

codex alimentarius commission E



FOOD AND AGRICULTURE
ORGANIZATION
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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
AD HOC CODEX INTERGOVERNMENTAL TASK FORCE
ON ANTIMICROBIAL RESISTANCE

First Session

Seoul, Republic of Korea, 23-26 October 2007

**CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER
TEXTS ON ANTIMICROBIAL RESISTANCE**

Comments from the United States

**PROPOSAL TO CREATE THREE WORKING GROUPS: WORKING GROUP ON PRIORITY
SETTING, WORKING GROUP ON RISK ASSESSMENT, AND WORKING GROUP ON RISK
MANAGEMENT**

A. WORKING GROUP ON PRIORITY SETTING

Objective:

Develop appropriate criteria, procedures, and other standards for identifying microbiological food safety issues and establishing risk profiles in order for the Task Force to set food safety priorities for possible commissioning of antimicrobial resistance risk assessments.

Scope:

It is proposed that the Codex Task Force will create a Working Group on Priority Setting (WGPS) that will create guidance specifying methods and criteria to identify antimicrobial resistance food safety issues, create risk profiles, and set antimicrobial resistance food safety priorities for use by Codex and national/regional authorities. Based on that guidance, the WGPS will then acquire data to develop risk profiles, and then set antimicrobial resistance food safety priorities which will be used by JEMRA and/or national/regional authorities when deciding whether to undertake full risk assessments. The WGPS will take full account of the prior work on risk analysis principles and standards of Codex and other relevant international organizations, such as FAO, WHO and OIE, and national/regional authorities.

Work Plan:

1. The WGPS will create a Priority Setting Guidance Document for Antimicrobial Resistance Risk Analysis describing criteria and methods used for the identification of food safety issues, creation of risk profiles, and setting antimicrobial resistance food and feed safety priorities (risk ranking)¹. The goal of the Priority Setting Guidance Document is to describe the process by which Codex or national/regional authorities can set priorities for risk assessment. The creation of criteria and methods is necessary because of the complex matrix of antimicrobials used in food animals, the foodborne bacteria involved, the different mechanisms by which they are disseminated independent and dependent on drug use, issues of co- and cross-resistance in the foodborne organisms, various types of foods derived from these food-producing animals, and human uses of antimicrobials as they may relate to the foodborne route of transmission of antimicrobial resistant microorganisms or determinants.

¹ These are the first three preliminary risk management activities described in the Codex Working Principles on Risk Analysis (<http://www.fao.org/docrep/006/y4800e/y4800e0o.htm>)

2. The WGPS will identify antimicrobial resistance food safety issues related to the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes where the presence in food or feed is suspected to be associated with the use of antimicrobials in food animals.

3. The WGPS will develop antimicrobial resistance food safety risk profiles for the identified food safety issues. A risk profile is defined in Codex as “the description of the food safety problem and its context” (Codex Alimentarius Procedural Manual 16th Edition). The use of risk profiles in Microbial Risk Management (MRM) has been further elaborated in Codex and is described as “a description of a food safety problem and its context that presents, in a concise form, the current state of knowledge related to a food safety issue, describes potential MRM options that have been identified to date, when any, and the food safety policy context that will influence further possible actions” (ALINORM 07/30/13 CCFH, Appendix IV).

www.codexalimentarius.net/download/report/671/al30_13e.pdf

The antimicrobial resistance food safety risk profiles should include elements from the Codex Committee on Food Hygiene Suggested Elements to Include In a Microbial Risk Profile, but these must be modified and expanded to include elements specific to antimicrobial resistance such as the medical and veterinary importance of a veterinary drug as identified by the WHO and OIE, known mechanisms of resistance and cross-resistance, and location of known resistance determinants, with some consideration of likelihood of co-resistance. The CCRVDF Code of Practice to Contain and Minimize Antimicrobial Resistance and the OIE risk analysis methodology document contain other information on what may be needed in an antimicrobial resistance risk profile.

4. The WGPS will collect and describe relevant data that is available concerning antimicrobial resistant microorganisms in feed, food animals (including aquaculture species), food production/processing, and retail foods as well as identification of important data that may need to be collected and analyzed; relying on data from national resistance monitoring programs, published sources and other data recognized as valid and applicable to the profile. The WGPS will determine applicability of ongoing international and national antimicrobial resistance monitoring programs of foodborne bacterial pathogens to provide data for risk profiling at the animal, intermediate food processing and retail food levels. The WHO document on Antimicrobial Resistance Surveillance Standards and the OIE Terrestrial Animal Health Code appendix on Surveillance could be helpful for this purpose. The WHO SalmSurv program may also provide some useful information.

5. The WGPS will provide guidance on antimicrobial resistance food safety issue priorities to be used by JEMRA and/or national/regional authorities. Priorities will be set based on an evaluation of the criteria developed by the WGPS to determine which combinations of antimicrobials, foodborne bacteria, and food product (with associated food animal species) should undergo risk assessment and, as needed, further risk management.

B. WORKING GROUP ON RISK ASSESSMENT

Objective:

Develop science-based risk assessment guidance regarding foodborne antimicrobial resistant microorganisms, using established Codex risk assessment principles and the relevant work and standards of other national, regional, and international organizations, such as FAO, WHO, and OIE.

Scope:

It is proposed that the Codex Task Force form a Working Group on Risk Assessment (WGRA) to draft guidance on appropriate activities needed to achieve the above objective. The intent of this guidance is to enable JEMRA and/or national/regional authorities to assess potential human health concerns associated with the presence in food and feed (including aquaculture), and the transmission through food and feed, of specific antimicrobial resistant microorganisms. The specified microorganisms for the risk assessment should be selected in accordance with established prioritization criteria.

Work Plan:

1. Identify the risk assessment components and processes that are deemed essential to food/feed safety assessments that have been developed by Codex, WHO, FAO, OIE, and/or national/regional authorities and adapt them to the specific circumstance of antimicrobial use and antimicrobial resistant foodborne microorganisms.

For example, the Codex document *Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC-GL 30-1999)* (<http://www.who.int/foodsafety/publications/micro/cac1999/en/>) describes a structured risk assessment method that has been developed for application to microbiological or other biological hazards. Such guidelines for microbial risk assessment can serve as a useful template for the work of the Task Force. A second relevant risk assessment framework is the work of OIE on the risk assessment for antimicrobial resistance (*Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals*, OIE Terrestrial Animal Health Code 2006, Part 3, and Section 3; http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm; and <http://www.oie.int/eng/publicat/rt/2003/VOSE.PDF>).

Other relevant completed or on-going work undertaken in similar areas at national, regional and international levels should also be taken into account, keeping in mind that the focus of the proposed work should be the overall risk to human health associated with antimicrobial use in food animals.

In identifying appropriate risk assessment methodology, The Task Force will consider processes that address both positive and negative aspects associated with the use of the specific antimicrobial in food animals

2. Define the appropriate endpoints (“human health concerns”) for the risk assessment process. The OIE Terrestrial Animal Health Code 2006 defines the risk as: “The infection of animals with micro-organisms that have acquired resistance from the use of a specific antimicrobial(s) in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.” However, the Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment (Geneva 2003) divided the human health consequences due to resistant organisms into two categories: 1) Infections that would otherwise not have occurred and 2) Increased frequency of treatment failures and increased severity of infections. Increased severity of infection includes prolonged duration of illness, increased frequency of bloodstream infections, increased hospitalization, and increased mortality.

The WGRA will weigh these, and other, approaches to defining human health consequences of antimicrobial resistant organisms with particular attention to whether such endpoints can be measured in an appropriate manner for use in risk estimates.

3. Outline a work plan to enable capacity-building in those countries or regions which may require assistance. Consideration might be given to assisting developing nations in the establishment of infrastructure and/or appropriate national capacities needed to implement the Codex risk assessment guidelines. The Codex guidance developed by the Task Force may provide a framework for developing countries to respond to antimicrobial resistance risk when they lack the capacity to carry out risk assessments.

4. Risk Communication strategies will be addressed within the context of the FAO Risk Analysis Report #87. Risk assessors and risk managers must communicate effectively to ensure that the appropriate work is undertaken. The WGRA will detail the specific steps to be taken.

C. WORKING GROUP ON RISK MANAGEMENT

Objective:

Provide specific risk management and, as appropriate, risk communication advice for national/regional level action to minimize and contain antimicrobial resistant microorganisms such as those associate with the use of antimicrobials in food and feed production and procession (including aquaculture) based on the outcome of risk assessments.

Scope:

It is proposed that the Codex Task Force form a Working Group on Risk Management (WGRM) to draft guidance on appropriate activities needed to achieve the above objective. These activities will be directed toward two main areas as an interconnected continuum; pre-harvest (such as responsible use guidelines and codes of practice documents which are specifically directed to antimicrobial agents and their use in food animals, animal production practices, assessment/reassessment by regulatory authorities) and post-harvest (such as food hygiene practices which are specifically directed to foodborne contamination interventions). To illustrate the important elements of this continuum showing the appropriate organizational responsibilities and document types, please see the diagrams below. Risk management options appropriate to the identified risk will be outlined and should include a process for measurement of effectiveness. Capacity building will be addressed to enable implementation. Risk Communication shall also be addressed.

Work Plan:

1. The WGRM will develop appropriate risk management options throughout the “farm-to-table” continuum. This will be done by utilizing relevant Codex, OIE, WHO and FAO documents. Implementation will be facilitated by multiple participants throughout the food chain (please see below). The goal is to minimize and contain antimicrobial resistant foodborne bacteria and transmission through the food chain for improved human health through interventions that include responsible uses of antimicrobial agents in food animal production. Risk management options for various food chain participants may include:

- Regulatory authorities- antimicrobial product approval/non-approval, surveillance/compliance, regulatory controls on conditions of use
- National authorities - resistance monitoring of foodborne pathogens and selected commensal bacteria from animals, food and humans; and, foodborne disease surveillance
- National authorities or other stakeholders - Antimicrobial usage monitoring – accounting of use
- Veterinary associations and allied organizations – implementation of responsible use guidelines; education of veterinarians and clients
- Animal feed industry – processes and controls on animal feed production
- Food animal (including aquaculture) producers – quality assurance programs
- Food production industry – food processing and hygiene controls (HACCP)
- Veterinary pharmaceutical industry – responsible use guidelines, compliance with regulatory controls and good manufacturing practices for quality products

2. The WGRM will provide guidance for national authorities as to the most appropriate actions (from the options identified above) to be implemented for a particular antimicrobial risk. As outlined in the FAO Risk Analysis Report #87

(<ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf>), “in the ideal situation, the following information should be available for evaluating individual or groups of possible risk management options:

- A “menu” of estimates of risk that would result from application of potential risk management measures (either singly or in combination), expressed either qualitatively or quantitatively.
- Estimates of the relative impact of different potential risk management measures (either singly or in combination) on risk estimates.
- Technical information on the feasibility and practicality of implementing different options.
- Benefit-cost analysis of different potential measures, including both magnitude and distribution (i.e. who benefits, who pays the costs).
- WTO SPS implications of different options in international trade situations.”

The WGRM shall describe how the recommendations might be implemented on a regional/national basis. Depending on feasibility (for example, infrastructure, expertise, funding, etc.), recommendations on responsible use, resistance monitoring, feed controls, quality assurance programs, food hygiene and various codes of practice should be implemented as much as possible by the appropriate groups within the food chain.

For those antimicrobial products and associated antimicrobial resistant bacteria that will be of the highest risk classification, it is proposed that the following additional options should be considered for priority implementation by the national authorities:

- Regulatory review of currently antimicrobials by national risk assessment guidelines
- Resistance monitoring and usage monitoring (specifics to be determined)
- Responsible use guidelines including consideration of alternative treatments or conditions of use

3. The WGRM will describe methods to measure the effectiveness of the risk management options such as:

- Trends in antimicrobial resistant foodborne bacteria by monitoring of animals, foods and humans
- Trends in human foodborne disease (matched to public health goals)
- Number of animals “covered” by a particular guideline and effects on animal health and welfare compared to food contamination and foodborne disease trends
- Antimicrobial usage monitoring trends, etc.

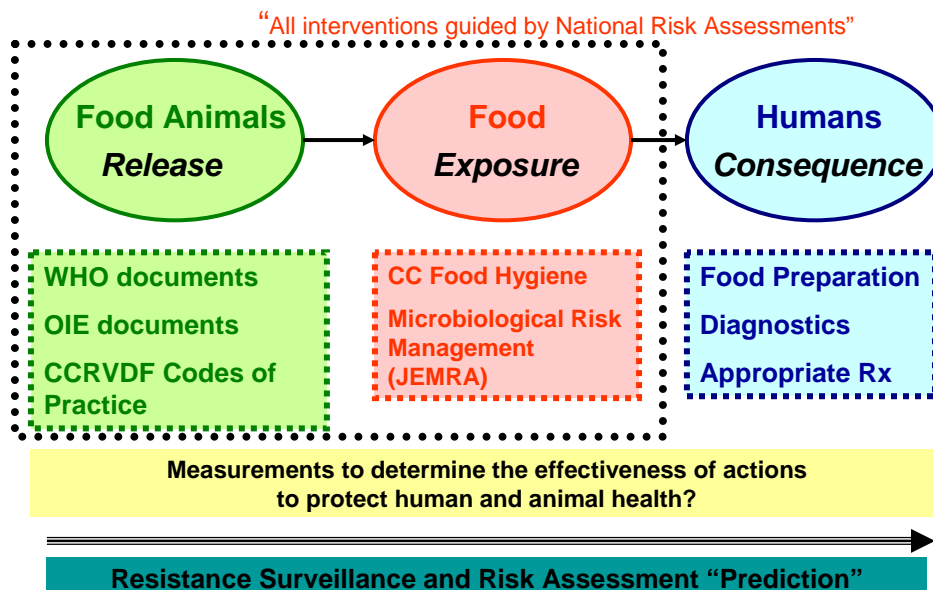
4. The WGRM will recommend actions to be taken for capacity building to enable implementation in resource-limited regions/nations. To enable implementation of risk management options, it is proposed that resource-limited regional/national authorities work cooperatively with nations/organizations/companies that have programs in place. Capacity building has been discussed such as in the following two examples:

<http://www.fao.org/docrep/009/a0083e/a0083e00.htm>

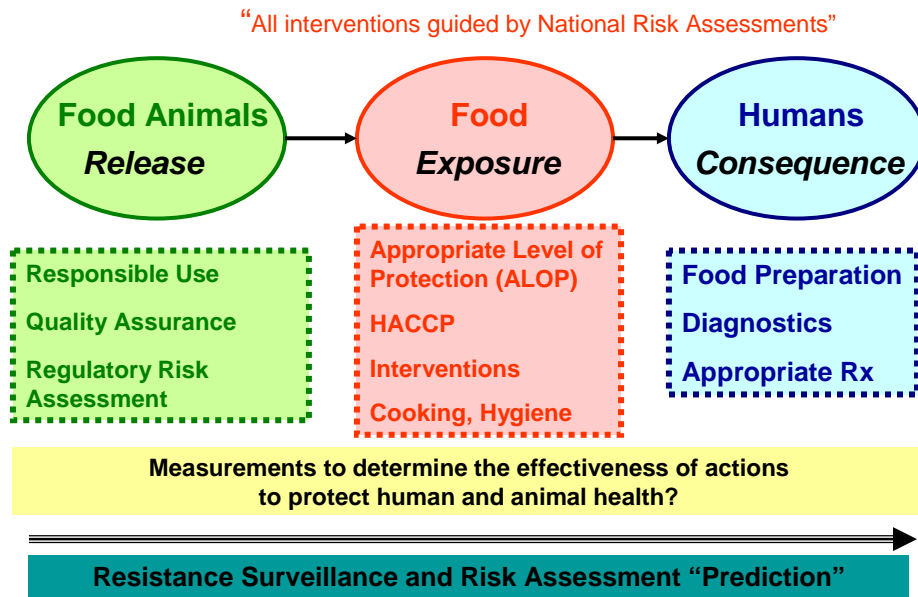
http://www.who.int/topics/foodborne_diseases/aquaculture_rep_13_16june2006%20.pdf

5. Risk Communication strategies will be addressed within the context of the FAO Risk Analysis Report #87. Risk assessors and risk managers must communicate effectively to ensure that the appropriate work is undertaken. The WGRM will detail the specific steps to be taken.

Continuum of Codex TF Risk Management Options



Continuum of Codex TF Risk Management Options



Additional References:

For additional references and URL citations, please refer to the U.S. Delegation Circular Letter Response.