



Report of the U.S. Delegate, 3rd Session of the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance

The Third Session of the Codex [ad hoc Intergovernmental Task Force on Antimicrobial Resistance](#) was held October 12-16, 2009, in Jeju, Republic of Korea. The session was attended by 148 delegates from 43 member countries, 1 member organization and observers from 8 international organizations and FAO and WHO. The objective of the task force is to develop science-based guidance to help countries assess the risks to human health associated with the presence in food and feed and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance determinants and to develop risk management advice based on that assessment to reduce such risk.

The Task Force made significant progress in advancing the document titled *Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CX/AMR 09/3/4)*, agreeing to forward the proposed draft guidelines to the 33rd Session of the Codex Alimentarius Commission for adoption at Step 5. This progress was facilitated by four intersession working groups on the following topics: table 1, monitoring and surveillance, figures, and definitions.

The Task Force has been directed to complete its work within four sessions. The fourth session of the Task Force is tentatively scheduled to be held in 2010 in Korea, with a specific date and location subject to further discussions between the Korean and Codex Secretariats. A physical working group, chaired by Canada, will meet immediately before the next Session to further consider Appendix 1, "Elements of a Risk Profile" and to prepare a revised document based on comments submitted.

Background

Development of the draft guidelines began in 2007, with a project proposal for creation of three working groups to address risk assessment (chaired by Canada), risk profiling (chaired by the United States) and risk management (chaired by Denmark and France).

A physical working group was held in Brussels following the 1st session (May 2008), where the three working groups developed their respective documents. The resulting three draft documents were circulated for comment at step 3.

At the 2nd session in 2008, the Task Force decided to integrate the three working group drafts into one harmonized guidance document. Following the opportunity for country comments, an electronic working group, chaired by the United States, integrated the three documents. The integrated document was presented for consideration at Step 3 at the 3rd session in October 2009.



A full report of the meeting is posted on the web site of the Codex Alimentarius Commission at the following link: <http://www.codexalimentarius.net>. The following is a brief summary of key decisions made by the Task Force at the 3rd session.

Key Decisions made by the Task Force

The following decisions regarding the draft guidelines were made:

Introduction

- The Task Force agreed that the document needed to be thorough enough to provide adequate guidance without too much duplication of existing Codex documents.
- The Task Force agreed with the decision of the United States in the electronic working group to adopt a chronological approach to the organization of the guideline.
- The United States asked that the following sentence be added to the introduction so that other references to trade later in the document could be eliminated to reduce redundancy:

These guidelines should be applied in a manner consistent with countries' WTO SPS obligations and other international agreements, as applicable.

The Codex Secretariat said such a statement was not appropriate in the guidelines as all Codex members are not necessarily WTO members. Further, it was explained that Codex texts were voluntary in nature and references to the WTO SPS Agreement were not appropriate in the text. The United States voiced its reservation when a similar reference later in the document was deleted by the Codex Secretariat.

Scope

- A new, overarching "scope" section will cover the consolidated document.
- The United States stated its belief that there was an overemphasis on plant/crop and food processing sources of antimicrobial resistance as opposed to veterinary applications, particularly because few or no human analogs are used in the non-veterinary sources. As the objectives for the Task Force were to put into perspective the different areas of use, the United States proposed a statement that the focus of the guideline should be on veterinary applications of antimicrobial drugs that may impact human health through the selection and dissemination of antimicrobial resistant foodborne bacteria and resistance determinants. The Task Force did not agree to the proposal, indicating that the document was providing a tool or methodology, and contributions of various sources to antimicrobial resistance would be addressed through the risk analysis

process described in the document. Further, the Task Force did not believe that one source should be singled out as circumstances may change in the future.

Terminology

- The Task Force agreed to use the phrases, "foodborne antimicrobial resistance (AMR)", "selection and dissemination", and "production to consumption" where appropriate throughout the document for consistency and accuracy. In addition, the phrase "antimicrobial agent" would be used instead of "antimicrobial," to be consistent with terminology from the WHO/FAO/OIE 2007 expert meeting report.

Structure of the document

- The Task Force agreed to retain the current structure of the document, which describes risk analysis of foodborne antimicrobial resistance in a chronological sequence of events, rather than change the document to a functional structure by grouping all risk management activities together separate from risk assessment and risk communication.
- The Task Force debated the advantages of a long document, where language from other relevant documents is repeated within the text, versus a short document, where such repetition is kept to a minimum. The Task Force agreed that the guidelines should be practical, relevant, specific to foodborne antimicrobial resistance and not overly prescriptive. Thus, the document would be shortened where possible to avoid duplication with other Codex texts while still ensuring readability and usefulness.
- The Task Force agreed that the reference section will be removed, and relevant references will be included via footnotes throughout the document to be consistent with the format of other Codex texts.

Definitions

- The Task Force agreed to remove any definitions already included in the Codex Procedural Manual and to incorporate in the text of the Guidelines the definitions for terms that appeared only once. The definition for "national treatment guideline" was inserted as footnote. Definitions that could not be agreed upon (exposure assessment, hazard, risk manager, weight of evidence) were deleted. Two new definitions for "food producing animal" and "interpretive criteria" were added.

General Principles

- For General Principle 6, the Task Force agreed to focus on the following combination of factors for foodborne antimicrobial resistance risk analysis

throughout the document: food commodity, the microorganism/resistance determinants, and the antimicrobial agent to which resistance is expressed.

- There was considerable discussion regarding adding a new principle that indicated risk managers should consider animal health and animal welfare with respect to risk management options. The New Zealand Delegation brought up the fact that the *Codex Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account*, state that governments may have legitimate concerns when establishing their national legislation that are not generally applicable or relevant worldwide, and it would therefore not be appropriate to include animal welfare in the document. *The Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* further highlights that risk analysis should be conducted in accordance with these Statements of Principle. A new General Principle 8 was added to emphasize that the evaluation of pre-harvest foodborne AMR risk management options should include, whenever appropriate, animal health aspects relevant to food safety. Animal welfare was not included in this new principle because it was acknowledged as being outside the mandate of the Codex Alimentarius Commission.

Preliminary Risk Management Activities

- A number of paragraphs in the preliminary risk management activities were deleted.
- The Task Force considered a revised Appendix for risk profiling prepared by the United States and presented in Conference Room Document (CRD) 12. In view of time constraints, the Task Force agreed to put the entire Appendix in square brackets for consideration at its next session.

Figures

- The Task Force agreed to delete language in the text concerning the need for clear evidence in decision-making for an immediate public health concern. Language remaining in Figure 1 indicates the ability to take an "immediate (and/or provisional) decision" when a risk profile indicates the need for such.
- The in-session working group on figures proposed deleting Figure 2, and the Task Force agreed.
- There was extensive discussion on whether Figure 3 should be deleted, which describes the integration of exposure assessment and hazard characterization. The Task Force agreed to keep the figure with suggested modifications.

Risk Management

- The introductory paragraphs and the text in the section on identification of risk management options was substantially rewritten in a CRD developed by Canada with assistance from the United States. The Task Force agreed to the revised language with minor modification.
- The Task Force agreed to retain Table 1 (list of risk management options) in the main body of the text as proposed by the European Community and supported by the United States.
- Table 1 was substantially revised by the in-session working group and agreed to by the Task Force during the plenary session.
- Because the table lists risk management options, the Task Force agreed it was not necessary to insert the word "consider" before each option to emphasize its voluntary nature since the table listed examples.
- Animal Feed Production: The Task Force agreed to move the statement on monitoring feed and feed ingredients to a new section on surveillance. Subsequently, monitoring of feed and feed ingredients was only addressed in a general way. The bullet concerning the setting of maximum limits was deleted, and the statement regarding prohibition was modified to limit the scope of the prohibition to the presence of AMR organisms/determinants identified as contributing to a specific food safety problem.
- Food animal production: All bullets under biosecurity were deleted to make the table shorter as their essence was captured in the biosecurity introductory statement; remaining bullets were divided between regulatory/non-regulatory controls; the bullet on prohibiting extra/off label antimicrobial use was changed to restricting antimicrobial use, in part due to the need to provide medications for minor species; the bullet on antimicrobial use for disease prevention/prophylaxis in healthy animals was deleted as it was too difficult to come to consensus on the definition of prevention/prophylaxis.
- Food crop production: Bullets were divided between regulatory/non-regulatory controls; the bullet on prohibiting antimicrobial use was changed to restricting antimicrobial use; the bullet on antimicrobial use for disease prevention/prophylaxis in healthy crops was deleted as it was too difficult to come to consensus on the definition of prevention/prophylaxis; a bullet on evaluating the safety of viable microorganisms used as supplements was added.
- Waste management: The waste management section was made more concise and more specific to address food safety. The Task Force agreed to move the bullet on monitoring biosolids, manure and other natural fertilizers to the new section on surveillance (and subsequently addressed only in a general way). The Task Force agreed to delete the bullet on prohibition of biosolids, manure and other natural fertilizers containing AMR microorganisms/determinants.
- Post-harvest: The statement concerning food withdrawal was modified to more specifically describe the public health risk.



- In the section on evaluation of risk management options the United States proposed, and the Task Force agreed, to delete the bullet on benefit cost analysis. The bullet on WTO SPS implications was also deleted following the remarks of the Codex Secretariat (see above). The United States proposed, and the Task Force agreed, to delete paragraph 67, that included a reference to animal health and animal welfare, in lieu of new General Principle 8 (see above).
- In the section on selection of risk management options, the United States proposed, and the Task Force agreed, to delete paragraph 72, which required risk managers to consider cost-benefit, ethical considerations, and other factors. The United States proposed, and the Task Force agreed, to delete paragraph 75, which described measures to be taken when there is a high level of risk, as being redundant with measures already included in Table 1.
- The Task Force agreed that it was appropriate to have separate sections for (1) monitoring and review of antimicrobial resistant risk management options and (2) surveillance of antimicrobial use and antimicrobial resistant microorganisms and determinants as proposed by the United States. An in-session working group on monitoring and surveillance was held to address content and to determine where in the document to place the sections. The sections were substantially redrafted and the language was agreed to by the Task Force during the plenary session.

Risk Communication

- The section on Risk Communication was simplified and shortened.

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