CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 and 6 **CRD7**

ORINGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Seventh Session

Comments of Kenya

Agenda 5

Section 1. Introduction

Kenya takes note of the proposed amendments to paragraphs 1, 4 and 6, and supports the adoption of the revised text as recommended by the EWG.

Section 2. Scope

Kenya takes note of the proposed amendments to paragraphs 9, 11 and 12, and supports the adoption of the revised text as recommended by the EWG.

Section 3. Definitions

***Food production environment**:*

The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.

Position: Kenya proposes amendment to the definition of Food production environment by replacing the term "reasonable" with the term "significant" to read "*The immediate vicinity of food to be harvested or processed that has <u>significant</u> probability to contribute to foodborne AMR"*.

Rationale: The term "reasonable" in the definition is subjective. The use of the term "Significant" will provide for a quantifiable indicator to the environment that could contribute to foodborne AMR.

Therapeutic use:

Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis or and prevention/prophylaxis of disease.

Position: Kenya supports the definition of therapeutic use since it is consistent with the OIE definition.

Medically Important Antimicrobials

Antimicrobial agents important for therapeutic use in humans taking into account those described in the WHO list of critically important antimicrobials and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national lists, where available. It does not include ~~ionophores or other~~ antimicrobial agents not important for human therapeutic use, such as ionophores.

Position: Kenya proposes retention of the initial definition of medically important antimicrobials but also to include "regional" list to the definition. It is also proposed to maintain the former text concerning ionophores.

The revised text of the definition as proposed is *"Antimicrobial agents important for therapeutic use in humans taking into account those described in the WHO list of critically important antimicrobials and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in <u>regional or</u> national lists, where available. It does not include ionophores or other antimicrobial agents not important for human therapeutic use~~, such as ionophores~~."*

Rationale: There exists regional list of medically important antimicrobials in some regions.

The OIE glossary of terms regarding antimicrobial classes for use in animals does not consider ionophores among antimicrobial classes. Therefore, ionophores should not be given as example of antimicrobial agents.

***Plant/crop health professional*.**

An individual ~~professionally trained person~~ with current training, knowledge and experience in plant/crop health and protection practices.

Position: Kenya proposes the adoption of the term plant/crop health professionals for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases. The term is explicit.

Section 4. General Principles

Position: Kenya takes note of the recommendations of the EWG and makes the following comments regarding the general principles.

Principle 7 and 7bis:

Principle 7: When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration.

Principle 7bis When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.

Principle 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

Position: Kenya recommends the merger of 7 and 7bis:

The proposed text reads: "When used for prevention/prophylaxis of a specific disease risk or control of disease/metaphylaxis, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration."

Rationale: The two (7 and 7bis) address specific circumstances related to therapy and are applied within the same circumstances.

7ter is recommended for deletion since currently there is insufficient data on use of Medically Important Antimicrobials in plants. ISPM diagnostic protocols and phytosanitary treatment do not show AMR as an issue. There is as yet no list of critically important Antimicrobials in plants

Principle 9, 10 and 14

Kenya recommends adoption of principles 9, 10 and 14 as proposed by the EWG and accepts the proposal to re arrange the principles and group them into the 5 categories (Principles on AMR Risk Management (generally) (1,9,4&15); Principle on preventing infections and reducing the need for antimicrobials (2); Principles on the responsible and prudent use of antimicrobials (generally) (13,~~12~~,8,14,3); Principles on the use of antimicrobials in specific circumstances (5, 6,7,7bis &~~ 7ter~~); Principle on surveillance of antimicrobial resistance and use (10))

Section 5. Responsible Use of Antimicrobial Agents.

Kenya recommends the following amendments to the text in this section.

Paragraph 19: Addition of the word " regional" in the first sentence after national.

Paragraph 21: Addition of the word "/regional'' in last sentence after national.

Paragraph 23: Addition of "withdrawal period" to the bullets.

Paragraph 25: Editing the paragraph to read "Competent authorities should have in place a pharmacovigilance program. ~~for the monitoring and reporting of suspected adverse reactions to veterinary antimicrobial agents drugs, including lack of the expected efficacy that could be related to antimicrobial resistance~~. The information collected through the pharmacovigilance program can contribute to a ~~should form part of the~~ comprehensive strategy to minimize antimicrobial resistance in food.

Rationale: Pharmacovigilance is well defined in the definition section and does not require to be repeated in the text.

Paragraph 27: Edit the paragraph to read "Competent authorities should ensure approved antimicrobial agents including MIA are distributed through appropriate distribution systems through appropriately credentialed/ registered veterinarians, plant/crop health professionals or other suitably trained persons authorized in accordance with national legislation".

Paragraph 32: Amend the first sentence of sub paragraph 2, to read; "*Relevant information may include <u>but not limited to</u>*". In bullet 6, amend to read: "*understanding relevant risk analysis of antimicrobial agent<u>s</u> ~~products~~ and how to use that information*";

Paragraph 33: The first sentence is amended to read: "*The relevant authorities should (not can) encourage public and private research in the following areas* *but not limited to*":

In bullet 5, amend to read: "*assess the primary drivers leading to use of ~~medically important~~ antimicrobials at the farm*, *Sub-national~~ regional~~, and national levels, and the effectiveness of different interventions to change behavior and reduce the use of* *medically important* *antimicrobial agents in food production*;

Paragraph 34: Merge this paragraph with 33 to be the first sentence. To be read as*:"The relevant authorities should encourage public and private research to fill knowledge gaps by conducting relevant research related to foodborne AMR risk in the following fields:…"*

Paragraph 35: delete 'counterfeit' and replace with 'falsified and substandard'.

Paragraph 38: Add 'and safety' after quality.

Paragraph 47: Add 'manufacturer name and address' to the bullets.

Paragraph 51: Amend the first sentence to read; "Antimicrobial agents should only be ~~used~~ prescribed or administered when necessary, ~~as~~ only as long as required ~~necessary~~, and in an appropriate manner:

Bullet 2: amend the first sentence by deleting 'if feasible' and adding 'unless otherwise advised by the prescriber' at the end of the sentence to read: "*The quantity of the antimicrobial provided to the end-user should, ~~if feasible,~~ be limited only for the administration concerned* *unless otherwise advised by the prescriber*.

Paragraph 58: Restore the word 'administration' in the first sentence.

Agenda 6

Kenya appreciates the work done by the EWG and the advice provided pursuant to the responses to the questions.

1. Introduction

Kenya concurs with the advice of the EWG in paragraph 3, 6 and 7 of the introduction.

3. Definitions

Kenya takes note of the need to harmonize the definition of terms within the codex documents especially the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005), 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) whenever appropriate.

7. A progressive approach for the implementation of an integrated monitoring and surveillance system of foodborne AMR

Kenya takes note that a progressive approach for the design and implementation of an integrated monitoring and surveillance system will enable countries develop strategies as well as implement activities based on country specific scenarios and resources.

The revised text provides a good guidance to countries as they develop national AMR surveillance strategies. However, there is need for more data to provide appropriate evidence of the risk to human health due to foodborne AMR infections attributable to foods of plant origin.

9.0 Collection of national antimicrobial sales and use data in animals and plants.

Kenya takes note of the work of the EWG and makes the following general comments:

1. Reporting of AMU in animals is guided by the OIE and it will be advisable to make cross reference to the terrestrial and aquatic animal health code.
2. The calculation of biomass is work in progress by the OIE and this information will be accessible on the OIE website.
3. Recommend deletion of section 9.2 since it is well summarized in 7.2.2(B)
4. The extent to which antimicrobial use in plant production selects for the emergence and maintenance of antimicrobial resistant (AMR) organisms in plant production is unclear. Surveillance and further testing are needed to conduct comprehensive risk assessments and to monitor progress in implementing more sustainable plant health practices that reduce reliance on antimicrobials.
5. Countries should be encouraged to support research in foodborne AMR due to foods derived from plants.

6. The proposals contained/outlined in section 9.3 are derived from the OIE template for reporting AMU in animals. It is not certain if the same methodology will apply for reporting AMU in plants.
7. The international Plant Protection Convention (IPPC) should consider developing guidelines on AMU in plants to enable countries report on use of antimicrobials in the plant health sector.
8. This section in essence is still under development and most countries will not be able to implement surveillance in plants.