



May 7, 2019

U.S. Delegate Codex TFAMR

Donald A. Prater, DVM
Assistant Commissioner for Food Safety Integration
Office of Foods and Veterinary Medicine
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

US Alternate Delegate Codex TFAMR

Neena Anandaraman, DVM, MPH
Veterinary Science Policy Advisor
Office of Chief Scientist
U.S. Department of Agriculture
1200 Independence Avenue, SW, Room 339A
Washington, DC 20024

Re: Comments on Proposed Draft Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance

Dear Drs. Prater and Anandaraman:

On behalf of the National Milk Producers Federation (NMPF) and U.S. Dairy Export Council (USDEC), we would like to provide the attached comments on the draft *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* in response to the Codex Task Force on Antimicrobial Resistance Electronic Working Group on Surveillance. Please contact us at jjonker@nmpf.org, ngardner@usdec.org, or 703-243-6111 if you have any questions concerning these comments. Thank you for the opportunity and for your consideration.

Sincerely,

Jamie Jonker
NMPF Vice President
Sustainability & Scientific Affairs

Nicholas M. Gardner
USDEC Director
Codex and International Regulatory Affairs

The U.S. Dairy Export Council is a non-profit, independent membership organization that represents the global trade interests of U.S. dairy producers, proprietary processors and cooperatives, ingredient suppliers and export traders. Its mission is to enhance U.S. global competitiveness and assist the U.S. industry to increase its global dairy ingredient sales and exports of U.S. dairy products. USDEC accomplishes this through programs in market development that build global demand for U.S. dairy products, resolve market access barriers and advance industry trade policy goals. USDEC is supported by staff across the United States and overseas in Mexico, South America, Asia, Middle East and Europe. The U.S. Dairy Export Council prohibits discrimination on the basis of age, disability, national origin, race, color, religion, creed, gender, sexual orientation, political beliefs, marital status, military status, and arrest or conviction record. www.usdec.org.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies. For more on NMPF's activities, visit our website at www.nmpf.org.

Comment Matrix for Document Review

Instructions:

- Column 1—3: Enter Appropriate Information
- Column 4: Indicate the category of the comment:
 - **General**
 - **Substantive**
 - **Technical**
 - **Editorial** – Corrections in spelling, grammar, punctuation, syntax, etc. (These are less important at this early stage unless meaning or intent are lost).
- Column 5:
 - Insert text recommended to be revised using ~~strikeout~~ for text to be deleted and **bold underline for new text**
- Column 6: Provide rationale for response to question or requested edit

Paragraph #, and bullet #, or sentence # as applicable	Reviewer	Agency/Organization	Category	Recommended Revision	Rationale
Paragraph 4 Bullet 2	Jamie Jonker	National Milk Producers Federation		Recommend deleting “ WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important ”	The WHO list of critically important antimicrobials is not a consensus document from the World Health Assembly, so it is inappropriate to include in a Codex documents. REP18/EXEC2-Rev.1 addresses a situation where another Codex Committee has been asked to reference a WHO document. Although we recognize that the situation is not identical, we note the following (see para 14, specifically d): WHO “references must be relevant to the scope of the standard itself,
	Nick Gardner	U.S. Dairy Export Council			

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					<p>fall within the mandate of Codex, have a scientific basis, and have been developed through a transparent process.”</p> <p>We question whether the WHO list of critically important antimicrobials meets these important tests, so suggest it not be specifically referenced in the COP.</p>
Paragraph 5bis	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		<p>Concur with addition <u>“This document is designed to provide a framework, for the development of measures to mitigate the 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 priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.”</u></p>	<p>Moved from General Principles as suggested at TFAMR6. Maintaining the later part of this addition “and should not be used inappropriately to generate barriers to trade” is of vital importance to ensure that the progressive approach noted here cannot be used to penalize any country who is unable or unwilling to implement later stages of what is envisioned in the COP.</p>
Paragraph 8bis	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		<p>Recommend deleting “however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents”</p>	<p>It will be challenging to implement these recommendations across all types of antimicrobials and suggest deleting this phrase as a way to prioritize resources.</p>
Definition	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		<p>Concur with including “Food of plant origin: All edible parts of plants/crops used as foods”</p>	<p>This definition is necessary for clarity.</p>

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Definition	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with including “Therapeutic use: Administration of antimicrobial agents for the treatment, control/metaphylaxis and prevention/prophylaxis of disease.”	This definition is necessary for clarity.
Principal 5	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		<p>Recommend editing as follows “[Principle 5: Responsible and prudent use of antimicrobial agents follow <u>the recommendations in the OIE List of Antimicrobial Agents of Veterinary Importance, in particular regarding restrictions on the use of fluoroquinolones, third and fourth generation cephalosporins and colistin, and to phase out the use of antibiotics as growth promoters, in the absence of risk analysis, giving priority to the classes in the WHO category of Highest Priority Critically Important Antimicrobials</u> does not include the use for growth promotion of antimicrobial agents that are:</p> <ul style="list-style-type: none"> • considered medically important; or • able to cause cross or co-resistance to antimicrobial agents that are considered medical important. <p>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”</p>	Suggest edit to align Principal 5 OIE agreed language specifically 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents, 29-31 October 2018.
Principal 11	Jamie Jonker	National Milk Producers Federation		Concur with deletion “ Principle 11: This document is designed to provide a framework, for the development of measures to mitigate the risk of	Moved to Paragraph 5bis

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	Nick Gardner	U.S. Dairy Export Council		foodborne AMR, that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade"	
Paragraph 11	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested edit "...food-producing animals see <u>relevant national guidelines or harmonized guidelines, such as</u> the International..."	Edit for clarity. Inclusion of "relevant" and "harmonized" in this edit provide critical guidance for utilization of the COP. Those Codex members that implement the COP, must ensure they are thinking about the relevancy of existing guidelines with a mind towards harmonization.
Title Preceding Paragraph 12 and throughout rest of document	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested edit "Responsibilities of the <u>competent</u> regulatory authorities"	The term "regulatory authorities" is replaced with "competent authorities" throughout based on a decision at TFAMR6, see paragraph 76 of the report. This edit should be carried forward throughout the document.
Paragraph 22bis	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested edits "...elated to <u>anti</u> microbial resistance. The information collected through the pharmacovigilance program should form part of the comprehensive strategy to minimize <u>anti</u> microbial resistance."	Edit for clarity and consistency.

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Paragraphs 25-27	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		<p>Strike paragraphs 25-27</p> <p>25. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance with national legislation.</p> <p>26. Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.</p> <p>27. All advertising of medically important antimicrobial agents should be controlled by the relevant authorities.</p> <ul style="list-style-type: none"> • The authorities should ensure that advertising of antimicrobial agents: <ul style="list-style-type: none"> ○ complies with the marketing authorization granted, in particular with the content of the summary of product characteristics; and ○ complies with each country's national legislation. 	While advertising has been a subject of consideration in other Codex Committees, the role of Codex in developing advertising standards is at best unclear and at worst out of scope. The substance of this text relates to the implementation of advertising controls subject to national legislation and under the direction of the competent authority. This illustrates that this section adds little value to a country seeking to implement components of this COP. Given questions about scope and the controversial nature of the topic, we see minimal value in inclusion of this section.
Paragraphs 35-36	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		<p>Suggest deleting Paragraphs 35 and 36.</p> <p>“35. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise</p>	As noted above, Paragraphs 25-27 do not provide valuable or useful information for Codex members wishing to implement the COP.

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				<p>medically important antimicrobials to producers.</p> <p>36. Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged.”</p>	
Paragraph 36	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		Recommend editing as follows “	
Paragraph 50 (bullet 2)	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		Concur with suggested edit “The need to minimize the adverse health effect from the development of <u>antimicrobial</u> resistance based on...”	Edit for clarity and consistency.
Paragraphs 51-52	<p>Jamie Jonker</p> <p>Nick Gardner</p>	<p>National Milk Producers Federation</p> <p>U.S. Dairy Export Council</p>		Support Paragraphs 51-52 as written.	<p>For some disease conditions there may be no approved antimicrobials in a country, thus the ability for a veterinarian to utilize veterinary antimicrobial agent off-label for therapeutic purposes important for animal health, animal welfare, and food safety purposes. This may be particularly important in some developing countries where regulatory authorities have not approved veterinary antimicrobial agent for many disease conditions.</p> <p>It is also important that medically important antimicrobials are not</p>

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					permitted for off-label use for growth promotion.
Paragraph 58 (bullet 11 (iii))	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Recommend edits as follows <ul style="list-style-type: none"> ○ “.... ○ daily dose and number of treatment days; ○” 	Suggest deletion because this is duplicative to, and less clear than, the quantity and duration below.
Paragraph 60	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with deletion of Paragraph 60.	Incorporated into Section 6
Section 6	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested additions.	Deleted Paragraph 60 is incorporated into Section 6. Additional paragraphs incorporated appropriate Codex references.
Paragraph 61	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested edit “ <u>The WHO Five Keys to Safer Food Manual can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.</u> ”	Paragraph 61 revised and paragraph 63 deleted based on the suggestion of the Codex Secretariat, see TFAMR6 report, paragraph 81.
Paragraph 62	Jamie Jonker Nick Gardner	National Milk Producers Federation U.S. Dairy Export Council		Concur with suggested edit “...foodborne bacteria ₂ <u>application of a One Health approach</u> and FAO/WHO risk communication applied to food safety...”	Adds additional clarity.
Paragraph 63	Jamie Jonker	National Milk Producers Federation		Concur with deletion of Paragraph 63.	Paragraph 61 revised and paragraph 63 deleted based on the suggestion of the Codex Secretariat, see TFAMR6 report, paragraph 81.

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