codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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 2 **CX/NFSDU 00/2**
April 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-second Session
Berlin, 19 - 23 June 2000

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

1. MATTERS ARISING FROM THE 23RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION, ROME, ITALY, 28 JUNE -3 JULY 1999

1.1 AMENDMENTS TO THE PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION

1.1.1 Amendment to the Rules of Procedure

Rule X. 2 – Elaboration and adoption of Standards

The Commission adopted Rule X. 2 stressing the need for consensus when adopting standards and related texts (ALINORM 99/37, para. 62 and Appendix III)

The Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed.

1.1.2 Amendments to the Procedural Manual

Relations Between Commodity Committees and General Committees: Draft Amendment to the Food Hygiene Provisions

The Commission adopted the amendment concerning the food hygiene provisions to be used in the commodity standards as proposed by the CCFH (ALINORM 99/37, para. 68).

1.2 PRINCIPLES OF RISK ANALYSIS

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;
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.

1.3 Consideration of the draft medium-term plan for1998/2002

MEDIUM-TERM PLAN 1998 - 2002

Programme area	Medium-Term Objectives
Nutrition and consumer information	Review of the basis for nutrition requirements and relevant food labelling requirements in light of scientific evidence, risk analysis and legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade and consumer information. Guidelines on claims and certification procedures for alternative production processes. Integration of food labelling and nutrition requirements.
Commodity standards	Finalization of revision/simplification of Codex Commodity standards were justified

1.4 Decisions of the Commission concerning the work of the Nutrition Committee

Guidelines for the Use of Nutrient Claims: Draft Table of Conditions for Nutrient Contents (part B)[1]

- The Commission agreed to return Part B of the Draft Table of Conditions for Nutrient Contents of the Guidelines for the Use of Nutrient Claims to Step 6 for further comments and consideration by the Committee.
- This issue will be considered under Agenda Item 3.

[1] ALINORM 99/26, Appendix II; ALINORM 99/21 Part 1-Add.3 (Comments of Japan, Republic of Korea, Spain).

Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children[2]

The Commission decided to return the Proposed Draft Revised Standard to Step 3 for further discussion in the Committee.

The following Delegations expressed their opposition to returning the text to Step 3: Australia, Austria, Belgium, Finland, France, Germany, Italy, Spain, Switzerland, United Kingdom and United States.

- This issue will be considered under the Agenda Item 7.

2. MATTERS REFERED BY OTHER CODEX COMMITTEES

2.1 CODEX COMMITTEE ON FOOD LABELLING

Proposed Draft Amendment To The Guidelines On Nutrition Labelling (ALINORM 99/22A)

53. The Committee recalled that at the last session there were divergent opinions on the need for mandatory labelling of sugars, fibre, saturated fat and sodium when nutrition labelling was applicable. The Committee also noted that the Committee on Nutrition and Foods for Special Dietary Uses, at its 21st Session in September 1998, had discussed the public health needs for the mandatory labelling of those nutrients and that it had not reached any final conclusion so far.

54. The Delegation of Malaysia proposed to defer the discussion on this Agenda Item until such time as the advice from the CCNFSDU on the public health need for nutrition labelling became available.

55. Several delegations and observers expressed the view that the public health needs of consumers supported mandatory labelling of those four nutrients when nutrition labelling was applied. Several other delegations and observers indicated that the necessity of such labelling should be determined by national authorities, taking into account each country's status of public health. Those delegations also stressed the importance of consumer education on food and health. The Observer from IACFO supported easy-to-read mandatory nutrition labelling using this approach, regardless of whether a claim was made. The Delegation of Japan indicated that further discussion was necessary on the definition of the additional four nutrients.

56. The Delegation of Germany, speaking on behalf of the member states of the European Union, introduced the current legislation in the European Community on nutrition labelling (Directive 90/496/EEC) whereby only when nutrition claims related to sugar, saturated fat, fibre, or sodium were made, information on those four nutrients had to be provided. The Observer from the EC indicated that this approach balanced the consumer's need for information and the burden of labelling for the industry and provided more flexibility, and proposed to adopt this approach in the proposed draft amendment. Many delegations expressed their support for this proposal as it represented a good compromise and a significant progress to improve nutrition labelling.

57. The Committee agreed to change Section 3.2.1.2 to read as follows: "The amount of protein, available carbohydrate (i.e., carbohydrate excluding dietary fibre), fat: and where a nutrition claim is made for one or more of these nutrients, the amount of sugars, fibre, saturated fatty acids, and sodium

58. As regards the concept of "significant amount" of the vitamins and minerals (Section 3.2.5) and its footnote, the Delegation of Australia, other delegations and the Observer from the European Community proposed to change the figure of 5% to 10 or 15%. Several other delegations opposed this proposal, indicating that the revision would preclude the declaration of most sources of vitamins and minerals and needed further consideration. The Committee agreed to retain the current figure.

59. The Committee agreed to forward the Proposed Draft Amendment to the Commission for adoption at Step 5 (see Appendix VI of the ALINORM 99/22A).

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[2] ALINORM 99/26, Appendix IV

Proposed Draft Recommendations For The Use Of Health Claims (ALINORM 99/22A)

60. The Committee recalled that the 26th Session had discussed the Proposed Draft Recommendations and asked the advice of the CCNFSDU on the scientific basis of health claims. The 21st Session of the CCNFSDU had a general discussion on this question and agreed that a specific working document should be prepared for further consideration at its 22nd Session (June 2000).

61. The Delegation of Malaysia expressed the view that consideration of this issue should be deferred until the CCNFSDU had reached a conclusion. Several delegations pointed out that the responsibility of the CCNFSDU was to establish the scientific basis of health claims but that CCFL should continue its work in order to define such claims and determine under which conditions they could be used.

62. The Delegation of Norway and the Observer from Consumers International reiterated their position that health claims should not be permitted as they were misleading for consumers, and that only a balanced diet would provide health benefits. The Observer from IACFO stated that it was premature to set a Codex standard for health claims and expressed concern about significant loopholes, declining standards for scientific substantiation, premarket approval in the only two regulatory models for health claims.

63. Some delegations expressed the view that the Committee should not develop guidelines concerning health claims as this should be left to the national authorities in view of their specific public health concerns.

64. The Observer from the EC informed the Committee that currently therapeutic claims were not allowed according to EC legislation but that a general debate on all relevant aspects of this issue was underway in the EU. The Delegation of France indicated that it had considered this question in detail at the national level and had prepared a document which might be of use to the Committee in future discussions on health claims.

65. The Committee agreed to establish an informal Working Group[3] to consider the comments received and incorporate them in the current text. Following its meeting during the session, the Chair of the Working Group, Dr. F.E. Scarborough (United States) informed the Committee that the current Draft Recommendations had been revised in the light of the comments received but that due to time constraints the document still required detailed consideration. The Delegation of Canada proposed that in order to facilitate the revision of the text a Working Group should be established prior to the next session to consider the comments received in detail and achieve consensus on the definitions and conditions for use of health claims

66. The Committee agreed to return the Proposed Draft Recommendations, as amended during the present session to Step 3 for further comments (see Appendix VII of the ALINORM 99/22A) and consideration by the next session. It was also agreed that a Working Group, coordinated by the United States and Canada, in cooperation with France and the United Kingdom, would meet immediately prior to the session to facilitate consideration of this matter, the exact arrangements to be determined by the host country.

There also will be an oral information regarding the further consideration of this matter by the 28th Session of the CCFL.

2.2 CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (ALINORM 99/23)

Proprietary Methods

7. The Committee noted the request from the 21st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to this Committee to consider the use of proprietary methods. The CCNFSDU noted that in some cases a proprietary method was the most specific way to detect an analyte, such as in the case of gluten detection. The Committee recalled that at its last Session it had endorsed one proprietary method, "Phadebas method", for the determination of diastase activity in honey with a note that other commercially available calibrated substrate preparations can also be used.

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[3] Canada, United States, France, United Kingdom, New Zealand, Denmark, Japan, Sweden, Brazil, Chile, Germany, Italy, EC, CI, IACFO, IADSA, ILSI, ICGMA, IDF, CIAA

8. The Delegation of Sweden, supported by that of Finland, requested the Committee to consider the endorsement of an enzyme immunoassay method for gluten determination in food, as they felt that an appropriate method for gluten determination was urgently needed. However, the Committee was of the opinion that the CCNFSDU should first agree to include the above-mentioned method in the Standard for Gluten-Free Foods and to forward the method to this Committee for endorsement. The Committee **agreed** that it would have no objection to the use of proprietary methods, provided that similar methods or materials supplying similar results were available.

Checklists

60. During the consideration of sampling provisions, it was pointed out that information on the selection of sampling plan required in the *Procedural Manual*[4] had not been submitted to this Committee. It was pointed out that in the case of methods of analysis, no information was generally submitted by the commodity committies despite the *Recommendations for a Checklist of Information Required to Evaluate Methods of Analysis and Sampling for Endorsement*[5] required it. The Committee **agreed** to ask Codex commodity committees to provide information as required by the Checklists contained in the Codex Alimentarius, Volume 13, and the *Codex Alimentarius Commission Procedural Manual*, when they send methods of analysis and sampling to this Committee for endorsement.

Use of SI Unit System

62. The Committee recommended that commodity committies should select methods from the existing Codex general methods whenever possible. It also recommended that commodity committees should select methods from the existing Codex general methods wherever possible and use the SI unit system in the specifications of Codex standards.

Approaches for Sampling (paras 9-18)

The Committee on Methods of Analysis and Sampling has been elaborating the *General Guidelines on Sampling* to be applicable to all commodities. The Committee in relation to the *Draft Revised Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs* then being developed by the Codex Committee on Pesticide Residues recognized that these Methods of Sampling and the Guidelines of Sampling being develped by this Committee were based on two different approaches; the former on the practical approach for economic reasons, and the latter on the statistical approach, therefore it was **felt** inappropriate to combine these two documents. Since the Proposed Draft General Guidelines were based on statistical approach, the Committee **agreed** that information should be sought from commodity committees on the acceptance of the statistical approach to sampling when defining compliance with the specifications in Codex standards.

2.3 CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 99/24A)

Establishment of Specific MRLs for Cereal-Based Foods for Infants and Young Children

10. The 20th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) requested the CCPR to consider the feasibility of establishing specific MRLs for cereal-based foods and infant formula. The Committee noted clarification had been provided by the 21st Session of the CCNFSDU in response to the request of the CCPR made at its 29th Session.

11. The Committee noted that the European Community (EC) was of the opinion that the toxicological databases supporting ADIs might not be fully adequate in all cases to ensure that the special needs of infants and young children were covered, in particular, in such areas as endocrine disruption and reproductive tests, developmental neurotoxicity and immunotoxicity. It also noted that as a temporary precautionary measure and pending review of the databases supporting existing ADIs, MRLs at the level of 0.01 mg/kg would be adopted within the EC for all pesticides in baby food.

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4 *Codex Alimentarius Procedural Manual*, Tenth Edition, page 65.

5 *Codex Alimentarius*, Volume 13, pages 129-134.

12. The Observer from Consumers International (CI) expressed its view that Codex MRLs needed to be developed in a way that explicitly considers the greater exposure and greater susceptibility of children; that an additional 10-fold uncertainty factor should be applied to establish ADIs, unless there are reliable data supporting the use of another safety factor; and that the current MRL setting process used by JMPR/CCPR did not explicitly consider this. The Observer of CI welcomed the actions taken by the USA and EC in this area (see paras 11 & 37).

13. The Committee **requested** the Codex Secretariat, in collaboration with Germany, the United States of America, CI and the Commission of the EC to prepare a paper in response to the request of the CCNFSDU, in particular, possible unique toxicological concerns to children, for consideration at the next Session of the Committee. The Committee also **requested** the JMPR to consider at its next meeting the physiological and developmental characteristics of infants and young children.

14. The Observer from the Global Crop Protection Federation (GCPF) stated that a body of scientific evidence existed which did not support the premise of generally higher susceptibility of children to chemicals and drugs. The Observer encouraged the WHO Panel of the JMPR to review this issue and establish a position regarding an increased susceptibility of infants and young children and the validity of the ADIs established by WHO for these age groups. The Committee **requested** the JMPR to provide advice on this matter.

There also will be an oral information regarding the further consideration of this matter by the 32nd Session of the CCPR.

3. GENERAL MATTERS FROM FAO AND WHO

3.1 INTERNATIONAL FOOD TRADE BEYOND 2000. SCIENCE-BASED DECISIONS, HARMONIZATION, EQUIVALENCE AND MUTUAL RECOGNITION, MELBOURNE, AUSTRALIA 11-15 OCTOBER 1999

The Uruguay Round Agreements have been in effect for five years. In the light of the new round of multilateral trade negotiations FAO in cooperation with the World Health Organization and the World Trade Organization, hosted by the Commonwealth of Australia and the State of Victoria an intergovernmental conference on the implementation of Codex work with the aim to achieve the full involvement of Member Governments in existing and proposed activities related to the Codex Alimentarius and WTO was holded.

The Conference addressed how food quality and safety issues affect trade, health and development at both domestic and international levels while pointing the way from 2000 onwards, it took into account recommendations of the 1991 conference, current needs in the field of food trade and the Uruguay Round Agreements.

The Conference reviewed the response to the earlier FAO/WHO conference and the action taken by these two organizations, with WTO, to assist Member Governments in meeting their SPS and TBT obligations and this entailed a full analysis of current Codex, SPS and TBT procedures and of the prospects for further change. Such a review generated coherent recommendations on scientifically based approaches to promoting better-quality and safer foods in domestic and international trade.

The Report of this Conference is available on the Internet at the following URL:

http://www.fao.org/docrep/meeting/X4015e.htm

3.2 JOINT FAO/WHO EXPERT CONSULTATION ON HUMAN VITAMIN AND MINERAL REQUIREMENTS, BANGKOK, THAILAND, 21 TO 30 SEPTEMBER 1998.

The Provisional Report of the above consultation is attached. The updated version wil be available on the Internet at the following URL:

http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/NUTRI.HTM

3.3 Technical Consultation on Infant and Young Child Feeding

During the week of 13–17 March 2000, WHO convened in collaboration with UNICEF, a technical consultation on infant and young child feeding as one step in identifying future priorities and accelerating progress in this crucial area. Objectives were to:

- assess the strengths and weaknesses of current feeding policies and practices,
- identify barriers to policy implementation,
- review key interventions as a first step to identifying feasible and effective ways forward,
- contribute to the development of a comprehensive draft strategy that, when adopted, will guide Member States and the international community in the years to come.

As building blocks for a comprehensive global strategy and plan of action for infant and young child feeding, the consultation explored the implications of nine programmatic themes:

- Measuring trends and progress in infant-feeding practices
- Increasing rates of exclusive breastfeeding
- Improving complementary feeding
- Strengthening and expanding the Baby-friendly Hospital Initiative
- Integrating support throughout the health care system for appropriate feeding practices
- Identifying effective models for community support of breastfeeding women
- Promoting policies and practices to support breastfeeding in the workplace
- Strengthening implementation of the International Code of Marketing of Breast-milk Substitutes
- Understanding the impact of globalization on infant feeding

The consultation examined a number of cross-cutting issues in view of their significance for virtually all of the discussion themes; these included an overall human-rights perspective,[6] the nutritional status of women, protein-energy malnutrition, micronutrient malnutrition, growth and development, maternal and child morbidity and mortality, HIV and infant feeding, and feeding during emergencies.

As a result of this preparatory and consultative process, a draft strategy and plan of action are now being prepared for critical review by Member States and other interested parties; they will identify priorities, action areas and operational targets – for governments, international organizations and civil society – to improve the feeding of infants and young children. The strategy currently has three main objectives:

- to improve infant and child survival, health, nutritional status, and growth and development through optimal feeding. Ensuring the survival, health and nutritional status of women in their own right, and in the context of their role as mothers, are fundamental to attaining this objective;
- to guide government policy and action – and related support provided by the international community – for protecting, promoting and supporting optimal feeding practices for infants and young children;
- to enable mothers, families and caregivers in all circumstances to make – and carry out effectively – informed choices about optimal feeding practices for infants and young children.

Building on past achievements, the draft strategy will reaffirm commitment to existing action platforms, including attainment of the operational targets of the Innocenti Declaration,[7] implementation of the Baby-friendly Hospital Initiative and achievement of the aim of the International Code of Marketing of Breast-milk Substitutes. The draft strategy will also call for particular emphasis to be placed on three priority areas:

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[6] Especially as defined in the Convention on the Rights of the Child (the child's right to nutritious food and adequate feeding) and in the Convention on the Elimination of all Forms of Discrimination against Women (on the social significance of maternity).

[7] The Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding (1990) has four operational targets for all countries: an authoritative national breastfeeding coordinator and multisectoral committee; all maternity facilities "baby-friendly"; action to give effect to the principles and aim of the International Code; and legislation to protect breastfeeding rights of working women.

- **Exclusive breastfeeding**. Existing initiatives need to be strengthened, and new approaches developed, to protect, promote and support exclusive breastfeeding.[8]
- **Complementary feeding**. Timely, safe and adequate complementary feeding, with continued breastfeeding, needs to be accorded priority status on the global nutrition agenda.
- **Feeding in difficult circumstances.** New approaches are required for meeting the nutritional needs of infants and young children during emergencies (e.g. natural disasters, famine, civil unrest, and refugee settings); in the presence of HIV/AIDS; and when they are already severely malnourished.

WHO is proceeding with the development of a draft global strategy and plan of action for infant and young child feeding in the light of inputs provided during the technical consultation. A number of regional consultations will be organized where Member States will contribute further by assessing the suitability and anticipated effectiveness of the draft strategy and plan of action. The next step will be to circulate a further refined draft strategy and plan of action – for information and feedback – to Member States and other interested parties. Finally, the Director-General will submit the results of this process to the Executive Board at its 109th session (January 2002) and to the Fifty-fifth World Health Assembly (May 2002) for discussion, endorsement and decision.

[8] The WHO Multicentre Growth Reference Study is expected to contribute to improved understanding of the age range during which breast milk alone is sufficient to meet the healthy infant's nutritional requirements for growth and development. In addition, WHO is conducting a systematic review of the relevant scientific literature, for the period after the report (1995) of the WHO Expert Committee on physical status, in the context of the development of a new global strategy and plan of action for infant and young child feeding (see page 32 of document CX/NFSDU 00/7 in this connection).