

# CODEx ALIMENTARIUS COMMISSION



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Agenda Item 4

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE Fifth Session

### **AGENDA ITEM 4: PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (CAC/RCP 61-2005)**

*Prepared by the Chair of the EWG on the revision of CAC/RCP 61-2005*

**Background:** Comments submitted in response to the Electronic Working Group proposed draft revision (CX/AMR 17/5/5) of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP-61-2005) were used to further refine text for the “Introduction” and “Scope” sections to facilitate further consideration by the 5<sup>th</sup> Session of the Task Force on Antimicrobial Resistance.

#### **Introduction**

[1. Antimicrobial resistance (AMR) poses a complex, global, One Health challenge. AMR food chain integration is a subset of a One Health approach. Food chain AMR integration requires collaboration of a diverse set of stakeholders within the food supply chain to identify AMR food safety issues; determine occurrence and risk; prioritize risks; research effective solutions and educate on the solutions; and develop and execute mitigation strategies.]

[[2]The development of strategies along the food chain to minimize the possible risks associated with foodborne AMR, including guidance for good practices in agriculture and aquaculture including the responsible and prudent use of antimicrobial agents following a One Health approach will form a key part of multi-sectoral national action plans to address risks of foodborne AMR.]

[[3]There are shared responsibilities of all involved through the food production to consumption continuum, including respective responsibilities of authorities and groups [relevant stakeholders] involved in the authorization, production, control, distribution and use of veterinary antimicrobials [agents] such as the national regulatory authorities, the [veterinary] pharmaceutical industry [manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of food-producing animals to help to mitigate possible risks of foodborne AMR. The continued availability of antimicrobial drugs, which are essential for addressing health, will ultimately depend on the responsible use of these products by all those involved in the authorisation, production, control, distribution and use of antimicrobial agents.]

[ 2[4.] This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Proposed Draft Guidelines on Integrated Surveillance (CAC/GL xx-xxxx)*, *Principles and Guidelines for the Conduct*

*of Microbiological Risk Management (CAC/GL 63-2007), Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77-2011, relevant chapters of the OIE Terrestrial and Aquatic Animal Health Codes, and General Principles of Food Hygiene (CAC/RCP 1-1969). In addition, the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003), the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programs Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), the Code of Practice for Fish and Fishery Products (CAC/RCP 53-2003), the General Principles of Food Hygiene (CAC/RCP 1-1969), the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007); the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), and the OIE Terrestrial Animal Health Code, section 6.9.8.] are particularly relevant for use of antimicrobial agents on crops and animal feed]*

[[5] The following additional texts are relevant to read in conjunction with this Code: Chapter 6.10 Risk analysis for AMR arising from the use of antimicrobial agents in animals of the OIE Terrestrial Animal Health Code (2017), Chapter 6.5 Risk analysis for AMR arising from the use of antimicrobial agents in aquatic animals of the OIE Aquatic Animal Health Codes Code (2017), and the OIE List of Antimicrobials of Veterinary Importance. The WHO guidelines on Integrated surveillance of AMR in foodborne bacteria, Application of a One Health Approach (2017) and WHO Critically Important Antimicrobials for Human Medicine (2016) are relevant and should be considered.]

~~3-~~[6. Where available, national and local guidelines to minimize and contain AMR and best practices and guidelines on the responsible and prudent use of antimicrobial agents developed by governmental and professional organizations should also be considered].

~~1-4-~~ [7] This document provides guidance ~~for~~ [on relevant measures along the food chain to minimize the development and spread of foodborne AMR, including guidance on] the responsible and prudent use of antimicrobial agents in [the] food [chain]-~~producing animals~~. Its objectives are [part of a One Health approach] to minimize the potential adverse impact on human [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-~~producing animals~~, in particular the development of AMR. It is also important to provide for the safe and effective use of ~~veterinary antimicrobial [agents] drugs in veterinary medicine~~ by maintaining their efficacy.

~~2-5~~[8.]The marketing authorization procedure has a significant role in establishing the basis for [the responsible and] prudent use of ~~veterinary antimicrobial drugs [agents] in food-producing animals~~ through clear label indications, directions and warning statements by regulatory authorities.

~~4-6~~[9]. In keeping with the Codex mission, this Code [of Practice] focuses on antimicrobial use in [the] food-~~producing animals~~ [chain]. It is recognized that [the use of antimicrobial agents in the food chain may result in exposure in the environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products of assured quality should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the environment of antimicrobials and their metabolites from anthropogenic sources, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the environment.] ~~Antimicrobial resistance is also an ecological problem and that management of antimicrobial resistance may require addressing the persistence of resistant microorganisms in the environment. Although this issue is most relevant for CCRVDF with respect to food-producing~~

animals, the same principles apply to companion animals, which also harbor resistant microorganisms.]

### [Scope]

[10. While AMR food chain integration is a part of a One Health approach, One Health encompasses more than foodborne AMR. There are numerous sources of AMR development: soil bacteria; anthropogenic sources; co and cross resistance from a variety of compounds, and human, domestic animal and wildlife carriers posing a risk of transfer in multiple directions. The scope of this Code is not to determine and address every possible cause of AMR but rather to assist national authorities to prioritize and focus on the major contributors to the AMR food chain component of One Health based on science and risk.]

~~7-~~[11. The objective of this Code is to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. This Code of Practice addresses the management of risk of AMR microorganisms or determinants to human and animal health associated with their presence in the food chain, and the subsequent transmission through food to humans of AMR. It provides risk-based guidance on relevant measures along the food chain to minimize the development and spread of foodborne AMR, including guidance on the responsible and prudent use of antimicrobial agents in agriculture and aquaculture. All parties involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobial agents in the food chain together with those involved in the handling, preparation, food processing, distribution and consumption of food have a role to play in optimizing the use of antimicrobial agents and limiting the spread of AMR microorganisms and determinants.]

~~8-~~[12. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants and recombinant DNA microorganisms<sup>1</sup>; genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>2</sup>; and certain food ingredients, which could potentially carry AMR genes, such as probiotics<sup>3</sup>. This document is designed to provide a framework, for the development of measures to mitigate the public health risk of foodborne AMR that countries may implement as part of their national strategy on AMR, in accordance with their capabilities, based on their national situation/capacities, and within a reasonable period of time. A stepwise approach may utilized by some countries to properly implement all of the elements in this document.]

1 [The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).]

2 [The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* (CAC/GL 46-2003).]

3 [The food safety assessment on the use of probiotics in foods is addressed in a Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Foods (FAO/WHO, 2002).]