CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 11 **CAC/39 CRD/13**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

39th Session

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(COMMENTS OF THE UNITED STATES OF AMERICA)

AMR GLOBAL COMMITMENT TO ADDRESS A MAJOR PUBLIC HEALTH CONCERN

The United States is committed to addressing the issue of antimicrobial resistance as a major public health concern. In September 2014, the United States launched a National Strategy for Combating Antibiotic-Resistant Bacteria that envisions both domestic and international work to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensure the continued availability of therapeutics for the treatment of bacterial infections. Based on the National Strategy, a Task Force, co-chaired by the secretaries of Health and Human Services (HHS), the Department of Agriculture (USDA), and the Department of Defense (DOD), developed a National Action Plan for Combating Antibiotic-Resistant Bacteria in March 2015 that details a 5-year comprehensive approach for addressing antibiotic stewardship, surveillance, new product development, research, and international coordination. In addition, a Presidential Advisory Council, composed of leading non-governmental experts on antibiotic resistance issues was established in 2015 and has since held three public meetings.

The United States has implemented the National Antimicrobial Resistance Monitoring System (NARMS) to monitor the presence of antimicrobial resistant bacteria in humans, animals, and retail meats. The United States is active in international efforts such as the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), and works with international organizations such as the World Organisation for Animal Health (OIE), which strive to contain the threat of antimicrobial resistance through the prudent practice of veterinary medicine. The United States is also active in the World Health Organization (WHO) Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) to control the development and spread of antimicrobial resistant bacteria in the human population through the food supply. AGISAR has also identified the most Critically Important Antibiotics for use in human medicine that are also used in animals. The United States also notes that there are important initiatives underway regarding surveillance at OIE and the Food and Agriculture Organization (FAO).

The United States was a major contributor to the development of the Codex Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL77-2011), produced by the Taskforce on Antimicrobial Resistance. The concepts and steps identified in CAC/GL77 are implemented in the United States principally through the U.S. Food and Drug Administration Center for Veterinary Medicine Guidance for Industry (GFI) #152, entitled *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern*. The United States uses GFI#152 as a part of the pre-marketing evaluation of all antimicrobial drugs intended for use in food-producing animals. The United States has continued to consider these issues and released two additional guidance documents. These include GFI #209, entitled *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, and GFI #213, entitled *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209.* In addition, the United States has updated its Veterinary Feed Directive regulation to facilitate veterinary oversight of the use of medically important antibiotics in animal feed.

Once the policy from these documents is fully implemented by January 1, 2017, the use of all medically important antibiotics in animal feed or water will require the supervision of a licensed veterinarian and will only be available for therapeutic purposes—to treat, control, or prevent disease. The US Government is active in working with the animal agriculture and food production sectors in implementing the measures outlined in these documents along with other activities outlined in the National Action Plan. Through these and other measures the United States continues to evaluate and address issues of antimicrobial resistance consistent with

international guidance. We do not believe that CAC/GL77-2011 needs to be updated at this time as it contains a menu of risk management options at pre and post-harvest for animals and plants and the United States and other countries are in the process of implementing it. Initiating revision now could cause confusion and potentially delay action.

The United States also contributed to the development of the earlier Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), produced through the Codex Committee on Residues of Veterinary Drugs in Foods. The United States' animal agriculture industry is actively involved in implementing the current Code of Practice.

Next Steps for Codex: A Coordinated International Effort

Public health is best served by clear, non-contradictory guidance to member countries, and that guidance should be focused on the important issue of curbing the emergence of antimicrobial resistance to medically important drugs. There is currently much attention focused on this important issue in numerous and diverse fora. The Codex Alimentarius Commission should carefully and prudently reflect on all of the activities already underway, both nationally and internationally, and determine the specific needs that are uniquely within the purview of Codex and not being addressed in other venues. A coordinated international effort that does not result in conflicting or duplicative guideence is necessary. It is important to determine what gaps exist and what work within the mandate and scope of Codex could address these gaps. Establishing a Task Force prior to setting its scope would be an inefficient use of resources. A Codex working group (preferably electronic) reviewing existing activities and needs, clearly delineating the scope of new work to be undertaken by Codex, and developing terms of reference for provisions of consultative advice so that work products are relevant, useful, and non-redundant would be the most efficient and effective vehicle to accomplish this goal.

Proposed Electronic Working Group

Objective

With the aim of making recommendations to the Commission on what, if any, work regarding foodborne antimicrobial resistance a Codex ad hoc Task Force could address, the Working Group should develop recommendations specific to the following terms of reference:

Terms of Reference

Recommendations: The development of a document consisting of:

1) Identification of past, existing, and proposed efforts to address foodborne AMR through international bodies such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), World Organization for Animal Health (OIE), Global Health Security Agenda (GHSA), and other coordinated international efforts to address foodborne AMR;
2) Identification of areas that are not being addressed (gaps), prioritized by their need to be addressed;
3) Determination of any gaps within Codex's scope and mission to address;
4) Identification of international bodies having expertise to address gaps not in Codex's purview;
5) Terms of reference for consultative processes with affected international bodies [(WHO, FAO, OIE, International Plant Protection Conference (IPPC)] and others (GSHA, TATFAR) as appropriate.
6) Recommendation to Commission on whether to form a Codex task force and, if so, the terms of reference for the task force.
7) The working group should include affected international bodies in working group [(WHO, FAO, OIE, International Plant Protection Conference (IPPC)] and consult with or request input from member countries of other AMR coordination initiatives (GSHA, TATFAR) as appropriate.

Time Frame

The Electronic Working Group will complete its work within one year in time for discussion at the 2017 Commission meeting.