

CODEX ALIMENTARIUS COMMISSION



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Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Sixth Session

PROPOSED DRAFT GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE (REVISED)

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

The Chair and Co-chairs of the EWG of the Guidelines would like to offer the following information to facilitate the discussion on Sections 1 to 6 and Sections 11 to 13 of the Proposed draft Guidelines on Integrated surveillance on integrated monitoring and surveillance of foodborne antimicrobial resistance

Taking into account comments submitted in response to CL 2018/75-AMR, the Sections 1 to 6 and Sections 11 to 13, the following revisions have been made.

1. Introduction and purpose of the Guidelines

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 that incorporate an integrated approach to risk ~~management~~ analysis. The political declaration adopted during the High-Level Meeting on Antimicrobial Resistance at the General Assembly of the United Nations in 2016 committed member countries to developing multi-sectoral national action plans that involve all stakeholders within a "One Health" approach and to improving national systems of monitoring and surveillance of AMR and antimicrobial use (AMU).

2. For the purpose of these guidelines, "monitoring of AMR and AMU" is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and AMU related data in defined populations when these activities are not associated with a pre-defined risk mitigation plan or activity. "Surveillance of AMR and AMU" refers to the same activities when these are associated with a pre-defined risk mitigation plan or activity.

3. An integrated monitoring and surveillance system includes the coordinated and systematic collection of samples at appropriated stages along the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes ~~ing~~ the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices ~~as well as and~~ the integrated analysis of relevant epidemiological information from in humans, animals, foods, crops and environment to the greatest extent ~~practical~~ possible.

4. The data generated by integrated monitoring and surveillance systems provide essential information for the risk analysis of foodborne AMR. ~~It provides essential input to risk assessment and data. These data are also essential~~ for epidemiological studies, food source attribution studies and other operational research. It provides information to risk managers about AMR and AMU trends and for the planning, implementation and evaluation of risk mitigation measures to minimize any public health risk due to resistant ~~tee~~ microorganisms and resistance determinants.

5. It also contributes to the promotion and protection of public health by providing information to risk managers about, how ~~resistant~~ infections caused by resistant bacteria differ from ~~susceptible~~ infections caused by susceptible bacteria, and the impact of interventions designed to limit the emergence, selection, and dissemination ~~spread~~ of AMR.

6. These guidelines are intended to assist governments in the design and implementation of monitoring and surveillance systems for food-borne AMR along the food chain ~~at the national level~~. Such ~~programs~~ systems are a fundamental part of national strategies and plans to minimize foodborne AMR and are an important component of a comprehensive national food safety system.

7. ~~While these guidelines are primarily aimed at action at the national level, countries may also consider creating multi-national or regional monitoring and surveillance systems to share laboratory, data management and other necessary resources.~~

8. ~~Each country should design and implement a system for~~ monitoring and surveillance ~~system of foodborne AMR and AMU along the food chain is designed to ensure~~ that is appropriate ~~for these~~ national circumstances. This should be informed by all available knowledge on ~~priority~~ foodborne risks due to AMR while taking into consideration the international dimension of AMR and the need for data comparability between countries ~~and or~~ sectors.

9. New scientific knowledge should be incorporated into integrated monitoring and surveillance programs as it becomes available to improve the design of the ~~programs-systems~~ and to enhance analysis and utility of existing information and data. Design and implementation of ~~programs-systems~~ should also evolve as AMR policies and priorities change at the national and international level.

10. ~~National~~ AMR scenarios are likely to vary between countries and these guidelines should be used to foster a gradual implementation of monitoring and surveillance systems at the national level. Identification and implementation of priority activities should be followed by enhancements as ~~the national situation permits resources and capacity develop~~. A gradual approach to monitoring and surveillance should take into account broader capacity issues ~~e.g. including the~~ availability of information on AMU in humans, animals and crops, human health care infrastructure, human clinical AMR data and reporting, availability of food consumption and agriculture production data, and cross-sector laboratory proficiency and quality assurance.

~~These guidelines will contribute to the development and implementation of National Action Plans (NAP) on AMR that make the best use of available resources at the national level, with the goal of continuous enhancement as more scientific knowledge, technical capability, data and funding becomes available.~~

11. ~~Application of t~~These guidelines should be applied in conjunction with t 0020 z he *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005). Design and implementation aspects of these guidelines should specifically take into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011), as well as other relevant Codex texts including *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) whenever appropriate.

12. These guidelines should also be used ~~in taking into consideration conjunction with~~ those already developed by other international standard-setting organizations and advisory bodies especially the WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) *Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach* and OIE standards related to AMR and AMU published in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code*.

~~While these guidelines are aimed at action at national level, countries may consider creating multi-national or regional monitoring and surveillance systems to share laboratory, data management and other resources.~~

2. Scope

13. These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, including animals, crops and the production environment.

14. [These guidelines focus on foodborne AMR].

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

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

17. Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines. [In circumstances where a country may decide to include in the integrated system the monitoring and surveillance of biocides, the design and implementation should preferably be broadly consistent with these guidelines to facilitate comparability of data and analysis.]

18. Implementation of TThese guidelines will ~~provide aid facilitate in~~ the generation and use utilization of appropriate AMR and AMU data from humans, animals, crops, food and environment in order to conduct integrated analysis of all these data.

19. Reporting of standardized and harmonized data generated through national monitoring and surveillance systems to international organizations and in return use of information generated from global monitoring and surveillance databases ~~are is~~ highly desiredable aspects of integrated monitoring and surveillance systems at the national level.

3. Definitions

*Antimicrobial agent: (to be aligned with CXC 61-2005)

Any substance of natural, semi-synthetic or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target¹. The term antimicrobial agent is collective for antiviral, antibacterial, antifungal and antiprotozoal agents.

[Biocides]

*Crops/plants: (definition to be discussed and aligned with CXC 61-2005)

A cultivated plant that is grown for [as] food or feed, specially a grain, fruit or vegetable, including all edible parts.

*Food chain:

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

Hazard:

A biological, chemical or physical agent in, or condition of, food with the *potential* to cause an adverse health effect². For the purpose of these guidelines, the term hazard refers to AMR microorganism(s) and /or resistance determinant(s)³.

*One Health approach to AMR: (to be aligned with CXC 61-2005)

An internationally-recognized collaborative and trans-disciplinary approach working at the local, regional, national and global level, to design and implement programs, policies, legislation and research on AMR, in which recognizing the interconnection between humans, animals, plants and their shared environment, multiple sectors communicate and work together with the goal of minimizing the development of AMR and achieving optimal public health outcomes .

Prioritized antimicrobial agents:

For the purpose of integrated monitoring and surveillance, antimicrobial agents prioritized as being of importance to public health e.g. according to the *WHO List of Critically Important Antimicrobials* (WHO CIA List) and where these exist, national lists based on national official risk analysis and country's unique situation.

~~Risk-based approach to surveillance and monitoring of foodborne AMR:~~

~~For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system along the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.~~

4. Principles

These principles should be read in conjunction with the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

- **Principle 1:** An integrated monitoring and surveillance system for foodborne AMR should incorporate follow an "One Health" approach;
- **Principle 2:** Monitoring and surveillance programs-systems for AMR and AMU along the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and a core component of a national food safety system-program;
- **Principle 3:** A national monitoring and surveillance program-system should be tailored to the domestic national situation and priorities and may be designed and implemented according to a stepwise approach with the objective of continuous improvement and enhancement as resources permit;
- **Principle 4:** Monitoring and surveillance programs should include data on occurrence of AMR and patterns of AMU, in all relevant sectors so as to support risk analysis and policy initiatives (e.g. development of mitigation strategies);

¹ *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*

² Procedural Manual, Codex Alimentarius Commission

³ *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*

- **Principle 5:** Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance ~~program-systems~~ for AMR, with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health;
- **Principle 6:** ~~In using a stepwise approach,~~ Priority should be given to the most relevant design elements to be analysed from a public health perspective (e.g. defined combinations of the food commodities, the ~~AMR~~ microorganism and resistance determinants and the antimicrobial agent(s) to which resistance is expressed ~~to be analyzed~~);
- **Principle 7:** Monitoring and surveillance ~~programs-systems~~ should incorporate to the extent practical possible capacity for epidemiological investigation and identification of new and emerging foodborne AMR hazards/risks and trends;
- **Principle 8:** Laboratories involved in monitoring and surveillance should have effective quality assurance systems in place and participate in external proficiency testing schemes (External Quality Assessment Schemes);
- **Principle 9:** A national monitoring and surveillance system should strive to harmonize laboratory methodology, data collection, analysis and reporting across all sectors as part of an integrated approach. Use of internationally recognized, standardized and validated antimicrobial susceptibility testing (AST) methods and harmonized interpretative criteria are essential to ensure that data are comparable ~~at national level~~ and to enhance an integrated approach to data management and reporting at the international level;
- **Principle 10:** Countries should strive to conduct research projects and epidemiological studies to enhance the technical capability and effectiveness of the integrated monitoring and surveillance ~~program-system~~ (e.g. new analytical methods, source attribution studies, monitoring of indirect inputs to the food chain, cross-contamination of foods, molecular epidemiology of emerging clones and resistance determinants);
- **Principle 11:** Data generated from national monitoring and surveillance ~~programs-system~~ of AMR in imported foods should not be used to inappropriately generate barriers to trade.

5. Risk-based approach

20. For the purpose of these guidelines, a risk-based approach is the development and implementation of a monitoring and surveillance system along the food chain that is informed by data and scientific knowledge on the likely occurrence of AMR hazards at a step (or steps) in the food chain and their relationship with risks to human health.

~~In applying a risk-based approach to the design of an integrated monitoring and surveillance system, maximum use should be made of available information on foodborne AMR risks to human health at the national level.~~

22. Integrated monitoring and surveillance of AMR and AMU in the food chain along, with data regarding AMR transmission through food handling, environmental spread or other routes of transmission, provides essential information for risk assessment and risk management decision-making on appropriate control measures in human, plant and animal health.

23. While an integrated monitoring and surveillance system should ideally be designed according to knowledge of possible food-borne AMR risks to public health in the national situation, such knowledge is very limited in most countries. Consequently, most programs ~~will-should~~ [initially] be designed according to the 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 paragraph 26 of the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

24. Knowledge and information on foodborne AMR hazards, risk factors, etc. should be included on a risk profile as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*. Hazard identification should include human microbiological pathogens and bacterial commensals ~~likely-that maybe~~ transmit AMR to humans.

25. As countries improve their AMR systems over time, ~~an-stepwise~~ approach to the development and implementation of monitoring and surveillance systems should lead to an increasingly use of generated data for risk assessment ~~incorporate risk-assessment factors as an important element in design of the program and analysis of data.~~

26. Potential foodborne AMR risks to human health are subject to change over time and an integrated monitoring and surveillance system should be adjusted as new information becomes available e.g. changes in test methodologies, new antimicrobial resistance gens, new food chain exposure pathways, changing patterns of AMU in humans and animals. Any adjustments should be ~~properly~~ communicated with reference to methodological changes while retaining valid historical data or when relevant updating historical data for trend analysis.

27. ~~On a risk-based approach, t~~The revision of the monitoring and surveillance system should be based on information about hazards and risks incorporated in the risk analysis process as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*.

6. Regulatory framework, policy and roles

28. Competent authorities need access to sources of microbiological and antimicrobial use data. This should include access of livestock and crop production facilities when conducting epidemiological investigations of multidrug resistant foodborne outbreaks. Activities related to monitoring and surveillance of foodborne AMR and AMU should involve not only the relevant competent authorities, but a wider range of stakeholders. The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance ~~program-system~~ and the degree of integration. Ideally, all interested parties along the food chain should contribute to the development and implementation of ~~the-an integrated~~ monitoring and surveillance ~~programsystem~~.

6.1. ~~Policy and regulatory activities~~

29. An ~~national~~ integrated monitoring and surveillance system for AMR and AMU requires good governance and co-ordination by the relevant competent authorities. The competent authorities should develop an overarching policy framework for monitoring and surveillance activities along the food chain in collaboration with the human health, animal health, plant health, environmental and other relevant authorities. Other stakeholders in ~~all~~ relevant sectors should be included and collaborate in line with the NAP on AMR. Sharing of knowledge and data with international organizations and counterparts can improve the effectiveness of policies taken at local level. Capacity building might help to ensure the implementation of ~~programs interventions~~ for AMR risk management.

~~The regulatory activities carried out by the competent authorities should be in response to policy objectives that are embedded in national strategies and NAPs on AMR. Guidance on developing national action plans are outlined in the WHO Global Action Plan on Antimicrobial Resistance and specific manuals developed by WHO, FAO and OIE such as the Antimicrobial resistance: a manual for developing national action plans.~~

~~The use of antimicrobial agents in the food chain should be subject to regulation as described in the Code of practice to Minimize and Contain Antimicrobial Resistance and relevant OIE standards.~~

6.2. ~~Other activities~~

30. Stakeholders other than the competent authority, such as veterinarians, plant health professionals, farmers, consumer organizations, civil society, pharmaceutical industry or food and feed industry, retailers and others may carry out monitoring activities e.g. monitoring of AMU on a voluntary basis.

31. Competent authorities responsible for food safety may consider playing an active role in design, analysis and reporting of these activities as part of an integrated “One Health” approach in collaboration with other relevant authorities from the human, animal, plant, food and environmental sectors, recognizing that knowledge and resources available to address certain sectors may be more advance than others.

11. Evaluation of integrated surveillance programs

32. The evaluation of an integrated monitoring and surveillance system promotes the best use of data collection resources and provides assurance that systems operate effectively. Evaluation of systems also provides assurance the data and information reported is robust and surveillance objectives are being met.

33. The steps in developing an evaluation framework include:

- Identify the skills needed by evaluators.
- Describe the monitoring and surveillance system to be evaluated, including the objectives and desired outcomes (this may include a subsection of the entire system such as the sample collection component, laboratories, analysis and reporting).
- Identify key stakeholders for the evaluation.
- Identify key performance criteria to be evaluated.
- Collect evidence against the key performance criteria.
- Report results on evaluation.
- Draw conclusions on components of the evaluation.
- Share evaluation outcomes with stakeholders.

12. Risk communication

34. The implementation strategy of the monitoring and surveillance system should include the development a of risk communication plan which defines the objectives, the evaluation process and allows for timely improvement of the plan.

~~As part of broader risk communication plans for national strategies and NAPs, there are specific requirements for communicating the results of ongoing monitoring and surveillance program — industry, consumers, international organizations etc.~~

35. The value of consultation ~~ve in the and~~ risk communication processes should allow in the developing of partnerships and achieving should achieve commitment to activities ~~to for~~ optimizing and reducinge the use of antimicrobials and preserve the effectiveness of antimicrobial agents in humans, animals and plants/crops. _

36. An integrated monitoring and surveillance system of foodborne AMR will generate data and information of interest to the competent authorities and a wide range of stakeholders, including risk managers, veterinarians, farmers, food manufacturers, retailers, consumers, etc. Special attention should also be given to the communication strategy between the competent authorities and the different stakeholders.

37. Additional guidance on how to communicate risk can be found in the *Working Principles for Risk Analysis for Food Safety for Application by Governments* and the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

13. Training and capacity building

38. A tiered approach to the implementation of this guidance at the national level is recommended. Programs should aspire to use effectively available resources, technical capability and take advantage of potential for cross-sector integration while seeking continuous improvement.

39. Training programs such as capacity development programs carried out by FAO/WHO/OIE should include capacity to train the personnel of the relevant competent authorities in different aspects of the monitoring and surveillance ~~program system~~. This should include the capacity to train personnel in the collection, analysis and reporting of the monitoring and surveillance data.