.</p>	<p>Japan Japan reiterates that there is no reason to limit this paragraph to imported food.</p>
<p>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.</p>	<p>Thailand Thailand strongly supports to keep this paragraph in the document since it will encourage the implementation of the GLIS. In addition, we propose moving this paragraph to place it after paragraph 113 as the content of this paragraph is more relevant to Section 10.3. "Reporting of results".</p>

Section/paragraph	Member/Observer/ rationale
11. Los datos generados a partir de los programas nacionales de seguimiento y vigilancia de la RAM sobre alimentos [importados] no deben usarse para crear obstáculos injustificados al comercio.	Uruguay
11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.	USA As written, the statement leaves open the possibility that unjustified trade barriers could be applied to domestic food so “imported” should be deleted.
12. These Guidelines should be applied in conjunction with the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005). Design and implementation aspects of these Guidelines should specifically take into account the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011), as well as other relevant Codex texts including the Principles and Guidelines for National Food Control Systems (CXG 82-2013) or the General Guidelines on Sampling (CXG 50-2004), whenever appropriate.	Chile Delete
13. 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>whenever appropriate.</u>	Brazil Brazil suggests including “whenever appropriate” to be consistent with paragraphs 12 and 14, which also include this concept, when referencing to other documents.
13. These Guidelines should also be used taking into consideration <u>note, where appropriate</u> , 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.	Chile 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. This 2 documents are not from ISSBs, so only where appropriate, should be taking note of its contain.
13. These <u>Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</u> 14. Where appropriate, 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.	Japan New paragraph 13 (old paragraph 14): OIE standards are developed through Member State consensus as same as Para12 Codex guidelines. Therefore OIE standards should be listed immediately following Para12. New paragraph 14 (old paragraph 13): In the previous paragraphs, Codex Guidelines and OIE standards are considered “where appropriate.” WHO’s guidelines which did not go through adoption process should also be considered “where appropriate.”
13. Al mismo tiempo, estas Directrices deben utilizarse teniendo en cuenta las ya desarrolladas por otros organismos asesores <u>cuenta las normas de otras organizaciones internacionales encargadas de dictar normas, incluido el documento del Grupo Asesor en especial, aquellas de la Organización Mundial de la Salud (OMS) en Vigilancia Integrada Sanidad Animal (las normas de la RAM (AGISAR-OMS) titulado Vigilancia Integrada de la resistencia OIE) referidas a la RAM y el UAM publicadas en el Código Sanitario para los antimicrobianos Animales Terrestres y en bacterias transmitidas por el Código Sanitario para los alimentos: Aplicación del enfoque de Una Salud-Animales Acuáticos</u>	Uruguay Cambiar el orden, priorizando las Organizaciones Internacionales que generan normas basadas en el consenso de los países y organizaciones miembros (OIE, CIPF) sobre los documentos elaborados por asesores.

Section/paragraph	Member/Observer/ rationale
<p>13. 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>USA Rationale: Paragraphs 13 and 14 should be switched. International standard-setting bodies (ISSB's) such as Codex, OIE, and IPPC have international standing because standards are developed through Member State consensus. Advisory or expert groups such as WHO AGISAR develop documents without Member State input or consensus and do not carry the same weight as ISSB's.</p>
<p>14. Where appropriate, The standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</p>	<p>Australia Australia recommends moving para 14 to before para 13 due to the relevance of the OIE standards to this GLIS document, and also because the Standards currently in para 14 carry more weight than the Guideline documents currently in para 13.</p>
<p>14. Where appropriate, The standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</p>	<p>Chile Move to 12 at the end. When is not appropriate to consider and ISSBs?</p>
<p>14. Where appropriate, the standards of other international standard setting organizations, including the <u>relevant</u> standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</p>	<p>European Union EUMS: The paragraph could be simplified as follows: "Where appropriate, the standards of other international standard setting organizations, including the relevant standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU should be considered.</p>
<p>14. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</p>	<p>Japan</p>
<p>14. Cuando corresponda, se deben considerar las normas de otras organizaciones internacionales encargadas de dictar normas los documentos desarrolladas por otros organismos asesores, en especial, aquellas incluido el documento del Grupo Asesor de la Organización Mundial de Sanidad Animal (las normas de la OIE) referidas a Salud (OMS) en Vigilancia Integrada de la RAM y el UAM publicadas en el Código Sanitario para (AGISAR-OMS) titulado Vigilancia integrada de la resistencia a los Animales Terrestres y antimicrobianos en el Código Sanitario para bacterias transmitidas por los Animales Acuáticos. alimentos: Aplicación del enfoque de Una Salud.</p>	<p>Uruguay</p>
<p>14. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.</p>	<p>USA See comment under Paragraph 13.</p>
<p>2. Scope</p>	
<p>15. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR along the food chain and the food production environment <u>and implementation of AMU monitoring and surveillance program.</u></p>	<p>Chile AMU is a component , not an integrated monitoring and surveillance by itself.</p>

Section/paragraph	Member/Observer/ rationale
<p>15. Les présentes directives couvrent la conception et la mise en œuvre des programmes intégrés de suivi et de surveillance de la RAM d'origine alimentaire et de l'UAM sur l'ensemble de la chaîne alimentaire, y compris dans les environnements dédiés à la production alimentaire.</p> <p>Le Gte devrait limiter ses travaux aux seuls points inclus dans les termes de référence de 2016 et dans le document de projet original (CX/CAC 16/39/12 Annexe 2).</p> <p>* Plus précisément, le Gte (GLIS) devrait se concentrer sur la surveillance de la résistance aux antimicrobiens et compléter les éléments directeurs fondamentaux des systèmes de surveillance de la résistance aux antimicrobiens pour les pays.</p> <p>Justificatif : il faudrait éviter la redondance sur la partie concernant l'utilisation des antimicrobiens (AMU) dans les pays : en effet, le suivi de l'utilisation des antimicrobiens est actuellement effectué par l'OIE.</p>	<p>Morocco</p>
<p>16. 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) ("<u>One Health</u> approach") would be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans.</p>	<p>Canada</p> <p>To provide consistency and alignment with the use of the term "One Health" approach throughout the document.</p>
<p>17. Los microorganismos de que tratan estas Directrices son los patógenos transmitidos por los alimentos de relevancia para la salud pública y las bacterias indicadoras.</p>	<p>Colombia</p> <p>Se propone cambiar el término "las bacterias" por "los microorganismos indicadores".</p>
<p>18. Antimicrobials used as biocides. <u>Biocides</u>, including disinfectants, are excluded from the scope of these Guidelines.</p>	<p>Norway</p> <p>In order to avoid misinterpretation and confusion regarding terms we suggest referring directly to biocides and disinfectants.</p>
<p><u>Scope</u>: The current draft is not aligned with the Terms of Reference provided by the CAC in 2016 and 2017 and the Project Document for the development of Guidance on Integrated Surveillance of Antimicrobial Resistance (GLIS) (CX/CAC 16/39/12 Appendix 2). Antimicrobial Use (AMU) is outside of the remit of the TOR for TFAMR and the Project Document (CX/CAC 16/39/12 Appendix 2). Specifically, the project document for the Guidance on Integrated Surveillance of Antimicrobial Resistance includes the scope as follows: 'Integrated surveillance of AMR on foodborne bacteria is the coordinated sampling and testing of bacteria from food animals, foods and clinically ill humans and the subsequent evaluation of AMR trends throughout the food production and supply chain using harmonized methods. Global harmonization of an integrated surveillance program is needed so that surveillance data from different areas, countries or regions can be more easily compared.'</p> <p><u>Duplication</u>: AMU is very capably being coordinated by the World Organization for Animal Health (OIE). Many countries suggested it be removed from the document. To help facilitate the gathering or reporting of this data, the OIE maintains guidance on the methods to gather and report data. This guidance is regularly updated by expert staff member and advisors that are part of a formal AMR Work Group. Consequently, Section 9 should be removed from the document. It is out of scope of the Terms of Reference and Project Document.</p>	<p>Healthforanimals</p>

Section/paragraph	Member/Observer/ rationale
<p>Moving ahead: Focusing the scope of the document on design and implementation of a program for integrated surveillance of antimicrobial resistance, could make it possible to enable adoption at Step 5/8 at the next task force meeting. The document should provide practical stand-alone advice for countries. It should try to avoid areas where there are other technical sources, or international organizations providing guidance already.</p> <p>Trade: Discussions have shown that many countries believe there is a risk that this document could enable quantitative restrictions on food imports. This concern must be taken seriously, and it should be acknowledged explicitly that this document should not be misused for that purpose.</p>	
3. Definition	
	<p>Jamaica Include a definition for Antimicrobial Use</p>
<p>Nigeria proposes the inclusion of the following definitions for clarity.</p> <ol style="list-style-type: none"> 1. Clinical Breakpoints – “Numerical minimum inhibitory concentration (MIC) or zone diameter values used to indicate whether a bacteria isolate is susceptible, intermediate or resistant to an antibiotic.” 2. Epidemiological cut off abbreviated as ECV (CLSI) or ECOFF (EUCAST) – “are measures of a drug MIC distribution that separate bacterial populations into those representative of a wild type population and those with acquired or mutational resistance (non-wild type population) to the drug.” 3. Wild-type bacteria – “describes isolates of a bacteria with MIC below or equal to the ECOFF.” 4. Non-Wild Type Bacteria – “describes isolates of a bacteria with MIC above the ECOFF.” 	<p>Nigeria Rationale: These definitions are important because of the recommendation on data interpretation. When there is a lack of interpretive criteria (clinical breakpoints) for bacteria of animal origin, programs will use ECOFF. There is an issue with ECOFF data being reported as ‘resistant’ which is very misleading hence we are proposing that this should be clearly differentiated.</p>
<p>19. The definitions presented in the <i>Guidelines for risk analysis-Risk Analysis of foodborne antimicrobial resistance-Foodborne Antimicrobial Resistance (CXG77-2011) and Code of practice-Practice to minimize Minimize and contain antimicrobial resistance-Contain Antimicrobial Resistance (CXC 61-2005) are applicable to these Guidelines.</i></p>	<p>USA</p>
<p>Agente antimicrobiano: Cualquier sustancia de origen natural, semisintético o sintético que en concentraciones in vivo mata microorganismos o inhibe su crecimiento al interactuar con un objeto específico^[1].</p>	<p>Colombia Justificar todos los párrafos</p>
<p>Patógeno Transmitido por los Alimentos: Un patógeno presente en los alimentos, que puede causar enfermedades en humanos mediante el consumo de alimentos contaminados con el patógeno y/o los productos biológicos producidos por el patógeno¹.</p>	<p>Colombia Se considera cambiar patógeno por agente infeccioso porque hay bacterias como el caso de la salmonela gallinarum que son específicas de las aves y que no generan enfermedad o son muy raros los casos en humanos pero que podrían actuar como posibles reservorios de determinantes o elementos genéticos de resistencia.</p>
<p>Entorno de producción de alimentos: La cercanía inmediata de la cadena alimentaria cuando hay evidencias pertinentes de que podría contribuir a la RAM transmitida por los alimentos.</p>	<p>Colombia Se considera importante incluir el concepto ambiental dentro de esta definición.</p>

Section/paragraph	Member/Observer/ rationale
<p>Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect². For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and /or resistance determinant(s)¹.</p>	<p>Australia Australia recommends shortening the definition for hazard to better fit the use of this terminology in this document (used in Section 5), also the focus of these Guidelines should be a risk-based approach.</p>
<p>Hazard: A biological, chemical or physical agent <u>in, or condition of, in</u> food with the potential to cause an adverse health effect². For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and /or resistance determinant(s)¹.</p>	<p>Brazil Brazil suggests deleting “or condition of” to be consistent with CXC 1/1969 General Principles of Food Hygiene, last modified in 2020. We understand that it would be best to make the reference to this document, that has already been updated.</p>
<p>4. Principles</p>	
<p>Australia supports the revisions to Principles 8 and 9, the removal of part of Principle 2 and moving of Principle 10 into the Introduction.</p>	<p>Australia</p>
<p>Brazil agrees with the revision of Principle 8 and removal of part of Principle 2 and all of Principle 10 (considering our comments for new paragraph 11). Principle 9 still needs a minor revision.</p>	<p>Brazil</p>
<p>Korea agrees on the amendments in general to enhance flexibility in Section 4.</p>	<p>Republic of Korea</p>
<p>Principle 1: Integrated monitoring and surveillance program(s) for foodborne AMR and AMU should follow <u>consider</u> a “One Health” approach.</p>	<p>Brazil Deleting reference to AMU in this specific sentence is consistent to our previous comment, once AMU is a component of the AMR programs. Also replacing “follow” by “consider” will provide a better distinction on the differences between the “One Health” approach framework related to the national action plans and the need on “integrated” monitoring and surveillance activities.</p>
<p>Principle 1: Integrated monitoring and surveillance program(s) for foodborne AMR and AMU should follow a “One Health” approach. • Principle 1: Integrated monitoring and surveillance program(s) for foodborne AMR and AMU should follow <u>contribute to the</u> “One Health” approach <u>of the National Actions Plan</u>.</p>	<p>Chile Delete for foodborne AMR and AMU to have high level principles as it was suggested in the last CCEXEC 79. The One Health approach recognize the Human, animal, vegetal health and the environment their share as one, food borne AMR is just one part of the total OH Approach.</p>
<p>Principle 1: Integrated monitoring and surveillance program(s) for foodborne AMR and AMU should follow <u>contribute to</u> a “One Health” approach.</p>	<p>USA <u>Rationale:</u> It is not necessary to specify AMR and AMU as there is not agreement amongst Member States that integration means integrating AMR data across sectors or integration means integrating AMR and AMU. Integrating AMR across sectors is challenging in itself. Many countries have not been able to integrate AMR and AMU in many species. A good compromise would be to delete “foodborne AMR and AMU” and keep the statement high level.</p>

Section/paragraph	Member/Observer/ rationale
	<p>Since this guideline is only taking food safety into consideration, not animal or crop health, it is contributing to a One Health approach, but not a One Health approach in itself. Work must be implemented in coordination with work with human, animal, and crop health sectors for a true One Health approach. The term “contribute” is more appropriate than “follow”, which is very prescriptive for a Codex document.</p>
<p>Principle 2: Monitoring and surveillance program(s) for AMR and AMU along the food chain and the food production environment are an important part of national strategies to minimize the risk of foodborne AMR.</p>	<p>Brazil Deleting reference to AMU in this specific sentence is consistent to our previous comment, once AMU is a component of the AMR programs.</p>
<p>Principle 2: Monitoring and surveillance program(s) for AMR and AMU along the food chain and the food production environment are an important part of national strategies to <u>assess and then</u> minimize the risk of foodborne AMR.</p>	<p>Chile Monitoring and surveillance are tools that provides data that will be used by countries to assess first and then mitigate.</p>
<p>Principle 2: Monitoring and surveillance program(s) for AMR and <u>and, as appropriate to national circumstances,</u> AMU <u>and/or sales</u> along the food chain and the food production environment are an important part of national strategies to <u>minimize-inform</u> the risk <u>analysis</u> of foodborne AMR.</p>	<p>USA Rationale: If AMU is mentioned, it should be mentioned as “AMU and/or sales” as sales data monitoring is more globally achievable. Monitoring/surveillance data on its own does not minimize risk, so further context is provided.</p>
<p>Principle 3: Monitoring and surveillance program(s) should be <u>risk-based and</u> tailored to the national situation and priorities and may be designed and implemented with the objective of continuous improvement as resources permit.</p>	<p>Brazil Brazil suggests including “risk-based”, for clarity and coherence with Section 5 of this the document and to be consistent with the Codex mandate.</p>
<p>Principle 3: Monitoring and surveillance program(s) should be tailored to the national situation and <u>priorities</u> <u>priority</u> and may be designed and implemented with the objective of continuous improvement as resources permit.</p>	<p>China</p>
<p>Principle 3: Monitoring and surveillance program(s) should be tailored to the national situation and priorities and may be designed and implemented <u>with the objective of to allow</u> continuous improvement as resources permit.</p>	<p>Japan Improvement is not an objective.</p>
<p>Principle 4: Monitoring and surveillance program(s) should include data on occurrence of AMR and patterns of AMU, in all relevant sectors as inputs into risk analysis. <u>Proposed change:</u> "Monitoring and surveillance program(s) should include data on occurrence of <u>foodborne</u> AMR and patterns of AMU, in relevant sectors as inputs into risk analysis."</p>	<p>Australia Australia recommends addition of the word ‘foodborne’ to provide clarity that the Guidelines only relate to foodborne AMR. Australia recommends deletion of the word ‘all’ to make this principle more achievable for all countries.</p>
<p>Principle 4: Monitoring and surveillance program(s) should include data on occurrence of <u>foodborne</u> AMR and patterns of AMU, in all relevant sectors as inputs into risk analysis<u>-u</u></p>	<p>Japan “Foodborne” should not be omitted.</p>
<p>Principio 4: Los programas de seguimiento y vigilancia deben incluir datos sobre el surgimiento de la RAM <u>transmitida por los alimentos</u> y los patrones del UAM de todos los sectores correspondientes como elementos para el análisis de riesgos.</p>	<p>Uruguay</p>

Section/paragraph	Member/Observer/ rationale
<p>Principle 4: Monitoring and surveillance program(s) should include data on occurrence of <u>foodborne AMR and patterns of AMU and, as appropriate for national circumstances, AMU and/or antimicrobials sales</u>, in all relevant sectors as inputs into risk analysis.</p>	<p>USA <u>Rationale:</u> 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, and certainly not in all relevant sectors Edits are made to make this principle more globally achievable.</p>
<p>Principle 6: Priority for implementation should be given to the most relevant foodborne AMR issues (<u>combination of the food commodities, microorganisms and resistant determinant and AM agent(s) to which resistant is expressed</u>) to be analyzed from a <u>national</u> public health perspective.</p>	<p>Chile Insert description of AMR issue from Codex GL 77, to bring specification. "Issue" by itself is too broad.</p>
<p>Principle 6: Priority for implementation should be given to the most relevant foodborne AMR issues (<u>combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed</u>) to be analyzed from a <u>national</u> public health perspective.</p>	<p>USA <u>Rationale:</u> The text inserted in the parentheses is from CXG 77-2011 and explains what a foodborne AMR issue is. This is an important detail to include for the reader since a description for "foodborne AMR issue" is not anywhere in this document. It was deleted from Principle 6 to be added to the previous paragraph 37 as agreed by the Task Force. Now it has been struck from paragraph 37 as well and so should at least be reinserted here. Added "national" as this principle begins with "priorities" and priorities should be for national contexts.</p>
<p>Principle 7: Monitoring and surveillance program(s) should incorporate to the extent practicable, the capacity for epidemiological investigation and the identification of new and emerging foodborne AMR or trends <u>to inform epidemiological investigations</u>.</p>	<p>Chile</p>
<p>Principle 7: Monitoring and surveillance program(s) should incorporate to the extent practicable, the capacity for epidemiological investigation and identification of new and emerging foodborne AMR or trends. <u>trends to help inform epidemiological investigations</u>.</p>	<p>USA <u>Rationale:</u> Monitoring and surveillance inform epidemiologic investigations. Adding that there must be capacity for epidemiological investigations goes beyond a monitoring and surveillance program, the development of which was the mandate to the Task Force.</p>
<p>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.</p>	<p>Brazil 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, should not be in a principle.</p>
<p>Principle 9: Monitoring and surveillance program(s) should strive to harmonize laboratory methodology, data collection, analysis and reporting across sectors according to national <u>situation</u>, 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 facilitate that data are comparable, and to enhance an integrated approach to data management.</p>	<p>Chile</p>

Section/paragraph	Member/Observer/ rationale
<p>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.</p>	<p>European Union EUMS: See general comments. We can agree with proposed text.</p>
<p>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 <u>comparable data interpretation and</u> sharing of data-data, and to enhance an integrated approach to data management.</p>	<p>USA <u>Rationale:</u> The goal is not just to compare data. The sentence is edited to clarify the goal being to facilitate comparable data interpretation.</p>
<p>5. Risk-based approach</p>	
<p>22. For the purpose of these Guidelines, a risk-based approach is the development and implementation of monitoring and surveillance program(s) that is/are 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.</p>	<p>Canada To improve the flow of the sentence.</p>
<p>22. For the purpose of these Guidelines, a risk-based approach is the development and implementation of monitoring and surveillance program(s) that is/are informed by data and scientific knowledge on the likely occurrence of on foodborne AMR hazards along the food chain <u>to facilitate the risk assessment to determine</u> and their potential risks to human health.</p>	<p>Chile</p>
<p>22. For the purpose of these Guidelines, a risk-based approach <u>for microbial hazards is described in the development Principles and implementation of monitoring and surveillance program(s) that is/are informed by data and scientific knowledge on Guidelines for the likely occurrence</u> Conduct of foodborne AMR hazards along the food chain and their potential to pose risks to human health <u>Microbiological Risk Assessment (CXG 30-1999). Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.</u></p>	<p>USA <u>Rationale:</u> Paragraph 21 is inconsistent with CACGL-30 as written. The TFAMR should not be changing what a risk-based approach is and say that it is for the “purpose of these Guidelines”. Monitoring and surveillance data inform hazard Identification. They do not in themselves define a risk-based approach. 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>23. <u>Risk-based</u> information from integrated monitoring and surveillance of AMR and AMU along the food chain, including data (<u>preferably randomly sampled</u>) from other sources when available, provides important information for risk assessment and risk management decision-making on the appropriateness of the control measures to prevent and minimize foodborne AMR.</p>	<p>Australia This section implies that risk-based surveillance can be solely used to inform future risk assessments. Risk-based surveillance data is highly biased and should not be used for risk assessment unless supplemented with other (preferably randomly sampled) data.</p>

Section/paragraph	Member/Observer/ rationale
<p>23. Information from integrated monitoring and surveillance of AMR and AMU along the food chain, including data from other sources when available, provides important information for risk assessment and risk management decision-making on the appropriateness of the control measures to prevent and minimize foodborne AMR.</p>	<p>Brazil Deleting reference to AMU in this specific sentence is consistent to our previous comments, once AMU is a component of the AMR programs.</p>
<p>23. Information from integrated monitoring and surveillance of AMR and AMU along the food chain, including data from other sources when available, provides important information for risk assessment and <u>further</u> risk management decision-making on the appropriateness of the control measures to prevent and minimize foodborne AMR.</p>	<p>Chile 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>23. Information from integrated monitoring and surveillance of AMR and AMU along the food chain, including data from other sources when available, provides may provide important information for risk assessment and risk management decision-making on the appropriateness of the control measures to prevent and minimize foodborne AMR.</p>	<p>USA The appropriateness of a control measure is not always provided through surveillance</p>
<p>24. When knowledge of AMR risks in a national situation 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 <u>foodborne</u> 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 AMR</i>(GL77).</p>	<p>Chile</p>
<p>24. When knowledge 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 AMR risks opinions of experts. Relevant information includes data in a national situation is limited areas such as: clinical studies, monitoring epidemiological studies and surveillance program(s) may initially be designed according to surveillance, laboratory animal studies, investigations of the relevant evidence that is available on AMR hazards characteristics of microorganisms, 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 analogous microorganisms and situations. 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 AMR</i>.</p>	<p>USA <u>Rationale:</u> The first sentence under paragraph 24 does not provide further clarity or guidance. Recommend including text directly from CXG 30-1999 Section 4.3: “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. 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>25. 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>European Union EUMS can agree with proposed text.</p>
<p>6. Regulatory framework, policy and roles</p>	
<p>26. Integrated monitoring and surveillance program(s) for AMR and AMU requires good governance by the competent authorities. As part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p>	<p>Brazil Deleting reference to AMU in this specific sentence is consistent to our previous comments, once AMU is a component of the AMR programs</p>

Section/paragraph	Member/Observer/ rationale
<p>26. Integrated monitoring and surveillance program(s) for <u>foodborne</u> AMR and AMU requires good governance by the competent authorities. As part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with human health, animal health, plant health, the environment and other relevant authorities</p>	<p>Chile</p>
<p>26. Integrated monitoring and surveillance program(s) for AMR and AMU requires require(s) good governance by the competent authorities. As part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p>	<p>China</p>
<p>26. Integrated monitoring and surveillance program(s) for AMR and AMU requires good governance by the competent authorities. As <u>a</u> part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p>	<p>Republic of Korea The article "a" is used with the plural form "national action plans". Korea suggests remove the article "a" or move the article "a" forward of "part".</p>
<p>26. Un programa integrado de seguimiento y vigilancia de la RAM y del UAM precisa una buena gobernanza por parte de las autoridades competentes. Como parte de los planes de acción nacionales (PAN) para la RAMRAM cuando sea posible, tales autoridades deben proporcionar un marco general de políticas para las actividades de seguimiento y vigilancia a lo largo de la cadena alimentaria en colaboración con las autoridades encargadas de la salud humana, la sanidad animal, la sanidad vegetal, el medio ambiente y otras autoridades pertinentes.</p>	<p>Uruguay Menos prescriptivo que la oración original</p>
<p>26. Integrated monitoring and surveillance program(s) for AMR and AMU requires require good governance by the competent authorities. As authorities as part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain AMR in collaboration with human health, animal health, plant health, the environment and other relevant authorities.</p>	<p>USA <u>Rationale:</u> The sentence is too prescriptive. It is not clear how an “overarching policy framework” is being defined. National Action Plan covers it. This document is for guidance on developing surveillance guidelines. Policy formation is outside scope.</p>
<p>27. 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>	<p>Brazil Deleting reference to AMU in this specific sentence is consistent to our previous comments, once AMU is a component of the AMR programs.</p>
<p>28. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and to inform risk management decisions. <u>Proposed change:</u> "Sharing of knowledge and data with stakeholders should be encouraged since it may improve the understanding of foodborne AMR and inform <u>risk assessments and, in turn,</u> risk management decisions."</p>	<p>Australia Australia recommends deleting the text specifying ‘international’ and ‘global’ sharing as there is currently no internationally agreed system to support sharing of AMR surveillance data. Australia recommends modifying the text to match the Guidelines for risk analysis of foodborne antimicrobial resistance (CAC/GL 77-2011).</p>
<p>28. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and to inform risk management decisions.</p>	<p>Brazil Brazil suggests deleting “and data” once this is still unclear and outside the scope of this Task Force, consistent with comments on Principle 9.</p>

Section/paragraph	Member/Observer/ rationale
28. Sharing of knowledge and data <u>reports</u> internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and to inform risk management decisions.	Chile NO raw data, analyzed data through a report. LAsT part is not clear about who’s risk management desicions and data inform risk assessment, no risk management
28. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and to inform risk management decisions.	China
28. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and to inform risk management decisions assessment.	USA <u>Rationale:</u> The sentence is inaccurate as written and inconsistent with CXG 77-2011 and CXG 30-1999. Surveillance data is hazard identification that feeds risk assessments along with other data to then inform risk management.
29. It is important for competent authorities to have access to AMU data <u>available</u> in their country.	Chile
29. It is important for competent authorities to have access to AMU data in their country.	European Union EUMS can agree with proposed text
29. It is important for competent authorities to have access to consider all available sources of AMU and/or antimicrobial sales data in their country.	USA <u>Rationale:</u> The sentence as written appears to prescribe what competent authorities should have access to, which appears to be delving into national legislation, which is beyond the role of Codex. So it is modified to put the onus on competent authorities to consider all data sources. Further, edits are made as in previous comments to be inclusive of sales data.
7. Implementation of an integrated monitoring and surveillance program for foodborne AMR	
Brazil is of the opinion that Figure 1 does not add value to the document and it does not present an adequate reflection of the Guidelines, so it should be deleted to avoid confusion or misinterpretation.	Brazil
Implementation of an integrated monitoring and surveillance program program(s) for foodborne AMR	Canada For consistency throughout the document.
30. The concept of continuous improvement facilitates the design and implementation of integrated monitoring and surveillance program(s) and allows countries to carry out activities to that progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s).	Canada To add clarity to the sentence.
30. The concept of continuous improvement facilitates the design and implementation of integrated monitoring and surveillance program(s) and allows countries to carry out activities to progress according to country specific objectives, <u>situation</u> , priorities, infrastructure, technical capability, resources, and new scientific knowledge. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s).	Chile

Section/paragraph	Member/Observer/ rationale
<p>30. The concept of continuous improvement facilitates the <u>Country should</u> design and implementation of integrated monitoring and surveillance program(s) and allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s).</p>	<p>Thailand</p> <p>We are of the opinion that the implementation of integrated monitoring and surveillance program(s) should begin with system design and the later step should be followed by “continuous improvement”. Moreover, it is already stated in the appropriate section (Section 11 Evaluation of the integrated monitoring and surveillance program(s), para 117).</p> <p>For greater clarity and understanding, we suggest amending para 30 as follows: “Country should design and implementation of integrated monitoring and surveillance program(s) to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s).”</p>
<p>Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain. <u>Proposed change:</u> "Addition of a footnote to the ‘AMU Component’ to link this with the OIE standards (as has been done for other components in the figure)."</p>	<p>Australia</p> <p>Australia recommends retaining the figure with the addition of a footnote.</p>
<p>Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p>Brazil</p> <p>Brazil is of the opinion that Figure 1 does not add value to the document and it does not present an adequate reflection of the Guidelines, so it should be deleted to avoid confusion or misinterpretation.</p>
<p>Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p>Chile</p> <p>The need of this figure should be revised at step 5.</p>
<p>Figure 1: The figure can be kept for better explanation and help readers understand the Guidelines.</p>	<p>China</p>
<p>Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p>European Union</p> <p>EUMS agree to retain figure 1 and revise it according to the finalised guidelines”.</p>
<p>Figure 1: Korea supports Figure 1 in general. As a minor correction, Korea would like to replace CAC/GL 77-2011 with CXC 77-2011, which follows the current reference system of Codex.</p>	<p>Republic of Korea</p>
<p>Cuadro 1. Marco para el diseño y la implementación de uno o más programas integrados de seguimiento y vigilancia de la RAM transmitida por los alimentos y del UAM a lo largo de la cadena alimentaria.</p>	<p>Uruguay</p> <p>Sugerimos la remoción del cuadro. Existen aspectos como el desarrollo de las métricas en UAM que entendemos no deben ser abordadas en estas directrices y por lo tanto el cuadro es inconsistente y podría generar confusión</p>

Section/paragraph	Member/Observer/ rationale
<p>Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.</p>	<p>USA</p> <p>The United States recommends deletion of the figure.</p> <p><u>Rationale:</u> 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 would likely not meet these criteria. The Task Force should concentrate efforts on getting the text correct in the remaining time.</p>
<p>7.1 Preliminary activities</p>	
<p>7.1.1. Establishing the monitoring and surveillance objectives</p>	
<p>31. 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, AMR NAPs and relevant evidence of the AMR and AMU <u>national</u> situation, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop health sectors and the environment). Competent authorities should identify the challenges that they currently face during the implementation of these activities.</p>	<p>Chile</p>
<p>32.</p> <ul style="list-style-type: none"> The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk assessments and risk management, to obtain baseline information). 	<p>Chile</p> <p>The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk assessments and risk management, to obtain baseline information).</p>
<p>32.</p> <ul style="list-style-type: none"> The representativeness of the data collection (e.g., convenience <u>randomized</u> sampling). 	<p>Australia</p> <p>Australia recommends providing a more appropriate example, as convenience sampling is not an ideal method and does not cover the randomisation concept.</p>
<p>32.</p> <ul style="list-style-type: none"> The representativeness of the data collection (e.g., convenience <u>random or systematic</u> sampling). 	<p>European Union</p> <p>EUMS: In the second bullet point, the example in the bracket should be deleted. Convenience sampling does not allow representative data collection, thus this example is not appropriate. If an alternative is needed, ‘systematic sampling’ or ‘random sampling’ could be mentioned.</p>
<p>7.1.2. Considerations for prioritization</p>	
<p>33. When establishing monitoring and surveillance priorities, competent authorities should consider 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>Chile</p>
<p>33. 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>USA</p> <p><u>Rationale:</u> Remove Paragraph 33 as it is almost entirely repeated in Paragraph 34. In Paragraph 34, stating “public health data and knowledge” acknowledges epidemiology and public health implications.</p>

Section/paragraph	Member/Observer/ rationale
<p>34. 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 considerations of <u>the need for</u> risk profiles and risk assessments."</p>	<p>Australia Australia recommends addition of these words to improve the clarity of this paragraph.</p>
<p>34. 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 scientific knowledge where it exists. Competent authorities should identify existing data sources and gaps on AMR and AMU including considerations of <u>the need for</u> risk profiles and risk assessments.</p>	<p>Chile</p>
<p>34. 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 considerations of risk profiles and risk assessments.</p>	<p>Singapore Specific observation: Under section 7 para 34, the guideline recommends that competent authority should determine the infrastructure, capacity and resources required to meet the objectives, once the objectives and priorities have been established. Comment: Priorities may need to be reviewed, depending on infrastructure, capacity and resources available to support the monitoring and surveillance. <u>Justification</u>: The preliminary activities could be iterative decision-making processes, e.g. determining the infrastructure, capacity and resources may lead to review of prioritization based on the availability of resources and current national situation.</p>
<p>34. 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 considerations of <u>needs for</u> risk profiles and risk assessments.</p>	<p>USA <u>Rationale</u>: Consideration should be for data needs for risk profiles and risk assessment so text added for clarity.</p>
<p>7.1.3. Infrastructure and resources</p>	
<p>36. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. However, 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 an integrated analysis.</p>	<p>Australia Addition of a full stop after 'Guidelines'.</p>
<p>36. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. However, 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 an <u>for</u> integrated analysis.</p>	<p>Canada To add clarity</p>

Section/paragraph	Member/Observer/ rationale
<p>36. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. However, 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 an integrated analysis.</p>	<p>Chile Suggest to move to introduction</p>
<p>37. As part of initial planning, the competent authority should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authority should consider the possibilities of integration or expansion of the AMR or AMU monitoring and surveillance activities in within other already ongoing activities.</p>	<p>Canada</p>
<p>38. The competent authority should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, <u>when appropriate</u>, and develop a plan for receiving, analyzing and when feasible reporting data in a central repository.</p>	<p>Chile</p>
<p>7.1.4. Key design elements to be established before initiating the monitoring and surveillance activities</p>	
<p>39. <u>Undertaking pilot studies and testing can provide valuable inputs into the design for monitoring and surveillance program(s).</u> When designing the monitoring and surveillance program(s), the following elements should be considered:</p>	<p>USA <u>Rationale:</u> Pilot studies inform better design of larger scale work and help to test new technologies.</p>
<p>41.</p> <ul style="list-style-type: none"> Cuando sea posible, las cadenas-adenas de distribución de los antimicrobianos desde su fabricación o importación hasta el usuario final, incluidos los proveedores de datos sobre ventas/uso. 	<p>Uruguay Esto puede estar fuera de las capacidades de los países.</p>
<p>41.</p> <ul style="list-style-type: none"> Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers. 	<p>USA <u>Rationale</u> Delete the first bullet as it is not feasible in many countries.</p>
<p>41.</p> <ul style="list-style-type: none"> 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 the data may be useful. <p><u>Proposed change:</u> "AMU (refer to the OIE standards for further information):</p> <ul style="list-style-type: none"> <u>Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.</u> <u>Identification of the sectors where collection of data would be most relevant and efficient to meet surveillance objectives."</u> 	<p>Australia Australia recommends linking to the OIE standards here as AMU is the remit of the OIE. Australia recommends deleting the final dot point as legal frameworks are outside the remit of Codex.</p>
<p>41.</p> <ul style="list-style-type: none"> 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 the these data may be useful. 	<p>Canada</p>

Section/paragraph	Member/Observer/ rationale
<p>41.</p> <ul style="list-style-type: none"> 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 the data may be useful. 	<p>Chile</p>
<p>41.</p> <p>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 the data may be useful.</p>	<p>Japan</p> <p>It is beyond the mandate of this guideline to describe legal framework.</p>
<p>41.</p> <ul style="list-style-type: none"> 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 the data may be useful. 	<p>USA</p> <p><u>Rationale:</u> Delete the third bullet as it is beyond the mandate of Codex to provide legal advice, legal guidance or suggest the need for a domestic legal framework.</p>
<p>8. Components of integrated monitoring and surveillance program(s) for AMR</p>	
<p>Brazil is of the opinion that Section 8 still needs improvements. It is still too detailed and some of the examples should be deleted, since recommendations should be science based, practical and feasible, and that priorities vary regionally and can change over time.</p>	<p>Brazil</p>
<p>44. The design of a 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 is are collected through existing programs designed for another purpose, this will need to be specified and the different methodologies and data interpretation methods will need to be accounted for.</p>	<p>Canada</p>
<p>8.1 Sampling design</p>	
<p>44. The design of a 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 is collected through existing programs designed for another purpose, this will need to be specified and the different methodologies and data interpretation methods will need to should be accounted for described.</p>	<p>USA</p> <p><u>Rationale:</u> Clarity</p>
<p>45. Sampling design should consider temporal and geographical aspects of data collection.</p>	<p>European Union</p> <p>EUMS: We agree with rephrasing the text but instead of ‘aspects’ the term ‘coverage’ should be used to clearly highlight that it is important to collect data which are representative for the time periods and regions.</p>
<p>46. Once a sampling design is established, consistency in sample types and methodology should be achieved is desirable to achieve for long-term, comparability and accurate interpretation of results, especially when new methodologies are added and the program is adjusted.</p>	<p>USA</p> <p><u>Rationale:</u> Edited to convey that consistency is desirable to achieve but is still challenging to do so.</p>

Section/paragraph	Member/Observer/ rationale
8.2 Sampling plans	
47. <ul style="list-style-type: none"> The procedure to collect a representative sample from the selected sample source(s) at the selected point(s) in the food chain. 	USA <u>Rationale:</u> The sample may be a convenience rather than representative.
47. <ul style="list-style-type: none"> Sample size, statistical methods and underlying assumptions of the data used to calculate the number of samples and isolates (e.g. frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored). 	Brazil Brazil suggests deleting the examples in the second bullet point, to avoid confusion or misinterpretation. They do not add value to the document.
48. The following elements should be considered in the sampling plan: EUMS: As regards the second bullet point, “and food production environment” needs to be added to ensure full coverage of all relevant areas. This was highlighted before (previous version of the GLIS) in para 46, which is now deleted.	European Union
48. <ul style="list-style-type: none"> Sampling strategy (e.g., active or passive). 	Brazil Brazil suggests deleting the examples in the first bullet point, to avoid confusion or misinterpretation. They do not add value to the document.
49. As the program(s) develop, the sampling plan can be broadened to include additional food commodities and gradually be more representative of the population of interest.	European Union EUMS: This sentence still needs some rewording. Broadening the sampling should not be restricted to food commodities, thus ‘target population’ might be used instead. More importantly, sampling always needs to be representative of the population covered. Improvements could cover the type of populations covered (regional, in more detail), the points in the food chain, the sampling strategies used as well as sample size (to improve the precision of the estimate). The following wording might be used: ‘As the program(s) develop, the sampling plan can be broadened to include additional animal or plant/crop species and production types or food commodities, points in the food chain, sampling strategies including sample size, and gradually cover better the populations of interest’.
8.3 Sampling sources	
Fuentes de las muestras: Proponemos considerar la inclusión de los vehículos de transporte de alimentos y lo relacionado con animales (roedores) cómo vectores de transmisión de bacterias con RAM en el numeral 8.3. Fuentes de las muestras.	Colombia
50. When identifying the sample sources to be included in the monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure. <u>Proposed change:</u> "When identifying the sample sources to be included in the monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure <u>pathways</u> ."	Australia Remove the underline under the letter ‘e’ in sample. Australia recommends the addition of the word ‘pathways’ for clarity.
50. When identifying the sample sources to be included in the monitoring and surveillance program program(s) , consideration should be given to the major direct and indirect food exposure.	Canada

Section/paragraph	Member/Observer/ rationale
50. When identifying the sample sources to be included in the monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure.	China
50. When identifying the sample sources to be included in the monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure food-based hazard release and exposure pathways.	USA <u>Rationale:</u> Additional context provided for clarity.
51. Initial implementation might include a limited selection of sample sources at one or more specific points along the food chain, with those closest to consumption and posing the most risk being the priority . The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne AMR.	USA <u>Rationale:</u> 1) This section includes so many sample types, it does not clarify what the priority sample types are. Those samples closest to the consumption should be the priority as that is the sample type posing the greatest risk to the consumer. 2) Keeping context within Codex scope.
52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances.	USA <u>Rationale:</u> The term “progressively” is unnecessary, and the intent of inclusion is unclear.
53. The integrated program(s) should reflect the food production in the country and cover samples from all relevant stages of the food chain.	Australia Australia recommends deletion of the word ‘all’ to make this principle more achievable for all countries.
53. The integrated program(s) should reflect the food production in the country and cover samples from all relevant stages of the food chain chain where there is relevant evidence that they could contribute to foodborne AMR.	Brazil Brazil suggests deleting “all relevant” and including “where there is relevant evidence that they could contribute to foodborne AMR”, for clarity and consistency with Codex principles.
53. The integrated program(s) should reflect the food production in the country and cover samples from all relevant stages of the food chain chain that pose the greatest risk of foodborne AMR.	USA <u>Rationale:</u> The term “all” is too prescriptive and unnecessary. What does “relevant” mean? Why not clearly state what is important for safe food? The focus should be on sample types that pose the greatest risk of foodborne AMR. We are unaware of any country with endless resources and such statements provide no guidance if the guidance is to do everything.
54. Considerations for the selection of possible sample sources at different points of the food chain are:	Brazil Brazil suggests deleting many of the examples in the bullet points for “Food producing animals” and “Plants/Crops” and to delete the bullet point for “Farm inputs”. This deletions and revisions proposed are to avoid duplication, to provide clarity and to help members to adequately prioritize their actions on practical and feasible options of sample sources. Brazil suggests adding “bio” to fertilizers to provide clarity, since it does not apply to chemical fertilizers.
54. A continuación figuran consideraciones a tener en cuenta para aspectos que podrían considerarse al seleccionar posibles fuentes de muestras en diferentes puntos de la cadena alimentaria:	Uruguay

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Food producing animals For integration, samples Samples from food-producing animals should be collected from the same animal species at the slaughterhouse and retail. 	<p>Canada</p> <p>There may be many reasons why you want samples should be collected from the same species, therefore Canada suggests to delete the first part of the paragraph for brevity and flexibility.</p>
<ul style="list-style-type: none"> Food producing animals For integration, samples from food-producing animals should be collected from the same animal species at the slaughterhouse and retail. 	<p>European Union</p> <p>EUMS: Whereas we agree with moving this sentence to this place, we suggest to keep the original text saying ‘from the same animal species as retail samples.’ The rationale is that we should not fix that sampling needs to be performed at slaughterhouse, as also sampling at farm level might be relevant for integration purposes. And for some production types (e.g. egg production), slaughter is not the relevant point in the food chain. Thus more flexibility should be allowed.</p>
<ul style="list-style-type: none"> Food producing animals For integration, samples from food-producing animals should may be collected from the same animal species at the slaughterhouse and retail, though sampling may be expanded at slaughter or retail individually as resources allow. 	<p>USA</p> <p><u>Rationale:</u> There may be resources in one area and not the other, so the text should not be prohibitive to expansion as resources allow.</p>
<ul style="list-style-type: none"> Food producing animals Las Cuando sea posible las muestras de animales sanos destinados al sacrificio pueden obtenerse en el establecimiento agropecuario, en el corral de espera o en el matadero. Obtener muestras de animales que no ingresen inmediatamente a la cadena alimentaria puede brindar información adicional acerca de la RAM a nivel de la población. 	<p>Uruguay</p> <p>El texto debe ser flexible y contemplar las distintas capacidades y recursos de los países.</p>
<ul style="list-style-type: none"> Food producing animals Samples taken from healthy animals destined for slaughter may be collected on-farm, during lairage, or at the slaughter. Collection of samples from animals not immediately entering the food chain can provide additional information on AMR at the population-level population-level but may be a lower priority than for those animals directly entering the food supply. 	<p>USA</p> <p><u>Rationale:</u> Extra context is provided for clarity for countries that are trying to prioritize.</p>
<ul style="list-style-type: none"> Food producing animals <ul style="list-style-type: none"> At the farm-level, sample options may include faeces, feed, litter or bedding, dust, fluff, water, soil, sewage, sludge or manure. 	<p>Brazil</p>
<ul style="list-style-type: none"> Food producing animals <ul style="list-style-type: none"> At the farm-level, sample options may include faeces, feed, litter or bedding, dust, fluff, water, soil, sewage, sludge or manure. 	<p>Thailand</p> <p>Thailand supports the deletion of examples. We are of the view that the number of examples should be reduced and remained only the important examples which are directly related to prevalence of AMR in order to avoid confusion.</p> <p>These 2 bullets will be read as follows:</p> <ul style="list-style-type: none"> At the farm-level, sample options may include faeces. At lairage, sample options may include pen floors.

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At the farm level, sample options may include faeces, feed, litter or bedding, dust, fluff, water, soil, sewage, sludge or manure. 	<p>USA</p> <p>Bullet starting with “At the farm level” should be deleted.</p> <p><u>Rationale:</u> These samples for most countries would be collected at the research level, not monitoring/surveillance level.</p> <p>This document should be globally achievable and prioritize sample types closest to food to be consumed by the consumer to provide appropriate risk-based guidance. It is difficult to believe that more than a handful of countries at most are collecting any of these sample types as priorities for a national foodborne AMR monitoring and surveillance system.</p> <p>Further, most of these are environmental samples, not food animal samples. How are litter, dust and water considered food animal samples? Feed is covered under “farm input” below and is duplicative here.</p> <p>Collection of these sample types may be appropriate for periodic research studies, or more general monitoring for AMR (beyond just foodborne AMR, the scope of Codex) but do not appear appropriate for a basic national monitoring and surveillance program to assure safe food.</p>
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At the farm-level, sample options may include faeces, feed, litter or bedding, dust, fluff, water, soil, sewage, sludge or manure. 	<p>IFIF</p> <p>We propose to delete ‘feed’ - Reason: care should be taken to avoid sampling feed at the farm as cross contamination can occur at any point that the feed is exposed to the air or conditions at the farm. This should be deleted as sampling feed on farm would not provide data representative of the feed itself and would not be a good use of time and resources.</p>
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At lairage, sample options may include pen floors, trucks, crates, or dust. 	<p>Brazil</p>
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At lairage, sample options may include pen floors, trucks, crates, or dust. 	<p>Thailand</p> <p>Thailand supports the deletion of examples. We are of the view that the number of examples should be reduced and remained only the important examples which are directly related to prevalence of AMR in order to avoid confusion.</p>
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At lairage, sample options may include pen floors, trucks, crates, or dust. 	<p>USA</p> <p>Delete 2nd bullet beginning with “At lairage”.</p> <p><u>Rationale:</u> These are environmental, not food animal samples. And again, these are more appropriate for further research to identify sources based on hypotheses generated from surveillance rather than surveillance itself. How many countries have these sample types as part of their ongoing national monitoring/surveillance system for foodborne AMR? This does not appear to be globally achievable.</p>

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At slaughter, slaughter and processing in the slaughterhouse sample options may include caecal carcass, caecal/intestinal contents or lymph nodes. In some animal species, these samples may be representative of the pre-slaughter environment and 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. 	<p>Brazil</p>
<ul style="list-style-type: none"> • Food producing animals <ul style="list-style-type: none"> ○ At slaughter, sample options may include meat, poultry, seafood, caecal contents or lymph nodes. In some animal species, these samples caecal contents or lymph nodes may be representative of the pre-slaughter environment and 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. 	<p>USA</p> <p><u>Rationale:</u> Meat, poultry, seafood samples would be the food products closest to consumption and of most risk for foodborne AMR from food animals that could be collected at slaughter. Food samples are the priority for sampling for foodborne AMR risk.</p>
<p>Plants/crops</p> <p>The selection of plants/crops should be risk-based and relevant to the country’s production systems. Information related to this approach will be determined by the relevant international organization in due course.</p> <ul style="list-style-type: none"> ● At the harvest and farm levels, sample options may include plants/crops, soils, fertilizers or irrigation water. ● At post harvest level, sample may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water 	<p>Australia</p> <p>Australia recommends modification to this text, including deletion of the detailed text, as there are currently no internationally agreed plant health requirements for AMU. The development of such requirements is most appropriately addressed by the relevant international organization.</p>
<p>Plants/crops</p>	<p>Thailand</p> <p><u>General comment:</u></p> <p>We would like to express our concern on the texts related to plants/crops as there are different AMR and AMU patterns in different countries and the limited availability of scientific information on AMU and AMR in plants/crops. We are of the view that the specific content related to AMU and AMR in plants/crops should be considered the flexibility and feasibility for the implementation of member countries before inclusion to the document. Moreover, we propose the deletion of the detailed information that mentioned to plants/crops throughout the document.</p> <p><u>Specific comment:</u></p> <p>We propose the deletion of this section and all bullets as the reason stated in our general comments.</p>
<p>The selection of plants/crops should be risk based and relevant to the country’s production systems.</p>	<p>Thailand</p> <p>We propose the deletion of this section and all bullets.</p>

Section/paragraph	Member/Observer/ rationale
<p>La selección de plantas/cultivos debe basarse en los riesgos y debe guardar relación con los sistemas de producción del país. <u>Cuando sea posible, las muestras se podrán obtener</u></p>	<p>Uruguay El texto debe ser flexible y contemplar las distintas capacidades y recursos de los países.</p>
<p>The selection of plants/crops should be risk based and relevant to the country's production systems. Scientific data describing foodborne AMR risk from use of antimicrobial pesticides in crops are lacking and standardized methodologies for monitoring and surveillance programs (sample sources, target microorganisms, sample design, laboratory testing methodology, data analysis and reporting) require further research and development prior to issuing specific guidance.</p>	<p>USA Rationale: Plants/crops are included under “food” and “food production environment” to the extent appropriate, given current science. This section does not provide any guidance other than stating that surveillance should be done, so it is premature to issue guidance at this time. While the Joint FAO/WHO Expert Meeting 2019, providing scientific advice for the TFAMR found evidence of contamination with AMR, it acknowledged that, “...the extent to which the treatment of crops with antimicrobial promotes AMR in bacteria found on edible portions of fresh plant produce is uncertain.” Further, the FAO/WHO Expert Meeting found data gaps remain on appropriate indicator bacteria for monitoring AMR. Similar to above comments, assessing irrigation water pre-harvest or surfaces, dust, or water post-harvest are examples of environmental contamination rather than representing food. It would be appropriate for gathering data through research to understand whether there is a need for ongoing monitoring and identify appropriate targets and methodologies.</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At the harvest and farm levels, sample options may include plants/crops, soils, fertilizers biofertilizers or irrigation water. 	<p>Brazil</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At the harvest and farm levels, sample options may include plants/crops, soils, fertilizers or irrigation water. 	<p>Thailand We propose the deletion of this section and all bullets as the reason stated in our general comments.</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At the harvest and farm levels, sample options may include plants/crops, soils, fertilizers or irrigation water. 	<p>USA</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At post-harvest level, sample may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water. 	<p>Brazil</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At post-harvest level, sample samples may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water. 	<p>Canada</p>
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At post-harvest level, sample may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water. 	<p>Thailand We propose the deletion of this section and all bullets as the reason stated in our general comments.</p>

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> • Plants/crops <ul style="list-style-type: none"> ○ At post harvest level, sample may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water. 	<p>USA</p>
<p>Farm input</p>	<p>Brazil</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular feed or medicated feed, fertilizers or other relevant food production inputs. <u>Proposed change:</u> "Examples of sample options may include feed (<u>unmedicated</u> or medicated), fertilizers or other relevant food production inputs." 	<p>Australia Australia recommends editing the text to be consistent with the OIE Standards terminology.</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular feed or medicated feed, fertilizers or other relevant food production inputs. 	<p>Brazil</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular<u>non-medicated</u> feed or medicated feed, fertilizers or other relevant food production inputs. 	<p>Japan To be consistent with OIE terminology.</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular<u>non-medicated</u> feed or medicated feed, fertilizers or other relevant food production inputs. 	<p>USA Text edited to be consistent with OIE terminology.</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular feed or medicated feed, fertilizers or other relevant food production inputs.<u>Feed should be sampled at the manufacturing or production sight for the most accurate sampling results.</u> 	<p>IFIF</p>
<ul style="list-style-type: none"> • Farm input Examples of sample options may include regular<u>non-medicated</u> feed or medicated feed, fertilizers or other relevant food production inputs. 	<p>IFIF For consistency within Codex texts, it is suggested to change “regular” to “non-medicated” as this is the term used in the Code of Practice on Good Animal Feeding</p>
<ul style="list-style-type: none"> • Food Food samples may be collected at processing, packaging, wholesale or retail. Sample-Samples may include both domestically-produced and imported food sources. 	<p>Canada</p>
<ul style="list-style-type: none"> • Food Food samples may be collected at processing, packaging, wholesale or retail. Sample-Samples may include both domestically-produced and imported food sources. 	<p>USA</p>

Section/paragraph	Member/Observer/ rationale
<p>• Food production environment Examples of sample options may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets.</p>	<p>Canada The text may not provide enough detail to be useful. Could more detail be added, such as water samples in the farm environment and surfaces of processing areas (food contact and non-food contact) further along the chain?</p>
<p>8.4 Target microorganisms and resistance determinants</p>	
<p>55. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to public health. <u>Proposed change:</u> "Selection of the target microorganisms and resistance determinants should be considered based on their relevance to <u>food safety and public health.</u>"</p>	<p>Australia Australia recommends addition of 'food safety' to highlight that these Guidelines focus on foodborne AMR.</p>
<p>55. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to public health.</p>	<p>European Union EUMS: To improve clarity of the text, it could be modified as follows: 'Selection of the target microorganisms and resistance determinants should consider their relevance to public health.'</p>
<p>55. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to <u>public health</u> <u>foodborne AMR.</u></p>	<p>USA Foodborne AMR makes the paragraph tied closely to Codex mandate.</p>
<p>56. 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>Australia Remove the underline under the space before the word virulence.</p>
<p>56. 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>Canada</p>
<p>56. 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>China</p>
<p>57. Examples of bacterial species for consideration may include: Examples of bacterial species for consideration may include:</p> <ul style="list-style-type: none"> • Foodborne pathogens such as <i>Salmonella</i> spp., <i>Campylobacter</i> or other food borne pathogens depending on national or regional epidemiology and risks. 	<p>Australia Remove the underline under the full stop in <i>Salmonella</i> spp.</p>
<p>57.</p> <ul style="list-style-type: none"> • Foodborne pathogens such as <i>Salmonella</i> <i>Salmonella</i> spp., <i>Campylobacter</i> or other food borne pathogens depending on national or regional epidemiology and risks. 	<p>Canada To be consistent with the formatting of other bacterial genus names in this paragraph.</p>

Section/paragraph	Member/Observer/ rationale
57. • Foodborne pathogens such as <i>Salmonella</i> spp., <i>Campylobacter</i> or other food-borne foodborne pathogens depending on national or regional epidemiology and risks.	Republic of Korea The blank between "food" and "bourne" is not necessary
57. • Commensal bacteria such as <i>Escherichia coli</i> and Enterococcus <i>Enterococi (Enterococcus faecium and E. faecalis)</i> , which can contaminate food and harbor transferable resistance genes.	Thailand To be consistent with the OIE Terrestrial Code Chapter 6.8, Article 6.8.5, we would like to retain the original version of this text. “Enterococci (Enterococcus faecium and E. faecalis)”.
58. Target microorganisms from aquatic animals and food of non-animal origin should be determined based on available <u>scientific</u> evidence and relevance to public health.	Japan This guideline should be science-base.
58. Los microorganismos objetivo de animales acuáticos y alimentos de origen no animal deben determinarse sobre la base de la evidencia <u>científica</u> disponible y de la importancia para la salud pública.	Uruguay
58. Target microorganisms from aquatic animals and food of non-animal origin should be determined based on available <u>scientific</u> evidence and relevance to public health.	USA <u>Rationale:</u> Scientific evidence would be appropriate for Codex as Codex is science-based.
59. Whenever possible the characterization of bacterial isolates to the species-level, and as feasible, molecular analysis of particular isolates that may present a public health concern, may be undertaken.	Australia Addition and deletion of commas to improve readability.
59. Whenever possible the characterization of bacterial isolates to the species-level (and beyond) <u>should be undertaken</u> as feasible, molecular analysis of particular isolates that may present a public health concern may be undertaken should be considered.	European Union EUMS: Whereas we agree with the suggested shortening the text we do not believe that it is sufficient to require only characterization at species level, e.g. for Salmonella. Furthermore, characterization at species level (and beyond) should always be undertaken.
8.5 Laboratories	
61. Laboratories participating in the monitoring and surveillance program(s) should consider:	Brazil Brazil suggests rewording topics b. and c. for clarity and flexibility, and also deleting the examples in item d. because they are unnecessary and can lead to confusion.
a. Aislar bacterias, identificar (a nivel de especie), tipificar y realizar las pruebas de susceptibilidad antimicrobiana (AST) con métodos estandarizados y validados, para lo cual deben contar con personal capacitado en tales métodos. Los laboratorios que participan ...: a. Aislar bacterias, identificar (a nivel de especie y el serotipo), tipificar y realizar	Colombia La identificación del serotipo, como el caso de salmonella y listeria, es un principio básico fundamental para el análisis epidemiológico y molecular en el estudio de las dinámicas de transmisión de la RAM in las bacterias de importancia en salud pública.
b. Accreditation in accordance with national or international guidance or have a <u>validated Standard Operating Procedure for the monitoring purposes-quality management system</u> in place.	Brazil
c. <u>Whenever possible, participating</u> 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).	Brazil

Section/paragraph	Member/Observer/ rationale
c. 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) <u>program(s) if available (or if necessary)</u> .	Republic of Korea The proficiency testing should be performed considering the national situation. Hence, Korea suggests adding to 'if available' or 'if necessary' at the end of the sentence for its clarity.
d. Being equipped with facilities and having procedures to maintain sample integrity (e.g. storage temperature and time between sample reception and analysis) and traceability.	Brazil
e. Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary <u>and carry out molecular characterization where feasible</u> .	European Union EUMS: We agree with the suggested rephrasing of the text. In section a) the word 'performed' should be deleted as it is now repetitive. The aspect of molecular analysis of particular isolates as highlighted in para 58 needs to be addressed in the section 8.5. on laboratories. In section f) it might be added: 'and carry out molecular characterization where feasible.'
8.6 Antimicrobial susceptibility testing	
8.6.1. Methods and interpretative criteria	
62. Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by internationally recognized organizations where available, should be used. <u>Phenotypic or genotypic methodology might be considered in the future for antimicrobial susceptibility testing. For both approaches, the methods need to be standardized and validated by internationally recognized organizations where available</u>	European Union EUMS: According to the current text, 'susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by internationally recognized organizations where available, should be used to ensure reliable and comparable data.' This might be outdated in the future and be replaced by genotypic methods. Nevertheless, the details listed might be quite relevant for most monitoring and surveillance approaches. Therefore, we suggest to keep the text, but to introduce a new paragraph reading as follows: "Phenotypic or genotypic methodology might be considered in the future for antimicrobial susceptibility testing. For both approaches, the methods need to be standardized and validated by internationally recognized organizations where available."
64. Interpretation of results for MICs or disk diffusion, diffusion should be undertaken according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., disk diffusion zone diameters or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.	Canada
64. Interpretation of results for MICs or disk diffusion, should be <u>consistently</u> undertaken according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., disk diffusion zone diameters or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.	European Union EUMS: We agree with the adjusted text but we would prefer the keep the word 'consistently' (...results for MICs or disk diffusion, should be 'consistently' undertaken according to...) as it may be relevant to use over time always the same interpretation criteria.

Section/paragraph	Member/Observer/ rationale
<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, and should include quantitative results (i.e., disk diffusion zone with disk content of antimicrobials diameters or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.</p>	<p>Japan It is necessary to record not only the disk diffusion zone but also the concentration of disk.</p>
<p>65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) (i.e., wild-type or non-wild type) or clinical breakpoint (i.e. resistant, intermediate or susceptible). 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. The use of clinical breakpoints may differ between animal species. The interpretative criteria or category used should be included in the reporting, interpretation and analysis of data.</p>	<p>European Union EUMS: We agree with the adjusted text as it allows some flexibility but also ensures clarity. The second last sentence should read as follows: 'Clinical breakpoints may differ between animal species' as just the values are different but not the way the values are applied.</p>
<p>65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) (i.e., which should be reported as wild-type or non-wild type) type or clinical breakpoint (i.e. resistant, intermediate or susceptible). 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. The use of clinical breakpoints may differ between animal species countries and/or regions. The interpretative criteria or category used should be included in the reporting, interpretation and analysis of data.</p>	<p>USA Rationale: 1) Additional text added to clarify the need to report ECOFFs as wild-type or non-wild type to prevent common confusion in reporting results. 2) Differences in breakpoints for animal species is less relevant for Codex than differences between countries/regions. Clinical breakpoints often times differ by countries/regions due to different dosage regimens authorized.</p>
<p>8.6.2. The panel of antimicrobials for susceptibility testing</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>Canada</p>
<p>71. Antimicrobials to be tested may be prioritized based on antimicrobials those that have been ranked with higher priority for human health and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Antimicrobials specified from national risk prioritization may also be considered for inclusion in the susceptibility testing panels.</p>	<p>Canada To improve readability and avoid repetition.</p>
<p>71. Antimicrobials to be tested may <u>should</u> be prioritized based on antimicrobials that have been ranked with higher priority for human health and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Antimicrobials specified from national risk prioritization may also be considered for inclusion in the susceptibility testing panels.</p>	<p>European Union EUMS: Whereas we can agree with rephrasing previous paragraphs, the requirement should remain to prioritize antimicrobials that have been ranked with higher priority for human health, as this is very important to follow the One Health approach, i.e. the first sentence in para 70 should read: 'Antimicrobials to be tested may should be prioritized based on antimicrobials that have been ranked with higher priority for human health...'</p>

Section/paragraph	Member/Observer/ rationale
8.6.3. Concentration ranges of antimicrobials	
72. The concentration ranges used , used should ensure that both ECOFFs and clinical breakpoints, when available, are included in order to allow comparability of results with human data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) used for each antimicrobial agent.	Canada
8.6.4. Molecular testing	
73. Molecular testing may needs to be used for the detection of resistance determinants and for epidemiological analysis, according to country specific scenarios and resources.	European Union EUMS: Whereas we can agree to delete all the examples, instead of ‘may be used’ it should be said ‘needs to be used’ as only these methods allow to detect and analyse the aspects mentioned. As already said in para 58, this needs to be applied if feasible.
74. Molecular characterization is an important tool may be useful for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization may 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 in humans, animals, food and environmental reservoirs.	European Union EUMS: We do not agree with the suggested amendments. As already said in para 58, this needs to be applied if feasible. But it is obvious that without application of molecular methods, resistance determinants cannot be detected, clusters not identified and sources and transmission pathways not determined. The text in para 73 should remain as originally drafted and read as follows: ‘Molecular characterization is an important tool for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization 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 in humans, animals, food and environmental reservoirs.’
74. Molecular characterization may be useful for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization 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 in humans, animals, <u>plants/crops</u> , food and environmental reservoirs.	Republic of Korea Korea would like to add to 'plants/crops at the last sentence.
74. Molecular characterization may be useful for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization <u>characterization, in conjunction with epidemiologic information</u> , 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 in humans, animals, food and environmental reservoirs.	USA <u>Rationale:</u> Molecular testing on its own cannot identify sources. It needs to be used in conjunction with epidemiological data to provide source attribution information in most cases.

Section/paragraph	Member/Observer/ rationale
75. Sequence data <u>generated and stored</u> with appropriate metadata may be used for retrospective and prospective surveillance.	<p>European Union</p> <p>EUMS: Whereas we can agree to delete some text here, we need to make sure that sequence data are generated and stored.</p> <p>Therefore, the para should read as follows: ‘Sequence data generated and stored with appropriate metadata may be used for retrospective and prospective surveillance.’</p>
76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and for the early detection of resistant microorganisms of high public health importance.	<p>Australia</p> <p>Australia advises that with the number of isolates being analysed globally, ‘early detection’ of resistant organisms is not a realistic expectation of this guideline.</p>
76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and <u>needs to be used</u> for the early detection <u>or confirmation</u> of resistant microorganisms of high public health importance.	<p>European Union</p> <p>EUMS: Whereas we can agree to delete the specific mentioning of WGS, molecular testing is needed to confirm the presumptive early detection of resistant microorganisms of high public health importance. Therefore, instead of ‘may be useful’ it should be said ‘needs to be used’ for the early detection of resistant microorganisms of high public health importance.</p> <p>The sentence would read as follows: ‘Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and needs to be used for the early detection or confirmation of resistant microorganisms of high public health importance.’</p>
8.7 Collection and reporting of resistance data	
79. Information for each individual sample may <u>should</u> include:	<p>European Union</p> <p>EUMS: Whereas we can agree with most of the rephrasing of the text as suggested, we consider it important to say that the information listed should be collected as this is necessary for correct interpretation and use of the data. The first sentence would read as follows: ‘Information for each individual sample should include:’</p>
a. General description of the sampling design and randomization procedure.	<p>Brazil</p> <p>Brazil suggests deleting the first bullet point, for clarity, once it does not make sense as an information for each individual sample. This information has to be part of the description of the program and included in the report.</p>
b. Specific information about the origin of the sample (e.g., food producing animal or plan/crop species, type of production, where and when the sample was collected, etc <u>collected</u>).	<p>Canada</p> <p>The use of both “e.g.,” and “etc.” in the brackets is redundant.</p>
b. Specific information about the origin of the sample (e.g., food producing animal or plan/crop <u>plant/crop</u> species, type of production, where and when the sample was collected, etc.).	<p>Republic of Korea</p> <p>Korea adds 't' after "plan".</p>
b. Specific information about the origin of the sample (e.g., food producing animal or plan/crop <u>plants/crops</u> species, type of production, where and when the sample was collected, etc.).	<p>Thailand</p>

Section/paragraph	Member/Observer/ rationale
<p>c. General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate .</p> <p><u>Proposed change</u>: "c. General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate."</p>	<p>Australia</p> <p>Remove the space before the full stop.</p>
<p>c. General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate<u>appropriate</u>.</p>	<p>USA</p>
<p>80. Reporting of results from the monitoring and surveillance program<u>program(s)</u> should be timely.</p>	<p>Canada</p>
<p>9. Components of integrated monitoring and surveillance program(s) for AMR</p>	
<p><u>Proposed change</u>: "Deletion of Section 9 from para 86 point one through to para 98 (inclusive)."</p>	<p>Australia</p> <p>Australia recommends deletion of this text as it is duplicative of the OIE work. Australia is concerned that if Codex is duplicative of the OIE, this will potentially lead to the development of a different AMU system to that of the OIE, which will impose unnecessary burdens on countries.</p>
	<p>Brazil</p> <p>Brazil is of the opinion that Section 9 should be carefully revised and shortened, 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. It is also important to avoid duplication, overlap and conflicts with the ongoing work and efforts by OIE related to this topic. Brazil suggests shortening this section by proposing a new topic 9.3 and deleting actual topics 9.3, 9.4 and 9.5.</p>
<p>Components of integrated monitoring and surveillance program(s) for AMU<u>AMU to be considered for AMR data interpretation</u></p>	<p>Japan</p> <p>To clarify the purpose of AMU surveillance.</p>
<p>82. Antimicrobial use refers to the quantities of antimicrobials intended for use in animals or plants/crops, which may include the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops.</p>	<p>European Union</p> <p>EUMS: This is a repetition to text in para 2 and can be deleted.</p>
<p>82. Antimicrobial use refers to the quantities of antimicrobials intended for use in animals or plants/crops, which may include the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops.</p>	<p>Ghana</p> <p><u>Position</u>: Ghana proposes the deletion paragraph 82.</p> <p><u>Rationale</u>: The definition for "antimicrobial use" and its abbreviation as used in the Guideline document is required in the Section 1 rather than Section 9 for clarity to the reader right from the onset.</p>
<p>82. Antimicrobial use refers to the quantities of antimicrobials intended for use in animals or plants/crops, which may include the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops.</p>	<p>Thailand</p> <p>We propose to delete this paragraph. The description of antimicrobial use should be address in Section 1.</p>

Section/paragraph	Member/Observer/ rationale
<p>82. Antimicrobial use refers to the quantities of antimicrobials intended for use in animals or plants/crops, which may include the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops. Additional information included with AMU estimates would be dose, route of administration and duration of use. Because obtaining precise estimates of AMU can be challenging, surrogates are often needed. One surrogate for AMU commonly collected by countries would be the quantities of antimicrobials sold and/or the quantities intended for use in food-animals or plants. Importantly, sales data are not synonymous with actual AMU and should not be construed as such. For animals, the OIE has been collecting data on antimicrobials intended for use.</p>	<p>USA Rationale: Additional text is provided for clarity. There are very few countries in the world that are monitoring antimicrobial use data. Most are monitoring antimicrobial sales. There is much confusion around these terms and Codex should provide clarity so further explanation is provided here.</p>
<p>9.1 Design of an integrated monitoring and surveillance program for antimicrobial agents intended for use in animals or plants/crops</p>	
<p>Design of an integrated monitoring and surveillance program-program(s) for antimicrobial agents intended for use in animals or plants/crops</p>	<p>Canada</p>
<p>Design of an integrated monitoring and surveillance program for antimicrobial agents intended for use in food-producing animals or plants/crops</p>	<p>Thailand</p>
<p>Diseño de un programa integrado de seguimiento y vigilancia de agentes antimicrobianos a ser usado en animales o plantas/cultivos</p>	<p>Uruguay Para animales, en este punto deben referenciarse las normas de la OIE sobre uso responsable y prudente contemplada en el Capítulo 6.9. del Código Sanitario para los Animales Terrestres y el Capítulo 6.3. del Código Sanitario para los Animales Acuáticos.</p>
<p>83. 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. Through pilot studies, competent authorities may explore collection of antimicrobial use data. Some aspects of data collection or reporting need to be specified for sales vs. other types of use data; this is reflected below.</p>	<p>European Union EUMS: The third sentence in para 82 may be deleted as it does not really contribute to clarity of the text. Instead, the second sentence of para 83 may be moved here. The new para 82 would read as follows: "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 vs. other types of use data; this is reflected below."</p>
<p>82bis. 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. 83. 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. Through pilot studies, competent authorities may explore collection of antimicrobial use data. Some aspects of data collection or reporting need to be specified for sales vs. other types of use data; this is reflected below.</p>	<p>Japan 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>

Section/paragraph	Member/Observer/ rationale
<p>82 bis. 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. 83. 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. Through pilot studies, competent authorities may explore collection of antimicrobial use data. Some aspects of data collection or reporting need to be specified for sales vs. other types of use data; this is reflected below.</p>	<p>USA Rationale for new Paragraph 82 bis: OIE codes for monitoring use and a description of antimicrobial use and sales should be referenced and are edited into the beginning of Section 9. Codex should also not provide conflicting advice with OIE which is regularly updating OIE standards and guidance on AMU collection. Reference to OIE should be made here and further explanations should stop at Paragraph 89 to avoid duplication of efforts with OIE. OIE is also collecting data globally and constantly evaluating and improving the process.</p>
<p>84. Sales data can be a valuable indicator to monitor trends although it may not always reflect actual use, administration or application. The competent authority should consider the limitations of each type of data.</p>	<p>Canada</p>
<p>84. Sales data can be valuable indicator to monitor trends although it may not always reflect actual use, administration or application. The competent authority should consider the limitations of each type of data.</p>	<p>European Union EUMS: As suggested above, the second sentence of para 83 would be better placed as 3rd sentence in para 82 as it fits to both types of data.</p>
<p>85. 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 actually being used.</p>	<p>Canada</p>
<p>87. The following elements should be considered when deciding on the approach to collect sales and/or use data. "When deciding on the approach to collect sales and/or use data, consider the elements described in the OIE standards (chapter on AMU)."</p>	<p>Australia Australia recommends linking to the OIE standards here, noting that internationally agreed standards for AMU in plant health are not available.</p>
<p>87. The following elements should be considered when deciding on the approach to collect sales and/or use data:</p>	<p>Canada</p>
<p>87. The following elements should be considered when deciding on the approach to collect sales and/or use data.</p>	<p>Thailand We are of the view that all elements should be deleted and referred to OIE standard.</p>
<p>1. Identification of the scope of the data to be captured (e.g., the antimicrobial agents, classes or sub-classes). The scope may also consider mechanisms of antimicrobial action, relevant resistance data and reporting requirements.</p>	<p>Thailand</p>
<p>2. Identification of the most appropriate points of data collection and the stakeholders that can provide the data. 3. Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) and quantitative information on the antimicrobials intended for use in food producing animals or plants/crops. 4. Nomenclature of antimicrobial agents harmonized with international standards where available. 5. Identification, where possible, of the plant/crop type and species of food producing animals for which the antimicrobials were intended to be used. 6. Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).</p>	<p>Thailand We are of the view that all elements should be deleted and referred to OIE standard.</p>

Section/paragraph	Member/Observer/ rationale
7. Information, where possible, on antimicrobial dose, dosing interval and duration dosage.	Brazil Brazil suggests replacing “dose, dosing interval and duration” for “dosage” in item 7, for clarity.
7. Information, where possible, on antimicrobial dose, dosing interval and duration.	Thailand We are of the view that all elements should be deleted and referred to OIE standard.
Technical units of measurement for reporting antimicrobial sales or use.	Thailand We are of the view that all elements should be deleted and referred to OIE standard.
9.2. Sources of sales/use data	
88. a. <u>Sales data</u> : may be collected from registration authorities, marketing authorization holders, wholesalers, veterinarians, retailers, pharmacies, feed mills, farm shops/agricultural suppliers, pharmaceutical associations, cooperatives or industry trade associations or any combination of these them.	China
89. Data on quantities of antimicrobials sold or used at the national level may differ. Differences may include; loss during transport, storage (<u>due expiry date</u>), and administration (<u>not whole package administered</u>) or <u>loss due package damages</u> , stock purchased and held for future use, off-label use, and <u>influenced by</u> fluctuations in animal or plant/crop populations.	European Union EUMS: In order to clarify the examples and to avoid that they describe bad practices, the second sentence should be modified as follows: “Differences may include: loss during storage (due expiry date), administration (not whole package administered) or loss due package damages, stock purchased and held for future use, influenced by fluctuations in animal or plant/crop populations and/or infectious diseases incidence.”
89. Data on quantities of antimicrobials sold or used <u>at the national level within a country</u> may differ. Differences may include; loss during transport, storage and administration, stock purchased and held for future use, off-label use, and fluctuations in animal or plant/crop populations.	USA <u>Rationale</u> : Text edited for clarity as “within a country” is clearer than “at the national level”. All data collected and collated within a country may not be collected at “a national level”.
9.3 Data collection : Animal population/ plant/crop production	
Data collection: Antimicrobial quantities (numerator)-Collection and reporting of AMU data	Brazil Brazil suggests a new topic 9.3 about “Collection and reporting of AMU data” and a new paragraph 90 to replace the proposed topics 9.3, 9.4 and 9.5. These topics should be deleted, to avoid repetition, confusion and misunderstanding, duplication, overlap and conflicts, since these aspects are still in need for further international harmonization.
Data collection: Antimicrobial quantities (numerator)	Japan Japan suggests deleting Section 9.3, 9.4 and 9.5 about animal sector and add the references of OIE standards. Section 9 should focus on plants/crops AMU.
Obtención de datos: Cantidades de antimicrobianos (numerador)	Uruguay

Section/paragraph	Member/Observer/ rationale
<p>Data collection: Antimicrobial quantities (numerator)</p>	<p>USA</p> <p>Everything from here on should be deleted. The information in Section 9 should be high level and stop at Section 9.2. It does not need to duplicate OIE or run counter to the ongoing work at OIE to improve antimicrobial use data collection. Countries are also doing work on developing appropriate metrics for antimicrobial use and it is premature for Codex to provide guidance that ties countries down to what a few countries or regions may be doing. Codex should not develop duplicative or contrary guidance to OIE as OIE is updating their guidance regularly. Any TFAMR guidance may be outdated quickly.</p>
<p>90. The numerator or Data collection should cover antimicrobial quantities represents representing the amount of antimicrobial agents sold or used and in some cases may be based on estimates. The numerator is per year, normally expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year ingredient. The numerator may also take into consideration the daily dose Multiple units of the antimicrobial administrated (i.e. Defined Daily Dose). Numerators measurement for reporting of sales and/or use data may vary be appropriate, depending on the objectives of national situation and the monitoring and surveillance program(s) objectives. To provide context for reporting and analyzing the data and to calculate the denominator, further information on the total number of food-producing animals by species, type of production and source animal weight in kilograms for food production per year (as relevant to the country of data production) or quantities (kg) of harvested crops or area (hectares) of land used for crop production is important and may be collected, whenever possible.</p>	<p>Brazil</p>
<p>90. The numerator or antimicrobial quantities represents the amount of antimicrobial agents sold or used and in some cases may be based on estimates. The numerator is normally may be expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year. The numerator may also take into consideration the daily dose of the antimicrobial administrated (i.e. Defined Daily Dose). Numerators for sales and/or use data may vary depending on the objectives of the monitoring and surveillance program(s) and the type and source of data.</p>	<p>European Union</p> <p>EUMS: Whereas we can agree with some of the rephrasing, the text in the first two sentences should be further improved for clarity and to allow flexibility and not to encourage using estimates in establishing the numerator. It should therefore read as follows: ‘The numerator represents the amount of antimicrobial agents sold or used. The numerator may be expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year.’</p>
<p>90. The numerator or antimicrobial quantities represents the amount of antimicrobial agents sold or used and in some cases may be based on estimates. The numerator is normally expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year. The numerator may also take into consideration the daily dose of the antimicrobial administrated (i.e. Defined Daily Dose). Numerators for sales and/or use data may vary depending on the objectives of the monitoring and surveillance program(s) and the type and source of data.</p>	<p>Japan</p>
<p>90. El numerador o la cantidad de antimicrobianos representa la cantidad de agentes antimicrobianos vendida o utilizada y, en algunos casos, estimada. Normalmente, el numerador se expresa por peso en kilogramos del principio activo de los antimicrobianos vendidos o utilizados por año. El numerador también puede tomar en cuenta la dosis diaria de antimicrobiano administrada (es decir, la Dosis Diaria Definida). Los numeradores para datos de ventas y/o uso pueden variar de acuerdo con los objetivos de los programas de seguimiento y vigilancia, y el tipo y la fuente de los datos.</p>	<p>Uruguay</p>

Section/paragraph	Member/Observer/ rationale
<p>90. The numerator or antimicrobial quantities represents the amount of antimicrobial agents sold or used and in some cases may be based on estimates. The numerator is normally expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year. The numerator may also take into consideration the daily dose of the antimicrobial administrated (i.e. Defined Daily Dose). Numerators for sales and/or use data may vary depending on the objectives of the monitoring and surveillance program(s) and the type and source of data.</p>	<p>USA</p>
<p>91. To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit. The sales data can be converted to kilograms of active substance.</p>	<p>Brazil</p>
<p>91. To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit. The sales data can be converted to kilograms of active substance.</p>	<p>European Union EUMS: As the focus in the text is on sales data, the text needs some more clarification. It should read as follows: ‘To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold, the pack size and the strength per unit.’</p>
<p>91. To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit. The sales data can be converted to kilograms of active substance.</p>	<p>Japan</p>
<p>91. Para calcular las cantidades de antimicrobianos vendidos, los datos deben incluir la identificación del producto antimicrobiano, la cantidad de paquetes vendidos o utilizados, el tamaño del paquete y la concentración por unidad. Los datos de ventas pueden convertirse a kilogramos de principio activo.</p>	<p>Uruguay</p>
<p>91. To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit. The sales data can be converted to kilograms of active substance.</p>	<p>USA</p>
<p>92. To calculate the quantities of antimicrobials used, the data should include characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial (e.g. area, species, type, number, body weight, age).</p>	<p>Brazil</p>
<p>92. To calculate the quantities of antimicrobials used, the data should include characteristics of the population of food producing animals or plants/crops treated <u>administered</u> with the relevant antimicrobial (e.g. area, species, type, number, body weight, age).</p>	<p>European Union EUMS: As not all reasons for administering antimicrobials to animals would be understood as “treatment”, the term “treated” should be replaced with “administered”.</p>
<p>92. To calculate the quantities of antimicrobials used, the data should include characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial (e.g. area, species, type, number, body weight, age).</p>	<p>Japan</p>
<p>92. Para calcular las cantidades de antimicrobianos utilizadas, los datos deben incluir las características de la población de animales destinados a la producción de alimentos o de las plantas/cultivos tratados con el antimicrobiano en cuestión (por ejemplo, área, especie, tipo, número, peso corporal, edad).</p>	<p>Uruguay</p>

Section/paragraph	Member/Observer/ rationale
92. To calculate the quantities of antimicrobials used, the data should include characteristics of the population of food-producing animals or plants/crops treated with the relevant antimicrobial (e.g. area, species, type, number, body weight, age).	USA
93. Information about the coverage of the data collected (e.g., percentage of farms included in the monitoring and surveillance program(s)) is also important to further interpret these data.	Brazil
93. Information about the coverage of the data collected (e.g., percentage of farms included in the monitoring and surveillance program(s)) is also important to further interpret these data.	Japan
93. Asimismo importante para una interpretación más detallada de los datos es la información acerca de la cobertura de los datos obtenidos (por ejemplo, el porcentaje de los establecimientos agropecuarios incluidos en los programas de seguimiento y vigilancia).	Uruguay
93. Information about the coverage of the data collected (e.g., percentage of farms included in the monitoring and surveillance program(s)) is also important to further interpret these data.	USA
9.4 Data collection: Animal population / plant/crop production (denominator)	
Data collection: Animal population / plant/crop production (denominator)	Brazil
Data collection: Animal population / plant/crop production (denominator)	Japan
Obtención de datos: población animal / producción de plantas/cultivos (denominator)	Uruguay
Data collection: Animal population / plant/crop production (denominator)	USA
94. The denominator provides context for reporting and analyzing the sales and/or use data. The denominator represents 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.	Brazil
94. The denominator provides context for reporting and analyzing the sales and/or use data. The denominator represents 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.	Japan
94. El denominador brinda el contexto para informar y analizar los datos de ventas y/o uso. Representa la población total de animales destinados a la producción de alimentos, el área de plantas/cultivos o la cantidad recolectada que puede estar expuesta a los antimicrobianos informados durante el período de seguimiento y vigilancia.	Uruguay
94. The denominator provides context for reporting and analyzing the sales and/or use data. The denominator represents 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.	USA
95. Information collected may include the number of animals, animal species, animal production type, estimated animal weights, plant species, plant/crop production and plant/crop area.	Brazil
95. Information collected may include the number of animals, animal species, animal production type, estimated animal weights, plant species, plant/crop production and plant/crop area.	Japan

Section/paragraph	Member/Observer/ rationale
95. La información reunida puede incluir el número de animales, la especie, el tipo de producción animal, el peso estimado del animal, la especie vegetal, la producción de plantas/cultivos y el área de plantas/cultivos.	Uruguay
95. Information collected may include the number of animals, animal species, animal production type, estimated animal weights, plant species, plant/crop production and plant/crop area.	USA
96. The denominator for reporting of antimicrobial sales or use may be determined in parallel to setting up collection of sales or use data. Elements for calculation the denominator may include:	Brazil
96. The denominator for reporting of antimicrobial sales or use may be determined in parallel to setting up collection of sales or use data. Elements for calculation the denominator may include:	Japan
96. El denominador para informar las ventas o el uso de antimicrobianos puede determinarse al mismo tiempo que se configura la recopilación de datos de ventas o uso. Los elementos para calcular el denominador pueden ser los siguientes:	Uruguay
96. The denominator for reporting of antimicrobial sales or use may be determined in parallel to setting up collection of sales or use data. Elements for calculation the denominator may include:	USA
A. For animals	Brazil
A. For animals	Japan
A. Para animales	Uruguay
A. For animals	USA
<ul style="list-style-type: none"> • Sales denominator: animal populations and weights (i.e. biomass) and the monitoring and/or surveillance period. 	Brazil
<ul style="list-style-type: none"> • Sales denominator: animal populations and weights (i.e. biomass) and the monitoring and/or surveillance period. 	Japan
<ul style="list-style-type: none"> • Denominador de ventas: poblaciones animales y peso (es decir, biomasa) y período de seguimiento y/o vigilancia. 	Uruguay
<ul style="list-style-type: none"> • Sales denominator: animal populations and weights (i.e. biomass) and the monitoring and/or surveillance period. 	USA
<ul style="list-style-type: none"> • Use denominator: the number of animals, the average body weight or age at treatment and/or the total weight of slaughtered or marketed animals and the time they are under monitoring and/or surveillance. 	Brazil
<ul style="list-style-type: none"> • Use denominator: the number of animals, the average body weight or age at <u>treatment administration</u> and/or the total weight of slaughtered or marketed animals and the time they are under monitoring and/or surveillance. 	European Union EUMS: The term “treatment” in bullet point 2 should be replaced with “administration” (see our comment on para 92).
<ul style="list-style-type: none"> • Use denominator: the number of animals, the average body weight or age at treatment and/or the total weight of slaughtered or marketed animals and the time they are under monitoring and/or surveillance. 	Japan

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> Denominador de uso: número de animales, edad o peso corporal promedio en el momento del tratamiento y/o peso total de los animales sacrificados o comercializados y tiempo durante el cual tuvieron seguimiento y/o vigilancia. 	Uruguay
<ul style="list-style-type: none"> Use denominator: the number of animals, the average body weight or age at treatment and/or the total weight of slaughtered or marketed animals and the time they are under monitoring and/or surveillance. 	USA
B. For plants/crops	Brazil
B. For plants/crops	Japan
B. For plants/crops	Thailand We propose the deletion of section B and all bullets as the reason stated in our general comments.
B. Para plantas/cultivos	Uruguay
B. For plants/crops	USA
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents. 	Brazil
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents. 	Japan
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents. 	Republic of Korea Korea removes the 'of' in the last sentence.
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested erops plants/crops or area (hectares) of land used for erop-plant/crop crop production that may be at risk of being exposed to the of antimicrobial agents. 	Republic of Korea Korea would like to replace crops or crop with "plants/crops" or "plant/crop" respectively for the consistency.
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents. 	Thailand We propose the deletion of section B and all bullets as the reason stated in our general comments.
<ul style="list-style-type: none"> En caso de no tener o no haber disponibles normas internacionales vigentes, se pueden establecer los denominadores de plantas/cultivos de acuerdo con la situación nacional, y considerar las cantidades (Kg) de cultivos recolectados o áreas (hectáreas) de tierra utilizadas para la producción de cultivos que corren el riesgo de quedar expuestas a los agentes antimicrobianos. 	Uruguay

Section/paragraph	Member/Observer/ rationale
<ul style="list-style-type: none"> If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents. 	USA
9.5 Units of measurement (numerator/denominator)	
Units of measurement (numerator/denominator)	Brazil
Units of measurement (numerator/denominator)	Japan
Unidades de medida (numerador/denominador)	Uruguay
Units of measurement (numerator/denominator)	USA
97. 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.	Brazil
97. 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.	Japan
97. En función de la situación nacional y los objetivos de seguimiento y vigilancia pueden utilizarse múltiples unidades de medida para informar sobre ventas y/o uso.	Uruguay
97. 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.	USA
98. Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass.	Brazil
98. Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass <u>or number of Used Daily Doses/1000 animals at risk.</u>	<p>European Union</p> <p>EUMS: Whereas we can agree with most of the rephrased text, we still think that it is important to also introduce the concept of animal days under risk as currently only the biomass concept is exemplified.</p> <p>The para should read as follows: 'Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass or number of Used Daily Doses/1000 animals at risk.'</p>
98. Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass.	Japan
98. Constituyen ejemplos de unidades de medida para ventas y/o uso en animales, entre otras, las siguientes: mg de principio activo vendido o utilizado/kg de biomasa animal o la cantidad de Dosis Diarias Definidas para animales (DDDvet)/kg de biomasa animal.	Uruguay

Section/paragraph	Member/Observer/ rationale
98. Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass.	USA
99. Units of measurement described in international guidelines to collect antimicrobial sales and use data should be used where possible for international reporting.	Brazil
99. Units of measurement described in international guidelines to collect antimicrobial sales and use data should be used where possible for international reporting.	Japan
99. Toda vez que sea posible, para la presentación de informes internacionales deben utilizarse las unidades de medida descritas en las directrices internacionales para la obtención de datos sobre la venta y el uso de antimicrobianos.	Uruguay
99. Units of measurement described in international guidelines to collect antimicrobial sales and use data should be used where possible for international reporting.	USA
10. Integrated analysis and reporting of results	
10.1 Management of data	
100. To facilitate the management of data, database(s) should be structured to allow the appropriate and easy extraction of data (e.g. centralized location) when required and accommodate for expansion as the integrated monitoring and surveillance program(s) improves.	Brazil Brazil suggests deleting the example to avoid confusion or misinterpretation.
102. To facilitate the management of data, ongoing (or regular) validation of the data should be performed.	Brazil Brazil asks for clarification.
103. A description of sampling designs, stratification and randomization procedures per animal populations and plant/crop, food production environment or food categories should be recorded for linking the data within and across surveillance and/or monitoring <u>and surveillance</u> components.	Canada
10.2 Analysis of results	
104. The data from the integrated monitoring and surveillance program(s) may be analyzed as described in CXG 77/2011 for risk assessment and to inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials and to address foodborne AMR.	Canada
104. The data from the integrated monitoring and surveillance program(s) may be analyzed as described in CXG 77/2011-77-2011 for risk assessment and to inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials and to address foodborne AMR.	USA
105. Analysis of data from the integrated monitoring and surveillance of AMR may include the comparison of AMR and AMU within or between sectors across the One Health spectrum, to evaluate trends over time, between regions or across host species, across bacterial species or antimicrobial classes.	Canada

Section/paragraph	Member/Observer/ rationale
<p>105. Analysis of data from integrated monitoring and surveillance of AMR may include the comparison evaluation of AMR-AMR, AMU, epidemiologic data, and AMU-other contextual data, within or between sectors across the One Health spectrum, to evaluate trends over time, between regions or across host species, across bacterial species or antimicrobial classes.</p>	<p>USA <u>Rationale:</u> “Comparison” should be replaced with “evaluation” or “assessment” because data across sectors, methodologies, and contexts need to be evaluated before a determination can be made regarding comparability. Further, AMU is not the only consideration for understanding AMR so the text is modified to reflect that.</p>
<p>106. 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>Thailand For clarity and consistency with the definition of the COP, we propose to replace the term “animals” with “food-producing animals”.</p>
<p>107. 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 the relationship between AMU and AMR within or across the food-producing animal, plant/crop-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, investigation of relationships between AMR and AMU.</p>	<p>Thailand For clarity and consistency with the definition of the COP, we propose to replace the term “animals” with “food-producing animals”.</p>
<p>107. 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 the drivers of foodborne AMR including any relationship between AMU and AMR within or across the animal, plant/crop 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, investigation of relationships between AMR and its drivers, but not limited to AMU.</p>	<p>USA <u>Rationale:</u> As written, it sounds as though the relationships between AMU and AMR is the only one of concern. A lot of what we see is clonal spread of resistant bacteria regardless of AMU, so the statement is limited in its considerations and will miss important drivers for AMR.</p>
<p>108. Relevant human isolates to consider for inclusion should be based on data from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.</p>	<p>Australia Australia recommends deletion of this para to streamline the document as it is duplicative of Section 8.4.</p>
<p>108. Relevant human isolates to consider for inclusion should be based on data from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.</p>	<p>USA Paragraph 108 should be deleted. <u>Rationale:</u> This sentence is very unclear. “Isolates to consider for inclusion” for what? Section 8.4 includes the target microorganisms for surveillance based on human health concerns. This sentence appears duplicative of Section 8.4. What is its purpose here?</p>
<p>109. Integration of data from surveillance of human clinical isolates should facilitate identifying trends in AMR-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>USA <u>Rationale:</u> Grammatical/clarity</p>

Section/paragraph	Member/Observer/ rationale
10.3 Reporting of results	
111. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders <u>under 'One Health approach'</u> should be encouraged.	<p>European Union</p> <p>EUMS: It would be useful to refer to the One Health approach in reporting of the results. To this end, the paragraph could read: 'Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders under 'One Health approach' should be encouraged.</p>
112. Results of foodborne AMR and AMU <u>and/or sales</u> monitoring and surveillance should be reported regularly, where resources allow.	<p>USA</p> <p><u>Rationale:</u> Consistency of reference to AMU and/or sales throughout the text.</p>
113. When available, summary reports on the integrated monitoring and surveillance program(s) of <u>AMR and AMR including</u> AMU <u>data</u> , across humans, animals, plants/crops, food and the food production environment may be made publically available.	<p>Brazil</p> <p>Brazil suggest rewording this sentence, to make an adequate reference to AMU data, and to be consistent to our previous comments, once AMU is a component of the AMR programs.</p>
113. When available, summary reports on the integrated monitoring and surveillance program(s) of AMR and AMU across humans, animals, plants/crops, food and the food production environment may be made publically available. <u>11. Data generated from national monitoring and surveillance program(s) on AMR in [imported] food should not be used to generate unjustified barriers to trade.</u>	<p>Thailand</p> <p>Thailand strongly supports to keep this paragraph in the document since it will encourage the implementation of the GLIS.</p> <p>In addition, we propose moving this paragraph to place it after paragraph 113 as the content of this paragraph is more relevant to Section 10.3. "Reporting of results".</p>
113. When available, summary reports on the integrated monitoring and surveillance program(s) of AMR and AMU <u>and/or sales</u> across humans, animals, plants/crops, food and the food production environment may be made <u>publically-publicly</u> available.	<p>USA</p> <p><u>Rationale:</u> Consistency of reference to AMU and/or sales throughout the text.</p>
11. Evaluation of the integrated monitoring and surveillance program(s)	
114. Evaluation of the integrated monitoring and surveillance program(s) provides assurance that the data and information reported are robust and the <u>program</u> objectives are being met. The evaluation will also provide the best use of data collection resources.	<p>Canada</p>
116. • Identification of relevant monitoring and surveillance program adjustments.	<p>USA</p> <p>"Identify" or "provide for identification"? for parallel construction of bullets</p>
117. 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, <u>that</u> historical data are maintained and <u>continue that the program continues</u> to meet the objectives.	<p>USA</p> <p><u>Rationale:</u> Edited for grammar/clarity</p>