

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 2,3,4 and 5

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Seventh Session

Comments of Egypt

Agenda	Content		Egypt's Comments
Agenda Item 2	<b>A. MATTERS ARISING FROM OTHER CODEX SUBSIDIARY BODIES MATTERS FOR INFORMATION EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION (77th Session) 1</b>	1 2. CCEXEC77 encouraged TFAMR to find consensus and advance the work in the step procedure to finalize within the given timeframe. 3. CCEXEC77 further noted that TFAMR will need to use four sessions to complete its work (possible adoption at CAC44 in 2021). 4. It was emphasized that the work is in response to an urgent public health topic and with links to ongoing work of high priority at the international level.	<p>In view of The WHO has issued repeated calls to urge Member States to develop national plans to combat antimicrobial resistance (AMR). This problem has become serious that the topic has been included in the work of the United Nations General Assembly meetings of 2016 and 2017, respectively. The Arab Republic of Egypt as a pioneer in the field of health regionally and globally address and respond to this problem. The Ministry of Health and Population has taken the initiative to develop the national anti-microbial resistance plan in cooperation and coordination with all ministries, bodies and institutions concerned with public, animal and environmental health.</p> <p>As we issue the National Action Plan for the Control of Antimicrobial resistant Microbes. We hope that it will contribute to the improvement of community health and help rational and optimal use of antibiotics, guided by the vision and directives of His Excellency the President of Egypt, which has ensured that an integrated health system is one of the pillars that effectively contribute to achieve Sustainable development goals.</p>
<b>CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR51)2</b>	<i>Use of antimicrobials in plant agriculture</i> 5. The Representative of FAO encouraged members, especially in low and middle income countries, to submit data for use of antimicrobials in plant agriculture to contribute to the follow-up of the FAO/WHO (in collaboration with OIE) Expert Meeting on Foodborne AMR: Role of Environment, Crops and Biocides (June 2018).		
Agenda Item 3	<b>MATTERS ARISING FROM FAO, WHO AND OIE</b>		
Agenda Item 4	<b>MATTERS ARISING FROM OTHER RELEVANT INTERNATIONAL ORGANIZATIONS</b>		
Agenda Item 5  PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE	<b>PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)</b>	<b>Section 1. Introduction</b> 1. Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. Throughout 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 animal production (terrestrial and aquatic), plant/crop production of <del>feed of plant origin</del> and food/feed processing, packaging, storage, transport, and	<i>Egypt agrees with replacing “food of animal origin” with “plants/crops”</i>

<p><b>ZE AND CONTA IN FOODB ORNE ANTIMI CROBI AL RESIST ANCE (CXC 61- 2005)</b></p>		<p>wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR.</p>	
	<p>Paragraph 6, bullet 2.</p>	<p><input type="checkbox"/> <i>WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach;</i></p>	<p><i>Egypt agrees with retention of the text as drafted at TFAMR06 as drafted, places emphasis on the Annex containing the actual list without necessarily being exclusive.</i></p>
		<p><b>Section 2. Scope</b> <b>Paragraph 9</b> 9 7. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed 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 animal production (terrestrial and aquatic), plant/crop production, [food of plant origin] and feed and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.</p>	<p><i>Egypt agrees with replacement of the term “food of animal origin” with “plant/crop production”</i></p>

		<p><b>Paragraph 11</b> 11 8bis. 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, where scientific evidence supports foodborne AMR risk to human health.]</p>	<p><i>Egypt agrees with</i> retention of both the initial bracketed text “however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents” and the additional text “where scientific evidence supports foodborne AMR risk to human health”.</p>
		<p>12 9. 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/crops<sup>1</sup> and recombinant DNA microorganisms<sup>2</sup>; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>3</sup>; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics<sup>4</sup>. In addition, AMR from non-food animals, non-food plants/crops, or non-food routes are also outside the scope of this document.</p>	<p><i>Egypt agrees with</i> a suggestion was made in Round 2 to add “non-food plants/crops” to the list of areas agreed at TFAMR06 that are outside the scope of the document. The rationale is to</p>
		<p><b>Section 3. Definitions</b>  <b>[Food production environment:</b> The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.]  <b>[Plant/crop health professional / plant pathologist:</b> An individual professionally trained person with current training, knowledge and experience in plant/crop health and protection practices.]  <b>[Competent Authority(ies):</b> The official government organization/agency(ies) having jurisdiction.]</p>	<p>Egypt agrees with the current definitions</p>

		<p><b>Food chain</b> Production to consumption continuum including, primary production (food-producing animals, plants/crops), <u>feed</u>, harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption</p>	Egypt agrees with include “feed” in the definition of food chain for completeness
		<p><b>Section 4. General Principles</b>  <b>[Principle 5:</b> Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents <u>that are considered medically important.</u>  <u>Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.:</u>  <input type="checkbox"/> <del>considered medically important; or</del>  <input type="checkbox"/> <del>able to cause cross- or co-resistance to antimicrobial agents that are considered medically important.</del>  <del>Antimicrobial agents, others than those referred to above should not be used for growth promotion in the absence of risk analysis in accordance with CXG77.]</del></p>	Egypt agrees with the suggestion principle
		<p><b>[Principle 6:</b> Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]</p>	Egypt agrees with the suggestion principle
		<p><b>[Principle 7:</b> 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. Medically important antimicrobial agents should only be used in well-defined circumstances for the</p>	Egypt agrees with the suggestion principle

		<p>prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]</p> <p><b>[Principle 7bis:</b> 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.]</p> <p><b>[Principle 7ter:</b> 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.]</p>	
		<p><b>Principle 9:</b> Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the <i>Guidelines for risk analysis of foodborne antimicrobial resistance</i>. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures. <u>When considering animal or plant health aspects risk managers should take into account relevant OIE and IPPC standards.</u></p>	Egypt agrees with the additional sentence to reference OIE and the International Plant Protection Convention (IPPC).
		<p><b>Principle 10</b></p>	Egypt agrees with The addition of “plants/crops as an additional factor to consider through the foodborne AMR risk analysis process
		<p><b>[Principle 12:</b> Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.]</p>	“medically important” should be deleted making this Principle applicable to all antimicrobial agents
		<p><b>Principle 14:</b> The choice of which antimicrobial agent to use should take into consideration</p>	suggestion to add “antimicrobial” before susceptibility testing to improve clarity and

		relevant professional guidelines, where available, results of antimicrobial susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident	suggested replacing “production setting” with “food production environment”.
	<b>Section 5. Responsible Use of Antimicrobial Agents</b>	<b>Paragraph 13</b>	A suggestion was made to add the OIE List of Antimicrobial Agents of Veterinary Importance.
		<b>Paragraph 14</b>	The EWG Co-Chairs suggested a revision. Round 1 comments indicated support for the revision suggested by the EWG Co-Chairs. Round 2 comments include suggestions to replace the reference to VICH with “internationally harmonized guidelines”.
		<b>Section 5.1.</b>	Replace “regulatory authorities” with “competent authorities” based on a decision at TFAMR06.
		<b>Paragraph 15:</b>	A suggestion was made to move the first sentence of Paragraph 16 to the end of Paragraph 15.
		<b>. Paragraph 16</b>	A minor edit was suggested to align the text with the title of the COP.
		<b>Paragraph 17</b>	Additional text was suggested in Round 1 and amended in Round 2.
		<b>. Paragraph 18</b>	Round 1 comments include a suggestion of 14alt as a replacement for paragraph 14. Round 2 comments included suggestions for combining paragraph 14 and 14 alt.
		<b>Paragraph 19</b>	Additional text was suggested to strengthen the paragraph in terms of quality control
		<b>Paragraph 20</b>	Edits were suggested to improve the clarity of the text regarding assessment of efficacy.
		<b>Paragraph 21</b>	Minor edits were made to improve clarity
		<b>Paragraph 22:</b>	<b>Previous paragraph 18</b> Merged with paragraph 22 Egypt agrees with suggested the following as alternative criteria in the first sentence: “environmental fate and behavior data of antimicrobial agents (e.g. degradation of the active constituents, mobility, likely transport and final destination in the environment) to help estimate the

			predicted environmental concentrations in different environmental compartments—soils, sediment, water and dung—as appropriate, based on the proposed use pattern and physicochemical properties of the chemical.”
		<b>Paragraph 23</b>	Egypt agrees with Round 2 comments included proposed bullets. In addition, pharmacokinetic (PK), pharmacodynamic, and susceptibility breakpoints for target pathogens were suggested. The EWG Co-Chairs question whether this paragraph can be generalized to include plant/crop protection products by removing “veterinary medicinal”. The
		<b>Paragraph 24</b>	Egypt agrees with indicate a preponderance of support for the proposal. The EWG Co-Chairs also note the previous paragraph 22 has been deleted as agreed at TFAMR06.
		<b>Paragraph 25</b>	Egypt agrees with the text
		<b>Paragraph 26</b>	Egypt agrees with the text
		<b>Paragraph 27</b>	Egypt agrees with Round 2 comment suggested deleting the second half of the sentence starting with “...including that and medically important antimicrobials
		<b>Paragraph 28</b>	Egypt agrees with A Round 2 comments requested deletion of the phrase “to the extent possible
		<b>Paragraph 29</b>	Egypt agrees with Round 1 comments stated that monitoring of antimicrobial use is described in the GLIS and therefore the second half of the sentence is no longer needed based on a previous reference to the GLIS. CX/AMR 19/7/5 6
		<b>Paragraphs 30 and 31:</b>	Egypt agrees with Round 2 comments generally support control of advertising by competent authorities (CAs) according to national legislation and specific regulatory requirements, which should conform to the marketing authorization and any content required. Comments also stated that policies and prudent use guidelines may not be enforceable by the CA and therefore may be better suited for consideration in other sections.



			Redundant text was been removed and consolidated into 2 paragraphs.
		<b>Paragraph 32:</b>	Egypt agrees with proposed revised text to focus on the role of the CAs based on comments in Round 2 including a new name for the title of the section.
		<b>Paragraph 33</b>	Egypt agrees with the text
		<b>Paragraph 34:</b>	Egypt agrees with the text.
		<b>Paragraph 35:</b>	Egypt agrees with the text
		<b>Paragraph 36</b>	Egypt agrees with the text.
		<b>Paragraph 37</b>	Egypt agrees with the text
		<b>Paragraph 39</b>	Egypt agrees with the text
		<b>Paragraph 40</b>	Egypt agrees with the text
		<b>Paragraph 41</b>	Egypt agrees with the text
		<b>Paragraph</b>	Egypt agrees with the text
		<b>Paragraph 43:</b>	Egypt agrees with the text
		<b>78. Paragraph 44</b>	Egypt agrees with the text
		<b>79. Paragraph 45</b>	Egypt agrees with the text was revised to reflect that research of new and alternative products by the pharmaceutical industry should be encouraged
		<b>80. Paragraph 46</b>	Egypt agrees with expanded to include orders from plant/crop professionals and this sentence should be limited to medically important antimicrobial agents
		<b>Paragraph 47</b>	Egypt agrees with the text
		<b>82. Paragraph 48</b>	Egypt agrees with the text
		<b>83. Paragraph 49</b>	Egypt agrees with the text
		<b>84. Paragraph 50</b>	Egypt agrees with include "other organizations" and revised to "encourage" development of species or sector-specific guidelines.
		<b>85. Paragraph 51</b>	Egypt agrees with the text.
		<b>86. Paragraph 52</b>	Egypt agrees with the text
		<b>Paragraph 53</b>	Egypt agrees with the text
		<b>Paragraph 54</b>	Egypt agrees with the text
		<b>Paragraph 55</b>	Egypt agrees with the text
		<b>Paragraph 56.</b>	Egypt agrees with the text

		<b>Paragraph 57</b> help obtain consensus.	Egypt agrees with suggest this paragraph be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.
		<b>Paragraph 58</b>	Egypt agrees with the text
		<b>Paragraph 59</b>	Egypt agrees with the text
		<b>Paragraph 60</b>	Egypt agrees with the text
		<b>Previous paragraph 51bis</b>	Egypt agrees with the proposed for deletion based on Comments in Rounds 1 & 2. Reasons cited included; redundant with Principle 5, ambiguous with respect to Principle 5 (could imply exceptions), including specific classes is redundant with Principle 5 as well as ambiguous (could imply exceptions for certain classes).
		<b>Paragraph 61</b>	Egypt agrees with the text.
		<b>Paragraph 62</b>	Egypt agrees with the text.
		<b>Paragraph 63.</b>	Egypt agrees with a comment in Round 2 observed the paragraph is quite long and could be divided into smaller paragraphs.
	<b>Section 7. Communication to Consumers</b>	103. <b>Paragraph 68</b>	Egypt support for the paragraph as revised
		. <b>Paragraph 69.</b>	Egypt agrees with Round 1 comments indicated a preponderance of support for the paragraph as revised. Few comments were received in Round 2.
		<b>Paragraph 63</b>	Egypt Support for deleting with inclusion of some text into Paragraph 68.