

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Eighth Session

Virtual

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GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

(AT STEP 4)

(Prepared by the by Working Group led by the Netherlands and
co-chaired by Canada, Chile, China and New Zealand)

Codex members and observers wishing to submit comments at Step 3 on this document
should do so as instructed in CL 2021/59 OCS-AMR¹.

SUMMARY

1. The Seventh Session of the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR07 (2019)) agreed to return the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance to Step 2/3 for re-drafting. In doing so, it agreed to establish an electronic working group (EWG), chaired by the Netherlands, and co-chaired by Canada, Chile, China and New Zealand, working in English only and open to all members and observers. The EWG was tasked to review and revise the Guidelines based on the text in CRD03, focusing on those areas that were not considered at the physical working group (PWG) that met prior to TFAMR07, and not reopening definitions already agreed in the *Code of practice to contain and minimize food antimicrobial resistance* (CXC 61-2005) (COP); and to prepare a revised version of the Guidelines for consideration by TFAMR08. Since then the EWG worked to further develop the guidelines and two webinars were convened in January 2021 to provide an overview of progress and seek further input from the members and observers. A revised version of the guidelines was circulated for comments in April 2021 and then discussed at a virtual meeting of the working group (WG) in June 2021. The Chair and co-Chairs of the WG subsequently prepared a revised version of the Guidelines which is attached as Appendix I. In submitting this revision, and based on all the input received during the two rounds of comment submissions in the EWG, the webinars in January 2021 and the WG and the analysis thereof, the chair and co-chairs of the WG recommend that TFAMR08:

- Not re-open the sections on Scope and Definitions, as these were previously agreed upon in TFAMR06.
- Ensure the guidelines are stand-alone and future-proofed.
- Review the guidelines in their entirety from start to finish, taking into consideration the conclusions made in this report, and keeping in mind the need for accuracy of language to provide useful guidance. In particular:
 - Review the excessive use of qualifiers (e.g. if available, where feasible, examples of options, etc.) throughout these Guidelines.
 - Review the use of “*may*” versus “*should*” throughout the text, as in some cases the use of “*should*” better reflects the content of the guidance and “*may*” could be confusing for practical implementation and technical accuracy.

¹ Codex circular letters are available on the Codex webpage/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

or on the dedicated TFAMR/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=TFAMR>

- ✓ For example in Section 8 where the sample is collected from (e.g., a chicken) *should* be documented for any analysis, *may* is not appropriate in this circumstance.
- ✓ As another example in Section 8, states “when possible, molecular testing may be used for the detection of resistance determinants...”. Molecular testing is needed for the detection of resistance determinants, hence *should* is more appropriate.
 - Review the use of the word “national”, as in some cases, “national” was added to reflect a national perspective/context and to add flexibility. However, national data may not exist and countries will need somewhere to go for a reference (e.g., see Paragraph 71). Sometimes adding “national” removes the flexibility from the document and can cause confusion.

In addition, for the reasons outlined in the report below, the Chair and co-Chairs of the WG propose that TFAMR08 consider retaining the following concepts, texts and figures in the Guidelines;

- Antimicrobial use within the Scope as it is in line with the Terms of Reference provided by CAC;
- Antimicrobial use within the introduction as it is essential and is used throughout the Guidelines. This is also in line with the approach used in the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011 where terms are described but formal definitions are not created);
- Paragraphs 3 and 4 as agreed by the TFAMR, as they define the concept of integrated monitoring and surveillance program(s). Integration may be appropriate within a sector or across AMU and AMR; integration should be applied to meet the monitoring and surveillance objectives;
- Figure 1 as it contains essential guidance for the practical implementation of the monitoring and surveillance program(s) and an overview of the interrelatedness of the relevant Codex texts and that TFAMR08 consider the revisions that have been made to Figure 1 in order to reflect the rest of the document and discussions to date;
- The refined Section 9 as it contains the minimum essential information to provide practical guidance; and
- Noting that monitoring and surveillance data are useful for many purposes, as outlined in CXG 77, which states “...input for risk profiling and risk assessment, to measure the effect of interventions and to identify trends.”, and, to ensure consistency the Chair and co-Chairs recommend that all these purposes of monitoring and surveillance are covered by the Guidelines. In addition, as per CXG 77 monitoring and surveillance data is one of several types of input into preliminary risk management activities (i.e., risk profiles), risk assessment, and risk management decision-making.

1. INTRODUCTION

1. TFAMR07 (2019) agreed to re-establish the EWG chaired by the Netherlands and co-chaired by Canada, Chile, China and New Zealand to prepare a revised version of the Guidelines for integrated monitoring and surveillance of foodborne antimicrobial resistance for consideration by TFAMR08. As the Guidelines were not discussed during the TFAMR07, the EWG was requested to review and revise the Guidelines based on the text in CRD03, focusing on those areas that were not considered at the PWG that was held on 8th December 2019 in Pyeongchang and not reopening definitions already agreed.
2. Codex members and observers were invited to register their experts on the Codex electronic platform. A total of 43 Codex members (42 Member States and 1 Member Organization) and 9 observers registered. The EWG organized two rounds of discussions to review the document and to address the specific requests from TFAMR07. The first round for comments was launched in March 2020 and the second round for comments in June 2020. Two webinars² were convened in January to provide an overview of progress and seek further input from the members and observers. The report of the EWG³ together with the revised Guidelines was circulated to all members and observers for comments through the Codex online Commenting System in April 2021 with a deadline of 21 May 2021. The collated comments⁴ were published on the Codex website in preparation for a virtual meeting of the physical working group.

² Webinar details and recordings are available on the TFAMR08 webpage <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=8>

³ Available at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2FCodex%2FCircular%252520Letters%252FCL%2525202021-33-OCS%252Fcl21_33e.pdf

⁴ Available at [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2FCodex%2FMeetings%2FCX-804-08%2FCOMMENTS%2520GL%2520\(CL%25202021-33-AMR\)%2FGLIS_CL2021-33-AMRx.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2FCodex%2FMeetings%2FCX-804-08%2FCOMMENTS%2520GL%2520(CL%25202021-33-AMR)%2FGLIS_CL2021-33-AMRx.pdf)

3. A working group (WG)⁵ was held virtually on June 10, 11, 15, 16 and 18 2021 to consider the proposed revisions of the draft Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance. The virtual meeting of the WG was chaired by the Netherlands assisted by the co-Chairs Canada and New Zealand and was open to all members and observers. Chile and China did not participate in the virtual meeting of the WG as co-Chairs but as member countries.
4. In preparation for the virtual meeting of the WG, and in light of the comments received from members and observers in response to CL 2021/33/OCS-AMR, the Chair and co-Chairs revised the Guidelines. The Chair and co-Chairs carefully considered all submitted comments and created proposed text for consideration by the virtual meeting of the WG. Editorial comments or suggestions were separated from more substantial comments or suggestions. The Chair and co-Chairs discussed the range of comments with the WG in June that were submitted by the members and observers. The Chair and co-Chairs also drafted and presented new text, including its rationale, which was intended to be a compromise of the comments received and balanced with the original intent of the paragraphs and the scope of the Guidelines.
5. The virtual meeting of the WG completed its review of Sections 8 to 12. The WG made several changes to the text in these sections, as summarised below and reflected in the revised version of the Guidelines attached as Appendix I. This revised version contains some additional editorial amendments made by the Chair and co-Chairs to ensure consistency of wording, to remove redundancies and to enhance flow of these Guidelines. Sections 1 to 7 could not be addressed during the virtual meeting of the WG due to time constraints. The revised text for Sections 1 to 7 in Appendix I reflects the proposals by the Chair and co-Chairs based on the comments received from members and observers in response to CL 2021/33/OCS-AMR, following a similar approach to that described above. To facilitate transparency a tracked changes version of Appendix 1 is available in English on the TFAMR08 webpage⁶.

2. REVISION OF SECTIONS 8-12: KEY DISCUSSIONS AND DECISIONS

2.1. SECTION 8: COMPONENTS OF AN INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR AMR⁷

General comments:

6. One of the challenges with Section 8 was finding the balance between having guidance that is “stand alone” and guidance which is not too prescriptive. Another challenge was ensuring the guidance was achievable by members, yet “future proofed” to acknowledge the rapid evolution in the foodborne AMR field. During the virtual meeting of the WG, the text of each paragraph was reviewed in detail and the use of examples was carefully discussed and considered by the WG. Throughout Section 8, any suggestions to add “foodborne” before “AMR” were accepted.

Introduction and Section 8.1 Sampling Design

7. All the editorial proposals were accepted by the virtual meeting of the WG hereafter called “WG”.

Section 8.2 Sampling Plans

8. Paragraphs 47-48: Some examples were deleted (e.g., “the size of the population to be monitored”). Other examples were either moved to a different part of the paragraph to improve clarity or into the main body of the text, as they reflected essential guidance. “Food production environment” was added to the bullet on “target animal or plant/crop species or food commodities”, as the food production environment was previously missing from the sampling plan.
9. Paragraphs 51 and 49: The WG agreed to new text proposed by members regarding where the sampling plans can be broadened. The WG agreed to a rearrangement of the paragraphs for better flow of the information; hence Paragraph 51 was moved from Section 8.3 to Section 8.2. Concepts in the original Paragraph 52 on “implementation advances according to priorities and resources” were incorporated into Paragraph 49 to remove redundancy in the text; resulting in the deletion of the original Paragraph 52.

⁵ The List of participants is available as Appendix II.

⁶ Available at: <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-08%252FLINKS%252FCX-AMR-185-Guidelines-TC-version-of-Appendix1.pdf>

⁷ Sections and paragraphs referred to the Guidelines as presented in CL 2021/33-AMR available at: <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=TFAMR> and in the tracked changes version available at: <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-08%252FLINKS%252FCX-AMR-185-Guidelines-TC-version-of-Appendix1.pdf>

Section 8.3 Sample sources

10. There was substantial discussion on the text needed to introduce the concepts of **Section 8.3**, regarding what initial implementation might include, what the selection of samples should reflect, and what should happen as the program(s) develop.
11. **Paragraph 50**: Text changes to replace “exposure” with “exposure pathways” were accepted by the WG.
12. One of the most debated paragraphs of the WG was **Paragraph 53**, as this paragraph provides the framework for the subsequent bullets under **Paragraph 54** regarding food producing animals, food, plants/crops, and the food production environment. One Member country proposed a different presentation of Paragraph 54, which was presented to the WG. This proposal involved moving the information out of sections into broader groupings based on what countries with national monitoring/surveillance systems for foodborne AMR collect and may find most relevant. The rationale for this proposal was that it may help to put the focus of the sampling section on food, removing sample types that are not directly associated with food, to avoid duplication with OIE, and acknowledge that some examples may be more appropriate for surveillance or research.
13. The WG agreed upon the following text for **Paragraph 53** “The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR”. The latter underlined text of this paragraph was a compromise, reflecting the types of information that might be available regarding where and what to sample in the food chain. The WG was reminded that all sample sources listed in this paragraph were “considerations” of “possible sample sources” which “may be collected”; language intentionally drafted to strike the balance of useful guidance, while not being overly prescriptive. The WG proposed to merge **Paragraphs 53** and **54** to ensure the considerations of sample sources were closely tied to the agreed upon text of **Paragraph 53**. The WG discussions included **priority setting** for countries for sample collection, as a list of sampling options may need further guidance on priority areas for implementation of monitoring and surveillance. Hence, new text was added to reflect priorities (i.e., “Collection of samples from animals not immediately entering the food chain may provide additional information on foodborne AMR at the population-level, but may be a lower priority than those animals directly entering the food supply”) and the subsections were reordered to reflect the emphasis on “food producing animals”, “food”, “plants/crops”, and the “food production environment”. The subsection of “farm input” was deleted, though the WG agreed that the concept of having farm input was considered important for retention and hence, this text was added to the bullet on sample options at the farm-level.
14. Throughout **Paragraph 54**, the sample options were carefully considered by the WG to ensure the text reflected the distinction between “where” sampling may occur (e.g., at process or packaging) versus “what” samples may be taken (e.g., carcass swabs or caecal contents).
 - For **food producing animals**, the WG had substantial discussion considering that for integration of information along the food chain, the samples should be taken from the same animal species along the food chain. The WG agreed to more flexible text indicating that samples “may” be collected from the same animal species at “different relevant points along the food chain”. However, upon reflection of the WG decision on this section, the co-Chairs suggest that this “may” needs to be “should”. The rationale is that if you do not sample from the same animal species along the food chain, then you cannot integrate. For example, if you sample from pigs on a farm, cattle at slaughter and chicken at retail, then there are no findings which can be integrated along the food chain. A reference to the OIE was added under “Food producing animals”. The sentence “for integration” was moved to the end of this subsection to improve the flow of information.
 - For **lairage**, the OIE confirmed that they have no guidance available for sample collection. The WG noted that “lairage” reflects “where” samples may be collected; text was added to reflect “what” samples may be collected at lairage (i.e., “rectal samples or faecal samples from the pen floors or crates”). The sample options of “trucks” was deleted and “dust” was moved to food production environment.
 - For sampling at **slaughter**, the WG discussed that some sample types (“what”) will reflect AMR of farm-origin (i.e., caecal samples), yet other sample types will reflect AMR contamination happening during lairage or at the slaughter plant (i.e., carcass swabs). Hence, the WG agreed to following text that reflects this; “may or may not provide an estimate of AMR arising at the farm-level”. Acknowledging that there are different interpretations of the data because of the types of samples collected is important guidance for members.
 - The WG agreed to the addition of “feed ingredients” and agreed that **where feed and feed ingredients** are sampled affects the interpretation of the findings. The WG decided to have text on “feed and feed ingredients” under the heading of “food producing animals”, with an associated footnote explaining that samples taken at different locations provide different types of information.

- “**Water**” was retained as a sample option for both the “food producing animals” (as animals consume water) and for the “food production environment” (as water sources could be sampled leaving the farm).
- For **plants/crops**, the IPPC provided an update on their activities. The IPPC currently has no guidance on how to collect samples for antimicrobial susceptibility testing for plants/crops. In light of this, for **Paragraph 54**, there was discussion on how to provide guidance for sampling plants/crops, and the WG concluded with “The selection of plants/crops should be risk-based and guided by the relevant international standard setting bodies”. The details on “what” samples may be collected were deleted and only the locations (i.e., “where” samples may be collected) were retained. Upon further reflection, the co-Chairs propose to change “and” to “and/or”, in the situation where there is no information available from international standard setting bodies. The co-Chairs additionally added “where available” to the end of the sentence to further account for the current lack of international standards. The new sentence is “The selection of plants/crops should be risk-based and/or guided by the relevant international standard setting bodies where available”.
- For the **food production environment**, the same type of introductory text as for plants/crops was added (i.e., “should be risk-based”). For clarity, some examples from **Paragraph 54** were moved to “food production environment” (e.g., “dust” was moved from food producing animals to food production environment). For **food production environment**, “where” the samples may be collected was retained in the bullet, but the sample types (i.e., “what”) were moved to a footnote. Moving sample types to a footnote was suggested by the WG to assist with priority setting. The examples of “fluff” and “sludge” were deleted. “**Organic fertilizers**” were added to this same footnote. One member raised the concept of “**integrated farming**”, wherein animal and plant/crops are raised together and whether the sample options, particularly under “food production environment”, were sufficient to capture the situation of integrated farming. This needs further reflection by the Task Force.

Section 8.4 Target Microorganisms and Resistance Determinants

15. **Paragraphs 55-61** were re-ordered to improve the flow of information (55-57-58-60-56-59). Several editorial revisions were agreed upon by the WG for this subsection. “Food safety” was added to the considerations for selection of targeted microorganisms and resistance determinants in **Paragraph 55**. For **Paragraph 58**, the WG agreed to add the word “scientific” in front of evidence.

Section 8.5 Laboratories

16. For **Paragraph 61** editorial suggestions were agreed upon and for some of the bullets, words were added to ensure flexibility according to the national situation. For **Bullet b**, regarding accreditation of laboratories, “validated Standard Operating Procedure” was replaced with “a quality management system”. For **Bullet d**, after noting that the bracketed text did not reflect examples, but rather good laboratory practices, the text was moved out of the brackets and into the main body of the bullet. An additional change for clarity was added to have “appropriate” before “storage temperature”. For **Bullet f**, the WG agreed to add “and carry out molecular characterization where feasible”.

Section 8.6 Antimicrobial Susceptibility Testing

17. A new **Paragraph 62 bis** was proposed for inclusion regarding phenotypic or genotypic methodology. The WG agreed to the inclusion of a slightly modified version of this new text. Upon further reflection of the agreed upon text for Paragraph 62bis, the co-Chairs noted more clarity was needed. New text was proposed by the co-Chairs which reads “Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations”.
18. For **Paragraph 64**, additional text was added to emphasize that susceptibility testing should be “consistently” undertaken according to standards and that the quantitative results should also include documentation of the disc content of the antimicrobials.
19. Text changes were made to **Paragraph 65**, which were agreed to by the WG to enhance the understanding of the technical content of the paragraph. Editorial suggestions for **Paragraphs 68** and **70** were agreed to by the WG.
20. The WG discussed how antimicrobials to be tested may be prioritized and agreed to the addition of “national contexts” to **Paragraph 71**. Upon reflection of the new text for **Paragraph 71**, the co-Chairs noted that the two sentences were highly duplicative and proposed to delete the second sentence.

Section 8.6.3 Concentration Ranges of Antimicrobials.

21. There were only editorial suggestions for this section which were appropriately addressed.

Section 8.6.4 Molecular Testing

22. For **Paragraph 73**, the WG discussed the factual statements made within the paragraph and balanced that with the need to provide guidance. The language of the paragraph was softened by adding “When possible” to the beginning of the paragraph. “Identification” was added to the sentence to improve the technical accuracy of the paragraph. For technical accuracy, the Chair and co-Chairs changed “may” to “should”, as molecular testing is needed for identification and detection of resistance determinant and because flexibility is already provided by the adding “When possible”.
23. Similar discussions arose for **Paragraph 74**, regarding the balance of statements of factual accuracy in light of the need to provide guidance to users of the document. The WG agreed to compromise language stating that “Molecular characterization is a useful tool which may be used for the rapid identification of resistance clusters...”. There was agreement by the WG to include language that reflected that molecular characterization used in conjunction with epidemiological information may be of value for certain types of analyses. The latter part of the paragraph was shortened for simplicity as a compromise to what might or might not be included in a detailed listing of the sectors.
24. Proposed editorial suggestions for **Paragraph 75** were agreed to by the WG. For **Paragraph 76**, text was added to reflect that molecular testing “may” be used for the early detection or detection of resistant microorganisms of high public health importance.

Section 8.7 Collection and Reporting of Resistance Data

25. For **Paragraph 79**, the WG discussed whether this paragraph should reflect what information “may” accompany each sample versus what “should” accompany each sample. The discussion reflected that for good monitoring and surveillance, this paragraph reflected information that “should” accompany each sample. The WG also recognized that in terms of the data structure itself, the actual descriptions of the sampling design will not accompany information on each isolate or sample, but rather there needs to be an accompanying reference to the sampling design; hence the WG agreed to text to make this adjustment to **Bullet a**. For **Bullet b**, the WG agreed to simplify the text to only include the core elements needed for reporting where and when the samples were collected. Minor editorial suggestions were agreed to by the WG for **Paragraph 80**.

2.2 SECTION 9: COMPONENTS OF INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S) FOR AMU

26. A proposal was made to change the title of Section 9 to define the purpose of monitoring and surveillance of AMU, however the original title has been retained. The aim of a title is to easily highlight the core content of the section without being overly prescriptive, as in the context of these Guidelines members may also use AMU data for other purposes. The current title is also in line with other titles through the Guidelines (e.g., Section 8 Components of integrated monitoring and surveillance program(s) for AMR) and is reflective of the scope to cover the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU.
27. **Paragraph 82**: A lot of time was spent on Paragraph 82 during the WG. As not all countries are currently able to monitor AMU data, the addition of antimicrobials “sold and/or used” allows flexibility. The wording for Paragraph 82 is in line with the OIE definition of “Sales of antimicrobial agent(s) used in animals” and “Use data” as described in the “OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Fourth Report”. Furthermore, under the guidance for completing the OIE template for the collection of data on antimicrobial agents intended for use in animals, the OIE notes “Sales of antimicrobial agents intended for use in animals can be used as an indicator of actual use”.
28. The co-Chairs have elected to delete Paragraph 82 from Section 9, and leave the wording in the introduction (**Paragraph 2**) so AMU is defined where the term is first used in the text.

Section 9.1 Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops

29. **Title**: Two editorial additions were made to add “(s)” after “program” and to add “food-producing” before “animals” for consistency throughout the text.
30. **Paragraph 83**: Regarding concerns that sales data may not reflect patterns of antimicrobial use, Paragraph 83 elaborates on this point stating “The competent authority should consider the limitations of each type of data”. This sentence was moved to **Paragraph 83** from **Paragraph 84** at the request of the WG. The sentence “Through pilot studies, competent authorities may explore antimicrobial use data” has been removed as it was agreed the sentence does not provide additional clarity or guidance to the text.

31. **Paragraph 84:** The text has been edited to soften the wording. The meaning of the paragraph remains the same.
32. **Paragraph 85:** The word “actual” has been removed as it was considered redundant. The meaning of the paragraph remains the same.
33. **Paragraph 87:** No changes have been made to this paragraph. While some of the contents are included in OIEs Terrestrial and Aquatic Codes, the chairs have elected to keep the contents as the information is presented concisely as a list, none of the contents are contrary to OIE information, and without the paragraph, the Guidelines would not read as a stand-alone document. During the WG, one member suggested a change in wording for **Bullet 7** to replace “dose, dosing interval and duration” with “dosing”. The co-Chairs have elected to keep the current wording as it aligns with OIE wording in the Terrestrial and Aquatic Health Codes.

Section 9.2 Sources of sales/use data

34. **Paragraph 89:** Text “at the national level” has been changed to “within a country” to ensure clarity of the text in the first sentence. Examples were added to the second sentence to add clarity. No objections were made about these changes during the WG.

Sections 9.3-9.5 Collection and reporting of AMU

35. Several participants of the WG proposed to delete these sections from the text due to concern that the sections were repetitive of OIE text and outside of the scope set by TFAMR. Others requested to keep these sections. There was also discussion on wording required for AMU collection and reporting in plants/crops, as this is not covered by OIE, and there is no current international guidance. Based on discussion in the EWG and WG, Sections 9.3-9.5 were combined by the co-Chairs into one section named “**Collection and reporting of AMU**”. This section was divided into 2 subsections: one on ‘Collection of data’ and one on ‘Reporting of data’.
36. In the proposed new section:
 - Each paragraph remains applicable to data collection/reporting for both animals and plants.
 - Reference to the terms ‘numerator’ and ‘denominator’ have been kept to add value and provide clarity.
 - The co-Chairs reviewed the OIE Terrestrial and Aquatic Health Codes to ensure the new proposed text adds clarity and is not duplicative of these codes.
 - Any information covered in both the OIE Terrestrial and Aquatic Health Codes as well as in the proposed sections was retained by the co-Chairs to enable these Guidelines to be read as a stand-alone document.
 - None of the text as currently written is in contradiction to the OIE Codes.
 - The proposed text is short and includes reference to the OIE Terrestrial and Aquatic Codes.
37. Taking into account comments received on the proposed text, small edits have been made to ensure clarity around the numerator and denominator. There was no consensus on whether the new revised text would be accepted, and it is acknowledged that no time was given to the WG to read the new proposal prior to discussions during the last session of the WG.
38. To conclude on Sections 9.3-9.5, some countries requested to delete and to only refer to OIE codes, others agreed on the proposed text and some stated that more time was needed to read through the proposed text. This text may be further revised during the Task Force in October.

2.3 SECTION 10: INTEGRATED ANALYSIS AND REPORTING OF RESULTS

Section 10.1 Management of data

39. **Paragraph 100:** Time was spent discussing whether the bracketed examples in Paragraph 100 (e.g., centralized location) should be removed from the text, as some countries are unable to store data in a centralized location. As a compromise the following was added to the body of the text to state “data, database(s) should be structured *and where feasible, centralized...*”. The term “where feasible” replaced “ideally” to add flexibility and to be consistent with terms used in Codex texts.
40. **Paragraph 102:** The co-Chairs were asked to explain the meaning of Paragraph 102. The co-Chairs clarified that simply having data doesn’t mean it is good or clean data and so an integral part of data management is to ensure there is a process for ongoing validation. Several versions of the sentence were proposed including to “guarantee data quality”, and to “protect data quality: Following these discussions, the text was mostly retained, however the language was softened by removing “should” and replacing it with “may”.

Section 10.2 Analysis of results

41. **Paragraph 105:** This paragraph was extensively discussed during the WG. The main concerns raised included reference to “regions”, whether the term “evaluate”, “comparison” or “assessment” should be used when referring to AMU and AMR data and how the data can be used to allow integration. The term “assessment” seemed to be the most accepted wording and is reflected in the proposed paragraph. The term “regions” was changed to “temporal and geographical trends”, to include evaluation across multiple potential geographical areas and across time. The last sentence referring to “other contextual information” has been retained as it was considered important to include such data as noted by several members. The following wording is now proposed: *105. Analysis of data from ~~the integrated monitoring and surveillance of AMR and AMU~~ program(s) may include the assessment comparison of AMR and AMU within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, ~~between regions or~~ across host species, across bacterial species or antimicrobial classes. Other contextual information such as epidemiological data may be considered when available.*
42. **Paragraph 107:** This was extensively discussed during the WG. One member proposed the term “drivers” of AMU to be included in the text, while others were unsure of what “drivers” referred to and suggested clearer wording was needed. The co-Chairs have provided new text, which includes using the word “factors” instead of drivers. The word “factors” aligns with wording used in CXG 77 to describe other risks that may affect either selection or dissemination of resistance.
43. **Paragraph 108:** Two members suggested the deletion of Paragraph 108 during the WG because they felt it was covered elsewhere in the text and that other organizations cover human monitoring and surveillance data. Other members felt the paragraph was important to retain as it is part of the scope in line with the One health approach, and that there is a need for information on how to link the data between humans, animals, plants/crops and the environment. Others noted that human isolates might be considered “contextual” data as mentioned in Paragraph 105. During the session, it was suggested that **Paragraph 108** could be moved below **Paragraph 105** to enhance flow of the Guidelines. The original order of the text has been retained, further discussion may be required to allow flexibility and obtain consensus on the current text.

Section 10.3 Reporting of results

44. **Paragraph 111:** “under a One Health approach” has been added to give context to who should be included when reporting results of the programme.
45. **Paragraph 113:** The co-Chairs had proposed new wording to delete reference to AMU and AMR data at the request of one member, and to instead emphasize the reporting of the program(s). One suggestion was made to incorporate **Paragraph 11** about unjustified trade barriers in **Paragraph 113**. This was not accepted by the co-Chairs as trade barriers are relevant to the text as a whole, rather than just reporting. It was agreed that this paragraph should be revisited following review/discussion on **Paragraph 4** about the meaning of ‘integrated’.

2.4 SECTION 11: EVALUATION OF THE INTEGRATED MONITORING AND SURVEILLANCE PROGRAM(S)

46. Minor edits were made to this section during the WG.

2.5 SECTION 12: TRAINING AND CAPACITY BUILDING

47. No changes were suggested or made to this section during the WG. To conclude, Sections 8-12 were discussed and revised in depth during the WG. The Chair and co-Chairs recommend to review the changes made and included in the revised guidelines in **Appendix I**⁸, to ensure clarity of the text and to enable quick revision and agreement of these sections during TFAMR08.

3. REVISION OF SECTIONS 1 TO 7: OVERVIEW OF AMENDMENTS

48. Sections 1-7 were not discussed during the WG. The Chair and co-Chairs revised these sections based on comments received through OCS in response to [CL 2021/33/OCS-AMR](#). The discussions during the webinars in January 2021⁹ have also been considered when redrafting Sections 1-7. The new proposed text is included in **Appendix I** and an overview of the key amendments is provided below:

⁸ A tracked changes version of Appendix 1 is available on the TFAMR8 webpage at <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-804-08%252FLINKS%252FCX-AMR-1-8-5-Guidelines-TC-version-of-Appendix1.pdf>

⁹ Webinar details and recordings are available on the TFAMR08 webpage <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=8>

SECTION 1: Introduction

49. **Paragraph 1:** Some members suggested alternative wording to clarify the One Health approach and how it should be implemented within the context of integrated monitoring and surveillance. Amendments were made to delete the word “integrated” before “One Health approach” to avoid confusion with the use of the phrase “integrated monitoring and surveillance program(s)” throughout the document which is described in **Paragraph 4**. The suggestion of deleting AMU has not been incorporated as AMU remains within the scope of the document and is stated under paragraphs 10(e), 10(f) and 12(c) of the political declaration of the United Nations General Assembly (UNGA)¹⁰ in 2016, which refer to both the use and sale of antimicrobials. The content was also considered as a foundation for the discussion during the 2016 physical working group meeting in London¹¹ which developed the project document for this work.
50. **Paragraph 2:** For this paragraph, some members suggested to either delete **Paragraph 2** as it duplicative of **Paragraph 82** in Section 9, to add AMU as a definition under Section 3, or to retain the text within the introduction. The Chair and co-Chairs have retained this paragraph in the Introduction as the term is used throughout the document and needs to be introduced in the text before Section 9.
51. **Paragraph 3:** This paragraph was not modified as the text was previously agreed upon at TFAMR06. While some countries suggested to include language around “risk assessments and, in turn, risk management actions” under Paragraph 3, the co-Chairs did not include this wording as it was considered to be very prescriptive and did not reflect all options for how data may be used for monitoring and surveillance, limiting the possibilities of the risk analysis process. The Chair and co-Chairs also note that **Paragraph 6** refers to how data generated by monitoring and surveillance program(s) can inform the risk analysis processes.
52. **Paragraph 4:** Minor editorial changes were provided for consistency throughout the document. This paragraph was not modified as the text was previously agreed upon at TFAMR06.
53. **Paragraph 5:** Minor editorial changes have been introduced for clarity and consistency.
54. **Paragraph 6:** Amendments were made to introduce components for risk analysis which includes assessment, management and communication, as suggested by some members. Additional wording was also provided by some members around the uses of data generated from integrated monitoring and surveillance program(s). As stated in **Paragraph 3**, the Chair and co-chairs have not included this additional text as it is very prescriptive to state that data from monitoring and surveillance can only be used for risk assessment purposes. The second sentence of Paragraph 6 was deleted as it is duplicative of the last sentence in the paragraph.
55. **Paragraph 7:** No changes have been introduced.
56. **Paragraph 8:** Minor editorial changes have been introduced.
57. **Paragraph 9:** The text has been retained with minor changes for clarity, as the focus of Paragraph 9 provides the basis for prioritization when designing and implementing monitoring and surveillance program(s). Language around priorities at the “national” and “international” level were further retained as both may be relevant to the design and implementation of these program(s) (see Section 8).
58. **Paragraph 10:** The text has been retained with minor changes for consistency and clarity. Paragraph 10 introduced the concept of continuous improvement and how priorities may evolve within the monitoring and surveillance program(s).
59. **Paragraph 11:** Amendments were made to delete “imported” as suggested by member following the webinar in January 2021.
60. **Paragraph 12-14:** Editorial changes were introduced in Paragraphs 12-14 for consistency with the rest of the document and to align with the language in the COP (CXC 61-2005). The order of Paragraphs 13-14 were changed, with **Paragraph 13** placed after **Paragraph 14**. This was requested by some members as the documents from standard setting bodies such as OIE may be more relevant for the implementation of these Guidelines.

¹⁰ Available at: https://www.un.org/ga/search/view_doc.asp?symbol=A/71/L.2&referer=/english/&Lang=E

¹¹ CX/CAC 17/40/12-Add. 2. Available at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-40%252FWD%252Fcac40_12_Add2e.pdf

SECTION 2: Scope

61. No amendments have been introduced to this section. Antimicrobial use has been retained as it is an essential part of the mandate provided by the Codex Alimentarius Commission which was explained by the Codex secretariat during the webinars held in January 2021¹². The words “AMR and AMU” in several paragraphs of these Guidelines have been removed, as the term integrated monitoring and surveillance program(s) for foodborne AMR and AMU is included in the scope of these Guidelines.

SECTION 3: Definitions

62. While some members have provided new definitions or amendments to the current definitions, both the Chair and co-Chairs have decided to retain the current definitions to ensure alignment and consistency with CXC 61 and CXG 77, which are applicable to these Guidelines. A comment was made to update the definition of “Hazard” to be in line with the *General Principles of Food Hygiene* (CXC 1-1969). However, this definition was not updated in the Procedural Manual and in other documents like the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999). Therefore, the first half of the definition in reference to the Procedural Manual was deleted to avoid confusion and the latter half was retained in reference to CXG 77, which is directly relevant to these Guidelines. The Chair and co-Chairs will be seeking clarification from the Codex Secretariat around updates made to indirect definitions.

SECTION 4: Principles

63. **Principle 1:** The language “following a One Health approach” was retained over “consider” or “contribute to” as it is more appropriate in the context of these Guidelines. Both “AMR and AMU” have been removed to be consistent with the language used throughout the Principles, as the term “integrated monitoring and surveillance for foodborne AMR and AMU” is specified in **Paragraph 4** of the Introduction and in the scope of these Guidelines.
64. **Principle 2:** The wording AMR and AMU has been deleted (see comments under Section 2), which is in line with the discussions during the webinar to avoid repetition of the term throughout the text and to ensure alignment with CXC 61 which is relevant to these Guidelines. The words “and contain” have been added for consistency with CXC 61.
65. **Principle 3:** The concept of “risk-based” has not been introduced in this principle as suggested by one member as the focus of the principle is around national priorities and the concept of risk analysis is covered under **Principle 5**. Furthermore, some countries may not have enough data to undertake risk-based sampling initially. To provide added clarity around the concept of risk-based sampling and risk analysis, the Chair and co-Chairs propose to move Principle 5 before Principle 3.
66. **Principle 4:** The text “occurrence of”, “patterns of” and “all” have been deleted for consistency.
67. **Principle 5:** As stated above, **Principle 5** was moved before **Principle 3**.
68. **Principle 6:** The bracketed text was retained in this principle. While some members proposed removal of this text, the Chair and co-Chairs believe it provides added clarity for relevant foodborne AMR issues and provides alignment with CXG 77.
69. **Principle 7:** The text has been amended as capacity for epidemiological investigation may not be part of the monitoring and surveillance program(s).
70. **Principle 8:** No amendments were made to this Principle as no comments were received.
71. **Principle 9:** No amendments have been made to the text. Language around “sharing of data” has been retained, as a compromise text which was developed following the last sessions of the EWG and the webinars in January 2021. A suggestion was made to add “national situation”, however the Chair and co-Chairs note that this concept is covered under “national priorities”.

SECTION 5: Risked-based approach

72. **Paragraph 22:** Only minor editorial changes were introduced to enhance the flow of the sentence. The terms “scientific knowledge” was retained and “to facilitate risk assessment” was not added, as requested by one member as the current text is in line with CXG 77. One member provided new text from CXG 30. The Chair and co-Chairs have not included this text for the following reasons: the reference for risk analysis of foodborne AMR is under CXG 77, which is specific for these Guidelines. As stated in CXG 77, the development of a risk profile, before a risk assessment, is an option. This is an important option especially for countries beginning monitoring and surveillance program(s) with limited data or capacity to conduct full risk assessments. Additionally, CXG 77 refers to CXG 30 where appropriate

¹² [Informal meeting on Task Force on Antimicrobial Resistance - Zoom](#)

73. **Paragraph 23:** The terms “integrated” and “AMR and AMU along the food chain” were deleted for brevity as the term “integrated monitoring and surveillance for foodborne AMR and AMU” is specified in **Paragraph 4** of the introduction and the Scope. Comments were received to add the word “further” to read “risk assessment and further risk management...”. The Chair and co-Chairs did not include this wording as it is not in line with CXG 77 which state that risk management decisions may be taken based on the risk profile and not only after the full risk assessment result. The terms “risk-based” and “preferably randomly sampled” were suggested by some members, however these terms were not added as they are dependent on the purpose of the monitoring and surveillance program(s). The text “and contain” was added and “prevent and” was deleted to align the language with CXC 61.
74. **Paragraph 24:** Text was added to broaden knowledge of AMR “within a country”, instead of “AMR risks according to the national situation” for clarity. A proposed addition of “foodborne” before “food safety” was suggested. The Chair and co-Chairs noted this text does not add value or clarity and it was not included. New text was further proposed by one member to elaborate on information of AMR hazards. The Chair and co-Chairs note that this suggestion is covered by the term “scientific knowledge” under **Paragraph 22** and the current text for **Paragraph 24** is in line with CXG 77 which are specifically developed for the purpose of AMR risk analysis, have to be read in conjunction with CXC 61 and Guidelines for Integrated Surveillance, as noted in all these Codex documents.
75. **Paragraph 25:** No amendments were made to this paragraph as no comments were received.

SECTION 6: Regulatory framework, policy and roles

76. **Paragraph 26:** The text has been amended for clarity as suggested by one member. AMR and AMU has been deleted as it is included in the term monitoring and surveillance program(s) under **Paragraph 4** of the Introduction and Scope.
77. **Paragraph 27:** Amendments were made to the text to remove “foodborne AMR and AMU” as it is included in the term “integrated monitoring and surveillance” under **Paragraph 4** of the Introduction and scope.
78. **Paragraph 28:** Text has been added on “risk assessment”. The Chair and co-Chairs did not introduce any other amendments to the paragraph as the text around sharing knowledge and data is just encouraged.
79. **Paragraph 29:** Additional text was added to clarify access to “all available sources of AMU data” for flexibility and to facilitate understanding.

SECTION 7: Implementation of an integrated monitoring and surveillance program(s) for foodborne AMR

80. The title of 7.1 “Preliminary Activities” was moved to the heading of Section 7 to read “Preliminary Activities for Implementation of an integrated monitoring and surveillance program(s) for foodborne AMR”.
81. The following headings 7.1.1, 7.1.2, 7.1.3 and 7.1.4 for Section 7 were subsequently modified to reflect the numbering system of 7.1 to 7.4.
82. **Paragraph 30:** Amendments were made to enhance clarity and flow of the document. The term “continuous improvement” was retained as the term is used throughout the document. The term “situation” was suggested by one member for addition in the second sentence, however this term was not added as its addition is unclear and is covered by the language “country specific”. The suggestion made by one member regarding pilot studies for Paragraph 39 has been added at the end of this paragraph, as it is more appropriate here.
83. **Figure 1:** Amendments were made to align the figure with the current headings in the document and a link to the OIE standards for the AMU Component has been added.

Section 7.1: Preliminary activities

Section 7.1.1.: Establishing monitoring and surveillance objectives

84. **Paragraph 31:** The text “relevant evidence of the AMR and AMU situation” was replaced by “relevant information on AMR and AMU in the country” to add clarity to the sentence and avoid confusion. There was a comment to add “national situation” to the original sentence, however other information may be relevant to the establishment of monitoring and surveillance objectives.
85. **Paragraph 32:** The word convenience has been deleted and replaced with “random or systematic” sampling as commented by some member countries.

Section 7.1.2.: Considerations for prioritization

86. **Paragraph 33:** The paragraph has been retained as it provides added context on what competent authorities should consider for prioritization, and is complementary to **Paragraph 34**.

87. **Paragraph 34:** Amendments were made to the text to replace “considerations of risk profiles and risk assessments” with “data required for risk analysis or results of risk analysis”. A risk assessment/profile will identify both data gaps and existing data sources (i.e., the results of risk analysis can inform surveillance). However, to conduct a risk assessment/risk profile may need data from surveillance (i.e., surveillance data can inform the risk profile/assessment).

Section 7.1.3.: Infrastructure and resources

88. **Paragraphs 35-38:** Editorial changes were provided for flow and clarity and the term “competent authority” has been changed to “competent authorities” for consistency with the Guidelines. One member suggested to move Paragraph 36 to the introduction, however the Chair and co-Chairs decided to retain the paragraph under this section as it may be too detailed for the introduction.

Section 7.1.4.: Key design elements to be established before initiating the monitoring and surveillance activities

89. **Paragraph 39-40:** No amendments were made to these paragraphs. New text was provided by one member for **Paragraph 39**, which has been added to the end of **Paragraph 30**.

90. **Paragraph 41:** A reference to OIE has been introduced. One member proposed to delete “distribution chain”, however this text was retained as mapping out the antimicrobial distribution chain is an essential first step needed to design an AMU monitoring and surveillance system. Two members proposed to delete the last bullet point regarding the need to establish a legal framework as they considered it beyond the mandate of Codex. The Chair and co-Chairs have decided to retain this text as it is an essential element to consider when designing monitoring and surveillance program(s). Furthermore, the sentence on the legal framework starts with “assessment of the need” which provides flexibility to members based on their identified needs.

4. CONCLUSIONS

91. The Chair and co-Chairs concluded that the two rounds of comment submissions, the webinar and the WG were valuable in progressing the document.

92. During the virtual meeting of the WG in June, Sections 8-12 were reviewed, while Sections 1-7 were not discussed. The webinars convened in January 2021 and the comments received through the OCS in response to CL 2021/33/OCS-AMR were a useful tool for the Chair and co-Chairs to review these sections. Overall the Chair and co-Chairs would like to highlight that:

- In the original mandate of the Task Force consideration of CXG 77 was emphasized as it is specific for foodborne AMR risk analysis. Hence, the Chair and co-Chairs used CXG 77 as the foundation for these Guidelines.
- The wording in the document has been streamlined and shortened. References to the OIE have been made in the text where possible, to avoid duplication while retaining text that provides useful guidance as a stand-alone document. For example, OIE doesn't cover plants/crops and has as primary focus animal health.
- The Chair, co-Chairs, EWG and WG reviewed the use of examples throughout the Guidelines. Examples were included where they provided clarity or added guidance and were removed if they did not add value to the document.
- Following the WG, the Chair and co-Chairs critically reviewed the entire document and made subsequent changes to ensure consistency and clarity, and to ensure that these guidelines remain as a flexible stand-alone document. These subsequent changes are described in this report.
- Revisions to the document include consensus text in areas where compromise could be achieved during the EWG, webinar or the WG. Reasons for not including proposed edits during the WG in the document include: content is already covered in another paragraph or is duplicative, proposed edits change the meaning of the paragraph or the proposed edits did not have broad support during the WG.
- In order to facilitate consensus on Sections 9.3 to 9.5, the Chair and co-Chairs proposed new text that was substantially refined to provide a balance with OIE references where appropriate, while retaining essential content, including plants/crops in order to have a useful standalone document.

Recommendations

93. Based on EWG, the webinars in January 2021 and the virtual meeting of the WG, the Chair and co-Chairs have made the following recommendations to TFAMR08:

- Not to re-open the sections Scope and Definitions, as these were previously agreed upon in TFAMR06.
- Ensure the guidelines are stand alone and future-proofed.
- Review the guidelines in their entirety from start to finish, taking into consideration the conclusions made in this report, and keeping in mind the need for accuracy of language to provide useful guidance. Specially:
 - Review the excessive use of qualifiers (e.g. if available, where feasible, examples of options, etc.) throughout these Guidelines.
 - Review the use of “*may*” versus “*should*” throughout the text, as in some cases the use of “*should*” better reflects the content of the guidance and “*may*” could be confusing for practical implementation and technical accuracy.
 - ✓ For example in Section 8 where the sample is collected from (e.g., a chicken) *should* be documented for any analysis, *may* is not appropriate in this circumstance.
 - ✓ As another example in Section 8, states “when possible, molecular testing may be used for the detection of resistance determinants...”. Molecular testing is needed for the detection of resistance determinants, hence *should* is more appropriate.
 - Review the use of the word “national”, as in some cases, “national” was added to reflect a national perspective/context and to add flexibility. However, national data may not exist and countries will need somewhere to go for a reference (e.g., see Paragraph 71). Sometimes adding “national” removes the flexibility from the document and can cause confusion.

94. In addition, for the reasons outlined in the report above the Chair and co-Chairs of the virtual meeting of the WG propose that TFAMR08 consider retaining the following concepts, texts and figures in the Guidelines;

- antimicrobial use within the Scope as it is in line with the Terms of Reference provided by CAC;
- antimicrobial use within the introduction as it is essential and is used throughout the Guidelines. This is also in line with the approach used in CXG 77 where terms are described but formal definitions are not created;
- Paragraphs 3 and 4 as agreed by the TFAMR, as they define the concept of integrated monitoring and surveillance program(s). Integration may be appropriate within a sector or across AMU and AMR; integration should be applied to meet the monitoring and surveillance objectives;
- Figure 1 as it contains essential guidance for the practical implementation of the monitoring and surveillance program(s) and an overview of the interrelatedness of the relevant Codex texts and that TFAMR08 consider the revisions made to Figure 1 in order to reflect the rest of the document and discussions to date;
- refined Section 9 as it contains the minimum essential information to provide practical guidance; and
- noting that monitoring and surveillance data are useful for many purposes, as outlined in CXG 77, which states “...input for risk profiling and risk assessment, to measure the effect of interventions and to identify trends” and , to ensure consistency the Chair and co-Chairs recommend that all these purposes of monitoring and surveillance are covered by the Guidelines. In addition, as per CXG 77 monitoring and surveillance data is one of several types of input into preliminary risk management activities (i.e., risk profiles), risk assessment, and risk management decision-making.

**GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE
OF FOODBORNE ANTIMICROBIAL RESISTANCE
(For comments at Step 3)**

1. Introduction and purpose

1. World-wide recognition of the importance of antimicrobial resistance (AMR) as a public health threat has led to strong international calls for all countries to develop and implement national strategies and action plans within the framework of a “One Health” approach, including the design and implementation of national programs of monitoring and surveillance of foodborne AMR and antimicrobial use (AMU).

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.

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.

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

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 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.

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 based on their relevance to foodborne AMR priorities at the national and international level.

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

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 take into account the 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).

13. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines should also be used taking into consideration those already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.

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.

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.

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

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 target¹³.

Antimicrobial resistance (AMR)

The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same 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.

Plants/Crops

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

4. Principles

20.

¹³ *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*

- **Principle 1:** Monitoring and surveillance program(s) should follow a “One Health” approach.
- **Principle 2:** Monitoring and surveillance program(s) are an important part of national strategies to minimize and contain the risk of foodborne AMR.
- **Principle 3:** Risk analysis should guide the design, implementation and evaluation of monitoring and surveillance program(s).
- **Principle 4:** Monitoring and surveillance program(s) should include data on AMR and AMU, in relevant sectors as inputs into risk analysis.
- **Principle 5:** Monitoring and surveillance program(s) should be tailored to national priorities and may be designed and implemented with the objective of continuous improvement as resources permit.
- **Principle 6:** Priority for implementation should be given to the most relevant foodborne AMR issues ((combinations of the food commodities, the microorganism and resistance determinants and the antimicrobial agent(s)) to be analyzed from a public health perspective.
- **Principle 7:** Monitoring and surveillance program(s) should incorporate to the extent practicable, the identification of new and emerging foodborne AMR or trends and to facilitate epidemiological investigation.
- **Principle 8:** Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place.
- **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.

5. Risk-based approach

21. For the purpose of these Guidelines, a risk-based approach is the development and implementation of monitoring and surveillance program(s) informed by data and scientific knowledge on the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health.

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

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

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 (NAP) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain should ensure collaboration with human health, animal health, plant health, the environment and other relevant authorities.

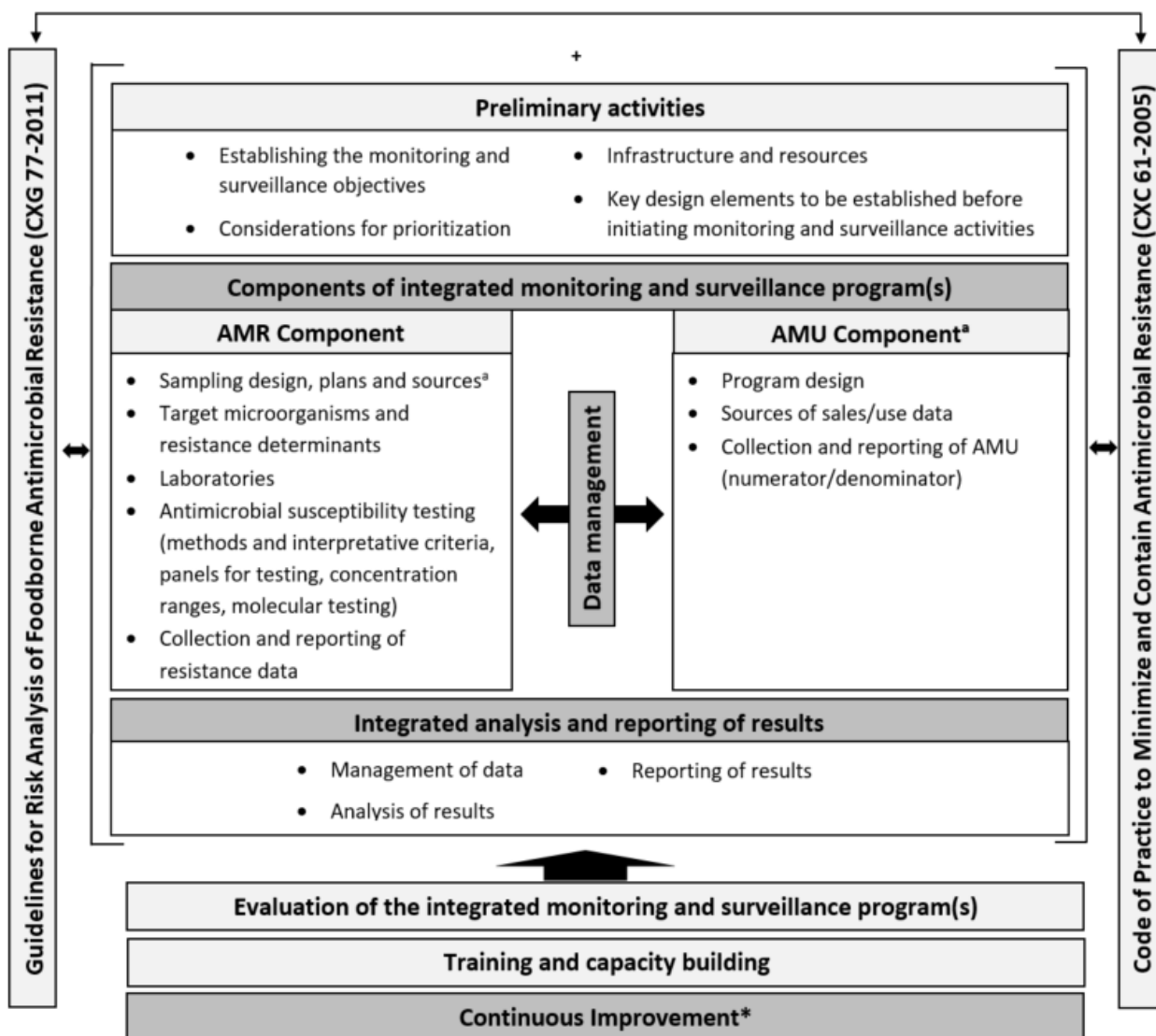
26. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).

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

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

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

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



* *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)*.

^a Where 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.

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 and the environment). Competent authorities should identify the challenges they currently face during the implementation of these activities.

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., random or systematic sampling).
- The setting of proposed timelines for sampling and reporting.
- A description of how the information will be reported and communicated (e.g., publication of report).

7.2. Considerations for prioritization

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

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

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. Antimicrobial use monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow for integrated analysis.

36. As part of initial planning, the competent authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of integration or expansion of the AMR or AMU monitoring and surveillance activities within other ongoing activities.

37. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing and when feasible reporting data in a central repository.

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:

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.

40. AMU:

- Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.
- Identification of the sectors where collection of data would be most relevant and 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 or to start the collection of AMU data on a voluntary basis in agreement with stakeholders that provide these data may be useful.

41. Consideration may be given to additional information provided in the OIE Terrestrial Animal and Aquatic Health Codes.

8. Components of integrated monitoring and surveillance program(s) for AMR

42. Integrated monitoring and surveillance program(s) for foodborne AMR should consider the following elements:

- Sampling design.
- Sampling plans.
- Sample sources.
- Target microorganisms and resistance determinants.
- Antimicrobials to be tested.
- Laboratory testing methodologies and quality assurance systems.
- Data management activities.

43. The initial scope and design of the monitoring and surveillance program(s) for AMR may be informed by previous research or surveillance findings, by national priorities or by national and international experience and recommendations. As the AMR program develops, the scope and design may be adjusted based on one or more of the following factors:

- Monitoring and surveillance findings.
- Epidemiology of antimicrobial-resistant microorganisms as available.
- Risk profile and risk assessment findings.

8.1. Sampling design

44. The design of monitoring and surveillance program(s) for AMR may build on or be integrated with existing monitoring and surveillance program(s), or may involve development of new infrastructures and activities only for the purpose of AMR data collection. If data are collected through existing programs designed for another purpose, this will need to be specified and the different methodologies and data interpretation methods should be described.

45. Sampling design should consider temporal and geographical coverage of data collection.

46. Once a sampling design is established, consistency in sample types and methodology is desirable to achieve long-term, comparability and accurate interpretation of results, especially when new methodologies are added and the program is adjusted.

8.2. Sampling plans

47. The sampling plan should describe the following:

- The procedure to collect a sample from the selected sample source(s) at the selected point(s) in the food chain.
- Sample size, statistical methods and underlying assumptions e.g., frequency of recovery, the initial or expected prevalence of AMR in that microorganism) of the data used to calculate the number of samples and isolates.
- Statistical power, precision and goals of testing.
- Limitations to data interpretation.

48. The following elements should be considered in the sampling plan:

- Sampling strategy may be active (i.e. designed for AMR surveillance) or passive (i.e. using a system already in place).
- Target animal or plant/crop species, food commodities or food production environment.
- Point(s) in the food chain where the samples will be taken and sample type.
- Selection of strata (levels) or risk clusters (groups) to best meet surveillance objectives.
- Target microorganisms, resistance phenotypes and resistance determinants.
- Frequency of sampling.
- Prevalence and seasonality of the microorganisms under study.

- Standard operating procedures for sample collection :
 - Who should be collecting the samples.
 - Procedures for collection of samples in accordance with the defined sampling strategy and to guarantee that traceability, security and quality assurance are maintained from collection through to analysis and storage.
 - Procedures for storing and transporting the samples in order to maintain sample integrity.

49. Initial implementation might include a limited selection of sample sources at one or more specific points along the food chain.

50. As the program(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, stages in the food chain or food commodities to gradually be more representative of the population of interest.

8.3. Sample sources

51. When identifying the sample sources to be included in the monitoring and surveillance program(s), consideration should be given to the major direct and indirect food exposure pathways.

52. The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne AMR.

53. The integrated program(s) should reflect the food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR. Possible sample sources are:

- **Food producing animals**

Samples should be, to the greatest extent possible, representative of the animal species and epidemiological unit being targeted.

The prevalence of the bacterial species should be considered to maximize the likelihood of detection.

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 may provide additional information on foodborne AMR at the population-level but may be a lower priority than those animals directly entering the food supply.

- At the farm-level, sample may include faeces, feed¹⁴ and/or feed ingredients, water, litter or bedding or other relevant food production inputs.

Consideration may be given to samples described in the OIE Terrestrial Animal and Aquatic Health Codes, specifically the chapters on Harmonisation of National AMR Surveillance and Monitoring Programmes as well as on the Development and Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic animals.

- At lairage, sample may include rectal samples or fecal samples from pen floors or crates.
- At slaughter, sample may include carcass swabs, caecal contents or lymph nodes. In some animal species, caecal contents or lymph nodes may be representative of the pre-slaughter environment and may or may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter (e.g., carcass) may provide an estimate of contamination arising from the slaughterhouse.

For integration, samples from food-producing animals should be collected from the same animal species at the different relevant points along the food chain.

- **Food**

Food samples may be collected at processing, packaging, wholesale or retail. Sample may include both domestically-produced and imported food sources.

The place where the food samples are collected should reflect the production system in the country and the purchasing habits of the consumer (e.g., sampling open markets or chain stores).

¹⁴ The location of where the feed or feed ingredient is sampled, the manufacturing plant (feed mill), production site or farm, may provide additional information for understanding foodborne AMR.

At the retail-level, food samples may include raw meat, fish or seafood, dairy products, other edible tissues, raw produce and other minimally processed animal products and produce. Food selection may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.

- **Plants/crops**

The selection of plants/crops should be risk-based and/or guided by the relevant standard setting bodies where available.

Samples may be collected from farm, pre-harvest or post-harvest

- **Food production environment**

The selection of samples from the food production environment should be risk-based and relevant to the food production system.

Sample may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets¹⁵.

8.4. Target microorganisms and resistance determinants

54. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and public health.

55. Bacterial species may include:

- Foodborne pathogens such as *Salmonella*, *Campylobacter* or other food borne pathogens depending on national or regional epidemiology and risks.
- Commensal bacteria such as *Escherichia coli* and enterococci (*Enterococcus faecium* and *Enterococcus faecalis*), which can contaminate food and harbor transferable resistance genes.

56. Target microorganisms from aquatic animals and food of non-animal origin should be determined based on available scientific evidence and relevance to public health.

57. The selection of target microorganisms should consider the presence of high priority AMR genes or mobile genetic elements and horizontal gene transfer in a given bacterial population.

58. Monitoring and surveillance program(s) may begin with phenotypic susceptibility testing for AMR in representative foodborne pathogens and/or commensal bacteria. Options for expansion may include a broader range of foodborne pathogens, or commensal bacteria, testing for genetic determinants of resistance, virulence and mobile genetic elements.

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 should be undertaken.

8.5. Laboratories

60. Laboratories participating in the monitoring and surveillance program(s) should consider:

- Bacterial isolation, identification (to species and serotype level), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.
- Accreditation in accordance with national or international guidance or have a quality management system in place.
- Whenever possible participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).
- Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and recording time between sample reception and analysis and traceability.
- Storing isolates and reference strains using methods that ensure viability and absence of change in the characteristics and purity of the strain.
- Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary and carry out molecular characterization where feasible.

¹⁵ Dust, soil, water, organic fertilizers, sewage or manure in the farm environment or in surfaces of processing areas.

8.6. Antimicrobial susceptibility testing

8.6.1. Methods and interpretative criteria

61. Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by internationally recognized organizations should be used where available.
62. Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations.
63. Quality control strains of bacteria should be included and used according to international standards where available to support validation of results.
64. Interpretation of results for MICs or disk diffusion, should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.
65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) which should be reported as wild-type or non-wild type or clinical breakpoint which should be reported according to the interpretative category. The use of ECOFFs as interpretative criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpretative criteria or category used should be included in the reporting, interpretation and analysis of data.
66. Raw quantitative data should be maintained in order to allow comparability of results, for early recognition of emerging AMR or reduced susceptibility in order to maximize the ability to analyze and compare results across sample sources.
67. Quantitative results are also necessary for the analysis of resistance patterns over time and when retrospective data analysis is needed due to changes in clinical breakpoints or ECOFFs. Quantitative results are also necessary for quantitative microbiological risk assessment.

8.6.2. The panel of antimicrobials for susceptibility testing

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.
69. The antimicrobials included in the panel should depend on the target bacteria, the clinical or epidemiological relevance of these antimicrobials and should allow for the tracking of isolates with particular patterns of resistance.
70. The antimicrobials included may take into account the classes and uses in the relevant animal and plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if they are not used in animal and plant/crop production sectors.
71. Antimicrobials to be tested may be prioritized based on those that have been ranked with higher priority for human health, based on national context and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance.

8.6.3. Concentration ranges of antimicrobials

72. The concentration ranges used should ensure that both ECOFFs and clinical breakpoints, when available, are included to allow for the 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.

8.6.4. Molecular testing

73. When possible, molecular testing should be used for the identification and detection of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.
74. Molecular characterization is a useful tool which may be used for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization in conjunction with epidemiological information, may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.

75. Sequence data generated and stored with appropriate metadata may be used for retrospective and prospective surveillance.

76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and may be used for the early detection or detection of resistant microorganisms of high public health importance.

77. Molecular methods may allow for the integration of resistance data with other relevant public health data (e.g., virulence determinants).

8.7. Collection and reporting of resistance data

78. The information collected and recorded may differ depending on the stage of sampling along the food chain, sampling design and the specific monitoring and surveillance objectives. To ensure consistency, sampling information should be recorded at the isolate and sample level.

79. Information for each individual sample should include:

- a. Reference to the general description of the sampling design and randomization procedure.
- b. Specific information about the origin of the sample such as from what, where and when the sample was collected.
- c. General information to identify the isolate, bacterial species, serovar, other subtyping information as appropriate.
- d. Specific information about the isolation of the bacteria and the AST (e.g., date of testing, method used, quantitative results). In the case of qualitative results interpretative criteria should be recorded.

80. Reporting of results from the monitoring and surveillance program should be timely.

81. Antimicrobial susceptibility testing methods, sample sources, analytical methods and interpretive criteria should be clearly described, and differences transparently explained to show where data may not be directly comparable.

9. Components of integrated monitoring and surveillance program(s) for AMU

9.1. Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops

82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.

83. Sales data may be a valuable indicator to monitor trends although it does not always reflect the actual use, administration or application.

84. The collection of use data from farms/producers may be challenging but provide valuable insight on the magnitude of use and species-specific information on how and why antimicrobials are being used.

85. The choice of units of measurement for AMU should be established depending on method and scope of the data collection and the monitoring and surveillance objectives.

86. The following elements should be considered when deciding on the approach to collect sales and/or use data.

- a. 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.
- b. Identification of the most appropriate points of data collection and the stakeholders that can provide the data.
- c. 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.
- d. Nomenclature of antimicrobial agents harmonized with international standards where available.
- e. Identification, where possible, of the plant/crop type and species of food-producing animals for which the antimicrobials were intended to be used.
- f. Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).
- g. Information, where possible, on antimicrobial dose, dosing interval and duration.
- h. Technical units of measurement for reporting antimicrobial sales or use.

9.2. Sources of sales/use data

87. Options for sources of data may include:

- a) Sales data: 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.
 - Import data: may be collected from the competent authorities that are in charge of registration of medicinal products or customs. Care must be taken to avoid double counting with sales data in the country and those antimicrobials not intended for use within the country.
- b) Use data: may be collected from farm/plant health professional records, livestock/plant production company records or estimated from veterinary prescriptions or farm surveys.

88. Data on quantities of antimicrobials sold or used within a country may differ. Differences may include loss during transport (pack damage), storage (due expiry date) and administration (whole package not administered), stock purchased and held for future use, and fluctuations in animal or plant/crop populations.

9.3. Collection and reporting of AMU

Collection of data

89. The data collection should cover the following elements:

The numerator

90. Antimicrobial quantities representing the amount of antimicrobial agents sold or used. This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used the monitoring and surveillance period. In some cases this may be based on estimates.

91. To calculate the numerator data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit.

The denominator

92. The total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. The denominator provides the context for reporting and analyzing the sales and/or use data.

93. Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) may also be considered.

94. For collection of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.

Reporting of data

95. Multiple units of measurement for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.

96. For plants/crops, the information above is applicable and additional units of measurement may be established according to national priorities.

97. For reporting of data in food-producing animals, the OIE's Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.

10. Integrated analysis and reporting of results

10.1. Management of data

98. To facilitate the management of data, database(s) should be structured, and where feasible, centralized to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance program(s) improves.

99. A confidentiality and data management policy should be put in place. Data should be collected and stored to maintain data integrity and to protect the confidentiality of personal and proprietary information.

100. To facilitate the management of data, ongoing or regular validation of the data may be performed.

101. A description of sampling designs, stratification and randomization procedures per animal populations and plant/crop, food production environment or food categories should be recorded to link the data within and across monitoring and surveillance components.

10.2. Analysis of results

102. The data from the integrated monitoring and surveillance program(s) may be analyzed as described in CXG 77-2011 for risk assessment to then inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials to address foodborne AMR.

103. Analysis of data from the integrated monitoring and surveillance of AMR and AMU may include the assessment within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. When available, other contextual information such as epidemiological data may be considered.

104. The detailed methodology and the epidemiological context of the monitoring and surveillance program(s) should be considered for the analysis. Where data are available, exposure pathways among people, food producing animals, plants/crops and their shared environment connecting resident bacterial populations may be incorporated into the analysis.

105. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of any relationship between AMU and AMR within or across the food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, and the investigation of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.

106. AMR data from relevant human isolates may be considered for inclusion in the analysis and reporting based on information from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.

107. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance in humans, plants/crops and animals.

108. Statistical analysis should be used to ensure proper interpretation of results.

10.3. Reporting of results

109. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders under the One Health approach should be encouraged.

110. Results of integrated monitoring and surveillance program(s) should be reported regularly, where resources allow.

111. When available, summary reports on the integrated monitoring and surveillance program(s) data across humans, animals, plants/crops, food and the food production environment may be made publicly available.

11. Evaluation of the integrated monitoring and surveillance program(s)

112. Evaluation of the integrated monitoring and surveillance program(s) provides assurance that the data and information reported are robust and the program objectives are being met. The evaluation will also provide the best use of data collection resources.

113. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and changing patterns of AMU in humans, animals and plants/crops, and to respond to changing national needs.

114. Competent authorities should develop a framework and plan to facilitate the evaluation and review of monitoring and/or surveillance activities, which may include the following:

- Identify the skills needed by evaluators.
- Describe the monitoring and surveillance program(s) to be evaluated, including the objectives and desired outcomes. This may involve a subsection of the entire program(s) (e.g., the sample collection, laboratories, analysis and reporting).
- Identify key stakeholders for the evaluation.

- Identify key performance criteria to be evaluated.
- Collect data to facilitate evaluation based on the key performance criteria.
- Consider stakeholder input/feedback.
- Report results of evaluation.
- Draw conclusions on components of the evaluation.
- Identify or provide identification of relevant monitoring and surveillance program adjustments.
- Share evaluation outcomes with stakeholders.

115. If the design of the monitoring and surveillance program(s) changes or expands, adjustments should ensure the ability of the program(s) to identify trends over-time remains, that historical data are maintained and that the program continues to meet the objectives.

12. Training and capacity building

116. Training and capacity building are important components of the integrated monitoring and surveillance program(s) and should be supported where possible, by the competent authorities.

117. Training of the relevant competent authorities should include different aspects of the monitoring and surveillance program(s): collection, analysis, interpretation and reporting of the data.

118. Training of relevant stakeholders at the national level is recommended.

APPENDIX II

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LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES**

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