

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 3, 5, 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Sixth Session

Comments of African Union

AGENDA ITEM 3: MATTERS ARISING FROM FAO, WHO AND OIE INCLUDING THE REPORT OF THE JOINT FAO/WHO EXPERT MEETING (IN COLLABORATION WITH OIE) ON **FOODBORNE ANTIMICROBIAL RESISTANCE (CX/AMR 18/6/3)**

Position: Africa Union appreciates the ongoing work of FAO, WHO and OIE in providing technical support in the area of antimicrobial resistance. African Union particularly notes the FAO/WHO/OIE tripartite activities on foodborne AMR in relation to the United Nations Interagency Coordination Group on AMR (IACG); the Global Development and Stewardship Framework to Combat Antimicrobial Resistance; the Tripartite Integrated Surveillance System on AMR/AMU (TISSA); and the Monitoring of the Global Action Plan on AMR. The African Union recognizes that AMR is a complex problem which requires changes in policy and practice across multiple sectors. The African Union endorses the “One Health” approach in which human, animal, and environmental sectors work jointly to raise awareness, gather credible data, implement programs, and promote evidence-based policy and practice. Through the AMR Framework of the Africa Centres for Disease Control and Prevention (ACDC), ACDC, AU Interafrican Bureau for Animal Resources (AU-IBAR) and other African Union institution are collaborating to support African Union member states to contribute to mitigating the threat associated with AMR.

AGENDA ITEM 5: PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN **FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005) (CX/AMR 18/6/5)**

Points for further comments and discussion at TFAMR06

African Union commends the Chair of the EWG the United States of America, and co-chairs China, Chile, Kenya, United Kingdom for leading work on the revision of the code of practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005) (CX/AMR 18/6/5). African Union notes that there are several issues that need further discussions and consensus to enable the advancement of the Code of Practice through the stepwise process. Our comments focus on some of the specific issues raised by the eWG for which guidance is needed.

1. Issue: Definition of plants/crops - Several comments indicate a need to consider the most appropriate term with respect to food of plant origin for human consumption. Some comments favor the use of “crops” in order to distinguish non-food plant substances (e.g. ornamental shrubs, fiber (cotton), etc.). Other comments favor the use of “plants/plant products” or “food of plant origin” to identify substances that would be consumed by humans. Other comments suggest that “fresh fruits and vegetables” may be more appropriate as these products are most likely to be consumed by humans without a kill step (i.e. cooking).

Some sections of the text refer to “agriculture (crops)” to refer to the growing of crops/plants. A consistent definition could provide clarity in these sections. For the revision of the COP, the use of “plants/crops” was selected together with a specific definition to address this request.

It is noted that CXG 77 use only the term “crops”, but that other Codex documents also refer to “plants”. Defining the term “plants”, “crops” or “plants/crops” may need to be considered in the larger context of Codex Alimentarius

Position: African Union takes note of the need to consider the most appropriate term with respect to food of plant origin. The Africa Union is in favor of the use of the term “crops” and supports the proposed definition as stated in the text *ie Crop: a cultivated plant that is grown as food or feed, especially a grain, fruit or vegetable, including all edible parts.*

Rationale: “Crops” is a sub-set of the plant kingdom, which refers to plants that are food. The use of the term crop will distinguish non-food plant substances such as ornamental shrubs, fiber etc and will enable CAC to focus on developing risk management measure directly related to food to address the threat of AMR.

2. Issue: The use of the term “Plant/crop health professional” - A key risk management measure described in the document is administration or application of medically important antimicrobials under the supervision of qualified professionals. For animals, this generally means a veterinarian or a professional similarly authorized by national legislation. Different terms for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases in lieu of “crop health professional” including “crop advisor and consultants” were offered. It was decided to replace “crop health professional” with the term “plant/crop advisor or consultant”, however specific application of this term to concepts in the document needs to be carefully considered by TFAMR06.

Position: Africa Union takes note of the different terms for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases in lieu of “crop health professional” including “crop advisor and consultants”. Africa Union proposes the use of the term “*Plant Pathologist*” as the professional to address the key risk management measures described in the document in relation to administration or application of medically important antimicrobials. Plant Pathologist can be referred to as the professional with knowledge and experience in crop production and protection practices.

Rationale: *Plant Pathology* is defined as the study of the organisms and environmental conditions that cause disease in plants, the mechanisms by which this occurs, the interactions between these causal agents and the plant (effects on plant growth, yield and quality), and the methods of managing or controlling plant disease. A plant pathologist is a professional with skills to manage and control diseases in plants and capable of prescribing the appropriate drugs for use in treatment of plant diseases.

3. Issue: Antimicrobials vs. antibacterials - Recognizing the term antimicrobials includes antibacterial, antiviral, antifungal, and antiparasitic agents, there were suggestions that the document should focus or be limited to guidance on antibacterial agents. Alternatively, there were suggestions that CXC 61 should address all antimicrobials and so the references to antibacterial, antibiotic, and antibiotic resistance should be changed to antimicrobials, and the definitions for the former terms deleted. TFAMR06 should consider whether references to antibacterials/antibiotics/antibiotic resistance should be changed to antimicrobial agents/antimicrobials/antimicrobial resistance and if paragraph 6 is sufficient or should be further revised.

Position: African Union supports the use of the term “antimicrobial”.

Rationale: Antimicrobial is more encompassing and includes antibacterial, antiviral, antifungal, and antiparasitic agents. This is also the approach taken by the OIE by the OIE with regards to definition of antimicrobials. The COP should not be limited to antibacterials but should accommodate all antimicrobials. However, since the bulk of the resistance is witnessed in bacterial organisms, the Africa Union has no objection to the COP referring to antibacterial/antibiotics/antibiotic resistance as and when necessary to provide clarity on specific situations. Paragraph 6 should be retained.

4. Issue: Medically important antimicrobials - Recognizing the need to differentiate antimicrobials that are important for therapeutic use in humans, and therefore may require additional risk management measures, from those substances with antimicrobial properties that are not relevant for human medicine, there were varying views on which references in the document are relevant for medically important antimicrobials and which references are relevant for all antimicrobials. The definition was revised to increase clarity around this distinction.

Position: Africa union supports the proposed definition of medically important antimicrobials with slight amendment and proposes a revised definition to read: *Medically important antimicrobials: Antimicrobial agents*

important for therapeutic use in humans as described in the WHO list of critically important antimicrobials or national lists, where available. It does not include ionophores or other antimicrobial agents not used for human therapeutic use.

Rationale: The inclusion of national lists to the definition may be used inappropriately as a barrier to trade. The use of national lists, which is at variance to the WHO list of critically important antimicrobials, should be backed with sufficient scientific evidence as required in cases of residues or contaminants in food.

5. Issue: Stepwise approach - Concerns about application of a stepwise approach and the potential for such an approach to be used to implement trade barriers have been raised. TFAMR06 should consider whether revisions to the proposed revised text are sufficient to address this concern.

Position: The Africa Union takes note of the concerns expressed with regard to the application of a stepwise approach. Africa Union supports the application of a stepwise approach provided that it is used in the context of providing a pathway to achieving the objectives of minimizing AMR and not as an inappropriate means of segmenting countries or to create trade barriers.

Rationale: Tackling the AMR challenge requires multiple actors and multiple strategies, which have a cumulative effect towards achieving the desired outcomes. Focusing these efforts requires a progressive pathway, which can facilitate implementation of the COP.

PROPOSED DRAFT REVISED CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)

Issue: Section 1 Introduction

Position: Africa Union takes note of the inclusion of paragraph 3bis in the introduction and proposes the deletion of the term “judicious” and replacement with the term “prudent” as indicated below.

3bis. This Code of Practice provides risk management advice, including the responsible and *prudent* ~~judicious~~ 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.

Rationale: the term *judicious* bears the same meaning as the term *prudent*. The use of the term *prudent* is consistent with the text used in the code in section five and other international standards such as the OIE standards. Consistency in the use of terms is important for a common understanding of the requirements of the Code of Practice.

Issue: Section 2. Scope

Position: Africa Union proposes deletion of the third sentence in paragraph 7 of the scope to read as outlined here below;

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 references to other best management practices as appropriate. ~~It also provides risk-based guidance on practices during production, processing, storage, transport, 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.

Rationale: The sentence is a repetition of the second sentence of paragraph 7.

Issue: Section 3. Definition of *Plant/crop health professional*. Plant/crop advisor and consultant: Plant/crop health professionals with knowledge and experience in crop production and protection practices.

Position: Africa Union takes note of the different terms for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases in lieu of “crop health professional” including “crop advisor and consultants”. Africa union proposes the use of the term “*Plant Pathologist*” as the professional to address the key risk management measures described in the document in relation to administration or application of medically important antimicrobials. Plant Pathologist can be referred to as the professional with knowledge and experience in crop production and protection practices.

Rationale: *Plant Pathology* is defined as the study of the organisms and environmental conditions that cause disease in plants, the mechanisms by which this occurs, the interactions between these causal agents and the plant (effects on plant growth, yield and quality), and the methods of managing or controlling plant disease. A plant pathologist is a professional with skills to manage and control diseases in plants and capable of prescribing the appropriate drugs for use in treatment of plant diseases.

Section 4. General principles to minimize and contain antimicrobial resistance

Position: African Union supports the proposed principles. However, the inclusion of the national list in principle 4 should be deleted. The sentence should read as follows: *Principle 4: The WHO list of critically important antimicrobials, or the OIE list of antimicrobials of veterinary importance, ~~or national lists, where available,~~ should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.*

Rationale: The inclusion of national lists to the definition may be used inappropriately as a barrier to trade. The use of national lists, which is at variance to the OIE and WHO list of critically important antimicrobials, should be backed with sufficient scientific evidence as required in cases of residues or contaminants in food.

Section 5. Responsible and prudent use of antimicrobial agents

Para 12 Responsibilities of the regulatory authorities

Position: The first sentence on paragraph 13 is misplaced and fits well as the last sentence in paragraph 12.

Para 12. The regulatory authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop advisors or consultants, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. *It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications.*

Para 13. ~~It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications.~~ National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy for the containment of antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.

Rationale: Paragraph 12 describes the responsibility of the regulatory authorities in relation to market authorization while the paragraph 13 deals with collaboration between national governments and other stakeholders.

Para 17: Assessment of the potential antimicrobial agents to select for resistant microorganisms

Position: African Union does not support the inclusion of the national list in paragraph 17

17. The regulatory authority should assess the potential of medically important antimicrobial agents to select for resistant microorganisms taking into account Guidelines for risk analysis of foodborne antimicrobial resistance, the WHO list of critically important antimicrobials, the OIE list of antimicrobials of veterinary importance, ~~or national lists, where available.~~

Rationale: The inclusion of national lists to the definition may be used inappropriately as a barrier to trade. The use of national lists, which is at variance to the OIE and WHO list of critically important antimicrobials, should be backed with sufficient scientific evidence as required in cases of residues or contaminants in food.

Para 23: Distribution of antimicrobial agents

Position: Replace plant /crop advisor or consultant with plant pathologist in paragraph 23 and the whole text for the same reasons as stated in *Points for further comments and discussion at TFAMR06* (ii).

Para 23. Regulatory authorities, to the extent possible, should make sure antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation and medically important antimicrobials are distributed to ~~appropriately credentialed/~~registered veterinarians, **plant pathologists** ~~plant/crop advisors or consultants~~, or other suitably trained persons authorized in accordance with national legislation.

Position: Africa Union proposes amendment to paragraph 24 as indicated here below:

Para 24. Distribution should be ~~regularly~~ controlled by the regulatory authorities, and **with regular** monitoring of sales of antimicrobial agents ~~could be~~ undertaken and information ~~could be~~ analyzed with appropriate context to identify areas of concern and potential follow up.

Rationale: It is the obligation of the regulatory authority to control and monitor sales of antimicrobial agents.

Para 59: Responsibilities of food producers

Position: African Union proposes the deletion of the fourth sentence of paragraph 59 in order to read as follows:

59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. ~~Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available.~~ Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.

Rationale: The fourth sentence is a repetition of the third sentence in this paragraph.

AGENDA ITEM 6: PROPOSED DRAFT GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE (CX/AMR 18/6/6)

Section 3. Definitions

Issue: *Prioritized antimicrobial agents* - For the purpose of integrated monitoring and surveillance, antimicrobial agents prioritized as being of importance to public health e.g. 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.

Rationale: National lists may be used inappropriately as a barrier to trade. The use of national lists based on country's unique situation needs to be clarified.

Section 6. Regulatory framework and roles

Issue: Sub-section 6.2. Other activities - Stakeholders other than the competent authority, such as veterinarians, **plant pathologist plant health professionals**, farmers, consumer organizations, civil society, pharmaceutical industry or food and feed industry, retail and others may carry out monitoring activities e.g. monitoring of AMU on a voluntary basis.

Position: Africa Union takes note of the different terms for professionals engaged in the diagnosis, prevention, and treatment of crop/plant diseases in lieu of “crop health professional” including “crop advisor and consultants”. Africa union proposes the use of the term “*Plant Pathologist*”. Plant Pathologist can be referred to as the professional with knowledge and experience in crop production and protection practices. Africa Union therefore proposes the replacement of the term *Plant health professional* with *plant pathologist*.

Rationale: *Plant Pathology* is defined as the study of the organisms and environmental conditions that cause disease in plants, the mechanisms by which this occurs, the interactions between these causal agents and the plant (effects on plant growth, yield and quality), and the methods of managing or controlling plant disease. A plant pathologist is a professional with skills to manage and control diseases in plants and capable of prescribing the appropriate drugs for use in treatment of plant diseases.

Section 8. Design of monitoring and surveillance programs for AMR

8.7.5. Molecular testing

Position: African Union proposes the deletion of the seventh paragraph in this sub section

~~.....Countries without current AMR surveillance programs may consider focusing on WGS in developing surveillance programs. Countries taking this approach should do some surveillance using conventional microbiology to monitor for previously undetected resistance genes. WGS approaches to surveillance are particularly suited to data sharing and there are several international initiatives to collect and share WGS data.~~

Rationale: Although this section is on molecular testing, there is undue emphasis on benefits of whole genome sequencing, which discriminates against other molecular tests.