

codex alimentarius commission

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FOOD AND AGRICULTURE
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Agenda Item 1

**CX/AMR 08/2/1 Add.1
September 2008**

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

Second Session

Seoul, Republic of Korea, 20-24 October 2008

PROVISIONAL AGENDA

On 8 September 2008, the Codex Secretariat received a communication from Japan, reproduced below.

In accordance with Rules VII.5 and XI.11 of the Rules of Procedure of the Codex Alimentarius Commission, the item "Structure of the Integrated Document" is hereby placed on a supplementary list.

The discussion paper is attached to the present document.

Japan wishes to request the inclusion of a new agenda item to the Provisional Agenda for the Second Session of the Ad hoc Codex International Task Force on Antimicrobial Resistance (CX/AMR 08/2/1) as follows in conformity with Rule VII (Agenda).5 and XI (Subsidiary bodies).11:

"Structure of the Integrated Document"

The three Working Groups made an identical recommendation in the last week of May (CX/AMR 08/2/4 para.48, CX/AMR 08/2/5 para. 28, CX/AMR 08/2/6 para. 11): "Three working group documents could be most usefully read by intended audiences as one integrated guidance document. With this approach, certain sections, such as introduction, definitions, documentation, and risk analysis general principles, could be harmonized, resulting in a more consistent and understandable guidance document. Furthermore, this approach would allow the inclusion of an overall flow chart that would guide the reader through the range of the activities discussed in the three separate but overlapping working group documents. Finally, the integrated document would include a harmonized section on risk communication, which is critical to all activities addressed by the guidance."

We think that the Task Force shall follow this recommendation and decide a way forward prior to discussing individual documents: Proposed Draft Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Organisms, Proposed Draft Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microorganisms for Setting Risk Assessment and Management Priorities, and Proposed Draft Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms. The structure of an integrated document shall be discussed before taking any action on individual documents.

Yours sincerely,

長田 朋二

NAGATA Tomoji, Codex Contact Point for Japan

Discussion Paper on the Integrated Guidance Document

Background

1. During its First Session, the Codex *Ad Hoc* International Task Force on Antimicrobial Resistance (ALINORM 08/31/42) agreed to undertake new work on the development of guidance documents on:

- i) Science-based risk assessment of foodborne antimicrobial resistant microorganisms (para.32 and Appendix III);
- ii) Risk management to contain foodborne antimicrobial resistant microorganisms (para.44 and Appendix IV); and
- iii) Creating risk profiles for antimicrobial resistant foodborne microorganisms for setting risk assessment and management priorities (para.52 and Appendix V).

2. The Task Force agreed to establish three physical working groups to prepare three proposed draft guidance documents for circulation at Step 3 and further consideration at Step 4 at the Second Session of the Task Force, pending the formal approval of new work by the Commission in July 2008 (paras 33,45 and 53 of ALINORM 08/31/42)

3. The three physical Working Groups met in Brussels from 26 to 30 May 2008 and made an identical recommendation(CX/AMR 08/2/4 para.48, CX/AMR 08/2/5 para.28, CX/AMR 08/2/6 para.11): “The three working group documents could be most usefully read by intended audiences as one integrated guidance document. With this approach, certain sections, such as introduction, definitions, documentation, and risk analysis general principles could be harmonized, resulting in a more consistent and understandable guidance document. Furthermore, this approach would allow the inclusion of an overall flow chart that would guide the reader through the range of the activities discussed in the three separate but overlapping working group documents. Finally, the integrated document would include a harmonized section on risk communication, which is critical to all activities addressed by the guidance.”

Actions to be taken in response to the Recommendation

4. The Task Force should integrate the three working group documents into one guidance document in response to the recommendation. Japan recommends that the Task Force should discuss the following subjects prior to discussing individual working group documents (Agenda Items 4-6 of CX/AMR 08/2/1) to decide a way forward to avoid overlapping of work and to ensure consistency throughout the document :

- i) The integrated document structure including flow chart and the sections to be included in it; and
- ii) Sections common to all or two existing individual guidance documents and their harmonization.

Proposal for the deliberation process

5. To avoid creating gaps or introducing contradiction in the integrated guidance document, we propose a process of deliberation for consideration on the assumption that the Task Force accepts the recommendation:

Proposed deliberation process

The Task Force should:

- i) determine the structure of the integrated document including flow chart;
- ii) identify the sections common to all or two current draft individual guidance documents and harmonize them;
- iii) compare the texts in the corresponding sections of individual draft guidance documents along with the agreed structure of the integrated guidance document (see the table in Annex);
- iv) discuss the contents of sections; and

- v) if sections specific to individual current draft guidance documents are identified, determine whether the sections should be included in the integrated guidance document or should be included in a separate document.
6. To facilitate consideration by the Task Force, Japan has prepared a table indicating a structure of the integrated guidance document with comparison of texts in the corresponding sections of current draft guidance documents per Annex attached.

[Annex] Table. Proposed Structure of the consolidated documents and contents of the three draft guidance documents

Title of Guidance		Risk Assessment	Risk Profiles	Risk Management
Document No.		CX/AMR 08/2/4	CX/AMR 08/2/5	CX/AMR 08/2/6
Structure		Contents in Draft/Comments by WG	Contents in Draft/Comments by WG	Contents in Draft/Comments by WG
	Introduction	WG; "This section may be finalized with merged AMR Risk Analysis Document."	[To be harmonized]	[To be harmonized]
	Scope	Scope Figure 1	Scope	Purpose and Scope
	Definitions	WG; "This section may be finalized with merged AMR Risk Analysis Document."	[To be harmonized]	-
	Risk Analysis General Principles	-	-	-
	Risk Assessment			
	General Principles	General Principles	-	-
	General Considerations	5.1. Purpose 5.2. Qualitative and quantitative AMR-RA 5.3. Sources of data or evidence Data and possible sources of information	-	-
	Process of AMR-RA	6.1. Hazard Identification 6.2. Exposure Assessment Table 1. Possible pre-harvest data requirements for exposure assessment Table 2. Possible post-harvest data requirements for exposure assessment 6.3. Hazard Characterization Figure 2. Scheme for the consolidated Hazard Characterization in AMR-RA Table 3. Possible data requirements for hazard characterization 6.4. Risk Characterization Table 4. Potential Points for Consideration in the Risk Characterization	-	-

Title of Guidance		Risk Assessment	Risk Profiles	Risk Management
Document No.		CX/AMR 08/2/4	CX/AMR 08/2/5	CX/AMR 08/2/6
Risk Management				
	General principles for Antimicrobial resistance risk management	-	Principle 1 ~ 10.	Principle 1 ~ 11.
	General considerations	-	-	-
	Preliminary antimicrobial resistance risk management activities	-	Guidelines for Activities 4.1. Identification of an antimicrobial resistance food safety issue 4.2. Development of an antimicrobial resistance risk profile 4.3. Rank food safety issues and set priorities for risk assessment and management 4.4. Establish broad risk management goals 4.5. Establish a risk assessment policy 4.6. Commission of a risk assessment 4.7. Consider the results of the risk assessment	-
	Identification and selection of antimicrobial resistance risk management options	-	-	IV.- Identification of the available options A.- Pre-harvest options A.1- General A.2- Food animal production A.3- Plant production B.- Post-harvest options V.- Evaluation of Risk Management Options (RMO) VI.- Selection of Risk Management (RM) Options A.- Identifying a appropriate level of consumer health protection A.1- Benefit-risk approach A.2- Threshold approach A.3- Precautionary approach A.4- ALARA approach B.- Reaching a decision on the preferred risk management options

Title of Guidance		Risk Assessment	Risk Profiles	Risk Management
Document No.		CX/AMR 08/2/4	CX/AMR 08/2/5	CX/AMR 08/2/6
	Implementation of antimicrobial resistance risk management options	-	-	Implementation of Risk Management Options
	Monitoring and review	-	-	Monitoring and review of Risk Management Options
	Documentation	WG; "This section may be moved, potentially expanded, and included in the integrated AMR Risk Analysis Document."	-	-
	Risk Communication	WG; "This section may be moved, potentially expanded and included in the integrated AMR Risk Analysis Document."	-	[To be harmonized]
	References	WG; "This section may be harmonized with reference section for overall AMR Risk Analysis Document."	-	-
	Annexes	Appendix 1. Outputs of Qualitative AMR-RA	Suggested Elements to Include in an Antimicrobial Resistance Risk Profile	Annex 1: possible endpoints (exposure end points to be separated from adverse health effect end points)
		Appendix 2. Outline of Information for an AMR-RA		Annex 2: step wise approach