

**European Union reply to CL 2021/33/OCS
on the Guidelines for integrated monitoring and surveillance of foodborne
antimicrobial resistance**

*Mixed Competence
European Union Vote*

The European Union and its Member States (EUMS) would like to provide the following comments in response to CL 2021/33/OCS:

3.1 General comments on:

a. the overall content of the Guidelines and the points necessary for discussion by the 8th Session of the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR08) (October 2021) with a view to their final adoption by the 44th Session of the Codex Alimentarius Commission (CAC44) (November 2021);

EUMS: The revised version has much improved. We welcome the shortening and simplification of the text. We can agree with the overall content of the draft Guidelines as currently drafted. Further discussions should concentrate on certain specific elements especially in chapters 1, 8 and 9.

b. major areas for improvement or inclusion to complement existing provisions in the Guidelines as needed;

EUMS: Some improvements are still needed in the introduction, as well as in chapters 8 and 9. Our main concern is linked with the future role of molecular testing. In shaping the text further, it should be taken into account that methods develop and 'susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) may be replaced by genotypic methods. Therefore, we suggest to introduce more flexibility in the text and highlight the need to use methods standardized and validated by internationally recognized organizations, where available. The details are highlighted in our specific comments in Annex II.

c. whether references to (i) other international organizations and (ii) antimicrobial use (AMU) are appropriately addressed in the Guidelines considering that, while developed within a One Health Approach, the Guidelines are intended for food safety and aim to ensure that Codex Members are aware of what is needed for monitoring and surveillance of foodborne AMR and AMU, while complementing and remaining consistent with the work of other international organizations; and

EUMS: In our view, references to (i) other international organisations and (ii) antimicrobial use (AMU) are appropriately addressed.

d. whether overall the level of detail provided in the Guidelines is appropriate and the balance needed to ensure that the Guidelines are actively used by Members has been achieved

EUMS: In our view, the overall level of detail is useful and provides, after some further refinement, a very useful basis for implementation of monitoring and surveillance of antimicrobial resistance and antimicrobial use in the food chain offering the necessary flexibility to be adapted to the national situation, either to start monitoring and surveillance systems or to improve the existing ones.

3.2 Specific comments on key aspects identified by the EWG under the following sections that will assist in the finalization of the Guidelines, while taking into account the agreements made by TFAMR07 (2019) on provisions which are common to both the *Code of practice to minimize and contain foodborne antimicrobial resistance* (COP) (CXC 62-2005) and the Guidelines:

Section 1: Comments on the description of AMU in the introduction rather than the inclusion of a formal definition on AMU in Section 3.

EUMS: Whereas we acknowledge that a definition for AMU would be useful, taking into account that finding a consensus for such definition would be very challenging, we support the proposal to introduce a description of AMU in the introduction instead of developing a formal definition for it. The current text for AMU is acceptable.

Additional comments to section 1 to para 7, 10, 11 and 14 are provided in the draft text provided in Annex II.

Sections 2, 3, 5, 6, 11 and 12: Any (i) outstanding issue(s) or (ii) particular point(s) that need refinement for accuracy and/or to improve coherence of the text including consistency with the COP and the *Guidelines for Risk Analysis Principles for Foodborne AMR* (CXG 77-2011).

EUMS: We have no further comments on these sections and can agree with proposed text.

Section 4: Confirm that the revisions to Principles 8 and 9 and removal of part of Principle 2 and all of Principle 10 to the Introduction now provides the flexibility requested by Members and observers.

EUMS: As a compromise, we can agree with the drafted principles (including principles 1-7) with the following comments:

Principle 8. We can accept the current wording of principle 8.

Principle 9. Whereas we would prefer to refer to the comparability of data internationally because this is an important aspect, we can support principle 9 as currently drafted and accept as a compromise that international comparability is described in the introduction.

Principle 10. We acknowledge that principle 10 has been deleted as it does not fit within the scope of the guidelines and that as a compromise, text has been included in the introduction.

Section 7: Figure 1. *Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.* Comments on the proposal to retain and revise the figure in order to provide a unique overview of the framework presented in the Guidelines. CL 2021/33/OCS-AMR 2

EUMS: We support to retain the figure as drafted. As regards the content of section 7, we welcome the shortening and simplification of the text. Specific comments to section 7 been included in the text provided in Annex II.

Sections 8, 9 and 10: Any (i) outstanding issue(s) or (ii) particular point(s) that need refinement for accuracy and/or to improve coherence of the text including consistency with the COP and the *Guidelines for Risk Analysis of Foodborne AMR*, noting that: the level of detail has been reduced to that which was considered essential to provide the intended audience with an overview of the key aspects of monitoring and surveillance with the removal of the overly technical, detailed or prescriptive information and examples except for those necessary for clarity of the text.

EUMS: We welcome the shortening and simplification of the text. Specific comments to sections 8 and 9 have been inserted in the text provided in Annex II.

3.3 Other comments not covered under points 3.1 – 3.2 that may be of relevance to Codex Members or Observers.

EUMS: The current draft text provides a very good basis to finalise the draft guidelines in the forthcoming 8th session of TFAMR.

Annex II

(with comments from EUMS)

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 an integrated “One Health” approach for 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” is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops which may include both the quantities of antimicrobials sold and/or the quantities used.

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. 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. An integrated program includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops/plants and the food production environment.

5. Depending on national priorities, AMR food safety issues, scientific evidence, capabilities and available resources, integrated monitoring and surveillance program(s) should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the program(s).

6. The data generated by integrated monitoring and surveillance programs provide valuable information for the risk analysis of foodborne AMR. It also provides information on the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information to risk managers about AMR and AMU trends and for the planning, 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.

EUMS: Whereas we would have preferred to keep principle 2 as originally drafted, highlighting that monitoring and surveillance program(s) for AMR and AMU along the food chain and the food production environment are an important part of national strategies to minimize the risk of foodborne AMR and contribute to a national food control system, we can accept as a compromise that the latter aspect is introduced in the introduction in para 7.

8. These Guidelines are intended to assist governments in the design and implementation of monitoring and surveillance program(s). They provide a continuum of flexible options for

implementation and expansion, considering resources, infrastructure, capacity, and priorities of countries. Each monitoring and surveillance program should be designed to be relevant for national, and when appropriate, regional circumstances. While these Guidelines are primarily aimed at action at the national level, countries may also consider creating or contributing to international, multi-national or regional, monitoring and surveillance program(s) to share laboratory, data management and other necessary resources.

9. Design and implementation of monitoring and surveillance program(s) should also be assessed on their relevance when foodborne AMR priorities change at the national and international level.

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

EUMS: The aspect of identification and implementation of priority activities, as mentioned in the previous version, is not sufficiently covered by the current text. Therefore, the sentence 'Identification and implementation of priority activities should be followed by enhancements as resources and capacity develop' should be retained. As a compromise, the current text could be adapted to include 'identified priorities'. It would read as follows: 'A continuous improvement of the monitoring and surveillance program(s) should take into account identified priorities, broader capacity issues including the availability of information on AMU and AMR in humans, animals and plants/crops, and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.'

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

EUMS: While we maintain our view that the scope of the guidelines should exclude trade related aspects, we can accept para 11 as a compromise for deleting principle 10. The square-bracketed term 'imported' should be deleted as the same rules should apply for all data from national programs.

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

13. These Guidelines should also be used taking into consideration those already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.

14. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code should be considered.

EUMS: The paragraph could be simplified as follows: "Where appropriate, the standards of other international standard setting organizations, including the relevant standards of the World Organization for Animal Health (OIE standards) related to AMR and AMU ~~published in the Terrestrial Animal Health Code and the Aquatic Animal Health Code~~ should be considered.

2. Scope

15. 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.

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

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

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

3. Definitions

19. The definitions presented in the *Guidelines for risk analysis of foodborne antimicrobial resistance (CXG77-2011)* and *Code of practice to minimize and contain antimicrobial resistance (CXC 61-2005)* are applicable to these Guidelines.

20. The following definitions are included to establish a common understanding of the terms used in this document.

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 target¹.

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

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect². For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and /or resistance determinant(s)¹.

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.

¹ *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*

² *Procedural Manual, Codex Alimentarius Commission*

4. Principles

21.

- **Principle 1:** Integrated monitoring and surveillance program(s) for foodborne AMR and AMU should follow a “One Health” approach.
- **Principle 2:** Monitoring and surveillance program(s) for AMR and AMU along the food chain and the food production environment are an important part of national strategies to minimize the risk of foodborne AMR.
- **Principle 3:** Monitoring and surveillance program(s) should be tailored to the national situation and priorities and may be designed and implemented with the objective of continuous improvement as resources permit.
- **Principle 4:** Monitoring and surveillance program(s) should include data on occurrence of AMR and patterns of AMU, in all relevant sectors as inputs into risk analysis.
- **Principle 5:** Risk analysis should guide the design, implementation and evaluation of national monitoring and surveillance program(s) for foodborne AMR.
- **Principle 6:** Priority for implementation should be given to the most relevant foodborne AMR issues to be analyzed from a public health perspective.
- **Principle 7:** Monitoring and surveillance program(s) should incorporate to the extent practicable, the capacity for epidemiological investigation and identification of new and emerging foodborne AMR or trends.
- **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.

EUMS: See general comments. We can agree with proposed text.

5. Risk-based approach

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

23. Information from integrated monitoring and surveillance of AMR and AMU along the food chain, including data from other sources when available, provides important information for risk assessment and risk management decision-making on the appropriateness of the control measures to prevent and minimize foodborne AMR.

24. When knowledge of AMR risks in a national situation is limited, monitoring and surveillance program(s) may initially be designed according to the relevant evidence that is available on AMR hazards and their potential to result in public health risks. AMR 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 AMR*.

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

EUMS can agree with proposed text.

6. Regulatory framework, policy and roles

26. Integrated monitoring and surveillance program(s) for AMR and AMU requires good governance by the competent authorities. As part of a national action plans (NAP) for AMR, the competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with human health, animal health, plant health, the environment and other relevant authorities.

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

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

29. It is important for competent authorities to have access to AMU data in their country.

EUMS can agree with proposed text

7. Implementation of an integrated monitoring and surveillance program for foodborne AMR

30. The concept of continuous improvement facilitates the design and implementation of integrated monitoring and surveillance program(s) and allows countries to carry out activities to progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge. Preliminary activities, initiating monitoring and surveillance activities, evaluation and review are part of the framework for monitoring and surveillance program(s).

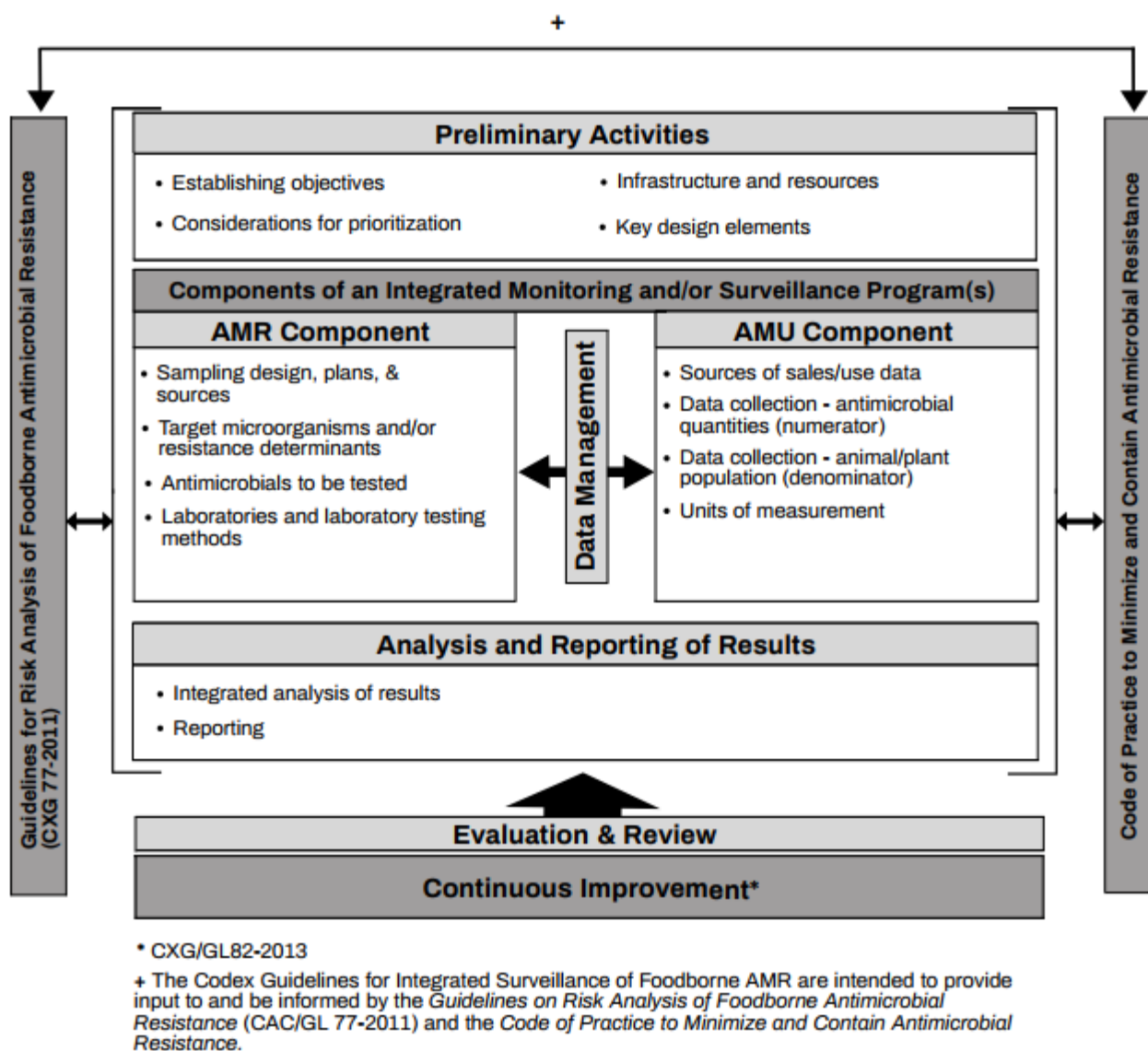


Figure 1. Framework for the design and implementation of integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.

EUMS agree to retain figure 1 and revise it according to the finalised guidelines”

7.1. Preliminary activities

7.1.1 Establishing the monitoring and surveillance objectives

31. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programs, AMR NAPs and relevant evidence of the AMR and AMU situation, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop health sectors and the environment). Competent authorities should identify the challenges that they currently face during the implementation of these activities.

32. 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., convenience 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).

EUMS: In the second bullet point, the example in the bracket should be deleted. Convenience sampling does not allow representative data collection, thus this example is not appropriate. If an alternative is needed, 'systematic sampling' or 'random sampling' could be mentioned.

7.1.2 Considerations for prioritization

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

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

7.1.3. Infrastructure and resources

35. Once the objectives and priorities have been established, the competent authority should determine the infrastructure, capacity and resources required to meet the objectives.

36. The evolution of integrated monitoring and surveillance program(s) does not need to strictly follow the order described in these Guidelines AMU monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. However, as both types of data benefit from a joint analysis, it is useful if the components of the program(s) are aligned during development to allow an integrated analysis.

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

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

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

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

40. 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.

41. 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 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 the data may be useful.

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 control/assurance procedures.
- 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 micro-organisms as available.
- Risk profile and risk assessment findings.

8.1. Sampling design

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

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

EUMS: We agree with rephrasing the text but instead of 'aspects' the term 'coverage' should be used to clearly highlight that it is important to collect data which are representative for the time periods and regions.

46. Once a sampling design is established, consistency in sample types and methodology should be achieved for 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 representative sample from the selected sample source at the selected point(s) in the food chain.
- Sample size, statistical methods and underlying assumptions of the data used to calculate the number of samples and isolates (e.g. frequency of recovery, the initial or expected prevalence

of AMR in that microorganism and the size of the population to be monitored).

- Statistical power, precision and goals of testing.
- Limitations to data interpretation.

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

- Sampling strategy (e.g., active or passive).
- Target animal or plant/crop species or food commodities.
- 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 should consider:
 - 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.

EUMS: As regards the second bullet point, “**and food production environment**” needs to be added to ensure full coverage of all relevant areas. This was highlighted before (previous version of the GLIS) in para 46, which is now deleted.

49. As the program(s) develop, the sampling plan can be broadened to include additional food commodities and gradually be more representative of the population of interest.

EUMS: This sentence still needs some rewording. Broadening the sampling should not be restricted to food commodities, thus ‘target population’ might be used instead. More importantly, sampling always needs to be representative of the population covered. Improvements could cover the type of populations covered (regional, in more detail), the points in the food chain, the sampling strategies used as well as sample size (to improve the precision of the estimate). The following wording might be used: ‘As the program(s) develop, the sampling plan can be broadened to include additional ~~food commodities~~ **animal or plant/crop species and production types** or food commodities, points in the food chain, sampling strategies including sample size, and **gradually be more representative cover better of the populations of interest**’.

8.3. Sample sources

50. When identifying the sample sources to be included in the monitoring and surveillance program, consideration should be given to the major direct and indirect food exposure.

51. Initial implementation might include a limited selection of sample sources at one or more specific points along the food chain. The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of AMR.

52. Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances.

53. The integrated program(s) should reflect the food production in the country and cover samples from all relevant stages of the food chain.

54. Considerations for the selection of possible sample sources at different points of the food chain are:

- **Food producing animals**

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

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

For integration, samples from food-producing animals should be collected from the same animal species at the slaughterhouse and retail.

EUMS: Whereas we agree with moving this sentence to this place, we suggest to keep the original text saying 'from the same animal species as retail samples.' The rationale is that we should not fix that sampling needs to be performed at slaughterhouse, as also sampling at farm level might be relevant for integration purposes. And for some production types (e.g. egg production), slaughter is not the relevant point in the food chain. Thus more flexibility should be allowed.

Samples taken from healthy animals destined for slaughter may be collected on-farm, during lairage, or at the slaughter. Collection of samples from animals not immediately entering the food chain can provide additional information on AMR at the population-level.

- At the farm-level, sample options may include faeces, feed, litter or bedding, dust, fluff, water, soil, sewage, sludge or manure.
- At lairage, sample options may include pen floors, trucks, crates, or dust.
- At slaughter, sample options may include caecal contents or lymph nodes. In some animal species, these samples may be representative of the pre-slaughter environment and may not provide an estimate of AMR arising at the farm level. Samples collected after slaughter (e.g., carcass) may provide an estimate of contamination arising from the slaughterhouse.

- **Plants/crops**

The selection of plants/crops should be risk-based and relevant to the country's production systems.

- At the harvest and farm levels, sample options may include plants/crops, soils, fertilizers or irrigation water.
- At post-harvest level, sample may be collected during transport, processing and packaging and sample options may include the plant/crop, surfaces, dust, washing or cooling water.

- **Farm input**

Examples of sample options may include regular feed or medicated feed, fertilizers or other relevant food production inputs.

- **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).

At the retail-level, examples of 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.

- **Food production environment**

Examples of sample options may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets.

8.4. Target microorganisms and resistance determinants

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

EUMS: To improve clarity of the text, it could be modified as follows: 'Selection of the target microorganisms and resistance determinants should be considered based on their relevance to public health.'

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

57. Examples of bacterial species for consideration may include:

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

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

59. Whenever possible the characterization of bacterial isolates to the species-level and as feasible, molecular analysis of particular isolates that may present a public health concern may be undertaken.

EUMS: Whereas we agree with the suggested shortening the text we do not believe that it is sufficient to require only characterization at species level, e.g. for *Salmonella*. Furthermore, characterization at species level (and beyond) should always be undertaken. The sentences may read as follows: 'Whenever possible the characterization of bacterial isolates to the species-level (and beyond) should be undertaken and as feasible, molecular analysis of particular isolates that may present a public health concern ~~may~~ should be considered undertaken.'

60. 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 population.

8.5. Laboratories

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

- a. Performing bacterial isolation, identification (to species level), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.
- b. Accreditation in accordance with national or international guidance or have a validated Standard Operating Procedure for the monitoring purposes in place.
- c. Participating in external quality assurance system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).
- d. Being equipped with facilities and having procedures to maintain sample integrity (e.g. storage temperature and time between sample reception and analysis) and traceability.
- e. Storing isolates and reference strains using methods that ensure viability and absence of change

in the characteristics and purity of the strain.

- f. Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary.

EUMS: We agree with the suggested rephrasing of the text. In section a) the word 'performed' should be deleted as it is now repetitive. The aspect of molecular analysis of particular isolates as highlighted in para 58 needs to be addressed in the section 8.5. on laboratories. In section f) it might be added: 'Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary and carry out molecular characterization where feasible.'

8.6. Antimicrobial susceptibility testing

8.6.1. Methods and interpretative criteria

62. Susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by internationally recognized organizations where available, should be used.

EUMS: According to the current text, 'susceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk diffusion) that are standardized and validated by internationally recognized organizations where available, should be used to ensure reliable and comparable data.' This might be outdated in the future and be replaced by genotypic methods. Nevertheless, the details listed might be quite relevant for most monitoring and surveillance approaches. Therefore, we suggest to keep the text, but to introduce a new paragraph reading as follows: "Phenotypic or genotypic methodology might be considered in the future for antimicrobial susceptibility testing. For both approaches, the methods need to be standardized and validated by internationally recognized organizations where available."

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 according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or Clinical Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., disk diffusion zone diameters or MIC values). When neither tables or standards are available program-specific interpretive criteria or categories may be used.

EUMS: We agree with the adjusted text but we would prefer to keep the word 'consistently' (...results for MICs or disk diffusion, should be **consistently** undertaken according to...) as it may be relevant to use over time always the same interpretation criteria.

65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off value (ECOFF) (i.e., wild-type or non-wild type) or clinical breakpoint (i.e. resistant, intermediate or susceptible). The use of ECOFFs as interpretative criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. The use of clinical breakpoints may differ between animal species. The interpretative criteria or category used, should be included in the reporting, interpretation and analysis of data.

EUMS: We agree with the adjusted text as it allows some flexibility but also ensures clarity. The second last sentence should read as follows 'The use of clinical breakpoints may differ between animal species' as just the values are different but not the way the values are applied.

66. Raw quantitative data should be maintained in order to allow comparability of results, for early recognition of emerging AMR or reduced susceptibility and 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 and 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 also take into account the classes and uses in the relevant animal and plant/crop production sectors and their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if not used in animal and plant/crop production sectors.

71. Antimicrobials to be tested may be prioritized based on antimicrobials that have been ranked with higher priority for human health and/or other relevant antimicrobials that have an influence on the selection or co-selection of resistance. Antimicrobials specified from national risk prioritization may also be considered for inclusion in the susceptibility testing panels.

EUMS: Whereas we can agree with rephrasing previous paragraphs, the requirement should remain to prioritize antimicrobials that have been ranked with higher priority for human health, as this is very important to follow the One Health approach, i.e. the first sentence in para 70 should read: 'Antimicrobials to be tested ~~may~~ should be prioritized based on antimicrobials that have been ranked with higher priority for human health...'

8.6.3. Concentration ranges of antimicrobials

72. The concentration ranges used, should ensure that both ECOFFs and clinical breakpoints, when available, are included in order to allow comparability of results with human 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. Molecular testing may be used for the detection of resistance determinants and for epidemiological analysis, according to country specific scenarios and resources.

EUMS: Whereas we can agree to delete all the examples, instead of 'may be used' it should be said 'needs to be used' as only these methods allow to detect and analyse the aspects mentioned. As already said in para 58, this needs to be applied if feasible.

74. Molecular characterization may be useful for the rapid identification of resistance clusters and outbreak investigations. Molecular characterization may inform the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants in humans, animals, food and environmental reservoirs.

EUMS: We do not agree with the suggested amendments. As already said in para 58, this needs to be applied if feasible. But it is obvious that without application of molecular methods, resistance determinants cannot be detected, clusters not identified and sources and transmission pathways not determined. The text in para 73 should remain as originally drafted and read as follows: 'Molecular characterization ~~may be useful~~ is an important tool for the rapid identification of resistance clusters

and outbreak investigations. Molecular characterization ~~may~~ informs the determination of epidemic source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants in humans, animals, food and environmental reservoirs.'

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

EUMS: Whereas we can agree to delete some text here, we need to make sure that sequence data are generated and stored. Therefore, the para should read as follows: '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 for the early detection of resistant microorganisms of high public health importance.

EUMS: Whereas we can agree to delete the specific mentioning of WGS, molecular testing is needed to confirm the presumptive early detection of resistant microorganisms of high public health importance. Therefore, instead of 'may be useful' it should be said 'needs to be used' for the early detection of resistant microorganisms of high public health importance. The sentence would read as follows: 'Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and needs to be used for the early detection or confirmation of resistant microorganisms of high public health importance.'

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 may include:

- a. General description of the sampling design and randomization procedure.
- b. Specific information about the origin of the sample (e.g., food producing animal or plant/crop species, type of production, where and when the sample was collected, etc.
- 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. It is also necessary to report the standard used for the interpretation of the results.

EUMS: Whereas we can agree with most of the rephrasing of the text as suggested, we consider it important to say that the information listed should be collected as this is necessary for correct interpretation and use of the data. The first sentence would read as follows: 'Information for each individual sample ~~may~~ should include:'

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

82. Antimicrobial use refers to the quantities of antimicrobials intended for use in animals or

plants/crops, which includes the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops.

EUMS: This is a repetition to text in para 2 and can be deleted.

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

83. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. Through pilot studies, competent authorities may explore collection of antimicrobial use data. Some aspects of data collection or reporting need to be specified for sales vs. other types of use data; this is reflected below.

EUMS: The third sentence in para 82 may be deleted as it does not really contribute to clarity of the text. Instead, the second sentence of para 83 may be moved here. The new para 82 would read as follows: "Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. ~~Through pilot studies, competent authorities may explore collection of antimicrobial use data.~~ Some aspects of data collection or reporting need to be specified for sales vs. other types of use data; this is reflected below.

84. Sales data can be valuable indicator to monitor trends although it may not always reflect actual use, administration or application. The competent authority should consider the limitations of each type of data.

EUMS: As suggested above, the second sentence of para 83 would be better placed as 3rd sentence in para 82 as it fits to both types of data.

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

86. 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.

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

1. Identification of the scope of the data to be captured (e.g., the antimicrobial agents, classes or sub-classes). The scope may also consider mechanisms of antimicrobial action, relevant resistance data and reporting requirements.
2. Identification of the most appropriate points of data collection and the stakeholders that can provide the data.
3. Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) and quantitative information on the antimicrobials intended for use in food producing animals or plants/crops.
4. Nomenclature of antimicrobial agents harmonized with international standards where available.
5. Identification, where possible, of the plant/crop type and species of food-producing animals for which the antimicrobials were intended to be used.
6. Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).
7. Information, where possible, on antimicrobial dose, dosing interval and duration.

8. Technical units of measurement for reporting antimicrobial sales or use.

9.2. Sources of sales/use data

88. 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.

89. Data on quantities of antimicrobials sold or used at the national level may differ. Differences may include; loss during transport, storage and administration, stock purchased and held for future use, off-label use, and fluctuations in animal or plant/crop populations.

EUMS: In order to clarify the examples and to avoid that they describe bad practices, the second sentence should be modified as follows: “Differences may include: loss during transport, storage (due expiry date), administration (not whole package administered) or loss due package damages, stock purchased and held for future use, offlabel use, and , influenced by fluctuations in animal or plant/crop populations and/or infectious diseases incidence.”

9.3. Data collection: Antimicrobial quantities (numerator)

90. The numerator or antimicrobial quantities represents the amount of antimicrobial agents sold or used and in some cases may be based on estimates. The numerator is normally expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year. The numerator may also take into consideration the daily dose of the antimicrobial administered (i.e. Defined Daily Dose). Numerators for sales and/or use data may vary depending on the objectives of the monitoring and surveillance program(s) and the type and source of data.

EUMS: Whereas we can agree with some of the rephrasing, the text in the first two sentences should be further improved for clarity and to allow flexibility and not to encourage using estimates in establishing the numerator. It should therefore read as follows: ‘The numerator ~~or antimicrobial quantities~~ represents the amount of antimicrobial agents sold or used ~~and in some cases may be based on estimates~~. The numerator ~~is normally~~ may be expressed as the weight in kilograms of the active ingredient of the antimicrobials sold or used per year.’

91. To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold or used, the pack size and the strength per unit. The sales data can be converted to kilograms of active substance.

EUMS: As the focus in the text is on sales data, the text needs some more clarification. It should read as follows: ‘To calculate the quantities of antimicrobials sold, the data should include identification of the antimicrobial product, the number of packs sold ~~or used~~, the pack size and the strength per unit.’

92. To calculate the quantities of antimicrobials used, the data should include characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial (e.g. area, species, type, number, body weight, age).

EUMS: As not all reasons for administering antimicrobials to animals would be understood as “treatment”, the term “treated” should be replaced with “administered”.

93. Information about the coverage of the data collected (e.g., percentage of farms included in the monitoring or surveillance program(s)) is also important to further interpret these data.

9.4. Data collection: Animal population / plant/crop production (denominator)

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

95. Information collected may include the number of animals, animal species, animal production type, estimated animal weights, plant species, plant/crop production and plant/crop area.

96. The denominator for reporting of antimicrobial sales or use may be determined in parallel to setting up collection of sales or use data. Elements for calculation the denominator may include:

A. For animals

- Sales denominator: animal populations and weights (i.e. biomass) and the monitoring and/or surveillance period.
- Use denominator: the number of animals, the average body weight or age at treatment and/or the total weight of slaughtered or marketed animals and the time they are under monitoring and/or surveillance.

EUMS: The term “treatment” in bullet point 2 should be replaced with “administration” (see our comment on para 92).

B. For plants/crops

- If no current international standards exists or are available, plants/crops denominators may be established according to the national situation and may consider the quantities (kg) of harvested crops or area (hectares) of land used for crop production that may be at risk of being exposed to the of antimicrobial agents.

9.5. Units of measurement (numerator/denominator)

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

98. Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass.

EUMS: Whereas we can agree with most of the rephrased text, we still think that it is important to also introduce the concept of animal days under risk as currently only the biomass concept is exemplified. The para should read as follows: ‘Options of units of measurements for sales and/or use in animals may include: mg of active ingredient sold or used/kg of animal biomass, or number of Defined Daily Doses for animals (DDDvet)/kg animal biomass or number of Used Daily Doses/1000 animals at risk.’

99. Units of measurement described in international guidelines to collect antimicrobial sales and use data should be used where possible for international reporting.

10. Integrated analysis and reporting of results

10.1. Management of data

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

101. A confidentiality and data management policy should be put in place. Data should be collected and

stored to maintain data integrity and protect the confidentiality of personal and proprietary information.

102. To facilitate the management of data, ongoing (or regular) validation of the data should be performed.

103. A description of sampling designs, stratification and randomization procedures per animal populations and platan/crop, food production environment or food categories should be recorded for linking the data within and across surveillance and/or monitoring components.

10.2. Analysis of results

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

105. Analysis of data from integrated monitoring and surveillance of AMR may include the comparison of AMR and AMU within or between sectors across the One Health spectrum, to evaluate trends over time, between regions or across host species, across bacterial species or antimicrobial classes.

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

107. Data may originate from different monitoring and surveillance program(s), so comparability is an important consideration. The choice of analytical approaches should allow the investigation of the relationship between AMU and AMR within or across the animal, plant/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized across these sectors to assist in the understanding, investigation of relationships between AMR and AMU.

108. Relevant human isolates to consider for inclusion should be based on data from significant foodborne pathogens according to national epidemiological information and, whenever possible, commensal flora.

109. Integration of data from surveillance of human clinical isolates should facilitate identifying trends in AMR 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.

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

10.3. Reporting of results

111. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders should be encouraged.

EUMS: It would be useful to refer to the One Health approach in reporting of the results. To this end, the paragraph could read: 'Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders under One Health approach should be encouraged.

112. Results of foodborne AMR and AMU monitoring and surveillance should be reported regularly, where resources allow.

113. When available, summary reports on the integrated monitoring and surveillance program(s) of AMR and AMU across humans, animals, plants/crops, food and the food production environment may be made publically available.

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

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

115. 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.

116. 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.
- Identification of relevant monitoring and surveillance program adjustments.
- Share evaluation outcomes with stakeholders.

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

12. Training and capacity building

118. 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.

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

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