

codex alimentarius commission E



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Opening of the Session

CRD 1

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

PROVISIONAL ANNOTATED AGENDA

Division of Competence

between the European Community and its Member States according to Rule of procedure II
paragraph 5 of the Codex Alimentarius

Agenda Item	Subject Matter	Document Reference
1	Adoption of the Agenda Member States Competence. Member States Vote. ¹	CX/AMR 07/1/1
2	Matters Referred to the Task Force by the Commission and the Other Codex Committees Part A: Adoption of the Establishment of the Ad Hoc Intergovernmental Task Force Mixed Competence. Member States Vote. Part B: Matters arising from the 30th Session of the CAC - Strategic Plan 2008 – 2013 Member States Competence. Member States Vote.	CX/AMR 07/1/2
3	Review of the Work by FAO, WHO and OIE on Antimicrobial Resistance Mixed Competence. European Community Vote. ²	CX/AMR 07/1/3

¹ This is without prejudice to the substantive competence that the Community has for individual items on the agenda.

² Division of competence and right to vote will be reviewed for the Second Session of the Task Force on Antimicrobial Resistance in the light of the new work agreed by the First Session of the Task Force.

4	<p>Consideration of the Elaboration of Standards, Guidelines or other Texts on Antimicrobial Resistance (comments submitted in response to CL 2006/38-AMR)</p> <p>Mixed Competence. European Community Vote. ³</p>	<p>CX/AMR 07/1/4</p> <p>CX/AMR 07/1/4 Add. 1</p>
5	<p>Other Business</p> <p><i>Competence and right to vote to be determined in the light of the issues to be dealt with (document not yet available).</i></p>	
6	<p>Date and Place of Next Session</p> <p>Member States Competence. Member States Vote.</p>	
7	<p>Adoption of the Draft Report</p> <p>Member States Competence. Member States Vote. ⁴</p>	

³ Division of competence and right to vote will be reviewed for the Second Session of the Task Force on Antimicrobial Resistance in the light of the new work agreed by the First Session of the Task Force.

⁴This is without prejudice to the substantive competence that the Community has for individual items in the Report.

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Agenda Item 4

CRD 2

(Original language only)

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

First Session

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COMMENTS OF NORWAY

Objectives (Annex 1) and Scope (Annex 2)

There seems to be a discrepancy between objectives and terms of reference for the Task Force defined by the Codex Alimentarius Commission, i.e. (Annex 1 to the agenda) and the scope (Annex 2 to the agenda). The objectives and the terms of reference use the terms risk analysis and risk assessment following non-human use of antimicrobials while the scope also include “consideration of the possible positive aspects to food safety of different antimicrobials used in food and feed production....”.

The Norwegian position is that positive/beneficial effect should be excluded from the scope (unless it should be interpreted as effectiveness of antimicrobials in clinical practice, i.e. post marketing evaluation) as it is outside the terms of reference for the Task Force as defined by the Codex Alimentarius Commission. The question regarding “benefit” of antimicrobials is addressed by the various medicine agencies in the premarketing evaluation process prior to the marketing of such drugs. This includes evaluation of efficacy against the actual bacterial diseases in the target animals. Consequently, if used prudently (labelled use) the infection for which the actual antimicrobial is approved, e.g salmonella in cattle, will be effectively treated and thus food derived from the treated animals would be safe.

Item 4, 1st bullet-point (see background)

Only antimicrobials used in food and feed production and processing are included in the scope (Appendix 2 to CL 2008/38-AMR). With reference to Annotation to Item 4, 1st bullet point Norway suggests that companion animals also should be considered to be addressed in the Task Force (see point 1, 2 and 3 below). Also water (see point 2 and 4) as well as use of sewage sludge and manure/slurry as fertilizer (see point 2 and 4 below) should be considered to be included.

Background

1. Report from First Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment, 1 – 5 December, 2003, Geneva

(http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_ZFK_2004.7.pdf) includes, among others, the following:

Page 13-14

Other reservoirs

1st paragraph

“Available scientific evidence shows that also antimicrobial usage in horticulture, aquaculture and companion animals can result in spread of resistant bacteria and resistance genes to humans. In general,

molecular characterization of resistance genes as well as other data indicates some movement of resistant bacteria and resistance determinants from aquaculture, companion animals, and horticulture to humans”.

3rd paragraph

Research has shown that transfer of multiple antimicrobial resistant *Staphylococcus intermedius* and quinolone resistant *Campylobacter jejuni* can occur between humans and dogs living in the same household (Guardabassi L. et al. 2004; Damborg P et al. 2004). Thus, antimicrobial usage in companion animals may ultimately have a public health effect, especially taking into consideration the close proximity between these animals and their owners, and the pattern of antimicrobial usage in companion animals.

2. **Report from Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options. 15–18 March 2004, Oslo, Norway** (http://www.who.int/foodborne_disease/resistance/fdb_antimicrobial_Mar04.pdf) includes, among others, the following:

2. Establish a national surveillance programme on antimicrobial resistance in bacteria from food and animals

Page 6, 2nd paragraph, line 5:

There is insufficient information on antimicrobial resistance in many areas, especially horticulture, aquaculture and companion animals. The methodology for sampling and susceptibility testing of bacteria in aquaculture and companion animals needs to be better defined, for example by determining suitable indicator bacterial species. In addition, there is a need to address data gaps with regard to design of surveillance programmes, and the methodologies to be applied for surveillance of water and food as well as animal by-products, manure, plants and feeds.

3. **Critically Important Antimicrobials for Human Medicine: Categorization for the Development of Risk Management Strategies to contain Antimicrobial Resistance due to Non-Human Antimicrobial Use. Report of the Second WHO Expert Meeting Copenhagen, 29–31 May 2007** (http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf)

Page 9

Methicillin-resistant *Staphylococcus aureus* in animals

From being almost exclusively a health-care-associated pathogen, Methicillin-resistant *Staphylococcus aureus* (MRSA) has emerged during the last two decades into the community and has recently also caused infections in and colonized pets and production animals. MRSA has been detected in cattle, chickens, horses, pigs, dogs, rabbits, seals, birds and cats. The colonization in animals has in several cases been implicated in infections in humans. It is important, however, to distinguish between the epidemiology of MRSA in relation to livestock, where a new clone (ST398) is seemingly emerging, to those of pet animals that are infected with classical human variants of MRSA. ST398 was first detected in 2004 in The Netherlands and has so far not been found among strains isolated prior to 2003.

Based on our current knowledge, some strains of MRSA should now be considered a zoonosis. Pet animals can act as a reservoir for the bacterium from where it can transfer to humans and cause infection. In infection control, pet animals should probably be treated in different. Thus, it seems likely that a single clone (ST398) has adapted itself to colonize livestock animals (pigs, chickens and cattle) from where it can spread to humans. The importance for human health and the implications for infection control are currently unclear and will need to be reviewed as more information becomes available.

4. Miscellaneous

After being administered to humans or animals, medical substances are excreted through the urine and faeces. The major source for environmental discharge of human antimicrobials and their metabolites is thought to be sewage treatment plants (STP) while for veterinary antimicrobials the main source is through spread of manure/slurry containing residues of such drugs. Following their use in human and veterinary medicine antimicrobials and their metabolites will inevitably enter

- surface water (from STP effluent water),
- ground water (run-off from application of sewage sludge or manure/slurry as fertilizer) or
- soil (application of sewage sludge or manure/slurry as fertilizer)

and may consequently end up in the food chain (Fig. 1).

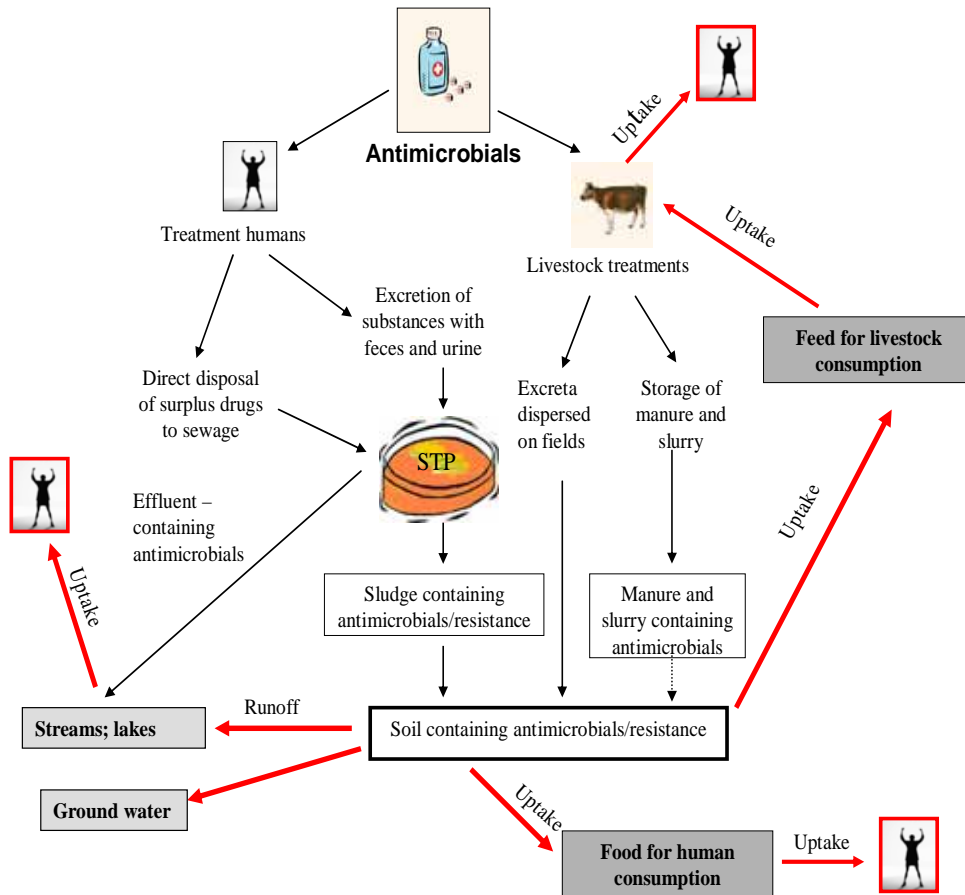


Fig. 1.

Discharge of antimicrobials and resistant bacteria/genes following use in humans and food animals and the potential human and animal exposure pathways of residues of antimicrobials and of resistant bacteria/genes

Data on the occurrence and fate of environmental antimicrobial residues and resistance are currently rather limited. Anyhow, the published papers have especially paid attention to the occurrence of fluoroquinolones in soil matrix following application of, e.g. sewage sludge as fertilizer because of their photostability, bindings and sorption capabilities as well as persistence and finally because the fluoroquinolones represent an important antimicrobial drug class in human medicine. For example, in Switzerland the fluoroquinolones ciprofloxacin and norfloxacin were detected in digested sewage sludge in concentrations up to 3.5 and 3.3 mg/kg sludge, respectively (Golet et al., 2003) while in a recent study from Sweden the corresponding figures were 6.3 and 6.7 mg/kg (Lindberg et al., 2006), respectively. Data on the occurrence of fluoroquinolones in soil has most recently been reviewed by Picó and Andreu (Pico and Andreu, 2007).

Published data on the occurrence in activated sludge of bacteria resistance against antimicrobials are rather few (Reinthal et al., 2003; Martins da et al., 2006). Martins et al (2006) isolated *Enterococcus* spp resistant against a variety of AM drugs from samples of influent, effluent and sludge from STPs in Portugal; in approximately 50% of the isolates multi-resistance was present. There were no significant difference between the proportion of *Enterococcus* spp. isolates resistant against various antimicrobials in the influent water, the effluent water and the sewage sludge. However, for 8 of the 14 STPs included in the study the numbers of *Enterococcus* spp. isolates in sludge were substantially higher expressed as colony forming units (CFU) per 1 ml/g sample. Also (Ferreira da et al., 2006) found that STPs may not efficiently eliminate commensal antibiotic-resistant enterococci from wastewater; indeed, for ciprofloxacin wastewater treatment led to an increase in the prevalence of resistant enterococci in the effluent.

Especially STP effluents and sewage sludge may contain a variety of antimicrobials generally at low concentrations; however, the development of antimicrobial resistance is usually favoured by low

concentrations. Sewage sludge is used as fertilizer on agricultural land in many countries. The importance and implications of environmental antimicrobial residues and resistance (e.g. in soil) are currently unclear and will need to be reviewed as more information becomes available.

References

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- Ferreira da, S.M., Tiago, I., Verissimo, A., Boaventura, R.A., Nunes, O.C., Manaia, C.M., 2006. Antibiotic resistance of enterococci and related bacteria in an urban wastewater treatment plant. FEMS Microbiol. Ecol. 55, 322-329.
- Guardabassi L, Løber ME, Jacobson A., 2004 Transmission of multiple antimicrobial-resistant *Staphylococcus intermedius* between dogs affected by deep pyoderma and their owners. Vet Microbiol. 98, 23-27
- Golet, E.M., Xifra, I., Siegrist, H., Alder, A.C., Giger, W., 2003. Environmental exposure assessment of fluoroquinolone antibacterial agents from sewage to soil. Environ. Sci. Technol. 37, 3243-3249.
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- Pico, Y., Andreu, V., 2007. Fluoroquinolones in soil - risks and challenges. Analytical and Bioanalytical Chemistry 387, 1287-1299.
- Reinthaler, F.F., Posch, J., Feierl, G., Wust, G., Haas, D., Ruckebauer, G., Mascher, F., Marth, E., 2003. Antibiotic resistance of E-coli in sewage and sludge. Water Research 37, 1685-1690.

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Agenda Item 4

CRD 3 – Rev.2

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

Report of the Working Group Chaired by Canada on the Preparation of a Project Document on Codex Guidance on Antimicrobial Risk Assessment¹

PROJECT DOCUMENT

DEVELOPMENT OF SCIENCE-BASED RISK ASSESSMENT GUIDANCE REGARDING FOOD-BORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

1. Purpose and scope of the proposed work

The purpose of the proposed work is to develop rational, science-based guidance, taking full account of the prior work on risk assessment principles and standards of Codex and other relevant international organizations, such as FAO, WHO and OIE, as well as of national/regional authorities. The intent of this guidance is to enable JEMRA and/or national/regional authorities to assess the potential overall risk to human health associated with the presence in food and feed (including aquaculture), and the transmission through food and feed, of antimicrobial resistant microorganisms and resistance determinants.

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 food safety risk assessment, built on Codex and OIE foundational documents.

The Codex guidance developed by the Task Force may provide a framework for member countries to respond to antimicrobial resistance risk when they lack the capacity to carry out risk assessments.

2. Relevance and timeliness

This work would be consistent with the proposed activities detailed in Annex 2 of CL 2006/38-AMR as well as the Terms of Reference of the Task Force. It is also consistent with Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and with the OIE Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals (OIE Terrestrial Animal Health Code 2007) guidance as well as the Codex Guideline CAC/GL-30 1999) on the Conduct of Microbiological Risk Assessment and the specific guidelines developed by JEMRA.

¹ All of the participants attended this in-session working group held in the Plenary Hall on 23rd and 24th October 2007.

One key point from the FAO/WHO/OIE consultations is that certain antimicrobial resistant food-borne microorganism were identified as being a possible microbiological food safety hazard. As such, Codex work on microbiological risk assessment for food-borne microorganisms are relevant because the presence of resistance gene reservoirs, gene acquisition, amplification, transmission and spread to susceptible hosts require propagation of resistance determinants within microbial hosts (i.e. resistance determinants themselves are not self-replicating). In addition, Codex and other work on risk analysis principles as applied to veterinary drugs used in food-producing animals are relevant because these drugs can select for resistant microorganisms in animals, which can be the source of antimicrobial resistant microorganism on food and/or in human patients with relevant illness. Therefore, the application of the relevant existing and developing Codex and other documents and guidelines on risk assessment should be used and modified or extended where necessary to encompass risk analysis of the human health concerns associated with antimicrobial resistant food-borne microorganism.

3. Main aspects to be covered

The Task Force will develop an appropriate risk assessment set of criteria and a process for JEMRA and/or national authorities to use to determine the overall risk to human health relating to antimicrobial resistant microorganisms and resistance determinants in feed, food animals (including aquaculture), food production/processing, and retail foods arising from the use of antimicrobials in animals. [When considering the risk related to a specific antimicrobial resistance concern, the Task Force will take into consideration the impact on human health.]

The completed guidance should:

- Address, if possible the overall risk of each antimicrobial application (usage, species, microorganisms, dosage regime).
- be a sequence of assessment steps covering the likelihood of transfer of resistant microorganisms and resistance determinants from animals to humans;
- provide techniques to evaluate the parameters at each step, using the appropriate data input to that step. These parameters and input need to be identified;
- provide techniques to enable the output of one step to be used as the input for the next step (e.g. flow charts, decision trees); and
- include a method to document data sources, procedures and results.

This Project Document Proposal will build upon the risk analysis processes already in place within Codex, JEMRA and within OIE for risk assessment with regard to human health concerns by adapting them to include antimicrobial resistance aspects similar to the OIE Risk Analysis Terrestrial Animal Code guideline (http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm).

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This Project Document Proposal would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganism, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk assessments, particularly for evaluating antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This Project Document Proposal would provide internationally-recognized scientific guidance that JEMRA and national/regional authorities may use to carry out risk assessment activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This Project Document Proposal is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH, CCRVDF, and JEMRA that focuses on food-borne microorganism that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5).
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

There are several existing Codex documents which are related and that must be considered in the development of the proposed guidance:

- Review of existing standards on Risk Analysis (OIE, WHO) including Microbial Risk Assessment
- Review of Good Practices manuals, including Codes of practice and codes of hygiene (especially those from the work of CCRVDF and CCFH)
<http://www.fao.org/docrep/005/Y1579E/y1579e02.htm>
<ftp://ftp.fao.org/docrep/fao/005/Y1579e/Y1579e.pdf>
www.codexalimentarius.net/download/standards/10213/CXP_061e.pdf
- Review of existing documents/guidelines on containment of antimicrobial resistance in animals for food. Those of the WHO website are listed, but there are many other national, regional, and international guidelines that are pertinent.
http://www.who.int/foodborne_disease/resistance/en/index.html
- JEMRA Guidelines
 Hazard Characterization Guidelines
http://www.fao.org/ag/agn/agns/jemra_guidelines_hazard_en.esp
 Exposure Assessment Guidelines
http://www.fao.org/ag/agns/jemra_guidelines_exposure_en.esp
 Risk Characterization Guidelines
http://www.fao.org/ag/agn/agns/jemra_guidelines_risk_en.esp

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options 15–18 March 2004 Oslo, Norway (report available at: <http://www.who.int/foodsafety/publications/micro/mar04/en/index.html>)
- First Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment, Geneva, 1-5 December 2003 (report available at: <http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html>)
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII available at http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf p.152
- Critically important antibacterial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation 15 - 18 February 2005, Canberra, Australia (available at: http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf)

- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance Seoul, Republic of Korea, 13–16 June 2006
http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm
- OIE Terrestrial code – Chapter3.9. Antimicrobial resistance
http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm ;
- Second WHO Expert Meeting on Critically Important Antimicrobials for Human Medicine, Copenhagen, 29-31 May 2007 (report available from
http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf)
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, 26-30 November 2007).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The task force will take into consideration existing scientific information including the reports referenced in 7 above. If required, the task force may request additional input including from FAO/WHO/OIE via JEMRA, to establish an expert consultation to provide additional scientific advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Envisaging the use of inter-sessional working groups the following is a proposed time-line:

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011

Relevant Codex Alimentarius Documents List ²ⁱ

Codex Alimentarius Commission Guideline 30 –Principles and Guidelines for the Conduct of Microbiological Risk Assessment)

(http://www.ipfsaph.org/servlet/BinaryDownloaderServlet?filename=/kopool_data/codex_0/en_cxg_030e.pdf).

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/FH 01/12).

www.codexalimentarius.net/download/report/116/al03_13e.pdf

Codex Committee on Food Hygiene. Discussion paper on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 1999 (CX/FH 99/12;

ftp://ftp.fao.org/codex/ccfh32/FH99_12e.pdf)

Codex Committee on Food Hygiene. Report of the Thirty-second Session, Washington, DC, 29 November–4 December 1999. Rome, Food and Agriculture Organization of the United Nations, 2001 (ALINORM 01/13;

ftp://ftp.fao.org/codex/alinorm01/AI01_13e.pdf).

Codex Committee on Residues of Veterinary Drugs in Foods. Antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/RVDF 00/4;

ftp://ftp.fao.org/codex/ccrvdf12/rv00_04e.pdf

ftp://ftp.fao.org/codex/alinorm01/AI01_31e.pdf

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11;

² Not all documents listed were cited above.

ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf

Codex Committee on Residues of Veterinary Drugs in Foods. Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance. Rome, Food and Agriculture Organization of the United Nations, 2002 (CX/RVDF 03/6;

ftp://ftp.fao.org/codex/ccrvdf14/rv03_06e.pdf

<ftp://ftp.fao.org/codex/alinorm03/A10331ae.pdf>

Codex Committee on Residues of Veterinary Drugs in Foods. Discussion paper on antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/RVDF 01/10;

ftp://ftp.fao.org/codex/ccrvdf13/rv01_10e.pdf

ftp://ftp.fao.org/codex/alinorm03/al03_31e.pdf

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11;

ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf

ftp://ftp.fao.org/codex/alinorm03/al03_13e.pdf

Recommended International Code of Practice General Principles of Food Hygiene, including Annex on HACCP and Guidelines for its application. CAC/RCP 1-1969, Rev. 4-2003

(www.codexalimentarius.net/download/standards/23/cxp_001e.pdf)

OTHER DOCUMENTS

Food Safety Risk Analysis: A Guide for National Governments, FAO Food and Nutrition Paper 87, 2006

(<ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf>)

Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.)

(http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm)

Guidelines for the Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.9, Chapter

(3.9.3(http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.3.htm))

Joint FAO/WHO Consultation in Kiel, Germany in 2002

(<http://www.who.int/foodsafety/publications/micro/en/march2002.pdf>)

Joint FAO/WHO expert meeting report on “The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to Improve Food Safety” (Kiel, Germany, 3-7 April 2006)

(<ftp://ftp.fao.org/ag/agn/food/kiel.pdf>)

Joint FAO/OIE/WHO Expert Workshops on Non-Human Antimicrobial Usage and Antimicrobial Resistance in 2003 and 2004 (http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_ZFK_2004.7.pdf and

http://www.who.int/foodsafety/publications/micro/en/oslo_report.pdf).

2001 WHO Global Strategy for Containment of Antimicrobial Resistance

(http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/).

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Agenda Item 4

CRD 4 Rev. 1
(Original language only)

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

PROJECT DOCUMENT

**DEVELOP GUIDANCE ON CREATING RISK PROFILES FOR ANTIMICROBIAL RESISTANT
FOODBORNE MICROORGANISMS FOR SETTING RISK ASSESSMENT AND MANAGEMENT
PRIORITIES**

*Report of the Working Group Chaired by the United States of America on the Preparation of a Project
Document on Codex Guidance on Antimicrobial Risk Assessment¹*

1. Purpose and scope of the proposed work

The purpose of this project is to develop guidance on

- identifying food safety issues related to antimicrobial resistance,
- data needed for risk profiles
- setting priorities with respect to risks related to antimicrobial resistant foodborne microorganisms.

This guidance can be used by JEMRA and/or national/regional authorities can undertake possible full risk assessments in the future. For the purpose of these principles, preliminary risk management activities are taken to include identification of a food safety problem; establishment of a risk profile, ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment, commissioning of the risk assessment, and consideration of the results of the risk assessment.

Establishment of risk profiles with respect to the presence in food (including aquaculture) and feed of antimicrobial resistant microorganisms and resistance determinants is critical to the development of the appropriate risk assessment and risk management options and strategies.

This guidance will take into 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, as well as of national/regional authorities. Other relevant completed or on-going work undertaken in similar areas directed at assessing preliminary data and setting priorities at national, regional and international levels should also be taken into account.

2. Relevance and timeliness

Antimicrobial resistance has been discussed at two prior joint consultations of WHO/OIE/FAO and the 29th CAC Session (July, 2006) recommended that the formation of the Task Force and the development of Project Documents are relevant next steps to be taken in a timely manner. One key point from the consultations is that certain antimicrobial resistant food-borne bacteria were identified as being possible microbiological food safety hazards.

¹ All of the participants attended this in-session working group held in the Plenary Hall on 24th October 2007.

3. Main aspects to be covered

With regard to priority-setting for future risk assessments, preliminary risk management activities comprise the initial process. It includes the establishment of a risk profile¹ to facilitate consideration of the issue within a particular context, and provides as much information as possible to guide further action. As a result of this process, the risk manager may commission a risk assessment as an independent scientific process to inform decision-making. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and if necessary modify the provisional decision. In those instances, the provisional nature of the decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after the completion of a risk assessment) should be articulated when the decision is communicated initially.

Criteria to be used for establishing risk priorities will build upon the processes that have already been identified, particularly those that are in place within Codex and within OIE (see OIE Risk Analysis Terrestrial Animal Code guideline) (http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm).

Other relevant activities undertaken in this area at international, regional and national levels should also be considered. For example, WHO and OIE information about critically important antimicrobials used in human and veterinary medicine, the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL63-2007), Risk profile on antimicrobial resistant bacteria in food (CX/FH 00/11) and the 2006 Joint FAO/WHO expert meeting Report from Kiel, Germany. The development of these criteria should also take into account national resistance monitoring program data, published sources and other data recognized as valid.

It is expected that this work could consider but not be limited to:

- Antimicrobial agents or classes used in food producing animals that would significantly impact on human medicine due to the development or dissemination of antimicrobial resistance?
- Importance of the drug in human medicine (indications, extent of use, level of resistance, availability of alternative drugs, resistance mechanisms, etc.).
- Information on drug use in various animal species.
- Relevant data that is available concerning antimicrobial resistant microorganisms in feed, food animals (including aquaculture), food production/processing, and retail foods as well as identification of important data that may need to be collected and analyzed; relying on national resistance monitoring program data, published sources and other data recognized as valid.
- Information about human exposure to hazard including routes of exposure.
- Information on adverse health effects in humans (e.g., dose-response, type and severity of adverse health effects, and at-risk population characteristics).

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This Project Document Proposal would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant bacteria, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk assessments, particularly for evaluating antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This Project Document Proposal would provide internationally-recognized scientific guidance that JEMRA and national/regional authorities may use to carry out risk assessment activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This Project Document Proposal is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH, CCRVDF, and JEMRA that focuses on food-borne bacteria that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5).
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will fully take into account the provisions in the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), in the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993), food safety risk analysis guide by FAO (#87) and in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).

There are several existing Codex documents which are related and that must be considered in the development of the proposed guidance:

- Review of existing standards on Risk Analysis (OIE, WHO) including Microbial Risk Assessment
- Review of Good Practices manuals, including Codes of practice and codes of hygiene (especially those from the work of CCRVDF and CCFH)
<http://www.fao.org/docrep/005/Y1579E/y1579e02.htm>
<ftp://ftp.fao.org/docrep/fao/005/Y1579e/Y1579e.pdf>
www.codexalimentarius.net/download/standards/10213/CXP_061e.pdf
- Review of existing documents/guidelines on containment of antimicrobial resistance in animals for food. Those of the WHO website are listed, but there are many other national, regional, and international guidelines that are pertinent.
http://www.who.int/foodborne_disease/resistance/en/index.html
- Additional Codex documents that may be of relevance are listed separately below.

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports will be taken into consideration:

- Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options 15–18 March 2004 Oslo, Norway (report available at: <http://www.who.int/foodsafety/publications/micro/mar04/en/index.html>)
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII available at http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf p.152
- Critically important antibacterial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation 15 - 18 February 2005, Canberra, Australia (available at: http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf)
- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance Seoul, Republic of Korea, 13–16 June 2006 http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm
- OIE Terrestrial code – Chapter3.9. Antimicrobial resistance
http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm;

- Joint FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials, Copenhagen, Denmark, May 2007
- Joint FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials, Rome, Italy, Nov 2007.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The Task Force will take into consideration existing risk profiling information including the reports referenced in 7 above. If required, the task force may request additional input including from FAO/OIE/WHO to establish an expert consultation to provide additional advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011

Relevant Codex Alimentarius Documents List²:

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/FH 01/12).

www.codexalimentarius.net/download/report/116/al03_13e.pdf

Codex Committee on Food Hygiene. Discussion paper on antimicrobial -resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 1999 (CX/FH 99/12; ftp://ftp.fao.org/codex/ccfh32/FH99_12e.pdf)

Codex Committee on Food Hygiene. Report of the Thirty-second Session, Washington, DC, 29 November–4 December 1999. Rome, Food and Agriculture Organization of the United Nations, 2001 (ALINORM 01/13; ftp://ftp.fao.org/codex/alinorm01/A101_13e.pdf).

Codex Committee on Residues of Veterinary Drugs in Foods. Antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/RVDF 00/4;

ftp://ftp.fao.org/codex/ccrvdf12/rv00_04e.pdf

ftp://ftp.fao.org/codex/alinorm01/A101_31e.pdf

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11; ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf)

Codex Committee on Residues of Veterinary Drugs in Foods. Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005). Rome, Food and Agriculture Organization of the United Nations, 2002

http://www.codexalimentarius.net/download/standards/10213/CXP_061e.pdf

Codex Committee on Residues of Veterinary Drugs in Foods. Discussion paper on antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/RVDF 01/10);

ftp://ftp.fao.org/codex/ccrvdf13/rv01_10e.pdf

ftp://ftp.fao.org/codex/alinorm03/al03_31e.pdf

² Not all documents listed were cited above.

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11);

ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf

ftp://ftp.fao.org/codex/alnorm03/al03_13e.pdf

Recommended International Code of Practice General Principles of Food Hygiene, including Annex on HACCP and Guidelines for its application. CAC/RCP 1-1969

www.codexalimentarius.net/download/standards/23/cxp_001e.pdf

OTHER DOCUMENTS

Food Safety Risk Analysis: A Guide for National Governments, FAO Food and Nutrition Paper 87, 2006

<ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf>

Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.)

http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm

Guidelines for the Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.9, Chapter (3.9.3

http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.3.htm

Joint FAO/WHO Consultation in Kiel, Germany in 2002

<http://www.who.int/foodsafety/publications/micro/en/march2002.pdf>

Joint FAO/WHO expert meeting report on “The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to Improve Food Safety” (Kiel, Germany, 3-7 April 2006)

<ftp://ftp.fao.org/ag/agn/food/kiel.pdf>

Joint FAO/OIE/WHO Expert Workshops on Non-Human Antimicrobial Usage and Antimicrobial Resistance in 2003 and 2004 (http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_ZFK_2004.7.pdf and

http://www.who.int/foodsafety/publications/micro/en/oslo_report.pdf).

2001 WHO Global Strategy for Containment of Antimicrobial Resistance

http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/).

Vose, D., J. Acar, F. Anthony, A. Franklin, R. Gupta, T. Nicholls, Y. Tamura, S. Thompson, E. J. Threlfall, M. Van Vuunen, D. G. White, H. C. Wegener & M. L. Costarrica. Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin. Rev. sci. tech. Off. Int. Epiz. 20(3):811-827. (<http://www.oie.int/eng/publicat/rt/2003/VOSE.PDF>).

U.S. Food and Drug Administration, 2003, Guidance to Industry. Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern

<http://www.fda.gov/cvm/Documents/fguide152.pdf>

codex alimentarius commission E



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 4

CRD 5

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

First Session, Seoul, Korea, 23-26 October 2007

Report of the Working Group Chaired by European Community on the Preparation of a Project Document on Codex Guidance on Antimicrobial Risk Management¹

PROJECT DOCUMENT

DEVELOP RISK MANAGEMENT GUIDANCE TO CONTAIN FOOD BORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

1. Purpose and scope of the proposed work

The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile documents. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.

The Task Force, in developing guidance, should consider a continuum of possible interventions along the entire food chain, each step of which can reduce risk by minimizing and containing antimicrobial resistant microorganisms and resistance determinants, appropriate to the food-producing animal, bacteria, and other practical considerations.

2. Relevance and timeliness

This work would be consistent with the proposed activities detailed in Annex 2 of CL 2006/38-AMR as well as the Terms of Reference of the Task Force. It is also consistent with Codex Code of Practice to minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and with the OIE Guidelines relating to risk management for antimicrobial resistance (Section 3.9 of OIE Terrestrial Animal Health Code 2007). Antimicrobial agents are essential for human and animal health and welfare. Antimicrobial agents are widely used in humans, food-producing animals, including aquaculture, plants and food processing in order to treat or prevent disease or as a production aid (growth promotion) or as a preservative.

Antimicrobial resistance of important human pathogenic bacteria is increasingly perceived as a threat to public health. Any use of antimicrobials, whether in humans, animals, horticulture or food-processing, may potentially lead to bacterial resistance.

¹ All of the participants attended this in-session working group held in the Plenary Hall on 24th October 2007.

The 2001 WHO Global Strategy for Containment of Antimicrobial Resistance (http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/) recognizes that antimicrobial resistance is a serious human health problem and that “improving antimicrobial use must be a key action in efforts to contain resistance.” In order to address that portion of resistance in human pathogens attributable to antimicrobial resistant food-borne bacteria, additional consultations were convened. Antimicrobial resistance has been discussed at two prior joint consultations of WHO/OIE/FAO (cited above) and the 29th CAC Session (July, 2006) recommended that the formation of the Task Force and the development of a Project Document are relevant next steps to be taken in a timely manner. Initial discussion of antimicrobial resistance within Codex is contained in CX/RVDF 01/10 July 2001. One key point from the consultations is that certain antimicrobial resistant food-borne bacteria were identified as being possible microbiological food safety hazard agents.

As such, Codex work on microbiological risk assessment and risk management for food-borne microbes are very relevant because the presence of resistance gene reservoirs, gene acquisition, amplification, transmission and spread to susceptible hosts requires propagation of resistance determinants within microbial hosts (i.e. resistance determinants themselves are not self-replicating). In addition, Codex and other work on risk analysis principles as applied to veterinary drugs used in food-producing animals are very relevant because these drugs can select for resistant microbes in animals which can be the source of resistant microbes on food and/or in human patients with relevant illness.

Therefore, the application of the relevant existing and developing Codex and other documents and guidelines on risk assessment, risk management, and risk communication should be used and modified or extended where necessary to encompass risk analysis of the human health concerns associated with antimicrobial resistant food-borne bacteria.

3. Main aspects to be covered

The Task Force 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. The goal is to protect human health by minimizing and containing antimicrobial resistant food borne bacteria and resistance determinants that may be transmitted through the food chain. Risk management options that can be implemented by the various food chain participants may include but are not limited to:

- Regulatory authorities - antimicrobial product approval/non-approval/withdrawal; surveillance/compliance; regulatory controls on conditions of use; establishment of co-ordinated and coherent surveillance networks at national/regional/international levels that may include links between established surveillance networks in human and veterinary medicines.
- National/regional/international authorities - resistance monitoring of food borne pathogens and selected commensal bacteria isolated from food-producing animals, food, humans, and plants, as appropriate; food borne disease surveillance; development and implementation of responsible use guidelines
- National authorities or other stakeholders - Antimicrobial usage monitoring; accounting of use.
- Veterinary associations and allied organizations – development and 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; hygiene controls (e.g., HACCP; decontamination of carcasses).
- Veterinary pharmaceutical industry – development and implementation of responsible use guidelines; compliance with regulatory controls; good manufacturing practices for quality products.

Additionally, risk management options may include programs promoting the development of new antimicrobial agents, alternative treatments, and prevention programs such as vaccination.

The Task Force will provide guidance for national/regional authorities as to the most appropriate actions to be implemented for a particular food borne antimicrobial risk. The guidance will take into account that antimicrobials administered to animals also play a major role in animal health.

The Task Force will provide guidance on how the recommendations might be implemented on a regional/national basis taking into account the feasibility (for example, infrastructure, expertise, funding, etc.) of implementation.

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

- Regulatory review of currently approved 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.

The Task Force will describe methods to measure the effectiveness of the risk management options such as:

- Trends in antimicrobial resistant food borne bacteria by monitoring of animals, foods and humans.
- Trends in human food borne disease (matched to public health goals).
- Antimicrobial usage monitoring trends, etc.

The Task Force 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
- http://www.oie.int/eng/oie/organisation/en_vet_eval_tool.htm?e1d2

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 Task Force will detail in its guidance the specific steps to be taken. For example, see “The application of risk communication to food standards and safety matters” as developed by FAO; <http://www.fao.org/docrep/005/x1271e/x1271e00.htm>.

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries:

This Project Document Proposal would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant bacteria, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk assessments, particularly for evaluating antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This Project Document Proposal would provide internationally-recognized scientific guidance that JEMRA and national/regional authorities may use to carry out risk assessment activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This Project Document Proposal is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH, CCRVDF, and JEMRA that focuses on food-borne bacteria that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5).
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will fully take into account the provisions in the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), in the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) and in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007). Upon adoption of the proposed document, the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) should be revoked or amended as appropriate, to ensure consistency and avoid duplication within the Codex Alimentarius.

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options 15–18 March 2004 Oslo, Norway (report available at: <http://www.who.int/foodsafety/publications/micro/mar04/en/index.html>)
- First Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment, Geneva, 1-5 December 2003 (report available at: <http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html>)
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII available at http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf p.152
- Critically important antibacterial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation 15 - 18 February 2005, Canberra, Australia (available at: http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf)
- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance Seoul, Republic of Korea, 13–16 June 2006 http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm
- OIE Terrestrial code – Chapter3.9. Antimicrobial resistance http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm ;
- Second WHO Expert Meeting on Critically Important Antimicrobials for Human Medicine, Copenhagen, 29-31 May 2007 (report available from http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf)
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, 26-30 November 2007).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The Task Force will take into consideration existing risk management information including the reports referenced in 7 above. If required, the task force may request additional input including from FAO/OIE/WHO to establish an expert consultation to provide additional advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Envisaging the use of inter-sessional working groups the following is a proposed time-line:

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011

Relevant Codex Alimentarius Documents List²:

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/FH 01/12).
www.codexalimentarius.net/download/report/116/al03_13e.pdf

Codex Committee on Food Hygiene. Discussion paper on antimicrobial -resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 1999 (CX/FH 99/12;
ftp://ftp.fao.org/codex/ccfh32/FH99_12e.pdf)

Codex Committee on Food Hygiene. Report of the Thirty-second Session, Washington, DC, 29 November–4 December 1999. Rome, Food and Agriculture Organization of the United Nations, 2001 (ALINORM 01/13;
ftp://ftp.fao.org/codex/alinorm01/A101_13e.pdf).

Codex Committee on Residues of Veterinary Drugs in Foods. Antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/RVDF 00/4;
ftp://ftp.fao.org/codex/ccrvdf12/rv00_04e.pdf
ftp://ftp.fao.org/codex/alinorm01/A101_31e.pdf

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11
ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf

Codex Committee on Residues of Veterinary Drugs in Foods. Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance. Rome, Food and Agriculture Organization of the United Nations, 2002 (CX/RVDF 03/6;
ftp://ftp.fao.org/codex/ccrvdf14/rv03_06e.pdf
<ftp://ftp.fao.org/codex/alinorm03/A10331ae.pdf>

Codex Committee on Residues of Veterinary Drugs in Foods. Discussion paper on antimicrobial resistance and the use of antimicrobials in animal production. Rome, Food and Agriculture Organization of the United Nations, 2001 (CX/RVDF 01/10;
ftp://ftp.fao.org/codex/ccrvdf13/rv01_10e.pdf
ftp://ftp.fao.org/codex/alinorm03/al03_31e.pdf

Codex Committee on Food Hygiene. Risk profile on antimicrobial-resistant bacteria in food. Rome, Food and Agriculture Organization of the United Nations, 2000 (CX/FH 00/11;
ftp://ftp.fao.org/codex/ccfh33/fh00_11e.pdf

² Not all documents listed were cited above.

ftp://ftp.fao.org/codex/alinorm03/al03_13e.pdf

Recommended International Code of Practice General Principles of Food Hygiene, including Annex on HACCP and Guidelines for its application. CAC/RCP 1-1969, Rev. 4-2003
(www.codexalimentarius.net/download/standards/23/cxp_001e.pdf)

OTHER DOCUMENTS

Food Safety Risk Analysis: A Guide for National Governments, FAO Food and Nutrition Paper 87, 2006
<ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf>

Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.9.
(http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm)

Guidelines for the Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine, OIE Terrestrial Animal Health Code 2006, Part 3, Section 3.9, Chapter 3.9.3
(http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.3.htm)

Joint FAO/WHO Consultation in Kiel, Germany in 2002
(<http://www.who.int/foodsafety/publications/micro/en/march2002.pdf>)

Joint FAO/WHO expert meeting report on “The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to Improve Food Safety” (Kiel, Germany, 3-7 April 2006)
(<ftp://ftp.fao.org/ag/agn/food/kiel.pdf>)

Joint FAO/OIE/WHO Expert Workshops on Non-Human Antimicrobial Usage and Antimicrobial Resistance in 2003 and 2004 (http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_ZFK_2004.7.pdf and http://www.who.int/foodsafety/publications/micro/en/oslo_report.pdf).

2001 WHO Global Strategy for Containment of Antimicrobial Resistance
(http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/).

Additional references to specific HACCP plans, specific antimicrobial resistance monitoring plans, and specific Good Veterinary Practice and Good Agricultural Practice guidance would be useful.

codex alimentarius commission



FOOD AND AGRICULTURE
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ORGANIZATION



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Agenda Item 2

CRD 6

(Original language only)

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

COMMENTS OF KENYA

Agenda Item 2 : Matters referred to the Task Force by the Commission and the other Codex Committees
- CX/AMR07/1/2

Kenya supports the proposal on the uses of **quinolones**, **cephalosporins** and **macrolides** that are relatively new products in the market.