



U.S. Delegate's Report, 6th Session of the Codex Alimentarius Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR)

December 10-14, 2018

Busan, Republic of Korea

Introduction

The 6th Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR6), chaired by the Republic of Korea, was held in Busan, Republic of Korea, December 10-14, 2018. The Session was attended by 45 member countries, one member organization (the European Union), and observers from 13 international organizations, including the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Organization for Animal Health (OIE).

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; four additional governmental advisors; and seven non-governmental advisors. The United States continued in its leadership role 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.

Highlights

The Task Force completed a productive session working on two documents: Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and Proposed Draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance. The Task Force came to agreement on specific text for certain sections, including introduction, scope, definitions and general principles.

The TFAMR agreed to maintain the proposed draft documents at Step 2/3 for redrafting, and established EWGs for continued development of the work, with the understanding that agreed text should not be reopened to the extent possible, noting further that the reports from the two EWGs should be provided to the Codex Secretariat at least three months prior to the next session for circulation and comment.

The Task Force shared views on areas where there is a divergence of opinions on the remaining text requiring work to facilitate further consensus during the next round of EWGs. Differences of opinion continue regarding whether the guidance should be aspirational or practical and how to address sectors of the food chain where data and knowledge gaps exist. Some major points of discussion included:

- 1) Consideration of data and knowledge gaps in certain sectors of the food chain, noting the report of the Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of Crops, Environment, and Biocides;
- 2) Concerns by several delegations about the approach of categorizing countries monitoring and surveillance systems for antimicrobial resistance (AMR) and antimicrobial use (AMU) and whether such categorization could result in barriers to trade.

- 3) The role of national lists and international lists of critically important antimicrobials (i.e., WHO List of Critically Important Antimicrobials, OIE List of Antimicrobials of Veterinary Importance);
- 4) Appropriate approaches to referencing relevant texts, including Codex texts and those developed by member country consensus and recognized under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement);
- 5) Consideration of relevant risks from various sectors of the food supply chain taking into account available scientific information along with data and knowledge gaps (e.g., hazard vs. risk);
- 6) Focus on the mandate of Codex Alimentarius when considering the scope of the work (e.g., environment vs. food production environment, all animals vs. food-producing animals, all plants vs. food crops); and
- 7) Approaches to the use of antimicrobials for production purposes vs. therapeutic purposes (i.e., assuring health), all antimicrobials vs. medically important antimicrobials, monitoring vs. surveillance, oversight of antimicrobial use by professionals, and control of advertising and promotion of antimicrobials.

Following is a summary of major issues discussed at the session. The full report of TFAMR6 along with associated working and conference room documents (CRD) can be found at: <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=6> .

Meeting Summary

MATTERS REFERRED

Codex Committee on Pesticides and Residues (CCPR): The FAO reported on the outcome of a survey conducted through CCPR contact points on the use of antibacterials in crops which indicated that antibacterials are approved for use to treat plant diseases in at least 20 countries. Regulations and oversight of antibiotic use are strong, and residues present on foods of plant origin are minimal. Data on the amounts and types of antimicrobials used, crops treated, and the potential for antimicrobial resistance (AMR) development are lacking. To develop science-based recommendations to mitigate AMR, the use of antimicrobials in plant production resulting in occupational exposure, food, and environmental contamination need to be assessed. FAO will continue to work on this area together with WHO and OIE.

FAO/WHO expert meeting on Foodborne Antimicrobial Resistance: Role of Environment, Crops and Biocides: The FAO representative described highlights from the workshop report:

- Biocides can drive AMR but there is no evidence to document the extent to which this occurs in food production or the processing environment. Products should be used according to manufacturer instructions.
- Cross-contamination of crops could be a source of foodborne AMR, Good agricultural practices should be employed to prevent AMR development.
- The environment can serve as a “sink” and a “source” of AMR organisms. Good stewardship practices should be used.

The FAO representative recommended that country-level priorities inform development of surveillance systems. FAO can help countries to assess their national systems through FAO’s Assessment Tool for Laboratories and Antimicrobial Resistance Surveillance Systems (ATLASS) program.

Discussion regarding work of other international bodies:

- WHO: Japan requested that WHO clarify the standing of WHO expert group recommendations like the WHO's list of Critically Important Antimicrobials (CIA) in human medicine and Guidelines on use of medically important antimicrobials in food-producing animals versus the WHO Global Action Plan which was adopted by Member States. The WHO clarified that the guidelines on use of medically important antimicrobials in food-producing animals was drafted on request by veterinary colleagues on how to use the CIA list and were based on antimicrobial agent value to human medicine. The WHO delegate explained that CIA list and guidelines for food producing animals were not cleared by the World Health Assembly (Member States) but done by experts on human medicine based on what the WHO representative characterized as good science.
- World Trade Organization (WTO): The WTO report described the concerns raised recently in the Sanitary and Phytosanitary (SPS) Committee in response to notification by the European Union of new regulations for veterinary medicines. Several countries expressed concerns that the new regulations seek to inappropriately impose conditions of use in the EU on other countries. Some countries (Argentina, Australia, Brazil, Canada, Chile, Columbia, United States) raised the issue as a specific trade concern. Argentina noted the EU rules would require exporters of animals and animal products to meet EU standards concerning the use of certain antimicrobial medicinal products, as a condition for maintaining access to the EU market, despite the differences in the prevailing sanitary conditions. Other countries noted that if the EU rules were applied extraterritorially, these restrictions would undermine multilateral efforts to combat AMR.

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

The United States, as Chair of the EWG on revising CAC/RCP 61-2005, explained the key elements considered by the EWG and the conclusions and recommendations based on written comments, outlining the areas where consensus could be more easily reached and those that would likely need to be further refined by an EWG. Norway expressed support for a physical working group to address those areas where it may be difficult to find consensus. The EU expressed support for inclusion of the whole food chain in the draft but believed that the scope still appeared limited to that of similar guidance in OIE and expressed an interest to expand the scope. Japan reminded the Task Force of the need for a scientific, risk-based approach, that risk management should be based on risk assessment, that all countries should not be obligated to do work they do not have the resources for, and that countries that are willing to conduct risk analysis to determine whether there is a risk to public health should have the option to do so.

The International Association of Food Consumer Organizations (IAFCO), supported by Uganda, asked for stronger language to characterize the global problem of AMR and Nigeria asked to include feed with food. The word "prioritize" was added to strengthen the introduction in reference to the AMR issue. IAFCO asked that the "food production" qualifier be removed from environment, but Chile, Australia, Japan, and the United States all intervened to keep it. Norway asked to reference the just released FAO/WHO 2018 report. India supported Norway and asked to reference the WHO guidelines on use of medically important antimicrobials in food-producing animals. Consumers International supported addition of the WHO guidelines and Norway asked to make a general reference to "WHO guidelines" to cover any that are developed in future. The United States intervened that they did not support reference to the WHO guidelines on use of medically important antimicrobials in food-producing animals and expressed concern that it would not be appropriate to reference all future guidelines as we

do not know what will be in them. Chile, Australia and Japan supported the United States intervention. Chile, supported by the United States, Australia, Japan, and Brazil intervened to reference only the WHO CIA appendix 1 (list of critically important antimicrobials) rather than the entire WHO CIA document. The EU, Netherlands, Norway, and Consumers International intervened supporting reference to the entire document. Without consensus, the Task Force tabled the issue for further consideration by the EWG.

During discussion on scope, the Task Force considered whether the term food includes feed, deciding it did not, so both “food” and “feed” were included to be consistent with the Codex Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011). The Task Force did not agree on limiting scope to antibacterials, vs. antimicrobials.

The Task Force agreed to General Principles 1, 2, 3, 4, 8, 9, 10, 13, 14, and 15 with minor revisions. Ghana and Zimbabwe intervened to delete reference to national lists. Norway, the EU, and Zambia stated that the WHO list is international in scope. The United States, Japan, Australia, and Indonesia did not support the change to only reference the WHO CIA list, noting that national lists are developed to reflect national conditions and risk. References to both national lists and the WHO CIA list were retained. This was consistent with the conclusions of the last meeting of the Task Force and supported by an intervention by WHO regarding the role of national lists. During discussion of Principle 11, the Task Force agreed to use the term “progressive” to show gradual implementation of activities. This removed the categorization of countries that some countries believed was implied by the term “stepwise” and was seen by many as a potential trade barrier.

The Task Force considered whether to retain reference to the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines. Brazil explained that since all Member States do not participate, they cannot give input on future changes and therefore it was inappropriate to reference VICH. The OIE noted reference to VICH appears in the Terrestrial and Aquatic Animal Health Codes. The Task Force considered whether to keep the sections on advertising and marketing. Russia asked that advertising for medically important antimicrobials be prohibited. In the absence of consensus, the sections were retained for further consideration by the EWG.

The Task Force considered Principle 5 regarding the phasing out of medically important antimicrobials for growth promotion. The United States urged the TFAMR to join with it to protect consumers by eliminating the use of medically important antimicrobial agents in food-producing animals for production purposes, that is, for growth promotion and feed efficiency. The United States stated that it had eliminated the use of medically important antimicrobials in food-producing animals for production purposes. The Delegation further encouraged the TFAMR to define medically important antimicrobial agents as those that are important for therapeutic use in humans as described by established national lists, or where such lists are not available, by the WHO list of critically important antimicrobials. The United States further urged the Task Force to ground the work of the TFAMR in science and risk assessment and proposed the addition of a proposed separate general principle regarding risk analysis based on scientific evidence. The United States proposed removal of the phrase “in the absence of a risk analysis” for phasing out medically important antimicrobials for production purposes (growth promotion) and retaining risk analysis in a separate principle.

The EU suggested the text call for phasing out the use of *all* antimicrobial agents, not just those that are medically important. Japan stated that countries that wish to do the work of risk analysis to determine

relevance to human health should be able to do so, reminding the Task Force that “in the absence of a risk analysis” language was consistent with OIE language. Brazil, Australia, China, Kenya, and Uganda supported Japan with some suggestions for merging Principles 5,6, and 7. Spain, India, Kazakhstan, Switzerland, and Sweden supported the EU position. The EU asked that “therapeutic” be replaced with “veterinary medicinal purposes” as agreed to at OIE, and to add treatment, but not prevention and control, as uses for plants. Russia asked to remove the term medically important and treatment and control as therapeutic uses. Consumers International supported removal of prevention as a therapeutic use. France supported the EU suggestion and WHO reminded The Task Force of the WHO guidelines’ recommendations to restrict preventive uses. The United States explained the term medically important helps distinguish those antimicrobial agents that are important for therapeutic use in humans , explained that the term therapeutic is more applicable to a One Health approach rather than “veterinary medicinal purposes” as it relates to mitigating disease, and offered to have plant/crop experts describe how antibacterials legally authorized for use in the United States are used. The European Union agreed to retain the terms treatment, control, and prevention. Chile asked that the Task Force to consider the definition of medically important which would further aid in the discussion of the principles.

The United States asked the EU which antimicrobials they meant when they said “all antimicrobials” should be removed for growth promotion, that is, does the EU include all substances in Annex 2 of the WHO CIA List which are not used in human medicine? The EU explained they included all antimicrobial agents. New Zealand asked for clarification whether the EU included ionophores in their definition of “all antimicrobials”. The EU stated that it did as they consider the use, “growth promotion”, rather than the compound, to be the problem, so they believed no antimicrobial agents should be used for growth promotion purposes.

The Task Force expressed many views regarding the term, medically important. The EU did not support the term and Norway, France, and Russia agreed. The International Poultry Council expressed concern that stakeholders had come to an understanding around the term, medically important, and it was useful for defining what was and what was not important to human medicine. The United States, Australia, Brazil, and Canada all supported the need for the term. Additionally, the United States asked the definition include “important for therapeutic use in humans” instead of “used in humans”. The Task Force initially agreed to the definition, but Norway later expressed concern and the definition was reopened for consideration by the EWG.

The Task Force agreed on definitions for the following terms under Section 3, Definitions: “antibacterial”, “adverse health effect”, “AMR”, “AMR determinant”, “disease control/metaphylaxis”, “co-resistance”, “cross resistance”, “extra-label use”, “food chain”, “food-producing animal”, “growth promotion”, “marketing authorization”, “One Health approach”, “pharmaceutical industry”, “pharmacovigilance”, “plants/crops”, “prevention and treatment”. Definitions for “food of plant origin”, “plant/crop professional”, “medically important”, “therapeutic use”, and “food production environment” (a new definition proposed by the United States during the GLIS discussion) will be further developed by 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 conclusions and recommendations based on written comments. The Netherlands Chair noted the need to discuss key points such as the stepwise approach on the remaining sections, specifically 7.3.

Australia clarified that monitoring could be intermittent, unlike surveillance, and consistent with OIE which the United States supported. Canada offered additional language, and multiple delegations including Consumers International, Norway, the European Union, Japan, Zimbabwe, Ecuador and Switzerland intervened with language describing monitoring as the collection of data and surveillance as the continual collection of data to inform action and measure impact

The United States noted that Paragraph 3 in the introduction was not supported by the current state of the science in some sectors. As drafted, the guidelines would require national integrated surveillance systems to include sampling for AMR and AMU for humans, animals, crops, and the environment. The United States made the point that fundamental components, such as sample sources, target organisms, and analytical methods, have not been determined or developed that would support a harmonized system. The United States offered language from WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) that reflects the core components necessary for an integrated foodborne AMR surveillance system: AMR from humans, food animals, and retail meat. Chile added crops. Norway and the European Union intervened to keep the original language as they argued that AMU, crops and the environment are necessary to include in the introduction. The WHO intervened to say the AGISAR language was a few years old and it needed to be updated with new science. The FAO intervened that their recent report in response to the TFAMR5 (2017) request for scientific advice described the need to survey crops and the environment. Canada, Thailand, and the Codex Secretariat agreed that language in the introduction could be left overarching and that further down in the document, the Task Force could provide clarification that specific areas could be included in a progressive manner, potentially incorporating the AGISAR language. During the break, at the request of the Chair, several delegations including Australia, the United States, Norway, Canada, and the European Union further refined the text and during Task Force deliberation, but the language remained bracketed as consensus could not be reached by the Task Force.

During discussion of Paragraph 4, the United States asked to include the term “foodborne” to remain within Codex scope and after further discussion on Paragraph 5, the Task Force agreed to insert the term “foodborne” where appropriate in the text of the whole document. In Paragraph 6, Chile explained the term “national food control system” could necessitate more resources and pose potential trade implications for countries and asked that the phrase be removed, which was supported by Brazil, Australia, New Zealand, Japan, Thailand, and Nicaragua. The European Union stated the phrase was not intended to be a trade barrier and asked for its retention with a change in term from “food safety” to “food control.” Thailand stated it still may be used as a trade barrier and asked the text to be left in square brackets for the EWG to consider, which Australia and the United States supported.

During discussion of Scope, the FAO suggested “feed” should be included within the scope since the FAO/WHO expert meeting report identified feed as a source of AMR bacterial contamination. The United States noted the scientific advice provided by FAO/WHO and reminded participants that it is the role of the Task Force to suggest additions to the text. The European Union then asked to revisit the definitions to see if feed is included as “food,” Chile asked for clarity as they did not understand that surveillance included surveillance for feed, and the Task Force continued to share views on whether to incorporate “feed” in the definition of “food chain” without a decision and deferred the matter for further consideration by the EWG.

Chile asked that “environment” be qualified using the term, “food production environment.” The United States supported Chile and offered a definition. The TFAMR6 Chair asked that the definition be further considered by the EWG.

IAFCO asked to include biocides within the scope based on information in the recent FAO/WHO report. The United States noted the section of the FAO/WHO report which stated, “Although there is theoretical and experimental evidence that certain microbiocidal agents may co-select for AMR, there is an absence of empirical data to indicate that the use of biocides drives this co-selection under the conditions present in the food production or processing environments.” The United States reminded the Task Force that Codex is based on science and risk, not theoretical concerns, and asked that biocides remain outside the scope, which was agreed to by the Task Force as no others intervened.

The Task Force agreed to harmonize definitions with those in the Code of Practice, delete “prioritized antimicrobial agents”, and leave “food chain” and “food production environment” for further consideration by the EWG. General Principle 1 regarding use of a “One Health” approach was agreed to with the addition of “antimicrobial use”.

There was much discussion around Principle 2 regarding surveillance being a core component of food safety systems. Chile asked to delete the principle as it was captured in the introduction. Kenya concurred and expressed concern that the language may be used as a trade barrier. New Zealand, Brazil, Ghana, Australia, and the United States agreed. The European Union, Norway, Russia, and Switzerland asked it to be retained. The language remains in square brackets for consideration by the EWG. The United States intervened to 1) keep the language in Principle 7 to be what is “practical” instead of what is “possible”; 2) add language to principle 9 to specify “according to national priorities and resources” and asked to remove the term “inappropriately” in Principle 11 to avoid any suggestion that there are appropriate trade barriers. There were no other interventions and the committee agreed with the U.S. proposal. Under the Risk Communication section, for Paragraph 35, the United States asked for “inappropriate” be added to read as “reduce inappropriate use” rather than “reduce use.” Norway disagreed and the TFAMR6 Chair asked for further consideration of Paragraph 35 by the EWG.

Significant discussion around the table in Section 7.3 occurred around the potential for use of the table to categorize countries by level of surveillance system that could be used as a trade barrier. Brazil intervened asking for deletion of the table citing concerns that the table will be used to categorize countries for trade purposes and that falls outside the scope of Codex. The United States, India, Indonesia, Nicaragua, Chile, Paraguay, Australia, Zimbabwe, Kenya, and IICA all supported the intervention by Brazil. Canada suggested taking off the headings of categories and further develop the content into an appendix, a suggestion with which Nigeria and Uganda concurred. The European Union supported keeping the table and the stepwise approach. Norway agreed with the European Union and Canada. The United Kingdom suggested that the Terms of Reference for the EWG be to review and revise content without the suggestion of categorization, a suggestion with which the Codex Secretariat and Task Force agreed.

DATE AND PLACE OF THE NEXT SESSION

The next Session of the TFAMR will take place in approximately one year and will be determined by the host for the TFAMR and Codex Secretariat.