



# TFAMR8 Q&A

## Revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance

CAC43 adopted the revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance at Step 5 in November 2020. In this Q & A, **Donald Prater, Chairperson of the electronic working group**, explains how the guidelines have been revised and updated and the remaining outstanding issues. He outlines his plans and expectations for the working group sessions which will take place virtually on 14 and 17 June and how these discussions could help TFAMR8 in finalizing this document at its next meeting in October 2021.

### 1. What are the main changes that have been made to the Codex of Practice in the course of its revision?



The COP at Step 6 contains many significant advancements in AMR risk management based on the best available scientific information, is risk-based, practical and feasible for implementation by countries, aligns with OIE standards and appropriately references other Codex and WHO texts, represents a significant amount of careful thinking, negotiation and compromises, and recognizes areas for the future where data and knowledge gaps can be filled to further advance AMR risk management.

Significant advancements and guidance include:

- a. Expanded and augmented guidance that goes beyond the current version of the COP which was developed in 2005 and focused on the animal sector.
- b. Introduction of the concept of the “**food chain**” with respect to risk management of AMR. A new definition was developed and used it throughout the document.
- c. Description of the important roles and responsibilities of all participants in the food chain (expanded from the current version) to manage risks associated with the use of antimicrobial agents.
- d. Introduction of the **One Health Approach** (absent in current version of the COP) taking it into consideration throughout the document to address the interconnection between human health, animals and plants/crops, and the environment.
- e. Clear inclusion of both **terrestrial and aquatic production**.
- f. Description of the many activities along the food chain where risk management measures may be taken into account. For example, in addition to primary production, the revised COP now covers **processing, storage, transport, wholesale and retail distribution of food**.
- g. Placement of the COP in context with other key AMR texts in the Codex Alimentarius, including most notably the Guidelines for Risk Analysis of Foodborne AMR developed in the last Task Force.
- h. Provision of a framework for **integration of texts** in Codex with other relevant international guidance, particularly the OIE standards which contain guidance on AMR such as the Terrestrial and Aquatic Animal Health Codes and OIE List of Antimicrobial Agents of Veterinary Importance.
- i. Key guidance on the use of WHO List of Critically Important Antimicrobials for Human Medicine and integrated surveillance are referenced – as well as the essential role of national guidance on AMR where it is available.
- j. Addressing implementation by countries to ensure it is in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time – and in a way that is proportionate to the risk and avoids unjustified barriers to trade.
- k. Affirmation that most of the recommendations in the Code of Practice focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where there is scientific evidence of foodborne AMR risk to human health.

## 2.

So the COP has undergone a major revision.

Given the expanded coverage of the COP that you described above, did you have to add new definitions?



Yes in order to accomplish its mandate to expand the AMR risk management guidance along the entire food chain, the COP contains new definitions to address advancements in AMR risk management subsequent to the last version of the document (adopted in 2005) and to apply the One Health Approach.

a

To facilitate understanding of risk management measures related to the responsible and prudent use of antimicrobial agents, the COP contains updated definitions for **treatment of disease**, **control of disease/metaphylaxis**, and **prevention of disease/prophylaxis**.

b

To help further highlight those antimicrobials that may need appropriate risk management measures due to their importance for therapeutic use in humans, a definition of **medically important antimicrobials** was developed. “Medically important antimicrobials” is an important risk management concept that has been used by WHO and some national authorities.

c

A definition of the **One Health Approach** for the purpose of the revised Code of Practice was developed.

d

To support the advice for the plant/crop sector, new definitions for “**plants/crops**” were developed as well as “**plant/crop health professional**”. These definitions are essential for understanding the risk management advice, to expand the COP along the food chain, and to implement a One Health Approach.

e

And a new definition of **pharmacovigilance** was developed to address collection and analysis of data on how antimicrobial agents perform in the field after authorization.

## 3.

A new Section on General Principles was developed to highlight and underscore key concepts – at a high level – that are important to minimize and contain AMR.

Can you give an overview of what those principles cover?



Yes we can group the principles into several areas as follows:

a

A set of **Principles to address AMR Risk Management – generally**

- the One Health Approach;
- integration with OIE and IPPC standards;
- integration with GL77 and consideration of unintended consequences;
- guidance on the use of WHO List of Critically Important Antimicrobials for Human Medicine, the OIE List of Antimicrobial Agents of Veterinary Importance, and national lists, where available; and
- guidance on progressive implementation of risk management measures with prioritization of public health impact.

b

A **principle on preventing infections and reducing the need for antimicrobials**.

c

A set of **principles to promote the responsible and prudent use of antimicrobials** (generally)

- The use of professional judgement and consideration of results of bacterial cultures and integrated resistance surveillance and monitoring;
- Limitations on the use of medically important antimicrobials only with professional oversight as authorized in accordance with national legislation;
- Restriction of the use of antimicrobial agents to those that are legally authorized or except where specific legal exemptions apply;
- Considerations for selecting the most appropriate antimicrobial agent;

d

**Principles to address the use of antimicrobials in specific circumstances**, including:

- Prohibitions of the use of medically important antimicrobial agents for growth promotion;
- Limiting the use of medically important antimicrobials to therapeutic uses, i.e. for treatment, control, or prevention of disease; and
- Additional measures limiting the use of medically important antimicrobial agents for metaphylaxis and prophylaxis.

## 4.

### Section 5 is the largest section of the COP.

#### Can you give an overview of what that covers?



Section 5 contains risk management guidance for different participants along the food chain, including guidance to competent authorities on systems for granting evaluating antimicrobial agents and granting a marketing authorization.

The COP contains the concept of the “**food production environment**” as a means to address the environmental component of the One Health Approach in line with the mandate of Codex and addresses specific potential sources of contamination in the food production environment.

The role of **pharmacovigilance systems** to collect data on adverse reactions, including lack of efficacy that could be related to foodborne antimicrobial resistance, is addressed and guidance is provided on how these systems can be used in conjunction with monitoring and surveillance programs.

Substantively expanded sections on **training** on foodborne antimicrobial resistance and the responsible use of antimicrobial agents have been included.

Sections recognizing the **current knowledge gaps** and providing a range of areas where additional data and information are needed to minimize and contain AMR have been included as well as guidance to countries on these areas can help focus research to make further advances in AMR risk management.

Reference is made, for the first time, to **substandard and falsified drugs, and illegally marketed antimicrobial agents** with guidance to develop effective procedures for the safe collection and disposal. Additional guidance on advertising and promotion of antimicrobial agents.

Specific advice for both **Veterinarians** and for the first time **Plant/Crop Health Professionals** is included. This is especially important for the plant sector, where limited guidance may be available with respect to minimizing and containing AMR.

## 5.

### The revised COP now goes beyond primary production. How was that achieved?



A new Section 6 was added to the COP to address practices during production, processing, storage, transport, retail and distribution of food. The section references HACCP and Codex General Principles of Food Hygiene as **risk management measures which can minimize the introduction, presence and growth of microorganisms**, which apart from having the potential to cause spoilage and foodborne illnesses can also disseminate foodborne AMR.

## 6.

### How does the revised COP address actors at the end of the food chain – consumers?



A new Section 7 was added to the COP to address communication to consumers. This section focuses on how government, food industry, and other stakeholders can **inform and educate consumers on the risks of foodborne illness, including infection with resistant microorganisms**. Minimizing foodborne infections in the first place lowers the risk of acquiring a potentially resistant infection as well as reducing the need to use antimicrobial agents.

## 7.

### What were the remaining issues that the EWG addressed since TFAMR7 and did the EWG reach consensus on these issues?



At the conclusion of TFAMR7, an electronic working group was established “to address the outstanding issues in square brackets and report back to the next session of TFAMR8.” The text in square brackets included the definition of “therapeutic use”, a General Principle stating, “Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)”, and a reference to “therapeutic” in paragraph 54.

The EWG was held from May 2020 through February 2021 and received a total of 34 sets of comments from 20 Codex Members, 1 Codex Member Organization, and 4 Observers. After considering the comments and noting a divergence of opinion, the EWG Co-Chairpersons recommended making a refinement of the definition of “therapeutic use” with the aim to have greater clarity in the guidance provided in Principle 6 and in places where this term is used throughout the Code of Practice. The EWG Co-Chairpersons, with respect to Principle 6 and paragraph 54, recommended retaining the text as written.

## 8.

### What are the key issues to be discussed in the working group in June?



Reflecting on the consensus achieved at the conclusion of TFAMR7, the discussion at CAC43, and comments provided in response to the Circular Letter (CL) at Step 6 ([Replies to CL 2021/31-AMR](#)), the entire COP should be reviewed during the virtual Physical Working Group (PWG).

Further discussion on the General Principles to address the use of antimicrobials in specific circumstances, including: prohibitions of the use of medically important antimicrobial agents for growth promotion; limiting the use of medically important antimicrobials to therapeutic uses, i.e. for treatment, control, or prevention of disease; and additional measures limiting the use of medically important antimicrobial agents for metaphylaxis and prophylaxis may be useful to gain additional consensus.

## 9.

### Do you expect any challenges or surprises?



Considering the careful thinking, negotiation and compromises undertaken by the Task Force over the past four years to arrive at AMR risk management guidance based on best available scientific information, that is risk-based, practical and feasible for implementation by countries, and aligns with OIE standards and appropriately references other Codex and WHO texts, a significant challenge may be the well-intentioned desire of Members and Observers to “improve” the existing text. Such “improvements” could inadvertently risk unravelling interconnected concepts and the shared understanding and level of consensus obtained at TFAMR7. While a few key concepts merit discussion to see if additional consensus can be gained and the entire document should be reviewed for coherence, the PWG should be careful to avoid re-opening text where previous consensus has already been achieved.

## 10.

### How are you planning to approach the working group?



The approach for the working group will be a straightforward review of the COP from beginning to end with an aim to review the document for coherence and addressing key concepts as they arise with a particular focus on General Principles to address the use of antimicrobials in specific circumstances and the definition of therapeutic use as discussed in the EWG-COP4 and taking note of comments provided in the CL at Step 6.

We will begin the first day with the Section 1. Introduction and proceed through Section 4. General principles to minimize and contain foodborne antimicrobial resistance. As the section General Principles to address the use of antimicrobials in specific circumstances occurs at the end of Section 4, we will continue discussion of Section 4, if needed, on the second day. If the discussion of Section 4 is concluded on the first day, we will begin discussion on the second day with Section 5. Responsible and prudent use of antimicrobial agents.

During the working group meeting, we will not endeavor to perform line-by-line editing of the entire document; rather we will collect comments, identify areas of consensus and incorporate them into a revised document following the working group for further comment and subsequent discussion at TFAMR8. In the event line-by-line editing is needed to gain additional consensus on specific points, we will endeavor to do our best to conduct this in the virtual environment. Should we encounter challenges we will similarly do our best to capture the consensus and present it in a revised document following the working group for further comment and subsequent discussion at TFAMR8.

## 11.

### How should delegates prepare for the working group?



Be familiar with the past discussions and areas where consensus had been reached in the version adopted at Step 5. Be familiar with the current version of the document and the report of the [EWG-COP4](#) noting that TFAMR should finish its work this year so the aim is to submit this revision for final adoption to the commission in November. Be familiar with the linkages with the existing Risk Analysis document ([CXG 77-2011](#)) and the GLIS document under development. Be familiar with the recommendations of CAC43.

## 12.

### What do you want to achieve by the end of the working group?



Important goals for the working group include review of the document for overall coherence and addressing key concepts where additional consensus may be gained. Other important goals include taking note of the significant advances in AMR risk management contained in the updated and revised document and developing a shared understanding of the critical need for advancing the work in Codex Alimentarius as part of the global effort to minimize and contain AMR.

## 13.

### What will happen after the working group?



As needed the co-chairs and myself will revise the document based on the working group discussions and that updated version will be shared for discussion at TFAMR8 in October.

