

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 9

CX/LAC 01/9

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN

12th Session

Santo Domingo, Dominican Republic, 13 – 16 February 2001

REPORT ON RISK ANALYSIS ACTIVITIES IN CODEX

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

1. The 23rd Session of the Codex Alimentarius Commission (Rome, Italy, 28 June - 3 July 1999) made a series of recommendations to be applied in the framework of Codex and endorsed others addressed to member governments, FAO and WHO.¹ The 47th Session of the Executive Committee (Geneva, Switzerland, 2-7 July 2000) made a number of decisions to implement the Commission's recommendations on risk analysis. The recommendations of the Commission and the Executive Committee are attached to this report as Annex I and II respectively.

CODEX COMMITTEE ON GENERAL PRINCIPLES

Working Principles for Risk Analysis

2. The 22nd Session of the Codex Alimentarius Commission (Geneva, Switzerland, 23-28 June 1997) considered the application of risk analysis principles in Codex and agreed on an *Action Plan for Codex-wide Development and Application of Risk Analysis Principles and Guidelines*. The Commission requested the Codex Committee on General Principles (CCGP) to elaborate integrated principles for risk management and risk assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual.² As a result, the CCGP have been considering *Proposed Draft Working Principles for Risk Analysis* at its 13th, 14th and 15th Sessions.

3. The last CCGP (Paris, France, 10-14 April 2000) considered the revised *Proposed Draft Working Principles for Risk Analysis* and agreed on a number of amendments to different sections of the document. However, the Committee recognised that the application of "precaution" in risk management still needed additional discussion and therefore, it agreed to retain the text at Step 3 for further consideration at its next session.³

Food Safety Objectives (FSOs)

4. The CCGP first considered "*Food Safety Objectives*" at its 14th Session due to a request arising from the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) to elaborate *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* which included consideration of the concept of Food Safety Objectives.⁴

¹ ALINORM 99/37 paras. 56-58

² ALINORM 97/37 para. 163

³ ALINORM 01/33 paras. 8-73 & Appendix III

⁴ The 47th Session of the CCEXEC approved the elaboration of *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* as new work for the CCFICS. A Proposed Draft Guidelines was circulated for comments prior to its consideration by the 9th Session of the Committee (Perth, Australia, 11-15 December 2000).

5. In discussing this issue, the last CCGP felt that it was premature to generalise the concept of food safety objectives with a specific definition. It was therefore agreed that the concept could be further developed by other relevant Committees in order to identify how it could be applied to specific food safety issues while the Committee should continue to oversee the consistency in the definition and application of the concept.⁵

Review of the Statements of Principle on the Role of Science and the Extent to which Other Factors are taken into account in relation to Risk Analysis

6. The 14th Session of the CCGP considered the role of other legitimate factors and agreed to ask the relevant Codex committees⁶ to identify and clarify the relevant factors taken into account in their work in the framework of risk analysis as this would facilitate the general debate in the CCGP. The 15th session of the CCGP had an exchange of views on this issue and agreed to introduce some amendments in the text.

7. In considering the examples on "other factors" provided by the Codex committees involved in risk management, the CCGP recalled that its mandate, as endorsed by the 22nd session of the Commission⁷ and contained in the Medium-Term Plan 1998-2002 approved by the 23rd session of the Commission⁸, included the development of general guidance on the identification, management, application and interpretation of other legitimate factors as defined in the second Statement of Principle. In view of this, ongoing debate in the Committees responsible for risk analysis could assist in the general discussion in the CCGP but it should proceed within its own mandate to develop general guidance. The Committee also acknowledged that this issue had not been addressed to the Task Forces⁹ which reported directly to the Executive Committee and the Commission.

8. In addition, the last Session of the Executive Committee, while answering a question posed by the Codex Committee on Food Additives and Contaminants related to the current status of the consideration of other legitimate factors within Codex with a view to providing advice on a uniform approach to the matter, confirmed that responsibility for a system-wide approach to the consideration of these factors rested with the Committee on General Principles and that no further action on this matter should be taken by other Committees at the moment.¹⁰

9. The CCGP agreed to consider further the role of "other legitimate factors" in relation to risk analysis at its next session.¹¹

CODEX COMMITTEE ON FOOD HYGIENE

Principles and Guidelines for the Conduct of Microbiological Risk Assessment

10. The 32nd Session of the Codex Committee on Food Hygiene (Orlando, U.S.A, 26-30 October 1998) advanced the above-mentioned guidelines to the 23rd Session of the Commission for final adoption and the Commission concurred with this proposal.¹²

⁵ ALINORM 01/33 paras. 65-66

⁶ Risk analysis within the Codex is being carried out by the following committees: Codex Committee on Food Additives and Contaminants, Pesticide Residues, Residues of Veterinary Drugs in Foods; Food Hygiene and Nutrition and Foods for Special Dietary Use (on some matters).

⁷ The 22nd CAC (Geneva, Switzerland, 23-28 June 1997) requested the CCGP to consider the application of "other legitimate factors" than science in relation to BST and PST. The 13rd CCGP (Paris, France, 7-11 September 1998) addressed this issue and decided to separate the matter into "other legitimate factors in the framework of risk analysis" and "other legitimate factors in the case of BST". The 14th CCGP (Paris, France, 19-23 April 1999) could not reach consensus on the application of "other legitimate factors" in the case of BST and informed the 23rd CAC accordingly. However, it agreed to continue considering the application of "other legitimate factors in relation to risk analysis" at its next session.

⁸ ALINORM 99/37, paras. 25-34 & App. II

⁹ The 23rd CAC agreed on the establishment of three *Ad Hoc* Intergovernmental Task Forces namely: Animal Feeding, Foods derived from Biotechnology and Fruit and Vegetable Juices. The two firsts incorporate risk analysis in the development of the standards.

¹⁰ ALINORM 01/3 para. 56

¹¹ ALINORM 01/33 paras. 85-95

¹² ALINORM 99/13 para. 34/Appendix II and ALINORM 99/37 para. 114/Appendix VII-Part 1.

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

11. The 29th Session of the Codex Committee on Food Hygiene (Washington D.C., U.S.A., 21-15 October 1996) agreed to develop recommendations for the management of microbiological hazards for foods in international trade¹³ and the 22nd session of the Commission agreed on this proposal.¹⁴ The Committee has been considering this issue since then. Significant discussion occurred on the structure of the document, on the relationship between risk management and risk assessment, on the use of "precaution", and on need for flexibility with respect to the use of the draft principles and guidelines by developing countries.

12. In revising the document, the last CCFH agreed to request information from Codex members on their views on food safety objectives and, if possible, examples of them. It was agreed that the text would be revised for consideration by next CCFH and therefore, the document was retained at Step 3.¹⁵

OTHER CODEX COMMITTEES

Application of Risk Analysis in Different Codex Committees

13. The 1991 FAO/WHO Food Conference on Food Standards, Chemicals in Food and Food Trade recommended that "*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*".¹⁶ This recommendation was endorsed by the 19th Session of the Commission.¹⁷ Following this recommendation, the relevant Codex committees has been working on the application of risk analysis principles in their respective field.

Codex Committee on Food Additives and Contaminants (CCFAC)

14. The CCFAC is currently considering a Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants aimed at strengthening the standard setting activities of the Committee by clarifying its risk management role and the risk assessment role of Joint FAO/WHO Expert Committee on Food Additives (JECFA) and improving risk communication between the two bodies. The document would be revised on the basis of the written comments submitted and the Committee's discussion for circulation, comments and further consideration at its next session. It was further agreed that a separate Annex on "Other Legitimate Factors" could be appended to the paper.

Codex Committee on Pesticide Residues (CCPR)

15. The last session of the CCPR agreed that a paper on risk analysis principles and methodologies be prepared for consideration at the next session so as to enable this Committee to report the development and application of risk analysis to the 24th Session of the Commission. In addition, it noted that a number of recommendations of the 24th Session of the Commission concerning risk analysis namely: development of quality criteria for data used for risk assessment, consideration of acute aspects of dietary exposure, risk assessment based on global data and feasibility of risk management options in developing countries, had been already taken into consideration or currently worked on by the Committee and Joint FAO/WHO Meeting on Pesticide Residues (JMPR).¹⁸

Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

16. The last CCRVD agreed that it would consider (1) the development and application of risk analysis principles and methodologies appropriate to the specific mandate within the framework of the Action Plan, and (2) development of quality criteria for data used for risk assessment. It noted, for implementation as appropriate, the other recommendations of the Codex Alimentarius Commission regarding risk analysis principles. The Committee further agreed that a discussion paper, containing solid recommendations regarding risk analysis principles and methodologies including risk assessment policy; use of microbiological endpoints for the setting of ADIs; as well as data requirements and the use of extrapolation for establishing MRLs for "minor" species, would be prepared for consideration by the next CCRVDF.¹⁹

¹³ ALINORM 97/13A para. 66

¹⁴ ALINORM 97/37 Appendix IV

¹⁵ ALINORM 01/13A paras. 83-95

¹⁶ ALICOM 91/22 para. 210 and Appendix I-9

¹⁷ ALINORM 91/40 Appendix IV

¹⁸ ALINORM 01/24 paras. 6-8

¹⁹ ALINORM 01/31 paras. 15-19; 65 and 142

In order to facilitate the preparation of the paper, the Committee invited Codex members to submit comments on a paper entitled "Risk Analysis in the Codex Committee on Residues of Veterinary Drugs in Foods" appended to the report of the previous meeting of the Committee.²⁰

Other Activities in the area of Risk Analysis

Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

17. In discussing the recommendations of the *FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals*²¹ (Geneva, Switzerland, 10-14 February 1997), the last CCNFSDU agreed to seek information on experience with risk assessment for nutrition issues at government levels, including methodology and principles for consideration by its next session.²²

Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology

The 1st Session of the Task Force (Chiba, Japan, 14-17 March 2000) agreed that a set of broad general principle for risk analysis of food derived from biotechnology and specific guidance on the risk assessment of this sort of food should be set up as priority work for the Task Force. A Drafting Group was established for this purpose which has met twice during the year and has prepared a *Proposed Draft General Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* and a *Proposed Draft Guidelines for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants* for discussion by the next session of the Task Force to be held in Tokyo, Japan from 26 to 30 March 2001 (see also CX/LAC 01/2-Add.1 *Status of Work as of November 2000 of the Codex Alimentarius Commission and FAO/WHO Expert Consultations regarding Foods Derived from Biotechnology*).

²⁰ ALINORM 99/31, Appendix IX

²¹ WHO/FSE/FOS/97.5

²² ALINORM 01/26, para. 131

RECOMMENDATIONS CONCERNING RISK ANALYSIS

*23rd Session of the Codex Alimentarius Commission
(ALINORM 99/37, para. 56)*

The Commission adopted the following recommendations within the framework of Codex:

Recommendation

- Programmes that contribute to risk analysis should have high priority;
 - 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;
 - 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;
 - 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 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;
 - Relevant Codex committees should appoint a co-author from a developing country for position papers, where the main author(s) is from a developed country;
 - 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;
 - Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;
 - 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;
 - 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.
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ANNEX II

**IMPLEMENTATION OF THE COMMISSION'S RECOMMENDATIONS CONCERNING
RISK ANALYSIS**

*47th Session of the Executive Committee of the Codex Alimentarius Commission
(ALINORM 01/3, Appendix)*

Recommendation	Implementation
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.
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;	The Executive Committee referred these recommendations to the Committees concerned. (see also para. 42 of the report)
Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;	
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;	
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.	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.