codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/NFSDU 01/2**
August 2001

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-third Session
Berlin, 26 - 30 November 2001

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

1. MATTERS ARISING FROM THE 48TH SESSION OF THE EXECUTIVE COMMITTEE

Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children ALINORM 01/4 (paras 38-39)

The Executive Committee noted that the 23rd Session of the CAC had returned the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children to Step 3 for further comments and consideration by the Committee on Nutrition and Foods for Special Dietary Uses. This Committee had recognized that it was not possible to reach consensus on the fundamental issue of the Scope (namely the age or age range of introduction of these foods to the diet) at this stage and that it would not be possible to make further progress on the revision.[7] However, the Executive Committee also noted that the Fifty-fourth World Health Assembly (WHA54.2, Annex I) adopted a comprehensive resolution on infant and young child nutrition[8]. The technical background for that resolution is attached as Annex II.

The Executive Committee recommended that the World Health Assemble Resolution should be taken into account by the Committee on Nutrition and Foods for Special Dietary Uses and that the Committee should proceed to a conclusion of the revised standard as quickly as possible in order to satisfy the need for an adequate standard ensuring the quality and safety of these products in international trade.

The Committee is invited to take into account the resolution on infant feeding adopted by the Fifty-fourth World Health Assembly while revising the Proposed Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children under Agenda Item 6. (see also Section 4.2 of this document).

2. MATTERS ARISING FROM THE 24TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION (ALINORM 01/41)

The following items considered by the 24th Session of the Commission are pertinent to the work of the Committee.

2.1 FAO CONFERENCE ON INTERNATIONAL TRADE BEYOND THE YEAR 2000: SCIENCE-BASED DECISIONS, HARMONIZATION, EQUIVALENCE AND MUTUAL RECOGNITION (PARAS 42-44)

It was noted that the Melbourne Conference had directed to the Codex Alimentarius Commission certain recommendations. Other recommendations had been directed to FAO and WHO or else to Member governments.[1] The Commission specifically **endorsed** the following recommendations of the Melbourne Conference and requested the Executive Committee to monitor their applications and their incorporation in the Medium-Term Plan as appropriate:

Recommendation 12: exchange of information about potentially hazardous foodstuffs moving in international trade;

Recommendation 13: urgency of Codex guidance on the judgement of equivalence;

Recommendation 14: consideration of the special needs of developing countries;

Recommendation 16: standards development for food composition, sensory quality and safety;

Recommendation 17: standards not to be over-prescriptive or unnecessarily stringent;

Recommendation 18: promote and extend the General Principles of Food Hygiene and HACCP to the whole food chain;

Recommendation 21: effectiveness of the use of written comments.

The Committee is invited to use the above recommendations where appropriate.

2.2 CONSIDERATION OF THE DRAFT STRATEGIC FRAMEWORK, PROPOSED DRAFT MEDIUM PLAN 2003-2007 AND THE CHAIRPERSON'S ACTION PLAN[2] (PARAS 46-70)

The Commission **adopted** the draft Strategic Framework, including the Strategic Vision Statement (for details see Appendix II of ALINORM 01/41), the web:

http://www.codexalimentarius.net/cac24/alinorm0141/appiie.htm#E9E18

- The Commission **agreed** that the draft Medium-Term Plan should be revised by the Secretariat in the light of the Strategic Framework, the Commission's discussion and the written comments received, and should incorporate the elements of the Chairperson's Action Plan agreed to by the Commission.

The Commission agreed that the activities envisaged in the Medium Term Plan should include cost estimates to determine whether the objectives could be achieved within available resources and that the revised draft Medium-Term-Plan be circulated for the inputs of the Codex Coordinating Committees, other Codex Committees, Member governments and international organizations for further consideration and finalization at the 25th Session of the Commission (see CL 2001/26-EXE).

The Committee is therefore invited **to provide its input** to the draft Medium-Term-Plan.

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1 Recommendations 1,2,3,5,7,9,10,13,15,19,20 of the Melbourne Conference.

2 ALINORM 01/6, ALINORM 01/6-Add. 1 and 3, Commission/CAC/LIM 1 and ALINORM 01/4

2.3 RISK ANALYSIS POLICIES OF THE CODEX ALIMENTARIUS COMMISSION[3] (PARAS 71-85)

The Commission **adopted** the position, in regard to the consideration of precaution, that:

> *"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence" (para. 83)*

2.4 STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE IN THE CODEX DECISION–MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT: CRITERIA (PARAS 93-98)

The Commission amended and adopted Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principle on the Role of Science related to "other legitimate factors" in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account.

For details see:

http://www.codexalimentarius.net/cac24/alinorm0141/appiiie.htm#E10E31

2.5 TEXTS ELABORATED BY THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (PARA 165)

Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Content (Part B)[4]

The Commission **adopted** the Draft Table at Step 8 as presented.

3. MATTERS REFERED BY OTHER CODEX COMMITTEES

3.1 CODEX COMMITTEE ON FOOD LABELLING

Proposed Draft Amendment to the Guidelines on Nutrition Labelling (ALINORM 01/22A, Appendix VII)

The Committee on Food Labelling is considering the Proposed Draft Amendment to the Guidelines on Nutrition Labelling. For full details of the consideration see paras 87-95 of the above ALINORM. Web:

ftp://ftp.fao.org/codex/alinorm01/al0122ae.pdf

After an extensive exchange of views, the Committee **agreed** to retain section 3.2.2 dealing with the conditions of labelling of sugars, fibre, saturated fat and sodium, the last sentence of section 3.2.3 regarding dietary fibre and the last sentence of section 3.2.4 regarding fatty acids and cholesterol in square brackets. The declaration of trans fatty acids was included in sections 3.2.2 and 3.2.4, and the reference to cholesterol was retained without square brackets in section 3.2.4 (declaration of fatty acids).

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[3] ALINORM 01/9, CAC/LIM 1 (comments of Consumers International), CAC/LIM 11 (comments of Argentina)

[4] ALINORM 01/26, Appendix II; ALINORM 01/21, Part 1&Add.2 (Comments of New Zealand).

The Committee **agreed** to return the Proposed Draft Amendment, as amended at the current session, to Step 3 for further comments and consideration at the next session (see Appendix VII of ALINORM 01/22A). Web:

ftp://ftp.fao.org/codex/alinorm01/al0122ae.pdf

Proposed Draft Recommendations for the Use of Health Claims (ALINORM 01/22A, Appendix VIII)

The Committee on Food Labelling is developing the Proposed Draft Guidelines for the Use of Nutrition and Health Claims (Proposed Draft Recommendations for the Use of Health Claims). For full details of the consideration see paras 96-109 of the above ALINORM. Web:

ftp://ftp.fao.org/codex/alinorm01/al0122ae.pdf

While considering the above Guidelines the Committee **agreed** with the proposal of the Delegation of Sweden to include a table of examples of health claims at the end of the Guidelines and agreed to add to this table the examples of claims which were already included in other sections of the Guidelines (see Appendix VIII).

The Committee **agreed** to include under Section 1 Scope a provision that health claims are not permitted for foods for infants and young children, unless specifically provided for in relevant Codex standards established by relevant Committees such as the Codex Committee on Nutrition and Foods for Special Dietary Uses.

The Committee **agreed** that, for "Reduction of Disease Risk Claims", in addition to information on an accepted diet-health relationship, information on the composition of the product relevant to the relationship would be required "unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents in the food". The text was amended accordingly.

The Committee **agreed** that the Proposed Draft Guidelines needed further development and to return them to Step 3 for further comments and consideration at the next session. It was agreed that a Working Group open to all member countries and international organizations chaired by Canada would meet between the sessions and immediately prior to the next session in order to facilitate the revision of the text.

3.2 CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 01/24A)

Apropriateness of the Current ADI AND MRL Setting in Relation to Infants and Children (Agenda Item 6 (b))[5]

67. The Delegation of the Netherlands introduced the document based on contributions received in response to the CL 2000/27-PR from the US, New Zealand, the European Community and Consumers International which focused on national policies related to the protection of infants and children. The Delegation indicated that the document provided a set of recommendations to acknowledge a possibility of additional vulnerability of infants and children; the necessity of clear confirmation of the applicability of ADIs and MRLs for all population groups including infants and children while clearly stating uncertainties; to make a primary screening of the lists of pesticides and pesticide/commodity combinations contained in contributions received, to clarify if they could be of concern to infants and children; to encourage the Committee to take an appropriate risk management decision in those cases where health concerns could not be addressed; and consider the need for an expert consultation to

[5] CX/PR 01/8, CRD 11 (comments of US and Consumers International), Section 2.7 of the 1999 JMPR Report, CRD 4 (comments of the European Community), CRD 5 (comments of Consumers International),.

address the possible toxicological concerns of extra vulnerability and intake assessment of infants and children.

The Observer of Consumers International pointed out that there were four main matters to be addressed and proposed the following solutions as stated in CRD 5:

- In order to identify how pesticides that are really of concern, CI suggested three criteria: toxicity of pesticides to key developmental processes (if known), the presence of residues in foods that children eat in significant amounts and the frequency of exposure at toxicologically significant levels;
- CCPR was encouraged to take an appropriate risk management decision for cases where serious concerns for the health of infants and children might exist (as was the case for organophosphate insecticides as listed in CRD 5);
- An expert consultation should be convened to consider issues of toxicology and intake assessment in relation to infants and children, as there was no longer an international consensus that the current procedures were adequate, and
- The criteria used by JMPR to determine the adequacy of the database to assess risks to infants and children should be more transparent.

69. The Delegation of the United States clarified that Table 1 of CRD 11 was a list of pesticides that had been or were being evaluated and did not necessarily mean that they represented a greater risk for infants and children.

70. The Committee had an extensive debate on the recommendations contained in the document CX/PR 01/8. Many delegations agreed that the possible extra vulnerability of infants and children needed to be taken into account when performing risk assessment. However, it was pointed out that the situation should not be exaggerated.

71. The Observer of GCPF indicated that it did not believe that infants and children were generally more susceptible to chemicals, although this could occur occasionally at pharmaco-toxicologically active levels, this should not be the case with usual exposure from pesticide residues. The Observer did not support the concept of using default limits for residues or the use of additional uncertainty factors to ensure a reasonable protection of infants and children, and proposed that until new data become available JMPR continue working according to their current procedures in establishing ADIs and estimating MRLs.

72. Many delegations were of the view that the current process adequately addressed the sensitivity of infants and children and that ADIs and MRLs covered all population groups including infants and children and therefore there was no need to develop a new methodology.

73. The WHO Joint Secretary of JMPR indicated that the 1999 JMPR addressed the issue of susceptibility of infants and children and that the Meeting emphasized that possible differences between adult and developing mammals was currently addressed in the commonly performed studies of reproductive and developmental toxicity in various species. Therefore the Meeting concluded that it had no basis for changing its approach to addressing the susceptibility of developing mammals as compared with that of adult organisms in the toxicological evaluation of pesticides and that the routine use of safety factors in addition to those currently used was not justified on the basis of current information.

74. While it was acknowledged by some delegations that developmental neurotoxicity studies were valuable in assessing risks for infants and children, it was not clear whether the availability of those studies would lead to an adjustment of the ADI or MRLs. Some delegations indicated that

additional scientific data in this area were needed, especially on the methodology of cumulative and aggregate risk assessment.

75. Some delegations were of the view that constructing a list of compounds that might give rise to concerns for infants and children would be costly and require extensive evaluation before any conclusive decision could be taken. The Committee agreed not to develop such a list at this time due to the lack of enough support from governments.

76. The Representative of WHO drew the attention of the Committee to the fact that there was not enough actual consumption data for some foods commonly consumed by children (e.g. apple or banana). It was not clear how much they were consuming expressed on a body weight basis which presented problems in conducting chronic risk assessment, at the international level. The Representative indicated that WHO was planning to organize a Workshop on Total Diet Studies in Australia and that might assist countries, especially developing countries, to generate relevant data.

77. The Committee **concluded** that ADIs and MRLs should cover all population groups including infants and children. The Committee also **concluded** that the possible increased vulnerability of infants and children was an important issue which needed to be explicitly integrated into the work of the CCPR and JMPR and agreed by means of a Circular Letter to request Member governments to provide information to the JMPR Secretariat on the availability of studies on developmental neurotoxicity that have been submitted to them, along with contact details on the data owners. This information should be submitted by 1 November 2001, which should provide sufficient time for the Secretariat to obtain the data for consideration by the 2002 JMPR.

78. The Committee **agreed** that the development of cumulative risk assessment required further consideration, especially regarding the development of common understanding of methodology. Therefore, it requested the Delegation of the United States to prepare a paper on this matter for consideration by the next session of the committee. The Committee **decided** that it was premature to recommend convening an expert consultation on the various issues in relation to infants and children.

3.3 *AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON FRUIT AND VEGETABLE JUICES

Proposed Draft Codex General Standard for Fruit Juices and Nectars (ALINORM 01/39, para. 24)

While considering the Proposed Draft Codex General Standard for Fruit Juices and Nectars at Step 3, the Task Force aggreed to add a new subsection 3.1.2 (g) to allow for the addition of essential nutrients for fortification purposes in accordance with those texts established by the Codex Alimentarius Commission for this purpose. The Task Force was informed that this provision did not include dietary fibre as this subject was still under discussion by the Codex Committee on Nutrition and Foods for Special Dietary Uses. The Task Force agreed to leave the remainder of Section 3.1.2 unchanged pending further discussions.

Annex I

FIFTY-FOURTH WORLD HEALTH ASSEMBLY

RESOLUTION WHA54.2

INFANT AND YOUNG CHILD NUTRITION

The Fifty-fourth World Health Assembly, Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34, WHA46.7, WHA47.5 and WHA49.15 on infant and young child nutrition, appropriate feeding practices and related questions;

Deeply concerned to improve infant and young child nutrition and to alleviate all forms of malnutrition in the world, because more than one-third of under-five children are still malnourished – whether stunted, wasted, or deficient in iodine, vitamin A, iron or other micronutrients – and because malnutrition still contributes to nearly half of the 10.5 million deaths each year among preschool children worldwide;

Deeply alarmed that malnutrition of infants and young children remains one of the most severe global public health problems, at once a major cause and consequence of poverty, deprivation, food insecurity and social inequality, and that malnutrition is a cause not only of increased vulnerability to infection and other diseases, including growth retardation, but also of intellectual, mental, social and developmental handicap, and of increased risk of disease throughout childhood, adolescence and adult life;

Recognizing the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger, and that every effort should be made with a view to achieving progressively the full realization of this right;

Acknowledging the need for all sectors of society – including governments, civil society, health professional associations, nongovernmental organizations, commercial enterprises and international bodies – to contribute to improved nutrition for infants and young children by using every possible means at their disposal, especially by fostering optimal feeding practices, incorporating a comprehensive multisectoral, holistic and strategic approach;

Noting the guidance of the Convention on the Rights of the Child, in particular Article 24, which recognizes, *inter ali*a, the need for access to and availability of both support and information concerning the use of basic knowledge of child health and nutrition, and the advantages of breastfeeding for all segments of society, in particular parents and children;

Conscious that despite the fact that the International Code of Marketing of Breast-milk Substitutes and relevant, subsequent Health Assembly resolutions state that there should be no advertising or other forms of promotion of products within its scope, new modern communication methods, including electronic means, are currently increasingly being used to promote such products; and conscious of the need for the Codex Alimentarius Commission to take the International Code and subsequent relevant Health Assembly resolutions into consideration in dealing with health claims in the development of food standards and guidelines;

Mindful that 2001 marks the twentieth anniversary of the adoption of the International Code of Marketing of Breast-milk Substitutes, and that the adoption of the present resolution provides an opportunity to reinforce the International Code's fundamental role in protecting, promoting and supporting breastfeeding;

Recognizing that there is a sound scientific basis for policy decisions to reinforce activities of Member States and those of WHO; for proposing new and innovative approaches to monitoring growth and

improving nutrition; for promoting improved breastfeeding and complementary feeding practices, and sound culture-specific counselling; for improving the nutritional status of women of reproductive age, especially during and after pregnancy; for alleviating all forms of malnutrition; and for providing guidance on feeding practices for infants of mothers who are HIV-positive;

Noting the need for effective systems for assessing the magnitude and geographical distribution of all forms of malnutrition, together with their consequences and contributing factors, and of foodborne diseases; and for monitoring food security;

Welcoming the efforts made by WHO, in close collaboration with UNICEF and other international partners, to develop a comprehensive global strategy for infant and young child feeding, and to use the ACC Sub-Committee on Nutrition as an interagency forum for coordination and exchange of information in this connection,

1. THANKS the Director-General for the progress report on the development of a new global strategy for infant and young child feeding;

2. URGES Member States:

(1) to recognize the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger, and that every effort should be made with a view to achieving progressively the full realization of this right and to call on all sectors of society to cooperate in efforts to improve the nutrition of infants and young children;

(2) to take necessary measures as States Parties effectively to implement the Convention on the Rights of the Child, in order to ensure every child's right to the highest attainable standard of health and health care;

(3) to set up or strengthen interinstitutional and intersectoral discussion forums with all stakeholders in order to reach national consensus on strategies and policies including reinforcing, in collaboration with ILO, policies that support breastfeeding by working women, in order substantially to improve infant and young child feeding and to develop participatory mechanisms for establishing and implementing specific nutrition programmes and projects aimed at new initiatives and innovative approaches;

(4) to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding[6], and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices;

(5) to support the Baby-friendly Hospital Initiative and to create mechanisms, including regulations, legislation or other measures, designed, directly and indirectly, to support periodic reassessment of hospitals, and to ensure maintenance of standards and the Initiative's long-term sustainability and credibility;

(6) to improve complementary foods and feeding practices by ensuring sound and culture-specific nutrition counselling to mothers of young children, recommending the widest possible use of indigenous nutrient-rich foodstuffs; and to give priority to the development and dissemination of guidelines on nutrition of children under two years of age, to the training of health workers and community leaders on this subject, and to the integration of these messages into strategies for health and nutrition information, education and communication;

[6] As formulated in the conclusions and recommendations of the expert consultation (Geneva, 28 to 30 March 2001) that completed the systematic review of the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

(7) to strengthen monitoring of growth and improvement of nutrition, focusing on community-based strategies, and to strive to ensure that all malnourished children, whether in a community or hospital setting, are correctly diagnosed and treated;

(8) to develop, implement or strengthen sustainable measures including, where appropriate, legislative measures, aimed at reducing all forms of malnutrition in young children and women of reproductive age, especially iron, vitamin A and iodine deficiencies, through a combination of strategies that include supplementation, food fortification and diet diversification, through recommended feeding practices that are culture-specific and based on local foods, as well as through other community-based approaches;

(9) to strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media, to encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; and to inform the general public on progress in implementing the Code and subsequent relevant Health Assembly resolutions;

(10) to recognize and assess the available scientific evidence on the balance of risk of HIV transmission through breastfeeding compared with the risk of not breastfeeding, and the need for independent research in this connection; to strive to ensure adequate nutrition of infants of HIV-positive mothers; to increase accessibility to voluntary and confidential counselling and testing so as to facilitate the provision of information and informed decision-making; and to recognize that when replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-positive women is recommended; otherwise, exclusive breastfeeding is recommended during the first months of life; and that those who choose other options should be encouraged to use them free from commercial influences;

(11) to take all necessary measures to protect all women from the risk of HIV infection, especially during pregnancy and lactation;

(12) to strengthen their information systems, together with their epidemiological surveillance systems, in order to assess the magnitude and geographical distribution of malnutrition, in all its forms, and of foodborne disease;

3. REQUESTS the Director-General:

(1) to give, greater emphasis to infant and young child nutrition, in view of WHO's leadership in public health, consistent with and guided by the Convention on the Rights of the Child and other relevant human rights instruments, in partnership with ILO, FAO, UNICEF, UNFPA and other competent organizations both within and outside the United Nations system;

(2) to foster, with all relevant sectors of society, a constructive and transparent dialogue in order to monitor progress towards implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions, in an independent manner and free from commercial influence, and to provide support to Member States in their efforts to monitor implementation of the Code;

(3) to provide support to Member States in the identification, implementation and evaluation of innovative approaches to improving infant and young child feeding, emphasizing exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding[7], the provision

[7] As formulated in the conclusions and recommendations of the expert consultation (Geneva, 28 to 30 March 2001) that completed the systematic review of the optimal duration of exclusive breastfeeding (see document A54/INF.DOC./4).

of safe and appropriate complementary foods, with continued breastfeeding up to two years of age or beyond, and community-based and cross-sector activities;

(4) to continue the step-by-step country- and region-based approach to developing the new global strategy on infant and young child feeding, and to involve the international health and development community, in particular UNICEF, and other stakeholders as appropriate;

(5) to encourage and support further independent research on HIV transmission through breastfeeding and on other measures to improve the nutritional status of mothers and children already affected by HIV/AIDS;

(6) to submit the global strategy for consideration to the Executive Board at its 109th session in January 2002 and to the Fifty-fifth World Health Assembly (May 2002).

Seventh plenary meeting, 18 May 2001

A54/VR/7

Annex II

WORLD HEALTH ORGANIZATION

FIFTY-FOURTH WORLD HEALTH ASSEMBLY
Document A54/INF.DOC./4, 1 May 2001

GLOBAL STRATEGY FOR INFANT AND YOUNG CHILD FEEDING

THE OPTIMAL DURATION OF EXCLUSIVE BREASTFEEDING

1. Appropriate feeding practices are of fundamental importance for the survival, growth, development, health and nutrition of infants and children everywhere. In this light, the optimal duration of exclusive breastfeeding is one of the crucial public health issues that WHO keeps under continual review. There has long been consensus on the need for exclusive breastfeeding; however, there has been considerable debate on its optimal duration.

2. In view of the continuing debate, early in 2000, WHO commissioned a systematic review of the published scientific literature on the optimal duration of exclusive breastfeeding; more than 3000 references were identified for independent review and evaluation. The outcome of this process was subjected to global peer review, after which all findings were submitted for technical scrutiny during an expert consultation (Geneva, 28 to 30 March 2001). The expert consultation's conclusions and recommendations for both practice and research is annexed.

3. The duration of exclusive breastfeeding, and the timely introduction of adequate, safe and appropriate complementary foods in conjunction with continued breastfeeding, are of direct relevance for much of WHO's work concerning infants and young children. This work includes two current major global initiatives.

- a multicountry study, involving more than 10 000 children, with the aim of establishing a new **international growth reference** that reflects growth patterns of healthy breastfed infants and children, thereby setting the norm against which all alternative-feeding methods must be measured in terms of growth, health and development; [8]

- the formulation of a **global strategy on infant and young child feedin**g, whose aim is to ensure adequate, safe and appropriate feeding for all infants and young children.[9]

EXPERT CONSULTATION ON THE OPTIMAL DURATION OF EXCLUSIVE BREASTFEEDING

Conclusions and recommendations
(Geneva, 28 to 30 March 2001)

1. A systematic review of current scientific evidence on the optimal duration of exclusive breastfeeding[10] identified and summarized studies that compared exclusive breastfeeding for four to six months with

[8] See document EB105/INF.DOC./1.

[9] See document A54/7.

exclusive breastfeeding for six months in terms of growth, infant iron status, morbidity, atopic disease, motor development, postpartum weight loss, and amenorrhoea. It should be noted that the review was based on two small controlled trials and 17 observational studies that varied in both quality and geographical provenance.

2. The evidence does not suggest an adverse effect of exclusive breastfeeding for six months on infant growth on an overall population basis, that is on average. The sample sizes were insufficient, however, to rule out an increased risk of growth faltering in some infants who are exclusively breastfed for six months, particularly in populations with severe maternal malnutrition and a high prevalence of intrauterine growth retardation.

3. The evidence from one trial in Honduras demonstrates poorer iron status in infants exclusively breastfed for six months than in infants exclusively breastfed for four months followed by partial breastfeeding to six months. This finding is likely to apply to populations in which maternal iron status and infant endogenous stores of iron are not optimal. The available evidence is grossly inadequate to assess risks of deficiency of other micronutrients.

4. The available data suggest that exclusive breastfeeding for six months has protective effects against gastrointestinal infection. These data were derived from a setting (Belarus) where hygienically prepared complementary foods were used.

5. The evidence does not demonstrate a protective effect against respiratory tract infection (including otitis media) or atopic disease, in infants exclusively breastfed for six months compared to those exclusively breastfed for four to six months.

6. Because the data from the Honduran trials that reported more rapid motor development are inconsistent and susceptible to observer bias, they are insufficient to allow any inferences to be drawn about neuromotor development.

7. The results of two controlled trials in Honduras indicate that exclusive breastfeeding for six months (compared with four months) confers an advantage in prolonging the duration of lactational amenorrhoea in mothers who breastfeed frequently (mean 10-14 feedings/day).

8. The same Honduran trials demonstrated greater postpartum weight loss in mothers who exclusively breastfed for six months compared with mothers who exclusively breastfed for four months.

9. In developing-country settings, the most important potential advantage of exclusive breastfeeding for six months over exclusive breastfeeding for four months followed by partial breastfeeding to six months relates to infectious disease morbidity and mortality, especially those due to gastrointestinal infection (diarrhoeal disease). Because the evidence bearing directly on this issue was inadequate, however, the expert consultation also considered other published studies that did not meet the selection criteria for the systematic review. In particular, no mortality data were available that directly compared exclusive breastfeeding for four to six with that for six months. Moreover, the morbidity data from developing countries were limited to the two Honduran trials, which had insufficient statistical power to detect any advantage of exclusive breastfeeding to six months, and which used hygienically prepared complementary foods. However, the strong protective effect against gastrointestinal infection observed in Belarus, coupled with the high incidence of and mortality from gastrointestinal infection in many developing country settings, led the experts at the consultation to infer that exclusive breastfeeding for six months would protect against diarrhoeal morbidity and mortality in such settings. This inference is further strengthened by morbidity data relating to reduced risks of gastrointestinal infection and of all-cause mortality for

[10] Because the definition of "exclusive breastfeeding" in studies in the systematic review often included infants who were predominantly breastfed, the term is used here to include both true exclusive breastfeeding and predominant breastfeeding, as defined by WHO.

exclusively breastfed children compared with partially breastfed infants from four to six months, regardless of when the latter stopped exclusive breastfeeding.

10. In summary, the expert consultation concludes that exclusive breastfeeding to six months confers several benefits on the infant and the mother. However, exclusive breastfeeding to six months can lead to iron deficiency in susceptible infants. In addition, the available data are insufficient to exclude several other potential risks associated with exclusive breastfeeding for six months, including growth faltering and other micronutrient deficiencies, in some infants. In all circumstances, these risks must be weighed against the benefits provided by exclusive breastfeeding, especially the potential reduction in morbidity and mortality.

RECOMMENDATIONS FOR PRACTICE

11. The expert consultation recommends exclusive breastfeeding for six months, with introduction of complementary foods and continued breastfeeding thereafter. This recommendation applies to populations. The expert consultation recognizes that some mothers will be unable to, or choose not to, follow this recommendation; they should be supported to optimize their infants' nutrition.

12. The proportion of infants exclusively breastfed at six months can be maximized if potential problems with regard to the following are overcome:

- the nutritional status of pregnant and lactating mothers;
- micronutrient status of infants living in areas with high prevalence of deficiencies such as iron, zinc, and vitamin A;
- the routine primary health care of individual infants, including assessment of growth and of clinical signs of micronutrient deficiencies.

13. The expert consultation recognizes the need for complementary feeding at six months of age and recommends the introduction of nutritionally adequate, safe and appropriate complementary foods, in conjunction with continued breastfeeding.

14. The expert consultation also recognizes that exclusive breastfeeding to six months is still infrequent. However, it also notes that there have been substantial increases over time in several countries, particularly where lactation support is available. A prerequisite to the implementation of these recommendations is the provision of adequate social and nutritional support to lactating women.

RECOMMENDATIONS FOR RESEARCH

15. There are several unanswered questions that are important for policy-making with regard to defining the optimal duration of exclusive breastfeeding and maximizing its benefits. Therefore, the expert consultation recommends that priority be given to the following research areas:

- a comparison of exclusive breastfeeding/predominant breastfeeding and partial breastfeeding for four to six months based on the following outcomes, to improve precision of estimates and their general applicability:
  - – proportion of infants with growth faltering and malnutrition at six and 12 months,
  - – micronutrient status,
  - – diarrhoeal morbidity,
  - – neuromotor development,

and for the mothers:

– changes in weight,

– lactational amenorrhoea.

Priority must be given to investigating these outcomes in infants born small-for-gestational-age or, alternatively, in those with low weight-for-age at four months;

- assessment of breast-milk production and composition from mothers with a body mass index <18.5 and the adequacy of breast milk for meeting infant requirements to six months;
- identification of biological and social constraints to exclusive breastfeeding to six months in different geographical and cultural settings, and design of appropriate and effective interventions to deal with these barriers and their consequences, as it is recognized that rates of exclusive breastfeeding decline substantially after four months;
- use of available opportunities to gain greater insight into the impact on mortality of exclusive breastfeeding to six months – for example, incorporation of additional variables into the demographic and health surveys;
- formulation and evaluation of interventions for micronutrient supplementation and for complementary foods in different areas of the world – including formative studies to identify processing and preparation methods, and local ingredients required to prepare nutritionally adequate, safe and appropriate complementary foods; and
- assessment of the role of care during pregnancy in relation to the adequacy of lactation in the first six months.