# U.S. Delegate's Report 8<sup>th</sup> Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) October 4-16, 2021 Virtual

## Introduction

The 8<sup>th</sup> Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR8), chaired by the Republic of Korea, met virtually, October 4-16, 2021. The session was attended by 81 member countries, one member organization (the European Union), and observers from 16 international organizations, including the Food and Agriculture Organization (FAO), the World Health Organization (WHO), the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC).

The United States was represented by Delegate Dr. Donald Prater, Office of Food Policy and Response, U.S.Food and Drug Administration, U.S. Department of Health and Human Services; Alternate Delegate Dr. Neena Anandaraman, Office of the Chief Scientist, U.S. Department of Agriculture; 12 governmental advisors; and 6 non-governmental advisors. In preparation for TFAMR8, and during the session, the United States continued hits strong leadership role as Chair of the Electronic Working Group (EWG) on the revision and updating of the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005), by hosting a webinar and leading discussions in Virtual Working Group (VWG) sessions to help find consensus on remaining bracketed text.

#### Highlights

The United States is pleased that following eight days of intensive discussion, the time-limited Task Force completed a final, productive session, advancing:

- The Proposed Draft Revision of the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CAC/RCP 61-2005) to Step 8 for final adoption by the 44<sup>th</sup> Session of the Codex Alimentarius Commission (CAC44, November 2021).
  - Key Areas of Discussion:
    - The TFAMR worked to resolve divergent views on use of the term, "therapeutic use" in Principle 13 and other places in the document.
    - The TFAMR came to consensus on Principle 13 by using the term "veterinary medical use" to describe how medically important antimicrobials may be administered for treatment, control, and prevention of disease in animals (consistent with OIE) and referring to "phytosanitary use" in plants/crops (referencing IPPC).
    - A footnote was added to the definition of "veterinary medical use" to acknowledge this term may be recognized as "therapeutic use" in some jurisdictions and organizations.

- The Proposed Draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (GLIS) to accelerated final adoption at Step 5/8 by CAC44.
  - Key Areas of Discussion:
    - The GLIS EWG Chair and Co-chairs incorporated previously submitted U.S. comments relating to science, risk, and Codex scope; consistency with other international standard setting bodies; and allowing for flexibility as appropriate to national circumstances.
    - The Task Force agreed to refocus the guidelines as contributing to a One Health approach rather than constituting the One Health approach to AMR.
    - The Task Force agreed to refocus on foodborne antimicrobial resistance (AMR), the topic in the terms of reference for the TFAMR, rather than AMR and antimicrobial use (AMU).
    - The description of a risk-based approach, was modified to be in line with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011), noting that surveillance programs contribute data for risk assessment in the risk analysis framework, rather than implying that surveillance data alone could serve as the basis for risk management actions.
    - The TFAMR agreed to delete Figure 1 under preliminary activities as the TFAMR did not reach consensus on whether it was useful in further explaining the text.
    - New paragraphs at the beginning of sections describing sampling and data collection for AMR and AMU were introduced to recognize the variations in national context and resource availability, thereby highlighting that integrated monitoring and surveillance programs may vary between countries.

#### Meeting Summary

The following report summarizes issues of interest to the United States. The official TFAMR8 meeting report is posted on the Codex Alimentarius website at: <u>https://www.fao.org/fao-who-codexalimentarius/sh-</u>

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetin gs%252FCX-804-08%252FREPORT%252FFinalReport%252FREP21\_AMR08e.pdf.

#### MATTERS ARISING FROM FAO/WHO/OIE

As the Tripartite (OIE, FAO, WHO) Joint Secretariat on AMR, the FAO provides secretariat functions to global governance structures called for by the ad hoc Inter-Agency Coordination Group (IACG) on AMR. At TFAMR8, the FAO representative provided updates on related activities, including:

- The Global Leaders' Group on AMR was established in November 2020 to serve an advisory and advocacy role to catalyze political leadership and action to preserve antimicrobial medicines. Consisting of heads of government, government ministers, and leaders from private sector and civil society, in August 2021 the group published a call to action on AMR and food systems.
- The membership of the proposed AMR Multi-Stakeholder Partnership Platform will include government representatives, UN agencies, international, intergovernmental, and regional organizations, international financial institutions, civil society, private sector, academia, and research institutions. The purpose of the AMR Multi-Stakeholder Partnership Platform is to

bring together different voices across the human, animal, plant, and environment interface to strengthen a shared global vision on AMR, provide a venue for information-sharing and networking, and take action to reduce the impact of AMR.

- The Independent Panel on Evidence for Action against AMR is in development.
- The AMR Multi-Partner Trust Fund (AMR MPTF), which supports efforts by low- and middleincome countries to address AMR is currently funded by the Netherlands, Sweden, Germany, and the Fleming Fund (United Kingdom).
- The following Tripartite documents were published related to AMR: 1) Technical brief on water, sanitation, hygiene, and wastewater management to prevent infections and reduce the spread of antimicrobial resistance; 2) International instruments on the use of antimicrobials across the human, animal, and plant sectors.
- To measure progress on National Action Plan (NAP) implementation, the Tripartite administers an annual country self-assessment survey on AMR (TrACSS). While 139 countries have developed NAPs, only 94 have started implementing their plans, and only 31 countries are implementing and actively monitoring their national action plans.
- The Tripartite Integrated Surveillance System on AMR/AMU (TISSA) is being funded through the AMR MPTF. A platform is being created which intends to make available, in a user-friendly manner on a global and regional basis, validated and official data provided by countries to FAO, OIE and WHO on patterns and trends in AMU and AMR.

FAO, WHO, and OIE provided the following updates specific to their organizations:

- The FAO Action Plan on Antimicrobial Resistance 2021–2025 was approved by the 166<sup>th</sup> session of the FAO Council (April 2021) and will guide FAO's support to its Members to build capacity to minimize and contain AMR in the food and agriculture sectors.
- The WHO Advisory Group on Integrated Surveillance of AMR (AGISAR) together with WHO Collaborating Centers developed a global protocol on surveillance of extended spectrum betalactamase (ESBL) producing *Escherichia coli* using a One Health Approach ("Tricycle ESBL *E. coli* surveillance project"). The Tricycle ESBL *E. coli* surveillance protocol was launched in March 2021 and was described as intending to monitor what was referred to as the "prevalence of one single AMR indicator, ESBL *E. coli*" in humans, the food chain, and the environment. Nine countries have been trained to pilot the protocol. The WHO expects to have a list of priority fungal pathogens published by the end of 2022.
- The 5<sup>th</sup> report of the OIE Global Database on Antimicrobial Agents Intended for Use in Animals (2021) included data received from more than 150 countries and new quantitative data from 103 countries, confirming continuing progress and improvement of data quality. The 5<sup>th</sup> report provides, for the first time, an analysis of trends in the data reported by 69 countries to the OIE for 2015 to 2017 and indicates an overall decrease of 34% in the global quantity of antimicrobial agents reported by animal biomass (mg/kg). OIE reported that this is an indicator that can be compared between regions and over time.

## MATTERS ARISING FROM IPPC

• The IPPC explained that robust data on the extent and volume of antimicrobial use by the plant sector worldwide does not exist. Regional and national antibiotic use varies due to agricultural needs, legislation, availability, cropping systems, extension services, and/or pathogen incidence.

## MATTERS ARISING FROM OTHER RELEVANT INTERNATIONAL ORGANIZATIONS

- The World Customs Organization (WCO) discussed their operations intercepting and seizing illicit goods and anti-infective agents linked to COVID-19. The WCO has seized 130 million lots of anti-infective agents.
- The World Bank is providing financing to address AMR in 56 projects across 35 countries.
- In March 2021, the Organization for Economic Cooperation And Development (OECD) released a publication – "Assessing National Action Plans on Antimicrobial Resistance in Animal Production: What Lessons can be Drawn?" The OECD identifies policy gaps and calculates rates of return on investments in AMR-related research and mitigation strategies. The OECD representative also expressed ongoing interest in continuing close co-operation with Codex and other international organizations.

# PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (COP) (CAC/RCP 61-2005)

Following interim adoption of the COP at Step 5 by the 43<sup>rd</sup> Session of the Codex Alimentarius Commission (CAC43, November 2020), the TFAMR Chair asked TFAMR8 to focus attention in plenary on the remaining bracketed text and to not re-open discussions on previously-agreed text. The TFAMR Chair then turned to the U.S. Delegate, as chair of the EWG on the COP, who described how the revised draft COP fulfills the mandate the TFAMR as described in the original project document for the work and approved by the CAC, by:

- Broadening the scope of the COP and developing risk-based guidance on the management of foodborne antimicrobial resistance that addresses the entire food chain, in line with the mandate of Codex, and that is scientifically supported and takes into account new developments, including the establishment of Lists of Critically Important Antimicrobials, and the work of FAO, WHO, and OIE in this area.
- Addressing risk mitigation measures, including all uses of antimicrobial agents along the food chain and providing updated information, in particular with regard to the inclusion of references to the lists of Critically Important Antimicrobials; the use of antimicrobials as growth promoters; and the use of alternatives to antimicrobials.

Although the TFAMR was reminded to focus on the bracketed text, the European Union (EU) intervened to indicate that although it would not seek to reopen Principle 12, the EU wanted to provide a statement for inclusion in the report reiterating that in their view "all uses of antimicrobial agents for growth promotion should be phased out globally, starting with the highest priority critically important antimicrobials." Norway, Switzerland, and Russia supported the intervention.

Aside from that, the TFAMR deliberated over the remaining bracketed text concerning the term "therapeutic use" in the following: Definitions, Principles (notably Principle 13), and Section 5, Responsible and prudent use of antimicrobial agents. Additional details on the discussions during plenary may be found below.

Principle 13: [Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)]

- The EWG Chair provided four options in Conference Room Document (CRD) 12<sup>1</sup>:
  - Option A-- Retain Principle 13 as written: [Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease).]. This had the most consensus throughout the duration of the TFAMR and included the term "therapeutic use."
  - Option B-- Combine Principles 8 and 13, including "therapeutic use," but added the specifications for use under Principle 8: [Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) and be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.]
  - Option C-- Revise Principle 13 by making reference to treatment, control, and prevention as uses for assuring health, but not including terminology associated with assuring health: [Medically important antimicrobial agents should only be used for disease treatment or control/metaphylaxis and/or prevention/prophylaxis purposes and only under the conditions laid down in principles 7-10, and 14 and 15).]
  - Option D-- Revise Principle 13: Replace "therapeutic use" with "veterinary medical use" and "phytosanitary use" to describe uses for assuring health for animals and plants/crops:[Medically important antimicrobial agents should only be used for veterinary medical/phytosanitary use (treatment, control/metaphylaxis or prevention/prophylaxis of disease).] The TFAMR noted that the term "veterinary medical use" is consistent with OIE and addition of the term "phytosanitary" would be an option for reference to use of antimicrobial pesticides on plants/crops, as the term is used by IPPC for plant/crop uses.
- Members and Observers who supported Options A and/or B justified their support in stating
  that they saw value in use of the term "therapeutic use" to distinguish uses that address health
  versus production purposes such as growth promotion; the principle was consistent with
  identifying uses for assuring health in OIE; and that inclusion of a definition did not promote any
  specific use identified in the definition. Supporters included Australia, Japan, New Zealand,
  Brazil, Korea, Paraguay, Costa Rica, Thailand, Ecuador, Uruguay, Argentina, India, China, Iran,
  Morocco, Kenya, Senegal, Egypt, Thailand, Honduras, Indonesia, New Zealand, the United
  States, Health for Animals and Crop Life International. The Health for Animals representative
  reminded the TFAMR that all countries allow use of medically important antimicrobials (MIA) for
  therapeutic purposes as defined in Option A.
- The EU stated that there was no agreement to use "therapeutic use" to cover the three uses listed under Option A so they could not support Option A. This position was supported by Norway, the United Kingdom, North Macedonia, Indonesia, Canada, Switzerland, Philippines, Uganda, Sri Lanka, Russia, Kazakhstan and Consumers International. Norway, Switzerland, Kazakhstan, and Canada expressed their belief that inclusion of the term "therapeutic use" encouraged preventive uses.
- While Nigeria, Tanzania, and Morocco were opposed to Option A, they could support Option B with the additional text from Principle 8 regarding specifications for use.

<sup>&</sup>lt;sup>1</sup> https://www.fao.org/fao-who-codexalimentarius/sh-

proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX -804-08%252FCRDs%252Famr08\_CRD12x\_Rev.pdf

 The TFAMR Chair noted that Options A-C received mixed support and therefore strongly endorsed the compromise text found in Option D (replacing "therapeutic use" with "veterinary medical use/phytosanitary use") and asked if countries could support this alternative option. Brazil and the EU stated they could see Option D as a way forward, followed by China, the UK, Chile, Jamaica, Costa Rica, Uruguay, Honduras, Nigeria, Kenya, and Argentina. Japan reiterated support for Option A, but when specifically asked if they could support Option D by the TFAMR Chair, said that they could. Seeing that Option D had gained widespread support, the TFAMR Chair proposed that countries accept Option D as a compromise. Russia noted a reservation on Principle 13 stating that they did not agree with any of the proposed options but did not offer an alternative option for the TFAMR to consider.

#### **Definition of Therapeutic Use**

- The TFAMR Chair then moved on to definition of "therapeutic use." Since Option D for Principle 13 no longer contained the term, Chile and Brazil proposed to replace "therapeutic use" with the term "veterinary medical use/phytosanitary use" since the compromise option of Option D was dependent on inclusion of consistent terms in the definitions section of the COP. This was supported by Australia, Argentina, Paraguay, Costa Rica, Uruguay, and Nigeria.
- Norway, Canada, and Russia proposed to delete the definition of veterinary medical use; The EU however supported its inclusion in the spirit of compromise.
- The EWG Chair provided footnotes to the OIE Terrestrial Code and IPPC standards to reference the terms "veterinary medical use/phytosanitary use" respectively in the document.
- The United States asked for an additional footnote for clarity on the newly agreed upon term "veterinary medical use/phytosanitary use" to indicate that the term is also referred to and recognized as therapeutic use in some jurisdictions, and provided the following justification for inclusion in the TFAMR8 report:

"The United States of America strongly recommends inclusion of a footnote in the definition of veterinary medical/phytosanitary use to recognize that the term therapeutic use is a well-understood and widely used alternate term for describing the administration of antimicrobial agents for treatment, control, and prevention of specific diseases in food-producing animals and plants/crops in many jurisdictions. Many national and professional bodies around the world have used the term for many years and using clear language is critical to progressing global stewardship to limiting use to purposes necessary to assure health, in contrast to production purposes including growth promotion. Failure to acknowledge the term therapeutic use in this guidance from Codex risks making it out-of-step with antimicrobial stewardship programs in many jurisdictions. Recognizing the significant amount of support for this term throughout the plenary and in various electronic and virtual fora, we implore the Task Force to acknowledge its use through incorporation of this footnote."

- Ghana, Japan, Chile, Tanzania, Costa Rica, Uruguay, Kenya, Argentina, Nigeria, Brazil, Paraguay, Australia, China supported the footnote referencing therapeutic use. The International Meat Secretariat (IMS) explained that the term, "therapeutic use" was important for global consistency and understanding of a well-recognized term. Exclusion of the footnote referencing the term, "therapeutic use," could create unnecessary global confusion.
- The EU reiterated that neither the definition nor the footnote was needed. Sweden, Germany, Kazakhstan, Canada, and Consumers International supported the EU position stating they

believed the footnote added confusion as they believed therapeutic use referred to treatment only.

- In an effort to find consensus, Chile suggested modifying the footnote to read: "also recognized as therapeutic use in some jurisdictions/organizations" for clarity. Uruguay, Chile, Paraguay, and Honduras supported the modified footnote. Norway and Colombia questioned reference to acceptance "in some jurisdictions/organizations" as reference to national legislation.
- The United States reiterated its support for the "therapeutic use" footnote, as well as edits from Chile, explaining that many members had compromised in accepting removal of the term "therapeutic use" from the Definitions and from Principle 13, and that others should now compromise to allow for inclusion of a footnote referencing therapeutic use in other jurisdictions.
- The EWG Chair proposed that the best location for the additional footnote would be after the term "veterinary medical use" as footnote 2 to the term. Australia, Nigeria, Morocco, and Ecuador supported inclusion of the therapeutic use footnote.
- The United States asked that the TFAMR accept the footnote and complete discussion on the COP, suggesting that those countries opposed could consider filing a reservation.
- The TFAMR Chair asked the EU whether they wanted to file a reservation on inclusion of the "therapeutic use" footnote, which the EU agreed to do. Canada, Colombia, Jamaica, Kazakhstan, Morocco, Norway, Russian Federation and Uganda also filed reservations on the footnote.

# PROPOSED DRAFT GUIDELINES ON INTEGRATED SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

The TFAMR Chair asked the Task Force to focus on finding compromise and completing the work at this session—a monumental task for a document that had been returned for redrafting following TFAMR7 (December 2019). The Netherlands, as Chair of the EWG, provided historical perspectives and a summary of the document's development. The EWG Chair and Co-chairs had extensively modified the text to incorporate comments received for TFAMR8 ensuring more flexibility and references to science and the scope of Codex in the document.

## Introduction and purpose

• The text was refocused on the guidelines as contributing to a One Health approach. In addition, the introduction was refocused on foodborne AMR, the topic in the terms of reference for the TFAMR, rather than AMR and antimicrobial use (AMU). AMU was still recognized as a part of the scope of the guidelines, but there was consensus to move details to Section 9, where AMU is specifically addressed. Other modifications included addition of the term, "foodborne" to specify Codex scope and inclusion of risk analysis terminology.

## Principles

• <u>Principle 6<sup>2</sup></u>: The United States expressed concern that the text should be in agreement with *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (*CXG 77-2011) regarding an "AMR food safety issue," which helps countries define the problem. Switzerland and Canada

<sup>&</sup>lt;sup>2</sup> Priority for implementation of monitoring and surveillance program(s) should be given to the most relevant foodborne AMR and/or AMR food safety issues (which are the defined combinations of the food commodity, the AMR microorganism and determinants and the antimicrobial agent(s) to which resistance is expressed as described in CXG 77-2011) from a public health perspective, taking into account national priorities.

explained that for surveillance, before the risk profiling step, the AMR food safety issue may not yet be defined, so as a compromise the Task Force agreed to include both "foodborne AMR" and "AMR food safety issue."

- <u>Principle 9<sup>3</sup></u>: Delegations expressed divergent views regarding reference to data. Delegations expressing concern with reference to data sharing (Brazil, Australia, Costa Rica, Thailand, Uruguay, Argentina, and the United States) cited confidentiality concerns and noted that mandating data sharing was beyond the remit of the TFAMR. Delegations supporting inclusion of reference to data sharing (EU, Norway, Sweden, Germany, Ecuador, and Consumers International) stated their view that data sharing was included in the TFAMR mandate.
- The TFAMR Chair proposed text to allow for comparability of data. The United States supported the Chair's proposal, with the understanding that the reason for harmonizing methodologies was to promote data comparability. The EU reminded the TFAMR that many countries are contributing data to OIE and FAO. OIE and FAO agreed that countries voluntarily share data with them. Compromise text was partially drawn from the TFAMR project document to allow for voluntary contribution of data to international organizations and multisectoral exchanges.

## **Risk-based approach**

• The section was modified to be in line with CXG 77-2011, to make it clear that surveillance programs contribute data for risk assessment in the risk analysis framework, rather than being the basis on their own for risk management actions.

## Regulatory framework, policy, and roles

• Members expressed concerns regarding data sharing, as for Principle 9. Text was modified to allow for voluntary sharing with international organizations.

# Preliminary activities for the implementation of an integrated monitoring and surveillance program(s) for foodborne AMR

- Text in the section was modified by the Co-chairs to include reference to science, clarify that the scope related to "foodborne" AMR, and provide appropriate flexibility.
- Figure 1, a diagram that attempted to capture pertinent points in the GLIS, had been further altered by the EWG Chair and Co-chairs based on comments received. Canada, the EU, Ghana, and Norway supported inclusion of the Figure.
- The United States did not agree that Figure 1 added clarity with reference to the CAC/RCP 61-2005 and CXG 77-2011, with arrows going to specific items in the diagram. Costa Rica, Brazil, Uruguay, and Nigeria supported deletion of Figure 1.
- The United Kingdom proposed Figure 1 be taken up at a later date and the Codex Secretariat mentioned that Figure 1 could be placed on the Codex website as an information document separate from the GLIS.
- The United States, Brazil, and Chile did not support placing Figure 1 on the Codex website as there was no agreement on the content of Figure 1.
- The EU and Switzerland supported moving forward with the GLIS, excluding the Figure, and the

<sup>&</sup>lt;sup>3</sup> Monitoring and surveillance program(s) should aim to harmonize laboratory methodology, data collection, analysis and reporting across sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized, and validated methods and harmonized interpretative criteria, where available, contributes to the comparability of data, facilitates the multisectoral exchange and analysis of data and enhances an integrated approach to data management, analysis, and interpretation.

Task Force agreed to delete Figure 1.

#### Components of integrated monitoring and surveillance program(s) for AMR

- The GLIS EWG Chair explained that a chapeau had been added to the section to allow added flexibility for countries in implementing sampling strategies. Norway expressed concern that inclusion of the text, "scientifically relevant," referring to indirect sample sources could limit the possibility of risk profiling at the early stage. The United States explained that Codex guidance did not limit a country from collecting any samples it would like to collect, but that Codex, as an international standard-setting body, needed to base its guidance on science and risk. The Chair of the EWG further explained that scientific relevance helped to sharpen focus. Chile, Brazil, Canada, China, Nigeria, and Japan supported the EWG Chair's explanation.
- Uganda expressed confusion on the inclusion of the term "lairage." Chile and the United States supported Uganda in that use of the term may not be clear to all. The OIE clarified that lairage is not included in OIE texts. The TFAMR Chair recommended deleting "lairage" and the reference to lairage was deleted.
- The United States, Australia, Chile, and Costa Rica supported deletion of "feed" as it is within OIE scope and covered in OIE standards, but the EU, Norway, Sweden, and Consumers International asked to retain the term as they viewed it as within the food chain scope of Codex. The TFAMR Chair recommended retaining "feed" in the GLIS and it was retained.
- Australia expressed concern that specification of "imported food sources" could present an unjustified barrier to trade. Jamaica asked to retain "imported food sources" because the term is important for Jamaica. The COP EWG Chair clarified that, during previous COP deliberations, it was decided that it was not useful to distinguish between domestic and imported food in the COP. The TFAMR Chair requested consistency with the COP and the reference to imported food was removed.
- The United States expressed concern that there was reference in the section to international standards for genotypic testing. Genotypic testing was covered in a different section and there are no international standards for genotypic testing. Other delegations asked to leave reference to international standards for genotypic testing to leave open the possibility for their development in the future. The GLIS EWG Chair and Co-chairs edited the statement to delete references to phenotypic and genotypic testing when stating that international standards should be used, where available. The compromise would help prevent confusion and also leave open the possibility for such standardization in future. TFAMR8 agreed to the revision.

## Components of integrated monitoring and surveillance program(s) for AMU

- The GLIS EWG Chair explained that a chapeau had been added to the section to allow increased flexibility for countries in implementing AMU data collection programs. Australia proposed text to better explain what "antimicrobial agents intended for use" are. Norway supported the text from Australia but was concerned that the acronym "AMU" is widely used and throughout the GLIS. The United States supported the text proposed by Australia and proposed replacing "AMU" with "antimicrobial agents intended for use," language used by OIE, to better represent various data collected including on farm and sales data. The United States stated its concern that there was much confusion around the term "antimicrobial use," which is different from sales data. Most current data collection focuses on sales data, not use data. The GLIS provided a chance for Codex to offer clarity rather than add to existing confusion around terminology. This intervention was supported by Ghana and Health for Animals.
- The EU explained that the terms antimicrobial use and "AMU" are already widely used, and

that sales data represents AMU data. The FAO reiterated that "AMU" is used by international organizations and in the scientific literature. The OIE provided clarification that it uses "antimicrobials intended for use" because in some cases they do not have data on the actual use, so some of the data is based on sales data. Following a lengthy debate, the United States proposed additional compromise text regarding differentiation between antimicrobial use and sales. The TFAMR agreed to the proposal.

• The EWG Chair and Co-chairs had proposed text regarding measurement units and indicators. The TFAMR agreed to add a footnote to provide further explanation of these terms. Australia and Brazil introduced proposals to clarify the use of the terms and provide flexibility for data collection. The EU and Norway opposed the new text, arguing that the existing text already provided enough flexibility. In an effort to find consensus, the United States proposed the addition of text to allow for qualitative data collection consistent with OIE. TFAMR8 agreed to accept the U.S. proposal.

#### Integrated analysis and reporting of results

• The EWG Chair and Co-chairs had redrafted this section to accommodate comments on the need to consider contributors to AMR other than AMU in evaluating results and data analyses. The changes were accepted by the TFAMR.

#### NEXT SESSION

Following adoption of the COP and the GLIS by the CAC44, the TFAMR will have concluded its work and will once again be dissolved until such time that further work on AMR may be warranted in Codex. No additional sessions of the TFAMR are now planned.