



Agenda Item 6

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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

Prepared by the Chair and co-chairs of the EWG (the Netherlands, Canada, Chile, China and New Zealand) based on the comments in reply to CL 2021/59-AMR

The chair and co-chairs have proposed revised text in some paragraphs based on the comments received with the aim of facilitating the discussions at TFAMR8 and finding a consensus. While TFAMR8 will consider all sections of the GLIS, this document focuses only on sections 1 to 7, as there was no time to discuss these during the virtual meeting of the working group convened in June 2021, and agreements on these sections are considered key to finding consensus on the remaining sections.

1. Introduction and purpose

~~1. World-wide recognition of the importance of antimicrobial resistance (AMR) as-is a global public health threat at the human, animal and environmental interface which necessitates has led to strong international calls for all countries to develop and implement national strategies and action plans within the framework of a “One Health”-Approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR contributes to the food safety component of such an approach. and antimicrobial use (AMU). Antimicrobial resistance (AMR) is a global public health threat.~~

Co-chair proposal:

New sentence.

Rationale: The main point of this paragraph is to situate AMR within the document and how monitoring and surveillance fits into a One Health approach. As a compromise, we have removed AMU, as it is later introduced in the introduction and scope to achieve consensus. The new sentence also make the document more timeless and clearer.

~~2. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.~~

Co-chair proposal:

Move to Section 9 (para 81bis or 82, between 9 and 9.1) and add a footnote on paragraph 3 to direct the readers of the Guidelines to the description of AMU in section 9).

Rationale: Compromise to focus introduction on AMR, with a footnote on AMU in paragraph 3 to achieve consensus

3. For the purpose of these Guidelines, monitoring refers to the collection and analysis of foodborne AMR₁ and antimicrobial use (AMU¹) and 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 risk analysis actions that can be taken. These data may and to enable the measurement of the ~~if~~ impact of risk management measures.

Co-chair proposal:

¹ See description of AMU in paragraph 81bis in Section 9

Rationale: "Foodborne" was added before AMR to be consistent throughout the document. To improve the technical accuracy of the paragraph with respect to risk analysis. Risk analysis encompasses all of risk assessment, risk management and risk communication. Footnote added to AMU, linking to the description in Section 9. The "AMR and AMU related" was deleted for simplicity.

4. The integrated monitoring and surveillance program(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and within the food production environment and the testing, analysis and reporting of ~~AMR and AMU data~~. The integrated program(s) includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices, as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, plants/crops and the food production environment.

Co-chairs proposal:

Rationale: Definition of food chain does not encompass food production environment. Deletion of AMR and AMU for simplicity in the document for compromise.

5. National priorities, AMR food safety issues and scientific evidence, capabilities and available resources should guide the development of integrated monitoring and surveillance program(s) which 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).

6. The data generated by integrated monitoring and surveillance program(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for trend analysis, epidemiological studies, food source attribution studies and research. ~~Additionally, these data provide information to risk managers about trends and may serve as inputs for the risk analysis processes including implementation and evaluation of risk mitigation measures to minimize the foodborne public health risk due to resistant microorganisms and resistance determinants.~~

Co-chairs proposal:

Rationale: Deletion of third sentence as it is duplicative of the brackets in the first sentence with the exception of trend analysis, which was added to the second sentence.

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.

8. These Guidelines are intended to assist governments in the design and implementation of integrated monitoring and surveillance program(s). They provide flexible options for implementation and expansion, considering resources, infrastructures, 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.

9. The design and implementation of monitoring and surveillance program(s) should be assessed or re-assessed based on their relevance to foodborne AMR priorities at the national and [when appropriate,] at the international level.

Co-chairs proposal:

Rationale: Added assessed or re-assessed, as you have to assess design and implementation the first time, and then re-assess monitoring and surveillance overtime.

"When appropriate" has been introduced here due to the mention of "international level", for compromise.

10. Continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement may includes: availability of collecting more information or having new sources of data on AMU and AMR in humans, animals and, plants/crops, availability of food consumption ~~data~~, agriculture and aquaculture production data, and improvement in cross-sector laboratory proficiency and quality assurance and reporting.

Co-chairs proposal:

Rationale: Revisions were for improved clarity of language and technical accuracy, keeping flexibility and in line with continuous improvement.

11. Data generated from national monitoring and surveillance program(s) on AMR in food should not be used to generate unjustified barriers to trade.

12. These Guidelines should be applied in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005) and the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011). Design and implementation aspects of these Guidelines should **specifically also** take into account **the** other relevant Codex texts including the *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) **and** the *General Guidelines on Sampling* (CXG 50-2004).

13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines **should may** also be used taking into consideration **guidance these** 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.

Co-chairs proposal:

Rationale: The first proposal is to add flexibility for the use of WHO-AGISAR, given repetitive comments from countries that it is not a standard setting body. The second edit in that sentence is editorial.

2. Scope

14. These Guidelines cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain and the food production environment.

Co-chairs proposal:

Retain original.

Rationale: The footnote explains that AMU includes antimicrobial sales in section 9 (footnote in the introduction). In an effort to find compromise, AMU has been deleted in places where it was detracting from the main objective of the paragraph, but maintained in the scope of the document.

15. Although these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated program within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans.

Co-chairs proposal:

Retain original.

Rationale: Member has suggested when available/when possible, change was not incorporated, as the language "informed by" is soft and flexible.

16. The microorganisms covered by these Guidelines are foodborne pathogens of public health relevance and indicator bacteria.

17. **Antimicrobials used as biocides**, including disinfectants, are excluded from the scope of these Guidelines.

3. Definitions

Rationale: Overall, for the definitions section, the approach was to avoid making changes to agreed-upon definitions, unless needed or to align definitions across the three Codex documents. Only the definition One Health approach has been aligned with the definition at CoP as agreed by TFAMR7.

18. The definitions presented in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011) and *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005) are applicable to these Guidelines.

19. The following definitions are included to establish a common understanding of the terms used in these Guidelines.

Antimicrobial agent

Any substance of natural, semi-synthetic or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganisms by interacting with a specific target².

Antimicrobial resistance (AMR)

The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent

² *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*

relative to the susceptible counterpart of the same species¹.

Food chain

Production to consumption continuum including, primary production (food producing animals, plants/crops, feed), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.

Foodborne pathogen

A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and/or the biological products produced by the pathogen¹.

Food production environment

The immediate vicinity of the food chain where there is relevant evidence that it could contribute to foodborne AMR.

Hazard

For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and/or resistance determinant(s)¹.

One Health approach

A collaborative, multisectoral and trans-disciplinary approach working **at the local, regional, national and global levels** with the goal of achieving optimal health outcomes, recognizing the interconnection between humans, animals, plants and their shared environment.

Co-chairs proposal:

Aligned with CoP as agreed at TFAMR7.

Plants/Crops

A plant or crop that is cultivated or harvested as food or feed.

4. Principles

20.

- **Principle 1:** Monitoring and surveillance program(s) should **be based on follow** a “One Health” **A**approach.

Co-chair proposal:

Rationale: “Should be based” is softer language than “follow” and may facilitate finding consensus.

- **Principle 2:** Monitoring and surveillance program(s) are an important part of national strategy(ies) to minimize and contain the risk of foodborne AMR.

Co-chair proposal:

Rationale: Language changed for technical accuracy and editorial improvement.

- **Principle 3:** Risk analysis should guide the design, implementation and evaluation of monitoring and surveillance program(s).

Co-chair proposal:

retain original text

Rationale: Risk management is already included in risk analysis, hence it is redundant to add “and risk management actions”. The language “should” was maintained as the language “guide” is soft and information from risk analysis is useful to inform surveillance program(s). The intent of this principle is to link the Codex Surveillance guidelines with CXG-77-2011.

- **Principle 4:** Monitoring and surveillance program(s) should **include-be designed to generate** data on AMR and AMU, in relevant sectors **as inputs into-to inform** risk analysis.

Co-chair proposal:

Rationale: The first proposed change in this principle is editorial, the second edit removes “AMU and AMR” as this is covered by the scope. The last proposal is editorial.

- **Principle 5:** Monitoring and surveillance program(s) should be tailored to national priorities and ~~may-should~~ be designed and implemented ~~to allow with the objective of~~ continuous improvement as resources permit.

Co-chair proposal:

Rationale: “Should” was retained because of the language “as resources permit” at the end of the sentence which allows flexibility. The second proposal “to allow” is editorial.

- **Principle 6:** Priority for implementation ~~of monitoring and surveillance program(s)~~ should be given to the most relevant foodborne AMR issues ~~(combinations of the food commodities, the microorganisms and resistance determinants and the antimicrobial agent(s))~~ ~~to be analyzed~~ from a public health perspective.

Co-chair proposal:

Rationale: The addition of monitoring and surveillance program(s) was added for clarity.

The phrase “to which resistance is expressed” (as proposed by a member country) was not included because in some cases antimicrobial resistance may not yet be detected. However, early detection is desired and it is important to include it in surveillance (for example, many countries currently include surveillance of carbapenem resistance). Third proposal deletion of “to be analysed” is editorial to improve readability of the sentence. Finally, a proposal by a member country to add “national” was not incorporated, to retain flexibility, as it could be local, regional, national or international.

- **Principle 7:** Monitoring and surveillance program(s) should incorporate, to the extent practicable, the identification of new and emerging foodborne AMR or trends and ~~should be designed to~~ ~~inform~~ ~~facilitate~~ epidemiological investigation.

Co-chair proposal:

Rationale: Proposed changes were editorial, to improve accuracy of text. Additionally, “inform” provides more flexibility.

- **Principle 8:** Laboratories involved in monitoring and surveillance should have effective quality assurance/~~management~~ systems in place.

Co-chair proposal:

Rationale: Principle was retained as it is important to highlight that laboratories have system in place to ensure robust and valid results. Editorial change was made to align language also used in Section 8.5, paragraph 60, to include “assurance/management” depending on the language used (the choice of this language may vary between countries)

- **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~~ ensures that data are comparable, ~~to~~ facilitates sharing of data and ~~to~~ enhance an integrated approach to data management ~~and analysis~~.

Co-chair proposal:

Rationale: Focus of the principle is on methodology, the “priorities” was deleted as it detracted from the main point of this principle and is covered elsewhere in these guidelines. “Analysis” was added for technical accuracy (as not just data management, but also integrated analysis depends on harmonized methods), and remaining editorial changes provide softer language. Other editorial changes to improve clarity.

5. Risk-based approach

21. For the purpose of these Guidelines, a risk ~~analysis-based~~ approach as described in the framework for Foodborne AMR risk analysis (CXG 77-2011), may inform ~~is~~ the development, ~~and~~ implementation and evaluation of monitoring and surveillance program(s) informed by ~~with~~ data and scientific knowledge ~~on~~ regarding the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health.

Co-Chair Proposal:

Rationale: Changes made to align language with CXG 77-2011. Other changes are editorial.

22. Information from monitoring and surveillance program(s) and available including data from other sources ~~when available~~, are important for risk assessment and ~~risk management decision-making may inform decisions~~ on the appropriateness of ~~the~~ control measures to minimize and contain foodborne AMR.

Co-Chair Proposal:

Rationale: Changes added to the text for flexibility and facilitate consensus.

23. When ~~information or data knowledge~~ of foodborne AMR within a country is limited, monitoring and surveillance program(s) may initially be designed according to the relevant data and/or scientific knowledge ~~evidence~~ that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*.

Co-Chair Proposal:

Rationale: "Data and/or scientific knowledge" was proposed to add all possible sources of data that are not collected through research, as proposed by one member. "AMR food safety issue" is language in CXG-77-2011.

24. ~~The implementation and continuous improvement of an integrated monitoring and surveillance program(s) should improve the quality of data generated for risk analysis.~~

Co-Chair Proposal:

Rationale: Paragraph reads more like a principle or a statement of fact, rather than guidance. This concept is reflected in other paragraphs in the Guidelines.

6. Regulatory framework, policy and roles

25. Integrated monitoring and surveillance program(s) requires good governance by the competent authorities. As part of national action plans (NAPs) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain, including the food production environment, should ensure collaboration with human health, animal health, plant/crop health, ~~the~~ environment and other relevant authorities.

Co-Chair Proposal:

Rationale: In the first sentence Competent authority has been kept in the text, as is in line with other codex documents and is appropriate Codex language. The addition of ' food production environment' was included to be consistent with the scope of the document, as the definition of food chain does not include "food production environment". Other editorial amendments.

26. Activities related to monitoring and surveillance of ~~foodborne AMR and AMU~~ program(s) should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance ~~program(s)~~.

Co-Chair Proposal:

Rationale: AMU and AMR has been removed as this is covered by the scope and may facilitate consensus.

27. Sharing of knowledge and data internationally and with stakeholders should be encouraged since it may improve the global understanding of foodborne AMR and inform risk assessment, ~~and~~ as well as risk management decisions.

Co-Chair Proposal:

Rationale: internationally was kept as language "should be encouraged" provides enough flexibility. Language of "as well as" is an editorial change.

28. It is important for competent authorities to have access to all available sources ~~of AMU~~ relevant data in their country.

Co-Chair Proposal:

Rationale: consideration of type of data is in the in the scope of Section 8 and 9. Deleting AMU may facilitate consensus.

7. Preliminary activities ~~on~~ for the implementation of an integrated monitoring and surveillance program(s) for foodborne AMR

29. Preliminary activities for implementation, ~~initiating monitoring and surveillance activities, evaluation and review~~ are part of the framework for monitoring and surveillance program(s). ~~The concept of continuous improvement allows countries to carry out activities and make to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge.~~ Undertaking pilot studies and testing may provide valuable insights into the design of ~~for~~ monitoring and surveillance program(s).

29.bis The concept of Counties should strive for continuous improvement allows countries to carry out of monitoring and surveillance activities and to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge.

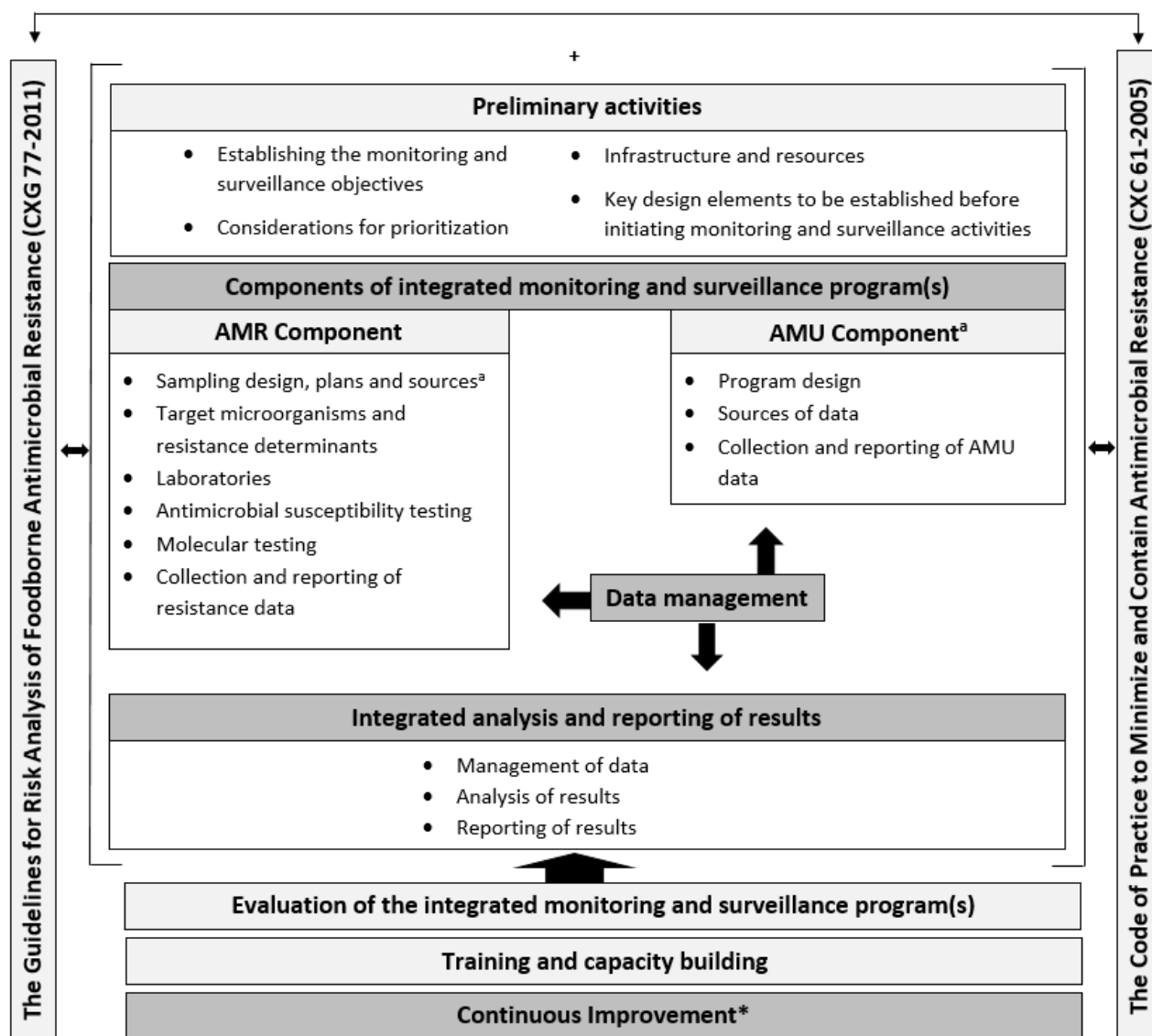
29ter. The framework for integrated monitoring and surveillance program(s) described in these Guidelines is shown in Figure 1, which is intended to provide input to and be informed by the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011) and Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005). Figure 1 is intended to show how these three documents are inter-related.

Co-Chair Proposal:

Rationale: For Paragraph 29, the first and third sentences were retained and simplified to introduce the purpose of the section.

The second sentence of the original paragraph was moved into Paragraph 29bis for added clarity on this as a separate point and to change the language from a statement to language that provides guidance for countries.

It is proposed to add Paragraph 29ter to include reference to Figure 1 in the text, as in the original document, Figure 1 was not cited in the text. This is consistent with other Codex documents with figures.



* *Guidelines on national food control systems (CXG 82-2013)*

+ The Codex Guidelines for Integrated Surveillance of Foodborne AMR are intended to provide input to and be informed by the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)* and the *Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005)*.

^aWhere appropriate, in the case of terrestrial and aquatic animals, the OIE standards may provide additional information

Figure 1. Framework for integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.

Co Chair proposal:

Retain the figure and amend as proposed.

Rationale:

The figure has added value as it shows the inter linkages between the three Codex texts and shows how the different aspects of integrated surveillance fit together. The size of the AMU component in the figure was reduced and details in the proposed bullets for AMU and AMR were simplified to align with the headings of these guidelines. The data management component was moved and an arrow was added to integrated analysis.

7.1. Establishing the monitoring and surveillance objectives

30. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programs, the AMR NAPs, relevant information on AMR and AMU in the country, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop, food and the environment). Competent authorities should identify the

challenges they currently face during the implementation of these activities.

Co-Chair Proposal:

Rationale: "Food" was added into Paragraph 30 as it was missing from this text. The proposal of replacing "should" by "can" was not included as establishing monitoring and surveillance objective(s) needs to involve consultation with relevant parties and needs to be in line with the NAPs.

31. The following aspects should be considered:

- 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).
- The representativeness of the data collection (e.g., randomized samples or systematic sampling).
- The setting of proposed timelines for sampling and reporting.
- A description of how ~~and to whom~~ the information will be reported and communicated (~~e.g., publication of report~~).

Co-Chair Proposal:

Rationale: An example was deleted to simplify the text, and editorial changes were made to improve clarity of the text. Risk management was deleted to not detract from the main intent of the bullet, which is that in establishing the monitoring and surveillance objectives, the primary reasons for the data collection need to be considered.

7.2. Considerations for prioritization

32. When establishing monitoring and surveillance priorities, ~~the~~ competent authorities should consider the epidemiology and public health implications of foodborne AMR, AMU patterns ~~and~~, available information on food production systems, food distribution, food consumption patterns and food exposure pathways.

Co-Chair Proposal:

Rationale: "Available" was added for flexibility to incorporate comments. The other change was editorial

33. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents and sample sources should be informed by national, regional and international public health data and ~~scientific~~ knowledge where it exists. Competent authorities should identify existing data sources and ~~data~~ gaps on ~~foodborne~~ AMR and AMU including data required for risk analysis or results of risk analysis.

Co-Chair Proposal:

Rationale: The word "scientific" was added to "knowledge", as "scientific knowledge" is used throughout the document for consistency. "Or results of risk analysis" was kept as from risk analysis will help prioritization of monitoring and surveillance activities.

7.3. Infrastructure and resources

34. Once ~~the~~ objectives and priorities have been established, ~~the~~ competent authorities should determine the infrastructure, capacity and resources required to meet the objectives.

35. ~~The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines. Implementation of AMR Antimicrobial use~~ monitoring and surveillance ~~can~~ may proceed at a different rate than ~~that of~~ AMRU monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis. ~~The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines.~~

Co-Chair Proposal:

Rationale: Changes to the text were editorial to improve flow of the sentence and to place greater emphasis on AMR monitoring and surveillance. The first sentence of paragraph 35 was moved to the end of paragraph 35 to improve flow

36. As part of initial planning, the competent authorities should also consider where harmonization and standardization

are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of integration ~~or expansion of the AMR or AMU~~ monitoring and surveillance activities with ~~in~~ other ongoing activities.

Co-Chair Proposal:

Rationale: "AMR and AMU" was deleted as it is covered under the scope for monitoring and surveillance, to be consistent throughout the document. "for expansion" was deleted as the focus of this paragraph is on integration and initial planning.

37. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing ~~and when feasible~~ reporting ~~and archiving~~ data. ~~in~~ ~~When possible,~~ a central repository ~~facilitates data management and can improve the efficiency of data analysis.~~

Co-Chair Proposal:

Rationale: The paragraph was modified for flexibility as not all countries have a central repository. The paragraph was divided to separate out the concept of the central repository, to add clarity.

7.4. Key design elements to be established before initiating the monitoring and surveillance activities

38. When designing the monitoring and surveillance program(s), the following elements should be considered:

Co-Chair Proposal:

keep original, suggested text stated is already covered and repetitive of final sentence Para 29

39. AMR:

- The highest priority microorganisms, panels of antimicrobials and sample sources to be targeted.
- Points in the food chain and frequency of sampling.
- Representative sampling methods, sampling plans, laboratory analysis and reporting protocols.
- Standardized and/or harmonized methodologies for sampling, ~~and~~ testing ~~and reporting~~.

Co-Chair Proposal:

Rationale: Addition for technical accuracy.

40. AMU:

- Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.
- Identification of the ~~appropriate points sectors where collection~~ of data ~~collection would be most relevant~~ and ~~the stakeholders that can provide the data efficient to meet monitoring and surveillance objectives.~~
- 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 ~~may be useful or to start.~~ ~~The~~ collection of AMU data ~~may be started~~ on a voluntary basis in agreement with stakeholders ~~that who have~~ ~~provide~~ these data ~~may be useful.~~

Co-Chair Proposal:

Rationale: Suggestion to delete these bullets was not incorporated. Retain bullets in this section, as these points are important preliminary activities for the design of the program. The second bullet point was taken from Paragraph 86 for accuracy and generality.

41. Consideration ~~may should~~ be given to additional information provided in the OIE Terrestrial Animal [Health Code](#) and Aquatic [Animal Health Codes](#).

Co-Chair Proposal:

Rationale: "May" was changed to "should" to provide clear guidance.