

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 3**

**CX/FAC 00/2**

January 2000

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-second Session

Beijing, People's Republic of China, 20-24 March 2000

### MATTERS REFERRED BY THE 23<sup>RD</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

#### REPORT ON THE FINANCIAL SITUATION OF THE JOINT FAO/WHO FOOD STANDARDS PROGRAMME FOR 1998/99 AND 2000/01<sup>1</sup>

1. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission noted the discussions held at the 46<sup>th</sup> Session of the Executive Committee<sup>2</sup> regarding the funding of the scientific advisory bodies, JECFA and JMPR and *ad hoc* consultations and expressed its concern that inadequate resources would seriously impair the work of the Programme. The Commission expressed the view that the independence and the scientific integrity of these bodies should continue to be strengthened and noted that FAO and WHO were considering issues related to the transparency of the selection process for experts; resolution or avoidance of conflicts of interest; expression of minority opinions by experts; and enlarging the basis of expert advice in the scientific bodies. The Commission considered the resolution proposed by the Executive Committee (CAC/LIM 17) in order to draw the attention of the parent Organizations to the importance of these issues and agreed to make the following amendments.
2. The Commission agreed with the proposal of the Delegation of the United Kingdom and the Observer from Consumers International to include a reference to the transparency of the opinion given by the expert bodies, in addition to their independence and scientific integrity. The Commission had an exchange of views on the concept of "risk-based" scientific advice and recognized that the advice provided by JECFA and JMPR was risk-based but that scientific advice was required in other areas such as nutrition, where the main objective was not to address risk, and the general reference to "scientific advice" was therefore retained.
3. The Commission adopted Resolution 99/1 as follows:

#### **The Codex Alimentarius Commission:**

Recognizing the importance of Codex work in providing recommendations to Member countries at the international level on food safety and quality and the need to ensure the scientific basis of Codex standards and related texts;

Recognizing the importance of Codex standards and related texts for food safety and quality in the protection of consumers' health and for ensuring fair practices in the food trade;

Having regard to the status of Codex standards and related texts as a reference in international trade in the framework of the WTO SPS and TBT Agreements;

<sup>1</sup> ALINORM 99/37, paras. 13-19.

<sup>2</sup> ALINORM 99/4, para. 5.

Recognizing the essential support provided to the Joint FAO/WHO Food Standard Programme by the ongoing Joint FAO/WHO Expert bodies (JECFA and JMPR) and the expert or technical consultations convened on an *ad hoc* basis to address specific food safety and quality issues and in particular the importance of the advice of these Expert bodies for the protection of consumers' health and public health in general;

Recognizing the importance of the transparency, independence and scientific integrity of the opinions of these bodies;

- Expresses its concern at possible real reductions in the budget allocated to the operation of the FAO/WHO expert bodies and consultations;
- Draws the attention of its parent organizations, FAO and WHO to the need for continued financial support for the FAO/WHO expert bodies in order to provide regularly updated scientific advice to the Codex Alimentarius Commission and its subsidiary bodies;
- Welcomes the continuing efforts by the Directors-General of FAO and WHO to maintain and strengthen the transparency, independence and scientific excellence of this advice.

#### **PRINCIPLES OF RISK ANALYSIS<sup>3</sup>**

4. The Representative of WHO introduced the document (ALINORM 99/9), which presented a progress report on the work undertaken so far to implement the Action Plan approved by the 22<sup>nd</sup> Session of the Commission (ALINORM 97/37, para. 164). The Commission expressed its appreciation to FAO and WHO for the organization of expert consultations and noted that most of the recommendations included in the document had been developed by these expert consultations. The Commission considered the recommendations in the working paper as amended by the 46<sup>th</sup> Session of the Executive Committee (ALINORM 99/4, paras. 9-16).

5. The Commission adopted the following recommendations to be applied in the framework of Codex:
- (a) Programmes that contribute to risk analysis should have high priority;
  - (b) 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;
  - (c) 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;
  - (d) 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;
  - (e) 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;
  - (f) 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;
  - (g) 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;
  - (h) Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;
  - (i) 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;

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<sup>3</sup> ALINORM 99/37, paras. 47-58.

- (j) 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.

6. The Commission also endorsed the following recommendations addressed to governments:

- (a) Member governments should participate actively in Codex work. Governments should also consider, to the extent possible, the views of all interested parties when formulating the national position on a Codex matter. Further, governments are encouraged to communicate and explain the basis of the decisions of Codex to those same interested parties and to the public at large;
- (b) Governments should adopt organizational structures and procedures that assure transparency and that allow National Codex Committees to consider consumer and private sector opinions. Cooperation should be developed with the consumer and private sectors in risk communication - especially in developing simple messages concerning food quality and safety;
- (c) Governments are encouraged to incorporate principles of risk analysis when establishing or updating national legislation on food safety matters.

7. The Commission endorsed the following recommendations addressed to FAO and WHO:

- (a) FAO and WHO should develop harmonized training or other programmes designed to increase the understanding of the risk analysis process and the role of risk communication, both for member countries and for international organizations active in Codex work;
- (b) FAO and WHO should continue to assist, on a priority basis, developing countries by providing training at regional, sub-regional or national levels in introducing and applying different aspects of risk analysis, HACCP and good manufacturing, agricultural and hygienic practices and development of ways to apply risk-based good practices in small businesses;
- (c) FAO and WHO should take greater steps to strengthen their work in assisting developing countries to undertake dietary/nutrition studies, monitoring programmes and intake/exposure assessment;
- (d) FAO and WHO should strengthen transparency in scientific risk assessment. This includes transparency in the choice of experts and the advice being given including how uncertainties are addressed;
- (e) FAO and WHO, as parent organizations, should emphasize the need for increased interaction and communication between expert bodies, such as JECFA and JMPR, and the Codex Committees, such as CCFAC, CCRVDF and CCPR, and should request the expert advisory bodies and the subsidiary committees to cooperate along the principles of risk analysis;
- (f) The Commission reiterated its request to FAO and WHO to convene an international expert advisory body similar to JECFA and JMPR on the microbiological aspects of food safety to address particularly microbiological risk assessment.

**NOTE:** The above recommendations, as well as discussions held at the 14<sup>th</sup> Session of the Codex Committee on General Principles (ALINORM 99/33A, paras. 10-37) concerning the development of Working Principles for Risk Analysis, should be taken into account by the CCFAC when considering the Discussion Paper on the Application of Risk Analysis Principles for Food Additives and Contaminants (CL 1999/22-FAC, Agenda Item 5).

**DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO  
FOOD SAFETY (RISK COMMUNICATION – RISK MANAGEMENT)**

8. The 23<sup>rd</sup> Session of the Commission adopted revised definitions for Risk Communication and Risk Management (ALINORM 99/37, para. 70 and Appendix IV), as follows:

- **Risk Communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
- **Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES AND CRITERIA FOR THE ESTABLISHMENT  
OF SUBSIDIARY BODIES OF THE COMMISSION<sup>4</sup>**

9. The 23<sup>rd</sup> Session of the Commission adopted amendments to the Codex Alimentarius Procedural Manual separating the criteria for work priorities from the criteria for establishing subsidiary bodies, which include provisions for the establishment of *ad hoc* Intergovernmental Task Forces operating for a limited period of time under closely defined terms of reference, but functioning in the same manner as established Codex Committees.

**NOTE:** The CCFAC should take the revised Criteria for Work Priorities into account when discussing its current and future programme of work.

**DRAFT STANDARDS AND RELATED TEXTS AT STEP 8 OR STEPS 5/8 OF THE NORMAL PROCEDURE, OR AT  
STEP 5 OF THE ACCELERATED PROCEDURE**

10. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission adopted several draft texts submitted for approval by the CCFAC and other Codex Committees, as indicated in Appendix VII – Part 1 of ALINORM 99/37. The following paragraphs provide additional information concerning the discussions that took place on certain items or contain additional decisions taken by the Commission in regard to the adoption of certain texts:

***Draft Revised Standard for Butter***

11. In relation to the maximum level for lead, the Commission noted (ALINORM 99/37, para. 86) that this level had been endorsed by the Codex Committee on Food Additives and Contaminants and that the Committee had been considering general maximum levels of lead in foods. It was agreed that when these general maximum levels were finally agreed by the CCFAC, it might be necessary for the Codex Committee on Milk and Milk Products to revisit the maximum lead level in butter.

***Draft Revised Standard for Cheese***

12. Some delegations expressed concerns about chlorophylls and titanium dioxide permitted for use in cheese when they were used as decolorants. The Commission noted (ALINORM 99/37, paras. 93-94) that these uses had been endorsed by the Committee on Food Additives and Contaminants. The Delegation of Switzerland pointed out that the use of pimaricin in sliced, cut, shredded or grated cheese was still a matter pending and required further discussion by the Committee on Milk and Milk Products.

13. The Commission adopted the Draft Revised Standard with, among other things, the deletion of four food additives not endorsed by the Codex Committee on Food Additives and Contaminants.

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<sup>4</sup> ALINORM 99/37, para. 67 and Appendix IV.

***Draft Maximum Level and Sampling Plans for Total Aflatoxins in Peanuts Intended for Further Processing***

14. The Commission adopted (ALINORM 99/37, paras. 100-102) the maximum level of 15 µg/kg for total aflatoxins in peanuts intended for further processing. The Commission also adopted the draft sampling plan on an interim basis, with the understanding that the issue would be further considered by the Committee and the Codex Committee on Methods of Analysis and Sampling on the basis of proposals to be developed by an electronic working group prior to their next Sessions.

**NOTE:** The 20<sup>th</sup> Session of the Codex Committee on Methods of Analysis and Sampling recommended the following methods. These methods approved by the 22<sup>nd</sup> Session of the Commission (July 1997).

Commodity	Provision	Method	Principle	Type
Peanut (raw)	Aflatoxin, total 15 µg/kg	AOAC 991.31	Immunoaffinity columnne (Afatest)	II
Peanut (raw)	Aflatoxin, total 15 µg/kg	AOAC 993.17	TLC	III
Peanuts (intended for further processing)	Aflatoxin, total 15 µg/kg	AOAC 975.36	Romer mini column	III
Peanuts (intended for further processing)	Aflatoxin, total 15 µg/kg	AOAC 979.18	Holaday-Velasco mini column	III
Corn	Alatoxin, total	AOAC 979.18	Holaday-Velasco mini column	II
Milk	Aflatoxin M <sub>1</sub> 0.05 µg/kg	IDF standard 171:1995	Immunoafficity column & LC	II

***Draft Maximum Level for Aflatoxin M<sub>1</sub> in Milk***

15. As the Commission could not reach a consensus (ALINORM 99/37, paras. 103-105), it agreed to return the draft Maximum Level for Aflatoxin M<sub>1</sub> in Milk to Step 6 for additional comments and further consideration by the Codex Committee on Food Additives and Contaminants. This decision was taken with the understanding that information should be provided on the public health and the potential economic implications of a higher level or a lower level as proposed, and the levels of aflatoxin contamination found in milk.

**NOTE:** Comments submitted at Step 6 in response to CL 1999/13-GEN on the draft Maximum Level for Aflatoxin M<sub>1</sub> in Milk are scheduled to be considered under Agenda Item 16a, document CX/FAC 00/16.

***Draft Amendments to the Food Additive Provisions in the Codex Standard for Food Grade Salt***

16. The Commission agreed (ALINORM 99/37, para. 106) with the endorsements of the Codex Committee on Food Additives and Contaminants, including the removal of specific provisions for the use of Salts of Myristic, Palmitic or Stearic Acids (aluminium, magnesium) from the Standard. The Commission confirmed that the maximum level for tricalcium orthophosphate should be 20 g/kg.

***Codex General Standard for Food Additives: Draft Provisions for Additives Permitted for Use Under Specified Conditions in Certain Food Categories or Individual Food Items (Table One)***

17. The Commission agreed (ALINORM 99/37, paras. 107-110) to the adoption of the CCFAC recommendation to add a footnote to Section 1.1 (Permitted Food Additives) of the Preamble to the General Standard for Food Additives to clarify that the Standard was being developed gradually. In view of the Committee's previous agreement to collaborate with the Office International de la Vigne et du Vin (OIV)<sup>5</sup>, especially on the matter of harmonization of provisions for additives, the Commission removed those provisions for the use of alpha-amylase, dimethyl dicarbonate, polydimethylsiloxane and polyvinylpyrrolidone in wines.

<sup>5</sup> ALINORM 99/12, para. 37.

18. The Commission noted that the Committee had previously agreed that numerical levels would be retained in preference to levels for additives based on good manufacturing practice for additives with numerical Acceptable Daily Intakes. In view of this decision, the Commission decided that the draft maximum use levels of “good manufacturing practice” for additives with a numerical Acceptable Daily Intake should include a note indicating that the elaboration of specific use levels was subject to future consideration.

19. The Commission confirmed that, prior to its publication, the General Standard should take into account the endorsed food additives provisions contained in Codex Commodity Standards.

20. The Commission adopted the draft provisions for the additives proposed with the deletions mentioned above, and agreed that these provisions should be updated on a regular basis.

***Codex General Standard for Food Additives: Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with Good Manufacturing Practice (Table 3) and Food Categories or Individual Food Items Excluded from the General Conditions of Table 3 (Annex to Table 3)***

21. The Commission agreed (ALINORM 99/37, paras. 111-112) to the suggestion of the Observer of the European Community, supported by other delegations, to include specific food categories for Concentrates (liquid and solid) for fruit juices (14.1.2.3), Canned or bottled (pasteurized) fruit nectar (14.1.3.1) and Concentrates (liquid and solid) for fruit nectar (14.1.3.3) to the Annex to Table 3.

***Draft Revised Standard for Sugars***

22. The Commission noted (ALINORM 99/37, paras. 167-171) that the draft Revised Standard had been elaborated through correspondence. Since the maximum levels for arsenic and lead had not been endorsed by the Codex Committee on Food Additives and Contaminants on the basis that this Committee had not finalized its work on developing general maximum levels for these elements, the Chair of the Committee on Sugars proposed to delete the values of maximum levels for arsenic and lead pending the completion of this work. This proposal was agreed to by the Commission. It was noted that maximum levels for arsenic and lead would be considered by the Committee on Food Additives and Contaminants as a matter of priority.

23. Other issues raised include: inclusion of new methods for arsenic, colour, sulphur dioxide and inverted sugars; reduction of the maximum levels of sulphur dioxide in white sugar, powdered sugar, dextrose anhydrous, dextrose monohydrate, powdered dextrose and fructose from 15 mg/kg to 10 mg/kg; lack of a method of analysis for determining polarization of powdered sugar to which starch had been added; and discrepancies in Table 1.

**PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP AT STEP 5**

24. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission adopted several proposed draft texts submitted for approval by the CCFAC and other Codex Committees, as indicated in Appendix VII – Part 2 of ALINORM 99/37. The following paragraphs provide additional information concerning the discussions that took place on certain items or contain additional decisions taken by the Commission in regard to the adoption of certain texts:

***Proposed Draft Maximum Levels for Tin***

25. The Commission noted (ALINORM 99/37, paras. 185-186) that there had been diverse opinions at the Committee on Food Additives and Contaminants and that JECFA had been requested to re-evaluate the acute toxicity of tin. Noting that Codex Standards should be based on available scientific evidence, the Commission decided to hold the Proposed Draft Maximum Level for Tin at Step 5 pending JECFA recommendations.

## CONSIDERATION OF ENDORSEMENTS TO ADOPTED STANDARDS

### *Codex Standard for Natural Mineral Waters: Limits for Health Related Substances*

26. The Commission recalled (ALINORM 99/37, paras. 197-200) that the levels for health-related substances in the Standard for Natural Mineral Waters had been sent for endorsement to the Committee on Food Additives and Contaminants after the adoption of the Standard and that the Committee had decided at its 31<sup>st</sup> Session that these levels should be aligned with the levels in the WHO *Guidelines for Drinking Water Quality*.

27. The Commission recognized that there was no consensus on the endorsement of levels for arsenic, barium, manganese and selenium and agreed that they should be returned for further consideration to the Committee on Natural Mineral Waters as a matter of priority, following which they would be submitted to the Committee on Food Additives and Contaminants for endorsement. Except those for arsenic, barium, manganese and selenium, the Commission adopted the limits for health related substances. The Commission noted that the published Standard for Natural Mineral Waters would specify that the levels for the above-mentioned elements had not been endorsed by the Committee on Food Additives and Contaminants.

## CONSIDERATION OF PROPOSALS TO ELABORATE NEW STANDARDS AND RELATED TEXTS

28. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission approved new work proposed by the CCFAC, as indicated in Appendix VIII of ALINORM 99/37.

### DIOXINS

29. The Delegation of Belgium (ALINORM 99/37, paras. 235-238) provided the 23<sup>rd</sup> Session of the Commission with information concerning the incident that had resulted in wide-spread concern among consumers and disruption in international trade, due to the contamination of poultry, cattle and pigs and derived products with dioxin and dioxin-like PCBs. It was noted that the contamination was due to a single incident and that measures had been taken to withdraw contaminated produce from the market and prohibit the marketing or export of foods from affected farms.

30. The Delegations of the Republic of Korea and The Philippines stated that the incident had drawn attention to the lack of adequate Codex guidance on an acceptable limit for the presence of dioxin in foods and called on the Codex Committee on Food Additives and Contaminants to give urgent and priority consideration to this work. The Chairperson of the Committee on Food Additives and Contaminants noted that work on dioxins had been re-commenced in 1999, and requested Members to provide the Committee with data that would allow the establishment of an appropriate guideline or maximum level.

**NOTE:** The Discussion Paper on Dioxins (CX/FAC 00/26) will be considered under Agenda Item 17(d).

## STATUS OF CODEX TEXTS WITHIN THE FRAMEWORK OF THE TBT AGREEMENT

31. The 14<sup>th</sup> Session of the Codex Committee on General Principles recalled (ALINORM 99/33A, paras. 58-61) that at its last meeting it had discussed the matter of so-called “advisory” Codex texts, especially the question of whether it was appropriate for the Commission to establish provisions intended for voluntary application by commercial partners and, as a consequence, whether the Annexes of certain standards containing such provisions should be withdrawn. Noting that such provisions could fall within the scope of the WTO TBT Agreement, the Committee requested the Secretariat to prepare, together with the Secretariat of the Committee on Technical Barriers to Trade, an analysis of the status of Codex standards with respect to that Agreement. The paper presented to the Committee had been prepared in consultation with the Secretariat of the TBT Committee and with the Legal Counsels of FAO and WHO. The Committee however could not arrive at a conclusion in relation to the proposals contained in the document (CX/GP 99/7) concerning the “voluntary Annexes”.

32. As regards the status of Codex texts under the TBT Agreement, the Committee agreed that all Codex texts, including standards and their annexes, were covered by the TBT definition of “standard”, and that distinctions based on Acceptance (under the Codex Procedures) were not relevant in the framework of WTO.

#### **CRITERIA FOR SETTING EXTRANEOUS MAXIMUM RESIDUE LIMITS FOR PESTICIDES**

33. The 31<sup>st</sup> Session of the Codex Committee on Pesticide Residues considered (ALINORM 99/24A, paras. 106-110 and Appendix VIII) criteria for setting extraneous maximum residue limits for pesticides, including the agreed CCPR positions, the new suggested positions on outliers and violation rates, the summary of government comments, and the comparison of the approaches used by this Committee and the CCFAC.

34. The Delegation of Australia introduced the comparison of the approaches used by the CCPR and CCFAC indicating that, while they were in parallel, there were a number of significant differences. It was also noted that the CCFAC approach was still under development within the framework of the General Standard for Contaminants and Toxins in Foods. For the sake of better harmonization and consistency throughout Codex, the Committee decided to send the “Agreed CCPR Positions on Setting EMRLs” (ALINORM 99/24A, Appendix VIII) to the CCFAC for their consideration.