DRAFT TANZANIA STANDARD

Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance

TANZANIA BUREAU OF STANDARDS

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Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance

0. Foreword

Antimicrobial resistance (AMR) is a global public health threat requiring a “One Health” approach, integrating human, animal, and environmental health. Monitoring and surveillance of foodborne AMR play a crucial role in ensuring food safety. An integrated programme should systematically collect and analyze data across the food chain while aligning methodologies and practices.

National’s programme should be guided by national priorities, scientific evidence, and available resources, adopting a phased approach for efficiency. The data generated supports risk analysis, epidemiological studies, and food safety improvements while aligning with regional and international standards. Continuous improvement should address emerging priorities, enhance laboratory capacity, and integrate data from multiple sectors. However, AMR monitoring data should not be misused to create unjustified trade barriers.

The purpose of these guidelines is to establish an integrated monitoring and surveillance system for foodborne AMR in the country. They aim to enhance food safety, support risk analysis, align with national and international standards, and promote continuous improvement while preventing unjustified trade barriers.

These Guidelines should be applied in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (AFDC 8 (2567) DTZS) and the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (AFDC 8 (2568) DTZS). Their design and implementation should also consider other relevant standards, including the *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) and the *General Guidelines on Sampling* (CXG 50-2004).

In the preparation of this Tanzania Standard, considerable assistance was drawn from *CXG 94-2021: Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance*, published by the Codex Alimentarius Commission.

1. Scope

This Tanzania standard covers the design and implementation of integrated monitoring and surveillance programme(s) for foodborne AMR and AMU along the food chain and the food production environment.

Although this Tanzania standard does not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated programme within the context of overall risk management of AMR using One Health approach may be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans.

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

This Tanzania standard excludes the antimicrobials used as biocides including disinfectants.

2. Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies;

AFDC 8 (2567) DTZS, Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance

AFDC 8 (2568) DTZS, Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance

CXG 82-2013, Principles and Guidelines for National Food Control Systems.

CXG 50-2004, General Guidelines on Sampling.

3. Terms and definitions

For the purpose of this Tanzania standard the following terms and definitions and those presented in the (AFDC 8 (2567) DTZS) and (AFDC 8 (2568) DTZS shall apply.

3.1 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

3.2 antimicrobial class

antimicrobial agents with related molecular structures, often with a similar mode of action because of interaction with a similar target and thus subject to similar mechanism of resistance. Variations in the properties of antimicrobial agents within a class often arise as a result of the presence of different molecular substitutions, which confer various intrinsic activities or various patterns of pharmacokinetic and pharmacodynamics properties

3.3 antimicrobial resistance (AMR)

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.

3.4 antimicrobial use (AMU)

refers to antimicrobials intended for use as it relates to sales, prescriptions/orders, manufacturing, imports and exports, information on actual administration or application, or any combination of these antimicrobials used for food-producing animals or plants/crops

3.5 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.

3.6 foodborne pathogen

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.

3.7 food production environment

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

3.8 hazard

refers to antimicrobial resistant microorganism(s) and/or resistance determinant(s)

3.9 one health approach

collaborative, multisectoral and trans-disciplinary approach working with the goal of achieving optimal health outcomes, recognizing the interconnection between humans, animals, plants and their shared environment

3.10 monitoring

refers to the collection and analysis of foodborne AMR, antimicrobial use (AMU) and related data and information

3.11 plants/crops

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

3.12 surveillance

systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of data and trends from defined populations to inform risk analysis

4. Principles

4.1 Principle 1: A One Health approach should be applied whenever possible and applicable when establishing monitoring and surveillance programmes for foodborne AMR; contributing to the food safety component of such an approach.

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

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

4.4 Principle 4: Monitoring and surveillance programme(s) should be designed to generate data on AMR and AMU, in relevant sectors to inform risk analysis.

4.5 Principle 5: Monitoring and surveillance programme(s) should be tailored to national priorities and should be designed and implemented to allow continuous improvement in order to safeguard the public against AMR threats.

4.6 Principle 6: Priority for implementation of monitoring and surveillance programme(s) should be given to the most relevant foodborne AMR and/or AMR food safety issues (which are the defined combinations of the food commodity, the AMR microorganism and determinants and the antimicrobial agent(s) to which resistance is expressed as described in AFDC 8 (2568) DTZS) from a public health perspective, taking into account national priorities.

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

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

4.9 Principle 9: Monitoring and surveillance programme(s) should aim 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, contributes to the comparability of data, facilitates the multisectoral sharing and analysis of data and enhances an integrated approach to data management, analysis and interpretation.

5. Risk-based approach

5.1 For the purpose of these Guidelines, a risk analysis approach – as described in the framework for foodborne AMR risk analysis (AFDC 8 (2568) DTZS) – may inform the development, implementation and evaluation of monitoring and surveillance programme(s) with data and scientific knowledge regarding the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health.

5.2 Information from monitoring and surveillance programme(s) and available data from other sources, are important for risk assessment and may inform decisions on the appropriateness of control measures to minimize and contain foodborne AMR.

5.3 When information or data of foodborne AMR within a country is limited, monitoring and surveillance programme(s) may initially be designed according to the relevant data and/or scientific knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (AFDC 8 (2568) DTZS).

6. Regulatory framework, policy and roles

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

6.2 Activities related to monitoring and surveillance programme(s) should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance.

6.3 Sharing of knowledge and monitoring and surveillance results with regional and international organizations on a voluntary basis, should be encouraged since it may improve the global understanding of foodborne AMR and inform risk analysis.

6.4 It is important for competent authorities to have access to all available sources of relevant data in the country.

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

7.1 Preliminary activities for implementation are part of the framework for monitoring and surveillance programme(s).

7.2 Undertaking pilot studies and testing provide valuable insights into the design of monitoring and surveillance programme(s).

7.3 Continuous improvement of monitoring and surveillance activities, progressing should be aligned with national objectives, priorities, infrastructure, technical capabilities, available resources, and emerging scientific knowledge.

8. Establishing the Monitoring and Surveillance Objectives

8.1 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 programmes, the NAPs -AMR, relevant information on AMR and AMU in the country, and any existing activities to address AMR in the different sectors (human, animal, plant/crop, food and the environment). Competent authorities should identify the challenges they face during the implementation of the objectives

8.2 The following aspects should be considered:

a) The primary reasons for the data collection (e.g. to evaluate trends over time and space; to provide data useful for risk assessments; to obtain baseline information).

b) The representativeness of the data collection (e.g. randomized samples; systematic sampling).

c) The setting of proposed timelines for sampling and reporting.

d) A description of how and to whom the information will be reported and communicated.

9. Considerations for prioritization

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

9.2 Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents and sample sources should be informed by national, regional and international public health data and scientific knowledge where it exists.

9.3 Competent authorities should identify existing data sources and data gaps on foodborne AMR and AMU including data required for risk management.

10. Infrastructure and resources

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

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

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

10.4 The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analysing, reporting and archiving data. When possible, a central repository should facilitate data management and improve the efficiency of data analysis.

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

11.1 When designing the monitoring and surveillance programme(s), the following elements should be considered:

AMR:

a) the highest priority microorganisms, panels of antimicrobials and sample sources to be targeted;

b) points in the food chain and frequency of sampling;

c) representative sampling methods, sampling plans, laboratory analysis and reporting protocols; and

d) standardized and/or harmonized methodologies for sampling, testing and reporting.

AMU:

a) antimicrobial distribution chains from manufacturing or import to end users including sales/use data providers;

b) identification of the appropriate points of data collection and stakeholders that can provide intended data;

c) an assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food-producing animals and plants/crops may be useful; and

d) the collection of AMU data may be started on a voluntary basis in agreement with stakeholders who have these data.

11.2 Consideration should be given to additional information provided in the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code.

12. Components of integrated monitoring and surveillance programme(s) for AMR

12.1 This clause is intended to provide an enabling framework, which the country can utilize to establish integrated monitoring, and surveillance of foodborne AMR appropriate to the national situation, and which includes considerations of available resources.

12.2 Integrated monitoring and surveillance programme(s) for foodborne AMR should consider the following elements:

a) sampling design;

b) sampling plans;

c) sample sources;

d) target microorganisms and resistance determinants;

e) antimicrobials to be tested;

f) laboratory testing methodologies and quality assurance systems; and

g) data management activities.

12.3 The initial scope and design of the monitoring and surveillance programme(s) for AMR should consider existing research or surveillance findings, national priorities or national and/or international experience and agreed recommendations. As the AMR programme develops, the scope and design may be adjusted based on one or more of the following factors:

a) monitoring and surveillance findings;

b) epidemiology of antimicrobial-resistant microorganisms as available;

c) risk profile and risk assessment findings; and

d) evaluation of the integrated monitoring and surveillance programme(s).

13. Sampling design

13.1 General consideration for sampling

13.1.1 The design of monitoring and surveillance programme(s) for AMR may build on or be integrated with existing monitoring and surveillance programme(s) or may involve development of new infrastructures and activities specifically for the purpose of foodborne AMR data collection. If data are collected through existing programmes designed for another purpose, this will need to be specified and the methodologies, data limitations and data interpretation should be described.

13.1.2 The sampling design should consider temporal and geographical coverage of data collection.

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

13.2 Sampling plan

13.2.1 The sampling plan should describe the following:

a) The procedure to collect a sample from the selected sample source(s) at the selected point(s) in the food chain;

b) Sample size, statistical methods and underlying assumptions (e.g. representativeness, frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored) of the data used to calculate the number of samples and isolates;

c) Statistical power, precision and objectives of testing; and

d) Strengths and limitations that affect data interpretation.

13.2.2 The following elements should be considered in the sampling plan:

a) Whether the sampling strategy is active (i.e. designed for AMR surveillance) or passive (i.e. using a system already in place);

b) Target animal or plant/crop species, food commodities or food production environment;

c) Point(s) in the food chain where the samples will be taken and sample type;

d) Strata (levels) or risk clusters (groups) to best meet surveillance objectives;

e) Opportunities to collect metadata if available;

f) Target microorganisms, resistance phenotypes (profile) and resistance determinants;

g) Frequency of sampling;

h) Prevalence and seasonality of the microorganisms under study, if known;
i) Standard operating procedures for sample collection;

j) who should collect the samples.

(i) procedures for collection of samples in accordance with the defined sampling strategy and to guarantee that traceability, biosecurity and quality assurance are maintained from collection through to analysis and storage; and

(ii) procedures for storing and transporting the samples in order to maintain sample integrity for testing.

13.2.3 Initial implementation of the sampling plan may include a limited selection of sample sources at one or more specific points along the food chain.

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

13.3 Sample sources

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

13.3.2 The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne AMR. The prevalence of the microbial species should be considered to maximize the likelihood of detection.

13.3.3 The integrated programme(s) should reflect food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR. For integration, samples should be collected from the same species at the different but relevant points along the food chain. Samples should be, to the greatest extent possible, representative of the target animals and plants/crops species and the epidemiological unit being targeted. Possible sample sources are:

a) Food-producing animals

Samples taken from healthy animals may be collected on-farm, live animals markets or at slaughter. Collection of samples from animals not immediately entering the food chain may provide additional information on foodborne AMR at the population-level but may be a lower priority than those animals directly entering the food supply.

- At the farm-level, samples may include faeces, rectal swabs, milk, eggs, feed, water, or other relevant food production inputs and outputs.

Consideration may be given to samples described in the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code, specifically the chapters on *Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes* and the *Development and Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic Animals*.

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

b) Food

(iii) Food product samples may be collected at processing plants, packaging plants, wholesale or retail.

(iv) 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).

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

c) Plants/crops

(vi) The selection of plants/crops should be risk-based and/or guided by the competent authority.

(vii) Samples may be collected from farms, pre-harvest or post-harvest.

d) Food production environment

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

(ix) Samples may be collected from the immediate environment of food-producing animals and plants/crops, processing plants, wholesale facilities or retail outlets e.g. soil, water, litter and bedding, organic fertilizers, sewage or manure.

e) Target microorganisms and resistance determinants

(x) Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and public health. Bacterial species may include:

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

(xi) Target microorganisms from aquatic animals and food of non-animal origin may be determined based on available scientific evidence and/or relevance to public health.

(xii) 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.

(xiii) Monitoring and surveillance programme(s) may begin with phenotypic susceptibility testing for AMR in representative foodborne pathogens and/or indicator bacteria. Options for

expansion may include a broader range of foodborne pathogens, or indicator bacteria, testing for genetic determinants of resistance, virulence and mobile genetic elements.

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

14. Laboratories

Laboratories participating in the monitoring and surveillance programme(s) should consider:

a) Bacterial isolation, identification (to species and serotype level, where relevant), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.
b) Laboratories should have quality assurance/management systems in place, or accreditation in accordance with national or international guidance.
c) Participating in external quality assurance/management system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance programme(s).
d) Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and records that track the time between sample reception and analysis and ensure 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.

15. Antimicrobial susceptibility testing

Methods that are standardized and validated by nationally or internationally recognized organizations should be used where available.

16. Methods and interpretative criteria

16.1 Quality control strains of bacteria should be included and used according to international standards where available to support validation of results and data harmonization.

16.2 Interpretation of results for minimum inhibitory concentration (MICs) or disk diffusion, should be undertaken consistently according to the latest available version of European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or the Clinical and Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e. inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, programme-specific interpretive criteria or categories may be used.

16.3 Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut-off values (ECOFFs) which should be reported as wild type, non-wild type or by clinical breakpoint, which should be reported according to the interpretive category. The use of ECOFFs as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpretive criteria or category used should be included in the analysis and reporting of the data.

16.4 Raw quantitative data should be maintained in order to allow comparability of results, for early recognition of emerging AMR or reduced susceptibility in order to maximize the ability to analyse and compare results across sample sources.

16.5 Quantitative results are 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 necessary for quantitative microbiological risk assessment.

17. The panel of antimicrobials for susceptibility testing

17.1 The panel of antimicrobials for phenotypic susceptibility testing should be harmonized within Tanzania's national monitoring and surveillance program to ensure data continuity and comparability. Efforts should be made to use consistent antimicrobial class representatives across different sample sources, geographic regions, and over time.

17.2 The antimicrobials included in the panel should depend on the target bacteria, the clinical or epidemiological relevance of these antimicrobials and should allow for the tracking of isolates with particular patterns of resistance.

17.3 The antimicrobials included may take into account the classes and uses in the relevant animal and/or plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be considered for inclusion in the panel. 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/or plant/crop production sectors.

17.4 Antimicrobials to be tested may be prioritized based on the Standard Treatment Guideline, and National Essential Medicine List (STG-NEMLIT) and Access Watch and Reserve (AWaRE) categorization for human health, the national context, and/or their influence on the selection or co-selection of resistance.

18. Concentration ranges of antimicrobials

The concentration ranges used should ensure that both ECOFFs and clinical breakpoints, when available, are included to allow for the comparability of results with human data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) used for each antimicrobial agent.

19. Molecular testing

19.1 Whenever possible, molecular testing should be conducted for the detection and characterization of resistance determinants and for epidemiological analysis according to national-specific scenarios and resources.

19.2 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.

19.3 For the rapid identification of resistance clusters and outbreak investigations, molecular characterization may be used.

19.4 Molecular characterization in conjunction with epidemiological information, informs the determination of source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.

19.5 Data generated and stored with appropriate metadata may be used for retrospective and prospective surveillance.

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

20. Collection and reporting of resistance data

20.1 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.

20.2 Information for each individual sample should include

a) reference to the general description of the sampling design and plan;
b) specific information about the origin of the sample such as from what, where and when the sample was collected;
c) general information to identify the isolate, bacterial species, serotype, other subtyping information as appropriate; and
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, the interpretative criteria should be recorded.

20.3 Reporting of results from the monitoring and surveillance programme(s) should be timely.

20.4 Sample sources, analytical methods, AST methods, and interpretive criteria should be clearly described, and differences transparently explained to show where data may not be directly comparable.

21. Components of integrated monitoring and surveillance programme(s) for AMU

21.1 It is important to note that antimicrobial sales data represent a summary of the volume of product sold or distributed through various outlets by the manufacturer intended for sale to the end user, not the volume of product ultimately purchased by the end user for administration to food-producing animals or application to plants/crops.

21.2 This section is intended to provide an enabling framework, which can be utilized to establish monitoring and surveillance of AMU appropriate to the national situation.

21.3 For the monitoring and surveillance of AMU, including sources of data and the collection and reporting of AMU data in food-producing animals, the OIE's *Terrestrial Animal Health and Aquatic Animal Health Codes* should be considered.

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

22.1 The types of data to be collected such as antimicrobial sales and/or use should base on the national monitoring and surveillance objectives. The collection of sales data may serve as a foundation for gradually expanding into antimicrobial use data collection. The competent authority should carefully consider the limitations associated with each type of data. Additionally, specific aspects of data collection and reporting should be clearly defined for sales data versus other types of use data to ensure accuracy, consistency, and relevance in surveillance efforts.

22.2 AMU data is important information to be considered during the interpretation of the results from the AMR monitoring and surveillance programme(s), along with other relevant epidemiological data.

22.3 Sales data may be used to monitor trends although sales data do not always reflect the real use, administration or application of antimicrobials.

22.4 The collection of data on the use of antimicrobials at farm/primary producer level, although may be challenging and resource demanding, should be considered, as it can provide information on the magnitude of species-specific use and on how and why antimicrobials are being administered.

22.5 The choice of units of measurement (i.e. numerator): a metric that expresses the quantities of antimicrobial agents.) and/or indicators (Indicator of AMU: a metric which combines a numerator with a denominator to contextualize the quantities of antimicrobial agents measured.) for AMU should be established depending on method and scope of the data collection and the monitoring and surveillance objectives.

22.6 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 subclasses). The scope may also consider mechanisms of antimicrobial action, relevant resistance data and reporting requirements;
b) Development of a protocol to collect qualitative (e.g. types of antimicrobials on farm) and/or quantitative information on the antimicrobials intended for use in food-producing animals or plants/crops;
c) Harmonization of the nomenclature of antimicrobial agents with international standards, where available;
d) Identification of the plant/crop type and/or species of food-producing animals for which the antimicrobials were intended to be used;
e) Identification of the level of detail required to meet the surveillance requirements (e.g. production type, route of administration or reason for use);
f) Information on antimicrobial dose, dosing interval and duration; and
g) Technical units of measurement for reporting antimicrobial sales or use in food producing animals.

23. Sources of AMU data

23.1 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 in charge of registration of medicinal products, the marketing authorization holder or customs. Care must be taken to avoid double

counting with sales data in the country and take into account that some imported antimicrobials agents may not be 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.

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

24. Collection and reporting of AMU

24.1 Collection of data

24.1.1 The numerator may be an expression qualitatively describing AMU (e.g. classes of antimicrobials agents) or may be the antimicrobial quantity representing the amount of antimicrobial agents sold or used in food-producing animals and/or plants/crops. The calculation of the numerator should consider the quantities of antimicrobial agents which may be reported in different units of measurement according to monitoring and surveillance objectives and the types of data collected

24.1.2 To interpret and/or analyse the data, considerations for the numerator may include identification of the antimicrobial agent or product, the quantity of packages sold or used, and the strength per unit.

24.1.3 The denominator, when used, is 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. Relevance to the food production systems in the country may be considered. The denominator may provide the context for reporting and analysing the sales and/or use data.

24.1.4 Additional considerations for the denominator may include the characteristics of the population of food-producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. species, type, number, body weight, age).

24.2 Reporting of data

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

25. Integrated analysis and reporting of results

25.1 Management of data

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

25.1.2 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.

25.1.3 To facilitate the management of data, ongoing or regular validation of the data should be considered.

25.1.4 Description of the sampling design(s) and sampling plan(s), such as stratification and randomization procedures, for food-producing animals, plants/crops, food production environment or food categories, should be recorded to link data within and across monitoring and surveillance components.

25.2 Analysis of results

25.2.1 The data from the integrated monitoring and surveillance programme(s) may be analysed as described in AFDC 8 (2568) DTZS for risk assessment purposes and to inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials to address foodborne AMR.

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

25.2.3 The detailed methodology and the epidemiological context of the monitoring and surveillance programme(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.

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

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

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

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

25.3 Reporting of results

25.3.1 Results of integrated monitoring and surveillance programme(s) should be reported regularly.,

25.3.2 Whenever possible, reports on the integrated monitoring and surveillance programme(s) data across humans, animals, plants/crops, food and the food production environment should be made publicly available.

25.3.3 Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders including the public should be considered.

26. Evaluation of the integrated monitoring and surveillance programme(s)

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

26.2 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 priorities.

26.3 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:

a) identify the skills needed by evaluators;
b) describe the monitoring and surveillance programme(s) to be evaluated, including the objectives and desired outcomes. This may involve a specific or single component of the entire programme(s) (e.g. sample collection, laboratories, analysis and reporting);
c) identify relevant stakeholders for the evaluation;
d) identify key performance criteria to be evaluated;
e) collect data to facilitate evaluation based on the key performance criteria;
f) consider relevant stakeholder input/feedback;
g) report results of evaluation;
h) draw conclusions on components of the evaluation;
i) identify or provide identification of relevant monitoring and surveillance programme adjustments; and
j) share evaluation outcomes with stakeholders.

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

27. Training and capacity-building

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

27.2 Training of the relevant competent authorities should include different aspects of the monitoring and surveillance programme(s) (e.g. collection, analysis, interpretation and reporting of the data).

27.3 Training of relevant stakeholders at the national level on different aspects of the monitoring and surveillance programme(s) is recommended.