ALINORM 08/31/9 E

April 2008

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-first Session

International Conference Centre, Geneva (Switzerland), 30 June - 4 July 2008

PROPOSALS FOR NEW WORK (INCLUDING PROJECT DOCUMENTS SUBMITTED) AND FOR THE DISCONTINUATION OF WORK

Matters Arising by 15 March 2008

A list of proposals to elaborate new standards and related texts is contained in Table 1. The Commission is invited to **decide** whether or not to undertake new work in each case, taking into account critical review conducted by the Executive Committee, and to decide which subsidiary body or other body should undertake the work. The Commission is invited to **consider** these proposals in light both of its *Strategic Plan* and the *Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies.*

A list of proposal for the discontinuation of work is contained in Table 2. The Commission is invited to **decide** whether or not to discontinue the work in each case.

The Project Documents for new work are attached in the Annex.

TABLE 1: PROPOSALS FOR NEW WORK

Responsible Committee	Standard and Related Texts	Reference	No of Project Doc.
CCRVDF	Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA	ALINORM 08/31/31, para. 89 and Appendix VII	*
CCRVDF	Risk Management Recommendations/Guidance for Veterinary Drugs for which no ADI and MRL has been Recommended by JECFA due to Specific Human Health Concerns	ALINORM 08/31/31, para. 115 and Appendix VIII	1
TFAMR	Science-based Risk Assessment Guidance Regarding Food-borne Antimicrobial Resistant Microorganisms	ALINORM 08/31/42, para. 32 and Appendix III	2
TFAMR	Risk Management Guidance to Contain Food-borne Antimicrobial Resistant Microorganisms	ALINORM 08/32/42, para. 44 and Appendix IV	3
TFAMR	Guidance on Creating Risk Profiles for Antimicrobial Resistant Food-borne Microorganisms for Setting Risk Assessment and Management Priorities	ALINORM 08/30/42, para. 52 and Appendix V	4
CCFH	Commodity-Specific Annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)	ALINORM 08/31/13, para. 156 and Appendix V	5
CCFH	Code of Hygienic Practice for *Vibrio* Species in Seafood	ALINORM 08/31/13, para. 156 and Appendix VI	6
CCNFSDU	Revision of Nutrient Reference Values of Vitamins and Minerals in the Guidelines for Nutrition Labelling (CAC/GL 2-1985)	ALINORM 08/31/26, para. 132 and Appendix VII	7
CCFICS	Principles and Guidelines for the Conduct of Foreign on-Site Audits and Inspections	ALINORM 08/31/30, para. 64 and Appendix III	8
CCFICS	Annex to the Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CAC/GL 38-2001): Generic Model Health Certificate	ALINORM 08/31/30, para. 85 and Appendix V	9
CCMAS	Guidelines on Criteria for Methods for the Detection and Identification of Foods Derived from Biotechnology	ALINORM 08/31/23, para. 93	10
CCMAS	Revision of the Guidelines on Measurement Uncertainty (CAC/GL 54-2004)	ALINORM 08/31/23, para. 101	11

* Project documents are not required, in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts, Part 2 Critical Review, para. 4.

TABLE 2: PROPOSALS FOR THE DISCONTINUATION OF WORK

Responsible Committee	Standard and Related Texts	Reference
CCRVDF	MRLs for flumequine in Black tiger shrimp and in shrimps	ALINORM 08/31/31, para. 34 and Appendix V
CCFH	Annex to the Code of Hygienic Practice for Egg and Egg Products: Application of Food Safety Metrics in Risk Management Decision Making – Pasteurized Liquid Whole Eggs	ALINORM 08/31/13, para. 148

ANNEX

PROJECT DOCUMENTS

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

PROJECT DOCUMENT NO. 1: PROPOSAL OF NEW WORK FOR THE DEVELOPMENT OF RISK MANAGEMENT RECOMMENDATIONS/GUIDANCE FOR VETERINARY DRUGS FOR WHICH NO ADI AND MRL HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS (ALINORM 08/31/31, Appendix VIII)

1. Purpose and Scope of the Standard

To provide risk management advice to national and regional authorities on substances for which acceptable daily intakes (ADI) and maximum residue limits (MRL) cannot be recommended.

2. Relevance and Timeliness

For certain veterinary drugs, JECFA was not able to propose an ADI and MRL due to specific human health concerns (e.g. toxicity to the human consumer, carcinogenicity). It is therefore proposed that CCRVDF should take risk management decisions on those veterinary drugs in order to provide risk management guidance to Codex members. The objective is to protect consumers from residues of these veterinary drugs and to ensure a smoother functioning of international trade.

Various Codex members appreciate the health concerns and thus prohibit the use in food producing animals of respective veterinary drugs. However, discrepancies in application exist between Codex members hampering international food trade. International standardisation would therefore improve consumer protection and facilitate international trade in food. Clear risk management guidance by Codex would be particularly helpful for developing countries.

3. Main Aspects to be covered

The objective of the new work is to develop specific recommendations/guidance on veterinary drugs for which no ADI and MRL has been recommended by JECFA due to specific human health concerns.

The outcome of this proposal is not to establish a negative list, but to develop risk management recommendations. These recommendations may also suggest the use of substances with no ADI/MRL if their unavailability creates animal health concern.

This will consist of:

- identifying the veterinary drugs for which no ADI and MRL has been recommended by JECFA due to specific human health concerns;
- summarising the specific concerns identified by JECFA for each of those veterinary drugs.
- agreeing which veterinary drugs should not be used in food producing animals due to human health concerns related to their residues in food and provide respective guidance to Codex members;
- consider options for communicating risk management recommendations on such substances.

Example:

Chloramphenicol was evaluated by the 42nd and 62nd JECFA meetings. JECFA was unable to set an ADI or recommend an MRL because of specific concerns about human health, i.e. aplastic anaemia and carcinogenicity. Therefore, CCRVDF recommends that chloramphenicol should not be used in food producing animals.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

This proposal is consistent with the Criteria for the Establishment of Work Priorities. These recommendations will aim at ensuring better consumer protection from the point of view of health and food safety and fair practices in the international food trade.

In addition, the following criteria are also relevant:

- diversification of national legislations and apparent resultant or potential impediments to international trade;
- such work has not already been undertaken by other international organisations;
- volume of consumption in individual countries and volume and pattern of trade between countries of concerned food products.

5. Relevance to the Codex Strategic Objectives

This proposal is congruent with the Codex Strategic Objectives 1 and 2.

Objective 1: Promoting Sound Regulatory Framework

This proposal will provide essential guidance for member countries and promote the development of national food control systems based on international principles and criteria for the reduction of health risk along the entire food chain.

Objective 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

JECFA strictly follows the principles of risk analysis as regards risk assessment of veterinary drugs. Development of international standardisation on veterinary drugs proposed to be prohibited in food producing animals would promote the consistent application of risk analysis principles by Codex members in line with the Working principles for Risk Analysis developed by Codex.

6. Information on the Relation between the Proposal and Other Existing Codex documents

This guidance provided to Codex members will complement the MRL for veterinary drugs already adopted by the CCRVDF.

7. Identification of any Requirement for and Availability of Expert Scientific Advice

These risk management recommendations/guidance will take into account evaluations made by JECFA and revised accordingly in the future.

8. Identification of any Need for Technical Input to the Standard from External Bodies so that this can be planned for

None.

9. 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

- Circulation of a proposal elaborated by a working group at step 3 after adoption of new work by the CAC;
- Consideration of the proposed draft at the 18th Session of CCRVDF;
- Adoption at Step 5 by the following CAC;
- Consideration of the proposal at the 19th Session of CCRVDF;
- Final adoption by the following CAC.

CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

PROJECT DOCUMENT NO. 2: DEVELOPMENT OF SCIENCE-BASED RISK ASSESSMENT GUIDANCE REGARDING FOOD-BORNE ANTIMICROBIAL RESISTANT MICROORGANISMS (ALINORM 08/31/42, Appendix III)

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 support JEMRA and/or national/regional authorities in assessing 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 have limited 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 (see section 7).

One key point from the FAO/WHO/OIE consultations is that certain antimicrobial resistant foodborne microorganism were identified as being a possible microbiological food safety hazard. As such, Codex work on microbiological risk assessment for foodborne microorganisms are relevant because the presence of resistance gene reservoirs, acquisition, amplification, transmission and spread to susceptible hosts require propagation of resistance determinants within microbial hosts. 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 foodborne microorganisms.

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/regional 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 non human use of antimicrobials. 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 to human health for each antimicrobial use (e.g. 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);
- provide techniques to evaluate risk management options as appropriate;
- include a method to document datasources, procedures and results.

This proposed new work 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 and consolidating them in the framework of risk assessment for antimicrobial resistance, similar to the OIE work on risk analysis included in its Terrestrial Animal Health Code (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 proposed new work 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 proposed new work 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 proposed new work 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 foodborne 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); and
- 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 Assessment (CAC/GL 30-1999).

7. Identification of any Requirement for and Availability of Expert Scientific Advice

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

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway, 15–18 March 2004) 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, Switzerland, 1-5 December 2003) http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII 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 (Canberra, Australia, 15 - 18 February 2005) 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 Animal Health Code – Part 3, Section 3.9. 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, Denmark, 29-31 May 2007) http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf;
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, Italy, 26-30 November 2007);
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food. http://www.who.int/foodborne_disease/resistance/en/index.html;
- JEMRA Guidelines:
  Hazard characterization for pathogens in food and water
  Microbiological risk assessment series 3, FAO/WHO (2004)
  http://www.fao.org/ag/agn/agns/jemra_guidelines_hazard_en.asp;
  Exposure Assessment Microbiological Risk Assessment Series 7, FAO/WHO
  http://www.fao.org/ag/agn/agns/jemra_guidelines_exposure_en.asp; and
  Risk Characterization
  http://www.fao.org/ag/agn/agns/jemra_guidelines_risk_en.asp.
  FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

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, including 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

PROJECT DOCUMENT NO. 3: DEVELOPMENT OF RISK MANAGEMENT GUIDANCE TO CONTAIN FOOD-BORNE ANTIMICROBIAL RESISTANT MICROORGANISMS (ALINORM 08/32/42, Appendix IV)

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 project documents prepared by the Task Force. 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.

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 microorganisms is increasingly perceived as a threat to public health. Any use of antimicrobials, whether in humans, animals, plants or food-processing, may potentially lead to antimicrobial resistance.

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 foodborne microorganisms, 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 FAO/OIE/WHO consultations is that certain antimicrobial resistant foodborne microorganisms were identified as being possible microbiological food safety hazard agents.

As such, Codex work on microbiological risk management for foodborne microbes is 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. 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 microorganisms in animals which can be the source of resistant microorganisms 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 foodborne microorganisms.

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 foodborne microorganisms 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 foodborne pathogens and selected commensal microorganisms isolated from food-producing animals, food, humans, and plants, as appropriate; foodborne 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 programmes promoting the development of new antimicrobial agents, alternative treatments, and prevention programmes 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 foodborne 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. 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.

For those antimicrobial products and associated foodborne antimicrobial resistant microorganisms 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 foodborne microorganisms by monitoring of animals, foods and humans.
- Trends in human foodborne 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 three 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/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006). 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” FAO/WHO, FAO Food and Nutrition Paper no.70; 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 proposed new work would provide additional guidance for national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganisms, 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 management for antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized risk management guidance that national/regional authorities may use to carry out risk management activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety risk management 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 proposed new work 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 and CCRVDF that focuses on foodborne microorganisms 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 and documentation will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway, 15-18 March 2004) 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, Switzerland, 1-5 December 2003) http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf, p.152
- Critically important antimicrobial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation (Canberra, Australia, 15 - 18 February 2005) http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntimicroorganismsl_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 Animal Health Code – Part 3, Section 3.9. 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, Denmark, 29-31 May 2007) http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, 26-30 November 2007)
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food http://www.who.int/foodborne_disease/resistance/en/index.html
- FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

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

PROJECT DOCUMENT NO. 4: DEVELOPMENT OF GUIDANCE ON CREATING RISK PROFILES FOR ANTIMICROBIAL RESISTANT FOOD-BORNE MICROORGANISMS FOR SETTING RISK ASSESSMENT AND MANAGEMENT PRIORITIES (ALINORM 08/32/42, Appendix V)

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; and
- setting priorities with respect to risks related to antimicrobial resistant foodborne microorganisms.

This guidance can be used by JEMRA and/or national/regional authorities when undertaking 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[1], 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.

[1] See the definition in the Codex Procedural Manual.

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 foodborne microorganisms were identified as being possible microbiological food safety hazards.

3. Main Aspects to be covered

Preliminary risk management activities include the establishment of a risk profile to facilitate consideration of the issue within a particular context, and provide 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 microorganisms 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 proposed new work would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganisms, 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 proposed new work 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 proposed new work 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 foodborne microorganisms 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).

7. Identification of any Requirement for and Availability of Expert Scientific Advice

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

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway 15-18 March 2004) http://www.who.int/foodsafety/publications/micro/mar04/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII 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 (Canberra, Australia, 15 - 18 February 2005) 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 Animal Health Code – Part 3, Section 3.9 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, 29-31 May 2007)
- Joint FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials (Rome, Italy, 26-30 November 2007)
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food http://www.who.int/foodborne_disease/resistance/en/index.html
- FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

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

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

CODEX COMMITTEE ON FOOD HYGIENE

PROJECT DOCUMENT NO. 5: ELABORATION OF A COMMODITY-SPECIFIC ANNEX TO THE CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES (ALINORM 07/30/13, Appendix V)

1. Purpose and Scope of the New Work

The purpose of the proposed new work is to provide to member countries and industry, within the framework of annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (the Code), guidance on control of microbial hazards associated with specific fresh fruits and vegetables. The scope of the new work encompasses several annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern, which would likely include leafy green vegetables, melons, green onions, sprouted seeds, herbs, berries, and root vegetables. The Committee is proposing to begin the process by developing a commodity-specific annex for leafy green vegetables.

2. Relevance and Timeliness

Outbreaks of foodborne illness due to contamination of fresh fruits and vegetables have been reported world-wide with increasing regularity. The global nature of produce production, processing, and marketing requires an international perspective in addressing this problem.

Over the past decade in the United States, there have been at least two dozen outbreaks associated with fresh leafy green vegetables, especially lettuce and spinach. In several instances where a source was identified, the outbreak was the result of sources from outside of the U.S. The international public health literature has documented outbreaks linked leafy green vegetables in several other countries.

The US CDC recently reported that 40% of foodborne outbreaks associated with produce from 1998-2004 implicated leafy greens as the source. In addition, the severity of illness from infection by the typical pathogen observed in leafy green vegetables during an outbreak, *E. coli* O157:H7, frequently includes the life-threatening development of hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia.

3. Main aspects to be covered

- Review the advice from expert consultations conducted by FAO/WHO regarding the safety of agricultural and manufacturing practices for fresh produce.
- Develop a draft annex to the current *Code of Hygienic Practice for Fresh Fruits and Vegetables* for leafy green vegetables.
- Consider the development of additional annexes for other vegetables and fruits.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

General Criterion

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade, and taking into account the identified needs of developing countries: This new work will enhance consumer protection by reducing microbial hazards associated with fresh produce, in particular leafy green vegetables.

Criteria Applicable to General Subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work will provide scientific guidance, in the form of annexes to the Code, which countries will be able to use to develop their own risk management strategies for the control of microbial hazards in leafy green vegetables. This may assist in providing a harmonized approach for these products internationally.

(b) *Scope of work and establishment of priorities between the various sections of the work:* The scope of the new work is envisioned to encompass several annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern. The Committee is proposing to begin the process by developing a commodity-specific annex for leafy green vegetables.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):* The new work does not duplicate work undertaken by other international organizations and it builds on work undertaken previously by CCFH in elaborating the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. It is also timely for CCFH to focus on this issue because FAO/WHO will have completed an expert consultation on microbial hazards in fresh fruits and vegetables by March 2008.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under all six Codex strategic objectives:

Objective 1: Promoting Sound Regulatory Framework

The results of this work will assist in promoting sound national food control infrastructure and promote the safety of foods entering domestic and international trade by expanding Good Agricultural Practices and Good Manufacturing Practices to help control microbial hazards associated with various produce commodities.

Objective 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

This work will establish sound working principles for the analysis and identification of microbial hazards associated with various agricultural and manufacturing practices in the production of fresh produce. By understanding the relative risk of various practices, the most effective mitigation strategies can be implemented to ensure the greatest public health benefit.

Objective 3: Promoting Linkages between Codex and other Multilateral Regulatory Instruments and Conventions

FAO and WHO will provide expert consultations for the development of the commodity-specific annexes. The involvement of FAO and WHO in CODEX activities has already formed a close link and their involvement in this effort will continue to support this linkage.

Objective 4: Enhance Capacity to Respond Effectively and Expeditiously to New Issues, Concerns and Developments in the Food Sector

By taking on this work and expanding its expertise with specific commodities, Codex will enhance its capacity and will be able to respond more quickly and effectively to commodity-specific safety issues.

Objective 5: Promoting Maximum Membership and Participation

By developing commodity-specific annexes to the Code, there is an opportunity for the CAC to reach out to member countries that may have an interest in a particular commodity for participation where they might not typically be involved.

Objective 6: Promoting Maximum Application of Codex Standards

Developing annexes to the Code which incorporate commodity-specific recommendations and the most up-to-date science currently available will make the document more relevant to potential users, thus expanding the application of these Codex standards.

6. Information on the Relation between Proposal and Other Existing Codex Documents

The proposed work would directly modify the *Code of Hygienic Practice for Fresh Fruits and Vegetables* through the addition of commodity-specific annexes.

7. Identification of any Requirement for and Availability of Expert Scientific Advice

FAO/WHO is convening expert consultations on international produce safety for CCFH. The scope of these consultations includes evaluation of pathogen-specific hazards associated with produce and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards for consumers. FAO/WHO is empanelling appropriate experts worldwide to focus on the identification, impact, and practical application of GAPs and GMPs on the safety of produce. The consultation will consider the entire farm-to-table continuum including processing and marketing. The consultation will also focus on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production and packing, and personnel health, personnel hygiene and sanitary facilities. While the greatest information needs are associated with primary production, the expert consultation will also consider packing establishments, field packing operations, and other post-harvest handling facilities, particularly key aspects of hygiene control systems such as post-harvest water use, worker health and hygiene, cleaning/sanitizing of equipment and facilities, and the maintenance of the cold chain.

8. Identification of any Need for Technical Input to the Standard from External Bodies that can be Planned for

None identified.

9. Proposed Timeline for Completion of the New Work, Including Start Date, the Proposed Date for Adoption at Step 5, and the Proposed Date for Adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years

A five-year timeline is proposed for the completion of the leafy green annex. The expert consultation on produce is scheduled to be completed by March 2008, with a report available soon after. A draft template for the leafy green vegetable annex would be ready for initial discussion by CCFH in 2008, with a proposed date for adoption at Step 5 in 2010 and adoption by the CAC in 2012.

PROJECT DOCUMENT NO. 6: ELABORATION OF A CODE OF HYGIENIC PRACTICE FOR VIBRIO SPECIES IN SEAFOOD (ALINORM 08/31/13, Appendix VI)

1. Purpose and Scope of the New Work

The purpose of the proposed new work is to provide to member countries and industry, within the framework of a code of hygienic practice, guidance on control of pathogenic *Vibrio* species in seafood. The scope of the new work is envisioned to encompass a base document for the control of all pathogenic *Vibrio* species, with annexes developed for individual *Vibrio* species or seafood products if CCFH finds that they are necessary to provide more specific guidance. It is anticipated that this new work would be undertaken in close collaboration with Codex Committee for Fish and Fishery Products (CCFFP).

2. Relevance and Timeliness

During the past several years there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. The incidence of *Vibrio parahaemolyticus* gastroenteritis has been increasing worldwide, causing both sporadic cases and large national and pandemic outbreaks. There have been several instances in the last few years where concerns about the presence of pathogenic *Vibrio* species in seafood have led to a disruption in international trade, impacting in particular developing countries. The food safety concerns associated with these microorganisms and the concomitant need to provide scientifically sound risk management guidance warrants the attention of the Committee.

This increased concern has been particularly evident with *V. parahaemolyticus* where there has been a series of pandemic outbreaks due to consumption of raw seafood, its emergence in regions of the world previously thought to be unaffected by this pathogen, and the emergence of strains with increased pathogenicity (i.e., serotype O3K6). The number of *Vibrio* species recognized as being potential human pathogens continues to increase.

3. Main Aspects to be covered

The proposed new work will focus on the development of risk management guidance for the control of pathogenic *Vibrio* species using the framework of code of hygienic practice. This focus on a core risk management document will include all general components of food safety systems that would be needed to control these pathogens in finfish, crustaceans, and bivalve shellfish. The general format outlined in the Codex Alimentarius General Requirements (Food Hygiene) will be followed, with a focus on identifying those components that are unique to this group of product/pathogen pairs that will require guidance in greater detail than outlined in the general text. The document will address each of the ten sections within the general international code of practice for food hygiene, spanning the continuum from primary production through consumer use.

It is anticipated that one or more annexes may need to be developed to cover in more detail specific guidance needed to adequately manage the food safety risk associated with specific *Vibrio* species/product combinations. An additional annex may be needed to provide the scientific rationale and details for any microbiological criteria or other risk management metrics recommended for development after consultation with CCFFP. The identification of how to assess and validate the effectiveness of food safety systems will be particular important with these classes of product where guidance must be flexible due to the anticipated development of new control measures and risk management strategies.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

General Criterion

Consumer protection from they point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: this new work will contribute to enhance of consumer protection by providing guidance as to how to manage risk associated with pathogenic *Vibrio* species in seafood.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work will provide scientific guidance which countries will be able to use to develop risk management guidance for the control of pathogenic *Vibrio* species using the framework of code of practice.

(b) Scope of work and establishment of priorities between the various sections of the work:
See Section 1. Target hazards including pathogenic *V.pagahemolyticus, V.vulnificus* and Choleragenic *Vibrio cholerae* in seafood, including finfish, crustaceans, and bivalve molluscan shellfish that are marketed in an uncooked state, and cooked state.
In addition, the new work focuses on the identification of risk-based control measures at different steps along with the entire food chain.
The body document of the Code of hygienic practice is the first priority, followed by annexes for individual *Vibrio* species or seafood products if CCFH finds that they are necessary.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):

The new work does not duplicate work undertaken by other international organizations and builds on work undertaken by the joint FAO/WHO Expert Consultations on Microbiological hazards in Food. It is also timely for CCFH to focus on this issue because FAO/WHO has conducted and, by fall of 2007, will have completed five risk assessments on various pathogenic *Vibrio*/product combinations.

5. Relevance to the Codex Strategic Objectives

The work proposed fall under all six Codex strategic objectives:

Objective 1. Promotion of Sound National Food Control and Regulatory Systems from Farm to Table.

The results of this work will assist in promoting sound national food control infrastructure and promote safety of seafoods entering domestic and international trade by using scientific knowledge and risk assessments to develop risk-based guidance that provides foci and options for prevention and mitigation strategies to control pathogenic *Vibrio* species in seafood.

Objective 2. Promotion of the Widest Application of Risk Analysis.

This work will establish risk management options and strategies for the control of pathogenic *Vibrio* species based on risk assessment and supporting scientific analyses. It will serve as a positive example of how risk analysis can be effectively used within a code of hygienic practice framework, including providing flexibility in achieving public health goals.

Objective 3. Promotion of Seamless Linkages between Codex and Other Multilateral Bodies.

This work is based on a close coordination between FAO, WHO, and CODEX and will additionally rely of ongoing close collaboration with CCFFP.

Objective 4. Increased Efficiency and Stronger Management Oversight of Codex Work.

By establishing a general framework for the management of food safety risks associated with seafood, CCFH will provide a general document that can be referenced by CCFFP and thereby eliminating the need for that committee to develop a detailed series of hygienic codes as they develop standards for fish and fish products.

Objective 5. Full Participation by Codex Members and Interested Parties.

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work.

Objective 6: Promoting Maximum Application of Codex Standards.

By articulating the risk management options that are effective for controlling pathogenic *Vibrio* spp. in seafoods, the hygienic guidance provided will enhance the application of the standards developed by the CCFFP. In addition developing Code of Hygienic Practice which incorporate the most up to date science currently available will make the document more relevant to potential users thus expanding the application of Codex standards.

6. Information on the Relation between Proposal and Other Existing Codex documents

The proposed new work may require review and possible modification of several existing Codex documents from different Codex committees, particularly documents from the Codex Committee for Fish and Fishery Products.

7. Identification of any Requirement for and Availability of Expert Scientific Advice

Substantial scientific advice has already been obtained or is pending, and additional scientific advice is not likely to be necessary for completion of the proposed new work. The FAO/WHO conducted five risk assessments on *Vibrio* species. in seafood to address the following pathogen/commodity combinations (see ALINORM 05/28/18, para 20 and 21):

- *Vibrio vulnificus* in oysters;
- Choleragenic *Vibrio cholerae* in warm waters shrimp in international trade;
- *Vibrio parahaemolyticus* in bloody clams;
- *Vibrio parahaemolyticus* in finfish; and
- *Vibrio parahaemolyticus* in oysters.

Of these five risk assessment, FAO/WHO has completed the risk assessments on *V. vulnificus* in oysters and choleragenic *Vibrio cholerae* in warm waters shrimp in international trade have been completed, and the other risk assessments related to *Vibrio parahemolyticus* in finfish and shellfish are being combined into a single report which is expected to be published during the fall of 2007.

In addition, the United States delegation led a CCFH working group that developed a risk profile in 2002 for CCFH that reviewed existing Codex guidance on codes of hygiene for the control of *Vibrio* in fish and shellfish.
Additional risk assessments and risk profiles developed by individual member nations are also available.

8. Identification of any Need for Technical Input to the Standard from External Bodies that can be planned for

None identified.

9. Proposed Timeline for Completion of the New Work, including Start Date, the Proposed Date for Adoption at Step 5 and the Proposed Date for Adoption by the Commission ; the timeframe for developing a standard should not normally exceeding 5 years

It should be feasible to produce the core code of hygienic practice within four years. Additional product or *Vibrio* species annexes should be feasible within the same time frame unless identified late in the process of developing the core document.

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

PROJECT DOCUMENT NO. 7: PROPOSAL FOR NEW WORK TO REVISE NUTRIENT REFERENCE VALUES OF VITAMINS AND MINERALS (CAC/GL 2-1985) (ALINORM 08/31/26, Appendix)

1. Purpose and the Scope of the Proposed New Work

Section 3.4.4 of the *Codex Guidelines for Nutrition Labelling* (CAC/CL 2-1985, Rev. 1-1993) provides that numerical information on vitamins, minerals and protein should be expressed as a percentage of the reference labeling value referred to as "Nutrient Reference Value" (NRV). Since the first introduction of this guideline in 1985, Section 3.4.4 was amended once in 1993 following the Report of a Joint FAO/WHO Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes (Helsinki, Finland, 12-16 September 1988). At that time, it was indicated that the definition and review of these values was on ongoing process, subject to revision according to new scientific data by the Committee of Food Labelling (CCFL). The CCFL also recognized a need for general principles to guide the choice and amendment of NRVs, and had requested the advice of the Committee on Nutrition and Foods for Special Dietary Uses in this respect (ALINORM 93/40)

Currently the list of NRVs in *Codex Guidelines for Nutrition Labelling* covers 9 vitamins (A, D, C, thiamin, riboflavin, niacin, B_6, folic acid and B_{12}), 5 minerals (Calcium, Magnesium, Iron, Zinc, Iodine) and protein, which were in general based on the Reference RDAs for adult men. These values are indicated as a basis for expressing nutrient content in nutrition labeling of food supplements in the *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005). Also the *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) indicates NRVs as a basis for criteria for nutrition and health claims.

At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed that the current list of NRVs in the *Codex Guidelines for Nutrition Labelling* was incomplete and required additions and updates. It was also pointed out that a set of principles should be developed for the establishment of NRVs taking into account the experience of member countries in the establishment of reference values for the purpose of labelling.

The purpose of the proposed new work is to develop the science-based general principles for establishing NRVs and to revise the list of NRVs in the *Codex Guidelines for Nutrition Labelling*, taking full account of the prior work related to nutrient reference values.

2. Its Relevance and Timeliness

WHA Resolution 57.17 endorsing the Global Strategy requested the Codex Alimentarius Commission to continue to give full consideration within the framework of its operational mandate, to measures which it might take to contribute towards the improvement of health standards of foods consistent with the aims and objectives of the Global Strategy.

Accordingly, the 28th Session of the Commission agreed to ask WHO and FAO to prepare a document focused on actions that could be taken by Codex including specific proposals for new work for consideration by the CCNFSDU and the CCFL. At its 29th Session of the Commission, it was agreed to complete a document containing concrete proposals for possible actions by Codex and to circulate for comments and consideration by the CCNFSDU and CCFL.

The CCNFSDU and CCFL had discussed extensively the proposals for actions and both Committees agreed for CCNFSDU to revise the NRVs of vitamins and minerals in the *Guidelines for Nutrition Labelling* (ALINORM 07/30/26). Therefore the proposal of this new work is timely as well as relevant.

3. The Main Aspects to be covered

This work would involve a process to develop the general principles for establishment of vitamin and mineral NRVs for the general population as a first step.

The next step would be a process to review all available reference values and their scientific basis by the principles agreed upon and, if appropriate, update and extend the current list of vitamin and mineral NRVs in the *Guidelines for the Nutrition Labelling*.

Once the above is completed, the Committee would establish vitamin and mineral NRVs for labelling for individuals 6 months to 36 months of age. The Committee could then begin to work to establish principles that would apply to NRVs for this age group, using as a basis the principles identified for NRVs for the general population and modifying them as appropriate. Once those principles are developed, the NRVs for this age group would be established.

4. An 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 proposed new work would provide Codex and national/regional authorities principles to be used in establishing NRVs, thus assisting in establishing appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with NRVs, particularly for selecting NRVs for labelling purposes.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized scientific general principles that Codex and national/regional authorities may use to carry out establishing NRVs for labelling purposes. Such internationally-agreed principles can help ensure consistent approaches for establishing NRVs for labelling purposes.

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 proposed new work is consistent with, complements, and builds upon work already undertaken by CCFL.

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 1.3);

Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3).

6. Information on the Relation between the Proposal and Other Existing Codex Documents

The *Codex Guidelines on Nutrition Labelling* (CAC/GL 2-1985, Rev. 1-1993) and *Codex Guidelines for Vitamin and Mineral Food Supplements* (CAC/GL 55-2005) indicate the NRVs as a basis for expressing nutrient content in nutrition labelling of all foods including conventional foods and food supplements. The *Codex Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) also indicates NRVs as a basis for criteria for nutrition and health claims.

7. Identification of any Requirement for and Availability of Expert Scientific Advice

Scientific advice from FAO/WHO could be identified at a later stage.

8. Identification of any Need for Technical Input to the Standard from External Bodies so that this can be planned for

None foreseen.

9. The Proposed Time-line for Completion of the New Work Including the Start Date, the Proposed Date for 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
The CCNFSDU agrees the work to be undertaken	Nov, 2007
Commission approves New Work	July 2008
Step 5	2009/2010
Adoption by the Commission	2011/2012

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

PROJECT DOCUMENT NO. 8: PROPOSAL TO DEVELOP PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF FOREIGN ON-SITE AUDITS AND INSPECTIONS (ALINORM 08/31/30, Appendix III)

1. The Purposes and Scope of the Proposed Standard

The purpose of the proposed standard would be to identify existing texts on the conduct of foreign on-site audits and inspections and to develop principles and guidelines for these activities.

2. Its Relevance and Timeliness

Foreign on-site audits and inspections are increasingly being used by importing countries to assess inspection and certification systems in exporting countries and reports of these evaluations are sometimes used by third countries to inform their own assessment of exporting country systems.

The concept of foreign on-site audits and inspections to evaluate whether activities and related results comply with the objectives or associated technical or sanitary measures is mentioned in many adopted Codex texts, however internationally no guidance exists for the conduct of these types of on-site evaluations to ensure consistency of approach and transparency in application.

3. The Main Aspects to be covered

The development of principles and guidelines for the conduct of foreign on-site audits and inspections with reference to existing Codex texts and other international standards. The document will provide a consistent framework for the conduct of foreign on-site audits and inspections.

4. An Assessment against the *Criteria for the Establishment of Work Priorities*

The proposal is consistent with the criteria as follows:

General Criterion

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: Given the importance and prominence of these importing country assessments in order to ensure consistency of approach, Codex development of principles and guidelines will contribute to the protection of consumers' health and the promotion of fair practices in the food trade.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: Several countries or groups of countries have developed their own legislative frameworks regarding foreign on-site audits and inspections. The envisaged guidelines would provide essential guidance on the consistent conduct of foreign on-site audits and inspections to the benefit of both exporting and importing countries and international trade. The potential for diverse conduct of such evaluations may impede international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: The proposed Guidelines the Committee will identify the rationale (or objective) for conducting foreign on-site audits and inspections of food inspection and certification systems and the process and procedures to be agreed between the importing and exporting country before, during and after the evaluation has been conducted.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): In developing these guidelines CCFICS will take into consideration other international standards.

5. Relevance to Codex Strategic Objectives

The proposal is consistent with:

Goal 1: Promoting Sound Regulatory Frameworks (Activity 1.4: Review and development Codex standards and related texts for food inspection and certification, and methods of sampling and analysis) which states:

- In strengthening the strategic focus of Codex in the development of risk-based, performance-based standards and related texts for broad application across a range of commodities, the CAC must give priority to establishing a coherent and integrated set of food standards covering the entire food chain. Such an approach can serve as a model for the members of CAC to pursue food regulatory systems that provide consumers with safe food and ensure fair practices in the food trade.

This work also supports the premise in the Strategic Plan that successful negotiation of bilateral mutual recognition and equivalence of food control systems depends on the abilities of countries to assure each other of the integrity and international conformity of their regulatory systems.

The work will benefit countries by providing them with the necessary tools and information to ensure that the assessment of their systems is consistent and transparent.

6. Information on the Relation between the Proposal and Other Existing Codex Documents

CCFICS has already included provisions for the conduct of foreign on-site audits and inspections in several of its documents. To complement this work and assist in implementation of existing guidance there is a need to develop a document that will provide a framework for the conduct of these activities which in turn will improve their transparency.

The concept of evaluating inspection and certification systems to determine whether activities and related results comply with the objectives or associated technical or sanitary measures is mentioned in many adopted Codex texts for example, *Guidelines for Food Import Control Systems* CAC/GL 47-2003), *Guidelines for the Design, Operation, Assessment and Accreditation of Food Inspection and Certification Systems* (CAC/GL 26-1997), *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999), *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) and the *Principles and Guidelines for Imported Food Based on Risk* (adopted in 2006).

7. Identification of any Requirement for and Availability of Expert Scientific Advice

None required

8. Identification of any Need for Technical Input to the Standard from External Bodies so that this can be planned for

None required

9. The Proposed Timeline 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

Subject to Commission approval at its 31st session in 2008, it is expected that this work can be completed in four years with:

- Consideration at Step 3 by CCFICS 17;
- Consideration at Step 5 by CCFICS 18; and
- Adoption of the proposed Guidelines by the Commission within 4 years.

PROJECT DOCUMENT NO. 9: PROPOSAL TO DEVELOP A GENERIC MODEL HEALTH CERTIFICATE
(ALINORM 07/30/30, Appendix V)

1. The Purposes and Scope of the Proposed Standard

The objective of the project is to develop an Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* which would contain a generic model health certificate that may be applicable to all types of commodities.

2. Relevance and Timelines

The Codex Alimentarius Commission adopted during its 30th Session a revised version of the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001). This revision was initiated with the objective of clarifying the use of export certificates and simplifying their use by eliminating those attestations which were identified as redundant, unnecessarily burdensome or discriminatory. The logical complement to these Guidelines would be a generic model health certificate applicable to all food commodities. There is significant parallel work going on under the United Nations system (e.g. United Nations Centre for Trade Facilitation and Electronic Business – UN/CEFACT) and there is a need for this work to be appropriately incorporated and referenced to avoid duplication and to ensure consistency.

The harmonization of a generic model health certificate at an international level would allow a reinforced cooperation and a better understanding between competent health authorities. It would make the reading of certificates easier, would standardize the interpretation of administrative information regarding the certificates.

3. The Main Aspects to be covered

The proposed generic model health certificate will focus on the data elements and their spatial layout in a paper certificate. Explanatory notes will be provided to clarify details on information for each field should the importing country consider it necessary.

4. An Assessment against the *Criteria for the Establishment of Work Priorities*

The proposal is consistent with the criteria as follows:

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: This work could improve protection against fraudulent practices and enhance consumer protection by harmonising the models used for health certificates thereby facilitating the clearance process.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: This work addresses the fact that a considerable number of models for health certificates have been developed by countries or groups of countries leading to impediment to international trade.

(b) Scope of work and establishment of priorities between the various sections of the work: This work will complement the revised Codex *Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates*, adopted by the 30th Session of the Codex Alimentarius Commission.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): There is significant parallel work ongoing under the United Nations system (e.g. UN/CEFACT) and there is a need for this work to be appropriately incorporated and referenced to avoid duplication and to ensure consistency. This work will be developed in close cooperation with the relevant United Nations bodies, World Customs Organization and the World Organisation for Animal Health (OIE) to avoid contradictions, gaps and duplications.

5. Relevance to Codex Strategic Objectives

This proposal is consistent with:

Goal 1: Promoting Sound Regulatory Frameworks (Activity 1.4: Review and development Codex standards and related texts for food inspection and certification, and methods of sampling and analysis). This work is consistent with the strategy of the Codex Alimentarius Commission regarding the periodic review and harmonisation of standards, taking into account the horizontal nature of the provisions foreseen, which would provide consistency across a wide range of products.

In addition this work is in line with Goal 4: Promoting cooperation between Codex and other relevant international organisations.

6. Information on the Relation between the Proposal and Other Existing Codex Documents

This new work is proposed to be an Annex to the "*Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*"(CAC/GL 38-2001) .

The Codex Committee on Fish and Fishery Products has developed a "*Model Certificate for Fish and Fishery Products*" (CAC/GL 48-2004) and the Codex Committee on Milk and Milk Products is currently developing a "*Model Export Certificate for Milk and Milk Products*", currently at Step 5 of the Codex Procedure. These model certificates currently only cover fishery and milk products and have not a harmonised approach and presentation.

7. Identification of any Requirement for and Availability of Expert Scientific Advice

None required

8. Identification of any Need for Technical Input to the Standard from External Bodies

Relevant United Nations bodies (e.g. UN/CEFACT), World Customs Organization and the World Organisation for Animal Health (OIE)

9. The Proposed Time-line for Completion the New Work

- Consideration of the draft proposal at Step 3 by CCFICS17.
- Consideration of the proposal at Step 5 by CCFICS18.
- Adoption of the standard by the CAC at Step 8: July 2010 (on the condition that the interval between CCFICS sessions is not modified).

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

PROJECT DOCUMENT NO. 10: PROPOSAL OF NEW WORK FOR THE DEVELOPMENT OF GUIDELINES ON CRITERIA FOR METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY

1. Purpose and Scope of the Guidelines

The purpose of this new work is to enable Codex member countries and industry to identify relevant methods to be used when ensuring compliance to Codex guidelines as regard the detection and identification of foods derived from biotechnology.

2. Relevance and Timeliness

The ad hoc Task Force on Foods derived from Biotechnology in 2002 sent to CCMAS a collection of methods for the detection and identification of foods derived from biotechnology for consideration.

In view of the ongoing discussions within Codex specific labelling provisions for foods derived from biotechnology and of difficulties with the practical application of new methodology in this area, the Committee proposed to develop recommendations with respect to criteria for methods of analysis and for quality control measures that should be introduced in laboratories offering GM analyses.

Consequently CCMAS decided to apply the criteria approach for the assessment of these methods and wished to develop the appropriate criteria.

Different countries have different testing requirements for foods derived from biotechnology. Harmonization of detection methods could facilitate international trade.

3. Main Aspects to be covered

The guidelines aim to give guidance on how to establish methods to detect and identify foods derived from biotechnology by defining appropriate validation criteria, and whether or not a method complies with these criteria based on the performance characteristics of a method.

The guidelines will specify the relevant criteria and give explanations on how to consider these criteria, i.e.:

- by giving the rationale for the most relevant criteria and

- by showing how to find out whether or not a method fulfils the given criteria requirements.

4. Assessment against the *Criteria for the Establishment of Work Priorities*

This proposal is consistent with the Criteria for the Establishment of work priorities. The proposed guidelines will facilitate fair trade practices and ensure the safe use of foods. The guidelines will also enable all countries including developing countries to use analytical methods, if appropriate.

In addition, the following criteria are also relevant:

- Diversification of national legislations and apparent resultant or potential impediments to international trade: The proposed guidelines will make it possible for the use of nationally approved analytical methods according to national legislation. This might reduce the possible obstacles in international trade and ensure the safe use of foods.

- Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): The proposed guidelines are intended to introduce criteria approach for detection methods for foods derived from biotechnology in the Codex system. The Criteria Approach is accepted by Codex and currently the way other international bodies work in the field of analytical methods.

- ISO recently adopted methodologies to detect and identify foods derived from biotechnology. It is therefore appropriate for Codex to develop validation criteria in order to select the relevant methods used by Codex members.

5. Relevance to the Codex Strategic Objectives

Objective/Goal 1 Promoting Sound Regulatory Frameworks

The proposal to develop the proposed guidelines is perfectly in line with objectives 1.2 and 1.4.

1.2 Review and develop Codex standards and related texts for food quality
Description:
Review and develop Codex standards and related texts for food quality, taking into account scientific and technological developments, to ensure that they are generic in nature and whilst maintaining inclusiveness, reflect global variations and focus on essential characteristics so as to avoid being overly prescriptive and not more trade restrictive than necessary, while respecting the basic objectives of the CAC, taking into consideration the technical and economic implications for all members as well as the special needs of developing countries including infrastructure, resources and technical and legal capabilities.
Timeline: Continuing
Responsible parties: Relevant Task Forces, Commodity Committees and FAO/WHO Coordinating Committees

1.4 Review and develop Codex standards and related texts for food inspection and certification, and methods of sampling and analysis

Description: Review and develop Codex standards and related texts for food inspection and certification as well as methods of sampling, including guidance on equivalence, mutual recognition and traceability / product tracing, taking into account scientific and technological developments, to ensure that they: emphasize a horizontal approach and the need to maintain inclusiveness, and reflect global variations so as to avoid being overly prescriptive and not more trade restrictive than necessary, while respecting the basic objectives of the CAC, taking into consideration the technical and economic implications for all members as well as the special needs of developing countries including infrastructure, resources and technical and legal capabilities.

Timeline: Continuing

Responsible parties: CCMAS, CCFICS

The proposed work has also to be considered according to Objective/Goal 4.1:

Goal 4

Promoting cooperation between Codex and other relevant international organizations

4.1 Track the activities of other international standard-setting bodies

Description: Track the activities of other international standard-setting bodies to identify areas of potential complementarities, gaps, duplication, or conflict. A summary of such activities relevant to Codex shall be reported to the Executive Committee and to the Commission annually.

Timeline: Continuing

Responsible parties: CAC, CCEXEC, Codex Secretariat, subsidiary bodies

6. Information on the Relation between the Proposal and Other Existing Codex Documents

The proposed guidelines have to be considered in relation to existing texts as produced by the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology and The Codex Committee on Food Labelling.

7. Identification of any Requirement for and Availability of Expert Advice

A working group under leadership of UK and Germany has already produced a discussion paper setting the basis for further elaborating these guidelines. No further expert advice is expected to be needed.

8. Identification of any Need for Technical Input to the Guidelines from external Bodies that can be planned for

None identified.

9. Proposed Timeline 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

Draft guidelines will be considered by the 30th session of CCMAS. The proposed guidelines are expected to be adopted at step 5 by the CAC in 2010 and finally adopted in 2011.

PROJECT DOCUMENT NO. 11: PROPOSAL FOR NEW WORK ON THE DEVELOPMENT OF GUIDANCE ON MEASUREMENT UNCERTAINTY AND THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004), PREVIOUSLY ADOPTED BY THE CODEX ALIMENTARIUS COMMISSION (CAC/GL 54-2004)

1. Purpose and Scope of the Guidelines

The purpose of this new work is to enable Codex Member Countries to have available to them additional information on the use of the Guidelines on Measurement Uncertainty (CAC/GL 54-2004). In addition, the guidelines themselves are to be revised as necessary.

2. Relevance and Timeliness

The Codex Alimentarius Commission adopted Guidelines on Measurement Uncertainty in 2004 (see CAC/GL 54-2004). These Guidelines lay down information on the application of measurement uncertainty.

In addition Codex has considered the use of analytical results, sampling plans, relationship between the analytical results, the measurement uncertainty, recovery factors and provisions in Codex Standards and has adopted information on these aspects. Some Codex Members have expressed concern about the application of measurement uncertainty within Codex and have requested additional information of its application.

This new work would be of direct relevance to the application of the existing Codex Guideline. It is also of direct relevance of the ongoing discussions across Codex in this area, including with respect to disputes, and also the discussions that have taken place and which are ongoing with respect to measurement uncertainty and its use in compliance. The 29th Session of the Commission referred to the CCMAS the request from some delegations for further guidance on measurement uncertainty.

3. Main Aspects to be covered

The project is to give further information, through the addition of explanatory notes, to the existing Guidelines on Measurement Uncertainty. In addition the opportunity will be taken to up-dating the existing Guidelines in the light of up-dating of international references etc.

The explanatory notes will:

- Aid the application of the Codex Guidelines on Measurement Uncertainty.
- Facilitate the appreciation of the significance of measurement uncertainty, particularly with respect to the compliance of analytical results to the Codex specification.

The Guidelines will only consider measurement uncertainty deriving from analysis and not sampling.

4. Assessment against the Criteria *for the Establishment of Work Priorities*

This proposal is consistent with the Criteria for the Establishment of work priorities. The proposed guidelines will facilitate fair trade practices and ensure the safe use of foods.

In addition, the following criteria are also relevant:

- Diversification of national legislations and apparent resultant or potential impediments to international trade: The proposed explanatory notes to the existing measurement uncertainty guidelines will make it possible for the use of nationally approved analytical methods according to national legislation. This might reduce the possible obstacles in international trade and ensure the safe use of foods.

5. Relevance to the Codex Strategic Objectives

Objective/Goal 1 Promoting Sound Regulatory Frameworks

The proposal to develop the proposed guidelines is perfectly in line with objectives 1.2 Review and develop Codex standards and related text for food quality and 1.4 Review and develop Codex standards and related texts for food inspection and certification, and methods of sampling and analysis.

The proposed work has also to be considered according to Objective/Goal 4.1 Promoting cooperation between Codex and other relevant international organizations

6. Information on the Relation between the Proposal and Other Existing Codex Documents

The proposed explanatory notes have to be considered in relation to existing texts as produced by Codex in particular CAC/GL 59-2006 and CAC/GL 50-2004.

7. Identification of any Requirement for and Availability of Expert Advice

A Working Group under leadership of UK has already produced a discussion paper setting out aspects that could be included in the explanatory notes. These were supported in principle at the 29th Session of the Codex Committee on Methods of Analysis and Sampling. No further expert advice is expected to be needed.

8. Identification of any Need for Technical Input to the Guidelines from External Bodies that can be planned for

None identified.

9. Proposed Timeline 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

Formal draft explanatory guidelines will be considered by the 30th session of CCMAS. The proposed guidelines are expected to be adopted at step 5 by the CAC in 2010 and finally adopted in 2011.