

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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WORLD  
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**Agenda Item 5**

**CX/NASWP 00/5**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC

Sixth Session

Perth, Australia, 5 - 8 December 2000

#### REPORT ON ACTIVITIES RELATED TO RISK ANALYSIS IN CODEX AND OTHER BODIES

1. The 23<sup>rd</sup> Session of the Commission made a number of recommendations addressed to FAO, WHO and Codex member governments in relation to risk analysis (ALINORM 99/37, paras. 56-58). The 47<sup>th</sup> Session of the Executive Committee made the following decisions to implement the Commission's recommendations on risk analysis (ALINORM 01/3, para. 42 and Appendix II):

<b>Recommendation</b>	<b>Implementation</b>
Programmes that contribute to risk analysis should have high priority;	This should be taken up in the context of Agenda Item 6: Preparation of the Medium-Term Plan 2003-2007.
Relevant Codex Committees should continue to develop and to apply risk analysis principles and methodologies appropriate to their specific mandates within the framework of the Action Plan and report their progress to the Commission on a regular basis;	Noted:On-going.
Proposals for new or amended definitions for use within the framework of risk analysis, as appropriate, should be considered by the Codex Committee on General Principles;	Noted:On-going.
To overcome confusion about the usage of the terms "risk analysis" and "hazard analysis", the Commission should reiterate its definitions for these concepts and explain how they apply in practice;	The Executive Committee referred this matter to the Codex Committee on Food Hygiene for a clear statement of the difference between the two terms and to the Committee on general Principles for subsequent action.
The Commission should continue and expand its efforts to increase the participation of those national governments and NGOs that are members or observers but that are not presently active participants in Codex matters;	The Executive Committee noted that the issue was relevant to all Codex work and not only to risk analysis and drew the attention of the countries concerned to the Commission's recommendation.

<p>Relevant Codex committees should consider developing quality criteria for data used for risk assessment. To the extent possible such criteria should be consistent with one another, taking into account the technical differences in the disciplines covered;</p>	<p>The Executive Committee referred these recommendations to the Committees concerned. (see also para. 42 of the report)</p>
<p>Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;</p>	
<p>Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies;</p>	
<p>Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk Management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.</p>	<p>The Executive Committee referred this recommendation to the Codex Committee on General Principles for consideration in relation to the development of appropriate texts for inclusion in the Procedural Manual.</p>

#### **CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS: RISK ANALYSIS PRINCIPLES**

2. The 47<sup>th</sup> CCEXEC noted (ALINORM 01/3, paras. 52-53) that the Codex Committee on Food Additives and Contaminants had asked for clarification of the status of a discussion paper entitled Risk Analysis Principles for Food Additives and Contaminants in the context of a uniform approach to the application of risk analysis in different committees. The Executive Committee noted that the origin of this work was the recommendation of the 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade the "the CAC and the relevant Codex Committees responsible for the development of standards, codes of practice or guidelines concerned with the protection of human health should make explicit the methods they have used to assess risk". This recommendation was endorsed by the 19th Session of the Commission (1991).

3. The Executive Committee noted that general principles for risk analysis were being finalized by the Committee on General Principles and there was no need for the Committee on Food Additives and Contaminants to duplicate this work. It was expected that the discussion of risk analysis by the 24<sup>th</sup> Session of the Commission would conclude the mandate established by the 19<sup>th</sup> Session of the Commission for the Commission and its subsidiary bodies to make explicit their risk methodologies. The Executive Committee was therefore of the opinion that the matter was urgent and requested the Committee on Food Additives and Contaminants to complete the report on the scientific basis used in risk analysis of food additives and contaminants as soon as possible.

#### **COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS: "OTHER LEGITIMATE FACTORS"**

4. The Codex Committee on Food Additives and Contaminants had asked the Executive Committee to clarify the current status of the consideration of "other legitimate factors" within Codex with a view towards providing advice on a uniform approach to the matter and is considering the inclusion of a separate Annex concerning "other legitimate factors" in the Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants. The Executive Committee noted (ALINORM 01/3, para. 56) that the matter of "other legitimate factors" was under consideration by the Committee on General Principles at the request of the Commission. The Committee on General Principles had requested relevant Codex Committees to provide examples of other legitimate factors taken into account in their decision-making processes so as to facilitate the general debate in the Committee on General Principles on other legitimate factors. The Executive Committee confirmed that responsibility for a system-wide approach to the consideration of "other legitimate factors" rested with the Committee on General Principles and that no

further action in this matter should be taken by the Committee on Food Additives and Contaminants (or any other Committee) at the moment.

### **33rd SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE**

#### **PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (ALINORM 01/13A, PARAS. 83 - 96)**

5. At the 33<sup>rd</sup> Session of the Codex Committee on Food Hygiene, the Delegation of France introduced document CX/FH 00/6 and pointed out that it had been restructured and revised since the last Session to take into account the recommendations of the joint FAO/WHO Expert Consultation on Risk Management and Food safety as well as comments received from Member Countries. The Delegation advised that the main changes were made to section 5.1 - Initial Risk Management Activities. The term Food Safety Objective (FSO) was changed to Microbiological Food Safety Objective (MFSO), though it was noted that this concept needed further development. The drafting group noted that no consensus had yet been reached on the "Precautionary Principle" in the CCGP and that, to facilitate the discussions in CCFH, the extract of the CCGP report was annexed to the document.

6. The Committee expressed its appreciation to the work of the Delegation of France and the drafting partners. The Delegation of New Zealand stressed the importance of the development of these principles and guidelines for the future work of the Committee and indicated that Microbiological Risk Management was a new area of work for the Committee. The Delegation pointed out that although the initial framework for this work had been borrowed from chemical risk assessment/ management, it has now become apparent that microbiological risk management was very different and that interaction between the risk assessor and the risk manager was a key factor in microbiological risk management. Also, there were many more risk management options to be considered for management of microbiological hazards compared to chemical hazards. It was also noted that, as of yet, there was no formal risk assessment for the Committee to consider.

7. Concerns were raised by a number of delegations regarding the definitions in this document. The Committee agreed that, where they existed, the definitions used should be those adopted by the CAC. The Delegation of the US requested that the definition of Microbiological Risk correlate to that of Risk already defined by the CAC. In relation to MFSO, it noted that it was premature to define this term as the concept was still under development. Delegations identified a number of additional terms that should be defined in section 2 of this document. These included: tolerable level of risk (TLR), microbiological hazard, appropriate level of protection, risk profile, interested parties, stakeholders, risk management policy and acceptable level of risk. The Delegation of Denmark pointed out that in defining terms such as TLR, MFSO, appropriate level of protection and microbiological criteria it was important to look at how these terms relate to each other and if all of them were necessary. The Committee also noted that for terms such as TLR and MFSO, further definition of the concepts was required before the terms can be defined.

8. The Delegation of the United Kingdom expressed some concern regarding the replacement of the term FSO with MFSO and suggested that this may be narrowing the concept of FSOs as it would be interpreted as microbiological criteria. To clarify this issue the Delegation of France pointed out that the scope of MFSO was identified in 5.2.1.1. The Representative of ICMSF informed the Committee that "microbiological" was included to clarify that the paper was discussing FSOs as they relate to microbiological hazards and to avoid any confusion with the concept discussed in CCGP and CCFICS and was not intended to limit the concept of an FSO. The Chairperson indicated that as the situation has changed and CCFH is now the only Committee addressing this concept it was now possible for CCFH to return to the use the term FSO.

9. The Committee had an extensive discussion on Principle 4 that referred to the risk management - risk assessment interface. The Delegation of New Zealand proposed that this Principle be made more flexible to highlight the importance of interaction between risk managers and risk assessors and that risk assessment policy could not be completely determined before the risk assessment commenced. The Delegation of the US expressed the concern that the principle did not reflect the need for identification of bias and proposed the inclusion of an additional sentence as follows: "Risk assessors must document the impact of these policies on the assessment". While many delegations expressed support for highlighting the need for interaction, the need to keep the principles as simple and focussed as possible was also stressed. The Committee decided to retain the first sentence of the principle with the addition of the phrase, "while ensuring transparent and appropriate interaction between them" based on the WHO Kiel Expert

Consultation<sup>1</sup> report. The second sentence of this principle as well as the inclusion proposed by the US delegation were moved to section 5.1.5.

10. Following discussion on Principle 6, the Committee decided to retain the square brackets, as the issue of precaution was still under discussion in the CCGP, and accepted the proposal of the European Commission to add “pending further scientific information” to the end of the sentence.

11. The Committee also had extensive discussions on Principle 8 that related to risk management decisions. Some delegations expressed concern over its inflexibility. The Committee, however, decided that this principle should focus on the importance of the whole food chain in risk management decisions, although it was recognized that not all risk management decisions require an examination of the whole food chain. Principle 8 was slightly modified to read "Risk Management decisions should take into account the whole food chain from primary production to consumption, including imported foods."

12. In relation to Principle 10 the Committee agreed to include the word “substantive” in recognition of the fact that it is not feasible to review a risk management decision every time a new piece of information becomes available. In Principle 11 the Committee noted that measures should be “revised” rather than “reviewed”.

13. The Delegation of New Zealand raised the issue of including monitoring and surveillance which are not currently included in this document as new principle principle of risk management. It was pointed out that these were important issues particularly in light of the data gaps identified by the Joint FAO/WHO Expert Consultation on Microbiological Risk Assessment. The Committee agreed that this issue be referred to the drafting group to consider its inclusion.

14. The Committee noted the status of the consideration of precaution by the CCGP. The Observer from Consumers International supported by some delegations suggested a circular letter be prepared requesting the Members to illustrate in a concrete way how precaution was or might be used in the context of microbiological risk assessment. The Secretariat informed the Committee that CCGP had already sent out a circular letter similar to that suggested. While there was some frustration at the lack of progress in this area, the Committee agreed that it was not the task of the CCFH to define the basic application of precaution in Codex work.

15. Following the proposal of the Delegation of Sweden, the Committee agreed that a Circular Letter be sent out to Member Countries requesting them to provide information on their views on Food Safety Objectives as presented in Section 5.2.1.1 of CX/FH 00/6 and, if possible, examples of FSO’s. Replies would be sent directly to the chair of the drafting group.

16. The following proposals for further developing the document were referred to the drafting group for consideration:

- Incorporate the changes proposed in CRD 13 (Finland), in particular, sampling and testing methods, in Section 5.2.3;
- Move section 5.1.8 to section 5.2;
- The report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards in Foods be considered in the further development of the text on Risk Profile;
- Include mass media in section 4;
- Change the title of section 5.1 to better describe the concept of “Initial risk management activities”;
- In Section 5.2.1, try to define what was meant by “scientific knowledge of the risk is insufficient”;
- ICMSF agreed to provide their results of deliberation regarding FSOs.

### **Status of the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management**

17. The Committee agreed to return the document to Step 3. It was further agreed that the Delegation of France, assisted by its drafting partners, would revise the document, taking into account the comments of this Session, the report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards and any comments that are received in response to the CL on FSOs. The Committee decided to draw the attention of CCGP to the importance of reaching a resolution on the issue of precaution in order for this document to progress.

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