JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

WORKING GROUP GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

The following text is the tracked changes version of the Guidelines that are included in the TFAMR08 working document CX/AMR 21/8/6 as Appendix 1, which is available on the TFAMR08 webpage. This document is provided to facilitate transparency on the outcome of the virtual meeting of the working group convened on 10, 11, 15, 16 and 18 June 2021 and the final review by the Guidelines by the Chair and co-Chairs of the working group. The report of the working group is available in CX/AMR 21/8/6.

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, including 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" are is used to refer to the quantities of antimicrobials intended for use in animals or plants/crops, which may be obtained include both the quantities of from data of antimicrobials sold and/or the quantities 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 Iintegrated 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 Iintegrated 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/plants and the food production environment.

5. Depending on nNational 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. They also provide information on the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR. These data may also be useful for epidemiological studies, food source attribution studies and research. Additionally, these data provide information to risk managers about AMR and AMU trends and may serve as inputs for the risk analysis processes including 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.

8. These Guidelines are intended to assist governments in the design and implementation of integrated monitoring and surveillance program(s). They provide a continuum of 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 Ddesign and implementation of monitoring and surveillance program(s) should also be assessed based on their relevance when to foodborne AMR priorities change at the national and international level.

10. A Ccontinuous improvement of the monitoring and surveillance program(s) should take into account identified priorities and broader capacity issues. Continuous improvement includes: ing the availability of information on AMU and AMR in humans, animals, and plants/crops, and reporting, availability of food consumption data, and 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 [imported] 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 ~~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~~.

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.~~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~~.

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 ~~r~~Risk ~~a~~Analysis of ~~f~~Foodborne ~~a~~Antimicrobial ~~r~~Resistance (CXG 77-2011) and Code of ~~p~~Practice to ~~m~~Minimize and ~~c~~Contain ~~a~~Antimicrobial ~~r~~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~~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 target[1].

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 species[1].

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 pathogen[1].

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 effect[2].~~ 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.

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[1] *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*

~~[2] Procedural Manual, Codex Alimentarius Commission~~

Plants/Crops

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

4. Principles

21.

- **Principle 1:** ~~Integrated m~~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 and contain the risk of foodborne AMR.
- **Principle 5:** Risk analysis should guide the design, implementation and evaluation of ~~national~~ monitoring and surveillance program(s) ~~for foodborne AMR~~.
- **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 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 ((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 ~~capacity for epidemiological investigation and~~ 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

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 program(s) ~~of AMR and AMU along the food chain,~~ including data from other sources when available, are important for ~~provides important information for~~ risk assessment and risk management decision-making on the appropriateness of the control measures to ~~prevent and~~ minimize and contain foodborne AMR.

24. When knowledge of AMR ~~risks in a national situation~~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 ~~AMR~~Antimicrobial Resistance (CXG 77-2011)*.

25. 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

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 responsible ~~should develop an overarching policy framework~~ for the monitoring and surveillance activities along the food chain should ensure ~~in~~ collaboration with human health, animal health, plant health, the environment and other relevant authorities.

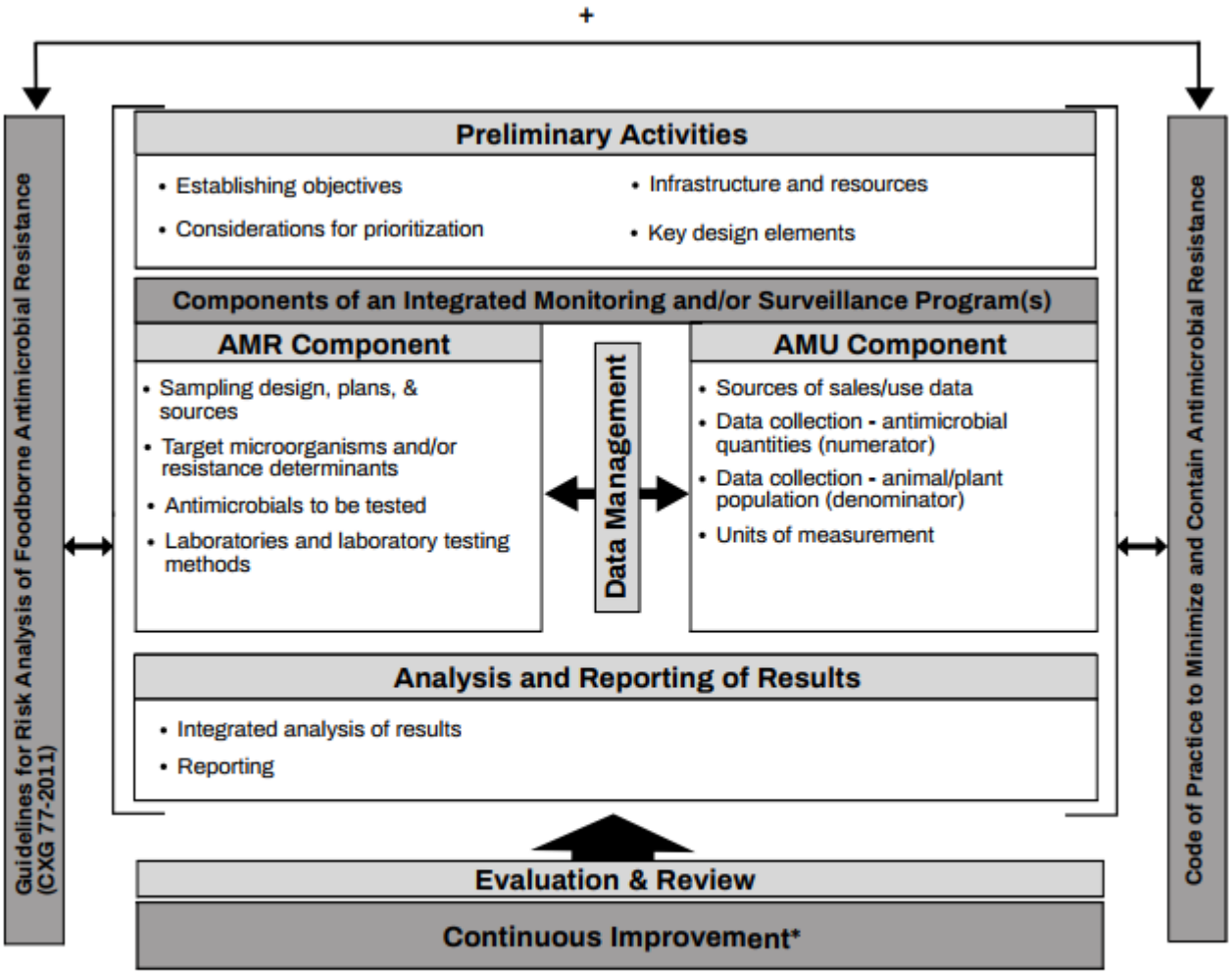
27. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance program(s).

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 assessment and risk management decisions.

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

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

30. 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 ~~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).~~ Undertaking pilot studies and testing may provide valuable insights the design for monitoring and surveillance program(s).



* CXG/GL82-2013

+ 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* (CAC/GL 77-2011) and the *Code of Practice to Minimize and Contain Antimicrobial Resistance*.

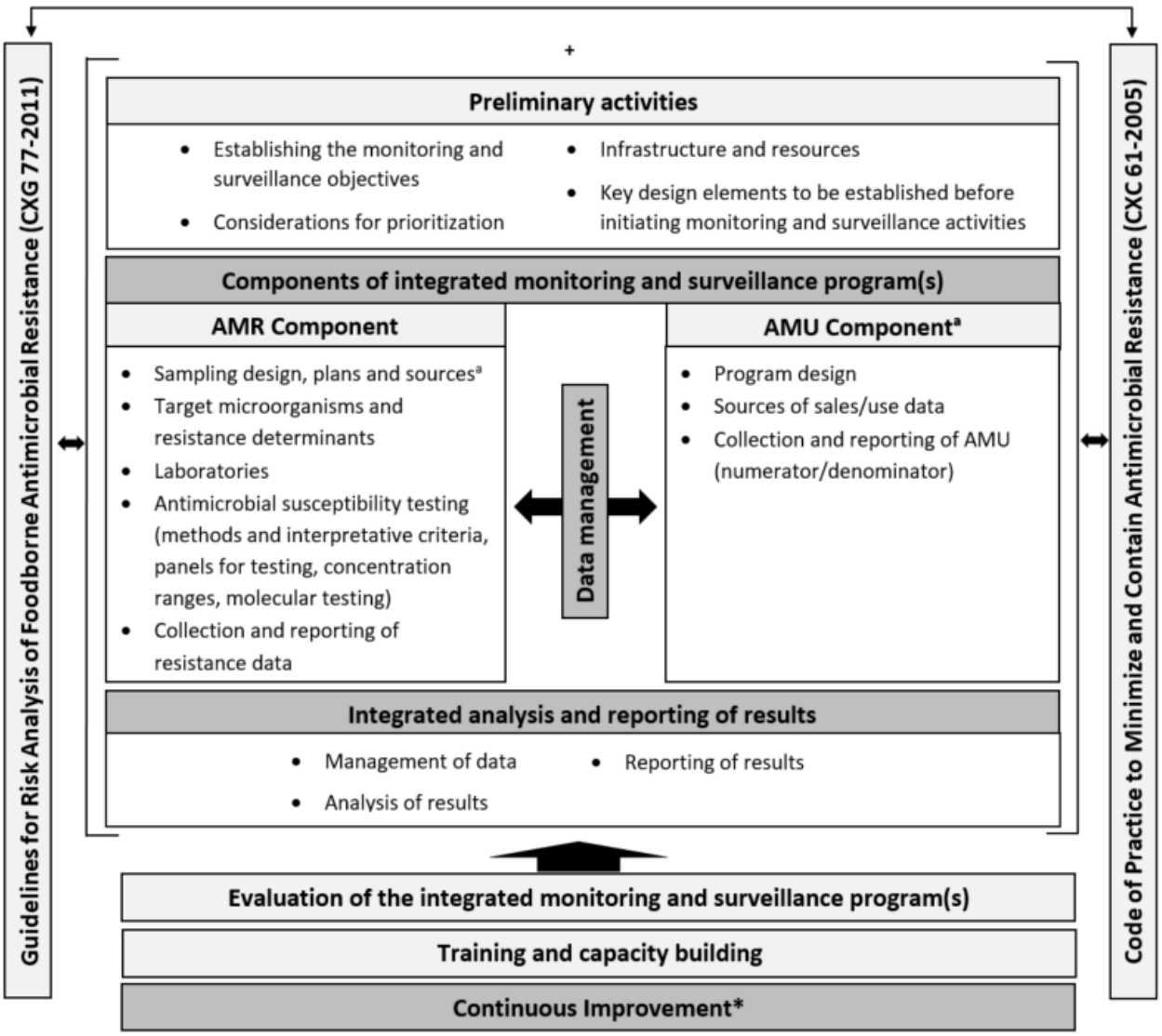


Figure 1. Framework for ~~the design and implementation of~~ integrated monitoring and surveillance program(s) for foodborne AMR and AMU along the food chain.

~~7.1. Preliminary activities~~

~~7.1.1.~~ 7.1 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, the AMR NAPs, ~~and~~ relevant information on ~~evidence of the~~ AMR and AMU ~~situation~~ in the country, 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~~ 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).

~~7.1.2.~~ 7.2 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 data required for risk analysis or results of risk analysis~~considerations of risk profiles and risk assessments~~.

~~7.1.3.~~ 7.3 Infrastructure and resources

35. Once the objectives and priorities have been established, the competent authorit~~y~~ies 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. Antimicrobial use ~~AMU~~ monitoring and surveillance can proceed at a different rate than AMR monitoring and surveillance and vice versa. ~~However, a~~ 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~~ for integrated analysis.

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

38. The competent authorit~~y~~ies 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.

~~7.1.4.~~ 7.4 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 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.

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

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

46. Once a sampling design is established, consistency in sample types and methodology ~~should be achieved for~~ 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 ~~representative~~ 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 ~~(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 may be active (i.e. designed for AMR surveillance) or passive (i.e. using a system already in place) ~~(e.g., active or passive)~~.
- Target animal or plant/crop species, ~~or~~ 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 ~~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.

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

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

8.3. Sample sources

50. 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.

~~51. Initial implementation might include a limited selection of sample sources at one or more specific points along the food chain.~~ 51bis. The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne 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 where there is science-based evidence that they could contribute to foodborne AMR.

54. ~~Considerations for the selection of p~~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 animal 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 different relevant points along the food chain slaughterhouse and retail.~~

  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~~ 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 ~~options~~ may include faeces, feed[3] and/or feed ingredients, water, litter or bedding~~, dust, fluff, water, soil, sewage, sludge or manure~~ 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 ~~options~~ may include rectal samples or fecal samples from pen floors or ~~, trucks,~~ crates~~, or dust~~.
  - At slaughter, sample ~~options~~ may include carcass swabs, caecal contents or lymph nodes. In some animal species, ~~these~~ caecal contents or lymph nodes~~samples~~ 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 ~~slaughterhouse and retail~~.

- **Food**

  Food samples may be collected at processing, packaging, wholesale or retail. Sample may include both

[3] 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

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.

- **Plants/crops**

The selection of plants/crops should be risk-based and/or guided by the relevant ~~to the country's production systems~~ standard setting bodies where available.

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

- ~~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**

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

~~Examples of s~~Sample ~~options~~ may include the environment of food producing animals and plants/crops, processing, wholesale facilities or retail outlets[4].

8.4. Target microorganisms and resistance determinants

55. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and 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 b~~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 enterococci (*Enterococcus*~~,~~ *faecium and Enterococcus faecalis),* 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 scientific evidence and relevance to public health.

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 bacterial population.

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.

59. Whenever possible the characterization of bacterial isolates to the species-level and as feasible, molecular analysis of

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

particular isolates that may present a public health concern ~~may~~ should be 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 b~~Bacterial isolation, identification (to species and serotype 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~~ quality management system in place.

c. Whenever possible ~~P~~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 including appropriate ~~(e.g.~~ storage temperatures and recording 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 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 where available.

62bis. 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 ~~disk diffusion~~ 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) ~~(i.e.,~~which should be reported as wild-type or non-wild type~~)~~ or clinical breakpoint which should be reported according to the interpretative category~~(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 c~~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 ~~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, as well as ~~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 they are not used in animal and plant/crop production sectors.

71. Antimicrobials to be tested may be prioritized based on ~~antimicrobials~~ 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. ~~Antimicrobials specified from national risk prioritization may also be considered for inclusion in the susceptibility testing panels.~~

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 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, ~~M~~molecular testing ~~may~~ 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 ~~may~~ is a~~be~~ 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 ~~in humans, animals, food and environmental reservoirs~~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 ~~may~~ should include:

a. Reference to the ~~G~~general description of the sampling design and randomization procedure.

b. Specific information about the origin of the sample such as from what, ~~(e.g., food producing animal or plan/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.~~

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 may include the quantities of antimicrobials sold and/or the quantities used in food-producing animals or plants/crops.~~

9.1. Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing 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. 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 versus~~.~~ other types of use data; this is reflected below.

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

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

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 within a country ~~at the national level~~ 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, ~~off-label use,~~ and fluctuations in animal or plant/crop populations.

9.3. ~~Data c~~Collection and reporting of AMU~~: Antimicrobial quantities (numerator)~~

Collection of data

The data collection should cover the following elements:

The numerator

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

91. To calculate the numerator ~~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.~~

The 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. The denominator provides the context for reporting and analyzing the sales and/or use data.

92. ~~To calculate the quantities of antimicrobials used, the data should include c~~Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance periode (e.g. area or quantities harvested, number/percentage of farms included, species, type, number, body weight, age) may also be considered.

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

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

~~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.~~

~~B. For plants/crops~~

- ~~If no current international standards exist 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)~~

Reporting of data

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.

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

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

~~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.~~

~~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, and where feasible, centralized to allow for the appropriate and easy extraction of data ~~(e.g. centralized location)~~ when required and to 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 to protect the confidentiality of personal and proprietary information.

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

103. A description of sampling designs, stratification and randomization procedures per animal populations and plant/crop, food production environment or food categories should be recorded ~~for~~ to link~~ing~~ the data within and across ~~surveillance and/or~~ monitoring and surveillance 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 then 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 the integrated monitoring and surveillance of AMR and AMU 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. When available, other contextual information such as epidemiological data may be considered.

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

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 any~~the~~ relationship between AMU and AMR within or across the food producing animal~~s~~, plant~~s~~/crop~~s~~ 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.

108. AMR data from ~~R~~relevant human isolates ~~to~~ may be considered for inclusion in the analysis and reporting ~~should be~~ based on ~~data~~ information 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~~ the ability to identify trends in ~~AMR~~ resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance in humans, plants/crops and animals.

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 under the One Health approach should be encouraged.

112. Results of integrated ~~foodborne AMR and AMU~~ monitoring and surveillance program(s) should be reported regularly, where resources allow.

113. When available, summary reports on the integrated monitoring and surveillance program(s) ~~of AMR and AMU~~ data across humans, animals, plants/crops, food and the food production environment may be made public~~al~~ly 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 program 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.
- **I**dentif~~ication~~ or provide 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, that historical data are maintained and that the program continues 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 data.

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