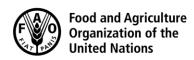
CODEX ALIMENTARIUS COMMISSION





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Agenda Item 5

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ORINGINAL LANGUAGE ONLY

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

Sixth Session
Busan, Republic of Korea, 10-14 December 2018

REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)

(Revised)

Prepared by the Electronic Working Group led by the United States of America and co-chaired by China, Chile, Kenya, United Kingdom)

The Chair and Co-Chairs of the EWG on the Code of Practice would like to offer the following information to facilitate discussion on Sections 1-3 of the Proposed Draft Revised Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005)

Taking into account comments submitted in response to CL 2018/74-AMR the Section 1: Introduction and Section 2: the following revisions have been made.

1. Introduction

- [1. Antimicrobial resistance (AMR) poses an important, complex, global public health challenge. Along Within the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in plant/crop production animal production (terrestrial and aquatic), plant/crop production, and food processing, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne antimicrobial resistance AMR.]
- [2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including the role of regulatorycompetent authorities, the pharmaceutical industry, veterinariansanimal and plant/crop health professionals and plant/crop advisors or consultants, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail and distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.]

[2bis. In keeping with the Codex mandate this Code of Practice focuses on addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure in the food production environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from anthropogenic sourcesfood production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.]

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[3. 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 *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003) and the *Code of practice on good animal feeding* (CXC 54-2004) are particularly relevant for use of agricultural chemicals on plants/crops and animal feed, respectively.]

[3bis. This Code of Practice provides risk management advice, including the responsible and <u>prudent judicious</u> use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk to introduce levels of protection appropriate for circumstances.]

- [4. The Principles and guidelines for the conduct of microbiological risk management (CXG 63-2007) contains guidance for developing and implementing risk management measures. WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach and critically important antimicrobials for human medicine and relevant chapters of the OIE terrestrial and aquatic animal health codes and the List of antimicrobials of veterinary importance and national list where they exist should also be referenced taken into account for setting priorities and identifying risk management measures.]
- [5. Where available, national and local guidelines to prevent, minimize and contain foodborne antimicrobial resistance AMR should be taken into consideration. Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.]
- [6. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents.]

2. Scope

- [7. This Code of Practice provides risk management guidance to address the risk to human health associated with the presence in food¹ and the transmission through food of antimicrobial resistant microorganisms or resistance determinants. It provides risk-based guidance on relevant measures along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in plant/crop production and animal production (terrestrial and aquatic) and plant/crop production and references to other best management practices as appropriate. It also provides risk-based guidance on practices during production, processing, storage, transport, and wholesale and retail and distribution of food to minimize and contain the development and spread of foodborne antimicrobial resistance. Its objectives are to minimize the potential adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.]
- [8. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents <u>inalong</u> the food chain together with those involved in the handling, preparation, food processing, <u>storage</u>, <u>transport</u>, <u>wholesale and retail</u> distribution and consumption of food who have a role to play in <u>optimizing ensuring the responsible and prudent the</u> use of antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.]

[9. As there are existing Codex or internationally recognized guidelines, the following areas related to

As described in the Code of practice on good animal feeding (CXC 54-2004), food means food for man or animals.

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antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms²; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose³; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics⁴. In addition, AMR from non-food animals or non-food routes are also outside the scope of this document.]

Section 3. - Definitions

With respect to definitions, the Chair and Co-Chairs request feedback from the TFAMR on which definitions may need further discussion (such as in a future EWG) and which definition may have good agreement at this stage. Taking into account comments submitted in response to CL 2018/74-AMR, Co-Chairs offered the following assessment.

Definitions followed * are harmonized with OIE.

Definitions followed by ** are taken From Codex GL 77-2011.

***Definitions preceded by *** appear in both the COP and GLIS documents.

Definitions Appearing to Have Good Consensus

- 1. Adverse health effect**
- 2. AMR**
- 3. AMR determinant**
- 4. Control of disease/metaphylaxis*
- Co-resistance**
- 6. Extra or off label use**
- 7. ***Food chain
- 8. Food producing animals**
- 9. Growth promotion*
- 10. Market authorization
- 11. Pharmaceutical industry
- 12. Prevention of disease/ prophylaxis*
- 13. Treatment of disease*

The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants* (CXG 45-2003).

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* (CXG 46-2003).

The food safety assessment on the use of probiotics in foods is addressed in the Report of the *Joint FAO/WHO* working group on drafting guidelines for the evaluation of probiotics in foods (FAO/WHO, 2002).

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Definitions That Could Benefit From Brief Discussion in Plenary

- Antibacterial -inclusion /exclusion from the document
- o Antibiotic resistance inclusion /exclusion from the document
- ***Antimicrobial agent
- o Antimicrobial class inclusion and further discussion at the EWG
- o AMR food safety inclusion and further discussion at the EWG
- o Cross resistance adoption as amended by Australia
- ***One health adoption as amended by Norway

Definitions Requiring Further Discussion

- Medically important antimicrobials
- o Therapeutic use / veterinary medical use
- o Plant/crop health professional
- ***Plants/crops
- o Pharmacovigilance