



James Mulhern, *President & Chief Executive Officer* | Randy Mooney, *Chairman*

November 15, 2015

Kenneth Lowery
International Issues Analyst
U.S. Codex Office
Room 4861 South Building
1400 Independence Avenue SW.
Washington, DC 20250

Dear Mr. Lowery,

In view of the recent adoptions by the World Health Organization of the *Global Action Plan to Combat Antimicrobial Resistance*ⁱ and by the Food and Agriculture Organization of the *Resolution of Antimicrobial Resistance*,ⁱⁱ the Codex Alimentarius Commission (CAC) requested input via a Circular Letter on *Codex Work in Antimicrobial Resistance (AMR)*.ⁱⁱⁱ The National Milk Producers Federation is pleased to provide the U.S. Codex Office comments on this Circular Letter and the important topic of antimicrobial resistance.

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 more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

U.S. Dairy Industry Antimicrobial Use Commitment

Among the measures available to treat and prevent the outbreak and spread of animal diseases among the nation's dairy cattle, the judicious and responsible use of antimicrobial drugs has a positive impact on animal health and well-being while maintaining a safe milk supply for the public.

For more than 20 years, the U.S. dairy industry has focused educational efforts on the judicious and responsible use of antimicrobial drugs through the annual publication of a Best Practices Manual. The 2016 edition of the National Dairy FARM Program: Farmers Assuring Responsible Management™ *Milk and Dairy Beef Drug Residue Prevention Manual* (published October 2015) developed by NMPF is the primary educational tool for dairy farm managers throughout the country on the judicious and responsible use of antibiotics including avoidance of drug residues in milk and meat.

Additionally, the 2016 edition of the Residue Prevention Manual provides dairy farm managers guidance about the implementation of the Food and Drug Administration Guidance #209^{iv} and #213^v and the revised Veterinary Feed Directive Rule.^{vi}

Codex and OIE Codes on AMR

In the past decade, two important texts have been produced by Codex to address AMR in food through the use of antimicrobials in food-producing animals. The Codex *Code of Practice to Minimise and Contain Antimicrobial Resistance*^{vii} defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary

Agri-Mark, Inc.
Associated Milk Producers Inc.
Bongards' Creameries
Cooperative Milk Producers Association
Cortland Bulk Milk Producers Cooperative
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
FarmFirst Dairy Cooperative
First District Association
Foremost Farms USA
Land O'Lakes, Inc.
Lone Star Milk Producers
Maryland & Virginia Milk Producers Cooperative Association
Michigan Milk Producers Association
Mid-West Dairymen's Company
Mount Joy Farmers Cooperative Association
Northwest Dairy Association
Oneida-Madison Milk Producers Cooperative Association
Prairie Farms Dairy, Inc.
Premier Milk Inc.
Scioto County Cooperative Milk Producers' Association
Select Milk Producers, Inc.
Southeast Milk, Inc.
St. Albans Cooperative Creamery, Inc.
Swiss Valley Farms Company
Tillamook County Creamery Association
United Dairymen of Arizona
Upstate Niagara Cooperative, Inc.
Zia Milk Producers, Inc.

pharmaceutical industry, veterinarians, distributors and producers of food-producing animals. The Codex *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance*^{viii} assess the risk to human health associated with the presence in food and animal feed, including aquaculture, and the transmission through food and animal feed, of AMR microorganisms and determinants, to provide advice on appropriate risk management activities to reduce such risk.

The World Organization for Animal Health (OIE) through the *Terrestrial Animal Health Code*,^{ix} the *Aquatic Animal Health Code*,^x and the *Manual for Diagnostic Tests and Vaccines for Terrestrial Animals*^{xi} has intergovernmental standards for that promote the responsible and prudent use of antimicrobial agents in terrestrial animals, so as to preserve their therapeutic efficacy and prolong their use in both animals and humans. Additionally, the OIE has developed intergovernmental standards on antimicrobial resistance and on the monitoring of the quantities of antimicrobial agents used.

U.S. Initiatives

On September 18, 2014, President Obama released *Executive Order 13676 on Combating Antibiotic-Resistant Bacteria*.^{xii} The Executive Order established a Task Force co-chaired by the Secretaries of Defense, Agriculture, and Health & Human Services. The Executive Order goal is stated as:

“The Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.”

On March 27, 2015 the White House released a *National Action Plan for Combating Antibiotic Resistant Bacteria*^{xiii} as a follow-up to the Executive Order. The goals of the National Action Plan include:

- “1. Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections.*
- 2. Strengthen National One-Health Surveillance Efforts to Combat Resistance.*
- 3. Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria.*
- 4. Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines.*
- 5. Improve International Collaboration and Capacities for Antibiotic-resistance Prevention, Surveillance, Control, and Antibiotic Research and Development.”*

CODEX Circular Letter

The Codex Circular Letter included four specific questions. With consideration to the aforementioned activities and careful review of current Codex and OIE codes, NMPF provides the following comments to the U.S. Codex Office on those four specific questions:

- 1. “Review the extent to which Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011) have been adopted and applied.”*

NMPF Comment: The U.S. is progressing with adopting and applying both the Codex and OIE codes. This is evidenced by on-going activities of the U.S. government including additional oversight of and restricting use of shared class antibiotics from production claims through the FDA Guidances for Industry #209 and 213 and the Veterinary Feed Directive. Additionally, the *National Action Plan for Combating Antibiotic Resistant Bacteria* will ensure conformance to these international standards.

2. *“Identify major capacity development gaps and any other challenges faced in adopting and applying CAC/RCP 61-2005 and CAC/GL 77-2011.”*

NMPF Comment: The U.S. does not have major capacity development gaps or other challenges to adopt and applying the Codex codes.

3. *“Review the existing CAC/RCP 61-2005 and CAC/GL 77-2011 and evaluate the need for their update, taking into consideration the developments in the area over the past 10 years.”*

NMPF Comment: The current existing Codex codes are appropriate to assure food safety as it relates to AMR. As such, there is no need at this time for additional work in this area by Codex. OIE is the appropriate venue to address other aspects of AMR with respect to antimicrobial use in animals.

4. *“Consider the need to request FAO, WHO and OIE to convene expert meetings to review any new scientific evidence related to the AMR in the food chain including risk management options for the containment of AMR in support of any revision of Codex texts.”*

NMPF Comment: The current existing Codex codes are appropriate to assure food safety as it relates to AMR. As such, there is no need at this time for additional work in this area by Codex and would be an unnecessary use of Codex’s limited resources.

Conclusions

The U.S. dairy industry is committed to the judicious and responsible use of antimicrobials. The current existing Codex codes are appropriate to assure food safety as it relates to AMR and the U.S. is progressing with their adoption. Therefore NMPF does not support additional work by Codex on AMR at this time.

Please contact me if you have any questions about these comments.

Sincerely,



Jamie Jonker
Vice President, Sustainability & Scientific Affairs

ⁱ WHA68.7 <http://apps.who.int/medicinedocs/en/m/abstract/Js21889en/>

ⁱⁱ C2015/28 Rev.1 <http://www.fao.org/3/a-mm736rev1e.pdf>

ⁱⁱⁱ CL 2015/21-CAC 2015 http://www.codexalimentarius.org/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FCircular%252520Letters%252FCircular%2525202015-21%252Fcl15_21e.pdf

^{iv} FDA Guidance for Industry #209

<http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf>

^v FDA Guidance for Industry #213

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>

^{vi} FDA Veterinary Feed Directive <http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf>

^{vii} CAC/RCP 61-2005 http://www.codexalimentarius.org/download/standards/10213/CXP_061e.pdf

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- viii CAC/GL 77-2011 http://www.codexalimentarius.org/download/standards/11776/CXG_077e.pdf
- ix <http://www.oie.int/en/international-standard-setting/terrestrial-code/>
- x <http://www.oie.int/en/international-standard-setting/aquatic-code/>
- xi <http://www.oie.int/en/international-standard-setting/terrestrial-manual/>
- xii <https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria>
- xiii https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf