# Report of the U.S. Delegate, 5th Session of the Codex Alimentarius Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance

*November 27- December 1, 2017*
*Jeju, Republic of Korea*

Introduction

The 5th Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR5), chaired by the Republic of Korea, was held in Jeju, Republic of Korea, from November 27-December 1, 2017. The Session was attended by 44 member countries, one member organization (the European Union), and observers from 11 international organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

The United States was represented by Delegate Dr. Donald Prater, Office of Foods and Veterinary Medicine, U.S. Food and Drug Administration; Dr. Neena Anandaraman, Office of the Chief Scientist, U.S. Department of Agriculture; Mr. Ken Lowery, U.S. Codex Office, U.S. Department of Agriculture; along with six additional governmental advisors and three non-governmental advisors. The United States provided leadership as Chair of the electronic working group (EWG) responsible for drafting revisions to the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) in preparation for the session and will continue in that role.

Highlights

The Task Force completed a productive session further clarifying written comments submitted through EWGs, soliciting comments for continued development of new and revised texts through continuing EWGs, and refining the terms of reference (ToR) for scientific advice to help inform the work. The United States Delegate set a foundation for discussion by framing the three Codex documents on AMR as related chapters:

1. *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) is an overarching guideline for risk analysis;
2. The new draft *Guidelines on Integrated Surveillance for Antimicrobial Resistance* (GLIS) will provide data and information as inputs to the risk analysis process described in CAC/GL 77 and;
3. The revised *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) will provide risk management advice, including the responsible and judicious use of antimicrobial agents.

The Task Force work is focused on the latter two documents. The Task Force agreed to ensure coherence in terminology, processes, and principles among the three Codex documents on antimicrobial resistance (AMR).

Some major areas that will require future work to achieve consensus include:

1. **Scope:** Taking into account the mandate of the Task Force to develop texts that address antimicrobial resistance along the entire food chain, in line with the mandate of Codex, there were diverse opinions on the availability of, and need for, scientific data and information to support the work. In order to appropriately address the scope of the two texts, the Task Force will be informed by scientific advice from FAO/WHO. The Task Force will need to find consensus on the quantity and quality of information related to risks to human health so that risk-based, practical guidance on surveillance systems and risk management measures across various sectors can be developed.
2. **Approach to risk management advice:** Considering the current *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) focuses on the responsible and prudent use of antimicrobial agents in food-producing animals as an important way to address antimicrobial resistance, the Task Force considered a range of risk management advice that could be developed to minimize and contain antimicrobial resistance, for example by reducing the need to use antimicrobial agents. The Task Force will need to find consensus on risk management advice along the food chain that addresses the risks to human health associated with foodborne antimicrobial resistance, is supported by science, and is line with the mandate of Codex.
3. **Flexible, prioritized, high-level versus detailed, prescriptive guidance:** The Task Force discussed the need for guidance to be flexible with respect to taking into account national priorities and resources; prioritized with respect to addressing areas of greatest public health impact; and based on sound science. Some delegations suggested the guidance should be aspirational, describing what could be accomplished. The Task Force will need to find consensus on an appropriate level of flexibility and detail to allow the guidance to be practical, feasible, and address the highest priority risks associated with foodborne antimicrobial resistance.

At this session, the TFAMR5:

- Adopted ToR for continuing the EWG updating the Code of Practice
- Refined the ToR for scientific advice, prioritizing areas where data gaps exist on the risks of foodborne AMR from antimicrobial agent use on crops, in the environment, and as biocides
- Agreed to hold the draft texts at Step 3 for continued development by the EWGs
    - Proposed draft revision of CAC/RCP 61-2005 (EWG chaired by the United States and co-chaired by China, Kenya, the United Kingdom, and Chile)
    - Proposed draft GLIS (EWG chaired by the Netherlands and co-chaired by Chile, China and New Zealand)

Following is a brief summary of major issues discussed at the session. The full report of TFAMR5 (REP 18/AMR) along with associated meeting documents, including conference room documents (CRD), can be found at: http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=TFAMR&session=5.

Meeting Summary

## BACKGROUND

The 39th Session of the Codex Alimentarius Commission (CAC), which met from June 27-July 1st, 2016, recognized the need to take additional steps to address AMR, agreed to re-activate the Task Force with the Republic of Korea continuing as chair, and established a physical working group (PWG) chaired by the United Kingdom and co-chaired by Australia and the United States, with the tasks of revising project documents for new work (CX/CAC 16/39/12, Appendix 1, parts 1 and 2), and revising the ToR for the request for scientific advice from the FAO and WHO in collaboration with the World Organisation for Animal Health (OIE) (CX/CAC 16/39/12, Appendix 3). The meeting of the PWG was held November 29-December 2, 2016, in London, United Kingdom. The 40th Session of the CAC (2017) approved the new work as recommended by the PWG and established two EWGs to develop a proposed draft revision of CAC/RCP 61-2005 (chaired by the United States and co-chaired by China, Kenya, and the United Kingdom), and a proposed draft guideline on integrated surveillance of antimicrobial resistance (chaired by the Netherlands and co-chaired by Chile, China and New Zealand). The EWGs solicited membership from interested Members and Observers in the summer of 2017 and prepared two draft documents for circulation in preparation for TFAMR5.

## PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE* (CXC 61-2005)

A side event preceded discussion of the draft revised CAC/RCP 61-2005 which included three presentations: antimicrobial resistance, animal origin; antimicrobial resistance, non-animal origin (plants/crops, biocides, environment); and experience with antimicrobial resistance control programs in the Republic of Korea. The presentations highlighted available scientific information as well as data and information gaps. In general, more information is available on the use of antimicrobials and antimicrobial resistance in food-producing animals – yet data gaps remain. With respect to antimicrobial use and antimicrobial resistance of non-animal origin, significant data gaps exist – yet some information is available. The range of data and information available to develop surveillance guidelines and risk management advice varies considerably across sectors, such as different animal species and classes and crops across different regions.

Preceding plenary discussion of the draft revision of CAC/RCP 61-2005, the United States as EWG Chair provided background leading up to the TFMAR5 and emphasized the need for coherence between CAC/RCP 61-2005, GLIS and CAC/GL 77-2011. As requested by the TFAMR Chair, the EWG Chair used comments submitted in response to the EWG proposed draft revision CAC/RCP-61-2005 to further refine text for the “Introduction” and “Scope” sections (CRD5) to facilitate further consideration by the Task Force.

Terms and references became a major focus of discussion. Delegations asked for clarity around the terms “One Health” and “food chain integration” and inclusion of language on “risk-based” and risk management activities “proportionate to the risk.” The Task Force agreed to use consistent terminology, include only value-added new terminology, and appropriately reference relevant text from existing international guidelines [FAO, WHO, OIE, and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)] to prevent redundancies. The Codex Secretariat provided clarifying guidance that “read in conjunction with” means that the text is not a stand-alone document and is dependent on the document being referenced while “additional guidance” means the text is independent of the referenced document. The Task Force agreed to take these clarifications into account while further developing text in the EWGs.

The Task Force further considered but did not reach consensus on whether and how to broaden the scope of the document (crops, environment, biocides, animal feed, food processing, animal health); whether to reference only medically important antimicrobial agents or all antimicrobial agents; how to clarify appropriate off-label use of antimicrobial agents, including circumstances regarding minor species and growth promotion use; and how to restructure sections to better reflect provisions along the entire food chain. The U.S. made the point that the Code of Practice should be based on sound science and the work should be informed by additional scientific advice, particularly with respect to the use of antimicrobial agents and antimicrobial resistance in plants/crops/the environment.

The Task Force noted that responsibilities of consumers should be redirected to encourage national authorities to provide educational information for consumers. The inclusion of a section on ‘Advocacy and Communication’ was questioned by multiple delegations, including Thailand, Brazil, the United States, and Health for Animals as the concept of ‘advocacy’ is not typically addressed in Codex and ‘risk communication’ guidance is already contained within CAC/GL 77-2011. The Codex Secretariat said that discussion on what is meant by advocacy is occurring in another Codex committee and it may be beyond Codex scope.

An in-session working group, chaired by the United States with New Zealand serving as rapporteur elaborated the ToR for the next EWG on revising CAC/RCP 61-2005 to further develop the document based on comments of the Task Force. In addition, the in-session working group refined the ToR for scientific advice (CRD 6) to inform development of both the revised CAC/RCP 61-2005 and GLIS.

The Task Force noted that scientific advice provided by FAO and WHO, in collaboration with OIE, would be limited by available data. To support the work of an Expert Consultation, delegations were encouraged to respond to the call for data issued by FAO and WHO. It was also agreed that the request for scientific advice would be a living document, to be updated based on the needs of the Task Force. The European Union, Norway, Netherlands, and Switzerland stated their view that the questions regarding risk were too specific and a lack of data should not stand in the way of

providing risk management advice, while the United States (as well as Australia, Canada, New Zealand, Japan, Brazil, South Africa, Costa Rica, Kenya, and Argentina) supported the need for establishing risk to maintain the integrity of the Codex process.

The Task Force agreed to defer discussion of the definitions and general principles until the next session (TFAMR6) and that the document prepared for the current session (CX/AMR 17/55/5) should be the basis for further revision of CAC/GL 61-2005 through the EWG.

**PROPOSED DRAFT GUIDELINES ON INTEGRATED SURVEILLANCE OF ANTIMICROBIAL RESISTANCE**

The Netherlands as EWG Chair explained the key elements considered by the EWG and the recommendations based on written comments provided by the delegations. The Task Force discussed how an integrated approach to monitoring and surveillance may include: coordinated sampling, testing and reporting of AMR along the food chain; the alignment of procedures and methodologies; and the integrated analysis of these data and other information on AMR and antimicrobial use (AMU). While some delegations advocated for the inclusion of risk management guidance within the guidelines on integrated surveillance, the United States made the point that risk analysis is covered within CAC/GL-77-2011. The guidelines on integrated surveillance should focus on guidance to establish the core components of a surveillance system for antimicrobial resistance. The outputs from surveillance systems can inform the risk analysis process. Specific risk management advice can then be found in the CAC/RCP 61-2005.

The Task Force agreed that the structure of the GLIS should be consistent with CAC/RCP 61-2005 to the extent possible and that information provided on the purposes and use of the guidelines could be either removed, revised and/or reorganized within other sections as appropriate.

Delegations expressed differing opinions on the sample sources that should/must be included as part of the core elements of an antimicrobial resistance surveillance system versus additional elements that could be considered as appropriate (e.g., dust, crops, crates, trucks, or other environmental sources). The United States expressed concern that items such as dust appeared to be required core elements as written in the surveillance document. Canada stated that sample sources for surveillance should be based on sufficient scientific information, resources, and national priorities. The United States noted that while it was important to consider the various sources of foodborne AMR within the risk analysis process, it may not be practical, feasible or scientifically supported to include all potential sources of AMR as part of the core elements of a national surveillance system: the guidelines developed by the Task Force should assist countries in prioritizing areas for surveillance. For areas where there are limited data, such as crops and the environment, the United States stated that the Task Force should consider the results of scientific advice from FAO and WHO, while the European Union, Norway, Netherlands, and Switzerland argued that the work was already in the CAC charge to the Task Force and should be elaborated upon regardless of scientific advice.

Norway clarified that environmental sampling for dust could be a possible option as dust is sampled for Methicillin Resistant Staphylococcus Aureus in Norway. The Task Force also noted that while the scope of the GLIS covers the design and implementation of an integrated surveillance program for AMR and AMU along the food chain, the implementation of the guidelines may follow a stepwise approach that allows for flexibility through an incremental application according to the capacity and priorities of countries.

The United States was in favor of excluding biocides and disinfectants and emphasized the need for coherence with existing Codex texts as well as other texts developed by international organizations (for example, OIE does not include these substances in their definition of antimicrobial agents). The OIE concurred. The United States, reiterated concerns about the inclusion of antimicrobial use on crops without further scientific data, re-emphasizing the need to prioritize the scope of surveillance.

Delegations and observers (the European Union, India, Consumers International, International Association of Consumer Food Organizations) in favor of the inclusion of biocides and disinfectants noted that some of these substances might lead to foodborne AMR, and that the Task Force should consider inclusion as a low priority within the stepwise approach of implementing surveillance. The Inter-American Institute for Cooperation on Agriculture expressed concern that the stepwise approach described in the draft guidelines was too prescriptive and could be used as a trade barrier against countries which are not at a specific step. The intervention was supported by Brazil, the United States, Tunisia, and Uganda. The Task Force agreed that the section could be written at a higher level, for example as a flowchart to better reflect flexibility for implementation. The Task Force also noted the need for the GLIS to be based on scientific information, resources, and national priorities.

The Netherlands mentioned that the GLIS EWG suggested inclusion of examples as part of the text. The Codex Secretariat explained that some delegations had expressed concern about inclusion of examples and potential impacts for trade. While examples were usually not part of final Codex documents, as they might be misinterpreted as provisions rather than an illustration of the provision, they could be useful during the elaboration of the text. Examples developed by other Codex committees in support of Codex texts could be transferred to information documents (having no status in Codex) or included in FAO and WHO manuals.

With respect to the use of lists of critically important antimicrobials, Australia, the United States, and Canada noted, and the WHO representative supported, that national lists, where they exist, could be taken into account to reflect national priorities. The WHO list of Critically Important Antimicrobials and the OIE list of Antimicrobials of Veterinary Importance are international lists that may be used by countries, including those without national lists, for prioritization for risk assessment and risk management. Canada, the United States, Japan, and Australia noted that the design of integrated surveillance programs should be driven by the risk to human health considering resources available and technical capability of competent authorities. India and Kenya noted that laboratory

accreditation should not be compulsory when establishing national integrated surveillance programs. The European Union, Norway, Netherlands, Switzerland, and the Russian Federation noted that surveillance should be broadened to include areas beyond antimicrobial agent use in animals. Health for Animals noted that sources of AMU should include data beyond sales data, since sales data are not necessarily representative of use data. The Task Force noted that management of data does not require a single database but rather compatible systems that could allow integration of data; and that pharmacovigilance is a risk management activity and should be considered in CAC-RCP 61-2005. The United States noted that “reduce” use should be replaced with “optimize” use of antimicrobial agents because there may be legitimate needs to increase use if animal populations or disease prevalence increase. The Inter-American Institute for Cooperation on Agriculture concurred with the United States, while the European Union, Norway, Netherlands, and Switzerland disagreed and said that language to “reduce use” should be included.

*DATE AND PLACE OF THE NEXT SESSION*

The next session of the TFAMR is tentatively scheduled for December 3-7, 2018. The final arrangements are subject to confirmation by the TFAMR host country and Codex Secretariats.